



FDA U.S. FOOD & DRUG
ADMINISTRATION

July 15, 2021

Fred Turner
Chief Executive Officer
Curative Inc.
1600 Adams Drive, Suite 105
Menlo Park, CA 94025
Re: Revocation of EUA200132

Dear Mr. Turner:

This letter is in response to Curative Inc.'s (Curative) request dated June 16, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200132) for the Curative SARS-CoV-2 Assay issued on April 16, 2020, under the original name Curative-Korva SARS-CoV-2 Assay, and amended on June 11, 2020. As was also announced in its June 16, 2021 press release,¹ Curative has indicated that it is transitioning to the use of different EUA-authorized SARS-CoV-2 tests for the testing offered at its laboratories. In its June 16 letter, Curative requested that the revocation of the Curative SARS-CoV-2 Assay be effective July 15, 2021, noting that it will no longer be in use as of July 15, 2021.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Curative has notified FDA that it will no longer be using the Curative SARS-CoV-2 Assay as of July 15, 2021 and requests FDA revoke the authorization effective that day, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200132 for the Curative SARS-CoV-2 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Curative SARS-CoV-2 Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

Denise M. Hinton -S
Digitally signed by
Denise M. Hinton -S
Date: 2021.07.15
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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

¹ <https://www.prnewswire.com/news-releases/curative-expands-testing-options-for-covid-19-flu-and-rsv-across-nationwide-healthcare-delivery-network-301314095.html>

Dated: August 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions, and Delegations of Authority

Part R (Health Resources and Services Administration) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human

Services (60 FR 56605, as amended November 6, 1995; as last amended at 86 FR 6344-6349 dated January 21, 2021) is amended to reorganize sections of the Office of the Administrator, the Healthcare Systems Bureau, and the Bureau of Primary Health Care.

Key functional changes include re-establishing, retaining and renaming the Healthcare Systems Bureau to the Health Systems Bureau; changing the name of the Office of Provider Support to the Provider Relief Bureau; changing the name of the Office of Regional

Operations to the Office of Intergovernmental and External Affairs; updating the division structure within the Office of Planning, Analysis and Evaluation; updating the organization and functional statement for the Office of Federal Assistance Management; and realigning the external engagement function from the Office of Planning, Analysis and Evaluation and the Tribal Affairs activities from the Office of Health Equity to the renamed Office of Intergovernmental and External Affairs.

This reorganization establishes, updates, realigns, and/or deletes the organization, functions, and delegation of authority for the (1) Health Resources and Services Administration (R); (2) Office of the Administrator (RA); (3) Office for the Advancement of Telehealth (RA3); (4) Office of Special Health Initiatives (RA4); (5) Office of Planning, Analysis and Evaluation (RA5); (6) Office of Provider Support (RD); (6) Bureau of Primary Health Care (RC); (7) Office of Federal Assistance Management (RJ); (8) Office of Regional Operations; and (9) Healthcare Systems Bureau (RR).

Chapter R—Health Resources and Services Administration

Section R.10 Organization

Delete the organization for the Health Resources and Services Administration (R) in its entirety and replace with the following:

The Health Resources and Services Administration (R) is headed by the Administrator, who reports directly to the Secretary, HHS. The Health Resources and Services Administration includes the following components:

- Office of the Administrator (RA);
- Office of Operations (RB);
- Office of Federal Assistance Management (RJ);
- Office of Intergovernmental and External Affairs (RE);
- Bureau of Health Workforce (RQ);
- Bureau of Primary Health Care (RC);
- HIV/AIDS Bureau (RV);
- Federal Office of Rural Health Policy (RH);
- Health Systems Bureau (RR);
- Maternal and Child Health Bureau (RM); and
- Provider Relief Bureau (RD).

Chapter RA—Office of the Administrator

Section RA.10 Organization

Delete the organization for the Office of the Administrator (RA) in its entirety and replace with the following:

- Immediate Office of the Administrator (RA);
- Office of Civil Rights, Diversity and Inclusion (RA2);

- Office for the Advancement of Telehealth (RA3);
 - Telehealth Innovation and Services Division (RA31);
- Office of Special Health Initiatives (RA4);
 - Office of Pharmacy Affairs (RA41);
 - Office of Global Health (RA42);
 - Division of Global Programs (RA421);
- Office of Planning, Analysis and Evaluation (RA5);
 - Division of Performance and Quality Management (RA5A);
 - Division of Oversight, Reporting and Regulatory Compliance (RA5B);
 - Division of Data Governance and Strategic Analysis (RA5C);
 - Division of Strategic Initiatives (RA5D);
- Office of Communications (RA6);
- Office of Legislation (RAE);
- Office of Health Equity (RAB); and
- Office of Women's Health (RAW).

Section RA.20 Function

(1) Delete the functional statement for the Immediate Office of the Administrator (RA) in its entirety and replace; (2) delete the functional statement for the Office for the Advancement of Telehealth (RA3) in its entirety and replace; (3) delete the functional statement for the Office of Special Health Initiatives, Office of the Director (RA4) and replace; (4) delete the functional statement for Division of Injury Compensation Programs and move to the Health Systems Bureau (RR); and (5) delete the functional statement for the Office of Planning, Analysis, and Evaluation (RA5) in its entirety and replace.

Immediate Office of the Administrator (RA)

The Immediate Office of the Administrator for the Health Resources and Services Administration (HRSA) leads and directs programs and activities of the agency and advises the Office of the Secretary of Health and Human Services on policy matters concerning them. Specifically, the Immediate Office of the Administrator: (1) Provides consultation and assistance to senior agency officials and others on clinical, health care delivery, and health workforce issues; (2) serves as the agency's focal point on efforts to strengthen the practice of public health as it pertains to the HRSA mission; (3) establishes and maintains communication with health organizations in the public and private sectors; (4) coordinates the agency's policy development, data strategy, evaluation and research planning processes; (5) manages the legislative

analysis and engagement for the agency; (6) administers HRSA's equal opportunity and civil rights activities; (7) provides overall leadership, direction, coordination and planning in support of the agency's special health initiatives; (8) manages programs to advance the use of telehealth and coordination of health information technology; (9) manages HRSA's global health issues, including the President's Emergency Plan For AIDS Relief (PEPFAR); (10) administers PEPFAR grants and oversees HRSA's implementation of PEPFAR funding and activities; (11) leads HRSA's efforts to improve the health, wellness, and safety of women and girls through policy, programming and outreach/education; (12) provides leadership and policy development in the administration of the 340B Drug Pricing Program; (13) implements efforts to advance health equity in HRSA programs; and (14) provides cross-cutting leadership on HRSA's behavioral health and oral health programs.

Office for the Advancement of Telehealth (RA3)

Office of the Director (RA3)

The Office for the Advancement of Telehealth (1) promotes the use of telehealth technologies for health care delivery, education, and health information services; (2) serves as the central focal point for the Department of Health and Human Services (HHS) efforts in leveraging telehealth programs and policies to improve access, enhance outcomes, and support clinicians and patients; (3) administers grant programs focused on telehealth for direct services, research, and technical assistance; (4) advances the provision of telehealth services to rural and underserved communities; (5) builds the evidence-base for telehealth research; (6) manages *Telehealth.HHS.gov* as the HHS hub for telehealth resources for both patients and health care providers; (7) collaborates with HHS components and other federal agencies to improve access to telehealth and broadband services; (8) provides overall direction and leadership over the management of programs to advance the use of telehealth; (9) provides professional assistance and support in developing telehealth initiatives; (10) provides consultation to and coordinates activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations to leverage telehealth to improve access to care, enhance outcomes, and support clinicians and patients; (11) promotes

the use of telehealth technologies for health care delivery, education and health information services; and (12) serves as the operational focal point for coordinating and advancing the use of telehealth technologies across all of HRSA's programs including, but not limited to, the provision of health care at a distance (telemedicine), distance based learning to improve the knowledge of agency grantees and others, and improved information dissemination to both consumers and providers about the latest developments in telemedicine.

Telehealth Innovation and Services Division (RA31)

The Telehealth Innovation and Services Division serves as the focal point in the Office for the Advancement of Telehealth to support innovative grant programs for direct services and technical assistance in the field of telehealth. Specifically, the Telehealth Services Division carries out the following functions: (1) Develops and coordinates telehealth network grant programs, telehealth resource center grant programs, the telehealth centers of excellence, the licensure portability grant program, and the telehealth broadband pilot program; (2) administers grant programs to promulgate and evaluate the use of appropriate telehealth technologies among HRSA grantees and others; (3) monitors the performance of telehealth grant programs, making programmatic recommendations and providing assistance to improve performance, where appropriate; (4) coordinates and provides technical assistance and expertise to grantees of funded programs; and (5) develops funding opportunity announcements and program guidance documents.

Office of Special Health Initiatives (RA4)

Office of the Director (RA4)

The Office of Special Health Initiatives (OSHI) provides a crosscutting focal point for HRSA to deliver on population health and Secretarial priorities, especially those that may be more clinical in nature. Specifically, OSHI (1) coordinates and collaborates with components in HHS that align with the work of OSHI; (2) serves as the principal advisor within HRSA on global health issues; (3) provides agency-wide leadership and policy development in the administration of the 340B Drug Pricing Program to promote access to clinically and cost effective pharmacy services to the country's most vulnerable patient

populations; (4) serves as the lead on behavioral health issues that span HRSA; and (5) provides cross-cutting leadership on HRSA oral health programs.

Office of Planning, Analysis and Evaluation (RA5)

Office of the Director (RA5)

The Office of Planning, Analysis and Evaluation provides (1) agency-wide leadership for performance management and data governance; (2) directs the agency's long term strategic planning process; (3) conducts and/or guides analyses, research, and program evaluation; (4) facilitates policy development by serving as the analytic liaison between the Administrator, other Operating/Staff Divisions, Office of the Secretary staff components, and other Departments on critical matters involving agency program policies; (5) provides oversight and coordination of program performance reports and plans, including to the Department and OMB; (6) provides support, agency direction, and leadership for HRSA's data-driven, health quality efforts; (7) coordinates the agency's participation in Department and federal strategic initiatives related to organizational performance and implementation of executive directives; (8) coordinates HRSA innovation activities across the agency and with HHS Operating/Staff Divisions to support HRSA programs and operations; (9) provides data-driven technical assistance to agency programs in order to help them respond to emerging issues affecting the health care safety net; (10) conducts special studies and analyses and/or provides analytic support and information to support the agency's goals and directions; (11) oversees and coordinates HRSA innovation activities, including the identification of agency capability gaps and potential solutions to fill the gaps; (12) directs life cycle management of innovation pilot programs and challenge competitions; (13) provides technical assistance to HRSA divisions in the identification of areas for innovation, including funding and solution development; (14) collaborates with other HHS agencies to promote innovation and resource sharing; and (15) leads external innovation partnership development to enhance HRSA staff awareness of non-governmental innovations that could benefit the agency.

Division of Performance and Quality Management (RA5A)

The Division of Performance and Quality Management (1) serves as the principal agency resource for

performance and quality measurement (2) leads HRSA implementation of program performance-related legislation; (3) produces regular HRSA-wide program performance reports and plans in compliance legislative, OMB, and departmental directives; (4) assists HRSA divisions in the selection, development, maintenance, and alignment of performance measures; (5) leads HRSA strategic planning processes and serves as primary liaison to HHS in the development of the Department's strategic plan and associated requirements; (6) provides support, policy direction, and leadership for HRSA's health quality measurement efforts; (7) collaborates with other HHS agencies to promote improvements in the availability of performance- and quality-related information; (8) serves as HRSA liaison to the Department in the development of HHS research and evaluation initiatives; (9) coordinates HRSA's survey activities; (10) conducts, guides, and/or participates in major program evaluation efforts and prepares reports on HRSA program efficiencies; (11) coordinates the HRSA-wide evaluation resource investments; (12) performs technical assistance to support HRSA program staff development and implement program evaluations, and (13) coordinates HRSA input for the Healthy People initiative.

Division of Oversight, Reporting and Regulatory Compliance (RA5B)

The Division of Oversight, Reporting and Regulatory Compliance (1) serves as the agency liaison to manage and coordinate study engagements with the Government Accountability Office and the HHS Office of the Inspector General, Office of Evaluation and Inspections; (2) manages coordination with the Department and OMB for oversight, reporting, and compliance policies, engagements, and requirements; (3) provides technical assistance to support HRSA program staff development to meet compliance-related reporting requirements; (4) coordinates HRSA participation in institutional review boards, the protection of human subjects, and serves as the agency's Privacy Act Officer; (5) manages HRSA activity related to the Paperwork Reduction Act, and other OMB policies; (6) leads the Data Disclosure Review Board; and (7) serves as the agency lead to oversee development and management of Agency Data Use Agreements.

Division of Data Governance and Strategic Analysis (RA5C)

The Division of Data Governance and Strategic Analysis (1) leads

development and implementation of the HRSA Data Strategic Plan; (2) serves as the agency lead in the coordination of all data governance and analytics; (3) analyzes and coordinates HRSA's need for information and data for use in the management and direction of agency programs; (4) catalyzes new capabilities in data-related activities by providing agency leadership and coordination; (5) maintains an inventory of HRSA databases; (6) promotes the availability of HRSA data through websites and other on-line applications; (7) serves as the principal agency resource for policy analysis; (8) analyzes issues arising from legislation, budget proposals, regulatory actions, and other program or policy actions; (9) serves as focal point within HRSA for analysis of health care payment systems and financing issues; (10) conducts HRSA-wide trainings on health care policy and financing issues; and (11) collaborates with HHS Operating/Staff Divisions to examine the impact of Medicare, Medicaid, and Children's Health Insurance Program on HRSA grantees and safety net providers.

Division of Strategic Initiatives (RA5D)

The Division of Strategic Initiatives (1) provides HRSA-wide leadership on cross-agency initiatives and departmental priorities; (2) serves as agency lead and liaison between the Administrator, other Operating/Staff Divisions, Office of the Secretary staff components, and other Departments on priority initiatives; (3) provides technical assistance to agency programs in order to help them respond to emerging issues affecting the health care safety net; and (4) provides agency leadership and guidance on policy development.

Chapter RC—Bureau of Primary Health Care (RC)

Section RC.10 Organization

Delete the organization for the Bureau of Primary Health Care (RC) in its entirety and replace with the following:

The Bureau of Primary Health Care (RC) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Bureau of Primary Health Care (RC) includes the following components:

- Office of the Associate Administrator (RC);
- Division of Workforce Management (RC2);
- Office of Strategic Business Operations (RCA);
- Office of Health Center Investment Oversight (RCC);
- Office of Health Center Program Monitoring (RCF);

- Office of Policy and Program Development (RCH); and
- Office of Quality Improvement (RCK).

Section RC.20 Function

(1) Delete the functional statement for the Office of the Associate Administrator and replace in its entirety; (2) delete the functional statement for the Office of Policy and Program Development (RCH); and (3) delete the functional statement for the Division of National Hansen's Disease Program (RC4) and move to the Health Systems Bureau (RR).

Office of the Associate Administrator (RC)

Provides overall leadership, direction, coordination, and planning in support of the Bureau of Primary Health Care's programs. Specifically, the Office of the Associate Administrator: (1) Establishes program goals, objectives, and priorities, and provides oversight to their execution; (2) plans, directs, coordinates, supports, and evaluates bureau wide management activities; and (3) maintains effective relationships within HRSA and with other HHS organizations, other federal agencies, state and local governments, and other public and private organizations concerned with primary health care, eliminating health disparities, and improving the health status of the nation's underserved and vulnerable populations.

Office of Policy and Program Development (RCH)

The Office of Policy and Program Development serves as the organizational focus for the development of the Bureau of Primary Health Care programs and policies. Specifically, the Office of Policy and Program Development: (1) Leads and monitors the strategic development of primary care programs, including health centers, special population programs, and other health systems; (2) provides assistance to communities, community-based organizations, and bureau programs related to the development and expansion of primary care; (3) develops bureau capital programs and oversees loan guarantee programs; (4) leads and coordinates the analysis, development, and drafting of budget and policy impacting bureau programs; (5) provides support to the National Advisory Council on Migrant Health; (6) performs environmental scanning on issues that affect bureau programs; and (7) consults and coordinates with other components within HRSA and HHS, and with other federal agencies, state

and local governments, and other public and private organizations on issues affecting bureau programs and policies.

Chapter RD—Provider Relief Bureau (RD)

Section RD.10 Organization

Rename the Office of Provider Support to the Provider Relief Bureau.

The Provider Relief Bureau (RD) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Provider Relief Bureau includes the following components:

- Office of the Associate Administrator (RD);
- Division of Policy and Program Operations (RD1);
- Division of Customer Support (RD2); and
- Division of Data Analytics and Program Integrity (RD3).

Chapter RE—Office of Intergovernmental and External Affairs (RE)

Section RE.10 Organization

Rename the Office of Regional Operations to the Office of Intergovernmental and External Affairs (RE).

The Office of Intergovernmental and External Affairs (RE) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA, and includes the following components:

- Office of the Associate Administrator (RE);
- Boston Regional Office (RE1);
- New York Regional Office (RE2);
- Philadelphia Regional Office (RE3);
- Atlanta Regional Office (RE4);
- Chicago Regional Office (RE5);
- Dallas Regional Office (RE6);
- Kansas City Regional Office (RE7);
- Denver Regional Office (RE8);
- San Francisco Regional Office (RE9); and
- Seattle Regional Office (RE10).

Section RE.20 Function

Delete the functional statement for the Office of Regional Operations and replace with the following:

Office of Intergovernmental and External Affairs (RE)

The Office of Intergovernmental and External Affairs serves as the principal Agency lead on intergovernmental and external affairs, regional operations, and tribal partnerships. The Office serves as the Agency liaison to the HHS Office of Intergovernmental and External Affairs. Specifically, the Office: (1) Provides the HRSA Administrator and agency leadership with a single point of contact

on all intergovernmental, stakeholder associations, and interest groups activities; (2) serves as the primary liaison to Department and other federal intergovernmental staff; (3) manages agency cross-Bureau cooperative agreements and activities with national organizations of state and local health leaders and elected officials; (4) coordinates tribal activities across the agency and strengthens HRSA's unique relationships with tribes; (5) coordinates HRSA activities with regional commissions, such as the Delta, Appalachian, Denali and Border Health commissions; (6) functions as the regional component of HRSA by providing leadership on HRSA's mission and priorities across headquarters, regions, states, tribes, territories, and local communities; (7) conducts outreach to expand knowledge of HRSA's programs to advance agency and Department priorities; (8) generates and sustains collaborative efforts with state and jurisdictional health care leaders to align HRSA and other resources; (9) presents regional surveillance and analysis of health care trends and makes recommendations to HRSA leadership, government officials and stakeholders to improve policies and programs; (10) exercises management authority for general administration of HRSA's regional offices; and (11) manages HRSA's Tribal Advisory Council, participates in HHS Tribal Consultations and collaborates with IHS and other federal and community stakeholders to address tribal issues.

Chapter RJ—Office of Federal Assistance Management (RJ)

Section RJ.10 Organization

Delete the organization for the Office of Federal Assistance Management (RJ) in its entirety and replace with the following:

The Office of Federal Assistance Management (RJ) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Office of Federal Assistance Management includes the following components:

- Office of the Associate Administrator (RJ);
- Office of Operations Management (RJA);
- Office of Systems and Data (RJB);
- Division of Financial Integrity (RJ1);
- Division of Grants Policy and Planning (RJ2);
- Division of Grants Management Operations (RJ3); and
- Division of Independent Review (RJ4).

Section RJ.20 Function

Delete the functional statement for the Office of the Federal Assistance Management (RJ) in its entirety and replace:

Office of Federal Assistance Management (RJ)

The Office of Federal Assistance Management (OFAM) provides national leadership in the administration and assurance of the financial integrity of HRSA's programs. Provides leadership, direction, and coordination to all phases of grants policy, administration, and independent review of Competitive grant applications. Specifically, OFAM: (1) Serves as the Administrator's principal source for grants policy and financial integrity of HRSA programs; (2) exercises oversight over the agency's business processes related to assistance programs; (3) facilitates, plans, directs, and coordinates the administration of HRSA grant policies and operations; (4) directs and carries out the independent review of grant applications for all of HRSA's programs; (5) exercises the responsibility within HRSA for grant and cooperative agreement receipt, award, and post-award processes; and (6) plans, directs plus manages the electronic systems and business operations that enable staff to perform their day-to-day work.

Office of Operations Management (RJA)

The Office of Operations Management provides OFAM-wide strategic organizational management and direction. Plans, directs and coordinates OFAM-wide business operations and administrative management activities. Specifically, the Office of Operations Management: (1) Serves as the principal source for administrative operations advice and assistance; (2) provides guidance and coordinates personnel activities for OFAM; (3) provides organization and management analysis, coordinating the allocation of personnel resources, developing policies and procedures for internal operations, interpreting and implementing OFAM management policies and procedures and systems; (4) develops and coordinates OFAM administrative delegations of authority activities (5) lead, plan, and coordinate all OFAM budgetary activities, such as contacts, procurements and inter-agency agreements, as well as, provides guidance and support to OFAM leadership in these areas; (6) provides OFAM-wide support services such as acquisition support, travel coordination, supply management, equipment utilization, printing, property

management, space management, records management, and management reports; (7) coordinates OFAM administrative management activities with other components within HRSA and HHS, and with other federal agencies, as appropriate; and (8) provides overall support for OFAM's continuity of operations and emergency support.

Office of Systems and Data (RJB)

The Office of Systems and Data provides strategic management and direction for OFAM-wide efforts addressing data analysis, evaluation and systems. Specifically, the Office of Systems and Data: (1) Coordinates and analyzes the agency's need for federal assistance data for all programs; (2) collects federal assistance data to quantify and measure financial assistance data for evaluation at the national level (3) provides coordination and strategic guidance for OFAM's Management of the Electronic Handbook, *Grants.gov*, and other Information Technology systems; (4) coordinates OFAM's Electronic Handbook data requests, dashboard and report development; and provides guidance on data management laws, regulations, governances and policy; (5) develops and manages OFAM performance measures; and (6) manages and maintains current data on all electronic sites.

Division of Financial Integrity (RJ1)

The Division of Financial Integrity: (1) Coordinates agency-wide efforts addressing HHS's Program Integrity Initiative/Enterprise Risk Management; (2) serves as the agency's focal point for resolving audit findings on HRSA programs resulting from the Single Audits and special reviews; (3) conducts financial and compliance reviews of non-federal entities use of HRSA funds; (4) conducts the pre-award financial assessment of HRSA non-federal entities; (5) conducts the pre-award and post-award review of grant applicant's and non-federal entities financial soundness and management including accounting systems for managing federal grants; (6) conducts ad hoc studies and reviews related to the financial integrity of the HRSA business processes related to assistance programs; (7) serves as the agency's liaison with the Office of Inspector General for issues related to HRSA programs; (8) coordinates non-federal entities appeal actions for the Department on HRSA decisions related to HRSA programs; (9) coordinates the preparation of informational reports on high risk non-federal entities; (10) coordinates contractor audit/financial

assessment assignments; (11) responds to data requests; (12) serves as the HRSA liaison with the Department on the Single Audit Compliance Supplement update; (13) conducts internal audits; and (14) serves as the outreach to HRSA staff and non-federal entities to increase monitoring efforts for non-federal entities.

Division of Grants Policy and Planning (RJ2)

The Division of Grants Policy and Planning analyzes, develops and implements HRSA's federal assistance award policy in compliance with statutes, regulations, Government-wide administrative requirements and Departmental policy. The Division recommends internal procedures to ensure consistent and effective stewardship of taxpayer dollars.

Division of Grants Management Operations (RJ3)

The Division of Grants Management Operations exercises responsibility within HRSA for all business aspects of grant and cooperative agreement award and post-award processes, and participates in the planning, development, and implementation of policies and procedures for grants and other federal financial assistance mechanisms. Specifically, the Division of Grants Management Operations: (1) Plans, directs and carries out the grants officer functions for all of HRSA's grant programs as well as awarding official functions for various scholarship, loan, and loan repayment assistance programs; (2) participates in the planning, development, and implementation of policies and procedures for grants and cooperative agreements; (3) provides assistance and technical consultation to program offices and grantees in the application of laws, regulations, policies, and guidelines relative to the agency's grant and cooperative agreement programs; (4) develops standard operating procedures, methods, and materials for the administration of the agency's grants programs; (5) establishes standards and guides for grants management operations; (6) reviews grantee financial status reports and prepares reports and analyses on the grantee's use of funds; (7) provides technical assistance to applicants and grantees on financial and administrative aspects of grant projects; (8) provides data and analyses as necessary for budget planning, hearings, operational planning, and management decisions; (9) participates in the development of program guidance and instructions for grant competitions; (10) oversees contracts in support of receipt

of applications, records management, and grant closeout operations; and (11) supports post-award monitoring and closeout by analyzing payment management system data and working with grants and program office staff.

Division of Independent Review (RJ4)

The Division of Independent Review is responsible for the management and oversight of HRSA's independent review of grant and cooperative agreement applications for funding. Specifically, the Division of Independent Review: (1) Plans, directs, and carries out HRSA's independent review of applications for grants and cooperative agreement funding, and assures that the process is fair, open, and competitive; (2) develops, implements, and maintains policies and procedures necessary to carry out the agency's independent review/peer review processes; (3) provides technical assistance to independent reviewers ensuring that reviewers are aware of and comply with appropriate administrative policies and regulations; (4) provides technical advice and guidance to the agency regarding the independent review processes; (5) coordinates and assures the development of program policies and rules relating to HRSA's extramural grant activities; and (6) provides HRSA's Offices and Bureaus with the final disposition of all reviewed applications.

Chapter RR—Health Systems Bureau

Section RR.10 Organization

Re-establish, retain and rename the Health Systems Bureau (RR). The Health Systems Bureau (RR) is headed by the Associate Administrator, who reports directly to the Administrator, HRSA. The Health Systems Bureau (RR) includes the following components:

- Office of the Associate Administrator (RR);
- Division of Transplantation (RR1);
- Division of Injury Compensation Programs (RR4); and
- Division of National Hansen's Disease Program (RRH).

Section RR.20 Function

Establish the following functional statement for the Health Systems Bureau (RR):

Office of the Associate Administrator (RR)

The Health Systems Bureau leads the agency in providing health care programs to eligible organizations around the country. Specifically, the Health Systems Bureau (1) oversees the implementation of blood stem cell and organ transplantation programs; (2)

manages the national program for compliance with the Hill-Burton uncompensated care requirement and other assurances; (3) administers community based and other grant awards; (4) directs and administers the National Vaccine Injury Compensation Program; (5) implements and administers the Countermeasures Injury Compensation Program; (6) provides professional and administrative support for the HHS Medical Review Claims Panel; and (7) manages the National Hansen's Disease Program in accordance with regulations of the Public Health Service.

Division of Transplantation (RR1)

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

Division of Injury Compensation Programs (RR4)

The Division of Injury Compensation Programs, on behalf of the Secretary of HHS, implements all statutory and charter authorities related to the operations of the National Vaccine Injury Compensation Program, the Countermeasures Injury Compensation Program, and the HHS Medical Review Claims Panel by: (1) Evaluating claims for compensation filed under the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program through medical review and assessment of compensability for all complete claims; (2) processing awards for compensation made under the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program; (3) promulgating regulations to develop and revise Vaccine and Countermeasures Injury Tables; (4) providing professional and administrative support to the Advisory Commission on Childhood Vaccines (ACCV) and the Medical Claims Review Panel; (5) maintaining responsibility for activities related to the ACCV; (8) maintaining a working relationship with the Department of Justice (DOJ) and the U.S. Court of Federal Claims through the DOJ, in the administration and operation of the National Vaccine Injury Compensation Program; (9) providing management, direction, budgetary

oversight, coordination, and logistical support for the Medical Expert Panel, as well as Clinical Reviewer contracts; (10) developing, reviewing, and analyzing pending and new legislation relating to program changes, new initiatives, the ACCV, and changes to the Vaccine and Countermeasures Injury Tables; (11) providing programmatic outreach efforts to maximize public exposure to private and public constituencies; and (12) providing guidance in using the results and decisions of the Medical Claims Review Panel to HHS Operating Divisions to improve the quality of health care in its facilities and by its practitioners.

Division of National Hansen's Disease Program (RRH)

The National Hansen's Disease Program, in accordance with regulations and the Public Health Service (PHS) Act, Sec. 320 as amended by Public Law 105–78, Sec. 211, (1) provides care and treatment for persons with Hansen's Disease (leprosy), including managing a national short-term and outpatient health care delivery program providing specialized services to persons with Hansen's Disease; (2) conducts and promotes the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of Hansen's disease and other mycobacterial diseases and complications related to such diseases; (3) conducts training in the diagnosis and management of Hansen's disease and related complications; (4) provides education and training to staff from the outpatient Hansen's Disease Clinics and to private physicians; (5) operates and oversees the National Hansen's Disease Museum and Cemetery; (6) consults on the coordination of activities within HRSA and HHS, and with other federal agencies, state and local governments, and other public and private organizations involved in Hansen's Disease activities; and (7) manages a network of contracted outpatient clinics providing care to persons with Hansen's Disease; and (8) manages and coordinates the National Hansen's Disease Program's administrative and operational activities with HRSA and HHS; other federal agencies, state and local governments; and other public and private organizations involved in Hansen's Disease activities.

Section R.30 Delegation of Authority

All prior delegations of authority and re-delegations of authority consistent with this reorganization are in effect. I affirm and ratify any actions taken by

HHS officials that involved the exercise of those authorities prior to the effective date of this reorganization.

(Authority: 44 U.S.C. 3101)

Dated: August 6, 2021.

Xavier Becerra,
Secretary.

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BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for the opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 1, 2021.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157—Revision.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary, by contract, provide for the establishment and operation of a private, non-profit entity: The Organ Procurement and Transplantation Network (OPTN). The data collected pursuant to the OPTN's regulatory authority in 42 CFR 121.11 of the OPTN Final Rule is collected through OMB approved data collection forms. Therefore, data approved for collection by the OPTN Board of Directors are submitted by HRSA for OMB approval under the Paperwork Reduction Act of 1995.

This is a request for revising the current OPTN data collection associated with an individual's clinical characteristics at the time of registration, transplant, and follow-up after the transplant to include data collection forms in the OPTN Organ Labeling, Packaging, and Tracking System, the OPTN Kidney Paired Donation Pilot Program (KPDPP), and the OPTN Patient Safety Reporting Portal (PSRP). This revision also includes OPTN Board of Directors approved changes to the existing OMB data collection forms. These specific data elements of the OPTN data system are collected from transplant hospitals, organ procurement organizations, and histocompatibility laboratories. The information is used to (1) facilitate organ placement and match donor organs with recipients; (2) monitor compliance of member organizations with Federal laws and regulations and with OPTN requirements; (3) review and report periodically to the public on the status of organ donation and transplantation in the United States; (4) provide data to researchers and government agencies to study the scientific and clinical status of organ transplantation; (5) perform transplantation-related public health surveillance including the possible transmission of donor disease.

HRSA is submitting the following changes to improve the OPTN organ matching and allocation process and improve OPTN member compliance with OPTN requirements. All of these proposed changes have been approved by the OPTN Board of Directors.

(1) Adding two data collection forms for the OPTN Organ Labeling, Packaging, and Tracking System to the existing OMB approved Data System for Organ Procurement and Transplantation Network. The system has two forms that are used through mobile and web-based applications to ensure the correct organ is transplanted into the correct patient, minimize labeling and transport errors, accelerate organ information transfer,