IV. Regulatory Impact Statement

The Regulatory Flexibility Act, 5 U.S.C. 601 through 612, requires a regulatory flexibility analysis for every rule subject to proposed rulemaking procedures under the Administrative Procedure Act, 5 U.S.C. 552, unless we certify that the rule will not have a significant economic impact on a substantial number of small entities. For purposes of a RFA, States and individuals are not considered small entities. However, providers are considered small entities. Additionally, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural hospitals. Such an 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.

We do not believe that this notice will have a significant economic impact on a substantial number of small entities because it reflects no new policies or procedures, and should have an overall positive impact on payments to disproportionate share hospitals by informing States of the extent to which DSH payments may be increased without violating statutory limitations. This notice sets forth no changes in our regulations; rather, it reflects the DSH allotments for each State as determined in accordance with 42 CFR 447.297 through 447.299.

We have discussed the method of calculating the preliminary FFY 1997 national DSH payment target and the preliminary FFY 1997 individual State DSH allotments in the previous sections of this preamble. These calculations should have a positive impact on payments to disproportionate share hospitals. Allotments will not be reduced for high-DSH States since we interpret the 12-percent limit as a target. Low-DSH States' allotments are equal to their prior FFY DSH allotments plus their growth and supplemental amounts, if any.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Assistance Program No. 93.778, Medical Assistance Program)

Dated: June 5, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: July 24, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–24281 Filed 9–12–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Uniform Data System (OMB No. 0915–0193)—Extension and Revision—This is a request for extension and revision of a reporting system, the Uniform Data System (UDS), that consolidated and replaced annual reporting requirements for the cluster of primary care grantees funded by the Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Outreach and Primary Health Services for Homeless Children and Public Housing Primary Care. Authorizing Legislation is found in Public Law 104–299, Health Center Consolidation Act of 1996, enacting Section 330 of the Public Health Service Act.

The Bureau of Primary Health Care collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policy makers on program accomplishments. To meet these objectives, BPHC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The UDS includes two components: the Universal Report, completed by all grantees, provides data on services, staffing, and financing; and the Grant Report, completed by grantees funded under the Homeless or Public Housing Program as well as one of the other programs, provides data on characteristics of users whose services fall within the scope of the Homeless or Public Housing Program grant. The first UDS reports were collected March 31, 1997 and analysis of data indicates that several revisions should be made. Program officials have noted that additional information needs to be collected which was included in previous reporting systems but was deleted from the UDS. Grantees will be asked to provide information on the charges, collections, bad debt write off and contractual disallowances by payor sources (Medicaid, Medicare, self pay and private insurance). Existing UDS forms are being reviewed to determine how the revenue/income reporting can be modified to accommodate these changes. Additional revisions will include annotating the forms to indicate which lines are subtotals and the lines to which they sum.

The proposed changes are not expected to add significantly to the reporting burden. Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Hours per response	Total burden hours
Universal Report	694	24	16,656
Grant Report	88	16	1,408

Type of report	Number of respondents	Hours per response	Total burden hours
Total	694		18,064

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this Notice.

Dated: September 5, 1997.

Jane Harrison,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. 97–24347 Filed 9–12–97; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Consensus Development Conference on Acupuncture

Notice is hereby given of the NIH Consensus Development Conference on ''Acupuncture,'' which will be held November 3–5, 1997, in the Natcher Conference Center of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:30 a.m. on November 3, at 8 a.m. on November 4, and at 9 a.m. on November 5.

Acupuncture and moxibustion are the two best known aspects of traditional Chinese medicine (TCM) in the U.S. and are used by many Americans. Acupuncture is a family of procedures involving penetration of specific superficial anatomic locations on the skin called acupuncture points with thin, solid, generally metallic, needles. Closely related to and often practices with acupuncture is moxibustion, the local and focused application of heat to acupuncture points using a compressed, powdered combustible substance (moxa), which is burned at or near the points to be stimulated.

There are a variety of approaches to functional diagnosis and treatment in American acupuncture that incorporate medical traditions from China, Japan, Korea, France, and other countries. Because an acupuncture treatment involves a procedure rather than a drug, it has been very difficult to study using the gold standard of randomized double-blind trials. Nevertheless, acupuncture is used by millions of American patients and performed by thousands of physicians, dentists, masters-degree level acupuncturists, and other practitioners for relief or prevention of pain and a variety of health problems. The FDA, after years of deliberation, recently removed acupuncture needles from the category of ''experimental medical devices'' and now regulates them just as it does other devices such as surgical scalpels and hypodermic syringes, under good manufacturing practices and single-use standards of sterility.

Over the years, NIH has funded a variety of research studies on acupuncture, including studies on the mechanisms by which acupuncture may have its effects as well as clinical trials and other studies. There is also a considerable body of international literature on the risks and benefits of acupuncture, and the World Health Organization (WHO) has listed a variety of medical conditions that may benefit from the use of acupuncture and/or moxibustion. Such applications may include prevention and treatment of nausea and vomiting; treatment of pain and addictions to alcohol, tobacco, and other drugs; prevention of pulmonary problems such as asthma and bronchitis and rehabilitation from neurological damage such as stroke.

To address the most important issues regarding the American use of acupuncture, the NIH has organized this 2½ day conference to evaluate the scientific and medical data on the uses, risks, and benefits of acupuncture procedures for a variety of conditions. The conference will bring together national and international experts in the fields of acupuncture, pain, psychology, psychiatry, physical medicine and rehabilitation, drug abuse, pulmonology, health policy, epidemiology, statistics, physiology, and biophysics as well as representatives from the public.

After 1½ days of presentations and audience discussion, an independent, non-Federal consensus panel chaired by Dr. David Ramsay, president of the University of Maryland Medical Center, will weigh the scientific evidence and write a draft statement that it will present to the audience on the third day. The consensus statement will address the following key questions:

* What is the efficacy of acupuncture, compared with placebo or sham acupuncture, in the conditions for which sufficient data are available to evaluate?

* What is the place of acupuncture in the treatment of various conditions (for which sufficient data are available), in comparison with or in combination with other interventions (including no intervention)?

* What is known about the biological effects of acupuncture that helps us understand how it works?

* What issues need to be addressed so that acupuncture may be appropriately incorporated into today's health care system?

* What are the directions for future research?

The primary sponsors of this meeting are the NIH Office of Alternative Medicine and the NIH Office of Medical Applications of Research. The conference is cosponsored by the National Cancer Institute, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Heart, Lung, and Blood Institute, the National Institute of Allergy and Infectious Diseases, the National Institute on Drug Abuse, and the NIH Office of Research on Women's Health.

Advance information on the conference program and conference registration materials may be obtained from Prospect Associates, 1801 Rockville Pike, Suite 500, Rockville, Maryland 20852, (301) 468–MEET, by e-mail at NIHconsensus@ProspectAssoc.com, or by visiting http://consensus.nih.gov on the World Wide Web.

The consensus statement will be submitted for publication in professional journals and other publications. In addition, the statement will be available beginning November 5, 1997, from the NIH Consensus Program Information Center, P.O. Box 2577, Kensington, Maryland 20891, phone 1–888–NIH–CONSENSUS (1–888–644–2667) and from the NIH Consensus Development Program site on the World Wide Web at http://consensus.nih.gov.

Dated: September 3, 1997.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 97–24274 Filed 9–12–97; 8:45 am]

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