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; as last amended at 75 FR 68806–68808 dated November 9, 2010).

This notice reflects organizational changes to the Health Resources and Services Administration. Specifically, this notice updates the Healthcare Systems Bureau (RR) mission and better aligns functional responsibility, improve management and administrative efficiencies, and optimize use of available staff resources.

Chapter RR—Healthcare Systems Bureau

Section RR–00, Mission

The Healthcare Systems Bureau leads the Agency in providing health care programs to eligible organizations around the country. This includes providing overall leadership and direction for the procurement allocation and transplantation of human organs, blood stem cell and cord blood; providing architectural/engineering support for construction/renovation of health care facility projects; managing and promoting the 340B Drug Pricing Program; directing and administering the Poison Center Support, Enhancement, and Awareness Act, the National Vaccine Injury Compensation and the Countermeasures Injury Compensation Programs.

Section RR–10, Organization

Delete in its entirety and replace with the following:

The Healthcare Systems Bureau (RR) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Healthcare Systems Bureau includes the following components:

(1) Office of the Associate Administrator (RR);

(2) Division of Transplantation (RR1);

(3) Division of Health Facilities (RR9);

(4) Division of Vaccine Injury Compensation (RR4); and

(5) Office of Pharmacy Affairs (RR7).

Section RR–20, Functions

Delete the functional statement for the Healthcare Systems Bureau (RR) and replace in its entirety.

Office of the Associate Administrator (RR)

The Healthcare Systems Bureau leads the Agency in providing health care programs to eligible organizations around the country. Specifically, (1) administers the Organ Transplantation Program (OTP) to include the Organ Procurement and Transplantation Network (OPTN) to facilitate the allocation of donor organs to patients waiting for an organ transplant and the Scientific Registry of Transplant Recipients that provides analytic support to the OPTN in the development and assessment of organ allocation and other OPTN policies; (2) administers the C.W. Bill Young Cell Transplantation Program to increase the number of unrelated blood stem cell transplants and improve the outcomes of blood stem cell transplants; (3) administers the National Cord Blood Inventory (NCBI) to increase the number of high quality cord blood units available for transplantation; (4) develops and maintains a national program of grants and contracts to organ procurement organizations and other entities to increase the number of organs made available for transplantation; (5) manages the national program for compliance with the Hill-Burton uncompensated care requirement and other assurances; (6) directs and administers a congressionally-directed grant program for the construction/renovation/equipping of health care and other facilities; (7) directs and administers the National Vaccine Injury Compensation Program; (8) manages and promotes the 340B Drug Pricing Program; (9) directs and administers the Poison Center Support, Enhancement, and Awareness Act; (10) directs and administers the State Health Access Program that awards grants to States to expand access to affordable healthcare coverage for people who are uninsured; and (11) implements and administers the Countermeasures Injury Compensation Program (CICP) under PREP Act authorities.

The Poison Control Program (PCP) administers the activities authorized by the Poison Center Support, Enhancement and Awareness Act of 2008, which includes: (1) Maintaining the national toll-free Poison Help hotline (800–222–1222), connecting callers to their local poison control center; (2) implementing and expanding a national media campaign to educate the public and health care providers about poison prevention and the availability of local poison control centers; and (3) awarding grants to certified poison control centers for the purposes of preventing and providing treatment recommendations for poisonings.

The Countermeasures Injury Compensation Program (CICP) administers the Federal compensation program established by the Public Readiness and Emergency Preparedness Act ("PREP Act") enacted as Division C of the Defense Appropriations Act for fiscal year 2006, Public Law 109–148, which added new authorities under the Public Health Service (PHS) Act to alleviate concerns about liability related to the manufacture, testing, development, distribution, administration, and use of countermeasures against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics. The Office discharges all PREP Act authorities regarding compensation including: (1) Developing and disseminating requests for benefits information to inform individuals that the CICP exists so that people requesting benefits do not miss the 1-year filing deadline; (2) accepting letters of intent to file requests for benefits so that individuals preserve their rights to file by the 1-year deadline; (3) evaluation of requests for benefits for compensation filed under the CICP through medical review and assessment of compensability for all complete claims; (4) processing of requests for benefits made under the CICP; (5) promulgation of regulations to create and revise the CICP Vaccine Injury Tables; (6) development and maintenance of all automated information systems necessary for Program implementation; and (7) collection, analysis and dissemination of Program information.

Division of Transplantation (RR1)

The Division of Transplantation (DoT), on behalf of the Secretary of Health and Human Services (HHS), administers national systems to facilitate solid organ and blood stem cell transplantation including: the Organ Transplantation Program (OTP), the C.W. Bill Young Cell Transplantation Program (CWBYCTP), the National Cord Blood Inventory (NCBI), cross-cutting medical activities and the breakthrough collaborative to increase the number of deceased donor organs made available for transplantation.

Division of Health Facilities (RR9)

The Division of Health Facilities (DOHF) substantiates health facilities'

compliance with the Hill-Burton uncompensated services assurance and administers construction grant programs under section 1610(b) of the Public Health Service Act, under the Health Care and Other Facilities (HCOF) program, and under the Patient Protection and Affordable Care Act, Public Law 111–148. Specifically, the Division: (1) Administers the process for awarding new construction and equipment grants, under section 1610(b), the HCOF, and the PPACA programs, including ensuring the delivery of comprehensive architectural and engineering services and ensuring compliance with historic preservation and other laws and regulations related to construction projects, maintains a computerized database of key project information, and provides technical assistance in application preparation to potential grantees under Division grant programs; (2) monitors grant projects during construction to assure compliance with the terms of the award, reviews requests for changes in scope to grant projects, and obtains information needed to close out completed grant projects; (3) establishes, develops, monitors, and enforces the implementation of Hill-Burton regulations, policies, procedures, and guidelines for use by staff and health care facilities; (4) maintains a system for receipt, analysis and disposition of audit appeals by Hill-Burton obligated facilities and for receiving and responding to patient complaints; (5) manages the recovery or waiver of recovery of Federal grant funds process for Titles VI and XVI; (6) manages the national Hill-Burton Hotline to ensure that consumers receive timely and accurate information on the program; and (7) provides architectural and engineering services to other Agencies such as the Administration for Children and Families and the Food and Drug Administration.

Division of Vaccine Injury Compensation (RR4)

This Division of Vaccine Injury Compensation (DVIC) administers all statutory authorities related to the operation of the National Vaccine Injury Compensation Program (VICP) by the: (1) Evaluation of petitions for compensation filed under the VICP through medical review and assessment of compensability for all complete claims; (2) processing of awards for compensation made under the VICP; (3) promulgation of regulations to revise the Vaccine Injury Table; (4) provision of professional and administrative support to the Advisory Commission on Childhood Vaccines (ACCV); (5) development and maintenance of all automated information systems necessary for program implementation; (6) provision and dissemination of program information; and (7) contributes to the understanding of vaccine-related adverse events through the analysis of VICP claims. The VICP maintains a working relationship with other relevant Federal and private sector partners in its administration and operation.

Office of Pharmacy Affairs (RR7)

The Office of Pharmacy Affairs (OPA) promotes access to clinical and cost effective pharmacy services to enable participating entities to stretch scarce Federal resources in order to serve more patients, expand their services or offer additional services. Specifically the office: (1) Manages the 340B involvement of pharmaceutical manufacturers that participate in the Medicaid program, through Pharmaceutical Pricing Agreements; (2) maintains a publicly accessible database of participating covered entities, sites, and contract pharmacies; (3) publishes guidelines/regulations to assist in the understanding and participation in the 340B Program; (4) maintains a Prime Vendor Program to increase the value of the 340B Program; (5) maintains the Pharmacy Services Support Center to assist OPA and the diverse Program stakeholders to understand and make best use of the 340B Program; (6) fosters mutually productive relationships with Federal and private sector partners; (7) provides a national platform for the coordination and development of leading practices for pharmacy services; (8) promotes comprehensive and efficient pharmacy management application and systems use to ensure safe and effective medication use; and (9) manages quality improvement activities such as the Patient Safety and Clinical Pharmacy Services Collaborative.

Section RR–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is upon date of signature.

Dated: March 28, 2011.

Mary K. Wakefield,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

New Molecules for HIV Therapeutics: Fab, scFv, and Related Binding Molecules Specific for HIV–1 Rev

Description of Invention: The invention offered for licensing and commercial development is in the field of HIV therapeutics. More specifically, the invention relates to methods and compositions for treating and/or inhibiting HIV infection or any other lentivirus. The invention describes the identification, though phage display, of a chimeric rabbit/human anti-Rev Fab (SJS–R1) that can inhibit polymerization of the HIV Rev protein and thus inhibit its normal function in virus replication. The Fab binds with very high affinity to a conformational epitope in the N-terminal half of HIV–1 Rev. The corresponding single chain antibody (scFv) was also prepared and characterized. Methods of making and using SJS–R1 Fab and SJS–R1 scFv, and antibodies and antibody fragments that share at least one CDR with SJS–R1 Fab, are provided. Specific described methods include methods of preventing or reversing polymerization of HIV Rev, methods of reducing infectivity of replication of a lentivirus, inhibiting Rev function in a cell infected with a lentivirus, and methods of treating a