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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 68 FR 7118-7123, dated February 12, 2003) is amended to reorganize the National Center for HIV, STD, and TB Prevention.

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

Delete in its entirety the functional statement for the Division of Tuberculosis Elimination and insert the following:

Division of Tuberculosis Elimination (CK4). To promote health and quality of life by preventing, controlling, and eventually eliminating tuberculosis from the United States, and by collaborating with other countries and international partners in controlling tuberculosis world-wide. For the purpose of fulfilling the mission, the Division administers and promotes a national program for the prevention, control, and elimination of tuberculosis (TB); provides leadership and formulates national policies and guidelines; conducts behavioral, health systems, and clinical research; supports a nationwide framework for surveillance of tuberculosis and evaluation of national TB prevention and control program performance; provides administrative support for the Federal TB Task Force, and supports and collaborates with the National Tuberculosis Controllers Association to promote effective national communications and coordinated feedback on urgent policy and program performance issues; provides technical supervision and training to Federal assignees working in the state and local tuberculosis control programs; develops training and educational materials, and provides technical assistance on

communications and training needs; participates in the development of policies and guidelines for TB prevention and control within populations at high risk, such as persons with human immunodeficiency virus (HIV); provides programmatic consultation, technical assistance, and outbreak response assistance to state and local health departments; and, provides technical assistance to TB programs in other countries by collaborating with international partners.

Office of the Director (CK41). (1) Provides leadership and guidance in program planning and management, policy formulation, and development of training, surveillance, and research programs; (2) directs and evaluates the operations of the Division; (3) establishes contact with, and promotes tuberculosis activities of, other national organizations which have an important role to play in achieving tuberculosis elimination; (4) provides administrative support services for the Division; (5) collaborates and coordinates Division activities with other components of the National Center for HIV, STD, and TB Prevention (NCHSTP) and the Centers for Disease Control and Prevention (CDC); (6) provides administrative and technical support to the Advisory Council for the Elimination of Tuberculosis (ACET); and, (7) provides administrative and technical support for the National Coalition for the Elimination of Tuberculosis (NCET).

Communications, Education, and Behavioral Studies Branch (CK42).

(1) Provides technical assistance to health departments and other health care providers in assessing and meeting their TB training, education, and communication needs and in assessing the impact of their training and education activities; (2) provides technical assistance to health departments and other TB health care providers regarding behavioral studies research and intervention development; (3) collaborates with the World Health Organization (WHO), the World Bank, the International Union Against Tuberculosis and Lung Diseases (IUATLD), and the United States Agency for International Development (USAID), and others, in assessing and meeting TB training, education, and communication needs in other countries; (4) provides consultation and assistance in coordinating TB training, education, behavioral studies and interventions, and communication activities carried out by other CDC programs, Model TB Centers, and NCET members; (5) develops, markets, and maintains a list serve of persons with

TB-related education, training, and communication responsibilities; (6) assists in planning and coordinating agendas necessary to conduct tuberculosis conferences and workshops sponsored by the Division; (7) provides coordination and oversight for duty officer functions; (8) organizes and maintains a library of scientific and non-scientific information related to TB; (9) conducts formative research and evaluation on approaches to patient, provider, and public education; (10) conducts research on individuals and social factors affecting health-care seeking and treatment outcomes related to tuberculosis; (11) based on research conducted, develops behavioral interventions targeted to health care providers, persons with or at risk for TB, and other high risk populations; (12) provides consultation to national and international organizations on behavioral research needs and study designs, and on the technical transfer of behavioral research findings into TB program practice and TB training and educational strategies; (13) provides consultation, technical assistance, and coordination to other branches within the division regarding development and implementation of behavioral interventions and training for branch specific activities such as TIMS, ARPE, and surveillance activities; (14) provides consultation and assistance in coordinating the writing of studies for publication of manuscripts in scientific journals; (15) presents findings at national and scientific meetings; (16) develops, produces, disseminates, and evaluates training and educational materials and courses providing tuberculosis information to the scientific and public health communities, as well as the general population; (17) conducts training and education needs assessments and identifies resources available for health department TB control officers and senior managers, TB nurse consultants, TB training and education directors and for senior staff carrying out TB activities in other programs or facilities serving persons at high risk for TB; (18) develops, conducts, and coordinates training courses on tuberculosis for state and big city TB program managers and nurse consultants; (19) based on needs assessments, develops and conducts or coordinates training courses and materials for staff who train and/or supervise front-line TB program staff; (20) plans, coordinates, and maintains the Division's Internet and Intranet Web sites; (21) conducts and/or coordinates communications programs designed to build public support and sustain public

interest and commitment to the elimination of TB; (22) conducts communications and research and identifies communications resources available for health department TB control officers and senior managers, TB nurse consultants, and for senior staff carrying out TB activities in other programs or facilities serving persons at high risk for TB; (23) provides writer/editor support to Division and coordinates and tracks materials for purposes of editing, clearance and approval for publications and presentations; (24) provides graphic support to the Division and senior field staff; (25) provides coordination and oversight for Division responses and relations with the media and public and serves as point of contact for telephonic, written, and electronic (e-mail) requests for information from the media and public; (26) maintains information and procedures for duty officer functions; (27) develops, coordinates, and staffs the Division's exhibit booth at conferences/meetings; (28) develops and provides support for, or coordinates a TB Voice and FAX Information System; (29) assists in developing or coordinating a clearing house of TB training and education resources; (30) maintains inventory of TB training opportunities and coordinates with employees and supervisors for training necessary to carry out their duties; and, (31) presents communication issues to the Advisory Council for the Elimination of Tuberculosis and to Division management staff.

Information Technology and Statistics Branch (CK43). (1) Provides computer programming, systems analysis, information management, and statistical services to the Division; (2) consults and assists in the development and implementation of appropriate data collection and management methods for scientific studies conducted Division-wide; (3) collaborates in the analysis of data and in the preparation of materials for publication; (4) maintains expertise in information science and technology to effect the best use of the Division's resources; (5) provides technical assistance in the selection and use of equipment, systems, and services to process information; (6) manages security for the Division's information systems; (7) maintains computer hardware; (8) provides training and consultation to headquarters and field staff in the use of computer hardware and software; and (9) develops, distributes, provides training for and supports the TB Information Management System (TIMS) to facilitate the collection and analyses of data, both

patient and program, to improve the effectiveness of prevention and control activities.

Field Services and Evaluation Branch (CK44). (1) Provides medical and programmatic consultation to assist state and local health departments in developing, implementing and evaluating their activities toward achieving tuberculosis prevention, control, and elimination; (2) promotes adoption of CDC tuberculosis-related policies by national organizations, health departments and health care providers; (3) acts as advocate for health departments when conveying resource needs; (4) participates in development of national policies and guidelines for tuberculosis elimination; (5) evaluates tuberculosis program performance; (6) provides technical assistance to states and localities for improving program operations; (7) develops funding guidelines, assists in application reviews, makes funding recommendations, and monitors performance of programmatic portion of Tuberculosis Cooperative Agreements with state and local health departments; (8) provides supervision to medical staff assigned to state and local health departments; (9) analyzes data to assess progress toward achieving national TB objectives and prepares program management and evaluation reports for publication; (10) supports program consultants in providing technical assistance and recommendations to health departments; (11) encourages and facilitates the transfer of new technology and guidelines into clinical and public health practice; (12) participates in the development of comprehensive evaluation methods for TB prevention and control programs; (13) serves as liaison or focal point to assist TB controllers in linking with proper resource persons and obtaining technical assistance, both within and outside the Division; (14) conducts a continuing analysis of the effectiveness of field personnel and utilization of other resources in relation to the tuberculosis problems; (15) provides consultation and assists state and local health departments in the methodology and application of tuberculosis control techniques recommended by CDC; (16) acts as advocate for state and local health department during needs assessments and requests for resources; (17) provides technical supervision and support for the CDC field staff; (18) identifies specific management, operational, and staff performance problems associated with not achieving TB control objectives or with not implementing essential TB components,

and recommends solutions; (19) provides input into the development of Branch and Division policy, priorities and operational procedures; (20) coordinates technical reviews of cooperative agreement applications and makes appropriate funding recommendations; and (21) serves as an agent of technology transfer to ensure that good program methodology in one program is known and made available to other state and local programs.

Clinical and Health Systems Research Branch (CK45). (1) Assesses the need for and conducts studies of new drug regimens used in the prevention and treatment of tuberculosis, including dosage, duration, and toxicity; (2) supports the TB Trials Consortium in the conduct of studies of new drugs, drug delivery systems, immunologic agents and other treatments for active tuberculosis and latent tuberculosis infection; (3) conducts studies to evaluate the safety and efficacy of recommended regimens for the treatment and prevention of tuberculosis; (4) provides clinical support and oversight for the distribution of investigational drugs for the treatment and prevention of tuberculosis by NCID/SR/Drug Service; (5) assesses the need for and conducts clinical and field trials of more specific and rapid tests to diagnose active tuberculosis and latent tuberculosis infection and to identify drug-resistant tuberculosis; (6) collaborates with and provides consultation and technical assistance to national and international organizations on the design and conduct of clinical trials and research needs; (7) conducts multidisciplinary studies (including the analysis of behavioral, economic, and epidemiologic factors) of health care systems to assess the cost, effectiveness, and impact of public health policies, programs, and practices on tuberculosis outcomes to further the goal of tuberculosis elimination in the U.S.; (8) targets these studies toward various populations at high risk for tuberculosis, including persons from high tuberculosis prevalent countries, homeless persons, HIV-infected persons, residents of correctional facilities, substance abusers, and health care workers; (9) provides consultation to local, state, national, and international organizations on health care systems research needs, study designs, and analyses; (10) conducts or facilitates training of tuberculosis program field staff in decision and economic analyses, epidemiology, evaluation techniques, and qualitative research methods; (11) reports study results to public health practitioners through direct

communication, articles in scientific journals and CRC publications, and oral/poster presentations at national and international scientific meetings; (12) provides input into statements and guidelines issued by the CRC, the Advisory Council on the Elimination of Tuberculosis, and other professional organizations.

Surveillance, Epidemiology, and Outbreak Investigations Branch (CK44).

(1) Directs national surveillance of tuberculosis to provide accurate and timely national data and to monitor progress toward the elimination of tuberculosis in the United States; (2) conducts analyses of national TB surveillance data to monitor national trends in TB in order to assist in program planning, evaluation, and policy development and to identify areas for further study to guide elimination efforts; (3) conducts surveillance related studies that evaluate current TB surveillance systems and develops new surveillance methods and systems in order to better monitor and accelerate TB elimination efforts; (4) provides technical surveillance expertise to state, local, and international tuberculosis control programs, other federal agencies, and other organizations involved in TB prevention and control; (5) conducts epidemiologic research to assess the characteristics of persons with *M. tuberculosis* disease and infection in the United States; (6) analyzes research findings to develop improved interventions for eliminating tuberculosis and better analytic tools for future studies; (7) provides technical epidemiologic expertise to state, local, and international tuberculosis control programs.; (8) supports the TB Epidemiologic Studies Consortium in the conduct of studies of programmatically relevant epidemiologic, behavioral, economic, laboratory, and operational research concerning the identification, diagnosis, prevention and control of TB disease and latent infection; (9) investigates outbreaks of tuberculosis; (10) provides consultation and technical expertise on TB surveillance, epidemiology, and outbreaks to state, local, and international tuberculosis control programs; (11) analyzes TB outbreak investigation findings in order to improve the ability of tuberculosis control programs to detect future outbreaks and respond to them promptly and appropriately to limit transmission; (12) supervises Epidemiologic Intelligence Service (EIS) officers in the conduct of their two year assignments; (13) prepares manuscripts for publication in scientific journals;

and, (14) presents findings at national and international scientific meetings.

International Research and Programs Branch (CK47). (1) Coordinates Division and Center international TB activities; (2) coordinates the assessment of immigration and its impact on TB patterns in the United States and assists with the evaluation of overseas TB screening procedures for immigrants and refugees; (3) conducts and coordinates operational research and demonstrations to improve both the overseas screening for tuberculosis of immigrants and refugees and the domestic follow-up those entering with suspected TB (done in collaboration with Division of Global Migration and Quarantine, NCID); (4) promotes the improved recognition and management of tuberculosis among the foreign-born through special studies on the U.S./ Mexico border and at other overseas sites; (5) collaborates with the World Health Organization (WHO), the World Bank, the International Union Against Tuberculosis and Lung Diseases (IUATLD), the United States Agency for International Development (USAID), and others to improve the quality of TB programs globally by supporting implementation of the WHO-recommended directly observed therapy, short-course (DOTS) strategy; (6) collaborates with the nation of Botswana, the WHO, the World Bank, the IUATLD, the USAID, and others, to conduct investigations into the diagnosis, management and prevention of tuberculosis in persons with and without HIV infection; (7) collaborates with the Global AIDS Program (GAP) in addressing the AIDS pandemic in countries where both HIV and TB are reported in epidemic proportions; (8) collaborates with the WHO, USAID, and several nations to reduce the impact of multi-drug resistant TB on global TB control; (9) prepares manuscripts for publication in scientific journals; (10) presents findings at national and international scientific meetings; and, (11) supervises Epidemic Intelligence Service (EIS) officers in the conduct of their two year assignments.

Delegations of Authority Statement

All delegations and redelegations of authority remain in effect until otherwise modified, superseded, or cancelled.

Section C–C, Order of Succession

Delete in its entirety Section C–C, Order of Succession, and insert the following:

During the absence or disability of the Director, CDC, or in the event of a vacancy in that office, the first official

listed below who is available shall act as Director, except that during a planned period of absence, the Director may specify a different order of succession:

1. Director of CDC
2. Deputy Director for Public Health Science
3. Deputy Director for Public Health Service
4. Chief Operating Officer
5. NCCDPHP Director

Dated: June 3, 2003.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–10087]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New collection.

Title of Information Collection: Evaluation of the Illinois and Wisconsin State Pharmacy Assistance Waivers.

Form No.: CMS–10087 (OMB# 0938–NEW).

Use: CMS has implemented the Pharmacy Plus Initiative to grant