Assessing Key Factors to Pharmacy Enrollment in the Vaccines for Children Program

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. The respondent universe for this information collection aligns with that of the O2C2. Data will be collected from two types of state, tribal, local, and territorial (STLT) public health department staff: 10 coordinators of the Vaccines for Children (VFC) program and 10 VFC field staff who interact most closely with immunization providers, acting in their official capacity. Field staff, either as a state employee or a contractor to state health departments, conduct between 50-80 compliance visits to providers each year to ensure that these providers understand and meet the specific requirements of the VFC program. Through this role, they interact closely and frequently with all types of immunization providers, including pharmacists. The 20 VFC staff (one coordinator and one field staff member per state) would be drawn from 10 states with pharmacy enrollment in the VFC program as of 2013 (MN, NV, WA, WI, TX, CA, AZ, OR, MD, TN). These 10 states are a subset of the 64 states and territories that receive immunization funding through cooperative agreements with CDC.

Data also will be collected from pharmacists who have participated in the Vaccines for Children (VFC) program. They are considered delegates of public health agencies for the following reasons:

1) As per 0920-0879 Generic ICR language, "delegates are governmental or non-governmental agents (agency, function, office or individual) acting for a principal or submitted by another to represent or act on STLT government behalf."
2) Immunization services delivery, irrespective of venue, is part of Essential Public Health Services #7: "Link people to needed personal health services and assure the provision of health care when otherwise unavailable."
3) Pharmacists who participate in the VFC program are extensions of STLT health departments. Many state programs no longer provide direct immunization services and contract these services through their local health units. In order to participate in the state VFC program, all providers, including pharmacists, sign a Provider Agreement form and can then provide immunization services for VFC-eligible children and adolescents within that state based on their respective state laws. They can provide VFC-funded vaccine to VFC-eligible children and adolescents who would otherwise have to be immunized in health departments or provider offices, whose capacity can be limited in some locales and that are often less convenient for working parents due to restricted hours and wait times.
4) In many states, pharmacists provide access to immunizations for adolescents and adults who are less likely to see a health care provider on a routine basis, and thus would otherwise remain unimmunized.
5) Respondents will be identified in the 10 above mentioned states that have allowed pharmacy immunizations of children and adolescents and have successfully enrolled or sought to enroll pharmacists in the program.

This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241). This information collection falls under the essential public health services of 1) linking people to needed personal health services and assure the provision of health care when otherwise unavailable, and 2) evaluating effectiveness, accessibility, and quality of personal and population-based health services.[1]

The VFC program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. VFC was created by the Omnibus Budget Reconciliation Act of 1993 as a new entitlement program to be a required part of each state's Medicaid program. It was created in response to the major 1989-1991 measles epidemic that led to hundreds of deaths. The program was officially implemented in October 1994. Funding for the VFC program is approved by the Office of Management and Budget (OMB) and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). CDC purchases vaccines at a discount and distributes them to awardees—i.e., state health departments and certain local and territorial public health agencies—who in turn distribute the vaccine at no charge to those private physicians' offices and public health clinics registered as VFC providers. The VFC program is designed to make childhood vaccinations more accessible for children who are eligible for Medicaid, uninsured, underinsured, or American Indian or Alaska Natives. See **Attachment A** for an infographic summarizing CDC data on the VFC program's significant impact on preventing illnesses, deaths, and societal costs since it was implemented in 1994.

The VFC program has been successful in extending immunization coverage to children who might otherwise remain unimmunized; unpublished CDC data suggest that 50% of U.S. children under the age of 19 are eligible for the program, which has contributed to immunization rates near or over 90% between 1994-2013. However, new challenges arise with each cohort of newborn children. As a recent *Morbidity and Mortality Weekly Report (MMWR)* analysis points out, "Although VFC has strengthened the U.S. immunization program, ongoing attention is needed to ensure that the program addresses challenges and incorporates methods that could improve delivery. Approximately 4 million children are born in the United States each year, each of whom is vulnerable to vaccine-preventable pathogens that continue to circulate. Importations from areas where measles is endemic are an ongoing challenge for public health workers and clinicians. Coverage with human papillomavirus vaccine for adolescent girls has not yet reached optimal levels."[2]

Understanding factors affecting pharmacy participation in the VFC program and the impact that pharmacy participation would have on state immunization programs is important to increasing and maintaining high immunization rates, especially as health reform brings newly insured populations into the health care system and strains existing primary care resources. All 50 states now allow pharmacists to provide vaccinations, but state laws vary in terms of which age groups of children and adolescents that pharmacists may vaccinate and what vaccines they may provide. In addition, pharmacy participation in the VFC program varies considerably from state to state and is not fully understood.

Recent studies exploring pharmacy participation in immunizations have focused on adult influenza immunizations and on pandemic preparedness, rather than on pediatric immunizations encompassing a wider spectrum of disease-specific immunizations. As pharmacies have played an increasingly important role in adult immunizations and pandemic preparedness, it is important to better understand the possible role that pharmacies can play within the VFC program for children and adolescents.

To identify and understand key considerations and their implications for childhood and adolescent immunization rates, data will be collected from state coordinators of the VFC program, VFC field staff, and pharmacists to gain a more complete and accurate picture of the relevant issues, as described above. The purpose of this information collection is to understand key considerations affecting pharmacy participation in the VFC program. An assessment of key considerations for VFC and pharmacy participation is needed to inform internal CDC discussions. This information will help CDC formulate guidance for state and local public health officials on pharmacy participation in VFC. As immunization programs continue to try to reach VFC-eligible children within their jurisdictions, a better understanding of pharmacies and their role within VFC is needed.

Overview of the Information Collection System

The information collection system consists of individual telephone interviews using a semi-structured interview guide (see **Attachment B: Interview Guide**). The interview format is used to best gather the richest and most nuanced information needed for the purposes of this initiative, and capture variations across states. These interviews will explore the key considerations for pharmacy participation in the VFC program and explore state-to-state variations that affect pharmacy participation in the VFC program. The information collection instrument was pilot tested by 9 public health professionals, who are Project Officers within CDC/NCIRD. Feedback from this group was used to refine questions as needed and establish the estimated time required to complete the information collection instrument. Interviewers are also trained and highly skilled in using the interview guide to facilitate a concise and focused conversation between the interviewer and the respondent. Qualitative data from the interviews will be imported into Dedoose® qualitative data analysis software (www.dedoose.com).

Items of Information to be Collected

The modular interview guide consists of four sections. The first two sections include general questions and questions about key considerations that will be asked of all respondents (7 questions). Since there is very little information available about pharmacy participation in the VFC program beyond the number of pharmacists enrolled in each state as of 2013, all telephone interview respondents will be asked how they view the general opportunities and challenges of pharmacists' participation in the program. Depending on how they respond to the initial questions, they will be asked which factors are most salient in their state or region, and why. This also helps CDC understand the role of variation in state laws governing pharmacy provision of pediatric immunizations. Respondents will be asked to reflect on the opportunities and challenges that appear to be most significant, as well as any unintended consequences that may not have been considered.

Following these first two sections covering general questions and key considerations, respondents will be asked a set of specific questions about their respective roles (6-7 questions). Pharmacy respondents will be asked for their views about pharmacy participation in their state, and how this is potentially affected by state pharmacy association roles, state legislation, anecdotal information shared within the pharmacy community, or other factors. State health department VFC coordinators and field staff will be asked about their experiences working with pharmacies, the need for specialized training or oversight compared to the participation of other providers, and advice for others considering enrollment of pharmacies in the program.

2. Purpose and Use of the Information Collection

The purpose of this data collection is to understand key considerations affecting pharmacy participation in the VFC program and to explore state-to-state variations that affect pharmacy participation in the VFC program. An assessment of key considerations for VFC and pharmacy participation is needed to inform internal CDC discussions. This information will help CDC formulate guidance for state and local public health officials on pharmacy participation in VFC. As immunization programs continue to try to reach VFC-eligible children within their jurisdictions, a better understanding of pharmacies and their role within VFC is needed.

No publication of these data is planned. This information will be for internal CDC use only, shared in a report developed by the Association of State and Territorial Health Officials (ASTHO) for CDC's Immunization Services Division (ISD), National Center for Infectious and Respiratory Diseases (NCIRD).

3. Use of Improved Information Technology and Burden Reduction

The interview format is used to best gather the richest and most nuanced information needed for the purposes of this initiative, and capture variations across states. Interviews will be scheduled according to each respondent's schedule, within a 2-week period. The questions are open-ended and seek impressions, reflections, and experiences relevant to the participation of pharmacists in the VFC program. Interview questions do not require additional preparation or data collection prior to or after the interview on the part of respondent. Interviewers are also trained and highly skilled in using the interview guide to facilitate a concise and focused conversation between the interviewer and the respondent.

Qualitative data from the interviews will be imported into Dedoose® qualitative data analysis software (www.dedoose.com). The collected qualitative data will be coded and analyzed thematically, where data analysts will identify key themes that emerged across groups of interviews by segment or other characteristics. Frequency and intensity of discussions on a specific topic will be key indicators used for extracting main themes.

4. Efforts to Identify Duplication and Use of Similar Information

A preliminary external literature review, environmental scan, and review of internal CDC/NCIRD reports did not identify any systematic compilations of data on pharmacy involvement in the VFC

program by CDC, state health departments, academic researchers, or other agencies. As noted above, the existing literature on pharmacies and immunizations focuses on state laws governing scope of practice, adult influenza immunizations, and pandemic preparedness. (See **Attachment C** for the executive summary of a recent ASTHO report[3] as one example.) Pharmacy participation in the VFC program is a recent phenomenon with variation across states; it has not been systematically studied or catalogued. Therefore, the data we are requesting to gather is not available in any other format.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

As immunization programs continue to try to reach VFC-eligible children and adolescents within their jurisdictions, a better understanding of pharmacies and the role within VFC is needed. Without these data, CDC will have less guidance to offer state and local health departments regarding:

- the participation of pharmacies in the VFC program,
- how state VFC staff and programs can interact more effectively with pharmacy representatives on this topic, and
- how pharmacy participation is affected by variations in state contexts, laws, and VFC program configurations.

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This information collection is being conducted using the Generic Information Collection mechanism of the OSTLTS OMB Clearance Center (O2C2) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 31, 2013, Vol. 78, No. 211; pp. 653 25-26. No comments were received.

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this information collection. Employees of state and local public health agencies will be speaking in their official roles and will not be asked for, nor will they provide, individually identifiable information. This information collection is not research involving human subjects.

10.1 Privacy Impact Assessment Information

No individually identifiable information (IIF) will be collected.

At the beginning of each interview, the interviewer will ask the respondent for permission to audio-record the interview. If permission is granted, then the interview will be audio-recorded and transcribed. If permission is denied, the interview will not be audio-recorded and the interviewer will take detailed, hand-written notes during the course of the interview and a typed summary will be produced after the interview has been completed. Each transcript or summary will be coded, analyzed using a qualitative analysis software program (www.dedoose.com) to identify main themes, and mined for illustrative quotes and examples. Information will be stored under password protection in the contractor's (Cole Communications, Inc.'s) account with the data analysis software vendor (Dedoose).

The final report to CDC will not identify any respondents by name or identifying information. The interviewers and data analysts will know the identity and affiliations of the interviewees, but no findings will be reported in ways that are linked to individual respondents.

11. Justification for Sensitive Questions

No information will be collected that is of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the information collection instruments by 9 public health professionals, who are Project Officers within CDC/NCIRD. In the pilot test, the average time to complete the instrument — including time for reviewing instructions, gathering needed information and completing the instrument — was approximately 45 minutes. Based on these results, the estimated time range for actual respondents to complete the instrument is 30-45 minutes. For the purposes of estimating burden hours, the upper limit of this range (i.e., 45 minutes) is used.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $34.50 is estimated for VFC coordinators, of $14.08 for VFC field staff, and $56.09 for pharmacy representatives. Table A-12 shows estimated burden and cost information for each type of respondent. The total estimated annualized burden hours is 24 hours; and the total estimated annualized burden cost is $838.00.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Data Collection Instrument: Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Telephone Interview Guide	STLT VFC Program Coordinators	10	1	45/60	8	34.50	276.00
	STLT VFC Program Field Staff	10	1	45/60	8	14.08	113.00
	STLT Delegates: Pharmacy Representatives	10	1	45/60	8	56.09	449.00
	TOTALS	**30**	**1**		**24**		**838.00**

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

There will be no direct costs to the respondents other than their time to participate in each information collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of the CDC staff and external contractors during the preparation of the interview guide, data collection, and analysis activities. The estimated cost to the federal government is $101,943. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
CDC Project Officer, GS-13	25	46.43	1161
Contractor to ASTHO/CDC	0	0	100782
Estimated Total Cost of Information Collection			**101943**

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Analysis Plan

All data from the telephone interview transcripts will be imported into Dedoose® qualitative data analysis software (www.dedoose.com). The collected qualitative data will be coded and analyzed thematically, where data analysts will identify key themes that emerged across groups of interviews by segment or other characteristics. Frequency and intensity of discussions on a specific topic will be key indicators used for extracting main themes. No publication of this data is planned. This information will be for internal CDC use only, shared in a report developed by ASTHO for CDC's Immunization Services Division (ISD), National Center for Infectious and Respiratory Diseases (NCIRD).

Project Time Schedule

	Task	Timeline
✓	Design interview guide tool	COMPLETE
✓	Develop data collection protocol, instructions, and analysis plan	COMPLETE
✓	Prepare OMB package for individual telephone interviews	COMPLETE
✓	Submit OMB package for individual telephone interviews	COMPLETE
❑	OMB approval	TBD
❑	Conduct telephone interviews	8 weeks
❑	Code, quality control, and analyze qualitative data from interviews	12 weeks
❑	Prepare draft report on interview findings	12 weeks
❑	Format/disseminate report	16 weeks

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

- **A.** CDC VFC Program Data
- **B.** Interview Guide
- **C.** ASTHO Report Summary

REFERENCE LIST

1. Centers for Disease Control and Prevention (CDC). "National Public Health Performance Standards Program (NPHPSP): 10 Essential Public Health Services." Available at http://www.cdc.gov/nphpsp/essentialservices.html. Accessed on 8/14/14.
2. Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994–2013, MMWR, April 25, 2014 / 63(16); 352-355.
3. Public Health and Pharmacy Collaboration in an Influenza Pandemic: Summary of Findings from an Exploratory Interview Project (ASTHO, 2014).