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

applicable, to document the availability and accessibility of core medical services.

Several commenters pointed out that it would be burdensome for grantees to conduct a separate public process around the annual waiver application. HRSA wishes to clarify that while a grantee may conduct a separate public process around the waiver application, they are not required to do so. Grantees must seek feedback on their waiver application from the public, but may do so through any public process that the grantee already uses, including those that are used to obtain input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, Statewide Coordinated Statement of Need, public planning, and/or needs assessment process. This requirement has not changed from the previous policy.

Another commenter requested that HRSA not include the waiver attachments and documentation requirements as part of the application's 10-page limit listed in requirement #4. HRSA wishes to clarify that the page limit only applies to the narrative section described in requirement #4. The documentation required by the other sections does not count towards the page limit outlined in the policy.

Another commenter mentioned concern regarding ''outreach and linkage of HIV-positive individuals not currently in care'' being considered a non-core service in the requirement #4(c) of the policy. The commenter indicated that outreach and linkage to care fell under early intervention services, and as such should not be considered a non-core service. HRSA wishes to clarify that section #4(c) of the policy is specifically referring to outreach and linkage to care as a support service, not early intervention services, which, as the commenter mentioned, are core medical services. In 42 U.S.C. 300ff–14(d)(1), 300ff–22(c)(1), 300ff–51(d)(1), outreach services are identified as support services. In addition, HAB policy 12–01 identifies outreach services as a service ''which has as their principal purpose targeting activities, under specific needs assessment-based service categories that can identify individuals with HIV disease. This includes those who know their HIV status and are not in care as well as those individuals who are unaware of their HIV status, so that they become aware of the availability of HIV-related services and enroll in primary care, AIDS Drug Assistance Programs, and support services that enable them to remain in care.''

Another commenter suggested that the requirement that all core services be available within 30 days is not reasonable. Access to routine medical and preventive care services within 30 days has been cited as an example of a reasonable availability standard for Medicare Coordinated Care Plans by the Department of Health and Human Services/Centers for Medicare and Medicaid Services (See Medicare Managed Care Manual, Chapter 4 Benefits and Beneficiary Protections, section 110.1 Access and Availability Rules for Coordinated Care Plans at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf.*). In addition, the RWHAP legislation specifies that core medical services must be ''available.'' This requirement has not changed from previous versions of this policy. Therefore, HRSA will maintain the requirement that all core medical services are available to individuals identified in the service area within 30 days, as this requirement serves as a benchmark for the availability of core medical services.

Other commenters suggested that the application acceptance timeframe be changed to a rolling basis, rather than requiring that waiver applications be submitted before, during, or after application deadlines, or that waiver applications be preapproved, with complete documentation submitted only when the grantee invokes the waiver. While HRSA agrees that these methods may be more straightforward, the current process and timelines used to manage and monitor grant applications makes either of these processes not feasible for HRSA.

This Final Notice reaffirms HRSA's position that these revisions to HAB Policy Notice 08–02 are intended to clarify the waiver process and respond to the changing needs of the grantee community, while at the same time ensuring that the waiver process is fair and sufficiently robust so that HRSA is able to undertake appropriate review. The policy will remain in effect, as originally published, and will be identified as HAB Policy Notice 13–07.

Policy

Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Parts, A, B, and C

POLICY NUMBER 13–07 (Replaces Policy Notice 08–02).

Scope of Policy

Ryan White Parts A, B, C.

Summary and Purpose of Policy

The purpose of this policy is to outline the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) requirements for applying for a waiver of the requirement that 75 percent of Ryan White HIV/AIDS program funds be spent on core medical services.

Background

Title XXVI of the Public Health Service Act, Part A section 2604(c), Part B section 2612(b), and Part C section 2651(c) requires that grantees expend not less than 75 percent of their grant funds on core medical services. These sections also grant 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 service area.

Policy

Grantees may submit a waiver request at any time prior to submission of the annual grant application, along with the annual grant application, or up to 4 months after the start of the grant year for which a waiver is being requested. Applications submitted before or after an annual grant application have different requirements than those submitted with an annual grant application. Applicants should choose the method that best meets their needs. The requirements for each process are outlined below.

Requirements To Apply for a Waiver Before or After an Annual Grant Application

This section outlines the requirements to submit a waiver application: (1) In advance of a grantee's annual grant application or (2) after the grant application has been submitted up to 4 months into the grant year for which a waiver is being requested. Waiver requests must be submitted through the EHB *Prior Approval* portal and must identify the grant year for which the waiver is being requested. The waiver request must be signed by the chief elected official or the Project Director, and include the following documentation that will be utilized by HRSA in determining whether to grant the waiver:

1. Letter signed by the Director of the Part B State/Territory Grantee indicating that there is no current or anticipated ADAP services waiting list in the State/Territory.

2. Evidence that all core medical services listed in the statute (Part A

section 2604(c)(3), Part B section 2612(b)(3), and Part C section 2651(c)(3)), regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available and accessible within 30 days for all identified and eligible individuals with HIV/AIDS in the service area, without need to expend at least 75 percent of Ryan White funds on these services. Acceptable evidence must include all of the following:

a. HIV/AIDS care and treatment services inventories, including identification of the specific core medical services available, from whom, and through what funding source;

b. HIV/AIDS client/patient service utilization data in addition to what has previously been submitted via the Ryan White Services Report (RSR); and

c. Letters from Medicaid and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers.

3. Evidence of a public process, which documents that the applicant has sought input from affected communities; including consumers and the Ryan White HIV/AIDS Program-funded core medical services providers, related to the availability of core medical services and the decision to request a waiver. This public process may be the same one that is utilized for obtaining input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, Statewide Coordinated Statement of Need (SCSN), public planning, and/or needs assessment process. Acceptable evidence must, at a minimum, include:

a. Letters from both the Planning Council Chair in the Metropolitan area (if grantee serves such area) and the State HIV/AIDS Director describing the public process that occurred in each jurisdiction.

4. A narrative of up to, but no more than, 10 pages that explains each item in a. through d. below:

a. Any underlying State or local issues that influenced the grantee's decision to request a waiver.

b. How the documentation submitted under item two supports the assertion that such core services are available and accessible to all individuals with HIV/AIDS, identified and eligible under Title XXVI in the service area.

c. How the approval of a waiver will positively contribute to the grantee's ability to address service needs for HIV/AIDS non-core services. Specifically address the grantee's ability to perform outreach and linkage of HIV-positive individuals not currently in care.

d. How the receipt of the core medical services waiver will allow for implementation consistent with the applicant's proposed percentage allocation of resources, comprehensive plan, and SCSN. Applicants must also document consistency by providing a proposed allocation table.

Waiver Review and Notification Process

HRSA/HAB will review the request and notify grantees of waiver approval or denial within eight weeks of receipt of the request. Core medical services waivers will be effective for the grant award period for which it is approved. Subsequent grant periods will require a new waiver request. Grantees that are approved for a core medical services waiver in advance of their annual grant application are not compelled to utilize the waiver should circumstances change.

Requirements To Apply for a Waiver With the Annual Grant Application

This section provides guidance for grantees who wish to submit a waiver request with their annual grant application. Waiver requests must be submitted as an attachment to the grantee's annual grant application and should *not* be submitted through the EHB *Prior Approval* portal. The waiver request must be signed by the chief elected official or the Project Director, and include the following documentation that will be utilized by HRSA in determining whether to grant the waiver:

1. Letter signed by the Director of the Part B State/Territory Grantee indicating that there is no current or anticipated ADAP services waiting list in the State/Territory.

2. Evidence that all core medical services listed in the statute (Part A section 2604(c)(3), Part B section 2612(b)(3), and Part C section 2651(c)(3)), regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available and accessible within 30 days for all identified and eligible individuals with HIV/AIDS in the service area, without need to expend at least 75 percent of Ryan White funds on these services. Acceptable evidence must include all of the following:

a. HIV/AIDS care and treatment services inventories, including identification of the specific core medical services available, from whom, and through what funding source;

b. HIV/AIDS client/patient service utilization data in addition to what has previously been submitted via the Ryan White Services Report (RSR); and

c. Letters from Medicaid and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers.

3. Evidence of a public process, which documents that the applicant has sought input from affected communities; including consumers and the Ryan White HIV/AIDS Program-funded core medical services providers, related to the availability of core medical services and the decision to request a waiver. This public process may be the same one that is utilized for obtaining input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, Statewide Coordinated Statement of Need (SCSN), public planning, and/or needs assessment process. Acceptable evidence must, at a minimum, include:

a. Letters from both the Planning Council Chair in the Metropolitan area (if grantee serves such area) and the State HIV/AIDS Director describing the public process that occurred in each jurisdiction.

4. A narrative of up to, but no more than, 10 pages that explains each item in a. through d. below:

a. Any underlying State or local issues that influenced the grantee's decision to request a waiver.

b. How the documentation submitted under item two supports the assertion that such core services are available and accessible to all individuals with HIV/AIDS, identified and eligible under Title XXVI in the service area.

c. How the approval of a waiver will positively contribute to the grantee's ability to address service needs for HIV/AIDS non-core services. Specifically address the grantee's ability to perform outreach and linkage of HIV-positive individuals not currently in care.

d. How the receipt of the core medical services waiver is consistent with the applicant's grant application, comprehensive plan, and SCSN. Applicants must also document consistency by providing the following:

i. Proposed allocation table, if not included as part of the grant application;

AND

ii. (PART A) ''Description of Priority Setting and Resource Allocation Processes'' and ''Unmet Need Estimate and Assessment'' sections of the current grant application;

OR

iii. (PART B) ''Needs Assessment and Unmet Need'' section of the current grant application;

OR

iv. (PART C) ''Description of the Local HIV Service Delivery System'' and ''Current and Projected Sources of Funding'' sections of the current grant application.

Waiver Review and Notification Process

HRSA/HAB will review the request and notify grantees of waiver approval or denial no later than the date of issuance of the Notice of Award (NoA). Core medical services waivers will be effective for the grant award period for which it is approved. Subsequent grant periods will require a new waiver request. Grantees that are approved for a core medical services waiver in their annual grant application are not compelled to utilize the waiver should circumstances change.

The Paperwork Reduction Act of 1995

This activity has been reviewed and approved by the Office of Management and Budget, under the Paperwork Reduction Act of 1995 (Control number 0915–0307).

Dated: October 18, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–25276 Filed 10–24–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

''Low-Income Levels'' Used for Various Health Professions and Nursing Programs

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is updating income levels used to identify a ''low-income family'' for the purpose of determining eligibility for programs that provide health professions and nursing training for individuals from disadvantaged backgrounds. These various programs are included in Titles III, VII, and VIII of the Public Health Service Act.

The Department periodically publishes in the **Federal Register** low-income levels used to determine eligibility for grants and cooperative agreements to institutions providing training for (1) disadvantaged individuals, (2) individuals from disadvantaged backgrounds, or (3) individuals from low-income families.

SUPPLEMENTARY INFORMATION: The various health professions and nursing grant and cooperative agreement programs that use the low-income levels to determine whether an individual is from an economically disadvantaged background in making eligibility and funding determinations generally make awards to: Accredited schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, nursing, chiropractic, public or private nonprofit schools which offer graduate programs in behavioral health and mental health practice, and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

The Secretary defines a ''low-income family/household'' for programs included in Titles III, VII, and VIII of the Public Health Service Act as having an annual income that does not exceed 200 percent of the Department's poverty guidelines. A family is a group of two or more individuals related by birth, marriage, or adoption who live together. On June 26, 2013, in U.S. v. Windsor, the Supreme Court held that section 3 of the Defense of Marriage Act, which prohibited federal recognition of same-sex spouses and same-sex marriages, was unconstitutional. In light of this decision, please note that same-sex marriages and same-sex spouses will be recognized on equal terms with opposite-sex spouses and opposite-sex marriages, regardless of where the couple resides. A ''household'' may be only one person. Most HRSA programs use the income of the student's parents to compute low-income status. Other programs, depending upon the legislative intent of the program, the programmatic purpose related to income level, as well as the age and circumstances of the participant, will apply these low income standards to the individual student to determine eligibility, as long as he or she is not listed as a dependent on his or her parents' tax form. Each program will announce the rationale and choice of methodology for determining low-income levels in their program guidance. The Department's poverty guidelines are based on poverty thresholds published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index.

The Secretary annually adjusts the low-income levels based on the Department's poverty guidelines and makes them available to persons responsible for administering the applicable programs. The income figures below have been updated to reflect increases in the Consumer Price Index through December 31, 2012.

2013 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Size of parents' family *	Income level **
1	$22,980
2	31,020
3	39,060
4	47,100
5	55,140
6	63,180
7	71,220
8	79,260

For families with more than 8 persons, add $8,040 for each additional person.

2013 POVERTY GUIDELINES FOR ALASKA

Size of parents' family*	Income level**
1	$28,700
2	38,760
3	48,820
4	58,880
5	68,940
6	79,000
7	89,060
8	99,120

For families with more than 8 persons, add $10,060 for each additional person.

2013 POVERTY GUIDELINES FOR HAWAII

Size of parents' family *	Income level **
1	$26,460
2	35,700
3	44,940
4	54,180
5	63,420
6	72,660
7	81,900
8	91,140

For families with more than 8 persons, add $9,240 for each additional person.

* Includes only dependents listed on federal income tax forms. Some programs will use the student's family rather than his or her parents' family.

** Adjusted gross income for calendar year 2012.

Separate poverty guidelines figures for Alaska and Hawaii reflect Office of Economic Opportunity administrative practice beginning in the 1966–1970 period. (Note that the Census Bureau poverty thresholds—the version of the poverty measure used for statistical purposes—have never had separate figures for Alaska and Hawaii). The poverty guidelines are not defined for Puerto Rico or other outlying jurisdictions. Puerto Rico or other outlying jurisdictions shall use income guidelines for the 48 contiguous states and the District of Columbia.