Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: July 26, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 96–19744 Filed 7–30–96; 3:29 pm]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPO–139–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—First Quarter 1996

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

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations and other Federal Register notices, and statements of policy that were published during January, February, and March of 1996 that relate to the Medicare and Medicaid programs. It also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that may be potentially covered under Medicare.

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, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this time frame. Generally, we also provide the content of revisions to the Medicare Coverage Issues Manual. There were no revisions published during the period January 1 through March 31, 1996. On August 21, 1989, we published the content of the Manual (54 FR 34555) and indicated that we will publish quarterly any updates. Adding to this listing the complete text of the changes to the Medicare Coverage Issues Manual fulfills this requirement in a manner that facilitates identification of coverage and other changes in our manuals.

FOR FURTHER INFORMATION CONTACT:

Margaret Cotton, (410) 786–5255 (For Medicare instruction information).

Pat Prete, (410) 786–3246 (For Medicaid instruction information).

Sharon Hippler, (410) 786–4633 (For Food and Drug Administration-approved investigational device exemption information).

Cathy Johnson, (410) 786–5241 (For all other information).

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 38 million Medicare beneficiaries and 36 million Medicaid recipients. Administration of these programs involves (1) Providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public, and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries and carriers 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 the Secretary under sections 1102, 1871, and 1902 and related provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the Federal Register at least every 3 months a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations. 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, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month time frame. Since the publication of our quarterly listing on June 12, 1992 (57 FR 24797), we decided to add Medicaid issuances to our quarterly listings. Accordingly, we list in this notice Medicaid issuances and Medicaid substantive and interpretive regulations published during January through March 1996.

II. Medicare Coverage Issues

We receive numerous inquiries from the general public about whether specific items or services are covered under Medicare. Providers, carriers, and intermediaries have copies of the Medicare Coverage Issues Manual, which identifies many of those medical items, services, technologies, or treatment procedures that can be paid for under Medicare. On August 21, 1989, we published a notice in the Federal Register (54 FR 34555) that

contained all the Medicare coverage decisions issued in that manual.

In that notice, we indicated that revisions to the Coverage Issues Manual will be published at least quarterly in the Federal Register. We also sometimes issue proposed or final national coverage decision changes in separate Federal Register notices. Readers should find this an easy way to identify both issuance changes to all our manuals and the text of changes to the Coverage Issues Manual.

Revisions to the Coverage Issues Manual are not published on a regular basis but on an as-needed basis. We publish revisions as a result of technological changes, medical practice changes, responses to inquiries we receive seeking clarifications, or the resolution of coverage issues under Medicare. If no Coverage Issues Manual revisions were published during a particular quarter, our listing will reflect that fact.

Not all revisions to the Coverage Issues Manual contain major changes. As with any instruction, sometimes minor clarifications or revisions are made within the text. This notice contains, as Addendum IV, reprinted manual revisions as transmitted to manual holders. The new text is shown in italics. We have not reprinted the table of contents, since the table of contents serves primarily as a finding aid for the user of the manual and does not identify items as covered or not.

III. How To Use the Addenda

This notice is organized so that a reader may review the subjects of all manual issuances, memoranda, substantive and interpretive regulations, coverage decisions, or Food and Drug Administration-approved investigational device exemptions published during the time frame to determine whether any are of particular interest. We expect it to be used in concert with previously published notices. Most notably, 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) and the notice published March 31, 1993 (58 FR 16837), and those desiring information on the Medicare Coverage Issues Manual may wish to review the August 21, 1989 publication (54 FR 34555).

To aid the reader, we have organized and divided this current listing into six addenda. Addendum I identifies updates that changed the Coverage Issues Manual. We published notices in the Federal Register that included the text of changes to the Coverage Issues Manual. These updates, when added to material from the manual published on August 21, 1989 constitute a complete manual as of the end of the quarter covered by this notice. Parties interested in obtaining a copy of the manual and revisions should follow the instructions in section IV of this notice.

Addendum II identifies previous Federal Register documents that contain a description of all previously published HCFA Medicare and Medicaid manuals and memoranda.

Addendum III of this notice lists, for each of our manuals or Program Memoranda, a HCFA transmittal number unique to that instruction and its subject matter. A transmittal may consist of a single instruction or many. Often it is necessary to use information in a transmittal in conjunction with information currently in the manuals.

Addendum IV sets forth the revisions to the Medicare Coverage Issues Manual that were published during the quarter covered by this notice. For the revisions, we give a brief synopsis of the revisions as they appear on the transmittal sheet, the manual section number, and the title of the section. We present a complete copy of the revised material, no matter how minor the revision, and identify the revisions by printing in italics the text that was changed. If the transmittal includes material unrelated to the revised section, for example, when the addition of revised material causes other sections to be repaginated, we do not reprint the unrelated material.

Addendum V 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, the Federal Register citation, the parts of the Code of Federal Regulations (CFR) that have changed (if applicable), the agency file code number, the title of the regulation, the ending date of the comment period (if applicable), and the effective date (if applicable).

On September 19, 1995, we published a final rule (60 FR 48417) establishing in regulations that certain devices with an investigational device exemption approved by the Food and Drug Administration and certain services related to those devices may be covered under Medicare. That final rule states that we will announce in this quarterly notice all investigational device exemption categorizations, using the investigational device exemption numbers the Food and Drug Administration assigns. Addendum VI includes listings of the Food and Drug Administration-approved investigational device exemption numbers that have been approved during the quarter covered by this notice. The listings are organized according to the categories to which the device numbers are assigned (that is, Category A or Category B, and identified by the investigational device exemption number). Future notices will announce investigational device exemption categorizations and the numbers assigned by the Food and Drug Administration for the quarter for which the notices cover.

IV. How To Obtain Listed Material

A. Manuals

An individual or organization interested in routinely receiving any manual and revisions to it may purchase a subscription to that manual. Those wishing to subscribe should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses:

Superintendent of Documents, Government Printing Office, ATTN: New Order, P.O. Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 512–1800, Fax number (202) 512–2250 (for credit card orders); or

National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487–4630.

In addition, individual manual transmittals and Program Memoranda listed in this notice can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell.

B. Regulations and Notices

Regulations and notices are published in the daily Federal Register. Interested individuals may purchase individual copies or subscribe to the Federal Register by contacting the GPO at the address given above. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The Federal Register is also available on 24x microfiche and as an online database through GPO Access. The online database is updated by 6 a.m. each day the Federal Register is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) forward. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using (1) the

World Wide Web—the Superintendent of Documents home page address is http://www.access.gpo.gov/su__docs/; (2) local WAIS client software, or (3) telnet—swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as guest (no password required). For general information about GPO Access, contact the GPO Access User Support Team by sending Internet e-mail to help@eids05.eids gpo.gov; by faxing to (202) 512–1262; or by calling (202) 512–1530 between 7 a.m. and 5 p.m. Eastern time, Monday–Friday, except for Federal holidays.

C. Rulings

We publish Rulings on an infrequent basis. Interested individuals can obtain copies from the nearest HCFA Regional Office or review them at the nearest regional depository library. We also sometimes publish Rulings in the Federal Register.

D. HCFA's Compact Disk-Read Only Memory (CD–ROM)

Our laws, regulations, and manuals are also available on CD–ROM, which may be purchased from GPO or NTIS on a subscription or single copy basis. The Superintendent of Documents list ID is HCLRM, and the stock number is 717–139–00000–3. The following material is on the CD–ROM disk:

- Titles XI, XVIII, and XIX of the Act.
- HCFA-related regulations.
- HCFA manuals and monthly revisions.
- HCFA program memoranda.

The titles of the Compilation of the Social Security Laws are current as of January 1, 1995. The remaining portions of CD–ROM are updated on a monthly basis.

Because of complaints about the unreadability of the Appendices (Interpretive Guidelines) in the State Operations Manual (SOM), as of March 1995, we deleted these appendices from CD–ROM. We intend to re-visit this issue in the near future, and with the aid of newer technology, we may again be able to include the appendices on CD–ROM.

Any cost report forms incorporated in the manuals are included on the CD–ROM disk as LOTUS files. LOTUS software is needed to view the reports once the files have been copied to a personal computer disk.

V. How To Review Listed Material

Transmittals or Program Memoranda can be reviewed at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1400 designated libraries throughout the United States. Interested parties may examine the documents at any one of the FDLs. Some may have arrangements to transfer material to a local library not designated as an FDL. To locate the nearest FDL, contact any library.

In addition, individuals may contact regional depository libraries, which receive and retain at least one copy of most Federal Government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. Superintendent of Documents numbers for each HCFA publication are shown in Addendum III, along with the HCFA publication and transmittal numbers. To help FDLs locate the instruction, use the Superintendent of Documents number, plus the HCFA transmittal number. For example, to find the Carriers Manual, Part 3—Claims Process (HCFA–Pub. 14–3) transmittal entitled ''Beneficiary Address Change,'' use the Superintendent of Documents No. HE 22.8/7 and the HCFA transmittal number 1538.

VI. General Information

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. Copies can be purchased or reviewed as noted above.

Questions concerning Medicare items in Addenda III may be addressed to Margaret Cotton, Bureau of Program Operations, Issuances Staff, Health Care Financing Administration, S3–01–27, 7500 Security Blvd., Baltimore, MD 21244–1850, Telephone (410) 786–5255.

Questions concerning Medicaid items in Addenda III may be addressed to Pat Prete, Medicaid Bureau, Office of Medicaid Policy, Health Care Financing Administration, C4–25–02, 7500 Security Boulevard, Baltimore, MD 21244–1850, Telephone (410) 786–3246.

Questions concerning Food and Drug Administration-approved investigational device exemptions may be addressed to Sharon Hippler, Bureau of Policy Development, Office of Chronic Care and Insurance Policy, Health Care Financing Administration, C4–11–04, 7500 Security Blvd., Baltimore, MD 21244–1850, Telephone (410) 786–4633.

Questions concerning all other information may be addressed to Cathy Johnson, Bureau of Policy Development, Office of Regulations, Health Care Financing Administration, C5–09–05, 7500 Security Blvd., Baltimore, MD 21244–1850, Telephone (410) 786–5241.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: July 19, 1996.

Carol J. Walton,

Director, Bureau of Program Operations.

Addendum I

This addendum lists the publication dates of the most recent quarterly listing of program issuances and coverage decision updates to the Coverage Issues Manual. For a complete listing of the quarterly updates to the Coverage Issues Manual published during March 20, 1990 through November 14, 1994, please refer to the January 3, 1995 update (60 FR 134).

January 3, 1995 (60 FR 132)
April 6, 1995 (60 FR 17538)
July 26, 1995 (60 FR 38344)
November 15, 1995 (60 FR 57435)
April 8, 1996 (61 FR 154)
June 26, 1996 (61 FR 33119)

Addendum II—Description of Manuals, Memoranda, and HCFA Rulings

An extensive descriptive listing of Medicare manuals and memoranda was published on June 9, 1988, at 53 FR 21730 and supplemented on September 22, 1988, at 53 FR 36891 and December 16, 1988, at 53 FR 50577. Also, a complete description of the Medicare Coverage Issues Manual was published on August 21, 1989, at 54 FR 34555. A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 16, 1992, at 57 FR 47468.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 1996

Trans. No.	Manual/Subject/Publication Number
	Intermediary Manual **Part 3—Claims Process (HCFA Pub. 13–3)** **(Superintendent of Documents No. HE 22.8/6–1)**
1671	• Claims Processing Terminology. Handling Incomplete or Invalid Claims. Data Element Requirements Matrix.
1672	• PRO Reporting on Medical Review.
1673	• Guidelines for Review of Claims for Epoetin.
	Carriers Manual **Part 3—Claims Process (HCFA Pub. 14–3)** **(Superintendent of Documents No. HE 22.8/7)**
1533	• Nomenclature and Organization of the List. Rebundling of CPT Codes. Added ASC Codes.
1534	• Positron Emission Tomography Scans. Billing Requirements for PET Scans. Claims Processing Instructions for PET Scan Claims.
1535	• Claims Processing Terminology. Handling Incomplete or Invalid Claims. Data Element Requirements Matrix. Conditional Data Element Requirements.
1536	• Reasonableness and Necessity.
1537	• Item 24—Type of Service.
1538	• Beneficiary Address Change.
	Carriers Manual **Part 4—Professional Relations (HCFA Pub. 14–4)** **(Superientendent of Documents No. HE 22.8/7–4)**
11	• Items 1–13—Patient and Insured Information. Items 14–33—Physician or Supplier Information. Place of Service Codes and Definitions.
	Program Memorandum **Intermediaries/Carriers (HCFA Pub. 60B)** **(Superintendent of Documents No. HE 22.8/6–5)**
B–96–1	• Coverage for Occupational Therapists in Independent Practice.
	Progam Memorandum **Carriers (HCFA Pub. 60A/B)** **(Superintendent of Documents No. HE 22.8/6–5)**
AB–96–1	• New Interest Rate Payable on Clean Claims Not Paid Timely.
AB–96–2	• Exclusion Process, § 1128(b)(7).
	Progam Memorandum **Insurance Commissioners (HCFA Pub. 80)** **(Superintendent of Documents No. HE 22.8/6–5)**
96–1	• Medigap Bulletin Series (Number Five).
	Peer Review Organization **(HCFA Pub. 19)** **(Superintendent of Documents No. HE 22.8/8–15)**
58	• Background. Beneficiary Hotline. Interaction with Beneficiary Groups. Other Activities.
59	• PRO Reporting on Medical Review. Tracking Adjustments. PRO/Intermediary/Carrier Coordination Activities. Additional PRO/Carrier Coordination Activities.
60	• Background.

ADDENDUM III—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS JANUARY THROUGH MARCH 1996—Continued

Trans. No.	Manual/Subject/Publication Number
	PRO Review Responsibilities. Types of Prohibited Actions That Circumvent PPS. Actions to be Taken by PRO. Authority. Types of Denial Determinations. Notification of Denial. Content of Denial Notice. Statutory and Regulatory Requirements. Requests for Reconsideration. Reconsideration Process. Circumvention of Prospective Payment System. Background. Appeals Council Review. Judicial Review. Circumvention of PPS Denial Model Notice. Circumvention of PPS Reconsideration Model Notice.
61	• Training. Citations and Authority.
	Hospice Manual (HCFA Pub. 21) (Superintendent of Documents No. HE 22.8/18)
47	• Credit Balance Reporting Requirements. Payment of Amounts Owed Medicare. Medicare Credit Balance Report Certification. Medicare Credit Balance Report (HCFA–838)
	Provider Reimbursement Manual Part 1—(HCFA Pub.15–1) (Superintendent of Documents No. HE 22.8/4)
389	• Travel Expense.
390	Regional Medicare Swing-Bed SNF Rates.
391	Interest. Necessary. Accounts Receivable Financing. Costs Included in Capital-Related Costs. Capital Related Costs of Related Organizations. Debt Issuance Costs, Debt Discounts, and Debt Redemption Costs. Costs Excluded From Capital-Related Costs. Jointly Owned Equipment. Unpaid Compensation.
392	• Ambulance Service.
	Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)
96–1	• Cumulative Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Sanctioned/Reinstated.
96–2	• Report of Physicians/Practioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated—December 1995 and January 1996.
96–3	• Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers/Reinstated—February 1996.

Addendum IV

There are no revisions to the Coverage Issues Manual for this quarter.

ADDENDUM V.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR Vol. 61 page	CFR Part	File code *	Regulation title	End of comment period	Effective date
01/19/96	1389–1390	.....	BPD–854–NC	Medicare and Medicaid Programs; Announcement of Applications from Hospitals Requesting Waivers for Organ Procurement Service Area.	03/19/96	01/19/96
01/23/96	1769–1772	.....	ORD–083–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: November 1995.	.....	.....

ADDENDUM V.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER—Continued

Publication date	FR Vol. 61 page	CFR Part	File code*	Regulation title	End of comment period	Effective date
01/26/96	2516–2519	.....	BPO–134–NC	Medicare Program; Revised Criteria and Standards for Evaluating Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Regional Carriers' Performance Beginning February 1, 1996.	02/26/96	02/01/96
01/26/96	2516	.....	ORD–078–N	Medicare Program; Announcement of Funding Availability for a Cooperative Agreement for an End-Stage Renal Disease (ESRD) Managed Care Demonstration.	.....	.....
01/29/96	2725–2727	412, 413	BPD–825–FCN	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1996 Rates; Corrections.	.....	10/01/95
02/27/96	7266	.....	ORD–084–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: December 1995.	.....	.....
02/29/96	7798	.....	ORD–085–N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: January 1996.	.....	.....
03/08/96	9405–9410	440	MB–071–P	Medicare Program; Coverage of Personal Care Services.	05/07/96	.....
03/27/96	13430–13450	417,434	OMC–010–FC	Medicare and Medicaid Programs; Requirements for Physician Incentive Plans in Prepaid Health Care Organizations.	05/28/96	04/26/96

*GN—General Notice; PN—Proposed Notice; FN—Final Notice; P—Notice of Proposed Rulemaking (NPRM); F—Final Rule; FC—Final Rule with Comment Period; CN—Correction Notice; SN—Suspension Notice; WN—Withdrawal Notice; NR—Notice of HCFA Ruling.

Addendum VI.—Categorization of Food and Drug Administration-Approved Investigational Device Exemptions

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes:

Class I—Devices for which the general controls of the Food, Drug, and Cosmetic Act, such as adherence to good manufacturing practice regulations, are sufficient to provide a reasonable assurance of safety and effectiveness.

Class II—Devices that, in addition to general controls, require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness.

Class III—Devices that cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness. Class III devices require premarket approval.

Under the new categorization process to assist HCFA, the Food and Drug Administration assigns each device with a Food and Drug Administration-approved investigational device exemption to one of two categories: Experimental/Investigational (Category A) Devices, or Non-Experimental/Investigational (Category B) Devices. Under this categorization process, an experimental/investigational (Category A) device is an innovative device in Class III for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the Food and Drug Administration is unsure whether the device type can be safe and effective). A non-experimental/investigational (Category B) device is a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained Food and Drug Administration approval for that device type.

The criteria the Food and Drug Administration uses to categorize an investigational device under Category B include the following:

(1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, that is, to establish substantial equivalence to a previously/currently legally marketed device.

(2) Class III devices whose technological characteristics and indication for use are comparable to a Pre-Market Approval (PMA)-approved device.

(3) Class III devices with technological advances compared to a PMA-approved device, that is, a device with technological changes that represent advances to a device that has already received PMA-approval (generational changes).

(4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modification to the device were required.

(5) Pre-amendments Class III devices that become the subject of an investigational device exemption after the Food and Drug Administration requires premarket approval, that is, no PMA application was submitted or the PMA application was denied.

(6) Nonsignificant risk device investigations for which the Food and Drug Administration required the submission of an investigational device exemption.

The following information presents the device number, category (in this case, A), and criterion code. G950168 A2, G950175 A1, G960026 A2, G960033 A1, G960034 A1, G960055 A2, G960060 A1, G960066 A2

The following information presents the device number, category (in this case, B), and criterion code. G950194 B1, G950210 B1, G950212 B3, G950217 B1, G950218 B1, G950229 B3, G950231 B, G960003 B4, G960018 B4, G960019 B4, G960021 B2, G960022 B4, G960023 B2, G960024 B3, G960025 B2, G960027 B4, G960028 B1, G960029 B4, G960030 B2, G960031 B2, G960035 B4, G960037 B4, G960038 B4, G960041 B4, G960043

B1, G960046 B1, G960051 B3, G960054 B3, G960056 B5, G960057 B2, G960059 B2, G960061 B2, G960062 B2

Note: Some investigational devices may exhibit unique characteristics or raise safety concerns that make additional consideration necessary. For these devices, HCFA and the Food and Drug Administration will agree on the additional criteria to be used. The Food and Drug Administration will use these criteria to assign the device(s) to a category. As experience is gained in the categorization process, this addendum may be modified.

[FR Doc. 96–19559 Filed 7–31–96; 8:45 am]
BILLING CODE 4120–01–P

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are *not* to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

Aegis Analytical Laboratories, Inc., 624 Grassmere Park Rd., Suite 21, Nashville, TN 37211, 615–331–5300

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931/205–263–5745

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 22021, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–227–2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Bayshore Clinical Laboratory, 4555 W. Schroeder Dr., Brown Deer, WI 53223, 414–355–4444/800–877–7016

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5810

Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310–215–6020

Clinical Reference Lab, 11850 West 85th St., Lenexa, KS 66214, 800–445–6917

CompuChem Laboratories, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–549–8263/800–833–3984 (Formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

CORNING Clinical Laboratories, 4771 Regent Blvd., Irving, TX 75063, 800–526–0947 (formerly: Damon Clinical Laboratories, Damon/MetPath)

CORNING Clinical Laboratories, 875 Greentree Rd., 4 Parkway Ctr., Pittsburgh, PA 15220–3610, 800–284–7515 (formerly: Med-Chek Laboratories, Inc., Med-Chek/Damon, MetPath Laboratories)

CORNING Clinical Laboratories, 4444 Giddings Road, Auburn Hills, MI 48326, 800–444–0106/810–373–9120 (formerly: HealthCare/Preferred Laboratories, HealthCare/MetPath)

CORNING Clinical Laboratories Inc., 1355 Mittel Blvd., Wood Dale, IL 60191, 708–595–3888 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories)

CORNING Clinical Laboratories, South Central Divison, 2320 Schuetz Rd., St. Louis, MO 63146, 800–288–7293 (formerly: Metropolitan Reference Laboratories, Inc.)

CORNING Clinical Laboratory, One Malcolm Ave., Teterboro, NJ 07608, 201–393–5000 (formerly: MetPath, Inc., CORNING MetPath Clinical Laboratories)

CORNING National Center for Forensic Science, 1901 Sulphur Spring Rd., Baltimore, MD 21227, 410–536–1485 (formerly: Maryland Medical Laboratory, Inc., National Center for Forensic Science)

CORNING Nichols Institute, 7470–A Mission Valley Rd., San Diego, CA 92108–4406, 800–446–4728/619–686–3200 (formerly: Nichols Institute, Nichols Institute Substance Abuse Testing (NISAT))

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–269–3093 (formerly: Cox Medical Centers)

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, Building 38–H, Great Lakes, IL 60088–5223, 708–688–2045/708–688–4171

Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 813–936–5446/800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912–244–4468

Drs. Weber, Palmer, Macy, Chartered, 338 N. Front St., Salina, KS 67401, 913–823–9246

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800–898–0180 / 206–386–2672 (formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.)

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 601–236–2609

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6267

Harrison Laboratories, Inc., 9930 W. Highway 80, Midland, TX 79706, 800–725–3784/915–563–3300 (formerly: Harrison & Associates Forensic Laboratories)

Jewish Hospital of Cincinnati, Inc., 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051

LabOne, Inc., 8915 Lenexa Dr., Overland Park, Kansas 66214, 913–888–3927 (formerly: Center for Laboratory Services, a Division of LabOne, Inc.)

Laboratory Corporation of America, 13900 Park Center Rd., Herndon, VA 22071, 703–742–3100 (Formerly: National Health Laboratories Incorporated)

Laboratory Corporation of America, 21903 68th Ave. South, Kent, WA 98032, 206–395–4000 (Formerly: Regional Toxicology Services)