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[FR Doc. 2014-28193 Filed 11-28-14; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Fee Schedule for Reference Biological Standards and Biological Preparations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces that HHS/CDC has reviewed and updated its fee schedule for reference biological standards and biological preparations required by OMB Circular A-25, User Charges. This notice also announces current contact information to obtain information on the availability of these products and the fees for these products.

DATES: These fees are effective January 2, 2015.

FOR FURTHER INFORMATION CONTACT: To obtain information on the current inventory of reference biological standards and biological preparations and the current fee schedule, please contact the Division of Scientific Resources, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop C-17, Atlanta, Georgia 30329; telephone 404-639-3466. Someone will be available to answer your inquiry between 8:00 a.m. and 4:30 p.m. Eastern Time, Monday through Friday, except on Federal holidays.

SUPPLEMENTARY INFORMATION: On July 22, 2013 HHS/CDC published a Direct Final Rule (DFR) titled "Distribution of Reference Biological Standards and Biological Preparations (78 FR 43817). In the DFR, HHS/CDC updated the agency name, location, and contact information for persons interested in obtaining reference biological standards and biological preparations.

On August 5, 2013, HHS/CDC published a General Notice (78 FR 47319) to inform the public that HHS/CDC has reviewed and updated its fee schedule per the requirements in OMB Circular A-25 (User Charges) and to provide contact information to obtain a

current inventory of products and an up-to-date fee schedule of charges (see **FOR FURTHER INFORMATION CONTACT**).

OMB Circular A-25 (User Charges) requires that agencies review user charges for agency programs every two years. This review should include any adjustment to reflect changes in costs or market value. HHS/CDC has conducted a review of the fees charged for reference biological standards and biological preparations. Based on this review, some reagents are being removed from our inventory because they are obsolete. No prices have increased or decreased at this time.

HHS/CDC prepares reference biological standards and biological preparations under the authority of 42 CFR Part 7. These regulations describe how private entities may obtain reference biological standards and biological preparations from HHS/CDC and how charges for these standards and preparations are determined. Persons interested in these products should contact the Division of Scientific Resources, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop C-17, Atlanta, Georgia 30329; telephone 404-639-3466, for the current inventory and fee schedule. Due to the changing inventory of the unique biological standards or biological preparations, some of which are prepared only upon request, it is best to contact HHS/CDC to determine the availability of a particular product.

Dated: November 25, 2014.

Ron A. Otten,

*Acting Deputy Associate Director for Science,
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[FR Doc. 2014-28226 Filed 11-28-14; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 79 FR 32739-32740, dated June 7, 2014) is amended to reflect the reorganization of the National Center for Immunization and Respiratory Diseases.

Section C-B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and the mission and function statements for the Immunization Services Division (CVGB) and insert the following:

Immunization Services Division (CVGB). The Immunization Services Division (ISD) protects individuals and communities from vaccine-preventable diseases through provision of federal funds and contracts to purchase and distribute vaccine, provision of technical and financial support of immunization programs, provider and public education, and evaluation and research.

Office of the Director (CVGB1). (1) Coordinates the division's program, policy, scientific activities and provides leadership for domestic programmatic activities; (2) links strategies and priorities of the primarily program-focused ISD branches with other NCIRD divisions working in the area of domestic immunizations and vaccine-preventable diseases; (3) facilitates development and ongoing implementation of vaccine coverage surveillance, health services and economic research, and program evaluation across the ISD branches; (4) interfaces with other CDC CIOs working in the area of immunizations and vaccine preventable diseases; (5) provides guidance for the protection of research subjects, OMB/PRA compliance, and scientific review and clearance of manuscripts and other written materials produced by ISD branches; (6) provides leadership for domestic adult immunizations in the ISD; (7) provides leadership across the branches with respect to linking preparedness and response elements to the overall influenza prevention and control strategy, and interfaces with other parts of CDC with this strategy; (8) represents ISD in other preparedness activities with vaccines as countermeasures; (9) in close coordination with NCIRD's Office of Policy, provides policy support to the ISD; (10) as appropriate, works through the NCIRD Office of Policy to serve as liaison to other policy offices, other government agencies, and external partners on policy, program, legislative, and budgetary issues related to ISD; (11) conducts policy analysis; (12) advises ISD leadership on policy and partnership issues and supports Center efforts in the management of Congressional and government relations; (13) manages cross-cutting policy issues within ISD and, as appropriate, with other policy offices within the Center and CDC; (14)

provides direct management oversight and execution of national vaccine supply contracts; (15) provides direct management and execution of procurement requisitions, contracts, and cooperative agreements, and performs administrative tasks related to initiating, processing, and maintaining interagency agreements; (16) provides direct management and execution of the administrative aspects of human resources across ISD, including training, and administration of policies and guidelines developed among others, by the Department of Health & Human Services, CDC Ethics Office, Office of the Chief Financial Officer, Office of Commissioned Corps Personnel, Office of Personnel Management, and Procurement and Grants Office; (17) provides direct management and execution of the coordination of office facilities, and supplies technical guidance and expertise regarding occupancy and facilities management including emergency situations; (18) provides direct and daily management and execution of the distribution, accountability, and maintenance of CDC property and equipment; and (19) provides direct and daily management and execution of domestic travel processing for federal employees, Commissioned Corps, and all CDC-invited guests.

Program Operations Branch (CVGGB). (1) Serves as CDC's primary interface with eligible immunization cooperative agreement awardees, supporting the awardees with development, implementation, assessment, and promotion of immunization-related activities with the goal of achieving and sustaining high immunization coverage level; (2) administers the Vaccines For Children (VFC) and Section 317 programs for eligible awardees; (3) provides technical assistance to awardees on program implementation, including implementation of all components of the VFC and Section 317 cooperative agreement; (4) monitors VFC and Section 317 cooperative agreement awardee performance; (5) manages immunization field staff; (6) supports efforts to assure accountability in the use of vaccines purchased with federal funding; (7) assures accountability of federal funds used to purchase vaccines; and (8) identifies and evaluates methods to improve immunization service delivery.

Vaccine Supply and Assurance Branch (CVGBC). (1) Oversees all aspects of domestic vaccine purchase and distribution; (2) manages centralized vaccine distribution contracts; (3) establishes and manages vaccine purchase contracts; (4) creates

and maintains pediatric vaccine stockpiles; (5) coordinates and reviews awardee spend plans for vaccine ordering; (6) manages national vaccine supply shortages, including public vaccine allocations when needed; (7) tracks and monitors national seasonal influenza vaccine distribution; (8) conducts data analyses related to vaccine purchase and distribution; (9) provides storage and handling technical assistance; (10) provides awardee support and conducts planning and testing in Vaccine Tracking System (VTrckS); and (11) develops VFC program resolutions for the Advisory Committee on Immunization Practices (ACIP).

Immunization Information Systems Support Branch (CVGBE). (1) Supports the CDC vision of "A nation without vaccine-preventable disease, disability, and death" by making high quality data from immunization information systems (ITS) available to clinical, administrative, public health, and other immunization stakeholders; (2) provides leadership, operational, technical and resource support to develop a nationwide network of fully operational and integrated IIS and other health systems; (3) ensures high-quality IIS data and system functionality by identifying, developing, implementing, promoting, and evaluating standards and best practices; (4) promotes the effective use of IIS data and system functions to support vaccination providers, public health programs, other immunization stakeholders, and policy needs; (5) monitors, evaluates, and reports emerging industry and environmental trends that influence IIS operations; and (6) supports the exchange of information about IIS and collaborative efforts to advance ITS operations with partners.

Assessment Branch (CVGBG). (1) Lead domestic vaccination coverage assessment across the lifespan; (2) assess the impact of interventions, policies and disseminating and promoting use of this information to improve vaccination coverage; (3) conducts assessment of vaccination coverage, related health services, and other factors associated with vaccination across the lifespan; (4) conducts and manages the National Immunization Survey (NIS) to assess vaccination coverage and related information among children aged 19–35 months and 13–17 years, and as needed, other age groups; (5) collects, analyzes, and disseminates accurate and timely vaccination coverage and related information using the NIS and other survey mechanisms and clinical data sources; (6) assists national, state and

local immunization programs in collection, analysis, interpretation, and use of vaccination coverage assessment and evaluation information to guide policy and program activities; (7) conducts research and evaluations to assess and reduce racial/ethnic and other disparities in vaccination, evaluate impact of interventions, policies, and program activities on vaccination coverage, and measure disease and economic impact of specific interventions and vaccination programs; and (8) conducts research to evaluate and improve the validity and cost-effectiveness of NIS and other assessment systems used to collect vaccination coverage data.

Communication and Education Branch (CVGBH). (1) Works through communications and educational efforts to improve knowledge and influence changes in behavior of domestic health care providers and the general public to reduce vaccine-preventable diseases across the life span; (2) collaborate with NCIRD Health Communication Science Office (HCSO) to develop communications strategies and provide communications and media support for ISD; (3) develops and disseminates domestic immunization messages, materials, and educational offerings for health care providers and consumers related to ISD's scientific and programmatic work; (4) supports the CDC immunization response system; (5) collaborates with national immunization partner groups to achieve programmatic goals; (6) through NCIRD HCSO provides technical assistance for national immunization communications campaigns; (7) provides Continuing Education credits for immunization-related education and training products; and (8) participates on the ACIP work groups and develops and promotes ACIP schedules and recommendations.

Dated: October 29, 2014.

Sherri A. Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2014–28220 Filed 11–28–14; 8:45 am]

BILLING CODE 4160–18–M