EPA's IESWTR establishing treatment technique requirements for *Cryptosporidium* in ground water under the influence of surface water does not apply to ground water used for the production of bottled water.

In addition, according to industry information (Ref. 2), the remaining 25 percent of bottled water sold in the United States is derived from public water systems. Public water systems serving at least 10,000 people or more, using surface water or ground water under the direct influence of surface water, must comply with EPA's IESWTR. In the **Federal Register** of April 10, 2000 (65 FR 19046), EPA published a proposed rule (Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule (LT1FBR)) to establish NPDWRs consisting of treatment technique requirements for reduction of *Cryptosporidium* in surface water and in ground water under the direct influence of surface water that public water systems serving less than 10,000 people use as their source water. Therefore, public water systems serving less than 10,000 people using surface water or ground water under the direct influence of surface water, will be subject to any EPA final rule on LT1FBR. Thus, under the EPA's IESWTR and LT1FBR if finalized as proposed, all water obtained from public water systems used for bottled water would be treated previously by public water systems to reduce the contaminant *Cryptosporidium*.

FDA concludes that because surface water and ground water under the direct influence of surface water would be subject to EPA's treatment technique requirements to reduce *Cryptosporidium*, a standard of quality regulation for bottled water derived from public water systems is not necessary to protect the public health. The contaminant may be contained in public water systems, which would be treated to reduce *Cryptosporidium* before such water would be used for bottled water. Further, because bottled water sources other than public drinking water are from ground water, which by definition (§ 165.110(a)(2)(ii)) must not be ground water under the direct influence of surface water, *Cryptosporidium* would not be expected to be present. Thus, FDA also concludes that a standard of quality regulation for bottled water derived from ground water is not necessary to protect the public health because *Cryptosporidium* would not be in ground water used for bottled water.

IV. References

The following references are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. MacKenzie, W. R., N. J. Hoxie, M. E. Proctor, M. S. Gradus, K. A. Blair, D. E. Peterson, J. J. Kazmierczak, D. G. Addiss, K. R. Fox, J. B. Rose, and J. P. Davis, ''A Massive Outbreak in Milwaukee of Cryptosporidium Infection Transmitted Through the Public Water Supply,'' *New England Journal of Medicine* 331:161–167 (1994).

2. Yablonski, C., International Bottled Water Association, letter to Henry Kim, March 23, 2001.

Dated: June 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–16910 Filed 7–2–01; 4:22 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–724]

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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare/Medicaid Psychiatric Hospital Survey Data and Supporting Regulations Contained in 42 CFR 482.60, 482.61 and 482.62; *Form No.:* HCFA–724 (OMB# 0938–0378); *Use:* The information collected on this form will assist HCFA in maintaining an accurate data base on providers participating in the Medicare psychiatric hospital program; *Frequency:* Annually; *Affected Public:* Federal government, Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 250; *Total Annual Responses:* 250; *Total Annual Hours:* 125.

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: Wendy Taylor,New Executive Office Building, Room 10235,Washington, DC 20503.

Dated: May 22, 2001.

John P. Burke III,

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

[FR Doc. 01–16819 Filed 7–3–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–417]

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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Hospice Request for Certification in the Medicare Program; *Form No.:* HCFA–417 (OMB# 0938–0313); *Use:* The Hospice Request for Certification Form is used for hospice identification, screening, and to initiate the certification process. The information captured on this form is entered into a data base which assists HCFA in determining whether providers have sufficient personnel to participate in the Medicare program; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 2,286; *Total Annual Responses:* 2,286; *Total Annual Hours:* 572.

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, DC 20503.

Dated: May 22, 2001.

John P. Burke III,

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

[FR Doc. 01–16820 Filed 7–3–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1060–N3]

RIN 0938–AJ57

Medicare Program; Cost-of-Living Adjustment (COLA) for the Territory of Guam in the Schedules of Per-Visit Limitations on Home Health Agency Costs

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

ACTION: Notice.

SUMMARY: This notice announces the cost-of-living adjustment for the territory of Guam for the schedules of per-visit limitations on home health agency (HHA) costs for open cost reporting periods beginning on or after October 1, 1997 and portions of cost reporting periods beginning before October 1, 2000.

EFFECTIVE DATE: This notice is effective on August 6, 2001.

FOR FURTHER INFORMATION CONTACT: Michael D. Bussacca, (410) 786–4602.

SUPPLEMENTARY INFORMATION: We have published the following notices to announce the HHA interim payment system per-visit limitations and updates to those limitations. These notices were published on January 2, 1998 (63 FR 89), effective on October 1, 1997; August 1, 1998 (63 FR 42911), effective October 1, 1998; and August 5, 1999 (64 FR 42766), effective on October 1, 1999.

It was our intention to include a COLA for each U.S. State and Territory eligible for those adjustments under the Office of Personnel Management (OPM) regulations. We inadvertently published these notices without a COLA for the Territory of Guam because we did not include COLA factors for Guam in the per-visit tables in the applicable notices. The COLA factor for Guam should have been 1.225 in each of these notices. The OPM has not updated the factor for Guam for these 3 cost reporting years; therefore, the COLA remains 1.225 for each cost reporting period. The COLA factor applies to the per-visit limitations for all open cost reporting periods beginning on or after October 1, 1997 (COLA Table at 63 FR 96), October 1, 1998 (COLA Table at 63 FR 42926), and October 1, 1999 (COLA Table at 64 FR 42777).

Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). We have determined that this is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. For purposes of the RFA, most HHAs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. We believe that there are no costs associated with this notice that apply to these governmental and private sectors. Therefore, the law does not apply.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of States.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that