support to maximize the effectiveness of the 54 Senior Medicare Patrol (SMP) projects in Medicare fraud prevention outreach and education. The administrative supplement for FY 2019 will be for $554,532, bringing the total award for FY 2019 to $1,194,532. With this supplemental funding, NEI3A will develop a targeted marketing and outreach campaign. This includes development of an SMP national video, which will seek to increase awareness of health care fraud and educate the public on when to contact their SMP to report health care fraud, errors, or abuse. An advertisement campaign will be developed to utilize on a national scale and reach Top 20 Markets including Good Morning America and early evening prime time news broadcasts. In addition, NEI3A will explore the possibility of updating one of their previously developed projects, the Personal Health Care Journal, including the possibility of providing a technologically up-to-date SMP application (app). This app would provide beneficiaries with helpful health care tips, important health care contact information, and a place to log their health care appointments for later comparison with Medicare Summary Notices (MSNs) and Explanations of Benefits (EOBs). This tool would be useful in preventing, detecting, and if needed, reporting any health care fraud, errors, or abuse. Lastly, NEI3A will utilize supplemental funding to expand existing contracts with SMP Subject Matter Experts.

Program Name: Senior Medicare Patrol National Resource Center (SMPRC).

Recipient: Northeast Iowa Area Agency on Aging, Inc. (NEI3A).

Period of Performance: The award will be issued for the current project period of September 1, 2019 through August 31, 2020.

Total Award Amount: $1,194,532 in FY 2019.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104–191.

Basis for Award: NEI3A is currently funded to carry out the SMPRC Project for the period of September 1, 2017 through August 31, 2020. Much work has already been completed and further tasks are currently being accomplished. It would be unnecessarily time consuming and disruptive to the SMPRC project and the beneficiaries being served for ACL to establish a new grantee at this time when critical services are presently being provided in an efficient manner.

NEI3A is uniquely placed to complete work under the SMPRC grant. Since 2003, NEI3A has effectively operated the SMPRC. NEI3A has a proven track record for providing assistance through successful working relationships with SMP grantees, is centrally located in a geographic location that boasts low costs, and also houses the State Health Insurance Assistance Program National Technical Assistance Center (SHIP TA Center). By housing both Centers, NEI3A is able to successfully leverage existing activities to lower overall cost and therefore expand capability of serving their target audience.

NEI3A accomplishes its mission by developing and sharing tools, resources, best practices, and strategies for reducing health care fraud, waste, and abuse via its online library, electronic and print publications, webinars, and training and technical assistance.

NEI3A is successfully meeting all programmatic goals under the current SMPRC grant.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Rebecca Kinney, U.S. Department of Health and Human Services, Administration for Community Living, Center for Integrated Programs, Office of Healthcare Information and Counseling; telephone (202) 795–7375; email *Rebecca.Kinney@acl.hhs.gov.*

Dated: July 18, 2019.

Mary Lazare,

Principal Deputy Administrator, Administration for Community Living.

[FR Doc. 2019–15694 Filed 7–23–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3406]

Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2020 annual fee rate for importers approved to participate in the Voluntary Qualified Importer Program (VQIP) that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). This fee is effective August 1, 2019, and will remain in effect through December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Donald Prater, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3202, Silver Spring, MD 20993, 301–348–3007.

SUPPLEMENTARY INFORMATION:

I. Background

Section 302 of FSMA, Voluntary Qualified Importer Program, amended the FD&C Act to create a new provision, section 806, under the same name. Section 806 of the FD&C Act (21 U.S.C. 384b) directs FDA to establish a program to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program, and a process, consistent with section 808 of the FD&C Act (21 U.S.C. 384d), for the issuance of a facility certification to accompany a food offered for importation by importers participating in the VQIP.

Section 743 of the FD&C Act (21 U.S.C. 379j–31) authorizes FDA to assess and collect fees from each importer participating in VQIP to cover FDA's costs of administering the program. Each fiscal year, fees are to be established based on an estimate of 100 percent of the costs for the year. The fee rates must be published in a **Federal Register** notice not later than 60 days before the start of each fiscal year (section 743(b)(1) of the FD&C Act). After FDA approves a VQIP application, the user fee must be paid before October 1, the start of the VQIP fiscal year, to begin receiving benefits for that VQIP fiscal year.

The FSMA FY 2020 VQIP user fee rate announced in this notice is effective on August 1, 2019, and will remain in effect through December 31, 2019. The FY 2020 VQIP user fee will support benefits from October 1, 2019, through September 30, 2020.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2020

Each fiscal year, fees are to be established based on an estimate of 100 percent of the costs for the year. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2020

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: Payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2020 cost. The FY 2020 FDA-wide average cost for payroll (salaries and benefits) is $160,885; non-payroll—including equipment, supplies, information technology, general and administrative overhead—is $92,828; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $24,888 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2020 average fully supported cost to $278,602 per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP user fees for FY 2020 prior to including travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2020 average fully supported cost of $278,602 per FTE by the average number of supported direct FDA work hours in FY 2018—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2018

Total number of hours in a paid staff year	2,080
Less:	
10 paid holidays	−80
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
26.5 days of general administration	−184
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2020 ($278,602) by the total number of supported direct work hours available for assignment in FY 2018 (1,160) results in an average fully supported cost of $240 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2020.

B. Adjusting FY 2018 Travel Costs for Inflation To Estimate FY 2020 Travel Costs

To adjust the hourly rate for FY 2020, FDA must estimate the cost of inflation in each year for FY 2019 and FY 2020. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1)), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2019 inflation rate to be 1.7708 percent; this rate was published in the FY 2019 PDUFA user fee rates notice in the **Federal Register** (83 FR 37504, August 1, 2018). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.7708 percent for FY 2019 and 2.3964 percent for FY 2020, and FDA intends to use this inflation rate to make inflation adjustments for FY 2020 for several of its user fee programs; the derivation of this rate is published in the **Federal Register** in the FY 2020 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2019 and 2020, therefore, is 1.042096 (or 4.2096 percent) (1 plus 1.7708 percent times 1 plus 2.3964 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $240 already takes into account inflation as the calculation above is based on FY 2020 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP fees for FY 2020 prior to including domestic or foreign travel costs as applicable for the activity. For the purpose of estimating the fee, we are using the travel cost rate for both domestic and foreign travel because we anticipate that a portion of onsite assessments made by FDA under this program will require foreign travel in addition to domestic travel.

In FY 2018 FDA's Office of Regulatory Affairs (ORA) spent a total of $6,027,291 for domestic regulatory inspection travel costs and General Services Administration Vehicle cost related to FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 9,976 CFSAN and CVM domestic inspections, which averages a total of $604 per inspection by 35.44 hours per inspection results in a total and an additional cost of $17 (rounded to the nearest dollar) per hour spent for domestic inspection travel cost in FY 2018. To adjust for the $17 per hour inflationary increases in FY 2019 and FY 2020, FDA must multiply it by the same inflation factor mentioned previously in this document (1.042096 or 4.2096 percent), which results in an estimated cost of $18 (rounded to the nearest dollar) per paid hour in addition to $240 for a total of $258 per paid hour ($240 plus $18) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2020 when domestic travel is required.

In FY 2018, the ORA spent a total of $3,229,335 on 455 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $7,097 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $7,097 per trip by 120 hours per trip results in a total and an additional cost of $59 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2018. To adjust $59 for inflationary increases in FY 2019 and FY 2020, FDA must multiply it by the same compounded inflation factor mentioned previously in this document (1.042096 or 4.2096 percent), which results in an estimated cost of $61 (rounded to the nearest dollar) per paid hour in addition to $240 for a total of $301 per paid hour ($240 plus $61) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2020 when foreign travel is required for the VQIP.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2020

Fee category	Fee rates for FY 2020
Hourly rate without travel	$240
Hourly rate if domestic travel is required	258
Hourly rate if foreign travel is required	301

III. Fees for Importers Approved To Participate in the Voluntary Qualified Importer Program Under Section 743 of the FD&C Act

FDA assesses fees for VQIP annually. Table 3 provides an overview of the fees for FY 2020.

TABLE 3—FSMA VQIP USER FEE SCHEDULE FOR FY 2020

Fee category	Fee rates for FY 2020
VQIP User Fee	$16,681

Section 743 of the FD&C Act requires that each importer participating in VQIP pay a fee to cover FDA's costs of administering the program. This fee represents the estimated average cost of the work FDA performs in reviewing and evaluating a VQIP importer. At this time, FDA is not offering an adjusted fee for small businesses. As required by section 743(b)(2)(B)(iii) of the FD&C Act, FDA previously published a set of guidelines in consideration of the burden of the VQIP fee on small businesses and provided for a period of public comment on the guidelines (80 FR 32136, June 5, 2015). While we did receive some comments in response, they did not address the questions posed, *i.e.,* how a small business fee reduction should be structured, what percentage of fee reduction would be appropriate, or what alternative structures FDA might consider in order to indirectly reduce fees for small businesses by charging different fee amounts to different VQIP participants. We plan on monitoring costs and collecting data to determine if, in future fiscal years, we will provide for a small business fee reduction. Consistent with section 743(b)(2)(B)(iii), we will adjust the fee schedule for small businesses only through notice and comment rulemaking.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 39 person-hours to review a VQIP application (including communication provided through the VQIP Importer's Help Desk), 16 person-hours for an onsite performance evaluation of a domestic VQIP importer (including travel and other steps necessary for a fully supported FTE to complete and document an onsite assessment), and 34 person-hours for an onsite performance evaluation of a foreign VQIP importer (including travel and other steps necessary for a fully supported FTE to complete and document an onsite assessment). Additional costs include maintenance costs of information technology of administering benefits of the program. These costs are estimated to be $2,209 per VQIP importer.

FDA employees are likely to review applications from their worksites, so we use the fully supported FTE hourly rate excluding travel, $240/hour, to calculate the portion of the user fee attributable to those activities: $240/hour × (39 hours) = $9,360.

FDA employees will conduct a VQIP inspection to verify the eligibility criteria and full implementation of the food safety and food defense systems established in the Quality Assurance Program. A VQIP importer may be located inside or outside of the United States. We have used an estimate that up to 20 percent of VQIP importers may be located outside of the United States.

FDA employees are likely to prepare for and report on the performance evaluation of a domestic VQIP importer at an FTE's worksite, so we use the fully supported FTE hourly rate excluding travel, $240/hour, to calculate the portion of the user fee attributable to those activities: $240/hour × (8 hours) = $1,920. For the portion of the fee covering onsite evaluation of a domestic VQIP importer, we use the fully supported FTE hourly rate for work requiring domestic travel, $258/hour, to calculate the portion of the user fee attributable to those activities: $258/hour × 8 hours (*i.e.,* one fully supported FTE × (1 day onsite × 8 hours)) = $2,064. Therefore, the total cost of conducting the domestic performance evaluation of a VQIP importer is determined to be $2,064 + $1,920 = $3,984.

Coordination of the onsite performance evaluation of a foreign VQIP importer is estimated to take place at an FTE's worksite, so we use the fully supported FTE hourly rate excluding travel, $240/hour, to calculate the portion of the user fee attributable to those activities: $240/hour × (10 hours) = $2,400. For the portion of the fee covering onsite evaluation of a foreign VQIP importer, we use the fully supported FTE hourly rate for work requiring foreign travel, $301/hour, to calculate the portion of the user fee attributable to those activities: $301/hour × 24 hours (*i.e.,* one fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $7,224. Therefore, the total cost of conducting the foreign performance evaluation of a VQIP importer is determined to be $2,400 + $7,224 = $9,624.

Therefore, the estimated average cost of the work FDA performs in total for approving an application for a VQIP importer based on these figures would be $2,209 + $9,360 + ($3,984 × 0.8) + ($9,624 × 0.2) = $16,681.

IV. How must the fee be paid?

An invoice will be sent to VQIP importers approved to participate in the program. Payment must be made prior to October 1, 2019, in order to be eligible for VQIP participation for the benefit year beginning October 1, 2019. FDA will not refund the VQIP user fee for any reason.

The payment must be made in U.S. currency from a U.S. bank by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* or the *Pay.gov* payment option, which is available to you after you submit a cover sheet. (*Note:* Only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please include the invoice number. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the invoice to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965. (*Note:* In no case should the payment for the fee be submitted to FDA with the invoice.)

V. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in Section J of ''FDA's Voluntary Qualified Importer Program; Guidance for Industry'' document (available at *https://www.fda.gov/media/92196/download*). If the user fee is not paid before October 1, a VQIP importer will not be eligible to participate in VQIP. For the first year a VQIP application is approved, if the user fee is not paid before October 1, 2019, you are not eligible to participate in VQIP. If you subsequently pay the user fee, FDA will begin your benefits after we receive the full payment. The user fee may not be paid after December 31, 2019. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP.

Dated: July 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15742 Filed 7–23–19; 8:45 am]

BILLING CODE 4164–01–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: Health Center Patient Survey, OMB No. 0915–0368—Reinstatement

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for 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 September 23, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 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, 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: Health Center Patient Survey, OMB No. 0915–0368—Reinstatement

Abstract: The Health Center Program, administered by HRSA, is authorized under section 330 of the Public Health Service Act, most recently amended by section 50901(b) of the Bipartisan Budget Act of 2018, Public Law 115–123. Health centers are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients regardless of their ability to pay. Nearly 1,400 health centers operate approximately 12,000 service delivery sites that provide primary health care to more than 27 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. In the past, HRSA has conducted the Health Center Patient Survey (HCPS), which surveys patients of HRSA-supported health centers. The HCPS collects information about sociodemographic characteristics, health conditions, health behaviors, access to and utilization of health care services, and satisfaction with health care received at HRSA-supported health centers. The reinstatement of the HCPS will utilize the same modules from the 2014 HCPS (OMB #0915–0368). Overarching improvements to the survey instrument will streamline the questionnaire to minimize burden and standardize questions with other national surveys to enable comparative analyses with a particular focus on HHS and HRSA priority areas (*e.g.,* mental health and substance use). Survey results come from in-person, one-on-one interviews with patients who are selected as nationally representative of the Health Center Program patient population.

Need and Proposed Use of the Information: The HCPS is unique because it focuses on comprehensive, nationally representative, individual level data from the perspective of health center patients. By investigating how well HRSA-supported health centers meet health care needs of the medically underserved and how patients perceive their quality of care, the HCPS serves as an empirically based resource to inform HRSA policy, funding, and planning decisions.

Likely Respondents: Patients at HRSA-supported health centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. Compared to the previous HCPS, the estimated burden hours for an individual respondent remain the same in this reinstatement. However, the total annual burden hours and number of survey respondents is anticipated to increase in order to reflect the growing number of patients served by the Health Center Program. The total annual burden hours estimated for this ICR are summarized in the table below.