the identification and tracing of certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee-1), which established product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Section 582 of the FD&C Act also imposed requirements for enhanced drug distribution security that go into effect on November 27, 2023.

Trading partners, along with Federal and State authorities, have an important role in ensuring the quality of prescription drugs and protecting the integrity of the pharmaceutical distribution supply chain. The DSCSA requirements, which have been phased in since 2013, improve supply chain security activities by trading partners involved in prescription drug manufacturing, repackaging, wholesale distribution, warehousing or related logistical activities, and dispensing. The gradual implementation of the DSCSA requirements for product tracing, product identification, authorized trading partners, and verification facilitates the development of electronic interoperability to enhance the security of the pharmaceutical distribution supply chain.

Section 582(g)(1) of the FD&C Act sets forth the requirements for enhanced drug distribution security as of November 27, 2023, including (as described in that provision and generally summarized here):

- The exchange of transaction information and transaction statements in a secure, interoperable, electronic manner.
- Transaction information that includes the product identifier at the package level for each package included in the transaction.
- Systems and processes for verification of product at the package level.
- Systems and processes needed to promptly respond to requests from FDA (or other appropriate Federal or State officials) for product transaction information in the event of a recall or to investigate suspect and illegitimate products.

This guidance clarifies the enhanced drug distribution security requirements and pursuant to section 582(h)(3) of the FD&C Act describes recommendations for system attributes necessary for enhanced product tracing and enhanced verification, including when the use of aggregation and inference may be appropriate.

This guidance finalizes the draft guidance entitled ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act'' issued on June 4, 2021 (86 FR 30053). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include removal of the term ''enhanced system'' when referring to the requirements in section 582(g) of the FD&C Act to avoid confusion and clarification of recommendations addressing (1) reconciliation of transaction information, (2) aggregation and inference, and (3) verification of saleable returns, including a brief discussion of the sunset provisions of section 582(k) of the FD&C Act. Changes also include clarification of requirements for provision of certain information in response to requests stemming from investigation of suspect or illegitimate product. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously approved collections of information found in FDA regulations or guidance.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18831 Filed 8–30–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Supporting Healthy Start Performance Project

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

ACTION: Announcing period of performance supplement for the Supporting Healthy Start Performance Project (SHSPP) recipient.

SUMMARY: HRSA will provide supplemental award funds to the current SHSPP recipient, in fiscal year 2023 to provide new and continued support to Healthy Start grant recipients.

FOR FURTHER INFORMATION CONTACT: Rochelle Logan, Healthy Start Team lead, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, Health Resources and Services Administration, at *rlogan@hrsa.gov* or (301) 443–0543.

SUPPLEMENTARY INFORMATION:

Amount of Non-Competitive Award(s): One award for $1,900,000.

Project Period: June 1, 2023, to May 31, 2024.

Assistance Listing (CFDA) Number: 93.926.

Award Instrument: Supplement.

Authority: 42 U.S.C. 254c–8 (title III, section 330H of the Public Health Service Act).

TABLE 1—RECIPIENTS AND AWARD AMOUNTS

Grant No.	Award recipient name	City, state	Award amount
UF5MC32750	National Institute for Children's Health Quality	Boston, MA	$1,900,000

Justification: HRSA will provide supplemental award funds to the current SHSPP recipient in fiscal year 2023 to provide new and continued support to Healthy Start grant recipients. The current recipient of the SHSPP is best positioned to address the objectives that to be supported by the supplemental funds, including supporting data collection and evaluation and implementing applicable Executive Orders.

Carole Johnson,

Administrator.

[FR Doc. 2023–18798 Filed 8–30–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA-Initiated Supplemental Funding to the Supporting Maternal Health Innovation Program

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

ACTION: Notice of supplemental award.

SUMMARY: HRSA is providing supplemental funds not to exceed $1,500,000 to the Supporting Maternal Health Innovation Program, also referred to as the Maternal Health Learning and Innovation Center (MHLIC), in fiscal year (FY) 2023 to provide support and capacity building to HRSA's new maternal health award recipients under the State Maternal Health Innovation (MHI) Program (HRSA–23–108).

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, Chief, Maternal and Women's Health Branch, Division of Healthy Start and Perinatal Services, Maternal and Child Health Bureau, HRSA, at *ksherman@hrsa.gov* or (301) 443–1702.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: One award to the University of North Carolina at Chapel Hill, the current recipient under the Supporting Maternal Health Innovation Program, now known as MHLIC, as listed in Table 1.

Amount of Non-Competitive Award: Up to $1,500,000.

Project Period: September 30, 2019, to September 29, 2024.

CFDA Number: 93.110.

Award Instrument: Supplement.

Authority: 42 U.S.C. 701(a)(2) (title V, section 501(a)(2) of the Social Security Act).

TABLE 1—SUPPORTING MHI PROGRAM AWARD RECIPIENT (2019–2024)

Grant No.	Grantee organization	City, state	Award amount
U7CMC33636	University of North Carolina at Chapel Hill	Raleigh, NC	$1,500,000

Justification: The Consolidated Appropriations Act, 2023 (Pub. L. 117–328) included additional Special Projects of Regional and National Significance funding. The Explanatory Statement accompanying the Consolidated Appropriations Act specified a $26 million increase for the State MHI Program to establish new cooperative agreements in FY 2023 with up to 23 new states. MHLIC provides support and capacity building to HRSA's maternal health award recipients. Supplemental funds to MHLIC will be used to provide support and capacity building to the new cohort of FY 2023 State MHI award recipients. The requested activities are within scope of the Supporting Maternal Health Innovation Program.

Carole Johnson,

Administrator.

[FR Doc. 2023–18799 Filed 8–30–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK SEP High Risk Multi-Center Clinical Study Cooperative Agreement U01.

Date: September 28, 2023.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cheryl Nordstrom, Ph.D., MPH, Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, 301–402–6711, *cheryl.nordstrom@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)