DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5047]

Draft Guidance for Industry on Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.'' This draft guidance provides recommendations to sponsors planning to conduct studies to assess the influence of hepatic impairment on the pharmacokinetics and, where appropriate, the pharmacodynamics of drugs or therapeutic biologics.

DATES: Submit written comments on the draft guidance for industry by February 7, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance entitled ''Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Mehul U. Mehta, Center for Drug Evaluation and Research (HFD–860), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2567; or

David Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling.'' This draft guidance provides recommendations on: (1) When pharmacokinetic studies in patients with hepatic impairments are or are not recommended; (2) the design and conduct of studies to characterize the effects of impaired hepatic function on the pharmacokinetics of a drug; (3) characteristics of patient populations to be studied; (4) analysis, interpretation, and reporting of the results of the studies; and (5) the description of study results in drug labeling.

The draft guidance reflects the current view that the liver generally plays an important role in the elimination (metabolism and/or excretion) of a drug and that the effect of hepatic impairment on the elimination of a new drug should generally be defined during drug development.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on pharmacokinetic studies in patients with impaired hepatic function. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before February 7, 2000, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31608 Filed 12–6–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–9004–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—First Quarter, 1999

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 that were published during January, February, and March of 1999, relating to the Medicare and Medicaid programs. It also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that potentially may be 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 also including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

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.

Questions concerning Medicare items in Addendum III may be addressed to Bridget Wilhite, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–5248.

Questions concerning Medicaid items in Addendum III may be addressed to Betty Stanton, Center for Medicaid State Operations, Policy Coordination and Planning Group, Health Care Financing Administration, S2–26–13, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–3247.

Questions concerning Food and Drug Administration-approved investigational device exemptions may be addressed to Sharon Hippler, Office

of Clinical Standards and Quality, Coverage and Analysis Group, Health Care Financing Administration, C4–11–04, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–4633.

Questions concerning all other information may be addressed to Trenesha Fultz, Office of Communications and Operations Support, Division of Regulations and Issuances, Health Care Financing Administration, C5–12–08, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–3822.

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) 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 these programs involves (1) furnishing 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 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, 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, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month time frame.

II. 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, or Food and Drug Administration-approved investigational device exemptions published during the timeframe, to determine whether any are of particular interest. We expect it 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 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 five 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 HCFA Medicare and Medicaid manuals and memoranda.
- Addendum III lists a unique HCFA transmittal number for each instruction in our manuals or Program Memoranda 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 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;
- Title of the regulation;
- Ending date of the comment period (if applicable); and
- Effective date (if applicable).
- Addendum V includes listings of the Food and Drug Administration-approved investigational device exemption numbers that have been approved or revised during the quarter covered by this notice. On September 19, 1995, we published a final rule (60 FR 48417) establishing in regulations at 42 CFR 405.201 *et seq*. that certain devices with an investigational device exemption approved by the Food and Drug Administration (FDA) and certain services related to those devices may be covered under Medicare. It is our practice to announce all investigational device exemption categorizations, using the investigational device exemption numbers the FDA assigns. 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).

III. How To Obtain Listed Material

A. Manuals

Those wishing to subscribe to program manuals 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 Orders, 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. Additionally, all manuals are available at the following Internet address: http://www.hcfa.gov/pubforms/progman.htm.

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 the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/su__docs/, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

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 have, on occasion, published rulings in the **Federal Register**. Rulings, beginning with those released in 1995, are available online, through the HCFA Home Page. The Internet address is http://www.hcfa.gov/regs/rulings.htm.

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

Our laws, regulations, and manuals are also available on CD–ROM and 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. (Updated titles of the Social Security Laws are available on the Internet at http://www.ssa.gov/OP__Home/ssact/comp-toc.htm.) 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, 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.

IV. 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 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL.

In addition, individuals may contact regional depository libraries that 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 materials, use the Superintendent of Documents number, plus the HCFA transmittal number. For example, to find the Intermediary Manual (HCFA Pub. 13–3) transmittal entitled ''Mammography Screening,'' use the Superintendent of Documents No. HE 22.8/6 and the HCFA transmittal number 1754.

(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: November 18, 1999.

Elizabeth Cusick,

Director, Office of Communications and Operations Support.

Addendum I

This addendum lists the publication dates of the most recent quarterly listings of program issuances.

June 4, 1998 (63 FR 30499)
August 11, 1998 (63 FR 42857)
September 16, 1998 (63 FR 49598)
December 9, 1998 (63 FR 67899)
May 11, 1999 (64 FR 25351)
November 2, 1999 (64 FR 59185)

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 (57 FR 47468).

Addendum III—Medicare and Medicaid Manual Instructions (January 1999 Through March 1999)

Transmittal No. and Manual/Subject/Publication Number

Intermediary Manual Part 3—Claims Process (HCFA Pub. 13–3) (Superintendent of Documents No. HE 22.8/6)

1766
- File specifications, Records Specifications, and Data Element Definitions for Electronic Media Claims Bills.

1767
- Model Development Letter Questions.

1768
- Bed-Hold Policies for Long-Term Care Facilities.

1769
- Medicare Rural Hospital Flexibility Program.

Grand fathering Existing Facilities.
Requirements for Critical Access Hospital Services and Critical Access Hospital Long-term Care Services.
Payment for Services Furnished by a Critical Access Hospital.
Payment for Post-Hospital Skilled Nursing Facilities Care Furnished by a Critical Access Hospital.
Review of Form HCFA–1450 for the Inpatient.

1770
- Comprehensive Medical Review Procedures Using Statistical Sampling for Overpayment Estimation.

1771
- Oral Anti-Nausea Drugs as Full Therapeutic Replacements for Intravenous Dosage Forms as Part of a Cancer Chemotherapeutic Regimen.

1772
- Coding for Adequacy of Hemodialysis.

Carriers Manual Part 3—Claims Process (HCFA Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)

1624
- Self-Administered Drugs and Biologicals.

1625
- Identifying a Screening Mammography Claim.

1626
- Requirements for Processing Electronic Media Claims.

1627
- Requirements for Processing Electronic Media Claims.

1628
- Payment for Oral Anti-Emetic Drugs When Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen.

1629
- General Claims Processing Requirements.

1630
- Type of Service.

Carriers Manual Part 4—Professional Relations (HCFA Pub. 14–4) (Superintendent of Documents No. HE 22.8/7)

- Registry of Physicians/Health Care Practitioners/Group Practices.

Ongoing Data Collection on Physicians/Health Care Practitioners/Group Practices Applications.

Physician/Health Care Practitioners/ Group Practices Record-Required Information and Format.

Maintaining Physician/Health Care and Practitioner/Group Practices Memberships.

Update Records.

Batching Procedures.

Privacy Act Requirements.

Physician Opted Out.

Carrier Record Requirements.

Unique Physician Identification Number Carrier Record Layout.

20

- Enrollment Instructions.

HCFA–855 R, Individual Reassignment of Benefits.

Enrolling Certified Providers/ Suppliers Who Enroll with Carriers.

Program Memorandum Intermediaries (HCFA Pub. 60A) (Superintendent of Documents No. HE 22.8/6–5)

A–99–1

- Clarification of the Implementation of § 510(a)(3) of the Omnibus Consolidated and Emergency Supplemental Appropriation Act, Fiscal Year 1999 Enacted on October 21, 1998 and the Wage Indices Applicable to Guam and the Virgin Islands.

A–99–2

- Hospital Outpatient Procedures: Billing for Contrast Material (Clarification).

A–99–3

- Hospital Outpatient Procedures: Medicare Changes for Radiology and Other Diagnostic Coding Due to the 1998 HCFA Common Procedures Coding System Update; Miscellaneous Changes.

A–99–4

- Hepatitis C Virus Look Back.

A–99–5

- Claims Processing Instructions for the National Institutes of Health National Emphysema Treatment.

A–99–6

- Information Requirements for Home Health Services—15 Minute Increment Reporting.

A–99–7

- Extension of Due Date for Filing Provider Cost Reports.

A–99–8

- Policy Clarification and Guidance for Services Furnished by Rural Health Clinics and Federally Qualified Health Centers and Announcement of Medicare Federally Qualified Health Centers and Rural Health Clinics Payment Rate Increases.

A–99–9

- Interim Rate Changes Due to the Elimination of the Formula Driven Overpayment.

A–99–10

- Rural Health Clinics and Federally Qualified Health Centers Provisions Enacted by § 4205 of the Balanced Budget Act of 1997.

A–99–11

- Clarification of Provider Cost Report Filing Requirements.

A–99–12

- Medicare Home Health Benefit—§ 4615 of the Balanced Budget Act of 1997; Clarification That No Home Health Benefits are Authorized Based Solely on Drawing Blood.

Program Memorandum Carriers (HCFA Pub. 60B) (Superintendent of Documents No. HE 22.8/6–5)

B–99–1

- Evaluating the Medical Necessity for Laboratory Panel Current Procedural Terminology Codes.

B–99–2

- Payment for Teleconsultations in Rural Health Professional Shortage Areas.

B–99–3

- Revisions to Transmittal No. AB–98–14 Dated April 1998 ''Claims Processing Instructions for the National Institutes of Health National Emphysema Treatment Trial.''

B–99–4

- Standard System Acceptance of Primary Payer Information at the Line Level.

B–99–5

- Changes to the 1999 Medicare Physician Fee Schedule Database.

B–99–6

- Matrix to Complete Provider/ Supplier Enrollment Application (Form HCFA–855).

B–99–7

- Millennium Changes for Forms HCFA–1491, 1490S, and 1490U.

B–99–8

- Health Professional Shortage Area Bonus Payment Clarification.

B–99–9

- Change to Health Insurance Claim Form HCFA–1500 Instructions for Processing Physician Claims in Global Payment Systems.

B–99–10

- Durable Medical Equipment Carrier Billing Procedures.

B–99–11

- Modifications to Form HCFA–1500 Instructions.

B–99–12

- Paramedic Intercept Provisions of the Balanced Budget Act of 1997.

Program Memorandum Intermediaries/ Carriers (HCFA Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6–5)

AB–99–1

- Activating Y2K ''Return as Unprocessable'' Edits for Paper and Electronic Media Claims.

AB–99–2

- Updates to the Mammography Quality Standards Act Record File Layout for Y2K Compliance.

AB–99–3

- Ending Suppression of Explanation of Medicare Benefits and Medicare Summary Notices for All Claim Types Except: Laboratory, Demonstrations, Exact Duplicates, and Statistical Adjustments.

AB–99–4

- Interim Claims Processing Instructions for Payment for Oral Anti-Emetic Drugs When Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen.

AB–99–5

- Instructions for Implementing and Tracking the Medicare Fraud and Abuse Incentive Reward Program.

AB–99–6

- Notice of New Interest Rates for Medicare Overpayments and Underpayments.

AB–99–7

- Notification to Medicare Providers and Suppliers of Beneficiary Right to an Itemized Statement.

AB–99–8

- Provider Outreach Activities Specific to Y2K Awareness.

AB–99–9

- Implementation of the Office of the Inspector General's Fraud Hot Line Number on Medicare Beneficiary Notices.

AB–99–10

- Provider Overpayment Recovery Physicians Supplier Overpayment Recovery Systems Overpayments Transferred to the Debt Collection Center for Cross Servicing.

AB–99–11

- Consolidated Billing for Skilled Nursing Facilities.

Program Memorandum Medicaid State Agencies (HCFA Pub. 17) (Superintendent of Documents No. HE 22.8/6–5)

99–1

- Title XIX of the Social Security Act, Post-Eligibility Treatment of Income.

State Operations Manual Provider Certification (HCFA Pub. 7) (Superintendent of Documents No. HE 22.8/12)

5
- Conducting Initial Surveys and Scheduled Resurveys.

Unannounced Surveys.
Survey Protocol for Long Term Care Facilities.

6
- Sanctions for Intermediate Care Facilities/Mental Retardation for Non-Immediate Jeopardy.

Directed Plan of Correction.
Directed In-Service Training.
State Monitoring.
Achieving Continuous Substantial Compliance.
Criteria for Review of State Plans for Approval or Disapproval of Alternative Sanctions.

7
- Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.

Peer Review Organization Manual (HCFA Pub. 19) (Superintendent of Documents No. HE 22.8/8–15)

69
- Introduction.

HCFA/Office of Clinical Standards and Quality Requirements.
Statutory and Regulatory Requirements.
Definitions.
Office of Management and Budget Clearance.
Items Not Subject to Office of Management and Budget Clearance.
Request for Exception from Office of Management and Budget Review.
Survey Justification and Methods.
Additional Considerations.
Documentation for HCFA.

70
- Introduction.

Anti-Dumping Violations.
Assistants at Cataract Surgery.
Beneficiary Complaints.
Hospital and Managed Care Plan Notices of Noncoverage.
Hospital-Requested Higher-Weighted Diagnostic Related Group Assignments.
Potential Concerns Identified During Project Data Collection.
Referrals.
Quality Review.
Admission Review.
Invasive Procedure Review.
Length-of-Stay Review.
Coverage Review.
Diagnostic Related Group Validation Review.
Discharge Review.
Day and Cost Outlier Review.
Ambulatory Surgery Review.
Limitation on Liability Determinations.
Readmission Review.
Transfer Review.
Non-physician Review.
First Level Physician Review.
Action Following Opportunity for Discussion.
Second Level Physician Review.
Third Level Physician Review.
Use of the Physician Reviewer Assessment Format.
Review of Medicare Services.
Review Settings.
Using Screening Criteria.
Requesting Medical Records/ Reviewing Documentation.
Providing Opportunity for Discussion.
Adhering to Review Time Frames.
Profiling Case Review Results.
Maintaining Memoranda of Agreements.
Monitoring an Important Message from Medicare.
Monitoring Hospitals' Physician Acknowledgment Statements.
Non-physician Reviewers.
Physician Reviews.
Health Care Practitioners Other Than Physicians.
Conflict of Interest.
Training.

71
- Quality Review—Overview.

Determination of Source of Concerns.
Notification of Quality Concerns to Affected Parties.
Peer Review Organization Quality Improvement Activities.
Peer Review Organization Review Reporting Requirements.
Scope of Review.
Complaints That Do Not Meet Statutory Requirements.
Referrals.
Review Process.
Notice of Disclosure.
Disclosure of Quality Review Information to Complainants.
Data Analysis and Reporting Requirements.
Peer Review Organization Review Responsibilities.
Actions to be Taken by Peer Review Organizations.

Hospital Manual (HCFA Pub. 10) (Superintendent of Documents No. HE 22.8/2)

739
- Identifying Other Primary Payers During the Admission Process.

Admission Questions to Ask Medicare Beneficiaries.

740
- Medicare Rural Hospital Flexibility Program.

Grandfathering Existing Facilities.
Requirements for Critical Access Hospital Services and Critical Access Hospital Long-term Care Services.
Payment for Services Furnished by a Critical Access Hospital.
Payment for Post-Hospital Skilled Nursing Facilities Care. Furnished by a Critical Access Hospital.
Review of Form HCFA–1450 for the Inpatient.

741
- Coding for Adequacy of Hemodialysis.

Religious Nonmedical Health Care Institutions (Hospital Manual Supplement) (HCFA Pub. 32) (Superintendent of Documents No. HE 22.8/2–2)

41
- Claims Processing Timeliness.

Home Health Agency Manual (HCFA Pub. 11) (Superintendent of Documents No. HE 22.8/5)

290
- Claims Processing Timeliness.

Skilled Nursing Facility Manual (HCFA Pub. 12) (Superintendent of Documents No. HE 22.8/3)

358
- Completion of Form HCFA–1450 for Inpatient and/or Outpatient Billing.

Provider Electronic Billing File and Record Formats.
Alphabetic Listing of Data Elements.

359
- Claims Processing Timeliness.

Rural Health Clinic and Federally Qualified Health Centers Manual (HCFA Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)

33
- Claims Processing Timeliness.

Renal Dialysis Facility Manual (Non-Hospital Operated) (HCFA Pub. 29) (Superintendent of Documents No. HE 22.8/13)

84
- Completion of Form HCFA–1450 by Independent Facilities for Home Dialysis Items and Services Billed Under the Composite Rate Method I.

85
- Claims Processing Timeliness.

86
- Coding for Adequacy of Hemodialysis.

Hospice Manual (HCFA Pub. 21) (Superintendent of Documents No. HE 22.8/18)

54

- Claims Processing Timeliness.

Outpatient Physical Therapy, Comprehensive Outpatient Rehabilitation Facility and Community Mental Health Center Manual (HCFA Pub. 9) (Superintendent of Documents No. HE 22.8/9)

6
- Claims Processing Timeliness.

Coverage Issues Manual (HCFA Pub. 6) (Superintendent of Documents No. HE 22.8/14)

106
- Positron Emission Tomography Scans.

107
- Durable Medical Equipment Reference List.

108
- Abortion.

Provider Reimbursement Manual—Part 1 (HCFA Pub. 15–1) (Superintendent of Documents No. HE 22.8/4)

408
- Travel Expense.

Effective Date of Change in Size of Participating Skilled Nursing Facility.

Effective Date of Change in Size at Beginning of Cost Reporting Quarter of Provider Following Approval by Regional Office.

Exceptions.

409
- Effective Date of Change in Size of Participating Skilled Nursing Facility.

Effective Date of Change in Size at Beginning of Cost Reporting Quarter of Provider Following Approval by Regional Office Exceptions.

State Medicaid Manual Part 4—Services (HCFA Pub. 45–4) Superintendent of Documents No. HE 22.8/10

72
- Personal Care Services.

Medicare/Medicaid Sanction—Reinstatement Report (HCFA Pub. 69)

99–1
- Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated-December 1998.

99–2
- Report of Physicians/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated-January 1999.

ADDENDUM IV.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR Vol. 64 page	CFR* part(s)	File code**	Regulation title	End of comment period	Effective date
01/04/99	69	Chapter IV	HCFA–3250–N2	Medicare Program; Negotiated Rulemaking; Coverage and Administrative Policies for Clinical Diagnostic Laboratory Tests; Announcement of Additional Public Meetings.	.....	.....
01/04/99	170–171	.....	HCFA–3889–N	Medicare Program; Open Town Hall Meeting to Discuss the Positron Emission Tomography.	.....	.....
01/12/99	1784–1785	409, 410, 411, 412, 413, 419, 489, 498, and 1003.	HCFA–1005–2N	Medicare Program; Prospective Payment System for Hospital Outpatient Services; Extension Of Comment Period.	03/09/99	.....
01/12/99	1785–1786	416 and 488	HCFA–1885–4N	Medicare Program; Update of Ratesetting Methodology, Payment Rates, Payment Policies, and the List of Covered Procedures for Ambulatory Surgical Centers Effective October 1, 1998; Extension of Comment Period.	03/09/99	.....
01/22/99	3474–3478	405	HCFA–1002–NOI	Medicare Program; Ambulance Fee Schedule; Intent to Form Negotiated Rulemaking Committee.	02/22/99	.....
01/25/99	3637–3650	409, 410, and 424.	HCFA–1813–FC	Medicare Program; Coverage of Ambulance Services and Vehicle and Staff Requirements.	03/26/99	02/24/99
01/25/99	3748–3763	484 and 488	HCFA–3006–IFC	Medicare and Medicaid Programs; Reporting Outcome and Assessment Information Set (OASIS) Data as Part of the Conditions of Participation for Home Health Agencies.	03/26/99	02/24/99
01/25/99	3764–3784	484	HCFA–3007–F	Medicare and Medicaid Programs; Comprehensive Assessment and Use of the OASIS as Part of the Conditions of Participation for Home Health Agencies.	.....	02/24/99
02/04/99	5667–5668	.....	HCFA–0001–N	Medicare Program; Year 2000 Readiness Letter.	.....	.....

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

Publication date	FR Vol. 64 page	CFR* part(s)	File code**	Regulation title	End of comment period	Effective date
02/08/99	6102–6108	.....	HCFA–2014–N	State Children's Health Insurance Program; Reserved Allotments to States for Fiscal Year 1999 and Revised Reserved Allotments to States for Fiscal Year 1998.	.....	.....
02/11/99	6827–6852	410, 414, 424, 476, and 498.	HCFA–3002–P	Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training Services.	04/12/99	.....
02/12/99	7198–7199	.....	HCFA–1064–N	Medicare Program; March 15, 1999, Meeting of the Practicing Physicians Advisory Council.	.....	.....
02/17/99	7968–7982	422	HCFA–1030–F	Medicare Program; Changes to the Medicare+Choice Program.	.....	03/19/99
02/17/99	7899–7900	.....	HCFA–4008–N	Medicare Program; Establishment of the Citizens Advisory Panel on Medicare Education and Requests for Nominations for Members.	.....	.....
02/25/99	9378–9399	412	HCFA–1049–F	Medicare Program; Changes to the Fiscal Year 1999 Hospital Inpatient Prospective Payment Wage Index and Standardized Amounts Resulting From Approved Requests for Wage Data Revisions.	.....	03/01/99
03/04/99	10479–10480	.....	HCFA–2041–N	Medicaid Program; Decision on Funding for the AIDS Healthcare Foundation START Program.	.....	02/25/99
03/11/99	12172–12173	.....	CFA–1068–N	Medicare Program; Meetings of the Competitive Pricing Demonstration Area Advisory Committee, Kansas City Metropolitan Area.	.....	.....
03/11/99	12173	.....	HCFA–1101–N	Medicare Program; Meetings of the Competitive Pricing Demonstration Area Advisory Committee, Maricopa County, AZ.	.....	.....
03/12/99	12277–12278	409, 410, 411, 412, 413, 419, 489, 498, and 1003.	HCFA–1005–3N	Medicare Program; Prospective Payment System for Hospital Outpatient Services; Extension of Comment Period.	06/30/99	.....
03/12/99	12278–12279	416 and 488	HCFA–1885–5N	Medicare Program; Update of Ratesetting Methodology, Payment Rates, Payment Policies and the List of Covered Procedures for Ambulatory Surgical Centers Effective October 1, 1998; Extension of Comment Period.	06/30/99	.....
03/12/99	12404	.....	HCFA–2014–N	State Children's Health Insurance Program; Reserved Allotments to States for Fiscal Year 1999 and Revised Reserved Allotments to States for Fiscal Year 1998.	.....	.....
03/18/99	13354–13362	488	HCFA–2035–FC	Medicare and Medicaid Programs; Civil Money Penalties for Nursing Homes (SNF/NF), Change in Notice Requirements, and Expansion of Discretionary Remedy Delegation.	05/17/99	05/17/99
03/23/99	13998–13999	.....	HCFA–1100–N	Medicare Program; Medicare Coordinated Care Demonstration Project and Request for Information on Potential Best Practices of Coordinated Care.	06/21/99	.....

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

Publication date	FR Vol. 64 page	CFR* part(s)	File code**	Regulation title	End of comment period	Effective date
03/26/99	14666	405	HCFA–1002–N	Medicare Program; Meetings of the Negotiated Rulemaking Committee on Ambulance Fee Schedule.	.....	.....
03/29/99	14931–14934	.....	HCFA–2032–N	Medicare Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Federal Fiscal Year 1999.	.....	10/01/98

*42 CFR except where noted.
**N—General Notice; PN—Proposed Notice; NC—Notice with Comment Period; FN—Final Notice; P—Notice of Proposed Rulemaking (NPRM); F—Final Rule; FC—Final Rule with Comment Period; CN—Correction Notice; IFC—Interim Final Rule with Comment Period; GNC—General Notice with Comment Period.

Addendum V—Categorization of Food and Drug Administration-Allowed Investigational Device Exemptions

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c), devices fall into one of three classes. Also, 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. To obtain more information about the classes or categories, please refer to the **Federal Register** notice published on April 21, 1997 (62 FR 19328).

The following information presents the device number, category (in this case, A), and criterion code.

G980173 A2
G980257 A1
G980263 A1
G980315 A1
G980320 A1
G980330 A2
G990028 A1
G990037 A1
G990043 A2
G990053 A1

The following information presents the device number, category (in this case, B), and criterion code.

G980095 B4
G980139 B4
G980143 B2
G980188 B4
G980243 B4
G980254 B4
G980273 B4
G980281 B3
G980307 B4
G980308 B4
G980310 B
G980312 B3
G980313 B4
G980314 B4
G980318 B2
G980319 B4
G980321 B4
G980322 B
G980323 B2
G980324 B4
G980326 B2
G980328 B3
G990004 B4
G990005 B1
G990006 B4
G990010 B4
G990011 B3
G990014 B3
G990016 B5
G990019 B4
G990020 B4
G990022 B2
G990023 B4
G990024 B3
G990026 B2
G990029 B4
G990031 B3
G990035 B1
G990036 B2
G990041 B4
G990042 B4
G990044 B1
G990046 B4
G990050 B2
G990051 B4

[FR Doc. 99–31601 Filed 12–6–99; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel.

Date: December 14, 1999.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 6120 Executive Blvd., Suite 350, Rockville, MD 20892.

Contact Person: Andrew P. Mariani, PhD, Chief, Scientific Review Branch, 6120 Executive Blvd, Suite 350, Rockville, MD 20892, 301/496–5561.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: November 30, 1999.

Anna Snouffer,

Acting Committee Management Officer, NIH.

[FR Doc. 99–31596 Filed 12–6–99; 8:45 am]
BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Disease; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.