pharmacology reviews of pediatric studies conducted for ABILIFY (aripiprazole), ANDROGEL (testosterone), and DIOVAN (valsartan). The summaries are being made available consistent with section 9 of the 2002 BPCA (Public Law 107–109). Enacted on January 4, 2002, the 2002 BPCA reauthorized, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the 2002 BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the 2002 BPCA, the 2002 BPCA required FDA to make available to the public, including by publication in the **Federal Register**, a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement within 180 days of study submission to FDA (21 U.S.C. 355a(j)(1)).

The pediatric exclusivity program described in section 505A of the act again was reauthorized on September 27, 2007, in title V of the Food and Drug Administration Amendments Act (FDAAA) (Public Law 110–85). FDAAA revised the public dissemination provision previously found in 21 U.S.C. 355a(j)(1). As revised, not later than 210 days after the date of submission of a report on a pediatric study conducted under the pediatric exclusivity program, FDA must make available to the public the medical, statistical, and clinical pharmacology reviews of the pediatric studies (21 U.S.C. 355a(k)(1)). Under FDAAA, publication in the **Federal Register** is no longer required. FDA currently posts these reviews on the Internet at *http://www.fda.gov/cder/pediatric/BpcaPrea_full_review.htm*.

The three sets of summaries being announced in this issue of the **Federal Register** are the last summaries of reviews of supplements subject to the 2002 BPCA dissemination provision. Because publication in the **Federal Register** is no longer required, this will be the last notice announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted under the pediatric exclusivity program. FDA has posted on the Internet at *http://www.fda.gov/cder/pediatric/index.htm* summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for ABILIFY (aripiprazole), ANDROGEL (testosterone), and DIOVAN (valsartan). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/pediatric/index.htm*.

Dated: June 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–13099 Filed 6–10–08; 8:45 am]

BILLING CODE 4160–01–S

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: The Health Resources and Services Administration (HRSA) is amending the uniform waiver standards for Ryan White HIV/AIDS Program grantees requesting a core medical services waiver for fiscal year (FY) 2009 and beyond. Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Ryan White HIV/AIDS Program), 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 legislation. HRSA has issued waiver standards for grantees under Parts A, B, and C of Title XXVI of the PHS Act. This **Federal Register** notice seeks to make public the final notice of Uniform Standard for Waiver of Core Medical Services Requirements for Grantees Under Parts A, B, and C effective FY 2009.

SUPPLEMENTARY INFORMATION: The Ryan White HIV/AIDS Program imposes two criteria for waiver eligibility: (1) no waiting lists for AIDS Drug Assistance Program (ADAP) services; and (2) core medical services availability within the relevant service area to all individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act. (See sections 2604(c)(2), 2612(b)(2), and 2651(c)(2) of the PHS Act.) HRSA's HIV/AIDS Bureau issued interim waiver eligibility guidance for FY 2007 to provide immediate implementation of these waiver provisions. The final Uniform Standard for Waiver of Core Medical Services Requirements for Grantees Under Parts A, B, and C reflects modifications based on public comment received in response to the guidance published in the **Federal Register** on November 27, 2007. During the 30-day comment period ending December 26, 2007, HAB received comments from the public.

Beginning in FY 2009, HRSA will utilize new standards for granting waivers of the core medical services requirement for Ryan White HIV/AIDS Program grantees. These standards meet the intent of the Ryan White HIV/AIDS Treatment Modernization Act of 2006 to increase access to core medical services, including antiretroviral drugs, for persons with HIV/AIDS and to ensure that grantees receiving waivers demonstrate the availability of such services for individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act. The purposes of this notice are: (1) To establish a uniform standard for core medical services waiver eligibility for grantees under Parts A, B, and C of Title XXVI of the PHS Act; and (2) to establish a process for waiver request submission, review and notification. The core medical services waiver uniform standard and waiver request process in this notice apply to Ryan White HIV/AIDS Program grant awards under Parts A, B, and C of Title XXVI of the PHS Act effective for the FY 2009 grant year.

Comments on the Proposed Uniform Standard for Waiver of Core Medical Services Requirements for Grantees Under Parts A, B, and C

There were several public comments in strong support of the draft policy stating that the proposed changes allow more funds to be allocated to life-saving core medical services, including medications. The following suggestions and concerns were the main issues raised in the public comments.

Issue (1): Types of Documentation and Evidence Required as Part of the Waiver Request.

(Comment) Submission of documentation letters from private payers should be optional, not required.

(Response) HRSA concurs with the suggestion and changed the sentence regarding private insurers to ''letters from Medicaid and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers''.

(Comment) Requiring submission of data demonstrating that services are ''being utilized'' is unreasonable and falls outside the provisions of the statute.

(Response) HRSA concurs with the comment. As amended, the standard requires grantees to provide specific verifiable evidence that all listed core medical services are available and *accessible* to meet the needs of persons with HIV/AIDS who are identified and eligible for Ryan White HIV/AIDS Program services without further infusion of Ryan White HIV/AIDS Program dollars.

(Comment) ''Verifiable evidence'' that core services are available and accessible is not replicable across jurisdictions and would not result in ''uniform waiver standards''.

(Response) HRSA does not concur with the comment. The core medical services waiver standards do not require that methods of providing ''verifiable evidence'' of service availability and accessibility be replicable across jurisdictions. When submitting a waiver request, each jurisdiction must submit clear and concise verifiable documentation as to the availability and accessibility of all core medical services in their service area. Each waiver request will be reviewed and assessed individually on its merits.

(Comment) There is no basis for the proposed standard that all core medical services must be available within 30 days.

(Response) The Ryan White HIV/AIDS Program legislation specifies that core medical services must be ''available.'' 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 (HHS/CMS). (See Medicare Managed Care Manual, Chapter 4 Benefits and Beneficiary Protections, section 120.2 Access and Availability Rules for Coordinated Care Plans at *http://www.cms.hhs.gov/manuals/downloads/mc86c04.pdf*.) 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.

Issue (2): Core Medical Services Waiver Requests Submitted as Part of the Annual Grant Application

(Comment) Core medical services waiver requests should be allowed to be submitted after awards are received, to better respond to fluctuations in funding.

(Response) HRSA does not agree with the recommendation to submit waiver requests after receipt of a Notice of Grant Awards (NGA). By law, the waiver will be granted at the time the award is made (See sections 2604(c)(2)(B), 2612(b)(2)(B), and 2651(c)(2)(B) of the PHS Act.)

Issue (3): Requests for Obtaining a Core Medical Services Waiver Need to be Strengthened to Require More Stringent Documentation Than That Proposed

(Comment) Requests for obtaining a core medical service waiver should include assurances that core services are available and accessible to those most in need. Documentation should include information about average waiting times for first appointments, average travel time to service locations as well as cost-sharing or service limits related to core services. Grantees should be required to identify all eligible people including those not yet diagnosed.

(Response) HRSA acknowledges the commenter's emphasis on the importance of access to services and follow-up, however, disagrees with the suggestion for additional documentation as this would be overly burdensome to grantees seeking core medical service waivers. Furthermore, the documentation imposed by this final notice is sufficiently detailed for HRSA to approve or deny core medical services waiver requests.

(Comment) Require that Ryan White HIV/AIDS Program-funded core medical services providers be included in the public process.

(Response) HRSA concurs. Grantees will be required to provide evidence of a public process for the dissemination of information and must document that they have sought input from affected communities, including Ryan White HIV/AIDS Program-funded core medical services providers.

(Comment) Public input should be independent of routine community planning.

(Response) HRSA does not concur. Requiring a public input process independent of routine community planning would be burdensome given Ryan White HIV/AIDS Program administrative cost caps.

(Comment) Require documentation demonstrating that grantees applying for waivers have made reasonable efforts to identify all eligible persons including those not yet diagnosed and link them to care. This should include using at least 25 percent of Ryan White HIV/AIDS Program funding on outreach and testing.

(Response) HRSA agrees with the commenter's emphasis on the importance of ensuring that all cases of HIV and AIDS are identified and brought into care, but disagrees with the proposal. HRSA urges all of the Ryan White HIV/AIDS Program grantees to utilize available outreach funding, including those available from the Centers for Disease Control and Prevention, to identify HIV-positive individuals and provide linkages to HIV care and treatment.

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

Grantees must submit a waiver request with the annual grant application containing the following certifications and documentation which will be utilized by HRSA in determining whether to grant a waiver. The waiver must be signed by the chief elected official or the fiscally responsible agent, and include:

1. Certification from the Part B State grantee that there are no current or anticipated ADAP services waiting lists in the State for the year in which such waiver request is made. This certification must also specify that there are no waiting lists for a particular core class of antiretroviral therapeutics established by the Secretary, *e.g.*, fusion inhibitors;

2. Certification 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 within 30 days for all identified and eligible individuals with HIV/AIDS in the service area;

3. Evidence that a public process was conducted to seek public input on availability of core medical services;

4. Evidence that receipt of the core medical services waiver is consistent with the grantee's Ryan White HIV/AIDS Program application (*e.g.*, ''Description of Priority Setting and Resource Allocation Processes'' and ''Unmet Need Estimate and Assessment'' sections of the application for Parts A, ''Needs Assessment and Unmet Need'' section of the application under Part B, and ''Description of the Local HIV Service Delivery System,'' and ''Current and Projected Sources of Funding'' sections of the application under Part C).

Types of Documentation and Evidence

Grantees must provide evidence that all of the core medical services listed in the statute, regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available to all individuals with HIV/AIDS identified and eligible under Title XXVI of the PHS Act in the service area within 30 days. Such documentation may include one or more of the following types of information for the service area for the prior fiscal year: HIV/AIDS care and treatment services inventories including funding sources, HIV/AIDS met and unmet need assessments, HIV/AIDS client/patient service utilization data, planning council core medical services priority setting and funding allocations documents, and letters from Medicaid and other State and local HIV/AIDS entitlement and benefits programs, which may include private insurers. Information provided by grantees must show specific verifiable evidence that all listed core medical services are available and accessible to meet the needs of persons with HIV/AIDS who are identified and eligible for Ryan White HIV/AIDS Program services without further infusion of Ryan White HIV/AIDS Program dollars. Such documentation must also describe which specific core medical services are available, from whom, and through what funding source.

Grantees must have evidence of a public process for the dissemination of information and must document that they have sought input from affected communities, including 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 utilized for obtaining input on community needs as part of the comprehensive planning process. In addition, grantees must describe in narrative form the following:

1. Local/State underlying issues that influenced the grantee's decision to request a waiver and how the submitted documentation supports the assertion that such services are available and accessible to all individuals with HIV/AIDS identified and eligible under Title XXVI in the service area.

2. How the approval of a waiver will impact the grantee's ability to address unmet need for HIV/AIDS services and perform outreach to HIV-positive individuals not currently in care.

3. The consistency of the waiver request with the grantee's grant application, including proposed service priorities and funding allocations.

Waiver Review and Notification Process

As indicated, grantees must submit a waiver request with their annual grant application. No waiver requests will be accepted at any other time (other than with the annual grant application). Application guidance documents will be amended to include this requirement. HRSA/HAB will review requests for waiver of the core medical services requirement and will notify grantees of waiver approval no later than the date of issuance of a NOGA. Core medical services waivers will be effective for a one-year period consistent with the grant award period.

The Paperwork Reduction Act of 1995

The burden for this activity has been reviewed and approved by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (OMB Number 0915–0307).

Dated: June 5, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–13102 Filed 6–10–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; 67 FR 46519, July 15, 2002; 68 FR 787–793, January 7, 2003; 68 FR 8515–8517, February 21, 2003; 68 FR 64357–64358, November 13, 2003; 69 FR 56433–56445, September 21, 2004; 70 FR 19962–19963, April 15, 2005; as last amended at FR 72 57588–57589, October 10, 2007). This Order of Succession supersedes the Order of Succession for the Administrator, HRSA, published at FR 72 57588–57589, October 10, 2007.

This notice deletes the Associate Administrator, Office of Management, from HRSA's hierarchy affecting the Order of Succession. It also adds, as a last echelon to the HRSA Administrator's order of succession, HRSA Regional Division Directors in the order in which they have received their permanent appointment as such. This notice is to reflect the new Order of Succession for HRSA.

Section R–30, Order of Succession

During the absence or disability of the Administrator, or in the event of a vacancy in the office, the officials designated below shall act as Administrator in the order in which they are listed:

1. Deputy Administrator;

2. Senior Advisor to the Administrator;

3. Chief Financial Officer;

4. Associate Administrator, Bureau of Primary Health Care;

5. Associate Administrator, Bureau of Health Professions;

6. Associate Administrator, HIV/AIDS Bureau;

7. Associate Administrator, Maternal and Child Health Bureau;

8. Associate Administrator, Bureau of Clinician Recruitment and Service;

9. Associate Administrator, Healthcare Systems Bureau;

10. Associate Administrator, Office of Performance Review, and

11. HRSA Regional Division Directors in the order in which they have received their permanent appointment as such.

Exceptions

(a) No official listed in this section who is serving in acting or temporary capacity shall, by virtue of so serving, act as Administrator pursuant to this section.

(b) Notwithstanding the provisions of this section, during a planned period of absence, the Administrator retains the discretion to specify a different order of succession.

Section R–40, Delegation of Authority

All delegations and redelegations of authorities to officers and employees of the Health Resources and Services Administration which were in effect immediately prior to the effective date of this action will be continued in effect in them or their successors, pending further redelegation, provided they are consistent with this action.

This document is effective upon date of signature.

Dated: June 5, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–13098 Filed 6–10–08; 8:45 am]

BILLING CODE 4165–15–P