

Harm Reduction Toolkit for Non-Prescription Syringe Sales in
Community Pharmacies

OMB No. 0920-NEW

Supporting Statement A

August 3, 2021

Kathy Byrd, MD, MPH, Project Officer
Centers of Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB
Prevention
Division of HIV/ AIDS Prevention- Surveillance and Epidemiology
HIV Epidemiology Branch
1600 Clifton Rd., MS US8-4
Atlanta, GA 30333
Phone: 404-639-3083
Fax: 404-639-6127
Email: gdh8@cdc.gov

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less Frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

References

EXHIBITS

Table A12-1: Estimated Annualized Burden Hours

Table A12-2: Estimated Annualized Burden Costs

Table A14: Annualized Cost to Government

Table A16: Project Time Schedule

LIST OF ATTACHMENTS

Attachment 1: Authorizing Legislation

Attachment 2: 60-Day Federal Register Notice

Attachment 2a: Public comment

Attachment 3: Pharmacy staff orientation protocol

Attachment 4: Email invitation

Attachment 5: Consent form

Attachment 6: Pre-test survey

Attachment 7: Post-test survey

Attachment 7a: Pre-test and Post-test survey screenshots

Attachment 8: Syringe sales and service referrals variables

Attachment 9: Website usage variables

Attachment 10: Institutional Review Board approval letter

- **Goals of project:** The overarching aim of the project is to create harm reduction products that can help: 1) facilitate greater access to sterile syringes through pharmacy-based non-prescription syringe sales (NPSS) 2) minimize the burden of NPSS distribution on pharmacists, and 3) improve pharmacy personnel's understanding of, and skills with, NPSS efforts.
- **Intended use:** Data collected will be used to demonstrate how pharmacy personnel and persons who inject drugs (PWID) can use three contractor developed resources for harm reduction: a harm reduction kit for PWID; online training videos for pharmacists and pharmacy personnel pertaining to NPSS; and a resource website for PWID.
- **Methods to be used to collect data:** Before and after in-field demonstration of the aforementioned resources, the following will be conducted: online surveys to determine pharmacy personnel's knowledge and skills related to NPSS; pharmacy and project log records abstraction to determine number of pharmacy syringe sales and service referrals (e.g., referrals for HIV testing and substance use treatment); and website administrative data will be downloaded and Google Analytics will be used to determine usage of the training website and resource website for PWID.
- **The subpopulation to be studied:** Pharmacy personnel and PWID.
- **How data will be analyzed:** Training website usage data will be paired with the pre-test and post-test surveys and skill scores and analyzed for correlations between usage and knowledge, comfort, and use of NPSS skills. The numbers of syringe customers and service referrals and usage of the resource website for PWID will be described.

Justification

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention requests OMB approval for two years for a new information collection for a project titled "Harm Reduction Toolkit for Non-Prescription Syringe Sales in Community Pharmacies."

Injection drug use, through shared use of injection equipment, increases risk of acquiring blood borne pathogens such as HIV and hepatitis C virus (HCV). In 2018, 9% of all HIV infections were attributed to injection drug use and an additional 7% to injection drug use and male to male sexual contact.[1] The attributable risk is highest for adolescences and women among whom 20% of cases are attributable to injection drug use.[1] Prevalence of HCV infection among persons who inject drugs (PWID) is particularly high at an estimated 53% [2] with an attributable fraction of 79%.[3]

Although large numbers of PWID continue to be at risk of HIV and HCV infection, there has been some success in reducing the incidence of these infections among this population. Estimated HIV incidence rates among PWID dropped nearly 80% between 1990-2006.[4] Today, 1 in 11 HIV diagnoses are among PWID; this represents a 31% decrease in annual HIV diagnoses between 2010-2016.[5] Unfortunately, behavioral trends have threatened prevention gains. In the past two decades, there has been a marked rise in the production and consumption of prescription opioids to treat non-cancer pain which has resulted in a dramatic increase in opioid misuse including transition to injection drug use.[6, 7]

While cessation of injection drug use is an optimal goal for preventing transmission of bloodborne pathogens among PWID, it is not always achievable.[8] However, use of sterile needles and syringes for each injection, can significantly reduce risk of acquiring bloodborne pathogens and access to sterile syringes can reduce needle sharing among PWID.

Community pharmacies are in a unique position to provide access to sterile syringes through non-prescription syringe sales (NPSS). Pharmacies are in this position partly because they are among the most accessible of healthcare settings. In fact, approximately 90% of urban costumers live within 2 miles of a pharmacy and 70% of rural costumers are within 15 miles of a pharmacy. Pharmacies also have extended hours of operations making them more accessible to patients. While pharmacies represent potential sites for NPSS, education and tools are needed to build pharmacists' NPSS-related skills and to support pharmacists in the delivery of NPSS and other harm reduction services.

The overarching aim of this project is to create harm reduction products that can help: 1) facilitate greater access to sterile syringes through pharmacy-based NPSS 2) minimize the burden of NPSS distribution on pharmacists, and 3) improve pharmacy personnel's understanding of, and skills with, NPSS efforts.

The project will demonstrate how pharmacy personnel can use a contractor developed harm reduction kit for PWID and online training videos for pharmacy personnel on NPSS, for HIV prevention.

The project is aligned with the following operational strategies of the President's *Ending the HIV Epidemic: A Plan for America* initiative:[9]

- Prevent

The project is also aligned with the following national HIV prevention goals from the National HIV/AIDS Strategy:[10]

1.B.1 Design and evaluate innovative prevention strategies and combination approaches for preventing HIV infection in high-risk populations and communities and prioritize and promote research to fill gaps in HIV prevention science among the highest risk populations and communities.

1.B.4 Expand prevention with persons living with HIV.

The following section of the U.S. Federal Code is relevant to this data collection: Section 301 of the Public Health Service Act (42 U.S.C.241) which authorizes conduct of "research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." (Att 1)

A.2 Purpose and Use of the Information Collected

Project overview

This project is a phase II Small Business Innovation Research project that builds upon work completed in Phase I (phase I was completed in September 2019). The SBIR program is a set-aside program that provides "seed funds" for small businesses to engage in Research/Research and Development (R&D) that has the potential for commercialization and public benefit. Phase I supports

exploration of the technical merit or feasibility of an idea or technology.

In Phase I, the contractor developed two *prototypes*:

- A harm reduction kit with safer injection supplies for PWID.
- Online videos designed to build MicroSkills™ for pharmacy personnel and prepare and support pharmacy personnel to communicate effectively with and to serve PWID purchasing non-prescription syringes. (MicroSkills™ are discrete portions of demonstrative skills that can be combined to make a larger skill. Combinations or sets of MicroSkills™ are considered a skill set).

In this phase II project, the contractor will complete the development of the harm reduction kit for PWID and online training videos for pharmacy personnel. The contractor will also develop a resource website for PWID and conduct an in-field demonstration and evaluation of the aforementioned resources.

Harm reduction kit for PWID

A harm reduction kit for PWID will be finalized. The kit will contain harm reduction supplies such as sterile syringes, sharps disposal container, alcohol pads, antibiotic ointment and bandages.

Online training videos for pharmacists and other pharmacy personnel on NPSS

A minimum of 50 MicroSkills™ training videos will be developed to cover a variety of skill sets related to NPSS including (but not limited to) informing and motivating pharmacy staff about NPSS, providing harm reduction consults, providing respectful service

that is compliant with state specific laws on NPSS, and responding to challenging situations. Each video will be 20 - 120 seconds in duration. Contractor staff will develop a concept to demonstrate each skill, write a script including all stage direction, and storyboard each planned video clip. Once all scripts are final, video production will begin.

Resource website for PWID

A website will be developed for PWID that includes a short video demonstrating how to use the components of the harm reduction kit most safely, emphasizing procedures that reduce the likelihood of acquiring HIV (i.e., not sharing syringes or other injection equipment) and sharps disposal. A short video by a substance use disorder counselor on what to expect when seeking substance use treatment services will be integrated into the website. The website will also contain a resource locator which shows the location of available resources that might be useful to PWID (e.g., syringe services programs, sharps disposal locations, substance use disorder treatment providers).

In field demonstration and evaluation of the harm reduction kit, resource website for PWID and online training videos.

Once finalized, the harm reduction kit, online training, and resource website for PWID will be subjected to an in-field demonstration and evaluation which will consist of the following: a pre-test survey to assess pharmacy personnel's knowledge and skills related to NPSS; a one-week period in which pharmacy staff have access to the online training videos and are encouraged to use them; and a post-test survey to assess pharmacy personnel's post-training knowledge and skills related to NPSS. After the pharmacy personnel have had access to the online training videos

for one week, PWID who purchase non-prescription syringes from the participant pharmacy will be given the harm reduction kit, free of cost, and all PWID clients will have access to the resource website for PWID for 30 days.

The in-field demonstration and evaluation will take place at a convenience sample of 12 pharmacies. The contractor will work with an Advisory Panel (comprised of pharmacists and harm reduction experts) to recruit pharmacies for participation. The convenience sample of pharmacies may be recruited through pharmacist professional organizations and at national public health conferences. Once each pharmacy is recruited, all pharmacy personnel will be invited to a virtual staff orientation meeting (**Att 3**) where the contractor will explain the project and demonstrate the harm reduction kit, online training and resource website for PWID. After the orientation meeting, each pharmacy personnel will receive an email invitation (**Att 4**) to participate in the project along with an online consent document (**Att 5**). Once the online consent is digitally signed, the participant is considered enrolled in the project and will be given access to the online pre-test survey (**Att 6 and 7a**).

Once the pre-test survey is completed, the participant is given access to the online training and encouraged to use it. The online training will consist of 50 MicroSkills™ training videos each lasting 20 - 120 seconds. If the participant views all training videos, the training will take a maximum of 100 minutes to complete. After the participant has had access to the training for one week, they will be sent a post-test survey to complete (**Att 7 and 7a**). The pre-test and post-test surveys are estimated to take 30 minutes each to complete. Each participant will be given a \$20 gift card for participating.

Overview of data collection

The project will collect data for the in-field demonstration and evaluation. The information collection has three primary components: 1) online pre-test and post-test surveys 2) number of pharmacy syringe sales and service referrals 3) website usage (for the training website and the resource website for PWID).

Each pharmacy personnel who participates in the in-field demonstration will complete a one-time online pre-test survey and a one-time online post-test survey. The pre-test survey will be completed in the week prior to the participants being given access to the online training and the post-test survey will be completed in the week following the one-week training period. Data from the pre/post-test surveys will be collected entirely online. The purpose of the surveys is to assess pharmacy personnel's knowledge and skills pertaining to NPSS before and after access to the NPSS online training.

Data on pharmacy syringe sales and service referrals (e.g., referrals for HIV testing and substance use treatment) will be collected from pharmacy store or log records before and after the one-week training period. Each participant pharmacy's manager will conduct a one-time data collection of aggregated data on syringe sales and service referrals (**Att 8**) from the 30-day period before and after the training period. The purpose of these data are to describe syringe sales and service referrals before and after pharmacy personnel's access to the NPSS online training.

Lastly, the contractor project director will determine usage of the training website, following the one-week training period, by downloading website administrative data; the training website

automatically collects data analytics on number of unique visitors as well as pages/resources viewed (i.e., which videos have been watched and how many times each video was viewed). (**Att 9**) The project director will also use Google Analytics to determine website usage (average session duration and average number of sessions) of the resource website for PWID in the 30 days following the training period. (**Att 9**) Each website usage data collection will be conducted once.

Project outcomes

Primary project outcomes include the following: the acceptability and usability of the online training videos for pharmacists and pharmacy personnel regarding NPSS; pharmacy personnel NPSS knowledge and skill before and after the online training period; and numbers of syringe customers and service referrals before and after the online training period.

MicroSkills™ scores will be calculated based on the short answer scenarios described in the pre-test and post-test surveys for pharmacy staff. During the pre-test and post-test surveys, participants will be asked to review three short video scenarios related to NPSS and provide a step-by-step description of how they would handle the interactions. Participants' answers will be graded based on a rubric of the MicroSkills™ modeled in the video curriculum. If the use of a MicroSkill™ is described in the participant's short answer, the participant will receive a grade point on the rubric. These points will be totaled to calculate participants' MicroSkill™ scores. The training website usage data will be paired with the online pre-test and post-test surveys and MicroSkill™ scores and analyzed for correlations between usage and knowledge, comfort, and use of MicroSkills™. The number of

syringe customers and service referrals (before and after the online training period) and usage of the resource website for PWID will be also described.

How Info, Data, or Bio specimens will be collected: Data will be collected from or by using the following: 1) pharmacy personnel pre/post-test surveys 2) website administrative data and Google Analytics and 3) pharmacy store or log records. The pre/post-test surveys will be collected entirely online. The pharmacy syringe sales and service referrals data will be abstracted from pharmacy store or log records. Usage of the training website and resource website for PWID will be determined by downloading website administrative data and using Google Analytics. Only aggregate level data from the pre/post-test surveys, syringe sales and service referrals and website usage will be sent to CDC.

A.3 Use of Improved Information Technology and Burden Reduction

No data will be collected on paper forms. The pre/post-test surveys will be conducted completely online. The pharmacy syringe sales data will be downloaded from each participants' pharmacy data system. The number of service referrals will either be downloaded from each participants' pharmacy data system or entered into and abstracted from an electronic log (spreadsheet). The burden of collection for these data is, therefore, minimal. Website administrative downloads and Google Analytics will be used to determine website usage for the online training website and resource website for PWID, again making burden of data collection minimal.

A.4 Efforts to Identify Duplication and Use of Similar Information

CDC personnel have conducted extensive computerized searches of PubMed. While there is available literature detailing various harm reduction programs, none are specific to the contractor's developed resources for harm reduction. As these resources are newly developed, no evaluation has previously been completed.

A.5. Impact on Small Businesses or Other Small Entities

Data will be collected from participant pharmacies some of which might be small businesses. To minimize the time burden on participants, only two 30-minute surveys (pre-test and post-test surveys) will be conducted, per participant. The post-test survey will be conducted after participants have completed a maximum of 100 minutes of online training related to NPSS; this training can be done at the participants' leisure over a one-week training period. Additionally, the time required to collect the syringe sales and service referral data is estimated to be minimal (~1 hour for the one-time data collection). Lastly, the contractor is a small business. The time required for the contractor project manager to determine usage of the training website and resource website for PWID is estimated to be minimal (~15 minutes for the one-time data collection).

A.6 Consequences of Collecting the Information Less Frequently

Data collection will take place over one six-week period. The pre-test and post-test surveys will be conducted in the week before and after the one-week training period, respectively. The pharmacy syringe sales and service referrals data and website usage data will be collected once, 30 days after the one-week training period. This infrequent data collection allows for evaluation of the in-field demonstration of the harm reduction

resources; collecting the data less frequently disables this evaluation.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Federal Register Notice was published in the *Federal Register* on 4/5/2021, Volume 86, Number 63, Pages 17604-17606 (**Att 2**). There was one public comment (**Att 2a**).

The development of project data procedures has been a collaborative effort between CDC and the contractor, dfusion Inc. The following persons have reviewed the data procedures for content, clarity, frequency of collection and necessity. Each individual was consulted in 2020 and each is either a subject matter expert in public health, health education, or online training and other technology development.

Regina Firpo-Triplett, Co-Principle Investigator dfusion Inc. 100 Enterprise Way, D305 Scotts Valley, CA 95066 regina.firpo@dfusioninc.com 831.440.2162	Tamara Kuhn, Co-Principle Investigator dfusion Inc. 100 Enterprise Way, D305 Scotts Valley, CA 95066 tamara.kuhn@dfusioninc.com 831.440.2104
Lane Edwards, Project Director dfusion Inc.	

100 Enterprise Way, D305 Scotts Valley, CA 95066 lane.edwards@dfusioninc.com	
---	--

A.9. Explanation of Any Payment or Gift to Respondents

Each pharmacy personnel who participates in the in-field demonstration and completes the pre-test and post-test surveys will be given a \$20 gift card. The token of appreciation was based on pharmacists' earnings of an average of \$60 per hour and the pre- and post-test surveys will take an estimated 1 hour to complete.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC National Center for HIV, Hepatitis, STD and Tuberculosis Prevention PRA Coordinator determined that the Privacy Act does not apply to this study because personally identifiable information is not being collected.

Consistent with Section 301(d) of the Public Health Service Act, a Certificate of Confidentiality (CoC) applies to this project because it is funded or supported by CDC and the following are true: the research involves Human Subjects as defined by 45 CFR Part 46; the research involves information about an individual for which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual. The Certificate of Confidentiality protects the privacy of subjects by limiting the disclosure of

identifiable, sensitive information; the research team cannot be forced (e.g., court subpoena) to disclose identifying information from project participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

The pre-test and post-test surveys are designed for mobile access and programmed in HTML. Use of an "https" link for survey initiation ensures SSL encryption will be used as the data are sent to the contractor's server. The web server utilizes Advanced Encryption Standard (AES) 256-bit encryption on secure survey links to transmit data back to the contractor's servers.

Each survey participant is assigned a unique participant ID and is sent a unique survey URL by email. Upon completion of survey data collection all email addresses will be deleted. Prior to deletion, email addresses will be held on the survey host's (Alchemer) secure cloud-based service. The consent forms will be downloaded from survey host's secure service into a password protected database and placed on the contractor's secure cloud server. The consent forms will be kept separate from the data files and no identifying information will link the consent forms to the data. The consent documents will be retained for three years and then deleted.

All project data (survey data, syringe sales and service referrals and website usage) will reside in a password protected project folder on a secure Windows SQL database on a firewalled private network with system-level, database-level, and application-level security. Access to the contractor's servers is limited to contractor project staff and access to the building in which the servers are housed requires keycard verification for entry. No identifying information will be associated with the

data and all digital files associated with the project will be destroyed three years after the termination of the project.

At the end of the project period, only aggregate level data from the pre/post-test surveys, syringe sales and service referrals and usage of the training website and resource website for PWID will be sent to CDC.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The study protocol has been approved by ETR IRB. No sensitive questions will be asked of participants. (Att 10)

A.12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

The estimated annualized burden hours are 217. It is anticipated that there will be 5 pharmacy personnel (2 pharmacists and 3 pharmacy technicians) at each of the 12 participant pharmacies (total of 60 participants) who will participate in the in-field demonstration. Each of the 60 participants will attend a one-time virtual staff orientation meeting (Att 3) which will last no more than 45 minutes resulting in 45 burden hours. Each participant will complete the one-time pre-test survey (Att 6). The pre-test survey is estimated to take 30 minutes to complete for a total of 30 burden hours. After each participant completes the pre-test survey, they will have access to the online training which will consist of 50 training videos each lasting 20 - 120 seconds. If a participant views all training videos, the training will take a maximum of 100 minutes per participant to complete which results in a total of 100 burden hours. After the training period has elapsed, each participant will complete the one-time post-test

survey (**Att 7**). Each post-test survey is estimated to take 30 minutes to complete for a total of 30 burden hours. Given that the online training is prerequisite to completion of the post-test survey, the burden hours for the online training and post-test survey are combined in Table A12-1. The pharmacy manager at each of the 12 participant pharmacies will abstract the number of pharmacy syringe sales and service referrals from pharmacy store or log records (**Att 8**), one time after the training period has elapsed. The data abstraction is estimated to take 1 hour to complete for a total of 12 burden hours. One project director will download website administrative data and use Google Analytics to determine usage of the training website and resource website for PWID (**Att 9**), one time after the training period has elapsed. The data collection is estimated to take 15 minutes to complete for a total of 0.25 burden hours.

Table A12-1: Estimated Annualized Burden Hours

Respondents	Form name	# respondents	# responses per respondent	Average burden per response (in hours)	Total burden hours
Pharmacists and pharmacy technicians	Pharmacy staff orientation protocol (Att 3)	60	1	0.75	45
Pharmacists and pharmacy technicians	Pre-test survey (Att 6)	60	1	0.50	30
Pharmacists and pharmacy technicians	Post-test survey* (Att 7)	60	1	2.17	130

Pharmacy manager	Pharmacy syringe sales and service referrals (Att 8)	12	1	1	12
Project director	Website usage (Att 9)	1	1	0.25	0.25
Total					217†

*The burden of completing the online training and post-test survey is combined.

†Estimate of total burden hours is rounded to the nearest whole number.

The annualized burden cost is \$9,219. It is anticipated that two pharmacists and three pharmacy technicians, from each of the 12 participant pharmacies, will participate in the in-field demonstration and attend the virtual staff orientation, complete the pre-test survey, and complete the online training and the post-test survey. The mean hourly wages of pharmacists and pharmacy technicians are \$62 and \$16, respectively. Each of the 60 participants of the in-field demonstration who completes the pre/post-test surveys will be given a \$20 gift card as a participation token. Each participant pharmacy's pharmacy manager will collect the pharmacy syringe sales and service referrals data. The mean hourly wage of a pharmacy manager is \$79. The contractor project manager will determine usage of the training website and resource website for PWID. The mean hourly wage for a project director is \$75.

All estimates of hourly wage rates are based on the 2018 Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for the United States.

Table A12-2: Estimated Annualized Burden Costs

Respondents	Form Name	Total burden hours	Hourly wage rate	Total respondent costs
Pharmacists	Pharmacy staff orientation protocol (Att 3)	18	\$62	\$1,116
Pharmacy technicians	Pharmacy staff orientation protocol (Att 3)	27	\$16	\$432
Pharmacists	Pre-test survey (Att 6)	12	\$62	\$744
Pharmacy technicians	Pre-test survey (Att 6)	18	\$16	\$288
Pharmacists	Post-test survey* (Att 7)	52	\$62	\$3,704†
Pharmacy technicians	Post-test survey* (Att 7)	78	\$16	\$1,968†
Pharmacy Manager	Pharmacy syringe sales and service referrals (Att 8)	12	\$79	\$948
Project Manager	Website usage (Att 9)	0.25	\$75	\$19

* Burden costs of the online training and post-test survey are combined.

† Respondent cost includes hourly wage rate and participation token of \$20 per participant.

A.13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers

There are no direct costs to respondents other than their time to participate in the data collection.

A.14. Annualized Cost to the Government

Table A14: Annualized Cost to the Government

	Federal salary grade	Salary	% effort	Annualized cost
Contract	----	----	----	\$561,488
CDC Project Officer	GS 14-10	\$149,129	25%	\$37,282
CDC Contracting Officer Representative	GS 13-10	\$126,202	25%	\$31,550
Project Coordinator	Contractor	\$67,523	50%	\$33,762
Total				\$664,082

The annualized cost to the government is \$664,082. The information collection described in this request will be funded, coordinated and managed through a contract with the contractor, dfusion Inc. The federal personnel involved in the project include a Project Officer at the GS 14 equivalent level, a CDC Contracting Officer Representative at the GS 13 level, and a Project Coordinator who is a CDC contractor.

Salary estimates were obtained from the US Office of Personnel Management salary scale at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/ATL.pdf>.

A.15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

A.16. Plans for Tabulation and Publication and Project Schedule

Table A16 Project Time Schedule

Activity	Time Schedule
Complete development of harm reduction kit	By month 3
Complete development of website resource for PWID	By month 15
OMB approval	By month 15
Complete development of online training	By month 18
Pharmacy recruitment for in-field demonstration	By month 18
Participant enrollment, in-field demonstration, and data collection	By month 21
Analyses of study outcomes and final report	By month 24

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

No data will be recorded on paper files; all data collection will be electronic.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

1. Centers for Disease Control and Prevention. *HIV Surveillance Report, 2018 (Updated); vol.31.* <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2020. Accessed December 12, 2020.
2. Degenhardt, L., et al., *Global prevalence of injecting drug use and sociodemographic characteristics and prevalence of HIV, HBV, and HCV in people who inject drugs: a multistage*

- systematic review. *Lancet Glob Health*, 2017. **5**(12): p. e1192-e1207.
3. Trickey, A., et al., *The contribution of injection drug use to hepatitis C virus transmission globally, regionally, and at country level: a modelling study*. *Lancet Gastroenterol Hepatol*, 2019. **4**(6): p. 435-444.
 4. Hall, H.I., et al., *Estimation of HIV incidence in the United States*. *JAMA*, 2008. **300**(5): p. 520-9.
 5. CDC. *HIV and People Who Inject Drugs*. Available at <https://www.cdc.gov/hiv/group/hiv-idu.html>. Accessed 5 January 2021.
 6. Jordan, A.E., D.D. Jarlais, and H. Hagan, *Prescription opioid misuse and its relation to injection drug use and hepatitis C virus infection: protocol for a systematic review and meta-analysis*. *Syst Rev*, 2014. **3**: p. 95.
 7. Rigg, K.K. and S.M. Monnat, *Urban vs. rural differences in prescription opioid misuse among adults in the United States: informing region specific drug policies and interventions*. *Int J Drug Policy*, 2015. **26**(5): p. 484-91.
 8. Garfein, R.S., et al., *Three years after legalization of nonprescription pharmacy syringe sales in California: where are we now?* *J Urban Health*, 2010. **87**(4): p. 576-85.
 9. Fauci, A.S., et al., *Ending the HIV Epidemic: A Plan for the United States*. *JAMA*, 2019. **321**(9): p. 844-845.
 10. *White House Office of National AIDS Policy. National HIV/AIDS strategy for the United States: updated to 2020*. Washington, DC: The White House Office of National AIDS Policy. <https://files.hiv.gov/s3fs-public/nhas-update.pdf>. Accessed 13 December 2020.

