E. Executive Order 13132: Federalism

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.''

This proposed rule does not have federalism implications. It will 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. Today's proposed rule is expected to primarily affect producers, suppliers, importers and exporters and users of methyl bromide. Thus, Executive Order 13132 does not apply to this proposed rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This proposed rule does not have tribal implications, as specified in Executive Order 13175. Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. The proposed rule does not impose any enforceable duties on communities of Indian tribal governments. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under Section 5–501 of the Order has the potential to influence the regulation. This proposed rule is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule does not pertain to any segment of the energy production economy nor does it regulate any manner of energy use. Further, we have concluded that this rule is not likely to have any adverse energy effects.

I. The National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Pub. L. 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 standards. This rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

Dated: August 23, 2005.

Stephen L. Johnson,

Administrator.

[FR Doc. 05–17190 Filed 8–29–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 410

[CMS–6024–P]

RIN 0938–AN10

Medicare Program; Prior Determination for Certain Items and Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: Section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Secretary to establish a process for Medicare contractors to provide eligible participating physicians and beneficiaries with a determination of coverage relating to medical necessity for certain physicians' services before the services are furnished. This rule is intended to afford the physician and beneficiary the opportunity to know the financial liability for a service before expenses are incurred. This proposed rule would establish reasonable limits on physicians' services for which a prior determination of coverage may be requested and discusses generally our plans for establishing the procedures by which those determinations may be obtained.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 31, 2005.

ADDRESSES: In commenting, please refer to file code CMS–6024–P. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* or to *http://www.regulations.gov* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6024–P, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Misty Whitaker, (410) 786–3087.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–6024–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

Section 1862(a)(1)(A) of the Social Security Act (the Act) prohibits Medicare payments for items and services that are not reasonable and necessary for the diagnosis and treatment of an illness or injury. However, section 1879 of the Act provides that under certain circumstances Medicare will pay for services that are not considered reasonable and necessary if both the beneficiary and physician did not know and could not have reasonably been expected to know that Medicare payment would not be made.

A physician may be held financially liable for noncovered services he or she furnishes if, for example, the Medicare contractor or CMS publishes specific requirements for those services or the physician has received a denial or reduction of payment for the same or similar service under similar circumstances. In cases where the physician believes that the service may not be covered as reasonable and necessary, an acceptable advance notice of Medicare's possible denial of payment must be given to the patient if the physician does not want to accept financial responsibility for the service. These notices are referred to as Advance Beneficiary Notices (ABNs).

ABNs must be given in writing, in advance of providing the service; include the description of service, as well as reasons why the service would not be covered; and must be signed and dated by the beneficiary to indicate that the beneficiary will assume financial responsibility for the service if Medicare payment is denied or reduced.

Notwithstanding these ABNs, there is the potential that beneficiaries may be discouraged from obtaining services because they are uncertain whether or not Medicare contractors will deem them reasonable and necessary. Currently, beneficiaries can find out whether or not items or services are generally covered. However, when there is a question of whether Medicare will cover a specific item or service for a particular beneficiary under specific circumstances, there currently exists no process by which the beneficiary or his or her physician can find out if that item or service would be considered reasonable and necessary for that beneficiary before incurring financial liability.

To address this issue, section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003) (MMA) requires the Secretary to establish a process whereby eligible requesters may submit to the contractor a request for a determination, before the furnishing of the physician's service, as to whether the physician's service is covered consistent with the applicable requirements of section 1862(a)(1)(A) of the Act (relating to medical necessity). This MMA section also provides that an eligible requester is either: A participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits and who has consented to the physician making the request for those services; or an individual entitled to benefits, but only with respect to a physician's service for which the individual receives an advance beneficiary notice under section 1879(a) of the Act.

Requesting a prior determination under this proposed process is at the discretion of the eligible beneficiary or physician. Full knowledge regarding financial liability for the service would be available to physicians and beneficiaries before expenses are incurred, but prior determination of coverage is not required for submission of a claim.

This proposed rule would establish reasonable limits on the physicians' services for which a prior determination of coverage may be requested and discusses generally our plans for establishing the process by which prior determinations may be obtained. The procedures that Medicare contractors would use to make the determinations would be established in our manuals.

II. Provisions of the Proposed Rule

[If you choose to comment on issues in this section, please include the caption ''Provisions of the Proposed Rule'' at the beginning of your comments.]

Section 1869(h)(1) of the Act, as added by section 938 of the MMA, requires the Secretary to establish a prior determination process for certain physicians' services. Sections 1869(h)(3) through (6) of the Act are specific with respect to various aspects of the prior determination process, and we intend to follow these and any other applicable provisions in establishing the prior determination process. We intend to issue the detailed procedures through our instructions to contractors in our manuals.

Section 1869(h)(2) of the Act, as added by section 938 of the MMA, requires the Secretary to establish by regulation reasonable limits on the

physicians' services for which a prior determination may be requested. This section provides that in establishing the reasonable limits, the Secretary may consider the dollar amount involved with respect to the physician's service, administrative costs and burdens, and other relevant factors.

We evaluated national data on physicians' services including payment amounts, utilization, and denial rates. We considered using denial rates as one of the factors to be considered, but we have decided to use other factors instead. Although a service may have a relatively high denial rate, that number may be insignificant depending on the number of services performed annually.

Based on our analysis, we are proposing to establish an initial pool of eligible physicians' services comprised of at least those 50 services with the highest allowed average charges that are performed at least 50 times annually. We will exclude from this initial pool any services for which a national or local coverage determination exists that, based on CMS' judgment, has sufficiently specific reasonable and necessary criteria to permit the beneficiary or physician to know whether the service is covered without a prior determination. We expect the number of physicians' services in the final list, after excluding services with adequate national and local coverage determinations, may be fewer than 50. We propose to start with at least 50 physicians' services in the initial pool, but may expand the number of services eligible for the prior determination pool in the future if the need arises. In addition, we propose to allow prior determination for plastic and covered dental surgeries that may be covered by Medicare and that have an average allowed charge of at least $1,000.

Specifically, in 42 CFR 410.20(d)(1), we propose to define a prior determination of medical necessity as a decision by a Medicare contractor, before a physician's service is furnished, as to whether or not the physician's service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity.

In § 410.20(d)(2), we propose that each Medicare contractor must, through the procedure established in CMS instructions, allow requests for prior determinations from eligible requesters under the contractor's respective jurisdiction for those services identified by CMS and posted on that specific Medicare contractor's Web site. Only those services listed on the date the request for a prior determination is made would be subject to prior determination.

Each contractor's list would consist of the following: At least the 50 most expensive physicians' services listed in the national ceiling fee schedule amount of the Medicare Physician Fee Schedule Database performed at least 50 times annually minus those services excluded by § 410.20(d)(3) (with adequate national or local coverage determinations); and plastic and dental surgeries that may be covered by Medicare and that have an average allowed charge of at least $1,000.

We have three reasons for proposing to establish the limit on physicians' services based on the dollar amount of the service and including certain plastic and dental surgeries. First, beneficiaries are more likely to be discouraged from obtaining the most expensive physicians' services because they are uncertain whether or not they would have to incur financial liability if Medicare does not pay for the service. The plastic and dental surgeries included are also relatively expensive, and there may be significant individual considerations in determining what is covered and what is excluded. Second, the majority of these services tend to be non-emergency surgical procedures generally performed in an inpatient setting. Since these services are not typically emergency services, beneficiaries would have adequate time to request a prior determination. Third, limiting prior determinations to these services is reasonable given the administrative cost to process each prior determination request.

In § 410.20(d)(3), we propose that those services for which there is a national coverage determination (NCD) in effect or a local coverage determination/local medical review policy (LCD/LMRP) in effect through the local contractor at the time of the request for prior determination will not be eligible for prior determination. This exclusion only applies when the NCD or LCD/LMRP, in CMS' judgment, provides the sufficiently specific reasonable and necessary criteria for the specific procedure for which the prior determination is requested.

Our reason for this provision is that many national and local policies already provide the information necessary to make an informed decision about whether or not the service will be covered. In establishing the prior determination procedures through our manuals, we will instruct CMS contractors that, in cases where a prior determination is requested but an NCD or LCD/LMRP exists, the contractor will send the beneficiary a copy of that policy along with the explanation of why a prior determination will not be made.

The lists will be consistent across all Medicare contractors except for the services excluded because of the presence of a local coverage determination. To ensure consistency, we will compile the list of at least 50 services with the highest allowed charges performed at least 50 times annually and the plastic and dental surgeries that Medicare may cover under some circumstances and that have an average allowed charge of at least $1,000. We will then exclude those services that have an NCD that provides the sufficiently specific reasonable and necessary criteria for that specific procedure. Each Medicare contractor will then exclude the services for which that contractor has a local policy and post the remaining services by Healthcare Common Procedure Coding System procedure code and code description on its Web site.

In § 410.20(d)(4), we propose that CMS may increase the number of services in the initial pool that are eligible for prior determination (over the minimum of 50) through manual instructions. Our reason for this provision is to ensure that CMS can provide for prior determinations for additional services when we detect a need. Sections 1869(h)(3) through (6) of the Act are specific with respect to various aspects of the prior determination process. Therefore, in § 410.20(d)(5), we specify those mandatory provisions. The detailed procedures to be followed by our contractors will be published in our manual instructions. Section 410.20(d)(5)(i) generally explains the prior determination process and accompanying documentation that may be required. Section 410.20(d)(5)(ii) describes how contractors will respond to prior determination requests. The statute provides that notice will be provided ''within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under section 1869(a)(2)(A) of the Act.'' Therefore, the statute requires that contractors must mail the requestor the decision no later than 45 days after the request is received. Contractors will be instructed to process the requests as quickly as possible (but no longer than 45 days), taking into consideration the beneficiary's physical condition, the urgency of treatment, and the availability of the necessary documentation. We are soliciting comments on this issue.

Section 410.20(d)(5)(iii) explains the binding nature of a positive

determination. Section 410.20(d)(5)(iv) explains the limitation on further review.

III. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on the information collection requirement discussed below, which are subject to the PRA.

Section 410.20 Physicians' Services

Prior determination of medical necessity for physicians' services. Before a physician's service is furnished, an eligible requester, such as a physician or beneficiary, may request an individualized decision, a ''Prior Determination of Medical Necessity,'' by a Medicare contractor as to whether or not the physician's service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity.

The burden associated with this proposed requirement would be the time spent by a requester to provide the appropriate level of documentation, as outlined in this section, to a Medicare contractor so that the contractor can provide a ''Prior Determination of Medical Necessity.''

We estimate 5000 requests will be made on an annual basis and it will require 15 minutes per request, for an annual burden of 1,250 hours.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: John Burke, CMS–6024–P, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer, CMS–6024–P, *Christopher_Martin@omb.eop.gov*. Fax (202) 395–6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule. Furthermore, this rule would not result in an increase in benefit spending.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule would have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation would not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

List of Subjects in 42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

1. The authority citation for part 410 continues to read as follows:

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

2. Section 410.20 is amended by adding new paragraph (d) to read as follows:

§ 410.20 Physicians' services.

* * * * *

(d) *Prior determination of medical necessity for physicians' services.*

(1) *Definition:* A ''Prior Determination of Medical Necessity'' means an individual decision by a Medicare contractor, before a physician's service is furnished, as to whether or not the physician's service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity.

(2) Each Medicare contractor will, through the procedures established in CMS manual instructions, allow requests for Prior Determinations of Medical Necessity from eligible requesters under its respective jurisdiction for those services identified by CMS and posted on that specific Medicare contractor's Web site. Only those services listed on the date the request for a prior determination is made are subject to prior determination. Each contractor's list will consist of the following:

(i) At least the 50 most expensive physicians' services listed in the national ceiling fee schedule amount of the Medicare Physician Fee Schedule Database performed at least 50 times annually minus those services excluded by paragraph (d)(3) of this section; and

(ii) Plastic and dental surgeries that may be covered by Medicare and that have an average allowed charge of at least $1,000.

(3) Within the services designated in paragraphs (d)(2)(i) and (d)(2)(ii) of this section, those services for which there is a national coverage determination (NCD) in effect or a local coverage determination/local medical review policy (LCD/LMRP) in effect through the local contractor at the time of the request for prior determination will be excluded from the list of services eligible for prior determination. This provision only applies when, in CMS' judgment, the national or local policy provides the sufficiently specific reasonable and necessary criteria for the specific procedure for which the prior determination is requested.

(4) CMS may increase the number of services that are eligible for prior determination through manual instructions.

(5) Under section 1869(h)(3) through (6) of the Act, the procedures established in CMS manual instructions will include the following provisions:

(i) *Request for prior determination.*

(A) *In general.* An eligible requester may submit to the contractor a request for a determination, before the furnishing of a physicians' service, as to whether the physicians' service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) of the Act (relating to medical necessity).

(B) *Accompanying documentation.* The Secretary may require that the request be accompanied by a description of the physicians' service, supporting documentation relating to the medical necessity for the physicians' service, and other appropriate documentation. In the case of a request submitted by an eligible requester who is described in section 1869(h)(1)(B)(ii) of the Act, the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(ii) *Response to request.*

(A) *General rule.* The contractor will provide the eligible requester with notice of a determination as to whether—

(*1*) The physicians' service is so covered;

(*2*) The physicians' service is not so covered; or

(*3*) The contractor lacks sufficient information to make a coverage determination with respect to the physicians' service.

(B) *Contents of notice for certain determinations.*

(*1*) *Noncoverage.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(*2*) of this section, the contractor will include in the notice a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and a description of any applicable rights under section 1869(a) of the Act.

(*2*) *Insufficient information.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(*3*) of this section, the contractor will include in the notice a description of the additional information required to make the coverage determination.

(C) *Deadline to respond.* That notice will be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under section 1869(a)(2)(A) of the Act.

(D) *Informing beneficiary in case of physician request.* In the case of a request by a participating physician, the process will provide that the individual to whom the physicians' service is proposed to be furnished will be informed of any determination described in paragraph (d)(5)(ii)(A)(*2*) of this section (relating to a determination of non-coverage) and the right to obtain the physicians' service and have a claim submitted for the physicians' service.

(iii) *Binding nature of positive determination.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(*1*) of this section, that determination will be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(iv) *Limitation on further review.*

(A) *General rule.* Contractor determinations described in paragraph (d)(5)(ii)(A)(*2*) of this section or (d)(5)(ii)(A)(*3*) of this section (relating to pre-service claims) are not subject to further administrative appeal or judicial review.

(B) *Decision not to seek prior determination or negative determination does not impact right to obtain services, seek reimbursement, or appeal rights.* Nothing in this paragraph will be construed as affecting the right of an individual who—

(*1*) Decides not to seek a prior determination under this paragraph with respect to physicians' services; or

(*2*) Seeks such a determination and has received a determination described in paragraph (d)(5)(ii)(A)(*2*) of this section, from receiving (and submitting a claim for) those physicians' services and from obtaining administrative or judicial review respecting that claim under the other applicable provisions of this section. Failure to seek a prior determination under this paragraph with respect to physicians' services will not be taken into account in that administrative or judicial review.

(C) *No prior determination after receipt of services.* Once an individual is provided physicians' services, there will be no prior determination under this paragraph with respect to those physicians' services.

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

Dated: September 29, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 23, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–17175 Filed 8–29–05; 8:45 am]

BILLING CODE 4120–01–P