

services under Medicare. Additionally, this notice identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that potentially may be covered under Medicare. Finally, this notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months.

Although we are not mandated to do so by statute, for the sake of completeness of the listing, and to foster more open and transparent collaboration efforts, we are also including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this 3-month time frame.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. (See Section III of this notice for how to obtain listed material.)

Questions concerning items in Addendum III may be addressed to Karen Bowman, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services, C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-5252.

Questions concerning national coverage determinations in Addendum V may be addressed to Patricia Brocato-Simons, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-0261.

Questions concerning Investigational Device Exemptions items in Addendum VI may be addressed to Sharon Hippler, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C5-13-27, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-4633.

Questions concerning approval numbers for collections of information in Addendum VII may be addressed to Dawn Willingham, Office of Strategic Operations and Regulatory Affairs,

Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-6141.

Questions concerning all other information may be addressed to Margie Teeters, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5-13-18, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-4678.

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs. These programs pay for health care and related services for 39 million Medicare beneficiaries and 35 million Medicaid recipients. Administration of the two programs involves (1) furnishing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public and (2) maintaining effective communications with regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act). We also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, and to foster more open and transparent collaboration, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the respective 3-month time frame.

II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of manual issuances, memoranda, substantive and interpretive regulations,

national coverage determinations (NCDs), and Food and Drug Administration (FDA)-approved investigational device exemptions (IDEs) published during the subject quarter to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) published in 1988, and the notice published March 31, 1993 (58 FR 16837). Those desiring information on the Medicare Coverage Issues Manual (CIM) may wish to review the August 21, 1989 publication (54 FR 34555). Those interested in the procedures used in making NCDs under the Medicare program may review the April 27, 1999 publication (64 FR 22619).

To aid the reader, we have organized and divided this current listing into six addenda:

- Addendum I lists the publication dates of the most recent quarterly listings of program issuances.
- Addendum II identifies previous **Federal Register** documents that contain a description of all previously published CMS Medicare and Medicaid manuals and memoranda.
- Addendum III lists a unique CMS transmittal number for each instruction in our manuals or Program Memoranda and its subject matter. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manuals.
- Addendum IV lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the **Federal Register** during the quarter covered by this notice. For each item, we list the—
 - Date published;
 - **Federal Register** citation;
 - Parts of the Code of Federal Regulations (CFR) that have changed (if applicable);
 - Agency file code number; and
 - Title of the regulation.
- Addendum V includes completed NCDs, or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the CIM in which the decision appears, the title, the date the publication was issued, and the effective date of the decision.
- Addendum VI includes listings of the FDA-approved IDE categorizations, using the IDE numbers the FDA assigns. The listings are organized according to the categories to which the device