DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3141-N]

Procedure for Producing Guidance Documents Describing Medicare's Coverage Process

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

ACTION: Notice.

SUMMARY: This notice implements part of section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 by describing a method of developing, and making available to the public, guidance documents under the Medicare program. The guidance documents would explain the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted on December 8, 2003), requires that the Secretary make available to the public the factors that are considered in making national coverage determinations of whether an item or service is reasonable

and necessary. That section further specifies that the Secretary develop guidance documents to implement section 731 of the MMA in a manner similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)). This notice describes the method we are adopting to develop and make public guidance documents consistent with these requirements.

II. CMS Guidance Documents

For the purposes of this notice, the term "guidance documents" means documents prepared for our staff, potential requestors of National Coverage Determinations (NCDs), and other interested parties explaining the NCD process and other issues involved in making coverage determinations. Those documents will be specifically labeled as guidance documents and do not include other CMS reports, documents, letters, or program instructions.

Guidance documents give the public, particularly individuals or organizations that might request an NCD, detailed information on current interpretations of the statute, the NCD process, and related evaluation and decision-making factors. A more precise understanding of these factors assists product developers and others in making decisions by understanding:

- The implications of making an NCD request.
- What content is necessary in an NCD request.
- Relevant timelines and their relation to the overall NCD process.
- What types of scientific and other information are considered in the process.
- How various types of evidence are evaluated for reasonable and necessary determinations.

In general, guidance documents reduce uncertainty about key aspects of the NCD process. Guidances may be useful in certain cases to help plan investment strategies, research and development efforts, and marketing and clinical diffusion strategies.

CMS strives to achieve consistent and fair review of NCDs. Guidances are an additional tool that may be used in this effort.

III. Effect of Guidance Documents

A guidance document represents the agency's current thinking on the relevant subject. It is not intended to be a comprehensive description or analysis of all issues and factors that might affect an individual NCD. A guidance document is not binding on the Agency or the public. For example, the guidance documents will describe how we will evaluate different types of study designs in determining

whether an item or service is reasonable and necessary. This does not mean the absence of a particular type of research will necessarily result in a noncoverage decision nor does submitting data from a particular type of study ensure coverage. Every effort will be made to describe in general terms the factors that are most important in making a coverage determination. Nonetheless, each NCD involves unique factors that cannot be described explicitly in the guidance documents.

IV. Development of Guidance Documents

For all guidance documents, the public will have an opportunity to comment upon issuance. Usually, guidance documents will not be considered in effect until CMS has analyzed public input received during a period for public comment. In cases of immediate need or for minor policy changes, however, guidance documents may be made effective upon issuance, prior to the public comment period. Each document will clearly denote the appropriate addresses for hard copy and electronic submission of comments. We will consider changes to the documents based on the comments as appropriate. Comments will be taken and reviewed on a continuous basis.

V. Public Notification of New Guidance Documents

We will provide notice of new guidance documents and

make them available on the internet at http://www.cms.hhs.gov/coverage. At regular intervals, we will update a list of all guidance documents in the **Federal Register**. Individuals who need assistance accessing the guidance documents for any reason may send an email to CAGInquiries@cms.hhs.gov.

VI. Public Input

We will provide a list of possible topics for guidance documents development related to section 731 of the MMA on our website. We invite public input regarding these and other possible topics for new guidance documents via the public comments function available at www.cms,hhs.gov/coverage. While these suggestions will be given serious consideration, we are not required to issue every document on the list and are not precluded from issuing other guidance documents not included on the list.

We will review existing guidance documents on a regular basis. The public may submit proposals for review and revision of existing documents on the basis that they are no longer current. A statement explaining why the existing document needs updating and/or revision must accompany each request. We will review the statement and, when appropriate, develop the necessary revisions in accordance with the procedures specified in this notice.

VII. Dissemination/Availability to the Public

A list of all guidance documents will be maintained on the CMS Coverage home page. The list will include the title of each document and issue and revision date.

VIII.List of Proposed Guidance Documents

We will update this list as we continue to develop guidance documents. The first guidance document will be the "Revised Process for Making Medicare National Coverage Determinations."

Authority: Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: _____

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Mark B. McClellan,

Administrator,

Centers for Medicare & Medicaid Services.

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