

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) added section 905 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 387e), establishing requirements for tobacco product establishment registration and product listing.

FDA revised the registration and listing guidance to include newly deemed tobacco products. Cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C Act, including section 905, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Pursuant to that authority, FDA issued a proposed rule seeking to deem all other products that meet the statutory definition of tobacco product, set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) (except for accessories of those products) (79 FR 23142). After review and consideration of comments on the proposed rule, FDA published the final rule on May 10, 2016 (81 FR 28974) (“the deeming rule”) and it will become effective on August 8, 2016. As a result, owners and operators of domestic establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products subject to the deeming rule are now required to comply with chapter IX of the FD&C Act, including the establishment registration and product listing requirements in section 905.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on registration and product listing for owners and operators of domestic tobacco product establishments. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The time required to complete this information collection is estimated to average 3.75 hours per response, including the time to review

instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to: Food and Drug Administration, Center for Tobacco Products, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910–0650 (expires June 30, 2019).

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either <http://www.regulations.gov> or <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: July 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Request for Nominations

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on the Council on Graduate Medical Education (COGME). COGME is authorized by Section 762 of the Public Health Service (PHS) Act (42 U.S.C. 294o), as amended. The Advisory Council is governed by the provisions of the Federal Advisory Act (FACA) (5 U.S.C. Appendix 2), as amended, which sets forth standards for the formation and use of advisory committees, and applies to the extent that the provisions of FACA do not conflict with the requirements of PHS Act Section 762.

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: All nominations should be submitted to Advisory Council Operations, Bureau of Health Workforce, HRSA, 11W45C, 5600

Fishers Lane, Rockville, Maryland 20857. Mail delivery should be addressed to Advisory Council Operations, Bureau of Health Workforce, HRSA, at the above address, or via email to: BHWAdvisoryCouncilFRN@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Joan Weiss, Ph.D., RN, CRNP, FAAN, Designated Federal Official, COGME at 301–443–0430 or email at jweiss@hrsa.gov. A copy of the current committee membership, charter, and reports can be obtained by accessing the Web site <http://www.hrsa.gov/advisorycommittees/bhpradvisory/COGME/index.html>.

SUPPLEMENTARY INFORMATION: COGME provides advice and makes policy recommendations to the Secretary of the U.S. Department of Health and Human Services (Secretary) and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the U.S. House of Representatives Committee on Energy and Commerce on matters concerning the supply and distribution of physicians in the United States, physician workforce trends, training issues, and financing policies. Meetings are held twice a year.

Specifically, HRSA is requesting nominations for voting members of COGME representing: Practicing primary care physicians, national and specialty physician organizations, foreign medical graduates, medical student and house staff associations, as well as representatives of schools of medicine, schools of osteopathic medicine, public and private teaching hospitals, health insurers, business, and labor. Among these nominations, medical students, residents, and/or fellows from these programs are encouraged to apply.

The Department of Health and Human Services (HHS) will consider nominations of all qualified individuals with the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership. Nominations shall state that the nominee is willing to serve as a member of COGME and appears to have no conflict of interest that would preclude COGME membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of COGME to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee:

(1) A letter of nomination from an employer, a colleague, or a professional organization stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of the COGME, and the nominee's field(s) of expertise);

(2) A letter of self-interest stating the reasons the nominee would like to serve on COGME;

(3) A biographical sketch of the nominee and a copy of his/her curriculum vitae; and

(4) The name, address, daytime telephone number, and email address at which the nominator can be contacted.

Nominations will be considered as vacancies occur on COGME.

Nominations should be updated and resubmitted every 3 years to continue to be considered for committee vacancies.

HHS strives to ensure that the membership of HHS federal advisory committees is balanced in terms of points of view represented and the committee's function. The Department encourages nominations of qualified candidates from all groups and locations. Appointment to COGME shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016-16751 Filed 7-14-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Availability of the Department of Health and Human Services FY 2015 Service Contract Inventory

AGENCY: Department of Health and Human Services.

ACTION: Notice of public availability of FY 2015 Service Contract Inventories.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111-117), Department of Health and Human Services (HHS) is publishing this notice to advise the public of the availability of its FY 2015 Service Contract Inventory. This inventory provides information on service contract actions over \$25,000 that was awarded in FY 2015. The information is

organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 and December 19, 2011 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at <http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf>. HHS has posted its inventory and a summary of the inventory on the HHS homepage at the following link: <http://www.hhs.gov/grants/contracts/get-ready-to-do-business/service-contract-inventory/index.html>.

FOR FURTHER INFORMATION CONTACT:

Questions regarding the service contract inventory should be directed to Dr. Angela Billups, Associate Deputy Assistant Secretary for Acquisition, Senior Procurement Executive HHS/Office of the Secretary, Assistant Secretary for Financial Resources at 202-260-6187 or Angela.Billups@hhs.gov.

Angela Billups,

Associate Deputy Assistant Secretary for Acquisition, Senior Procurement Executive, Assistant Secretary for Financial Resources, Office of the Secretary.

[FR Doc. 2016-16802 Filed 7-14-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education, Policy/Budget/Diabetes

Announcement Type: Limited New and Competing Continuation.

Funding Announcement Number: HHS-2016-IHS-NIHOE-1-PBD-0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: August 15, 2016.

Review Date: August 22, 2016.

Earliest Anticipated Start Date: September 15, 2016.

Proof of Non-Profit Status Due Date: August 15, 2016.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative

agreement applications for the National Indian Health Outreach and Education, Policy/Budget/Diabetes (NIHOE-I) limited competition cooperative agreement program. This award includes the following four components, as described in this announcement: "Line Item 128 Health Education and Outreach funds," "Health Care Policy Analysis and Review," "Budget Formulation," and "Tribal Leaders Diabetes Committee" (TLDC). This program is authorized under the Snyder Act, codified at 25 U.S.C. 13. The TLDC component is authorized by section 330C of the Public Health Service Act, codified at 42 U.S.C. 254c-3. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The NIHOE-I program carries out health program objectives in American Indian and Alaska Native (AI/AN) communities in the interest of improving Indian health care for all 567 Federally-recognized Tribes, including Tribal governments operating their own health care delivery systems through self-determination contracts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health program issues and disseminates educational information to all AI/AN Tribes and villages. This program requires that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. This program also requires that regional and national meetings be coordinated for information dissemination as well as the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS based on Tribal input through a broad based consumer network.

Purpose

The purpose of this IHS cooperative agreement is to further IHS's mission and goals related to providing quality health care to the AI/AN community through outreach and education efforts with the sole outcome of improving Indian health care. This award includes the following four health services components: Line Item 128 Health Education and Outreach funds, Health Care Policy Analysis and Review, Budget Formulation, and TLDC.

Limited Competition Justification

Competition for the award included in this announcement is limited to