meeting to obtain expert on opinion whether the agency should allow topical therapies to be made available for OTC use. The advisory committee recommended that women whose initial episode of vulvovaginal candidiasis was diagnosed and treated by a physician could adequately self-treat their condition without the supervision of a health care provider. The first 7-day intravaginal drug product for the treatment of vulvovaginal candidiasis was approved for OTC use in 1990; the first 3-day product in 1995; and the first single-dose product in 1997.

In the **Federal Register** of February 27, 1997 (62 FR 9024), the agency published a notice entitled ''Over-the-Counter Human Drugs; Proposed Labeling Requirements,'' proposing a standardized format for the labeling of OTC drug products. This proposed standardized format is frequently referred to as the ''Drug Facts Format.'' The agency is developing this guidance document on labeling for OTC drug products for the treatment of vaginal yeast infections in accordance with the ''Drug Facts Format.''

Labeling for OTC drug products for the treatment of vaginal yeast infections consists of three components: (1) The carton, (2) the educational brochure, and (3) the overwrap. With OTC drug products, the agency believes that labeling takes on the critical role of providing information to the consumer. Therefore, consumers must have information that is easily understood to allow for appropriate self-selection and appropriate use of the product. Since there are a variety of OTC products currently available for the treatment of vaginal yeast infections, and since in most cases, the content to be communicated in labeling is nearly identical for each product, the labeling for these products should convey a clear and consistent message to the consumer. The intent of the draft guidance is to provide labeling guidance for all OTC drug products for the treatment of vaginal yeast infections.

The draft guidance represents the agency's current thinking on the labeling of OTC topical drug products for the treatment of vaginal yeast infections. 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Interested persons may, on or before October 14, 1998, submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. The draft guidance document 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: July 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18879 Filed 7–15–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–116, HCFA–416, HCFA–R–148, and HCFA–R–231]

Agency Information Collection Activities: Submission for OMB Review; 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 summary 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:* Revision of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations in 42 CFR 493.1—.2001; Form No.: HCFA–116 (OMB# 0938–0581); *Use:* These certification requirements have been established for any entity that performs testing on human beings for diagnostic or treatment purposes. If a laboratory conducts relatively simple tests that are categorized as waived or provider performed microscopy test procedures (PPMP), it must obtain a certificate of waiver or certificate of PPMP. If the laboratory conducts any tests outside of these two categories, it must apply for a certificate of compliance or certificate of accreditation and initially obtain a registration certificate. These certificates ensure that laboratories are in compliance with CLIA.; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 20,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT) Participation Report and Supporting Regulations in 42 CFR 441.60; *Form No.:* HCFA–416 (OMB# 0938–0354); *Use:* States are required to submit an annual report on the provision of EPSDT services to HCFA pursuant to section 1902(a)(43) of the Social Security Act. These reports provide HCFA with data necessary to assess the effectiveness of State EPSDT programs. It is also helpful in developing trend patterns, national projections, responding to inquiries, and determining a State's results in achieving its participation goal.; *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Limitation on Provider-Related Donations and Health Care-Related Taxes; Limitations on Payments to Disproportionate Share Hospitals; Medicaid and Supporting Regulations in 42 CFR 433.68, 433.74, 447.74 and 447.272; *Form No.:* HCFA–R–148 (OMB# 0938–0618); *Use:* These information collection requirements specify limitations on the amount of Federal financial participation available for medical assistance expenditures in a fiscal year. States receive donated funds from providers and revenues are generated by health care related taxes. These donations and revenues are used to fund medical assistance programs.; *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* #3,892.

4. *Type of Information Request:* Revision of a currently approved collection; *Title of Information*

Collection: Medicare+Choice (M+C) Providers Sponsored Organization (PSO) Waiver Request Form and Supporting Regulations in 42 CFR 422.370–422.378; *Form Number:* HCFA–R–231; *Use:* The PSO waiver request form is for use by PSO's that do not have a State risk-bearing entity licence and that wish to enter into a M+C contract with HCFA to provide prepaid health care services to eligible Medicare beneficiaries. HCFA will use the information requested on this form to determine whether the applicant is eligible for a waiver of the state licensure requirement for M+C organizations as allowed under section 1855(a)(2) of the Social Security Act.; *Frequency:* One-time.; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Federal Government.; *Annual Number of Respondents:* 30.; *Total Annual Responses:* 30.; *Total Annual Hours Requested:* 300.

To obtain copies of the supporting statement and any related forms 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, phone number, OMB number, and HCFA document identifier, 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: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: July 9, 1998.

John P. Burke III,

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

[FR Doc. 98–19003 Filed 7–15–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Privacy Act of 1974; Report of Altered Systems

AGENCY: Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

ACTION: Notice of the global addition of three new routine uses to designated HCFA Systems of Records.

SUMMARY: HCFA is adding three additional routine uses to the Systems of Records specified in Appendix A. These routine uses will permit HCFA to disclose individual-specific information for the purpose of combating fraud or abuse in the health benefit programs administered by HCFA and for other compatible purposes. These new routine uses will permit HCFA to make disclosures as follows: (1) To a HCFA contractor, including but not necessarily limited to fiscal intermediaries and carriers under title XVIII of the Social Security Act, to administer some aspect of a HCFA-administered health benefits program, or to a grantee of a HCFA-administered grant program, which program is or could be affected by fraud or abuse, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating such fraud or abuse in such program; (2) To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States, including any state or local government agency, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating fraud or abuse in a health benefits program funded in whole or in part by Federal funds; and, (3) To any entity that makes payment for or oversees the administration of health care services, for the purpose of preventing, deterring, discovering, detecting, investigating, examining, prosecuting, suing with respect to, defending against, correcting, remedying, or otherwise combating fraud or abuse against such entity or the program or services administered by such entity, subject to certain conditions.

EFFECTIVE DATES: HCFA filed an altered system report with the Chairman of the Committee on Government Reform and Oversight of the House of Representatives, the Chairman of the Committee on Governmental Affairs of the Senate, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), on June 29, 1998. The proposed new routine uses will become effective 40 days from the date the altered system report is submitted to Congress and to OMB or 30 days from the publication of this notice, whichever is later.

ADDRESSES: The public should address comments to Phillip L. Brown, Director, Division of Freedom of Information and Privacy Office, C2–26–21, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location by appointment, Monday through Friday 9 a.m.–3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Mr. Nelson Berry, Director, Division of Data Liaison and Distribution, Office of Information Services, HCFA, N3–13–15, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. His telephone number is (410) 786–0182.

SUPPLEMENTARY INFORMATION: We are publishing this notice to inform the public of our intent to add three routine uses under which HCFA may release information without the consent of the individual to whom such information pertains in order to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud or abuse in the programs HCFA administers. Each proposed disclosure of information under these routine uses will be evaluated to ensure that the disclosure is legally permissible, including but not limited to ensuring that the purpose of the disclosure is compatible with the purpose for which the information was collected. Also, HCFA will require each prospective recipient of such information to agree in writing to certain conditions to ensure the continuing confidentiality of the information. More specifically, as a condition of each disclosure under these routine uses, HCFA will:

(a) Determine that no other Federal statute specifically prohibits disclosure of the information;

(b) Determine that the use or disclosure does not violate legal limitations under which the information was provided, collected, or obtained;

(c) Determine that the purpose for which the disclosure is to be made;

(1) Cannot reasonably be accomplished unless the information is provided in individually identifiable form;

(2) Is of sufficient importance to warrant the effect on or the risk to the privacy of the individual(s) that additional exposure of the record(s) might bring;

(3) There is a reasonable probability that the purpose of the disclosure will be accomplished;

(d) Require the recipient of the information to: