

**Material Incorporated by Reference**

(i) You must use Boeing 707 Alert Service Bulletin A3526, dated June 4, 2007, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124-2207.

(3) You may review copies of the service information incorporated by reference at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

Issued in Renton, Washington, on February 11, 2008.

**Stephen P. Boyd,**

*Assistant Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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**BILLING CODE 4910-13-P**

**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 301**

[TD 9378]

RIN 1545-BE35

**Release of Lien or Discharge of Property; Correction**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correcting amendments.

**SUMMARY:** This document contains corrections to final regulations (TD 9378) that were published in the **Federal Register** on Thursday, January 31, 2008 (73 FR 5741) relating to release of lien and discharge of property under sections 6325, 6503 and 7423 of the Internal Revenue Code. These regulations update existing regulations and contain procedures for processing a request made by a property owner for discharge of a Federal tax lien from his property under section 6325(b)(4). The regulations also clarify the impact of these procedures on sections 6503(f)(2) and 7426(a)(4) and (b)(5).

**DATES:** The correction is effective February 22, 2008.

**FOR FURTHER INFORMATION CONTACT:** Debra A. Kohn, (202) 622-7985 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:****Background**

The final regulations (TD 9378) that are the subject of the correction are under sections 6325, 6503 and 7426 of the Internal Revenue Code.

**Need for Correction**

As published, final regulations (TD 9378) contain errors that may prove to be misleading and are in need of clarification.

**List of Subjects in 26 CFR Part 301**

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

**Correction of Publication**

■ Accordingly, 26 CFR part 301 is corrected by making the following amendments:

**PART 301—PROCEDURE AND ADMINISTRATION**

■ **Paragraph 1.** The authority citation for part 301 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 \* \* \*

■ **Par. 2.** Section 301.6325-1 is amended by revising the second sentence of paragraph (b)(2)(i) and first sentence of paragraph (b)(4)(ii) to read as follows:

**§ 301.6025-1 Release of lien or discharge of property.**

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(i) \* \* \* In determining the amount to be paid, the appropriate official will take into consideration all the facts and circumstances of the case, including the expenses to which the government has been put in the matter. \* \* \*

\* \* \* \* \*

(4) \* \* \*

(ii) \* \* \* The appropriate official may, in his discretion, determine that either the entire unsatisfied tax liability listed on the notice of Federal tax lien can be satisfied from a source other than the property sought to be discharged, or the value of the interest of the United States is less than the prior determination of such value. \* \* \*

\* \* \* \* \*

**LaNita Van Dyke,**

*Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).*

[FR Doc. E8-3103 Filed 2-21-08; 8:45 am]

**BILLING CODE 4830-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****42 CFR Part 410**

[CMS-6024-F]

RIN 0938-AN10

**Medicare Program; Prior Determination for Certain Items and Services**

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

**ACTION:** Final rule.

**SUMMARY:** This final rule establishes 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 final rule establishes 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. This rule also responds to public comments on the August 30, 2005 proposed rule.

**DATES:** *Effective Date:* March 24, 2008.

**FOR FURTHER INFORMATION CONTACT:** Debbie Skinner, (410) 786-7480.

**SUPPLEMENTARY INFORMATION:****I. Background****A. Background of Rulemaking**

On August 30, 2005, we published a rule (70 FR 51321) proposing to implement section 938 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted on December 8, 2003), establishing the reasonable limits on physicians' services for which a prior determination of coverage may be requested and we discussed our plans for establishing the procedures by which those determinations may be obtained.

The notice and comment period closed on October 29, 2005. We received seven timely public comments, which were useful in identifying issues and concerns. We have made changes to this final rule to address the public comments.

### *B. Overview of Existing Statutes and Policies*

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. They must include: the description of the service; an explanation of why the service may not be covered; a good faith cost estimate for the service; and the beneficiary's signature indicating the beneficiary has received and understood the notice.

ABNs enable beneficiaries to make an informed decision about whether or not to receive an item or service that could potentially be denied as not reasonable and necessary. Currently, there is no process for the beneficiary or his or her physician to find out with greater certainty if that item or service would be considered reasonable and necessary for that beneficiary before incurring financial liability. Consequently, beneficiaries may still be discouraged from obtaining services because they are uncertain whether or not Medicare contractors will deem those services reasonable and necessary in their particular case.

To address this issue, section 938 of the 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 and consistent with the applicable requirements of section 1862(a)(1)(A) of the Act (relating to medical necessity). This MMA section also provides that the following are eligible requesters: 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; and an individual entitled to benefits, but only with respect to a physician's service for which the individual receives an ABN under section 1879(a) of the Act.

Requesting a prior determination under this 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. If the physician wants a prior determination, there must first be consent from the beneficiary. In cases where a prior determination has been requested, an ABN should only be provided if the beneficiary wants the procedure and (1) the prior determination confirms noncoverage; or (2) a decision could not be made because requested materials were not received; or (3) the decision on the prior determination has not yet been received. We note that if the decision is favorable, then an ABN is unnecessary.

This final rule establishes 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 will be established in our manuals.

### **II. Provisions of the Proposed Rule**

In 42 CFR 410.20(d)(1), we proposed 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 proposed 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.

We proposed that each contractor's list would consist of the following: At least the 50 most expensive physicians' services listed in the Medicare Physician Fee Schedule (MPFS) 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.

In § 410.20(d)(3), we proposed 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 would 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.

In § 410.20(d)(4), we proposed 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 was to ensure that CMS can provide for prior determinations for additional services when we detect a need. Sections 1869(h)(3) through (h)(6) of the Act are specific with respect to various aspects of the prior determination process. Therefore, in § 410.20(d)(5), we specified those mandatory provisions. The detailed procedures to be followed by our contractors would be published in our manual instructions. Section 410.20(d)(5)(i) generally explained the prior determination process and accompanying documentation that may be required. Section 410.20(d)(5)(ii) described how contractors will respond to prior determination requests. The statute requires that contractors must mail the requester the decision no later than 45 days after the request is received. Section 410.20(d)(5)(iii) explained the binding nature of a positive determination. Section 410.20(d)(5)(iv) explained the limitation on further review.

### **III. Analysis of and Response to Public Comments**

We received seven public comments on the proposed rule. Summaries of the comments received and our responses to those comments are set forth below.

### General

*Comment:* One commenter asked CMS to ensure that physicians give their patients ABNs only when they have analyzed a particular procedure and have formed a reasonable belief that it may not be covered.

*Response:* Regulations governing ABNs and other notices of noncoverage, meeting the requirements of section 1879 of the Act, are found at 42 CFR 411.408. Instructions specific to the ABN are found in the on-line Medicare Claims Processing Manual, Publication 100-04, Chapter 30. This comment will be considered by the agency, but is beyond the scope of this regulation.

### List of Eligible Services

*Comment:* We received several comments recommending that the list of services eligible for prior determination be expanded. Several of these commenters suggested the list of 50 eligible services should be expanded, while another commenter suggested that CMS should include all services above a certain dollar amount.

*Response:* We are revising § 410.20(d)(2) of this final rule to include a provision that will allow us to expand or contract the number of services eligible for prior determination in the future through manual instructions. We are also allowing prior determinations for plastic and dental surgeries over \$1,000.

We did not include all services above a certain dollar amount because administrative constraints necessitate that we control the number of eligible services. Using a monetary cut-off would lead to uncertainty regarding how many services would be eligible in subsequent years due to inflation cost of the services.

*Comment:* Several commenters agreed with our approach that allows plastic and dental surgeries to be eligible for prior determination since many providers and beneficiaries currently have no way of knowing whether these services will be considered reasonable and necessary.

*Response:* We agree that this approach will be beneficial to both providers and beneficiaries.

*Comment:* One commenter suggested that CMS take the denial rate into account when determining which services are eligible for prior determination.

*Response:* For administrative consistency and other reasons, we chose to focus on cost. Denial rates are contractor specific and therefore are not applicable to a list formulated for the entire nation. Additionally, although a

service may have a relatively high denial rate, that number may be insignificant depending on the number of services performed annually.

### Exclusion of Services for Which There Is a Local Coverage Determination (LCD) or National Coverage Determination (NCD)

*Comment:* We received several comments stating that CMS should not exclude from the list of eligible services those services for which there is an LCD or an NCD in place. One commenter stated that beneficiaries will not have access to LCDs. Several stated that a beneficiary requester would not necessarily understand the LCD or NCD, and it would not provide them with enough information to make an informed decision. Several commenters indicated concern that the LCD or NCD would not be clear enough to provide the requester with information to make an informed decision.

*Response:* We have clarified § 410.20(d)(3) to state that services for which there is an NCD or LCD in place will remain on the "list of eligible services." In cases where the NCD or LCD provides sufficiently specific reasonable and necessary criteria addressing the particular clinical indication for the physician's service for which the prior determination is requested, the NCD or LCD will serve as the prior determination. Requesters will be sent a copy of the NCD or LCD with an explanation that this NCD/LCD will serve as the prior determination because it provides the necessary information for the beneficiary or provider to know whether or not the service will be considered reasonable and necessary. These explanations should also contain summary information clear enough for providers and beneficiaries alike to understand what is covered and what is not covered. In cases where the NCD or LCD does not provide sufficiently specific reasonable and necessary criteria addressing the particular clinical indication for the physician's service at issue, requesters will be sent a prior determination that is not based upon the NCD/LCD.

*Comment:* One commenter wanted to know how CMS would make the determination as to whether the LCD/NCD in question provides sufficiently specific reasonable and necessary criteria for the procedure for which the prior determination is requested.

*Response:* The contractors will make that decision by reviewing the LCD or NCD to determine whether or not the specific reasonable and necessary criteria addressing the particular

clinical indication for the procedure is addressed by the LCD.

*Comment:* Several commenters suggested that since section 938 of the MMA requires CMS to include a copy of any relevant LCD or NCD with the prior determination decision, those services should not be initially excluded.

*Response:* We have clarified that services for which there is an NCD or LCD in place will not be excluded and will remain on the "list of eligible services," if they meet the other criteria for being placed on the list. In cases where the relevant LCD or NCD provides sufficiently specific reasonable and necessary criteria addressing the particular clinical indication for the physician's service at issue, the contractor will include a copy of the NCD or LCD with the decision of noncoverage, in accordance with section 938 of the MMA.

*Comment:* One commenter asked how CMS plans to handle instances where the specific clinical situation determines whether or not a service is medically necessary per an LCD or an NCD or how borderline cases will be handled (that is, physicians might disagree as to whether clinical criteria in the LCD are met).

*Response:* It will be up to the contractor to determine whether the clinical criteria in the NCD or LCD are met.

*Comment:* One commenter asked whether contractors would develop LCDs solely in response to a high volume of prior determination requests.

*Response:* Contractors will continue to develop LCDs in accordance with instructions in CMS manuals.

### Processing Timeframe

*Comment:* We received several comments stating that the 45-day processing time is too long to be helpful to the beneficiary or provider.

*Response:* Section 410.20(d)(5)(ii) requires that " \* \* \* notice will be provided within 45 days (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)." Contractors will be instructed to process requests and send out responses as quickly as possible, taking into consideration the beneficiary's physical condition, the urgency of treatment, and the availability of the necessary documentation.

### Miscellaneous Comments

*Comment:* Several commenters suggested that CMS needs to clarify how information on this process (including

the list of eligible services) will be disseminated to providers and beneficiaries.

*Response:* In addition to using the contractors' Web sites, we are looking into a number of ways to disseminate the information to both providers and beneficiaries. We will issue manual instructions regarding the list of eligible services.

*Comment:* One commenter stated that CMS should investigate the possibility of allowing for submission of prior determination requests electronically.

*Response:* We do not intend to accept these requests electronically. We do not consider this a "prior authorization," for which there is an electronic form, but rather a coverage determination request. (See the statutory excerpt in § 410.20(d)(5)(ii)(A)(3), specifically calling this decision a coverage determination.) This is an optional process, and it does not preclude either the beneficiary or the provider from obtaining or performing the service and submitting the claim for payment.

*Comment:* Several commenters stated that the regulation should include how frequently the list will be updated. Another commenter stated that contractors should be required to provide written notice of any changes to the list to providers and beneficiaries.

*Response:* We agree with the commenters that the regulation should include how frequently the list will be updated. In § 410.20(d)(2), we have added a phrase to state that the list will be updated annually in conjunction with the release of the MPFS. Written notice will be provided, at a minimum, on the contractors' Web sites.

*Comment:* One commenter stated that the process the contractors use should be subject to notice and comment.

*Response:* The statute provides the basic process contractors are to follow when processing requests (that is, who can make a request, what is to be included in a request, what is to be included in a response, processing timeframe, requester rights following a negative determination, and, requester rights not to request a prior determination). The statutory process to be used by contractors was included in the proposed rule and was subject to comment. The detailed administrative matters will be in the manuals, which will allow us the flexibility to modify the administrative issues quickly if we find the procedures could be performed in a more effective manner. Contractors must adhere to policy as stipulated in CMS manuals.

*Comment:* One commenter stated the list of 50 services should be subject to notice and comment. One commenter

also suggested that any additional services added under § 410.20(d)(4) should be subject to comment.

*Response:* The criteria we will use to select the list of services were provided in the August 2005 proposed rule (70 FR 51321) and were subject to public comment. This list will be updated annually based on the MPFS, which is also available to the public. Because the list will be determined annually based on a ministerial execution of the already-published criteria, rather than the adoption of new substantive rules, we do not believe that any further opportunity for public comment is either required by law or useful. Additionally, we do not believe it is prudent to solicit comments on the specific services since the list is not static and will change based on the fee schedule.

*Comment:* One commenter stated that the list of eligible services should be available to providers and beneficiaries somewhere other than the contractor's Web site.

*Response:* We agree that this would be helpful. We are looking into a number of other ways to disseminate the information to both providers and beneficiaries. We will issue manual instructions regarding the list of eligible services. The list will be available by calling 1-800-Medicare and on the [www.Medicare.gov](http://www.Medicare.gov) Web site.

*Comment:* One commenter stated that the regulation should specify that the requestor be given written notice.

*Response:* We agree with the commenter and have clarified in § 410.20(d)(5)(ii)(A) that the requestor must receive written notice, as required by statute.

*Comment:* One commenter stated that the notice of non-coverage should also be required to explain that someone who receives such a notice may still obtain the service, submit a claim to Medicare, and then appeal the claim if it is denied.

*Response:* We agree with the commenter. Section 410.20(d)(5)(iv)(B) of the regulation provides that a negative determination does not impact the right of the requestor to obtain services and appeal any denial under the existing claims appeals system. Through our manuals, we will require contractors to include that information in the prior determination notice, where there is a negative determination.

*Comment:* One commenter stated that the regulation should include recourse to the beneficiary, and a consequence to the provider, if a provider fails to submit the necessary accompanying documentation.

*Response:* With regard to instances where the provider fails to submit the necessary documentation, § 410.20(d)(5)(ii)(B)(2) provides that if a contractor makes a determination that it lacks sufficient information to make a coverage determination with respect to a physician's service, the contractor will include in the notice a description of the additional information that was required to make a coverage determination, as required by the statute. We believe this provides the type of recourse to beneficiaries to cure flaws in their original requests that the Congress intended.

*Comment:* One commenter requested that we clarify what we mean by "plastic and dental surgeries that have an average allowed charge of at least \$1,000."

*Response:* We have clarified in § 410.20(d)(2)(ii) that we mean at least \$1,000 based on the MPFS amount, (not including the adjustment for location by the geographic practice cost index (GPCI)).

*Comment:* One contractor requested that CMS provide contractors with the necessary resources to implement this process, and suggested that contractors be part of the development of the process.

*Response:* With contractor input, we will determine the resources and instructions the contractors will need to implement this process. Contractors will be involved in the necessary clearance processes.

*Comment:* One commenter requested that CMS clarify how contractors should handle requests submitted for services not on the list of eligible services.

*Response:* The detailed procedures specified in our manual instructions will include a provision that the contractor will send back the request with an explanation that it is not an eligible service.

*Comment:* One commenter asked us to clarify in the regulation text whether or not services receiving an affirmative prior determination decision are still subject to eligibility and reimbursement criteria.

*Response:* Yes, services receiving affirmative prior determinations are still subject to eligibility and reimbursement criteria when adjudicated on a claim.

#### IV. Provisions of the Final Rule

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 (h)(6) of the Act are specific with respect to various aspects of the prior determination process, and we

intend to follow these provisions in establishing the prior determination process. We will 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 determining factors. However, denial rates vary according to contractor, and although a service may have a relatively high denial rate, that number may be insignificant depending on the number of services performed annually. This information did not readily lend itself to establishing a national list. Accordingly, we have decided to use other factors instead.

Based on our analysis, we are establishing an initial pool of eligible physicians' services with the highest average allowed charges that are performed at least 50 times annually. The definition of physicians' services in the MMA provision (section 938) is the one in section 1848(j)(3) of the Act. The definition includes the physician administration of a drug (but not the cost of the drug itself) and certain services not traditionally performed by a physician, such as physical therapy and occupational therapy, which are paid using the MPFS.

We are also establishing a list of plastic and dental surgeries that may be covered by Medicare and that have an amount of at least \$1,000 in the MPFS (not including the adjustment for location by the GPCI). We will identify the specific services that are eligible for prior determinations through manual instructions based on the criteria outlined in the regulation. We have decided not to identify a specific number of eligible services in the regulation text in order to provide the agency with flexibility in identifying an adequate/sufficient list of services eligible for prior determinations.

Specifically, in § 410.20(d)(1)(i), we define a "prior determination of medical necessity" as 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. We have also incorporated the statutory definition of an "eligible requester," which had been included in the preamble to the proposed rule, into the regulatory text. Therefore, in § 410.20(d)(1)(ii), we define an "eligible requester" to include a participating physician or a physician who accepts assignment, but only with respect to physicians' services to be furnished to an individual who is entitled to receive benefits and who has consented to the physician making the request for those physician's services; and an individual entitled to benefits, but only with respect to a physician's service for which the individual receives, from a physician, an advance beneficiary notice under section 1879(a) of the Act. We clarified that physicians who accept assignment for services eligible for a prior determination are eligible requesters because this is consistent with the statute and will maximize the benefit of the prior determination process for beneficiaries.

In § 410.20(d)(2), we state that each Medicare contractor will, through the procedure established in our manual instructions, allow requests for prior determinations of medical necessity from eligible requesters under the contractor's respective jurisdiction for those services that we identify (updated in conjunction with the update to the MPFS) and posted on that specific Medicare contractor's Web site. Only those services listed on the contractor's Web site on the date the request for a prior determination is made would be subject to prior determination.

The list of services will be posted by the Healthcare Common Procedure Coding System procedure code and code description on each carrier's Web site and will include the following: The most expensive physicians' services included in the MPFS which are performed at least 50 times annually; and plastic and dental surgeries that may be covered by Medicare and that have an amount of at least \$1,000 (not including adjustment for location by the GPCI).

We have three reasons for establishing 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 resources required to process each prior determination request.

In § 410.20(d)(3), we state that in instances where an NCD or an LCD exists that has sufficiently specific reasonable and necessary criteria addressing the particular clinical indication for the physician's service for which the prior determination is requested, the contractor will send a copy of the LCD or NCD with an explanation that this NCD/LCD will serve as the prior determination. Our reason for this provision is that many NCDs and LCDs already provide the information necessary to make an informed decision about whether or not a service will be covered.

In § 410.20(d)(4), we state that we will identify through manual instructions the number of services that are eligible for a prior determination consistent with the criteria established in the regulation. Our reason for this provision is to ensure that we can adjust the number of eligible services when we detect a need.

Sections 1869(h)(3) through (h)(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. Section 938 of the MMA 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 requester 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. 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.

## V. 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 or not 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.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

### *Section 410.20 Physicians' Services*

#### Prior Determination of Medical Necessity for Physicians' Services

Section 410.20(d)(5) states that 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. CMS may require that the request be accompanied by a description of the physician's service, supporting documentation relating to the medical necessity of the physician's service, and other appropriate documentation. In the case of a request submitted by an eligible requestor who is described in section 1869(h)(1)(B)(ii) of the Act, the Secretary may also require that the request be accompanied by a copy of the advance beneficiary notice involved.

The burden associated with this 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 5,000 requests will be made on an annual basis, and it will require 15 minutes per request, for an annual burden of 1,250 hours.

We received one comment in response to the proposed rule stating that this estimate appeared to be too low. We stand by our original estimate that 5,000 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 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, Division of Regulations Development, Attn.: Melissa Musotto, CMS-6024-F, Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850. Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS-6024-F, *carolyn\_lovett@omb.eop.gov*. Fax (202) 395-6974.

## VI. 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 19, 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 will 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, non-profit organizations, and government jurisdictions. While most hospitals and most other providers and

suppliers are small entities, either by non-profit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year, individual physicians and beneficiaries are not included in the definition of a small entity.

Accordingly, we are not preparing an analysis for the RFA because we have determined that this rule will 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 604 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 will 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 \$120 million. This rule will 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 final 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 will 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 amends 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) Definitions.* (i) 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.

(ii) An "eligible requester" includes the following:

(A) A participating physician (or a physician that accepts assignment), but only with respect to physicians' services to be furnished to an individual who is entitled to receive benefits under this part and who has consented to the physician making the request under this section for those physicians' services.

(B) An individual entitled to benefits under this part, but only with respect to physicians' services for which the individual receives, from a physician, an advance beneficiary notice under section 1879(a) of the Act.

(2) *General rule.* 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 (updated annually in conjunction with the update to the MPFS and posted on that specific Medicare contractor's Web site by the Healthcare Common Procedure Coding System procedure code and code description). Only those services listed on that Medicare contractor's Web site 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) The national list, provided by CMS, of the most expensive physicians' services (as defined in section 1848(j)(3) of the Act) included in the MPFS which

are performed at least 50 times annually.

(ii) The national list, provided by CMS, of plastic and dental surgeries that may be covered by Medicare and that have an amount of at least \$1,000 on the MPFS (not including the adjustment for location by the GPCI).

(3) *Services with local coverage determinations (LCDs) or national coverage determinations (NCDs).* In instances where an LCD or an NCD exists that has sufficiently specific reasonable and necessary criteria addressing the particular clinical indication for the procedure for which the prior determination is requested, the contractor will send a copy of the LCD or NCD to the requestor along with an explanation that the LCD or NCD serves as the prior determination and that no further determination will be made.

(4) *Identification of eligible services.* CMS will identify the number of services that are eligible for a prior determination through manual instructions consistent with the criteria established in the regulation.

(5) *Statutory procedures.* Under sections 1869(h)(3) through (h)(6) of the Act, the following procedures apply:

(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 physician's service, as to whether the physician's 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.* CMS may require that the request be accompanied by a description of the physician's service, supporting documentation relating to the medical necessity of the physician's 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 written notice of a determination as to whether—

(1) The physician's service is covered (the physician's service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity); or

(2) The physician's service is not covered (the physician's service is not covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity); or

(3) The contractor lacks sufficient information to make a coverage

determination with respect to the physician's service.

(B) *Contents of notice for certain determinations—(1) Coverage.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(1) of this section, the contractor will indicate in the prior determination notice that the physician service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity.

(2) *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.

(3) *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.* The notice described in paragraphs (d)(5)(ii)(A)(1) through (d)(5)(ii)(A)(3) of this section will be provided by the contractor within 45 days of the date the request for a prior determination is received by the contractor.

(D) *Informing beneficiary in case of physician request.* In the case of a request by a participating physician or a physician accepting assignment, the process will provide that the individual to whom the physician's service is 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). The beneficiary will also be notified that, notwithstanding the determination of non-coverage, the beneficiary has the right to obtain the physician's service in question and have a claim submitted for the physician's 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 paragraph (d)(5)(ii)(A)(3) of this section (relating to pre-service claims) are not subject to administrative appeal or judicial review.

(B) *Decision not to seek prior determination or negative determination does not impact the 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 part 405 subpart I of this chapter. 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.

**Editorial Note:** This document was received at the Office of the Federal Register on February 11, 2008.

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

Dated: May 31, 2007.

**Leslie V. Norwalk,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: October 30, 2007.

**Michael O. Leavitt,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Parts 411 and 489

[CMS–6272–F]

RIN 0938–AN27

#### Medicare Program; Medicare Secondary Payer (MSP) Amendments

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

**ACTION:** Final rule.

**SUMMARY:** On February 24, 2006, we published an interim final rule with

comment period in the **Federal Register** that implemented amendments to the Medicare Secondary Payer (MSP) provisions under Title III of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The MMA clarified the MSP provisions regarding the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare.

In this final rule, we are finalizing several clarifications made to the MSP provisions. In addition, we are responding to public comments on the February 24, 2006 interim final rule with comment period that pertain to these MSP provisions.

**DATES: Effective Date:** These regulations are effective on March 24, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Suzanne Lewis, (410) 786–0970.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

##### A. Statutory Background

Beginning in 1980, the Congress enacted a series of amendments to section 1862(b) of the Social Security Act (the Act) (hereafter referred to as the Medicare Secondary Payer (MSP) provisions) to protect the financial integrity of the Medicare program by making Medicare a secondary payer, rather than a primary payer of health care services, when certain types of other health care coverage are available. (Workers' compensation had already been primary to Medicare since the implementation of the original Medicare statute.) In enacting the MSP provisions, the Congress intended that the MSP provisions be construed to make Medicare a secondary payer to the maximum extent possible. These statutory provisions are set forth in regulations at 42 CFR part 411, Exclusions From Medicare and Limitations on Medicare Payment.

On December 8, 2003, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173). The Congress passed section 301 under Title III of the MMA to address several interpretations of the MSP provisions being pressed by various parties that would, if ultimately accepted, severely limit the applicability of the MSP provisions at considerable expense to the Medicare program. As discussed in the February 24, 2006 interim final rule with comment period (71 FR 9466) many of these interpretations were

presented in the context of Federal court litigation over the meaning of various MSP provisions. The Congress rejected these attempts to incorrectly limit the application and scope of the MSP statute.

In the MMA, the Congress clarified its original intent regarding the MSP provisions under section 1862(b) of the Act, thereby indicating that these interpretations were incorrect and that the Secretary's interpretations were accurate. These clarifications were effective as if enacted on the date of the original legislation.

Section 301(a) of the MMA amended section 1862(b)(2)(A)(ii) of the Act to remove the term "promptly." This amendment establishes that various parties were incorrect in their interpretation that section 1862(b)(2)(A)(ii) of the Act applied only if the workers' compensation law or plan, liability insurance, or no-fault insurance has paid or could reasonably be expected to pay for services "promptly." This amendment also added language to section 1862(b)(2)(B) of the Act to clarify that the Secretary may make payment subject to reimbursement if the workers' compensation law or plan, liability insurance, or no-fault insurance has not paid or could not reasonably be expected to pay for services "promptly."

Section 301(b)(1) of the MMA amended section 1862(b)(2)(A) of the Act to clarify the application of the term "self-insured plan." It establishes that "an entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part."

Section 301(b)(2)(A) of the MMA amended section 1862(b)(2)(B) of the Act to specify that a primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment that the Secretary makes with respect to an item or service if it is demonstrated that the primary plan has or had a responsibility to make payment with respect to the item or service. It added language establishing that a primary plan's responsibility for this payment "may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means."

Section 301(b)(3) of the MMA amended section 1862(b)(2) of the Act to