Dated: March 20, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–6850 Filed 3–26–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Evaluating Locally-Developed (Homegrown) HIV Prevention Interventions for African-American and Hispanic/Latino Men Who Have Sex With Men (MSM), Funding Opportunity Announcement (FOA) Number PA 09–007 and Operational Research To Improve the Implementation of Evidence-Based Interventions That Are Supported by the Diffusion of Effective Behavioral Interventions (DEBI) Project, FOA Number PA 09–008

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 8 a.m.–5 p.m., April 28, 2009 (Closed).

Place: Sheraton Gateway Hotel, Atlanta Airport, 1900 Sullivan Road, Atlanta, GA 30337, Telephone (770) 997–1100.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to ''Evaluating Locally-Developed (Homegrown) HIV Prevention Interventions for African-American and Hispanic/Latino Men Who Have Sex with Men (MSM), FOA Number PA 09–007,'' and ''Operational Research to Improve the Implementation of Evidence-Based Interventions that are Supported by the Diffusion of Effective Behavioral Interventions (DEBI) Project, FOA Number PA 09–008.''

Contact Person for More Information: Gregory Anderson, M.P.H., M.S., Scientific Review Administrator, Strategic Science and Program Unit, Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, Mailstop E–60, Atlanta, GA 30333, Telephone: (404) 498–2275.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 20, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–6854 Filed 3–26–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Screening Targeted Populations To Interrupt On-going Chains of Transmission With Enhanced Partner Notification—The STOP Study, Funding Opportunity Announcement (FOA) Number PA 09–004 and Demonstration Project of Elective Adult Male Circumcision Conducted in Sexually Transmitted Disease (STD) Clinics in the United States, FOA Number PA 09–005

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 8 a.m.–5 p.m., April 27, 2009 (Closed).

Place: Sheraton Gateway Hotel, Atlanta Airport, 1900 Sullivan Road, Atlanta, GA 30337, Telephone (770) 997–1100.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to ''Screening Targeted Populations to Interrupt On-going Chains of Transmission with Enhanced Partner Notification—The STOP Study, FOA Number PA 09–004;'' and ''Demonstration Project of Elective Adult Male Circumcision Conducted in Sexually Transmitted Disease (STD) Clinics in the United States, FOA Number PA 09–005.''

Contact Person for More Information: Gregory Anderson, M.P.H., M.S., Scientific Review Administrator, Strategic Science and Program Unit, Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, Mailstop E–60, Atlanta, GA 30333, Telephone: (404) 498–2275.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 20, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–6859 Filed 3–26–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2284–N]

Deeming Notice for the College of American Pathologists (CAP) as an Accrediting Organization Under the Clinical laboratory Improvement Amendments of 1988

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the application of the College of American Pathologists (CAP) for approval as an accreditation organization for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program for all specialties and subspecialties. In this notice, we announce the approval and grant the CAP deeming authority for all CLIA specialties and subspecialties for a period of 6 years. We have determined that the CAP meets or exceeds the applicable CLIA requirements.

DATES: *Effective Date*: This notice is effective from March 27, 2009 until March 27, 2015.

FOR FURTHER INFORMATION CONTACT: Val Coppola, (410)786–3531.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100–578. CLIA amended section 353 of the Public Health Service Act. We issued a final rule implementing the accreditation provisions of CLIA on July 31, 1992 (57 FR 33992). Under the CLIA program, CMS may grant deeming authority to an accreditation organization that accredits clinical laboratories if the organization meets certain requirements. An organization's requirements for laboratories accredited under its program must be equal to or more stringent than the applicable CLIA program requirements in 42 CFR part 493 (Laboratory Requirements). This requirement and others in subpart E of that part (Accreditation by a Private,

Nonprofit Accreditation Organization or Exemption Under an approved State Laboratory Program) specify the requirements an accreditation organization must meet to be approved by CMS as an accreditation organization under CLIA.

II. Notice of Approval of Deeming Authority for the CAP

In this notice, we approve the College of American Pathologists (CAP) as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements in all specialties and subspecialties. We have examined the initial CAP application and all subsequent submissions to determine their accreditation program's equivalency with the requirements for approval of an accreditation organization under subpart E of part 493. We have determined that the CAP meets or exceeds the applicable CLIA requirements. We have also determined that the CAP's Laboratory Accreditation Program (LAP) will ensure that its accredited laboratories will meet or exceed the applicable requirements in subparts H, I, J, K, M, Q, and the applicable sections of R. Therefore, we grant the CAP approval as an accreditation organization under subpart E of part 493, for the period stated in the Effective Date section of this notice for all specialties and subspecialties. As a result of this determination, any laboratory that is accredited by the CAP during the time period stated in the Effective Date section of this notice is deemed to meet the CLIA requirements for laboratories found in part 493 of our regulations and, therefore, is generally not subject to routine inspections by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by CMS, or its agent(s).

III. Evaluation of the CAP Request for Approval as an Accreditation Organization Under CLIA

The following describes the process used to determine that the CAP's LAP meets the necessary requirements to be approved by CMS, and that, as such, CMS may approve the CAP's LAP as an accreditation program with deeming authority under the CLIA program. CAP formally applied to CMS for approval as an accreditation organization under CLIA for all specialties and subspecialties. In reviewing these materials, CMS found the following for each applicable subpart of the CLIA regulations:

A. Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

The CAP submitted its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements, a list of all its current laboratories and the expiration date of their accreditation, and a detailed comparison of the individual accreditation requirements with the comparable condition-level requirements. The CAP's policies and procedures for oversight of laboratories performing all laboratory testing covered by CLIA are equivalent to those of CLIA in the matters of inspection, monitoring proficiency testing (PT) performance, investigating complaints, and making PT information available. CAP's requirements for monitoring and inspecting laboratories are the same as those previously approved by CMS for laboratories in the areas of accreditation organization, data management, the inspection process, procedures for removal or withdrawal of accreditation, notification requirements, and accreditation organization resources. The requirements of the CAP are equal to the requirements of the CLIA regulations.

B. Subparts H–Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing; Subpart I—Proficiency Testing Programs for Nonwaived Testing; Subpart K—Quality System for Nonwaived Testing; and Subpart M—Personnel for Nonwaived Testing

Our evaluation identified areas of the CAP requirements that are more stringent than the CLIA requirements and apply to the laboratory as a whole. Rather than include them in the appropriate subparts multiple times, we list them as follows:

- CAP requires the directors of its accredited laboratories to sign an attestation that their laboratories are in compliance with all applicable Federal, State, and local laws;
- CAP requires quality and personnel standards for all waived tests;
- CAP lists extensive requirements for the Laboratory Information System (LIS) that include, but are not limited to, the following areas:

—Preservation, storage, and retrieval of laboratory and patient data.
—Review of LIS programs for appropriate content and testing before use, when a new program is to be put in place, or when changes are made to existing programming.
—Maintenance of the LIS facility (must be clean, well ventilated, and at proper temperature and humidity).
—Protection of LIS against power interruptions and surges.
—Readily available procedure manuals for LIS operators, adequately trained operators who know how to preserve data and equipment in emergency situations (for example, fire, software or hardware failure).
—Protection of the LIS, its data, patient information, and programs from unauthorized use.
—Entry of data and result reporting.
—Verification and maintenance of LIS hardware and software.
—Routine and emergency service and maintenance of the LIS.
—Evaluation from the laboratory director of the LIS performance as it pertains to patient and clinician needs.

- CAP also accredits laboratories that perform testing for any of the following non-CLIA areas and sets specific standards these accredited laboratories must comply:

—Forensic drug testing.
—Parentage testing.
—Reproductive laboratory testing (Andrology and embryology).

C. Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing and Listing of Analytes Requiring PT From Subpart I

The CAP requirements for PT are in conformance with the CLIA statute which requires that all laboratories be tested by PT for each test or examination for which PT is available. The CAP PT requirements are more stringent than the CLIA regulations in subpart H which specifies the tests in subpart I for which the laboratory must enroll, and also requires the laboratory participate in a CMS-approved PT program.

CLIA exempts waived testing from PT, whereas the CAP requires its accredited laboratories to participate in a CMS-approved PT program for all testing, including test systems waived under CLIA.

We have determined that the actions taken by the CAP to correct unsatisfactory (one failure) PT performance are equivalent to those of CLIA and that the actions taken to correct unsuccessful (2 in a row or 2 out of 3 failures) PT performance of its laboratories are more stringent than those of CLIA. The CAP utilizes an on-going electronic monitoring process that

flags both unsatisfactory and unsuccessful results for all PT performance of both analytes required by CLIA and all other testing for which PT is available and is required by the CAP.

For all PT performed in its accredited laboratories, the CAP requires investigation of each unsatisfactory result, as determined by the CAP (CMS does not apply PT requirements for analytes not listed in subpart I.). The laboratory is instructed to investigate and document the cause of the erroneous result and the corrective actions taken to avoid future failures. CLIA regulations state that, for only the analytes listed in subpart I, the laboratory must undertake appropriate training and employ the technical assistance that is necessary to correct problems associated with an unsatisfactory score, take remedial action, and document all steps taken.

Unsuccessful PT performance, as determined by the CAP, for analytes not listed in subpart I, initiates immediate communication between the CAP and the laboratory director. A written response must be submitted to the CAP, explaining the results of the laboratory's investigation of the problem, the actions taken to correct the problem, and evidence that the problem was successfully corrected. If, after review by the CAP, it is determined that the laboratory's subsequent PT performance is within acceptable limits, no further action is taken. If the laboratory does not respond, fails to seriously address the problem, or cannot bring performance into acceptable limits, the CAP would evaluate the situation and either request that the laboratory cease testing for the analyte, specialty, or subspecialty in question, or, if warranted, revoke accreditation. (Please see Subpart R, Enforcement Procedures, for specific actions taken by the CAP for PT failures of analytes listed in subpart I.)

CLIA regulations allow a laboratory to undertake training of its personnel or to obtain technical assistance or both, when the initial unsuccessful PT performance occurs, instead of imposing alternative or principal sanctions.

D. Subpart J—Facility Administration for Non-Waived Testing

The CAP requirements are equivalent or more stringent than the CLIA requirements at § 493.1100 through § 493.1105. We have determined that the CAP's more stringent requirements for environmental safety address electrical voltage, facility ventilation, lighting, temperature, humidity, and emergency power source, and require remedial actions to be taken when necessary. Its requirements for molecular amplification procedures, laboratory safety which includes requirements for handling and disposal of biohazardous materials, fire safety and prevention of fire hazards, and record maintenance are all more stringent than those of CLIA. The CAP's transfusion service requirements are more stringent than those of CLIA and the CAP's record retention requirements are more stringent than those of CLIA.

E. Subpart K—Quality System for Nonwaived Testing

The quality control (QC) requirements of CAP have been evaluated against those of the CLIA regulations. We have determined that the QC requirements of CAP are more stringent than the CLIA requirements, when taken as a whole. Some specific areas of QC that are more stringent are as follows:

- The CAP requires procedure manuals to include the principal and clinical significance for each test, and laboratory procedures must include documentation of initial review, review and approval of all subsequent changes, and annual review.
- The CAP requires its accredited laboratories performing gynecologic (GYN) cytology to enroll in its Interlaboratory (PAP Education) Comparison Program in GYN Cytology as well as a CMS approved GYN PT program. The CAP requires its accredited laboratories to use the appropriate reagent grade water for the testing performed, stating which type of water (from type I through type III) must be used in specific tests. Source water also must be evaluated for silicate levels.
- Laboratories accredited by the CAP must verify all non-class A volumetric glassware and pipettes for accuracy and reproducibility before use, and must recheck them periodically. These activities must be documented.
- Laboratories accredited by the CAP that perform maternal serum triple tests or quadruple tests, and acetyl cholinesterase have specific requirements that must be met. These include a qualitative specimen evaluation, requesting and reporting information necessary for interpretation of results such as gestational age, maternal birth date, race, maternal weight, presence of insulin-dependent diabetes mellitus, and multiple gestations. The CAP also requires medians be re-calculated or re-verified annually and patient test results are reported in multiples of the population median.
- The CAP lists extensive requirements for methodologies of molecular pathology and flow cytometry, which are presented in separate checklists, and immunohistochemistry has specific requirements within histology.

We have determined that the CAP's requirements are equal to, or more stringent than, the CLIA requirements for quality assurance purposes. The CAP also offers an educational program (Q–Probes) to its accredited laboratories that provides further information on quality assurance to the large, full service laboratories that allows peer review and comparisons between facilities.

F. Subpart M—Personnel for Nonwaived Testing

The CAP Standards for Laboratory Accreditation state at Standard I, Director and Personnel Requirements (under item D, Personnel) that all laboratory personnel must be in compliance with applicable Federal, State, and local laws and regulations. This standard is implemented in the general laboratory requirement that there must be evidence in personnel records that all testing personnel have been evaluated against CLIA regulatory requirements for high complexity testing, and that all individuals qualify. The CAP holds all technical personnel in its accredited laboratories to the high complexity personnel requirements of CLIA.

The CAP has implemented a new checklist specific to the laboratory director qualifications and responsibilities. Therefore, we have determined that the personnel requirements of the CAP are more stringent than the personnel requirements of CLIA, when taken as a whole.

G. Subpart Q—Inspection

We have determined that the CAP inspection requirements, taken as a whole, are equivalent to the CLIA inspection requirements.

The CAP will continue its policy of biennial on-site announced inspections. An unannounced inspection would be performed when a complaint, lodged against a laboratory accredited by the CAP, indicates that problems exist within that laboratory that are likely to have serious and immediate effects on patient care.

The CAP requires a mid-cycle self-inspection of all accredited laboratories. All requirements for the mid-cycle self-inspection must be responded to in writing, and the responses must be submitted to the CAP within a specified

timeframe. CLIA regulations do not have this requirement.

H. Subpart R—Enforcement Procedures

The CAP meets the requirements of subpart R to the extent that they apply to accreditation organizations. The CAP policy stipulates the actions it takes when laboratories it accredits do not comply with its requirements and standards for accreditation. As demonstrated during its first two periods of approval, the CAP denies accreditation to a laboratory when appropriate, and reports the denial to CMS within 30 days. The CAP also provides an appeal process for laboratories that have had accreditation denied.

Some specific actions the CAP takes in response to non-compliance or violation of its requirements or standards for accreditation include:

—The enrollment monitoring process runs continuously throughout the year. When no enrollment data or incomplete enrollment data are received based on the laboratory's test menu, letters are sent notifying the laboratory of its missing enrollments. If no enrollment is found after 60 days, the laboratory is sent a ''cease testing'' letter for the analytes not properly enrolled in PT.

—For all analytes listed in subpart I that the CAP accredited laboratories perform, the CAP technical staff reviews such testing to verify two previous PT performances, reviews PT evaluation to detect trends and repeats failures, contacts the laboratory to alert them if the status is critical, and issues cease testing letters when appropriate.

—When an accredited laboratory has unsatisfactory performance, a letter is sent instructing it to investigate and document the cause of the erroneous result and the corrective actions it takes to prevent recurrence.

—When there is an initial unsuccessful performance, the laboratory may either provide documentation of investigation and corrective action or the laboratory is given the option to voluntarily cease testing the unsuccessful analyte(s).

—If the laboratory indicates it will permanently cease testing of a non-initial unsuccessful PT performance, the activity is removed from the laboratory's test menu. If the laboratory wishes to resume testing at a later date, it must successfully perform two consecutive re-instatement PT testing events.

—When the CAP becomes aware of a problem in an accredited laboratory that is so severe and extensive that it could cause a serious risk of harm (an immediate jeopardy situation), an expedited evaluation is immediately undertaken by the Chair and Vice Chair of the Accreditation Committee, the Regional Commissioner and the Director of the Laboratory Accreditation Program. If it is determined that an immediate jeopardy situation exists, the laboratory is required to remove the jeopardy situation immediately or accreditation would be revoked and reported to CMS. An on-site focused re-inspection may be performed to verify that the immediate jeopardy no longer exists. These actions are similar to CMS actions for immediate jeopardy.

—The CAP requires its accredited laboratories to correct all deficiencies within 30 days. CLIA deficiencies that are not condition level must be corrected in a timeframe that is acceptable to CMS, but no longer than 12 months. CLIA deficiencies that are condition level that are not considered immediate jeopardy must be corrected in an acceptable timeframe; however, CMS may impose one or more alternate sanctions or a principal sanction to motivate laboratories to correct these deficiencies. The CAP timeframe for correction of deficiencies, when taken as a whole, is more stringent than CLIA.

We have determined that the CAP's laboratory enforcement and policies are equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the CAP may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, the State survey agencies, will be our principal means for verifying that the laboratories accredited by CAP remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the CAP, for cause, before the end of the effective date of approval. If we determine that the CAP has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the CAP would be allowed to address any identified issues. Should the CAP be unable to address the identified issues within that time frame, CMS may, in accordance with the applicable regulations, revoke CAP's deeming authority under CLIA.

Should circumstances result in our withdrawal of the CAP's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, and the implementing regulations in 42 CFR part 493, subpart E, are currently approved under OMB control number 0938–0686.

Authority: Section 353(p) of the Public Health Service Act (42 U.S.C. 263a).

Dated: February 26, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E9–6903 Filed 3–26–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2294–FN]

Medicare and Medicaid Programs; Approval of the Joint Commission for Continued Deeming Authority for Hospices

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces the approval of a deeming application from the Joint Commission for continued recognition as a national