F. How Does This Proposed Rule Comply With Executive Order 13084: Consultation and Coordination With Indian Tribal Governments?

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.

Today's proposed rule will not significantly or uniquely affect the communities of Indian tribal governments, and it will not impose substantial direct compliance costs on such communities. Although Indian tribal communities live in areas near the Androscoggin River, their governments will not be subject to any compliance costs relating to the proposed site-specific rule since the rule is directed at the International Paper mill. Nearby Indian tribal communities are, in fact, expected to benefit directly from the anticipated improvement in water quality. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

G. Does This Proposed Rule Comply With Executive Order 13132?

Executive Order 13132, entitled ''Federalism'' (64 FR 43255; August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.''

Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule does not have federalism implications. It would apply only to a single facility, and it will therefore not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

H. Does This Proposed Rule Comply With the National Technology Transfer and Advancement Act?

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standard. This proposed rulemaking does not involve technical standards developed by any voluntary consensus standards bodies. Therefore, EPA is not considering the use of any voluntary consensus standards. EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

List of Subjects in 40 CFR Part 430

Environmental protection, Reporting and recordkeeping requirements, Water pollution control.

Dated: May 10, 2000.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, title 40 chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 430—THE PULP, PAPER, AND PAPERBOARD POINT SOURCE CATEGORY

1. The authority citation for part 430 continues to read as follows:

Authority: Sections 301, 304, 306, 307, 308, 402, and 501 of the Clean Water Act, as amended, (33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342, and 1361), and section 112 of the Clean Air Act, as amended (42 U.S.C. 7412).

2. Section 430.03 is amended by adding paragraph (k) to read as follows:

§ 430.03 Best management practices (BMPs) for spent pulping liquor, soap, and turpentine management, spill prevention, and control.

* * * * *

(k) The provisions of paragraphs (c) through (j) of this section do not apply to the bleached papergrade kraft mill, commonly known as the Androscoggin Mill, that is owned by International Paper and located in Jay, Maine. In lieu of imposing the requirements specified in those paragraphs, the permitting authority shall establish conditions for the discharge of COD and color for this mill on the basis of best professional judgment.

[FR Doc. 00–12305 Filed 5–15–00; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 405

[HCFA–3432–NOI]

RIN 0938–AJ31

Medicare Program; Criteria for Making Coverage Decisions

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

ACTION: Notice of intent to publish a proposed rule.

SUMMARY: On April 27, 1999, we published a notice in the **Federal Register** that announced the process we

use to make national coverage decisions under the Medicare program. We also announced that we would not be adopting, as final, a 1989 proposed rule that set forth the criteria we would have used to make coverage decisions under Medicare. This notice announces our intention to publish a proposed rule and solicits advance public comments on the criteria we would use to make certain national coverage decisions and our contractors would use to make local coverage decisions.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 15, 2000.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–3432–NOI, P.O. Box 8016, Baltimore, MD 21244–8016.

If you prefer, you may deliver, by courier, your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

C5–14–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to those addresses may be delayed and received too late for us to consider them.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3432–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 443–G of the Department's offices at 200 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).

FOR FURTHER INFORMATION CONTACT: Susan Gleeson, (410) 786–0542.

SUPPLEMENTARY INFORMATION:

Comments, Procedures, Availability of Copies, and Electronic Access

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3432–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 443–G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 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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Overview

We are issuing this notice to announce our intention to publish a proposed rule and solicit public comments on the criteria we would use to make a national coverage decision (NCD) and our contractors would use to make a local coverage decision (LCD) under section 1862(a)(1) of the Social Security Act (the Act). These coverage decisions are prospective, population-based policies that apply to a clinical subset or class of Medicare beneficiaries and describe the clinical circumstances and setting under which an item or service is available (or not available). We are setting out in this notice the information and approaches we are considering at this time for making coverage decisions. We are interested in receiving public comments on this information and we will consider them when we develop the subsequent proposed rule.

This notice is narrower in scope than the January 30, 1989 proposed rule announcing the coverage criteria we would have used (54 FR 4302). We have already announced our process for making an NCD in an April 27, 1999 general notice (64 FR 22619). Also, rulemaking is not necessary for us to establish or modify the procedures our contractors will use to make LCDs. This notice only deals with the criteria for making national and local coverage decisions under the reasonable and necessary provisions of section 1862(a)(1) of the Act. This notice does not, and we do not anticipate that the proposed rule will, address individual medical necessity determinations and claims adjudication by our contractors and other adjudicators. Finally, this notice does not address Medicare payment policies and we do not anticipate that the proposed rule would include changes to our current rules on Medicare payment.

I. Background

A. Need for Timely and Expanded Medicare Coverage of Items and Services

Given the dynamic nature of the health care system, it is important that the Medicare program be responsive to the rapid advances in health care. Regulations describing our criteria for coverage under the Medicare program would facilitate timely and expanded access for Medicare beneficiaries to appropriate new technologies. Within the scope of the statutory benefit categories, these criteria would expand access for Medicare beneficiaries by covering the following:

1. A breakthrough technology without consideration of cost.

2. A medically beneficial item or service if no other medically beneficial alternative is available.

3. A medically beneficial item or service if it is a different clinical modality compared to an existing covered beneficial alternative, without consideration of cost or magnitude of benefit.

4. A medically beneficial item or service, even if a less expensive alternative, which is not a Medicare benefit, exists.

We anticipate that these criteria would also make the Medicare coverage process, both national and local, more transparent, timely, and predictable to manufacturers or other requestors seeking Medicare coverage of an item or service.

B. Framework of the Medicare Program

From the beginning of the Medicare program, one of the goals has been to

provide a health insurance system that would make ''the best of modern medicine'' available to Medicare beneficiaries. Over the last 35 years, there have been significant advances in medical science that have changed the Medicare program and improved the health of beneficiaries and others. Some of these changes have been mandated by the Congress in title XVIII of the Act, which authorizes coverage of, and payment for, items and services under the Medicare program. Other changes have occurred as a result of administrative actions. We have adapted the Medicare program to meet these changes.

While the Congress has demonstrated a strong interest in providing access to necessary medical care for Medicare beneficiaries, the Congress has been equally concerned with ensuring that the Medicare program operates on a sound financial basis. The Congress has established the specific scope of benefits that are included in the program and has defined many of the key terms in section 1861 of the Act. In addition, section 1862(a)(1)(A) of the Act requires that ''no payment'' may be made under Part A (hospital insurance) or Part B (supplementary medical insurance) for any expenses incurred for items or services that ''are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.'' If we do not cover the expenses incurred for a particular item or service under this provision, either the Medicare beneficiary or the health care provider or supplier may be financially liable for all of the incurred costs.

The main purpose of our proposed rule will be to explain how the term ''reasonable and necessary'' applies in making coverage decisions. A Medicare coverage decision, whether made nationally or locally, is a prospective, population-based, policy that applies to a clinical subset or class of Medicare beneficiaries and describes the clinical circumstances and setting under which an item or service is available (or is not available).

We have the authority to determine whether an item or service is reasonable and necessary by several distinct approaches. One approach is to make a national coverage decision (NCD). Under 42 CFR 405.732 and 405.860, an NCD either grants, limits, or excludes Medicare coverage for a specific medical service, procedure, or device. An NCD is binding on all carriers, fiscal intermediaries, Peer Review Organizations, and other contractors. Under § 422.256(b), an NCD that expands coverage is also binding on a Medicare + Choice Organization. Moreover, under §§ 405.732(b) and 405.860(b), an NCD made under section 1862(a)(1) of the Act is binding on an administrative law judge (ALJ) (''An ALJ may not disregard, set aside, or otherwise review an NCD.''). While an NCD is subject to judicial review, there are limitations on judicial review. This framework ensures that an NCD is consistently applied throughout the nation and enables a beneficiary to make an informed decision about whether to receive an item or service based on the knowledge that an item or service will be covered (or not covered) by the program.

Due to regional, local, or institutional differences in the practice of medicine, it is not always prudent to issue a prescriptive NCD. Sometimes there is not sufficient information for us to determine whether an item or service is an effective treatment on a national basis. In other circumstances, there are legitimate regional differences in the practice of medicine that would make a preemptive national rule inappropriate.

In the absence of an NCD, a decision concerning Medicare coverage for an individual could be resolved on a case-by-case basis after a claim is submitted. Our regulations separately provide broad appeal rights for certain individuals to administratively challenge our decision to deny payment for a claim before a neutral ALJ and, in some cases, Federal court (42 CFR part 405, subparts G and H). This case-by-case approach ensures that a beneficiary can present all relevant information concerning a particular need for payment for an item or service. This review only applies to claims that have been denied and is not a mechanism for attaining prior authorization for a specific item or service for an individual.

In order to provide some guidance to beneficiaries and health care providers and suppliers regarding which items and services will (or will not) be covered in a particular area in the absence of an NCD, our contractors may make an LCD. An LCD would provide guidance, in the absence of, or as an adjunct to, an NCD by describing the clinical circumstances and settings under which an item or service is available (or is not available) to a beneficiary under section 1862(a)(1)(A) of the Act. This notice seeks only to define the criteria for how we would make an NCD and our contractors would make an LCD.

An LCD is not binding on a contractor in another area of the country or on an ALJ who decides cases at higher stages of the appeal process. Still, an LCD provides a service to the public by giving some advance notice about an item or service a contractor is likely to cover or not cover. If a local contractor makes an affirmative finding through a published LCD that an item or service is reasonable and necessary under the statute, beneficiaries and providers could reasonably expect that the service is available to the beneficiaries in that jurisdiction for the circumstances described in the LCD.

C. Federal Register Publications

1. 1989 Proposed Rule

On January 30, 1989, we published a proposed rule (54 FR 4302), that identified four generally applicable criteria that we would use to make coverage decisions as to whether, and under what circumstances, specific health care technologies could be considered reasonable and necessary (and thus, covered under Medicare). The four proposed criteria were: (1) Safety and effectiveness, (2) experimental or investigational, (3) appropriateness, and (4) cost-effectiveness. At the time, we explained that each of the four criteria would not necessarily apply in all instances because of the complexity and variety of issues involved in making coverage decisions under Medicare. As explained earlier, we withdrew this proposed rule.

2. 1999 General Notice

On April 27, 1999, we published a general notice that announced the process we use to make an NCD (64 FR 22619). This notice formally withdrew the 1989 proposed rule. This procedural notice has been well-received by Medicare beneficiaries, the health care industry, and others who wanted our process to be open, responsive, and understandable to the public.

II. Intentions of This Notice

We are issuing this notice to announce our intention to publish a proposed rule and solicit public comments on the criteria we would use to make an NCD and our contractors would use to make an LCD under section 1862(a)(1) of the Act. We are setting out in this notice the information and approaches we are considering at this time. We are interested in receiving public comments on this information and we will consider them when we develop the subsequent proposed rule.

Before we can make an NCD or LCD, the item or service must fall within a statutory Medicare benefit category and not be otherwise statutorily excluded. Moreover, if regulated by the Food and

Drug Administration, the item or service must be lawfully marketed.

We would apply an NCD or LCD prospectively to all items and services furnished under identical circumstances within the respective jurisdiction after the effective date of the NCD or LCD. We anticipate the number of criteria we would apply could be reduced and simplified based on our experience. We intend that the criteria would make the Medicare coverage process more open, responsive, and understandable to the public. Finally, as mentioned above, we anticipate that the criteria would result in covering more items and services under Medicare. The criteria could also result in us beginning a new NCD to withdraw coverage of a currently covered item or service. In particular, if a new item or service is equivalent in benefit, is in the same clinical modality, is thus substitutable for the existing service, and is lower in costs, we would consider withdrawing coverage for the more expensive currently covered alternative service.

A. Criteria for Medicare Coverage Decisions

We anticipate applying two criteria when we make an NCD or one of our contractors makes an LCD. First, the item or service must demonstrate medical benefit, and, second, the item or service must demonstrate added value to the Medicare population. In order to ensure that we and our contractors consistently interpret and apply these criteria, we would use the following sequential steps:

Step 1—Medical Benefit: Is there sufficient evidence that demonstrates that the item or service is medically beneficial for a defined population?

If no, the item or service is not covered under Medicare.

If yes, proceed to Step 2.

Step 2—Added Value: For the defined patient population, is there a medically beneficial alternative item or service(s) that is the same clinical modality and is currently covered by Medicare?

- If no, the item or service is covered under Medicare for the defined population.
- If yes, proceed to Step 3.

Step 3—Added Value: Is the item or service substantially more or substantially less beneficial than the Medicare-covered alternative?

- If the item or service is substantially more beneficial (that is, a breakthrough), it is covered under Medicare for the defined population.
- If the item or service is substantially less beneficial, it is not covered under Medicare for the defined population.
- If the item or service is neither substantially more nor substantially less beneficial (that is, it is equivalent in benefit), proceed to Step 4.

Step 4—Added Value: Will the item or service result in equivalent or lower total costs for the Medicare population than the Medicare-covered alternative?

- If yes, the item or service is covered under Medicare for the defined population.
- If no, the item or service is not covered under Medicare.

When we (or our contractors) compare the medical benefit of two or more items or services, we would ensure that the comparisons involve both the same patient population, the same clinical circumstances, and the same clinical modality. We believe that the sequential steps would be administratively feasible and would produce results that are consistent with the statute. We invite public comments on this approach and suggestions as to feasible alternatives.

A requestor may use the coverage reconsideration process to modify a request that resulted in a denial of coverage for an item or service. For example, a requestor could seek a more limited coverage decision targeting a narrower population for which there is no Medicare-covered alternative. Alternatively, a requestor could submit new evidence that demonstrates that the item or service is substantially more beneficial than the Medicare-covered alternative.

B. Definitions, Discussion, and Questions

1. Medical Benefit

We believe an item or service is medically beneficial if it produces a health outcome better than the natural course of illness or disease with customary medical management of symptoms. We would require the requestor to demonstrate that an item or service is medically beneficial by objective clinical scientific evidence.

Given the importance of Medicare coverage decisions for our 39 million current beneficiaries (as well as future beneficiaries), we do not believe we should cover an item or service without adequate information that shows the item or service improves the diagnosis or treatment of an injury or illness, or improves the functioning of a malformed body member. It would be unreasonable and unnecessary to pay for expenses incurred for an item or service that are not proven to be effective for a defined population.

Although mortality and life-expectancy are quantifiable and, thus, ''hard'' health outcomes, we believe we should move towards ''quality of life'' as an acceptable health outcome. To help us (and our contractors) make coverage decisions, however, especially assessing comparative benefits, an acceptable health outcome should be quantifiable along a standard scale or metric. We seek suggestions on a standard metric system for measuring quality of life outcomes. Examples of nationally recognized scales are: QALY—Quality Adjusted Life Years, DALY—Disability Adjusted Life Years, or self-described health status as measured by the SF–36 (Short Form 36).

We believe a beneficiary's preference, compliance, and well-being are also meaningful outcomes. Similarly, we invite comments on the standardized metric systems or methodologies we should employ so that we can quantify and compare medical benefits that recognize these outcomes.

Another important consideration is how we would measure the magnitude of the improved health outcome. Also, if the treatment includes risks of adverse side-effects, how should we determine that the benefits outweigh the risks?

2. Added Value

We believe that an item or service adds value to the existing mix of covered items or services if it substantially improves health outcomes; provides access to a medically beneficial, different clinical modality; or if it can ''substitute'' for an existing item or service and lower costs for the Medicare population. There are several situations when a new item or service would add value compared to the current mix of services.

One situation is when a new item or service that falls within a Medicare benefit category would be medically beneficial for a beneficiary with a given clinical circumstance and there is no Medicare-covered medically beneficial alternative. We believe this item or service would add value to the program and we should cover it without consideration of costs during the coverage process.

Another situation is when a new item or service would be medically beneficial and it is a different clinical modality than a Medicare-covered medically beneficial alternative(s) (for example, a covered medication versus surgery). Giving Medicare beneficiaries and providers access to competing items or services of different clinical modalities adds value to the program and we believe we should also cover the items or services without consideration of costs during the coverage process. In particular, this adds value to the program because we recognize that there

are legitimate differences between beneficiaries, medical practices by region, and delivery systems' capabilities. We believe access to different modalities for a similar medical benefit is warranted.

In making Medicare coverage decisions under these new criteria, we would not compare an item or service that falls within a statutory benefit category to an item or service that is outside the scope of the Medicare program. We do not believe we should compare the effectiveness of an item or service that falls within a statutory benefit category to the effectiveness of a medically, beneficial alternative that is not included in a Medicare benefit category. Due to financial circumstances, a beneficiary may not have meaningful access to that alternative. We believe that by only comparing two items or services that are included in a Medicare benefit category, we increase beneficiary access and add value to the program.

Value also would be added when the magnitude of the benefit of an item or service is substantially more than a Medicare-covered alternative of similar clinical modality. We refer to this item or service as a ''breakthrough''. Even if two services are of the same clinical modality, we believe we should cover the substantially superior service without any consideration of cost during the coverage process.

We believe value would also be added when a new item or service is equivalent in benefit, and is in the same clinical modality (that is, substitutable) for a Medicare-covered alternative, and has equal or lower total costs for the Medicare population. It is possible that a beneficiary would not notice any difference in health outcomes, when an item or service is substituted for a Medicare-covered alternative. We would cover a substitutable item or service only if the total costs are equal or lower than the total costs of the Medicare-covered alternative. For clinically substitutable services, it is not reasonable or necessary to pay for incurred costs that exceed the cost of a Medicare-covered alternative that produces the same health outcome. Thus, only by assuring equal or lower costs for the substitutable service could we assure adding value to the program. When a service (that is, it has equivalent health outcomes and the same clinical modality) is substantially more expensive than a Medicare-covered alternative would cost considerations lead us to deny coverage for the service. Since we anticipate limiting the application of costs to a narrow situation when two services have equivalent health outcomes and are of the same clinical modality, we need to do only a simple cost-analysis.

We would like to receive input on the proposed added value criteria before developing a proposed rule. In particular, we would like suggestions on how broadly or narrowly we should define ''same clinical modality.'' Clearly surgery and prescription medications are not the same. But is an open surgical procedure the same clinical modality as a closed invasive procedure? What if they both require general anesthesia? What if they do not? Perhaps another way of defining ''same clinical modality'' would be to simply use the existing Medicare statutory benefit categories.

We would like the public's views on the scope of a ''Medicare-covered alternative.'' Recognizing that most Medicare coverage decisions have been made locally, and not nationally, we would have to create a standard for determining which services are currently covered. One alternative for the purposes of an NCD or an LCD is to define ''Medicare-covered alternative'' when a threshold percentage of the Medicare population nationally, or in the contractor's jurisdiction, has access to an item or service. What threshold percentage should we use for either alternative? Are there other alternative definitions?

Similarly, we encourage suggestions on how to best define ''substantially more beneficial.'' One way to define this term is that the benefit is so large that *most clinicians* would believe that the item or service should be the new standard of care and, thus, completely replace the Medicare-covered alternative. Another is that the benefit is so large that the clinical experts in the relevant clinical discipline believe that the item or service should be the new standard of care and, thus, we should cover the new item or service and withdraw coverage of the Medicare-covered alternative. A third way would be to try to establish a quantifiable statistical ''effect-size'' of the new item or service compared with the Medicare-covered alternative.

We are soliciting input on the definition of ''equivalent benefit.'' We anticipate defining ''equivalent benefit'' as neither substantially more, nor substantially less, beneficial than the Medicare-covered alternative. This leaves a range of medical benefit between marginally less beneficial, to equally beneficial, to marginally more beneficial. Is there an alternative definition of ''equivalent benefit?'' Is there a common metric system that could be used to measure the medical benefit and capture other meaningful health outcomes including beneficiary preference, compliance, and well-being?

We are also specifically requesting comments on the alternative of covering a new item or service that is ''substitutable'' for a Medicare-covered alternative. At a minimum, a substitutable item or service would seem to be one that is the same clinical modality and produces an equivalent health outcome. If the substitutable item or service has greater total costs to the Medicare program, should we deny coverage for the item or service and allow the requestor through the reconsideration process to alter the request to seek a positive coverage decision? Should we simply cover the new item or service but reduce the Medicare payment rate for the incurred expenses to the same rate as the Medicare-covered alternative? This principle has been called the ''least costly alternative'' adjustment and has been used for many years primarily for coverage of durable medical equipment.

Coverage of new items and services under new regulatory requirements may lead to the reexamination of current coverage policies. For example, if the new item or service is ''substitutable'' for a Medicare-covered alternative and has lower costs for the Medicare program, should we deny coverage for the Medicare-covered alternative or lower the payment for the Medicare-covered alternative so that the total costs for the Medicare program are, at a minimum, equal?

We are interested in suggestions on the type and extent of information that parties seeking coverage decisions should be required to provide in relation to the associated costs or savings to the program in addition to the direct costs of the item or service.

We are soliciting comments on the implications for private sector insurers of the proposed approach.

3. Demonstration Through Scientific Evidence

As previously mentioned, we would measure both the medical benefit and the added value criteria by clinical scientific evidence. We are interested in comments on the proper evidentiary standard. Should there be one standard for all services or should there be different standards for different health care sectors (for example, surgical procedures, diagnostic tests, and biologics)? Finally, recognizing that clinical evidence and trials are frequently imperfect, what is the best way to deal with bias and external validity when we consider applying the findings of clinical trials to coverage

decisions in the real world. More specifically, under what circumstances can clinical trial findings be generalized from the study population to the Medicare population? In addition, under what circumstances can the controlled delivery setting of the clinical trial be generalized and reproduced in the current health care delivery setting or to a different health care delivery setting?

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. The notice would not have any unfunded mandates.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a notice that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. The notice would not impose compliance costs on the governments mentioned.

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

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

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

Dated: April 5, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: April 20, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–12237 Filed 5–11–00; 12:00 pm]

BILLING CODE 4120–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 206

RIN 3067–AD08

Disaster Assistance; Debris Removal

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Proposed rule.

SUMMARY: We (FEMA) propose to change the scope of activities that are determined to be in the public interest following a declared disaster. We propose to provide funding for the removal of debris and wreckage when communities convert property acquired through a FEMA program for hazard mitigation purposes to uses compatible with open space, recreational, or wetlands management practices.

DATES: We invite your comments and will accept them until June 30, 2000.

ADDRESSES: Please send any comments to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, room 840, 500 C Street, SW., Washington, DC 20472, (facsimile) 202–646–4536, or (email) *rules@fema.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa M. Howard, Federal Emergency Management Agency, room 713, 500 C Street SW., Washington, DC 20472, (202) 646–4240, or (email) *melissa.howard@fema.gov.*

SUPPLEMENTARY INFORMATION: We consider that it is in the public interest to remove substantially damaged structures and related slabs, driveways, fencing, garages, sheds, and similar appurtenances from properties that are part of a FEMA-funded hazard mitigation buyout and relocation project. When the principal structure has been substantially damaged by a major disaster, the removal of such items will help mitigate the risk to life and property by converting the property to uses that are compatible with open space, recreational and wetland management practices. Federal assistance used in this way supports the effort to break the cycle of repetitive damage and repair and is in the public interest because it is less costly to taxpayers than the cycle of repetitive damage and repair. Mitigation through buyout and relocation also substantially reduces the risk of future infrastructure damage and personal hardship, loss and suffering.

National Environmental Policy Act

This rule is excluded from the preparation of an environmental assessment or environmental impact statement under 44 CFR 10.8(d)(2)(ii), where the rule is related to actions that qualify for categorical exclusion under 44 CFR 10.8(d)(2)(vii).

Executive Order 12866, Regulatory Planning and Review

This proposed rule would not adversely affect the availability of disaster assistance funding to small entities, would not have significant secondary or incidental effects on a substantial number of small entities, and would not create any additional burden on small entities. It adds a category of property eligible to receive public assistance following a declared disaster, and will thus benefit those small entities that qualify for this assistance.

As Director I certify that this proposed rule is not a significant regulatory action within the meaning of section 2(f) of E.O. 12866 of September 30, 1993, 58 FR 51735, and that it attempts to adhere to the regulatory principles set forth in E.O. 12866. The Office of Management and Budget has reviewed this rule under E.O. 12866.

Paperwork Reduction Act

This proposed rule does not contain a collection of information and therefore is not subject to the provisions of the Paperwork Reduction Act of 1995.

Executive Order 13132, Federalism

In publishing this proposed rule, we considered the President's Executive Order 13132 on Federalism. This proposed rule makes no changes in the division of governmental responsibilities between the Federal government and the States, but adds a category of property eligible to receive public assistance following a declared disaster. We have determined that Executive Order 13132 does not apply to this regulatory action, and we have not prepared a Federalism assessment.

List of Subjects in 44 CFR Part 206

Disaster assistance.

Accordingly, we propose to amend 44 CFR part 206 as follows:

1. The authority citation for part 206 continues to read as follows:

Authority: The Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.*; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412; and E.O. 12673, 54 FR 12571, 3 CFR, 1989 Comp., p. 214.

PART 206—FEDERAL DISASTER ASSISTANCE FOR DISASTERS DECLARED ON OR AFTER NOVEMBER 23, 1988

2. Amend § 206.224 by revising paragraph (a)(3) and adding paragraph (a)(4) to read as follows:

§ 206.224 Debris removal.

(a) * * *

(3) Ensure economic recovery of the affected community to the benefit of the community-at-large; or

(4) Mitigate the risk to life and property by removing substantially damaged structures and associated