

a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

XII. References

The following references have been placed on display in the Documents Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Reclassification Petition for the Suction Lipetomy Systems for Aesthetic Body Contouring, submitted by American Society for Aesthetic Surgery, December 28, 1989.
2. Transcript of the General and Plastic Surgery Devices Panel Meeting, January 26, 1989.
3. Transcript of the General and Plastic Surgery Devices Panel Meeting, March 10, 1989.
4. Pitman, G. H., "Instrumentation," *Liposuction and Aesthetic Surgery*, Quality Medical Publishing Inc., St. Louis, MO, Part I, 2:31-36.
5. Underwriters Laboratories, UL-544, Standard for Medical and Dental Equipment, 1976, Reprinted 1985.
6. Illouz, Y. G., "Illouz's Technique of Body Contouring by Lipolysis," *Clinics in Plastic Surgery*, 11:409-417, 1984.
7. Kesselring, U. K., "Body Contouring with Suction Lipetomy," *Clinics in Plastic Surgery*, 11:393-498, 1984.
8. Dillerud, E., "Suction Lipoplasty, A Report on Complications, Undesired Results, and Patient Satisfaction Based on 3,511 Procedures," *Plastic and Reconstructive Surgery*, 88:239-246, August 1991.
9. Dillerud, E., and L. L. Haheim, "Long-term Results of Blunt Suction Lipetomy Assessed By Questionnaire Survey," *Plastic and Reconstructive Surgery*, 92:35-42, July 1993.
10. Dolsky, R. L., J. Newman, J. R. Fetzek, et al., "Liposuction History, Techniques and Complications," *Dermatology Clinics of North America*, 5:313-333, 1987.
11. Teimourian, B. and W. B. Rogers, "A National Survey of Complications Associated with Suction Lipetomy: A Comparative Study," *Plastic and Reconstructive Surgery*, 84:628-631, 1989.
12. Fredricks, S., "Five-year Updated Evaluation of Suction-assisted Lipetomy," ASPRS Ad Hoc Committee on New Procedures, September 30, 1987.
13. Annual Book of American Society for Testing and Materials Standards, Medical Devices, vol. 13.01, 1088.
- F 639-79 Standard Specification for Polyethylene Plastics for Medical Applications.
- F 665-80 Standard Classification for Vinyl Chloride Plastics Used in Biomedical Application.
- F 719-81 Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation.
- F 720-81 Standard Practice for Testing Guinea Pig Maximization Test.
- F 748-87 Standard Practice for Selecting Generic Biological Test Method for Materials and Devices.

F 749-87 Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit.

F 750-87 Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse.

F 813-83 Standard Practice for Direct Cell Culture Evaluation of Materials for Medical Devices.

F 960-86 Standard Specification for Medical and Surgical Suction and Drainage Systems.

14. United States Pharmacopeia XXI, Biological Tests—Plastics.

15. ISO (International Organization for Standardization) 10079-1, Medical Suction Equipment, Part I, Electrically Powered Suction Equipment—Safety Requirements, 1993.

16. CSA (Canadian Standards Association), Standard Z168.11-94, Vacuum Devices Used for Suction and Drainage, 1994.

17. Grazer, F. M., "Suction-Assisted Lipetomy: Its Indications, Contraindications, and Complications," *Year Book Medical Publishers*, 1984.

18. Ersek, R. A., J. Zambrona, G. S. Surak, et al., "Suction-assisted Lipetomy for Correction of 202 Figure Faults in 101 Patients: Indications, Limitations, and Applications," *Plastic and Reconstructive Surgery*, 78:615-626, 1986.

19. Hetter, G. P., "Optimum Vacuum Pressures for Lipolysis," *Aesthetic Plastic Surgery*, 8:23-26, 1984.

20. Christman, K. D., "Death Following Lipetomy and Tissue," "Neither Panacea of Humberg," *Postgraduate Medicine*, 75:124, 126, 128, 1984.

21. Courtiss, E. H., "Suction Lipetomy: A Retrospective Analysis of 100 Patients," *Plastic and Reconstructive Surgery*, 73:780-796, 1984.

22. Badran, H. A., K. Z. Kodeara, and M. H. Mabrouk, "Blood Conservation in Massive Suction Lipetomy," *Plastic and Reconstructive Surgery*, 92:1298-1304, 1993.

23. Hunter, G. R., R. O. Crapo, and T. R. Broadbent, "Pulmonary Complications Following Abdominal Lipetomy," *Plastic and Reconstructive Surgery*, 71:809-817, 1983.

24. Background, "Liposuction" American Society of Plastic and Reconstructive Surgeons, July 1994.

25. Pitman, G. H., and B. Teimourian, "Suction Lipetomy: Complications and Results by Survey," *Plastic and Reconstructive Surgery*, 76:65-72, 1985.

26. Tripartite Biocompatibility Guidance for Medical Devices, September 1986.

27. Clinical Practice Guidelines, Plastic and Maxillofacial Surgery, American Society of Plastic and Reconstructive Surgeons, Chapter L: Localized Adiposity, September 1993.

28. International Standard ISO-10993 Biological Evaluation of Medical Devices Part I Evaluation and Testing, 1995.

XIII. Request for Comments

Interested persons may, on or before February 11, 1997, submit to the Dockets Management Branch (address above) written comments regarding this document. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 6, 1996.

Joseph A. Levitt,

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

[FR Doc. 96-29066 Filed 11-12-96; 8:45 am]

BILLING CODE 4160-01-F

Health Care Financing Administration

[Document Identifier: HCFA-1450]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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, is publishing the following summaries of proposed collections for public comment. 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 Information Collection Request:* Reinstatement, with change, of previously approved collection for which approval has expired; *Title of Information Collection:* Medicare Uniform Institutional Provider Bill Form HCFA-1450 (UB-92) and Instructions, and Supporting Regulations 42 CFR 424.5 (a) (5) (Claim for Payment), 42 CFR 424.32 (Basic Requirements for all Claims) and 42 CFR 412.60 (Diagnosis-Related Groups Classification and Weighting Factors); *Form No.:* HCFA-1450; *Use:* This form and instructions are standardized for use in the Medicare/Medicaid programs to apply for reimbursement for covered services. The HCFA-1450 is managed by the National Uniform Billing

Committee, a standards body sponsored by the American Hospital Association. Most major payers, such as the Blues network, the members of the Health Insurance Association of America, as well as the state hospital associations, are represented on this body. 42 CFR 424.5 (a) (5), 42 CFR 424.32, and 42 CFR 412.60 are regulations underlying the use of the form HCFA-1450 and the information captured on the form HCFA-1450, including the use of diagnostic and procedural coding systems. HCFA solicits comments on any and all aspects of the HCFA-1450, and the use of diagnostic and procedural coding systems: HCFA currently uses the most current version of the ICD-9-CM and CPT/HCPCS; *Frequency*: On occasion; *Affected Public*: Business or other for profit, not for profit institutions, State, local or tribal government, Federal Government; *Number of Respondents*: 133,100,000; *Total Annual Responses*: 133,100,000; *Total Annual Hours*: 993,250.

To obtain copies of the supporting statement and any related forms and instructions for the proposed paperwork collection referenced above, E-mail your request, including your address and phone number, to JBurke1@hcfa.gov, or call the Reports Clearance Office on (410) 786-1325. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: John Burke, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 4, 1996.

Edwin J. Glatzel,

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

[FR Doc. 96-28947 Filed 11-12-96; 8:45 am]

BILLING CODE 4120-03-P

[HCFA-R-199]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 request for emergency review. We are requesting an emergency review because the collection of Section 3515 of the Chief Financial Officers Act of 1990 requires government agencies to produce auditable financial statements in accordance with Office of Management and Budget guidelines on form and content. Beginning in fiscal year 1996, the Government Management and Reform Act of 1994 requires that all offices, bureaus and associated activities of the 24 CFO Act agencies must be covered in an agency-wide, audited financial statement. Because of the size of the Medicaid program, we believe that Medicaid payables and receivables are material to both financial statements. The agency cannot reasonably comply with the normal clearance procedures because it is imperative that HCFA collects this data in time for incorporation into HCFA's fiscal year 1996 financial statement. Failure to collect this information could result in a disclaimer on the audit opinion.

HCFA is requesting that OMB provide a completed review by November 15, 1996 and a 180 day approval. During this 180-day period, HCFA will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. Then HCFA will submit the requirements for OMB review and an extension of this emergency approval.

Title of Information Collection Request: New Collection; *Title of Information Collection*: Medicaid Report on Payables and Receivables; *Form No.*: HCFA-R-199; *Use*: The Chief Financial Officers Act of 1990 requires government agencies to produce auditable financial statements. Form HCFA-R-199 will collect accounting data from the States on payables and receivables. *Frequency*: Annually; *Affected Public*: State, Local or Tribal Government; *Number of Respondents*: 57; *Total Annual Responses*: 57; *Total Annual Hours Requested*: 171.

To request copies of the proposed paperwork collection referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 2 working days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Laura Oliven, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 6, 1996.

Edwin J. Glatzel,

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

[FR Doc. 96-29014 Filed 11-12-96; 8:45 am]

BILLING CODE 4120-03-P

[HCFA-1961]

Agency Information Collection Activities: Proposed Collection: 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 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*: Reinstatement, without change, of previously approved collection for which approval has expired; *Title of Information Collection*: HCFA Forms and manuals Order; *Form No.*: HCFA-1961; *Use*: The HCFA-1961 will be used by Medicare Intermediaries, Carriers, State Agencies, SSA and End Stage Renal Networks to order Medicare/Medicaid forms and program manuals from the Health Care Financing Administration; *Frequency*: Annually; *Affected Public*: Federal Government and State, local, or tribal government; *Number of Respondents*: 200; *Total Annual Responses*: 200; *Total Annual Hours*: 400.

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 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and