conditions and thereby have the potential to affect product safety, purity, or potency:

(a) Use of a previously unapproved manufacturing area or facility;

(b) Change in air quality, water quality, material, or personnel flow for licensed product manufacturing areas.

(c) Change from single product manufacturing to multiple product manufacturing using same equipment and/or personnel.

(d) Renovation to physical structure that alters product, material, and/or personnel flow.

xix. Addition to or replacement of an FDA-approved manufacturing step performed under contract to a second facility.

D. Categorization of Proposed Changes

Before implementing a change which is not identified above or does not clearly fit into one of the defined categories, manufacturers should discuss the proposed change with CBER. If guidance is not sought, the change should be reported in the form of a Category III supplement, subject to CBER approval prior to implementation.

Requests for information regarding categorization of proposed changes not included in the above categories may be addressed to the Director of the appropriate applications Division within the Office with assigned product, or establishment, responsibility at the Center for Biologics Evaluation and Research (HFM–99), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

E. Information Requested for Category I Periodic Reports

FDA requests that manufacturers submit the following information for each Category I change in the order shown: (1) Name of the manufacturer; (2) the establishment license number; (3) the report dates (time period covered by the report); (4) the product(s) affected (list each one); (5) the change implemented, including: (a) A brief description and reason for the change and/or modification, (b) the establishment location involved, (c) the date the change was implemented, and (d) a cross-reference to the Approved Validation Protocol or Standard Operating Procedure, if applicable; and (6) the signature of the Responsible Head and the date signed.

Dated: March 31, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–8382 Filed 4–5–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93F–0201]

Asahi Denka Kogyo K. K.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 3B4378) proposing that the food additive regulations be amended to provide for the safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl) phosphate as a clarifying agent in polypropylene articles intended for contact with food to include the use at temperatures up to and including retort conditions.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3092.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 29, 1993 (58 FR 40656), FDA announced that a food additive petition (FAP 3B4378) had been filed by Asahi Denka Kogyo K. K., c/o Japan Technical Information Center, Inc., 1002 Pennsylvania Ave. SE., Washington, DC 20003. The petition proposed to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl) phosphate as a clarifying agent in polypropylene articles intended for contact with food to include the use at temperatures up to and including retort conditions. Asahi Denka Kogyo K. K. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7)

Dated: March 22, 1995.

Eugene C. Coleman,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–8515 Filed 4–5–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94F–0121]

BASF Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 3B4384) proposing that the food additive regulations be amended to provide for the safe use of hydroxypropyl acrylate and butanediol diacrylate as monomers in the production of acrylic polymers intended for use in food packaging adhesives.

FOR FURTHER INFORMATION CONTACT: Diane E. Robertson, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 25, 1994 (59 FR 19730), FDA announced that a food additive petition (FAP 3B4384) had been filed by BASF Corp., 9401 Arrow Point Blvd., suite 200, Charlotte, NC 28273. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of hydroxypropyl acrylate and butanediol diacrylate as monomers in the production of acrylic polymers intended for use in food packaging adhesives. BASF Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 22, 1995.

Eugene C. Coleman,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–8516 Filed 4–5–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPO–130–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Fourth Quarter 1994

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 October, November, and December of 1994 that relate to the Medicare and Medicaid programs. 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 timeframe. We are also providing the content of revisions to the Medicare Coverage Issues Manual published between October 1 and December 31, 1994. 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 allows us to fulfill this requirement in a manner that facilitates identification of coverage and other changes in our manuals.

FOR FURTHER INFORMATION CONTACT: Margaret Cotton, (410) 966–5255 (For Medicare instruction information); Pat Prete, (410) 966–3246 (For Medicaid instruction information); Michael Robinson, (410) 966–5633 (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 who process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under 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 timeframe. 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 are listing in this notice Medicaid issuances and Medicaid substantive and interpretive regulations published from October 1 through December 31, 1994.

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 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. We have reprinted manual revisions as transmitted to manual holders. The new text is shown in italics. We will not reprint 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, or coverage decisions published during the timeframe 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 five 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 December 31, 1994. 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 title of the regulation, the parts of the Code of Federal Regulations (CFR) which have changed (if applicable), the agency file code number, the ending date of the comment period (if applicable), and the effective date (if applicable).

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 indicated above. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

C. Rulings

Rulings are published on an infrequent basis by HCFA. 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)

HCFA's laws, regulations, and manuals are now 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 contained 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, 1993. The remaining portions of CD–ROM are updated on a monthly basis.

The CD–ROM disk does not contain Appendix M (Interpretative Guidelines for Hospices). Copies of this appendix may be reviewed at a Federal Depository Library (FDL).

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 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, individuals should 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 2—Program Administration (HCFA-Pub. 14–2) transmittal entitled ''Files Maintenance Program General'', use the Superintendent of Documents No. HE 22.8/6–2 and the HCFA transmittal number 127.

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, Issuances Staff, Bureau of Program Operations, Health Care Financing Administration, Room 688 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–5255.

Questions concerning Medicaid items in Addenda III may be addressed to Pat Prete, Medicaid Bureau, Office of Medicaid Policy, Health Care Financing Administration, Room 233 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–3246.

Questions concerning all other information may be addressed to Michael Robinson, Office of Regulations, Health Care Financing Administration, Room 132 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–5633.

(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: March 23, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

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, please refer to the listing in the January 3, 1995 quarterly notice (60 FR 132).

March 17, 1994 (59 FR 12610)

August 5, 1994 (59 FR 40038)

November 14, 1994 (59 FR 56501)

January 3, 1995 (60 FR 132)

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

[October Through December 1994]

Trans. No.	Manual/Subject/Publication Number
	Intermediary Manual **Part 2—Audits, Reimbursement** **Program Administration (HCFA–Pub. 13–2)** **(Superintendent of Documents No. HE 22.8/6–1)**
400	• Files Maintenance Program—General. Records Retention and Disposal Schedule. Retention of Claims Files Materials. Microfilming of Files Material. Intermediary—Federal Records Center Relations. Location of Federal Records Centers. Procedures for Transfer of Material to Federal Records Centers. Requesting Forms for Transfer and Return of Material from Federal Records Centers. Report of Medicare Records—Form HCFA–2556. Exhibits.
401	• Location of Federal Records Centers.
	Intermediary Manual **Part 3—Claims Process (HCFA–13–3)** **(Superintendent of Documents No. HE 22.8/6)**
1636	• Responsibility for Medicare Secondary Payer Outreach Program. Quarterly Supplement to Intermediary Workload Report (Form HCFA–1566A) General. Completing Quarterly Supplement to the Intermediary Workload Report, HCFA–1566A, Pages 1 and 2. Completing Quarterly Supplement to the Intermediary Workload Report, HCFA–1566A, Page 3. Completing Quarterly Periodic Interim Payment Report, HCFA–1566C—General.
1637	• Reporting Outpatient Surgery and Other Services. PPS Pricer Program. Provider-Specific Data Record Layout and Description.
1638	• Mammography Screening. Mammography Quality Standards Act.
1639	• Disallowance Form Letters HCFA–1954 and HCFA–1955. Explanation of Medicare Benefits Notice Specifications.
1640	• General Effect of Liability Insurance on Medicare Payment. Appeals Procedures for MSP Liability Overpayments.
1641	• Mammography Screening.
	Carriers Manual **Part 2—Program Administration (HCFA–14–2)** **(Superintendent of Documents No. HE 22.8/6–2)**
127	• Files Maintenance Program—General. Records Retention and Disposal Schedule. Retention of Claims Files Materials. Microfilming of Files Materials. Report of Medicare Records—Form HCFA–2556. Location of Federal Records Centers. Procedures for Transfer of Material to Federal Records Centers. Requesting Forms for Transfer and Return of Material from Federal Records Centers. Exhibits.
128	• Location of Federal Records Centers.
	Carriers Manual **Part 4—Professional Relations (HCFA-Pub. 14–4)** **(Superintendent of Documents No. HE 22.8/7–4)**
9	• Responsibility in the Medicare Secondary Payer Outreach Program.
10	• National Registry of Physicians/Health Care Practitioners/Group Practices-Medicare Provider Identifier (UPIN). Ongoing Data Collection On Physicians/Health Care Practitioners/Group Applications. Physicians/Health Care Practitioners/Group Practices Record-Required Information and Format. Maintaining Physicians/Health Care Practitioner/Group Practice Membership. Validation of Physicians/Health Care Practitioners/Group Practices Credentials, Certifications, Sanction and License Information for Prior Practice. • UPIN Cross Referral Requirement. Maintenance of The Registry. Update Records. Rejections. Exceptions. Carrier Record Requirements. UPIN Carrier Record Layout.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 1994]

Trans. No.		Manual/Subject/Publication Number
		List of Medical School Codes.
		Carriers Manual **Part 3—Claims Process (HCFA-Pub. 14–3)** **(Superintendent of Documents No. HE 22.8/7)**
1501	•	Quarterly Supplements to the Carrier Performance Report (Forms HCFA–1565A, HCFA–1565B, HCFA–1565C, and HCFA–1565D)—General. Completing Form HCFA–1565A. Completion of Items on Form HCFA–1565A. Completing Medicare Fraud Unit Quarterly Workload Status Report, HCFA–1565B—General. Completing Form HCFA–1565C. Completion of Items on Form HCFA–1565C. Completing Comprehensive Limiting Charge Compliance Program Quarterly Report HCFA–1565D—General. Completing Medicare Fraud Unit Quarterly Status Report, Form HCFA–1565B. Completing Carrier Limiting Charge Compliance Program Quarterly Report, Form HCFA–1565D.
1502	•	Chiropractors. Manual Manipulation. Verification of Chiropractor's Qualifications.
1503	•	Part B Provider Access to Limited Eligibility Data. Eligibility Data Available. Contractor Implementation. Data Format. Part B Eligibility Data Security Requirements. HCFA Standard Part B Eligibility Data Security Requirements. HCFA Standard Part B Eligibility Inquiry Flat File Specifications. HCFA Standard Part B Eligibility Response Flat File Specifications.
1504	•	Type of Service.
1505	•	Self-Administering of Drug or Biological.
1506	•	List of Covered Surgical Procedures.
1507	•	Rebundling of CPT–4 Codes.
		Program Memorandum **Intermediaries (HCFA–Pub. 60A)** **(Superintendent of Documents No. HE 22.8/6–5)**
A–94–8	•	Revised Wages Indexes for Ambulatory Surgical Centers—Pricer for 7.0 and 8.0.
A–94–9	•	FY 1995 Prospective Payment System and Other Bill Processing Changes.
A–94–10	•	Ambulatory Surgical Center—Pricer 9.0.
		Program Memorandum **Carriers (HCFA–Pub. 60B)** **(Superintendent of Documents No. HE 22.8/6–5)**
B–94–6	•	1995 Physician, Practitioner and Supplier Participation Enrollment and Fee Schedule Disclosure.
B–94–7	•	1995 Physician, Practitioner and Supplier Participation Enrollment and Fee Schedule Disclosure.
B–94–8	•	Split Billing for Professional and Technical Components of Services.
		Program Memorandum **Intermediaries/Carriers (HCFA–Pub. 60AB)** **(Superintendent of Documents No. HE 22.8/6–5)**
AB–94–8	•	Revised Codes for Part B Ground Ambulance Services.
		Program Memorandum **Medicaid State Agencies (HCFA–Pub. 17)** **(Superintendent of Documents No. HE 22.8/6–5)**
94–8	•	Title XIX, Social Security Act, Vaccines for Children Program.
94–9	•	Title XIX, Social Security Act, Personal Care Services Provided in a Home or Other Location.
		Regional Office Manual **Standards and Certification (HCFA–Pub. 23–4)** **(Superintendent of Documents No. HE 22.28/5:90–1)**
55	•	Developing the Budget Approval. Submittal of Budget Approval. Distribution of Approved Funds. Disbursement of Authorized Funds.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 1994]

Trans. No.		Manual/Subject/Publication Number
		The Budget Call.
		Monitoring State Agency Fiscal Budgets.
56	•	Approval Procedures for Hospitals in the 50–99 Bed Category.
		Peer Review Organization Manual (HCFA–Pub. 19) (Superintendent of Documents No. HE 22.8/15)
40	•	Introduction.
		MOA with State Agencies Responsible for Licensing/Certification of Providers/Practitioners.
		Model Memorandum of Agreement.
41	•	Complaints to be Reviewed.
		Disposition of Complaints.
		Disclosing Information.
		Monitoring Hospital-Issued Notices of Noncoverage.
		Beneficiary Liability.
		Model Hospital-Issued Notice of Noncoverage Continued Stay—Swing Bed Only.
42	•	DRG Validation Review.
43	•	Training.
		Hospital Manual (HCFA–Pub. 10) (Superintendent of Documents No. HE 22.8/2)
673	•	Billing for Mammography Screening.
		Mammography Quality Standards Act.
674	•	Billing for Mammography Screening.
		Skilled Nursing Facility (HCFA–Pub. 12) (Superintendent of Documents No. HE 22.8/3)
332	•	Billing for Mammography Screening.
		Mammography Quality Standards Act.
333	•	Billing for Mammography Screening.
		State Medicaid Manual Part 3—Eligibility (HCFA–Pub. 45–3) (Superintendent of Documents No. HE 22.8/10)
64	•	Transfers of Assets for Less Than Fair Market Value.
		Treatment of Trusts.
		State Medicaid Manual Part 6—Payment for Services (HCFA–Pub. 45–6) (Superintendent of Documents No. HE 22.8/10)
26	•	Listing of Multiple Source Drugs.
		State Medicaid Manual Part 7—Quality Control (HCFA–Pub. 45–7) (Superintendent of Documents No. HE 22.8/10)
52	•	Computations of Financial Eligibility.
		Verification Guide—Coverage Code 02 for OASDI Recipients.
		Verification Guide—Coverage Code 01 or 03.
		Verification Guide—Coverage Code 18 for QDWI Individuals.
		Verification Guide—Coverage Code 25 for Individuals Whose Eligibility for Medicaid Has Otherwise Ceased.
		Verification Guide—Coverage Code 26 for Individuals Whose Eligibility for Medicaid Has Otherwise Ceased.
		Verification Guide—Coverage Code 29 for Individuals Receiving Home and Community-Based Services and Other Waiver Services.
		Verification Guide—Coverage Code 31.
		Verification Guide—Coverage Code 40 for AFDC Families.
		Coverage Issues Manual (HCFA–Pub. 6) (Superintendent of Documents No. HE 22.8/14)
72	•	Blood Transfusions.

ADDENDUM III.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[October Through December 1994]

Trans. No.		Manual/Subject/Publication Number
73	•	Hydrophilic Contact Lens for Corneal Bandage.
		Home Health Agency Manual (HCFA–Pub. 11) (Superintendent of Documents No. HE 22.8/5)
273	•	Home Health Certification and Plan of Care.
		State Operations Manual Provider Certification (HCFA–Pub. 7) (Superintendent of Documents No. HE 22.8/12)
265	•	Hospice Regulations and Non-Medicare Patients. Operation of a Hospice Across State Lines. Compliance with Advance Directives. Hospice—Citations and Description. Hospice Multiple Locations. Election of Hospice Benefit by Resident of a Skilled Nursing Facility, Nursing Facility, Intermediate Care Facility for the Mentally Retarded, or Non-Certified Facility. Hospice Inpatient Services Furnished Directly or Furnished Under Arrangements. Hospice Home Visit Procedures. Model Consent for Hospice Home Visit Form. Hospice Survey and Deficiencies Report. Interpretive Guidelines—Hospices.
		Rural Health Clinic and Federally Qualified Health Centers Manual (HCFA–Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)
16	•	Billing for Mammography Screening by Rural Health Clinic and Federally Qualified Health Centers. Mammography Qualified Standards Act.
17	•	Billing for Mammography Screening by Rural Health Clinics and Federally Qualified Health Centers.
		Medicare/Medicaid Sanction—Reinstatement Report
94–13	•	Report of Physician/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated.
94–14	•	Report of Physician/Practitioners, Providers and/or Other Health Care Suppliers Excluded/Reinstated.

Addendum IV—Medicare Coverage Issues Manual

(For the reader's convenience, new material and changes to previously published material are in italics. If any part of a sentence in the manual instruction has changed, the entire line is shown in italics. The transmittal includes material unrelated to revised sections. We are not reprinting the unrelated material.)

Transmittal No. 72; section 45–27 Blood Transfusions NEW INPLEMENTING INSTRUCTIONS—EFFECTIVE DATE: For services performed on or after 12–08–94.

Section 45–27, Blood Transfusions.—This section has been added to clarify the coverage and payment policies for blood transfusions.

45–27 BLOOD TRANSFUSIONS

Blood transfusions are used to restore blood volume after hemorrhage, to improve the oxygen carrying capacity of blood in severe anemia, and to combat shock in acute hemolytic anemia.

A. Definitions.—

1. Homologous Blood Transfusion.—Homologous blood transfusion is the infusion of blood or blood components that have been collected from the general public.

2. Autologous Blood Transfusion.—An autologous blood transfusion is the precollection and subsequent infusion of a patient's own blood.

3. Donor Directed Blood Transfusion.—A donor directed blood transfusion is the infusion of blood or blood components that have been precollected from a specific individual(s) other than the patient and subsequently infused into the specific patient for whom the blood is designated. For example, patient B's brother predeposits his blood for use by patient B during upcoming surgery.

4. Perioperative Blood Salvage.—Perioperative blood salvage is the collection and reinfusion of blood lost during and immediately after surgery.

B. Policy Governing Transfusions.—For Medicare coverage purposes, it is important to distinguish between a transfusion itself and preoperative blood services; e.g., collection, processing, storage. Medically necessary transfusion of blood, regardless of the type, may generally be a covered service under both Part A and Part B of Medicare. Coverage does not make a distinction between the transfusion of homologous, autologous, or donor-directed blood. With respect to the coverage of the services associated with the preoperative collection, processing, and storage of autologous and donor-directed blood, the following policies apply.

1. Hospital Part A and B Coverage and Payment.—Under § 1862(a)(14) of the Act, nonphysician services furnished to hospital patients are covered and paid for as hospital services. The inclusion of services

provided to hospital patients by an outside supplier as part of hospital services is referred to as ''bundling.'' In a situation where a hospital obtains either autologous or donor-directed blood from an independent supplier, the supplier collects, processes, and stores the blood and, typically, delivers it to the hospital. The hospital is responsible for paying the supplier.

Part A payment, as specified in § 1814(b) of the Act, and Part B payment, as specified in § 1833(a) of the Act, relate to reasonable cost as defined in § 1861(v) of the Act. Under this system, when a hospital obtains autologous or donor-directed blood from an independent blood bank, Medicare recognizes only a processing fee charged to the hospital by the independent blood bank because the blood has been replaced, albeit in advance. The processing fee is recorded by the hospital in the blood storing, processing, and transfusion cost center. This cost center also includes any costs the hospital itself incurs to process and administer the blood after it has been procured. This includes the cost of such activities as storing, type crossmatching, and transfusing the blood, as well as the cost of spoiled or defective blood. The hospital may generate a charge for these costs (except for spoiled or defective blood) and, under cost reimbursement, Medicare picks up its share of the costs through cost apportionment. As provided in § 1886 of the Act, under the prospective payment system (PPS), the diagnosis related group (DRG) payment to the hospital includes all covered blood and blood processing expenses, whether or not the blood is eventually used.

In a situation where the hospital operates its own blood collection activities, rather than using an independent blood supplier, the costs incurred to collect autologous or donor-directed blood are recorded in the whole blood and packed red blood cells cost center. Because the blood has been replaced, Medicare does not recognize a charge for the blood itself. Therefore, under cost reimbursement, these costs are shared by all patients through cost apportionment. The costs incurred by the hospital to store, process, and transfuse the blood, as well as the cost of spoiled or defective blood, are recorded in the blood storing, processing, and transfusion cost center. The hospital may generate a charge for these costs (except for the cost of spoiled or defective blood) and, under cost reimbursement, Medicare picks up its share of these costs through cost apportionment. Under PPS, the DRG payment is intended to pay for all covered blood and blood services, whether or not the blood is eventually used.

Under its provider agreement, a hospital is required to furnish or arrange for all covered services furnished to hospital patients. Medicare payment is made to the hospital, under PPS or cost reimbursement, for covered inpatient and outpatient services, and it is intended to reflect payment for all costs of furnishing those services.

2. Nonhospital Part B Coverage.—Under Part B, to be eligible for separate coverage, a service must fit the definition of one of the services authorized by § 1832 of the Act. These services are defined in 42 CFR 410.10 and do not include a separate category for a supplier's services associated with blood donation services, either autologous or donor-directed. That is, the collection, processing, and storage of blood for later transfusion into the beneficiary is not recognized as a separate service under Part B. Therefore, there is no avenue through which a blood supplier can receive direct payment under Part B for blood donation services.

C. Perioperative Blood Salvage.—When the perioperative blood salvage process is used in surgery on a hospital patient, payment made to the hospital (under PPS or through cost reimbursement) for the procedure in which that process is used is intended to encompass payment for all costs relating to that process.

Transmittal No. 73; Section 45–7, Hydrophilic Contact Lens for Corneal Bandage. CLARIFICATION—EFFECTIVE DATE: Not Applicable.

Section 45–7, Hydrophilic Contact Lens for Corneal Bandage.—This section has been revised to explain how payment is provided for hydrophilic contact lenses when they are furnished incident to a physician's services. Payment for the lenses is bundled into the payment for the physician service to which it is incident. If the lenses are covered as other than incident to a physician's service, they are not paid under the physicians' fee schedule and would be covered prosthetic devices, which follow other payment provisions of the Act.

45–7 HYDROPHILIC CONTACT LENS FOR CORNEAL BANDAGE

Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology, such as bullous keratopathy, dry eyes, corneal ulcers and erosion, keratitis, corneal edema, descemetocele, corneal ectasis, Mooren's ulcer, anterior corneal dystrophy, neurotrophic keratoconjunctivitis, and for other therapeutic reasons.

Payment may be made under § 1861(s)(2) of the Act for a hydrophilic contact lens approved by the Food and Drug Administration (FDA) and used as a supply incident to a physician's service. Payment for the lens is included in the payment for the physician's service to which the lens is incident. Contractors are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval. (See § 65–1 for coverage of a hydrophilic contact lens as a prosthetic device.) See Intermediary Manual, § 3112.4 and Carriers Manual, §§ 2050.1 and 15010.

ADDENDUM V.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR page numbers	CFR part	File code*	Regulation title	End of comment period	Effective date
10/03/94	50235–50240	.....	MB–084–NC	Medicaid Program; Charges for Vaccine Administration Under the Vaccines for Children (VFC) Program.	.....	10/01/94
10/03/94	50246–50253	.....	ORD–068–N	Medicare and Medicaid Programs; Small Business Innovation Research Grants for Fiscal Year 1995.	.....	10/03/94
10/07/94	51125–51130	403	OBS–001–FC	Medicare Program; Information, Counseling, and Assistance Grants Program.	12/06/94	10/07/94

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

Publication date	FR page numbers	CFR part	File code*	Regulation title	End of comment period	Effective date
10/13/94	51989		MB–084–CN	Medicaid Program; Charges for Vaccine Administration Under the Vaccines for Children (VFC) Program Correction.	12/12/94	10/01/94
10/14/94	52129–52132	418	BPD–820–N	Hospice Services Under Medicare Program; Intent To Form Negotiated Rulemaking Committee.	11/14/94	10/14/94
10/19/94	52862	488 489	BPD–393–IFC	Medicare Program; Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care OFR Correction.	08/22/94	07/22/94
10/20/94	52968–52971		HSQ–220–N	CLIA Program; Approval of the American Society for Histocompatibility and Immunogenetics for the Specialty of Histocompatibility.		10/20/94
10/20/94	52971–52972		OPL–002–N	Medicare Program; Request for Nominations for Members for the Practicing Physicians Advisory Council.		10/20/94
10/21/94	53187–53193		BPO–124–PN	Medicare Program; Data, Standards, and Methodology Used to Establish Fiscal Year 1995 Budgets for Fiscal Intermediaries and Carriers.	12/20/94	
11/10/94	56116–56252	401 431 435 440 441 442 447 483 488 489 498	HSQ–156–F	Medicare and Medicaid Programs, Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities.		07/01/95
11/14/94	56501–56510		BPO–127–N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Covered Decisions-Second Quarter 1994.		11/14/94
11/16/94	59241–61629		BPO–128–N	Medicare and Medicaid Programs; Delay in Implementation of the Medicare-Medicaid Coverage Data Bank Requirements.		11/16/94
11/17/94	59624		MB–060–P	Medicaid Program; Inpatient Psychiatric Services for Individuals Under Age 21.	01/17/94	
11/21/94	59933–59943	417	OMC–008–F	Medicare Program; Appeal Rights and Procedures for Beneficiaries Enrolled in Prepaid Health Care Plans.		12/21/94
11/22/94	60109–60156	205	MB–092–P	Aid to Families With Dependent Children; National Voter Registration Act of 1993; Implementation.	01/23/95	
11/23/94	60365		OPL–003–N	Medicare Program; Meeting of the Practicing Physicians Advisory Council.		11/23/94
12/01/94	61629–61628		OACT–046–N	Medicare Program; Part A Premium for 1995 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement.		01/01/95
12/01/94	61629–61633		OACT–047–N	Medicare Program; Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rates Beginning January 1, 1995.		01/01/95
12/01/94	61628–61633		OACT–048–N	Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1995.		01/01/95

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

Publication date	FR page numbers	CFR part	File code*	Regulation title	End of comment period	Effective date
12/06/94	62606–62609	493	HSQ–217–FC	Medicare, Medicaid and CLIA Programs; Extension of Certain Effective Dates for Clinical Laboratory Requirements and Personnel Requirements for Cytologists.	02/06/95	12/06/94
12/08/94	63410–63635	410 414	BPD–789–FC	Medicare Program; Refinements to Geographic Adjustment Factor Values, Revisions to Payment Policies, Adjustments to the Relative Value Units (RVUs) Under The Physician Fee Schedule for Calender Year 1995, and the 5–Year Refinement of RVUs.	02/06/95	01/01/95
12/08/94	63638–63646	.....	BPD–807–FN	Physician Fee Schedule Update for Calendar Year 1995 and Physician Volume Performance Standard Rates of Increase for Federal Fiscal Year 1995.	.....	01/01/95
12/13/94	64141–64153	405 482	BPD–421–F	Medicare and Medicaid Programs; Revisions to Conditions of Participation for Hospitals.	.....	01/12/95
12/13/94	64153–64156	412 413	BPD–802–CN	Medicare Program; Changes to the Hospital Inpatient Prospective Systems and Fiscal Year 1995 Rates; Correction.	.....	10/01/94
12/20/94	64482–65498	409 413 418 484	BPD–469–F	Medicare Program; Medicare Coverage of Home Health Services, Medicare Conditions of Participation, and Home Health Aide Supervision.	.....	02/21/95
12/23/94	66314–66316	.....	HSQ–221–N	Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Continuance of Exemption of Laboratories Licensed by the State of Washington.	.....	12/29/94
12/29/94	67264–67265	.....	BPD–822–N	Medicare Program; Hospice Wage Index.	.....	12/29/94
12/29/94	67265	.....	BPD–823–N	Medicare Program; Hospice Wage Index.	.....	12/29/94

*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.

[FR Doc. 95–8398 Filed 4–5–95; 8:45 am]
BILLING CODE 4120–01–P

Health Resources and Services Administration

Maternal and Child Health Services; Federal Set-Aside Program; Genetic Services and Maternal and Child Improvement Projects for Fiscal Year (FY) 1995: Cancellation/Changes of Cycle for Certain Grants and Cooperative Agreements; Extension of Certain Application Deadline Dates

Notice of Availability of Funds for Special Project Grants and Cooperative Agreements; Maternal and Child Health Services; Federal Set-Aside Program; Genetic Services and Maternal and Child Improvement Projects for fiscal year (FY) 1995, section 502(a), title V of the Social Security Act, was published on February 13, 1995, at 60 FR 8244. Section 4.1.2.1. of this notice announced the availability of funds for 4–6 grants in the Maternal, Infant, Child and Adolescent Health subcategory priority identified as ''Adolescent Health Resource Center.'' Section 4.1.2.3. of this notice announced the availability of funds for 5 grants in the Data Utilization subcategory,

Since publication of this notice, it has been determined that amounts allocated for grants under Section 4.1.2.1. are insufficient to permit the award of 4–6 grants in the ''Adolescent Health Resource Center'' priority for FY 1995. As a result, this competition will award one grant in FY 1995 of $200,000 per year for up to 5 years. The programmatic and technical information contact for this competition is Juanita Evans, M.S.W., telephone: (301) 443–4026. Additionally, it has been determined that amounts allocated for grants under Section 4.1.2.2. are insufficient to permit the award of 3 grants in the ''Mental Health Resource Grants'' priority for FY 1995. As a result, this competition will award 2 grants in FY 1995 of $500,000 each per year for up to 5 years. Finally, it has been determined that amounts allocated for grants under Section 4.1.2.3. are insufficient to permit the award of 5 grants in FY 1995 of $100,000 each per year for 3 years. As a result, this competition will award up to 5 grants totalling up to $200,000 in FY 1995, with awards ranging between $25,000 to $100,000 each per year for up to 3 years.

Three of the deadline dates announced in the February 13 Notice of