following mastectomy, and revision of a failed prosthesis.

DATES: Written comments concerning this draft guidance must be received by January 4, 2000.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Samie N. Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this document is to provide guidance to sponsors of breast implant prostheses on important preclinical, clinical, and labeling information that should be presented in an IDE, PMA, or PDP application. It may also be useful in the preparation of reclassification petitions and master files.

This draft guidance discusses information relevant to silicone gel-filled, saline-filled, and alternative-filled breast prostheses intended for prostheses for breast augmentation, breast reconstruction following mastectomy, and revision of a failed prosthesis. This draft guidance does not address tissue expanders, which are unclassified devices for temporary use. Additionally, this draft guidance does not address alternative shell materials for use in breast implants.

This draft guidance is intended to combine and replace the following three individual guidances that were previously developed for silicone gel, saline, and alternative breast prostheses:

(1) ''Draft Guidance for Preparation of FDA Submissions of Silicone Gel–Filled Breast Prostheses'' (May 11, 1992); (2) ''Draft Guidance for Testing of Alternative Breast Prostheses (Non–Silicone, Gel–Filled)'' (September 1, 1994); and (3) ''Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses'' (January 18, 1995).

In addition, this draft guidance involves the revisiting and updating of the scientific preclinical and the clinical and labeling information described in those guidances.

II. Significance of Guidance

This guidance document represents the agency's current thinking on preclinical, clinical, and labeling information for breast prostheses. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance document consistent with GGP's.

III. Electronic Access

In order to receive the ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1354) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' also will be available at http://www.fda.gov/cdrh/ode/1354.pdf.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of 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: September 21, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–25771 Filed 10–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–9042]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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 proposal for the collection of information. Interested persons are invited to send comments regarding the 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.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Request for Accelerated Payments and Supporting Regulations in 42 CFR, Section 412.116 & 413.64;

Form No.: HCFA–9042;

Use: Medicare reimbursements are usually arranged through a fiscal intermediary who serves as the Secretary's agent for reviewing claims and making payments equal to the provider's reasonable costs. When a delay in Medicare payment by a fiscal intermediary, for covered services, causes financial difficulties for a provider, the provider may request an accelerated payment. An accelerated payment may also be made in highly exceptional situations where a provider has incurred a temporary delay in its bill processing beyond the provider's normal billing cycle. An accelerated payment can be requested by a provider that is not receiving periodic interim payments. These forms are used by fiscal intermediaries to access a provider's eligibility for accelerated payments.

Frequency: On occasion;

Affected Public: Business or other for-profit, and Not for-profit institutions;

Number of Respondents: 890;

Total Annual Responses: 890;

Total Annual Hours Requested: 445.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk 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 20, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–25833 Filed 10–4–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1056–CN]

RIN 0938–AJ65

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update; Correction

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

ACTION: Notice; correction.

SUMMARY: This document corrects technical errors that appeared in the notice published in the **Federal Register** on July 30, 1999 entitled ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update.''

EFFECTIVE DATE: These corrections are effective October 1, 1999.

FOR FURTHER INFORMATION CONTACT: Bill Ullman, (410) 786–5667.

SUPPLEMENTARY INFORMATION:

Background

In FR Doc. 99–19479 of July 30, 1999 (64 FR 41684), there were a number of technical errors. The errors relate to the update factor that appears in the discussion of one issue, and to a column of incorrect figures displayed in one table.

Regarding the former, section III. of the preamble (64 FR 41697) discusses the statutory three-year, phased transition under which payment is based in part on a facility-specific per diem rate (which reflects an individual facility's historical cost experience) and in part on a Federal per diem rate. For facilities that received payment under the RUG–III demonstration during a cost reporting period that began in calender year 1997, the notice sets forth a three-step procedure for determining the facility-specific rate, in which the final step is an adjustment of the rate by an inflation factor of 1.031532. However, this factor inadvertently failed to reflect an update; as a consequence, the figure of 1.031532 as shown in the notice discussion should instead be 1.062244.

The other correction relates to a technical error in Table 8.C of the preamble (64 FR 41698–99), entitled ''Update Factors for Facility-Specific Portion of the SNF PPS Rates.'' This table provides numerical factors for use in updating a facility's base year costs through fiscal year (FY) 2000 (*i.e.*, the period beginning October 1, 1999, and ending September 30, 2000) by the SNF market basket percentage, as required under section 1888(e)(3)(D) of the Social Security Act (the Act). However, these update factors inadvertently reflected updates to the base period amounts only up to the midpoint of FY 2000 itself, rather than to the midpoint of the corresponding cost reporting periods that begin during FY 2000. This error resulted in incorrect figures being displayed for the update factors that appear in the right-hand column of Table 8.C.

Accordingly, we are reprinting this table below, with the corrected figures displayed in the right-hand column. Additionally, we note that while this correction causes all of the figures displayed in this column of the table to increase, this does not affect the associated budgetary projections, since they were made based on employing the correct methodology for calculating the update factors, as described in the SNF PPS interim final rule (63 FR 26252, May 12, 1998). The corrections appear in this document under the heading ''Correction of Errors.''

The provisions in this correction notice are effective as if they had been included in the document published in the **Federal Register** on July 30, 1999, that is, October 1, 1999.

Correction of Errors

In FR Doc. 99–19479 of July 30, 1999 (64 FR 41684), we are making the following corrections:

Corrections

Page 41697

In the second column, in the paragraph entitled ''Step 3.,'' the first sentence is revised to read as follows: ''Adjust the amount in Step 2. by 1.062244 (inflation factor)—Do not use 8.C.''

Page 41698

Corrected Table 8.C (Update Factors for Facility-Specific Portion of the SNF PPS Rates) is set forth below: