Reporter: Reporter is primary source of the information, i.e., a person who initially reports the facts. This should be distinguished from the sender of the message, though the reporter could also be a sender.

Sender: The person or entity creating the message for transmission. Although the reporter and sender may be the same person, the function of the sender should not be confused with that of the reporter.

Spontaneous adverse drug reaction report: An unsolicited communication to a company, regulatory authority, or other organization that describes an adverse medical reaction in a patient given one or more medical products and which does not derive from a study or any organized data collection scheme.

Attachment 1

Unit List

Mass

kg	kilogram(s)
g	gram(s)
mg	milligram(s)
µg	microgram(s)
ng	nanogram(s)
pg	picogram(s)
mg/kg	milligram(s)/kilogram
µg/kg	microgram(s)/kilogram
mg/m²	milligram(s)/sq. meter
µg/m²	microgram(s)/ sq. meter

Radioactivity

Bq	becquerel(s)
GBq	gigabecquerel(s)
MBq	megabecquerel(s)
Kbq	kilobecquerel(s)
Ci	curie(s)
mCi	millicurie(s)
µCi	microcurie(s)
nCi	nanocurie(s)

Volume

l	litre(s)
ml	millilitre(s)
µl	microlitre(s)

Other

mol	mole(s)
mmmol	millimole(s)
µmol	micromole(s)
iu	international unit(s)
kiu	iu(1000s)
Miu	iu(1,000,000s)
iu/kg	iu/kilogram
mEq	milliequivalent(s)
%	percent
gtt	drop(s)
DF	dosage form

User Guidance:

This is the list of accepted units. When having other measure units, transformation is recommended if possible. Otherwise use the free text field.

Definition of Interval List

Minutes
Hours
Days
Weeks
Months
Years
Cyclical
As necessary
Total

Attachment 2

Route of Administration List

Auricular
Buccal
Cutaneous
Dental
Endocervical
Endosinusial
Endotracheal
Epidural
Extra-amniotic
Hemodialysis
Intra corpus cavernosum
Intra-amniotic
Intra-arterial
Intra-articular
Intra-uterine
Intracardiac
Intracavernous
Intracerebral
Intracervical
Intracisternal
Intracorneal
Intracoronary
Intradermal
Intradiscal (intraspinal)
Intralesional
Intralymphatic
Intramedullar (bone marrow)
Intrameningeal
Intramuscular
Intraocular
Intrapericardial
Intraperitoneal
Intrapleural
Intrasynovial
Intrathecal
Intrathoracic
Intratracheal
Intravenous
Intravesical
Iontophoresis
Nasal
Occlusive dressing technique
Ophthalmic
Oral
Oropharyngeal
Other
Parenteral
Periarticular
Perineural
Rectal
Respiratory (inhalation)
Retrobulbar
Subconjunctival
Subcutaneous
Subdermal
Sublingual
Transdermal
Transmammary
Transplacental
Unknown
Urethral
Vaginal

Dated: September 24, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–25034 Filed 9–30–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0322]

Mammography Facility Performance, Calendar Year 1995; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the document entitled ''Mammography Facility Performance, Calendar Year 1995.'' This document, mandated by Congress in the Mammography Quality Standards Act of 1992 (the MQSA), is intended to inform physicians and the general public about mammography facility performance in the calendar year 1995.

ADDRESSES: Submit written requests for single copies of the document entitled ''Mammography Facility Performance, Calendar Year 1995'' to MQSA, c/o SciComm, Inc., P.O. Box 30224, Bethesda, MD 20824–9998. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. The document is also available on the Internet (http://www.fda.gov). ''Mammography Facility Performance, Calendar Year 1995'' is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Carole Sierka, Office of Health and Industry Programs, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3534, FAX 301–594–3306.

SUPPLEMENTARY INFORMATION: The MQSA of 1992 (Pub. L. 102–539) was enacted on October 27, 1992. Under the MQSA, FDA is required annually to compile and make available to physicians and to the general public information assisting in the selection of an FDA-certified facility. The report must include a list of facilities:

(1) That have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

(2) that have been subject to sanctions under MQSA together with a statement of the reasons for the sanctions;

(3) that have had certificates revoked or suspended, together with a statement of the reasons for the revocation or suspension;

(4) against which the Secretary of the Department of Health and Human Services has sought an injunction under MQSA, together with a statement of the reasons for the action;

(5) whose accreditation has been revoked, together with a statement of the reasons for the revocation;

(6) against which a State has taken adverse action; and

(7) that meets such other measures of performance as the Secretary may develop.

The information compiled in this report must be accompanied by information that will assist in the interpretation of the report.

Accordingly, FDA is making the list and explanatory information available through this report. This report also provides background information on quality mammography and directs consumers on how to acquire a list of FDA-certified mammography facilities.

Dated: September 27, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–25197 Filed 9–27–96; 12:11 pm]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–R–117]

Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements contained in 42 CFR 447.253; *Form No.:* HCFA–R–117; *Use:* In order to receive HCFA approval of a Medicaid State plan amendment which changes the methods and standards used to establish payment rates for inpatient hospital or long-term care services, a Medicaid State Agency must provide a statement which assures the HHS Secretary that the resulting rates will conform to all the requirements specified in section 1902(a)(13)(A) of the Social Security Act and implementing regulations at 42 CFR 447.253; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 54.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: September 23, 1996.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–25060 Filed 9–30–96; 8:45 am]

BILLING CODE 4120–03–P

[BPD–874–N]

Medicare Program; Update of Ambulatory Surgical Center Payment Rates Effective for Services on or After October 1, 1996

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

ACTION: Notice.

SUMMARY: This notice implements section 1833(i)(2)(C) of the Social Security Act, which mandates an automatic inflation adjustment to Medicare payment amounts for ambulatory surgical center (ASC) facility services during the years when the payment amounts are not updated based on a survey of the actual audited costs incurred by ASCs.

EFFECTIVE DATE: The payment rates contained in this notice are effective for services furnished on or after October 1, 1996.

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

This Federal Register document is also available from the Federal Register online database through *GPO Access*, a service of the U.S. Government Printing Office. 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 **X**docs/, by using local WAIS client software, or by telnet to 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 through Friday, except for Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joan Haile Sanow, (410) 786–5723.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) provides that benefits under the Medicare Supplementary Medical Insurance program (Part B) include services furnished in connection with those surgical procedures that, under section 1833(i)(1)(A) of the Act, are specified by the Secretary and are performed on an inpatient basis in a hospital but that also can be performed safely on an ambulatory basis in an ambulatory surgical center (ASC), in a rural primary care hospital, or in a hospital outpatient department. To participate in the Medicare program as an ASC, a facility must meet the standards specified under section 1832(a)(2)(F)(i) of the Act and 42 CFR 416.25, which set forth basic requirements for ASCs.

Generally, there are two elements in the total charge for a surgical procedure: A charge for the physician's professional services for performing the procedure, and a charge for the facility's