DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FR Doc. 2012–D–0558]

Compliance Policy Guide Sec. 230.110—Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the compliance policy guide (CPG) entitled “Sec. 230.110 Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products (CPG 7134.01),” dated June 17, 1974.

DATES: The withdrawal is effective June 29, 2012.

FOR FURTHER INFORMATION CONTACT: Robert L. Hummel, Division of Compliance Policy (HFC–230), Food and Drug Administration, 12420 Parklawn Dr., ELEM–4152, Rockville, MD 20857, 301–796–4510.

SUPPLEMENTARY INFORMATION: FDA issued the CPG entitled “Sec. 230.110 Registration of Blood Banks, Other Firms Collecting, Manufacturing, Preparing, or Processing Human Blood or Blood Products (CPG 7134.01)” on June 17, 1974. We originally issued CPG 7134.01 entitled “Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products,” to provide FDA’s current thinking regarding the registration required by 21 CFR part 607 of blood banks and other establishments collecting, manufacturing, preparing, or processing human blood or blood products. Since the last update to CPG 7134.01 in 2000, the regulations for blood establishment registration under part 607 have been amended several times. FDA is withdrawing CPG 7134.01 because it is obsolete.


Dara Corrigan,
Associate Commissioner for Regulatory Affairs.

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professionals with a service obligation may enter into service agreements to serve only in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain residency training program grants administered by BHRP. Many other Federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare and Medicaid Services, certain qualified providers in HPSAs are eligible for increased levels of Medicare reimbursement.

Development of the Designation and Withdrawal Lists: Criteria for designating HPSAs were published as final regulations (42 CFR part 5) in 1980. Criteria then were defined for each of seven health professional types (primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care). The criteria for correctional facility HPSAs were revised and published on March 2, 1989, in Federal Register (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473).

Currently-funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

Individual requests for designation or withdrawal of a particular geographic area, population group, or a facility as a HPSA are received and reviewed continuously by BHRP. The majority of the requests come from the Primary Care Office (PCO) in the State Health Departments, who have access to the online and computerized review system. Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, applicants are expected to share copies of the requests with other interested parties, including the Governor, the State Primary Care Association and State professional associations for their comments and recommendations.

Annually, lists of designated HPSAs are made available to all PCOs, state medical and dental societies and others with a request to review and update the data on which the designations are based. Emphasis is placed on updating those designations that are more than three years old or where significant changes relevant to the designation criteria have occurred.

Recommendations for possible additions, continuations, revisions or withdrawals from a HPSA list are reviewed by BHRP, and the review findings are provided by letter to the agency or individual requesting action or withdrawal and/or copying to other interested organizations and individuals. These letters constitute the official notice of designation as a HPSA, rejection of recommendations for HPSA designation, revision of a HPSA designation, and/or advance notice of pending withdrawals from the HPSA list. Designations (or revisions of designations) are effective as of the date of the notification letter from BHRP.

Proposed withdrawals become effective only after interested parties in the area affected have been afforded the opportunity to submit additional information to BHRP in support of its continued or revised designation. If no new data are submitted, or if BHRP review confirms the proposed withdrawal, the withdrawal becomes effective upon publication of the lists of designated HPSAs in the Federal Register. In addition, lists of HPSAs are continuously available on the HRSA Web site, http://bhpr.hrsa.gov/shortage/index.html, so that interested parties can access the most accurate and timely information.

Publication and Format of Lists: Due to the large volume of designations, this notice serves to inform the public of the availability of the complete listings of the designated HPSAs on the HRSA Web site. The three lists of designated HPSAs are available at a link on the Office of Shortage Designation Web site at http://bhpr.hrsa.gov/shortage/index.html. Each list (primary medical care, mental health, and dental) includes all those geographic areas, population groups, and facilities that were designated HPSAs as of April 1, 2012. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the Federal Register on November 3, 2011 (76 FR 68198). The lists include those automatic facility HPSAs that have been entered into the HPSA database. Automatic facility HPSAs, designated as a result of the Health Care Safety Net Amendments of 2002 (Pub. L. 107–251), are not subject to the updating requirements. The lists are constantly changing based on the identification of new sites that meet the eligibility criteria or current sites that lose their eligibility and need to be removed. Each list of designated HPSAs (primary medical care, mental health, and dental) is arranged by state. Within each state, the list is presented by county. If only a portion (or portions) of a county is (are) designated, or if the county is part of a larger designated service area, or if a population group residing in the county or a facility located in the county has been designated, the name of the service area, population group, or facility involved is listed under the county name. Counties that have a whole county geographic HPSA are indicated by the “Entire county HPSA” notation following the county name. Further details for the HPSAs listed can be found on the HRSA Web site: http://bhpr.hrsa.gov/shortage/index.html.

In addition to the specific listings included in this notice, all Indian Tribes that meet the definition of such Tribes in the Indian Health Care Improvement Act of 1976, 25 U.S.C. 1603(d), are automatically designated as population groups with primary medical care and dental health professional shortages. The Health Care Safety Net Amendments of 2002 also made the following entities eligible for automatic facility HPSA designations: all federally qualified health centers (FQHCs) and rural health clinics that offer services regardless of ability to pay. These entities include: FQHCs funded under section 330 of the PHS Act, FQHC Look-Alikes, and Tribal and Urban Indian clinics operating under the Indian Self-Determination and Education Act of 1975 (25 U.S.C. 450) or the Indian Health Care Improvement Act. Many, but not all, of these entities are included on this listing. Exclusion from this list does not exclude them from the list of HPSAs; all will be included in the database as they are identified.

Future Updates of Lists of Designated HPSAs: The lists of HPSAs on the HRSA Web site below consist of all those that were designated as of April 1, 2012. It should be noted that additional HPSAs may have been designated by letter since that date. The appropriate agencies and individuals have been or will be notified of these actions by letter. Those newly designated HPSAs will be included in the next publication of the HPSA list and are currently included on the HRSA Web site at http://hpsafind.hrsa.gov/.

Any designated HPSA listed on the HRSA Web site below is subject to withdrawal from designation if new information received and confirmed by HRSA indicates that the relevant data for the area involved have significantly changed since its designation. The effective date of such a withdrawal will be the next publication of a notice regarding this list in the Federal Register.

All requests for new designations, updates, or withdrawals should be based on the relevant criteria in regulations published at 42 CFR part 5.

Electronic Access Address: The complete list of HPSAs designated as of April 1, 2012, are available on the HRSA Web site at http://bhpr.hrsa.gov/shortage/index.html. Frequently updated information on HPSAs is also...

Mary K. Wakefield,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Institute of Nursing Research (NINR) Summer Genetics Institute Alumni Survey

SUMMARY: In compliance with the requirement of Section 350(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Nursing Research (NINR), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB).

Proposed Collection: Title: NIH/National Institute of Nursing Research (NINR) Summer Genetics Institute Alumni Survey. Type of Information Collection Request: NEW. Need and Use of Information Collection: The NINR Summer Genetics Institute Alumni Survey will obtain information on the long-term outcomes of this training program for nurse scientists and faculty. Target participants are alumni of this training institute which began in 2000. The survey inquires about career activities, including research, clinical, teaching and educational activities, since completion of the NINR Summer Genetics Institute. This is a 39-item survey that takes an average of 30 minutes to complete. The findings will provide valuable information on the influence of the Institute in developing genetics research capability among Institute alumni, and development and expansion of clinical practice in genetics among alumni who are nurse clinicians. Frequency of Response: Annual for three (3) years. Affected Public: Individual alumni of the NINR Summer Genetics Institute. Type of Respondents: Nurse scientists, clinicians, and faculty. The annual reporting burden is as follows: Estimated Number of Respondents: 150; Estimated Number of Responses per Respondent: 1; Average Burden Hours per Response: 0.5; and Estimated Total Annual Burden Hours Requested: 75. There are no Capital Costs, Operating or Maintenance Costs to report.

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Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Amanda Greene, Science Evaluation Officer, Office of Science Policy and Public Liaison, NINR, Democracy One, 6701 Democracy Blvd., Suite 700, Bethesda, MD 20892, or call non-toll-free number 301–496–9601, or email your request to amanda.greene@nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: June 22, 2012.
Amanda Greene,
NINR Project Clearance Officer, Science Evaluation Officer, NINR, National Institutes of Health.

[FR Doc. 2012–16022 Filed 6–28–12; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Child Health Disparities Substudy for the National Children’s Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on March 16, 2012, pages 15780–15782 (Volume 77, Number 52) of the Federal Register and allowed 60 days for public comment. No written comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Child Health Disparities Substudy for the National Children’s Study (NCS). Type of Information Collection Request: NEW. Need and Use of Information Collection: The Children’s Health Act of 2000 (Pub. L. 106–310) states:

(a) PURPOSE.—It is the purpose of this section to authorize the National Institute of Child Health and Human Development* to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children’s health and development.

(b) IN GENERAL.—The Director of the National Institute of Child Health and Human Development* shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency) to—

(1) Plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

(2) Investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that