of clinical trials. The course will cover a wide variety of key topics, including material on novel safety concerns, adverse event monitoring, compliance with the legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in the design and conduct of clinical studies. The faculty will include a diverse representation of senior FDA staff, enabling FDA to communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

**II. Description of the Training Course**

*A. Purpose*

The training course is designed to provide clinical investigators with an overview of the following information:

- The essential toxicological, pharmacological, and manufacturing data to support investigational use in humans;
- Fundamental issues in the design and conduct of clinical trials;
- Statistical and analytic considerations in the interpretation of trial data;
- Appropriate safety evaluation during studies; and
- The ethical considerations and regulatory requirements for clinical trials.

In addition, the course should accomplish the following:

- Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;
- Promote communication between clinical investigators and FDA;
- Enhance investigators' understanding of FDA's role in experimental medicine; and
- Improve the quality of data while enhancing subject protection in the performance of clinical trials.

*B. Proposed Agenda*

The course will be conducted over 3 days and comprised of approximately 26 lectures, each lasting between 30 and 45 minutes. The course will be presented mainly by senior FDA staff, with guest lecturers presenting selected topics.

The course will address FDA's role in clinical studies, regulatory considerations for clinical trials, and review of the material generally appearing in an ''investigator's brochure,'' i.e., the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presenters will discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. The course will also include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 14, 2013, participants will choose among three breakout sessions that will explain how to put together an application to FDA for drugs, biologics, or devices.

*C. Target Audience*

The course is targeted toward health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Dated: October 21, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–25127 Filed 10–24–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0001]**

### Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Tobacco Products Scientific Advisory Committee

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting that industry organizations interested in participating in the selection of a nonvoting industry representative to represent the interests of the tobacco manufacturing industry on the Tobacco Products Scientific Advisory Committee for the Center for Tobacco Products, notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for upcoming vacancy effective with this notice. Elsewhere in this issue of the **Federal Register**, FDA is publishing a separate document announcing the Request for Notification for Voting Members on the Tobacco Products Scientific Advisory Committee.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent the interests of the tobacco manufacturing industry must send a letter stating the interest to FDA by November 25, 2013, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by November 25, 2013.

**ADDRESSES:** All letters of interest and nominations should be submitted in writing to *TPSAC@fda.hhs.gov,* or by mail to Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

**FOR FURTHER INFORMATION CONTACT:** Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850,1–877–287–1373 (choose Option 5), FAX: 240–276–3655, email: *TPSAC@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The Agency requests nominations for a nonvoting industry representative on the Tobacco Products Scientific Advisory Committee to represent the interests of the tobacco manufacturing industry.

**I. Tobacco Products Scientific Advisory Committee**

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner of Food and Drugs.

The Committee includes three nonvoting members who represent industry interests. These members include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. The representative of the interests of the small business tobacco manufacturing industry may be filled on a rotating basis by representatives of different small business tobacco manufacturers based on areas of expertise relevant to the topics being considered by the Committee.

With this notice, nominations are sought for one representative of the interests of the tobacco manufacturing industry, and an alternate to this representative.

**II. Selection Procedure**

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days of the receipt of the FDA letter, to serve as the nonvoting member to represent the tobacco manufacturing industry for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

**III. Application Procedure**

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and therefore, encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the tobacco manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 21, 2013.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2013–25188 Filed 10–24–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### HIV/AIDS Bureau; Ryan White HIV/AIDS Program Core Medical Services Waiver; Application Requirements

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Final notice.

**SUMMARY:** Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White Program or RWHAP), requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS identified and eligible under the statute. The statute also grants the Secretary authority to waive this requirement if there are no waiting lists for the AIDS Drug Assistance Program (ADAP) and core medical services are available to all individuals identified and eligible under Title XXVI in an applicant's state, jurisdiction, or service area, as applicable.

The requirements for submitting an application to waive the statutory requirement that a grantee spend at least 75 percent of its funds on core medical were previously outlined in HIV/AIDS Bureau (HAB) Policy Notice 08–02. On May 24, 2013, the Health Resources and Services Administration (HRSA) published a Final Notice with Opportunity to Comment in the **Federal Register**, revising HAB Policy Notice 08–02, and requesting public comment on this revised policy. This **Federal Register** notice seeks to address comments made by the public and to implement this policy as originally written.

**DATES:** The policy will become effective on September 23, 2013.

**SUPPLEMENTARY INFORMATION:** HRSA received several comments on the waiver application process published in the **Federal Register**. Overall, the comments were supportive of the revised requirements. Commenters indicated that the revised application process will provide grantees with the flexibility to adjust resource allocation based on the current situation in their local environment.

Several commenters suggested that the application process and the documentation required to apply for a waiver was burdensome, especially for grantees with limited administrative staff to respond to the waiver requirements. HRSA believes that the application process and the documentation required are necessary for the agency to understand the availability of core medical services in the applicant's state, jurisdiction, or service area, as applicable. This required documentation is intended to provide HRSA with sufficient information to make an informed decision on each waiver request and to understand the availability of core medical services in a grantee's state, jurisdiction, or service area, as applicable. Further, the requirements are similar to those under the previous policy. Waiver applicants under the previous policy were expected to provide adequate documentation, which may have included additional data, supporting letters, and other information that justified the need for the waiver. As such, HRSA is only clarifying what documentation is necessary to meet each requirement in the application. This will ensure that the applicant provides adequate documentation to demonstrate the need for a waiver of the core medical services requirement

Under the previous policy, letters from Medicaid directors and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers, were optional. Under this revision, item #2(c) of the policy now requires the submission of documentation regarding the availability of relevant services, and lists examples of the types of programs that may provide documentation, including private insurers. Specific to this requirement, several commenters suggested that letters from private insurers would be burdensome to provide. HRSA wishes to clarify that letters from private insurers are not required; these entities are only listed to provide an example of a type of entitlement and benefit provider. Other types of entitlement and benefit providers might include local foundations that provide funding for medical care to low-income HIV patients or a county or state sponsored drug-assistance program. As part of their application, grantees must provide letters from the state Medicaid Director and relevant HIV/AIDS entitlement and benefits programs available in their state, jurisdiction, or service area, as