

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Labeling requirements for prescription drugs; §§ 201.56 and 201.57.	414	1.326	549	3,349	1,838,601
Labeling applicable to medical gas containers; §§ 201.161(b) and 201.328.	260	1,663	432,380	0.17 (10 minutes) ..	73,505
Exemption from barcode requirements § 201.25(d)	2	1	2	24	48
Safety labeling required under section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and rebuttal statement.	36	1	36	6	216
Safety labeling changes; posting approved letter on application holder's website.	351	1	351	4	1,404
Exceptions or alternatives to labeling requirements for human drug product held by SNS; § 201.26.	1	1	1	32	32
Hypertension claims; recommended labeling considerations.	5	1	5	18	90
Total			433,324		1,913,896

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our evaluation, we have retained the currently approved estimate that 414 applicants will prepare an average of 549 prescription drug labels annually, and assume it will require 3,349 hours to design, test, and submit to FDA as part of a new drug application or a biologics license application.

New medical gas containers must meet applicable requirements found in 21 CFR part 211, as well as specific labeling requirements in § 201.328. Consistent with statutory authority under the Consolidated Appropriations Act, 2017 (Pub. L. 115–31), we have revised the information collection to include burden associated new medical gas labeling requirements under § 201.161(b), established by a final rule published in the **Federal Register** of June 18, 2024 (89 FR 51738). We estimate 260 respondents will incur burden for the design, testing, production, and submission of labeling for new medical gas containers as established in § 201.328 and assume an average of 10 minutes (0.17) is required for these activities.

Based on our evaluation, few requests for exemption from barcode requirements are received and we have therefore made no changes to the currently approved estimate for this activity. Likewise, we have also retained the currently approved estimate for information collection activities

associated with safety labeling requirements established in section 505(o)(4) of the FD&C Act. Similarly, we retain the currently approved estimate for exceptions to labeling under § 201.26, however this activity was previously approved in OMB control number 0910–0614 and is a new element to the collection, adding 1 response and 32 hours annually.

Finally, we have combined activity elements associated with labeling recommendations regarding drug products that include a hypertension indication as discussed in the applicable guidance, reducing the overall estimate for this element by 4 hours annually.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding, Poison Control Centers Program

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

ACTION: Notice of supplemental award.

SUMMARY: HRSA is awarding supplemental funds in fiscal year 2024 to provide coverage for calls to the toll-free Poison Help line that originate from Puerto Rico. The current program period of performance ends on August 31, 2024.

FOR FURTHER INFORMATION CONTACT: Maureen Perkins, MPH; Team Lead; Poison Control Program; Division of Child, Adolescent and Family Health; Maternal and Child Health Bureau; HRSA, at mperkins@hrsa.gov and 301–443–9163.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: New York City Health & Hospitals Corporation.

Amount of Non-Competitive Award(s): One award of \$265,188.

Project Period: September 1, 2024, to August 31, 2025.

Assistance Listing (CFDA) Number: 93.253.

Award Instrument: Supplement for Poison Control Services.

Authority: 42 U.S.C. 300d–73 (title XII, 1273 of the Public Health Service Act).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	State	Award amount
H4BHS15477	New York City Health & Hospitals Corporation	NY	\$265,188

Justification: This non-competitive supplement will award \$265,188 to New York City Health & Hospitals Corporation to fund the New York City Poison Control Center (NYCPCC) to provide coverage of calls to the toll-free Poison Help line originating from Puerto Rico from September 1, 2024, through August 31, 2025. The Poison Control Program ensures that individuals can call a national toll-free Poison Help line (1-800-222-1222) to connect to a local poison control center in a poisoning emergency. As required by statute, calls to the Poison Help line must be directed to poison control centers that are accredited. In the most recent Notice of Funding Opportunity, HRSA-24-045, no application was received to respond to calls from Puerto Rico. To ensure uninterrupted poison control center coverage for Puerto Rico, HRSA identified NYCPCC as an accredited center that is capable of responding to Puerto Rico’s approximately 5,000 calls annually. NYCPCC historically has been able to provide temporary coverage for Puerto Rico’s calls on an ad hoc basis and has the qualifications, experience, and personnel to do so on a longer-term basis. Funds will be used for project activities within the scope of the current

award (as announced in HRSA-24-045); supplemental funds will support NYCPCC to provide coverage to calls to the Poison Help line originating from Puerto Rico for a period of 1 year. Future funds for coverage for Puerto Rico may be made available in a Notice of Funding Opportunity for a project period of September 1, 2025, to August 31, 2028, subject to the availability of funding for the activity.

Carole Johnson,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Award; Alumni Peer Navigator Services Pilot

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

ACTION: Notice of supplemental award.

SUMMARY: HRSA will provide supplemental award funds in fiscal year

2024 to the current recipient of the Supporting Healthy Start (HS) Performance Project cooperative agreement (HRSA-24-038) to support the second year of the Alumni Peer Navigator (APN) Services Pilot.

FOR FURTHER INFORMATION CONTACT: Aaron M. Lopata, MD, MPP, Senior Medical Officer, Division of HS and Perinatal Services, Maternal and Child Health Bureau, HRSA, at *alopata@hrsa.gov* and (312) 315-4270.

SUPPLEMENTARY INFORMATION:

Intended Recipient(s) of the Award: The National Institute for Children’s Health Quality (NICHQ).

Amount of Competitive or Non-Competitive Award(s): \$601,851.

Supplemental funding for similar activities may be considered in future years, subject to the availability of funding for the activity and the satisfactory performance of the recipient.

Project Period: June 1, 2024, to May 31, 2029.

Assistance Listing (CFDA) Number: 93.926.

Award Instrument: Supplement.

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

TABLE 1—RECIPIENT AND AWARD AMOUNTS

Grant No.	Award recipient name	City, State	Award amount
UF5MC32750	National Institute for Children’s Health Quality	Boston, MA	\$601,851

Justification: NICHQ, as the current HS Technical Assistance Support Center, and recipient of the Supporting HS Performance Project, provides national support to all HRSA HS project grantees. The supplemental funds will support new and continued APN activities. APN activities aim to reduce infant mortality rates, address disparities in maternal and infant health outcomes, and address social determinants of health. APNs are former HS participants who have navigated complex and often disparate health, education, and social services. These former HS participants, known as “peer navigators,” help current HS families by providing guidance and information about public benefits and help to address issues such as food insecurity, unstable housing, and lack of transportation.

NICHQ will use supplemental funds to support HS grantees to implement this peer-to-peer workforce model, the APN Services Pilot. The APN Services Pilot was previously known as the

Benefits Bundle Pilot. The APN Services Pilot is an interagency collaboration between the Department of Health and Human Services and the Office of Management and Budget/U.S. Digital Service.

The pilot consists of five HS projects in Florence, SC, Atlanta, GA, Baton Rouge, LA, Los Angeles, CA and Stoneville, Mississippi.

Carole Johnson,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

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

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.