

The Vaccines for Children Program: A Status Report for Kansas

June 2014

Sheena L. Smith, M.P.P.
Jennifer Woodward, M.D., M.P.H.



IMMUNIZE KANSAS KIDS

212 SW Eighth Avenue, Suite 300
Topeka, Kansas 66603-3936
(785) 233-5443
<http://www.immunizekansaskids.org>



IMMUNIZE KANSAS KIDS

The Immunize Kansas Kids project is a unique partnership among the Kansas Department of Health and Environment, the Kansas Health Institute and dozens of stakeholder organizations. The goal is simple: to protect every Kansas child from vaccine-preventable diseases.

Copyright© Immunize Kansas Kids 2014.
Materials may be reprinted with written permission.

TABLE OF CONTENTS

Acknowledgments	iv
Executive Summary	v
Background	1
History of VFC.....	2
VFC Provider Benefits and Financial Incentives	3
VFC Provider Requirements and Enrollment Process	4
VFC Participation in Kansas.....	6
Barriers to VFC Participation in Kansas: Data from Existing Literature.....	7
Objectives.....	7
Methods.....	8
Results.....	9
2013 VFC Program Participation in Kansas	9
Kansas VFC Enrollment and Participation Requirements	10
Barriers to VFC Enrollment Identified by Key Informant Interviews.....	12
Best Practices in VFC Enrollment and Participation.....	12
Additional Findings	13
Discussion	14
Study Limitations	15
Conclusion.....	16
Appendix A: 2014 VFC Provider Enrollment Packet	A-1
Appendix B: Key Informant Interview/Informed Consent.....	B-1

ACKNOWLEDGMENTS

We would like to acknowledge the Vaccines for Children program staff and the clinic staff who provided essential information for this report. Additionally, we would like to thank Immunize Kansas Kids partners and the following Kansas Health Institute staff members: Gianfranco Pezzino, M.D., M.P.H., Barbara LaClair, M.H.A., Catherine Shoults, M.P.H. and Ivan S. Williams, M.B.A. Funding was provided by the Kansas Health Foundation, Wichita, Kansas. The Kansas Health Foundation is a philanthropic organization whose mission is to improve the health of all Kansans.

EXECUTIVE SUMMARY

The purpose of this report is to provide a comprehensive description of the Vaccines for Children (VFC) program in Kansas by addressing the following areas:

1. Summarize the VFC program in Kansas.
2. Identify barriers to participation in VFC in Kansas.
3. Describe practices that may help address identified barriers.

The VFC program is a federally funded program with the goal of providing vaccinations to children who might not otherwise have access to them. The Centers for Disease Control and Prevention (CDC) purchases vaccines at a discounted cost and distributes them to state grantees. In Kansas, the Kansas Department of Health and Environment (KDHE) manages the VFC program and distributes the vaccines to participating clinics. Eligible children may receive all vaccines recommended by the Advisory Committee on Immunization Practices at no cost. In order to be eligible for VFC vaccine, the patient must be younger than nineteen and either qualify for Medicaid, be uninsured, underinsured, or an American Indian or Alaska Native.

Providers that enroll in the VFC program agree to comply with vaccine ordering, management, storage, and handling requirements, operate within a manner intended to avoid fraud and abuse, and participate in compliance site visits from program administrators (including unannounced visits) and other educational opportunities.

Previous studies in Kansas showed that approximately 50 percent of all immunizations occur in the private sector compared with 80 percent nationally. These studies also showed that 81 percent of private clinics across the United States are enrolled in the VFC program, compared with just over 50 percent in Kansas.

Barriers identified through key informant interviews completed for this report include the cost of a separate refrigerator and private vaccine stock, program participation's administrative burden, difficulty in developing a billing process to receive a reimbursement fee that is perceived to be too low, and too few children in the practice or coverage area to justify program

participation. Some barriers may be unavoidable, but others may be addressed with appropriate interventions, education and/or financial support.

BACKGROUND

The federal Vaccines for Children program (VFC) serves as a vaccine safety net for children in the United States. Vaccines are available at no charge to children whose parents or guardians might not be able to afford them. The removal of the cost barrier to children receiving vaccination has helped reduce disparities in vaccination coverage in the United States.¹

Vaccination rates in Kansas have varied over the past decade, at times ranking among the lowest in the United States. In response to these low rates, the Kansas Health Foundation (KHF) supported the creation of the Immunize Kansas Kids (IKK) coalition to address the issue. The coalition consists of representatives from the state health department, Kansas Health Institute (KHI), private providers, local health departments and school nurses, among others. IKK has commissioned several studies to better understand these low rates and identified that access to vaccination services to be an issue. Relative to other states, fewer private clinics in Kansas offer childhood immunizations and even fewer of that subset participate in the VFC program.

Because the VFC program is a federal program, much of the guidance is dictated to the state health departments who manage the program for the VFC providers in the state. This report contains a history of the VFC program, a description of the requirements that clinics must meet in order to become a VFC provider, and a discussion about the benefits the clinics may incur as a result of their participation. It also contains a review of the literature related to the VFC program in Kansas.

To fill in the remaining gaps in knowledge about the barriers to program participation in the state, key informant interviews were conducted with Kansas Department of Health and Environment (KDHE), VFC program staff and staff from private clinics in the state.

¹ Centers for Disease Control and Prevention. (2014). *Reduction of Racial/Ethnic Disparities in Vaccination Coverage, 1995-2011*. Retrieved May 1, 2014 from <http://www.cdc.gov/mmwr/preview/mmwrhtml/su6301a3.htm>

In this report, the term “provider” indicates a health care facility where routine vaccinations are administered to children. An individual facility may have multiple clinicians licensed to prescribe vaccines. A VFC provider indicates the facility is enrolled in the VFC program.

HISTORY OF VFC

The VFC program helps provide vaccinations to children whose parents or guardians might not be able to afford them. According to the CDC, the historical impetus for the program development was the 1989-1991 measles epidemic in the United States. Outbreak investigators found that more than half of the 55,000 Americans who were sickened with the virus, including 123 deaths, were unvaccinated.²

To increase the number of children who had access to vaccines, Congress passed the Omnibus Budget Reconciliation Act in 1993, creating the VFC program. It is a Medicaid entitlement program for eligible children age 18 and younger. The Centers for Medicare and Medicaid Services (CMS) delegates program management to the CDC who purchases vaccines and distributes them to VFC providers. CMS then reimburses the CDC for program management and vaccine costs.

The most recent data from the Department of Health and Human Services (HHS) estimates there were 44,000 VFC providers in the United States in 2010. These providers ordered roughly 82 million vaccine doses to provide to 40 million children. Approximately 70 percent of these VFC providers work in private clinics.³

In order to receive VFC vaccination, children must meet certain eligibility criteria. These criteria can be found in Table 1. According to HHS, approximately 70 percent of VFC eligible children were enrolled in Medicaid in 2011, the most recent data available.⁴

² Centers for Disease Control and Prevention. (2014). *Reduction of Racial/Ethnic Disparities in Vaccination Coverage, 1995-2011*. Retrieved May 1, 2014 from <http://www.cdc.gov/mmwr/preview/mmwrhtml/su6301a3.htm>

³ U.S. Department of Health and Human Services. Office of Inspector General. (2012). *Vaccines for Children Program: Vulnerabilities in Vaccine Management*. Retrieved on December 13, 2014 from <http://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf>

⁴ U.S. Department of Health and Human Services. Office of Inspector General. (2012). *Vaccines for Children Program: Vulnerabilities in Vaccine Management*. Retrieved on December 13, 2013 from <http://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf>

Table 1: VFC Eligibility Criteria

Medicaid-eligible
Uninsured
American Indian or Alaska Native
Underinsured¹ (Must receive VFC vaccines at a Federally Qualified Health Center or Rural Health Clinic)

¹ Underinsured is defined as a child who has health insurance, but the insurance does not cover vaccines, it doesn't cover certain vaccines, or if it covers vaccines, but has a fixed dollar limit or cap for vaccines; once the cap is reached, the child is eligible for VFC vaccines.

**Table 2: Advisory Committee on Immunization Practices:
Recommended vaccinations to protect children from 16
diseases as of April 2014**

Diphtheria	Mumps
Haemophilus influenzae type b (Hib)	Pertussis (whooping cough)
Hepatitis A	Pneumococcal disease
Hepatitis B	Polio
Human Papillomavirus (HPV)	Rotavirus
Influenza	Rubella (German measles)
Measles	Tetanus (lockjaw)
Meningococcal disease	Varicella (chickenpox)

VFC PROVIDER BENEFITS AND FINANCIAL INCENTIVES

Any clinician authorized to prescribe vaccines under state law can be a VFC provider. Once enrolled, out-of-pocket clinic costs are reduced by providing federally-purchased vaccines to eligible patients rather than privately-purchased vaccines. All vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP) are available through the VFC program (Table 2).

In addition to providing the vaccine at no cost, VFC clinics can charge a fee to patients for the associated administration and staff costs. Effective on Jan. 1, 2013, the Affordable Care Act (ACA) included a provision that required states to reimburse qualified providers at a rate that

would be paid if the service were covered by Medicare.⁵ Before these new rates were established, these fees had not been updated since the program was established in 1994.⁶ These fees differ from state to state and range from \$16.80 in Puerto Rico to \$24.23 in New Jersey. The rate in Kansas is \$20.26, which is lower than the median (\$21.43) and increased from the previous rate of \$14.80.

General pediatric and immunization-specific research in the past decade has concluded that administration of vaccinations in same location where children receive their general primary care has been more successful in increasing vaccination rates than obtaining primary care in one place and vaccinations in another⁷. Beyond the financial incentives, the ability to provide vaccinations to children who would otherwise not receive these vaccinations can help protect communities from vaccine-preventable disease.

VFC PROVIDER REQUIREMENTS AND ENROLLMENT PROCESS

The CDC stipulates certain requirements be met by VFC providers in order to ensure that the vaccines that are administered provide the maximum protection against disease and to reduce the risk of fraud, waste and abuse. These requirements are outlined in the VFC Operations Manual available from the CDC.⁸ Each state health department as well as health departments in six major metropolitan cities has a grantee responsible for program implementation and management in that state, often within the state health department. This includes preparing state-specific documentation outlining the requirements, maintaining records of required documents and plans and providing program technical assistance. Activities and training are required in each of the following 10 categories:

1. Vaccine storage equipment.

⁵ Centers for Medicare and Medicaid Services. *Qs & As on the Increased Medicaid Payment for Primary Care (CMS 2370-F)*. Retrieved on February 16, 2014 from <http://www.medicare.gov/AffordableCareAct/Provisions/Downloads/Q-and-A-Managed-Care-Increased-Payments-for-PCPs.pdf>

⁶ American Academy of Pediatrics. *FAQs on the Medicaid Payment Increase for Primary Care and Immunization Administration Services & Updates to the Vaccines for Children Program Regional Maximum Charges*. Retrieved on February 16, 2014 from http://www.aap.org/en-us/advocacy-and-policy/federal-advocacy/Documents/FAQGuideMedicaidPaymentRule_Dec2012.pdf

⁷ Smith, P.J., Santoli, J.M., Chu, S.Y., Ochoa, D.Q., Rodewald, L.E. (2005). The association between having a medical home and vaccination coverage among children eligible for the Vaccines for Children program. *Pediatrics*, 116:130–139.

⁸ Available from state health department upon request.

2. Vaccine storage practices.
3. Temperature monitoring.
4. Vaccine storage and handling plans.
5. Vaccine personnel.
6. Vaccine waste.
7. Vaccine security and equipment maintenance.
8. Vaccine ordering and inventory management.
9. Receiving vaccine shipments.
10. Vaccine preparation.

Additionally, each VFC provider must maintain the following documents related to the program:

1. Training records.
2. Documentation of process to ensure VFC vaccines are administered only to the VFC-eligible children.
3. Routine storage and handling plan.
4. Emergency storage and handling plan.
5. Current provider enrollment form.
6. Current provider profile form.
7. Temperature-monitoring logs.⁹

The 2014 VFC provider enrollment forms for private clinics include the contracts and additional details in Kansas and are available in Appendix A.

Once these requirements are met and adequately documented, the VFC program manager coordinates a site visit to review the administrative requirements and ensure proper storage and handling of vaccines when they are received. After this enrollment process, the provider is responsible for alerting patients of program and vaccine availability.

⁹ Office of the Inspector General. *Vaccines for Children Program: Vulnerabilities in Vaccine Management (OEI-04-10-00430)*. (2013). Retrieved on December 16, 2014 from <http://oig.hhs.gov/oei/reports/oei-04-10-00430.pdf>

VFC PARTICIPATION IN KANSAS

In 2002, LeBaron analyzed data from the 1997 National Immunization Survey and found that just 59 percent of all childhood immunization providers in Kansas were private, compared with 81 percent nationally. Of those private providers, just 61 percent were enrolled in the VFC program and 81 percent nationally¹⁰.

This study also found that 40 percent of Kansas children age 19 to 35 months, received their vaccinations exclusively in the private sector; 32 percent were vaccinated exclusively in the public sector; and the remaining 28 percent obtained vaccinations from a mixture of public and private providers. The national average for vaccinations obtained exclusively in the public sector at that time was 18 percent, a substantially lower rate than Kansas.

These statistics showed that the childhood immunization system in Kansas relied more heavily on the public providers than other states, and fewer private providers were enrolled in the VFC program. To investigate this more thoroughly, IKK has completed a series of reports over the past decade to better describe the childhood immunization system in Kansas, with a specific focus on the private sector. These reports included a survey of all known clinics that provide primary care to children in Kansas to identify which of those clinics provide immunizations.

In 2006, Pezzino found that 65 percent of private primary care clinics offered immunizations to at least some children and of those who did offer immunizations, just 51 percent were enrolled in the VFC program.¹¹

The subsequent clinic surveys found 70 percent (2009) and 65 percent (2012) of private clinics offered immunizations, and of those 55 and 56 percent respectively participated in VFC.¹²

13

¹⁰ LeBaron, C., Lyons, B., Massoudi, M., Stevenson, J. (2002). Childhood vaccination providers in the United States. *American Journal of Public Health, Vol 92*, No. 2.

¹¹ Pezzino, G., Rule, J., Mickle, S. (2007). *Who Vaccinates Our Children? A Map of the Immunization Delivery System in Kansas*. Topeka, KS: Kansas Health Institute.

¹² Pezzino, G., Nugent A. (2009). *The Private Immunization Delivery System for Children in Kansas*. Topeka, KS: Kansas Health Institute.

¹³ LaClair, B. (2013). *The Private Immunization Delivery System for Children in Kansas, 2012*. Topeka, KS: Kansas Health Institute.

In summary, both national and local survey data indicate that the immunization system in Kansas relies fairly heavily on the public sector for immunizations relative to the national average, and fewer private providers participate in the VFC program.

BARRIERS TO VFC PARTICIPATION IN KANSAS: DATA FROM EXISTING LITERATURE

A 2012 clinic survey completed by LaClair contained additional questions specific to the clinic participation in the VFC program. Staff from clinics that did not participate in the VFC program were asked to describe the reasons why they did not in an open-ended question format. These results are available in Table 3. Of note, the survey also found that 6.4 percent of the respondents requested additional information regarding VFC program enrollment.

Table 3: Barriers to VFC program participation in private clinics offering immunizations to children in Kansas, 2012

<i>Reasons or Barriers Cited</i>	<i>Percent (n=101)</i>
VFC administrative burden too high	30
Reimbursement too low	11
Separate vaccine inventory requirement	28
Practice does not accept Medicaid	21
Insufficient number of VFC-eligible children	19
Refer VFC-eligible children elsewhere	55
Other	9

OBJECTIVES

This report was completed at the request of the IKK coalition to provide a comprehensive description of the VFC program in Kansas by addressing the following areas:

1. Summarize the VFC program in Kansas.
2. Identify barriers to participation in VFC in Kansas through key informant interviews.

3. Describe practices that may help address identified barriers through key informant interviews.

METHODS

Current VFC Program Participation

Authors reviewed documents available on KDHE website including the 2013 Active Provider List and the 2014 VFC Provider Enrollment Packet.¹⁴ Microsoft Excel was used to code the Active Provider List by type of provider and to calculate the percentages of providers by type. Maps depicting Kansas participating VFC clinics were created using ArcGIS 10.2 mapping software based on data included in the 2013 Active Provider List.

Key Informant Interviews

The key informant interview process took place in two phases. First, KDHE VFC program staff was interviewed to provide a description of the history and background of the VFC program in Kansas and elaborate on state-specific program processes required by the CDC. Throughout this interview process, staff recommended 15 private clinics that would have knowledge regarding both barriers and best practices in VFC program enrollment and administration to complete the second phase of the interview process. Seven interviews were completed either by telephone or in person. Three participants were VFC providers and four were not. The provider questionnaire and informed consent document are available in Appendix B. Interview responses were coded with agreement by two team members to ensure consistency of results and aggregated by theme.

¹⁴ Kansas Department of Health and Environment. (2014). *2014 Private Provider VFC Enrollment Packet*. Retrieved on December 20, 2014 from http://www.kdheks.gov/immunize/imm_manual_pdf/Complete_VFC_ENROLLMENT_PACKET_PRIVATE.pdf

RESULTS

2013 VFC PROGRAM PARTICIPATION IN KANSAS

The 2013 Active Provider List¹⁵ for Kansas shows that private clinics make up approximately half of all the VFC providers in the state, consistent with the previous clinic survey results (Table 4).

Table 4: 2013 Kansas VFC Providers by Type

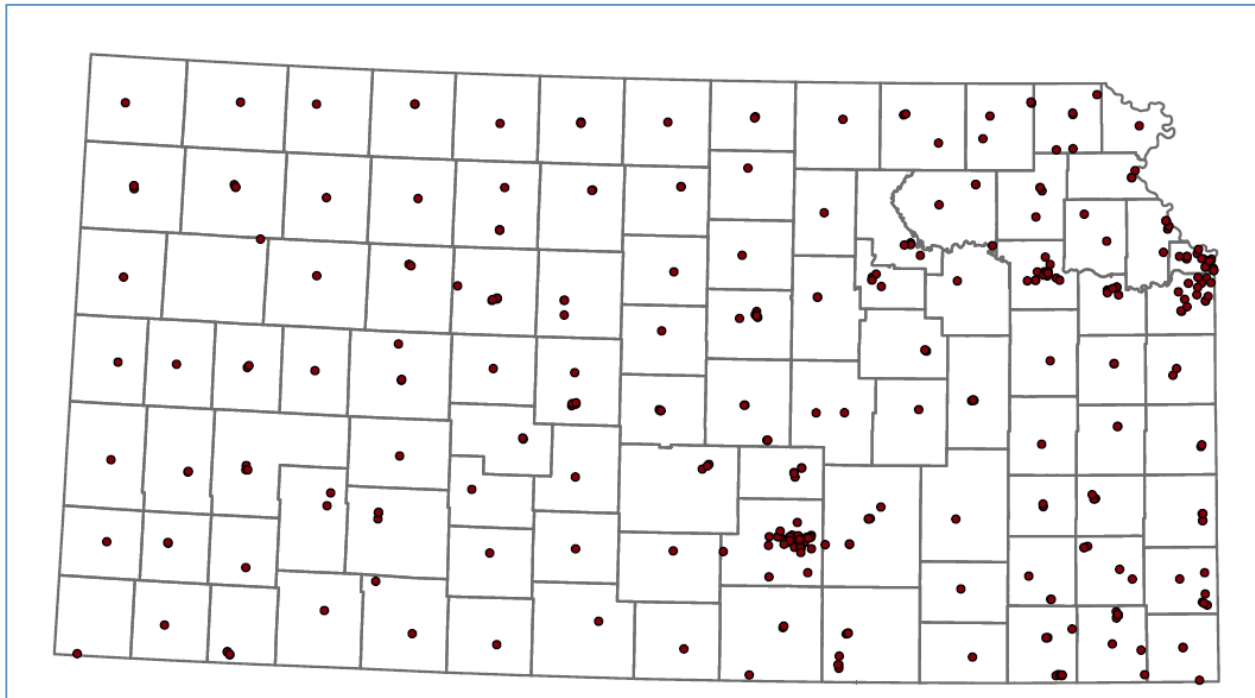
Type	Number	Percent
Federally Qualified Health Center	15	4%
Health Department ^a	109	28%
Hospital	52	13%
Indian Health Service	2	1%
Pharmacy	4	1%
Rural Health Clinic	4	1%
Safety Net Clinic	5	1%

a. There are 105 health departments in Kansas; several offer immunizations at multiple locations.

Figure 1 is a map of all the VFC providers in the state based upon KDHE's active provider list. Each dot represents a location of a VFC clinic in each county. Every local health department is enrolled in the VFC program, so individuals who live in counties with just one dot are dependent on the local health department for VFC vaccine. A large number of VFC providers are clustered in more densely populated areas, including Wyandotte, Johnson, Shawnee, Douglas, and Sedgwick Counties, while the rest of the counties have far fewer.

¹⁵ Kansas Department of Health and Environment. (2013). *KDHE Active VFC Provider List*.

Figure 1. Map of 2013 VFC Providers in Kansas



KANSAS VFC ENROLLMENT AND PARTICIPATION REQUIREMENTS

The VFC requirements and enrollment packet is available in Appendix A. It is a Kansas-specific document that follows the requirements set forth by the CDC.

During the key informant interviews, KDHE staff described the enrollment process as passive. Clinic staff is responsible for contacting KDHE if they are interested in enrolling and there are no specific outreach programs to encourage participation. First the clinic staff signs the enrollment contract and returns it to KDHE. Next, KDHE VFC program staff reviews and verifies the vaccine management and storage and handling procedures and ensures the clinic has the appropriate equipment available. KDHE also requires clinics to submit an annual provider profile that contains information on the populations served by each practice. This helps to ensure the clinic serves enough children to support the VFC program and avoid wasted vaccine.

After the enrollment paperwork is complete and the contracts are signed, KDHE program staff completes a site visit for additional education and technical assistance.

A follow up visit is scheduled for three to six months after the initial visit to ensure compliance, recommend improvements and best practices and develop a collaborative partnership. KDHE staff visits approximately 65–75 percent of all VFC providers every year. In 2009, the Office of the Inspector General issued a review of the VFC program and found a high level of wasted vaccine. The CDC has issued guidance to the program managers in each state, and KDHE program staff has taken several steps to address the issue in Kansas.

Waste reduction is emphasized in the required training program modules and requires providers to submit monthly inventory reports in order to receive the next order of vaccine. KDHE allows only three instances of wasted vaccine prior to program dis-enrollment. This process is intended to be collaborative and not punitive in nature, and encourages providers and staff members to identify issues that can be addressed before patterns of waste occur.

According to KDHE’s Wasted Vaccine Policy, repayment of wasted vaccine is a “dose-for-dose” replacement process. During 2014, the Kansas Immunization program will require replacement doses for the following situations:

1. When a provider receives an insurance payment for vaccine loss.
2. Due to gross negligence (unmonitored vaccine temperatures, or no actions taken to correct problems).
3. Provider has a pattern for \$500 or more waste per month.
4. Excessive vaccine stock is ordered and expires.

Beginning in 2015, all avoidable wasted vaccine will be repaid under the dose-for-dose replacement method as required by the CDC.¹⁶

In October 2013, the CDC released a policy requiring VFC providers to separate VFC funded vaccine from other publically or privately funded vaccines. The policy also states clinic staff can no longer freely “borrow” VFC vaccine for any non-VFC eligible child unless the transfer is approved by an appropriate authority. The Kansas Immunization Program submitted a proposal to modify the CDC mandate and CDC approved certain modifications for Kansas clinics,

¹⁶ Kansas Department of Health and Environment. (2013). *KDHE Immunization Manual*. Retrieved on July 15, 2013 from http://www.kdheks.gov/immunize/imm_manual_pdf/index.html

allowing storage of program-supplied vaccine in a “blended manner,” and vaccine to be “borrowed” on a rare, emergency basis. More details are available in the 2014 VFC Provider Enrollment Packet in Appendix A.

BARRIERS TO VFC ENROLLMENT IDENTIFIED BY KEY INFORMANT INTERVIEWS

Four major themes concerning barriers to participation in VFC emerged from the key informant interview process, in no particular order:

1. Cost of VFC enrollment—separate refrigerator, matched private vaccine stock.
2. Perceived low reimbursement rate.
3. Too few children in coverage area.

These results add more specificity to the perceived administrative and financial cost of VFC participation identified as barriers in previous studies. Study participants noted the cost of an additional refrigerator and requirement to maintain private vaccine stock for non-VFC eligible individuals as cost-prohibitive. The costs, combined with the perceived low reimbursement rate leads to a “not enough bang for your buck” point of view echoed by several study participants who were not VFC providers.

Additionally, one interviewee commented they completed the enrollment process and provided VFC vaccine, but after one year of participation realized there were too few children within the practice to sustain the program financially.

BEST PRACTICES IN VFC ENROLLMENT AND PARTICIPATION

Study participants described practices that have increased ease, effectiveness, and efficiency of the VFC enrollment process and maintenance of the program. Key best practices cited by interviewees are below.

1. KDHE enrollment guidance.
2. Continuous communication between KDHE and provider.
3. Modeling practices of other clinics with a highly successful VFC program.

Interview participants who were knowledgeable about the VFC enrollment process stated it appeared daunting initially but KDHE staff has processes in place to make enrollment

manageable and they are readily available to answer questions. Participants noted they often received advice about best practices and system improvement at the annual site visits and during the required monthly communication with KDHE staff. Peer-to-peer sharing of best practice guidance for an efficient VFC program occurs at KDHE's annual immunization conference and by sending staff to shadow at clinics that are known to have a highly successful VFC program. Staff members are able to replicate processes back at their clinic.

ADDITIONAL FINDINGS

The key informant interviews provide additional detail into one of the perceived barriers to VFC enrollment in VFC in Kansas. Currently there is no requirement for VFC providers to participate in the KSWebIZ immunization registry, however, several key informant interviewees cited electronic health record (EHR) integration with KSWebIZ as a barrier to VFC enrollment. Clinics not using the KSWebIZ system were asked about their reasons for non-participation and the reason most frequently answered (47 percent) was that they were waiting for an interface to become available. Of those who did participate in the registry, participants stated several administrative-related tasks as reasons why they did participate such as managing vaccine inventory, managing reports, and patient reminders and follow-up.

The clinic survey found that 49 percent of survey respondents participate in the KSWebIZ registry, but only 10 percent reported to access the system through an interface with their clinics EHR. The remaining 90 percent enter and retrieve data directly via the KSWebIZ user interface. According to KDHE, as of Dec. 10, 2013 there were a total of 380 immunization providers, including health departments, private clinics, and pharmacies, that were enrolled in the KSWebIZ system.¹⁷ Of the 275 private providers, 174 were VFC providers, and 101 were not. The majority, 211 interacted with the system via direct entry, and 64 via an interface with their own clinic's EHR system. KDHE is currently focusing its efforts to promote the development of interfaces with private clinics' EHR systems.

¹⁷ Kansas Department of Health and Environment (2013). *KDHE WebIZ Rollout Status*. Retrieved on February 19, 2014 from http://www.kdheks.gov/immunize/webiz_rollout.htm

One key informant interviewee had already made major upgrades and therefore major investments in an EHR for the clinic and an interface with KSWebIZ would require additional financial input. Without the upgrades clinic staff would be required to enter vaccination records twice—once into the EHR and again into KSWebIZ. In a busy clinic, this work is often considered burdensome.

DISCUSSION

This study sought to identify barriers to VFC participation that Kansas clinicians may experience by reviewing previously published reports and administrative records and conducting key informant interviews of staff from both clinics that participate in the VFC program and those that do not.

Barriers or reasons for not participating in the VFC program were similar in the 2012 clinic survey and in the key informant interviews, and the two sources together yield some potentially important information. One of the top reasons for non-VFC participation in Kansas from the clinic survey was that the VFC enrollment and participation administrative process burden is too high. Although the key informant interviews did echo that theme, those clinics that were VFC providers stated that the enrollment process to become a VFC provider appeared to be complex and daunting, but that some procedures and assistance that KDHE has in place made it much easier than it appeared to be.

Another barrier to VFC participation is that it is too expensive to purchase the necessary equipment and maintain the required stock of private vaccine in addition to the VFC vaccine, especially in a practice that serves very few children. Staff in these locations reported that it makes more sense to refer the children to the local health department for vaccinations. This may work well in some cases, but as previously discussed, the literature suggests that obtaining vaccination in the same place that children receive primary care results in higher vaccination completion rates and has additional advantages to promote the child's health. The recent increase in reimbursable administrative fees clinicians can charge for VFC vaccines could reduce this

perception, provided that adequate outreach activities are implemented to help non-participating providers overcome their reluctance.

KWebIZ is an integral part of the overall immunization system in Kansas and participation in a registry is named a best practice in the general immunization literature. Currently there is no requirement for VFC providers to also participate in the KWebIZ registry. As highlighted in the additional findings section, the key informant interviews revealed that some clinicians may view participation in VFC and KWebIZ as two elements that go hand-in-hand and together may help to ease the burden of the administrative tasks related to VFC program management.

This may be an area for additional investigation and education to understand how private providers not enrolled in VFC perceive the connection between VFC and KWebIZ. If clinicians consider KWebIZ to be a requirement for VFC participation, there may be a need for some education around the topic. On the other hand, if they feel that participation in KWebIZ would simply facilitate and enhance the provision of VFC vaccine and some may only be waiting until integration becomes more readily available.

Finally, when thinking about the future of VFC, there are broader issues related to how immunization services are likely to be delivered in the near future. Additional discussion about the effects the Affordable Care Act may have on the immunization system is necessary. As more children become insured and able to obtain vaccinations in the same location as they obtain primary care, the children and parents may become less reliant on the VFC program.

STUDY LIMITATIONS

Several limitations exist in this report. Qualitative data obtained in the key informant interviews is specific to the interviewees and not generalizable to every VFC provider or non-VFC provider in Kansas. Additionally, only seven clinics were available for interviews. The clinic survey acknowledged that data on existing immunizing clinics may be incomplete and

provides a representation of the private immunization system they may not be fully comprehensive.

Despite these limitations, the combination of information from this report together with information previously published can provide a picture of providers' perspectives, which can be used to determine action going forward.

CONCLUSION

The results of the detailed look at the VFC program in Kansas and additional information obtained from the key informant interviews lead to several possible conclusions and opportunities for system improvement.

1. Need for outreach and educational resources regarding VFC program financing and reimbursement to private clinicians.
2. Support for initial VFC required equipment.
3. Need for educational resources about KSWebIZ.
4. Need for EHR-KSWebIZ interface.

Key informant interview results were consistent with literature previously available regarding the real or perceived barrier of the cost of VFC program participation. The comments in the key informant interviews echoed those responses in the clinic survey stating that the reimbursement is too low to offset the cost of doing business. In Kansas, this administrative fee was increased from \$14.80 to \$20.26 in 2013. It is possible that some private providers who are not enrolled in the VFC program are not aware of this increase, and that knowledge would increase interest in participating.

Interviewee comments also reflected the responses seen in the clinic survey results related to the start-up costs associated with becoming a VFC provider; specifically, the cost to obtain the necessary refrigerators and to maintain separate private vaccine inventory. Education about the increased reimbursement for administrative fees may help offset some of this, but the additional availability of grants or other funding resources may also help with start-up costs.

In addition to this, the stricter waste control measures put in place by the CDC with the requirement to store public and private vaccine separately have the potential to increase costs and administrative tasks for VFC providers in general. KDHE has taken steps to address this issue by obtaining CDC approval to allow Kansas providers to store vaccine in a “blended manner,” but this may not resolve the issue entirely.

Regardless of these new vaccine waste measures, the perception of the increased time and paperwork required to complete the administrative tasks related to VFC program management was reported in the 2012 clinic survey as well as a survey completed by Paschal in 2009.¹⁸ In the key informant interviews, several participants reported that the interaction with KSWebIZ helped with the administrative tasks of vaccine tracking management, ordering and that the VFC program staff at KDHE was very responsive to any questions or issues that came up. Education about the usefulness of KSWebIZ for these tasks may help overcome this barrier.

Participants also stated that it was an issue if their EHR could not interface with KSWebIZ directly. For these clinics, in order to participate in KSWebIZ, staff would be required to enter vaccine administration information at least twice: once into the electronic health record and once into KSWebIZ, as well as whatever vaccine stock tracking mechanism is in place. Increasing the number of KSWebIZ users that can interact with the system directly via an interface would eliminate the double-entry burden for those users.

In addition, several providers interviewed for the clinic survey stated that they were not aware of the VFC program and would like more information about the program. More active outreach of education in general with emphasis on the increased reimbursement rate and potential for KSWebIZ to reduce the administrative burden of program participation could increase enrollment.

¹⁸ Paschal, A., Maryman, J., Oler-Manske, J. (2009). How can immunization coverage in urban counties be improved? A pilot study of a Kansas county. *Am J Infect Control*, 37(5):423–5.

The extent to which these improvements could be addressed is likely dependent upon available state resources and system compatibilities, while additional monetary support is largely at the discretion of the federal government.

APPENDIX A – 2014 VFC PROVIDER ENROLLMENT PACKET

Available from:

http://www.kdheks.gov/immunize/imm_manual_pdf/Complete_VFC_ENROLLMENT_PACKET_PRIVATE.pdf

Division of Public Health
Curtis State Office Building
1000 SW Jackson St., Suite 540
Topeka, KS 66612-0461



Phone: 785-296-1086
Fax: 785-368-6368
www.kdheks.gov

Robert Moser, MD, Secretary

Department of Health & Environment

Sam Brownback, Governor

To: Vaccines for Children (VFC) Providers

From: Pete Bodyk, Immunization Program Section Chief

Date: January 6, 2014

Subject: 2014 VFC Provider Enrollment

The Kansas Immunization Program (KIP) wishes to express our gratitude and appreciation for your service to the VFC program. The VFC program represents your dedication to providing immunization services to children who otherwise might not receive protection from vaccine preventable disease.

The 2014 VFC Enrollment Form is enclosed. The Centers for Disease Control (CDC) require that all immunization programs across the nation use this enrollment form and provider profile sheet beginning with the 2014 VFC enrollment. The changes to the enrollment are discussed below.

Please return the completed form no later than February 28, 2013 to Jackie Strecker. Timely completion and submission of your enrollment will assure your clinic of uninterrupted vaccine delivery. A copy of your 2013 vaccine profile is not enclosed since it did not show the number of CHIP (Title 21) children served. If you want a copy of the form, please contact Martha Froetschner at mfroetschner@kdheks.gov. It is important for each clinic to assess, as accurately as possible, the number of VFC-eligible, CHIP (Title 21), Underinsured (if an FQHC, RHC or deputized LHD only) and privately insured children served in 2013.

Effective October 1, 2013, the Centers for Disease Control (CDC) changed how providers may use, order and store VFC-funded vaccines. KIP began processing orders with vaccine funding splits and separating the number of doses of VFC and non-VFC funded vaccines in each provider order. These splits were based on the historical data KIP had on file for your clinic. The profile numbers are how many children you serve in each age cohort. It is imperative that a child only be counted one time for immunization services regardless of the number of visits. Accurate counts are critical. If you are a direct-entry KSWebIZ provider, KIP will assist you in running the VFC Category Patient Report to obtain the 2013 count of children served for the profile. Please call the registry helpdesk for assistance with this report (877-296-0464).

Important note, KIP submitted a proposal to modify the CDC mandate that became effective October 1, 2013. This proposal was approved and the modifications are as follows: Providers may keep (store) program supplied vaccine in a "blended manner." This means that providers do not have to separate VFC-funded vaccines from other program supplied vaccine (i.e., CHIP). Program vaccines must be kept separate from privately purchased vaccines. Screening and documenting a child's eligibility is mandatory for every immunization visit. Doses administered and ending inventories must be reported by the child's eligibility status and vaccine funding sources.

VFC providers may borrow program vaccine on a rare, emergency basis. Borrowing vaccine may not be done because of not keeping adequate stocks of private vaccine on

hand. The borrowing form must be completed for each incident of borrowing, and submitted monthly with all other VFC required reports. Please see the attached communication sent to all VFC providers December 30, 2013. Compliance with the CDC approved modified process is imperative as the CDC can rescind this approval at any time.

Important VFC program information for the 2014 VFC Enrollment form

The **Provider Profile Form** is the clinic demographic and profile pages. The responses to questions on this form are very important for receipt of VFC vaccine. Complete all sections of both pages.

- **Please note your delivery hours next to “Delivery address.”**
- **VFC Eligibility Categories-** complete these sections for the children or newborns served: For example, if you are a hospital, only indicate the number of annual births in the less than 1 year category; pharmacies need only indicate the number of children to be served for immunization services as allowed by statute.

VFC Provider Agreement Enrollment Contract

1. **Provider Agreement, Page 1** - Complete all fields on this page. Please read the instructions in the Medical Director or Equivalent section. The Medical Director and any secondary official health care provider (i.e., pharmacy or health department administrator, if appropriate) complete these boxes.
2. Please note the VFC coordinator and back-up must submit their certificates of completion of both CDC required modules from “You Call the Shots” with the completed enrollment form. KIP Education Policy (attached) describes this requirement.
3. **Page 2** is where all providers who practice medicine, or are pharmacists, are listed. If additional lines are needed for listing providers, see page 6. If you still need more space, please attach a separate sheet with the same information.
4. **Pages 3, 4 & 5** are the VFC contract conditions and the signature section of the enrollment contract. Again, both parties, as appropriate, must sign this section.
5. Screening and documenting a child’s eligibility at every immunization visit is mandatory. This assures that only VFC-eligible children receive VFC-funded vaccines and CHIP (Title 21) children receive CHIP-funded vaccines. Enrolled birthing hospitals receive 317-funded vaccine for the birth dose of hepatitis B, and an adult only provider who participates in special adult vaccine projects receive 317-funded vaccine only. Rarely will any provider receive State-funded vaccine. The funding streams for the vaccine shipped are on the packing list in each box shipped by McKesson (see enclosed packing slip). *Direct shipped vaccines from Merck (Varicella or MMRV) will not show funding splits.*
6. Providers need to assess their patient population to be sure the eligibility categories are accurate and that vaccine orders are in line with these eligibility numbers. Providers must report the doses administered and on-hand inventory by funding sources in their month-end reconciliation in KSWebIZ. This includes vaccine shipments received, transfers, and wasted vaccine doses. This data is required to be reported by the 10th of the month, for the preceding month. The following data is also required to be reported by the 10th of the month:
 - Temperatures for vaccine storage units (taken and recorded twice daily);

- Data logger downloads;
- All borrowed and wasted vaccine forms.

All reconciliations must be within 7 days of a vaccine order.

7. **Effective January 1, 2014, all VFC providers are allowed to order vaccine monthly between the 1st and 15th of every month. Those providers who have been ordering bi-monthly will do a transition (partial month) close out to move to the monthly schedule. Orders will be processed as VFC unless the provider specifically orders CHIP (See KIPs December 30, 2013 communication on the modified process). KIP encourages providers who have completed their separated vaccine storage to continue with this practice. This will assist your clinic greatly in overall vaccine management and monthly reporting.**
8. **Other documents included in the 2014 enrollment packet are:**
 - a. **KIP Modified Advance Credit Policy and Process**
 - b. **Change of VFC Contact Form**
 - c. **Vaccine Management Policy**
 - d. **Wasted Vaccine Policy**
 - e. **Wasted Vaccine Return Procedure and Form (note the November 2013 form must be used)**
 - f. **Borrowed Vaccine Guidance and Form**
 - g. **Routine Vaccine Storage and Handling Form**
 - h. **Vaccine Storage and Emergency Response Plan**
 - i. **Data Logger User Agreement**
 - j. **Education Policy**
9. **Please note the Wasted Vaccine Policy has changed and the repayment method is a “dose for dose” replacement process. During 2014, KIP will not require dose for dose replacement *except*:**
 - a) *When a provider receives an insurance payment for vaccine loss;*
 - b) *Due to gross negligence (i.e., vaccine temperatures are not monitored or actions not taken);*
 - c) *Provider has a pattern of \$500.00 or more waste per month*
 - d) *Excessive vaccine stock is ordered and expires*

During 2014, KIP expects providers to assess their wastage patterns and take actions to prevent future occurrences. In 2015, all avoidable wasted vaccine will be repaid under the dose-for-dose replacement method as required by the CDC.

KIP appreciates the stewardship each provider continues to demonstrate in assuring that VFC vaccines are managed appropriately so that each child is immunized with uncompromised vaccine. Your hard work and commitment to keeping children healthy and free of vaccine preventable disease is admirable.

Please contact Pete Bodyk at: pbodyk@kdheks.gov or Martha Froetschner at: mfroetschner@kdheks.gov with any questions. Thank you.

Enclosures as noted above

2014 Vaccines for Children (VFC) Program Provider Profile Form

All health care providers participating in the Vaccines for Children (VFC) program must complete this form annually or more frequently if the number of children served changes or the status of the facility changes during the calendar year.

Date: ____/____/____

Provider Identification Number# _____

FACILITY INFORMATION		
Provider's Name: _____		
Facility Name: _____		
Vaccine Delivery Address: _____		
City: _____	State: _____	Zip: _____
Telephone: _____	Email: _____	
FACILITY TYPE (select facility type)		
Private Facilities	Public Facilities	
<input type="checkbox"/> Private Hospital <input type="checkbox"/> Private Practice (solo/group/HMO) <input type="checkbox"/> Private Practice (solo/groups as agent for FQHC/RHC-deputized) <input type="checkbox"/> Community Health Center <input type="checkbox"/> Pharmacy <input type="checkbox"/> Birthing Hospital <input type="checkbox"/> School-Based Clinic <input type="checkbox"/> Teen Health Center <input type="checkbox"/> Adolescent Only Provider <input type="checkbox"/> Other _____	<div style="display: flex; justify-content: space-between;"> <div style="width: 65%;"> <input type="checkbox"/> Public Health Department Clinic <input type="checkbox"/> Public Health Department Clinic as agent for FQHC/RHC-deputized <input type="checkbox"/> Public Hospital <input type="checkbox"/> FQHC/RHC (Community/Migrant/Rural) <input type="checkbox"/> Community Health Center <input type="checkbox"/> Tribal/Indian Health Services Clinic <input type="checkbox"/> Woman Infants and children <input type="checkbox"/> Other _____ </div> <div style="width: 30%;"> <input type="checkbox"/> STD/HIV <input type="checkbox"/> Family Planning <input type="checkbox"/> Juvenile Detention Center <input type="checkbox"/> Correctional Facility <input type="checkbox"/> Drug Treatment Facility <input type="checkbox"/> Migrant Health Facility <input type="checkbox"/> Refugee Health Facility <input type="checkbox"/> School-Based Clinic <input type="checkbox"/> Teen Health Center <input type="checkbox"/> Adolescent Only </div> </div>	
VACCINES OFFERED (select only one box)		
<input type="checkbox"/> All ACIP Recommended Vaccines <input type="checkbox"/> Offers Select Vaccines (This option is only available for facilities designated as <u>Specialty Providers</u> by the VFC Program)		
<p>A "Specialty Provider" is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g. OB/GYN; STD clinic; family planning) or (2) a specific age group within the general population of children ages 0-18. Local health departments and pediatricians are not considered specialty providers. The VFC Program has the authority to designate VFC providers as specialty providers. At the discretion of the VFC Program, enrolled providers such as pharmacies and mass vaccinators may offer only influenza vaccine.</p>		
Select Vaccines Offered by Specialty Provider:		
<input type="radio"/> DTaP <input type="radio"/> Hepatitis A <input type="radio"/> Hepatitis B <input type="radio"/> Hib <input type="radio"/> HPV <input type="radio"/> Influenza	<input type="radio"/> Meningococcal Conjugate <input type="radio"/> MMR <input type="radio"/> Pneumococcal Conjugate <input type="radio"/> Pneumococcal Polysaccharide <input type="radio"/> Polio <input type="radio"/> Rotavirus	<input type="radio"/> TD <input type="radio"/> Tdap <input type="radio"/> Varicella <input type="radio"/> Other, specify: _____

PROVIDER POPULATION				
Provider Population based on patients seen during the previous 12 months. <i>Report the number of children who received vaccinations at your facility by age group. Only count a child <u>once</u> based on the status at the last immunization visit regardless of the number of visits made. The following table documents how many children received VFC vaccine by category, and how many received non-VFC vaccine.</i>				
VFC Vaccine Eligibility Categories	# of children who received VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Enrolled in Medicaid				
No Health Insurance				
American Indian/Alaska Native				
Underinsured in FQHC/RHC or deputized facility ¹				
Total VFC:				
Non-VFC Vaccine Eligibility Categories	# of children who received non-VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Insured (private pay/health insurance covers vaccines)				
Children's Health Insurance Program (CHIP) ²				
Total Non-VFC:				
Total Patients (must equal sum of Total VFC + Total Non-VFC)				
<p>¹Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance.</p> <p>In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate these underinsured children.</p> <p>²CHIP – Children enrolled in the state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.</p>				
TYPE OF DATA USED TO DETERMINE PROVIDER POPULATION (choose all that apply)				
<div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"> <input type="radio"/> Benchmarking </div> <div style="width: 50%;"> <input type="radio"/> Doses Administered </div> <div style="width: 50%;"> <input type="radio"/> Medicaid Claims Data </div> <div style="width: 50%;"> <input type="radio"/> Provider Encounter Data </div> <div style="width: 50%;"> <input type="radio"/> IIS </div> <div style="width: 50%;"> <input type="radio"/> Billing System </div> <div style="width: 50%;"> <input type="radio"/> Other (must describe): </div> </div>				

KANSAS IMMUNIZATION PROGRAM
2014

VACCINES FOR CHILDREN PROGRAM PROVIDER AGREEMENT

FACILITY INFORMATION			
Facility Name:			VFC Pin#:
Facility Address:			
City:	County:	State:	Zip:
Telephone:		Fax:	
Shipping Address (if different than facility address):			
City:	County:	State:	Zip:
MEDICAL DIRECTOR OR EQUIVALENT			
Instructions: The official VFC registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed here must sign the provider agreement.			
Last Name, First, MI:		Title:	Specialty:
License No.:		Medicaid or NPI No.:	Employer Identification No.:
<i>Provide Information for second individual as needed:</i>			
Last Name, First, MI:		Title:	Specialty:
License No.:		Medicaid or NPI No.:	Employer Identification No.:
VFC VACCINE COORDINATOR			
Primary Vaccine Coordinator Name:			
Telephone:		Email:	
Completed annual training: <input type="radio"/> Yes <input type="radio"/> No		Type of training received:	
Back-Up Vaccine Coordinator Name:			
Telephone:		Email:	
Completed annual training: <input type="radio"/> Yes <input type="radio"/> No		Type of training received:	

KANSAS IMMUNIZATION PROGRAM
2014

PROVIDERS PRACTICING AT THIS FACILITY <i>(additional spaces for providers at end of form)</i>				
Instructions: List below all licensed health care providers (MD, DO, NP, PA, pharmacist) at your facility who have prescribing authority.				
Provider Name	Title	License No.	Medicaid or NPI No.	EIN (Optional)

KANSAS IMMUNIZATION PROGRAM
2014

PROVIDER AGREEMENT	
<i>To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or practice administrator or equivalent:</i>	
1.	I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2.	<p>I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:</p> <p>A. Federally Vaccine-eligible Children (VFC eligible)</p> <ol style="list-style-type: none"> 1. Are an American Indian or Alaska Native; 2. Are enrolled in Medicaid; 3. Have no health insurance; 4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement. <p>B. State Vaccine-eligible Children</p> <ol style="list-style-type: none"> 1. In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children. <p>Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are not eligible to receive VFC-purchased vaccine.</p>
3.	<p>For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:</p> <ol style="list-style-type: none"> a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child; b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4.	I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5.	I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.

KANSAS IMMUNIZATION PROGRAM

2014

6.	I will not charge a vaccine administration fee to non-Medicaid federal and state vaccine-eligible children that exceeds the administration fee cap of \$20.26 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
7.	I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
8.	I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
9.	I will comply with the requirements for vaccine management including: <ul style="list-style-type: none"> a) Ordering vaccine and maintaining appropriate vaccine inventories; b) Not storing vaccine in dormitory-style units at any time; c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet the Kansas Immunization Program storage and handling recommendations and requirements; d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration
10.	<p>I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program:</p> <p>Fraud: is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.</p> <p>Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.</p>
11.	I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
12.	<p>For providers with a signed deputization Memorandum of Understanding between a FQHC or RHC and the Kansas Immunization Program to serve underinsured VFC-eligible children, I agree to:</p> <ul style="list-style-type: none"> a) Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit; b) Vaccinate "walk-in" VFC-eligible underinsured children; and c) Report required usage data

KANSAS IMMUNIZATION PROGRAM
2014

	Note: "Walk-in" in this context refers to any underinsured child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve underinsured patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to underinsured patients as well.
13.	<p>For pharmacies, urgent care, or school located vaccine clinics, I agree to:</p> <ul style="list-style-type: none"> a) Vaccinate all "walk-in" VFC-eligible children and b) Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee. <p>Note: "Walk-in" refers to any VFC eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well.</p>
14.	I agree to replace vaccine purchased with state and federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a <u>dose-for-dose</u> basis.
15.	I understand this facility or the Kansas Immunization Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the Kansas Immunization Program.

<i>By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.</i>	
Medical Director or Equivalent Name (print):	
Signature:	Date:
Name (print) <i>Second individual as needed:</i>	
Signature:	Date:

KANSAS IMMUNIZATION PROGRAM
2014

ADDITIONAL PROVIDERS

PROVIDERS PRACTICING AT THIS FACILITY <i>(attach additional pages as necessary)</i>				
Instructions: List below all licensed health care providers (MD, DO, NP, PA, pharmacist) at your facility who have prescribing authority.				
Provider Name	Title	License No.	Medicaid or NPI No.	EIN

To: Vaccines for Children (VFC) Providers

From: Pete Bodyk, Immunization Program Section Chief

Date: December 30, 2013

Subject: Kansas Modified Advanced Credit (Dose Level) Accountability Policy and Process

On December 19, 2013, the Centers for Disease Control (CDC) approved the modified proposal Kansas submitted to their October 1, 2013 mandate on Advance Credit (dose level) Accountability. The approval means the Kansas Immunization Program (KIP) may allow blended inventory of program supplied vaccines so long as the provider reports monthly data timely (each month's data by the 10th of the following month). The monthly data includes:

- all vaccine shipments received;
- on-hand inventory by funding source;
- doses administered by funding source;
- all borrowed vaccine;
- all wasted vaccine.

In order to decrease missed opportunities and unnecessary wasted vaccine, KIP may allow borrowing of any program supplied vaccines under the following circumstances:

1. The provider has submitted their 2014 VFC Enrollment by February 28, 2014;
2. The provider has documented their expected CHIP population as accurately as possible on the 2014 Provider Profile page of the VFC enrollment packet;
3. The provider submits all borrowing reports monthly, if applicable;
4. The provider does not/has not demonstrate(d) a pattern of immunizing non-eligible children with VFC vaccine;
5. The provider reports all month-end data timely and accurately.

It is also important to note that KIP received CDC's approval based on assurances that KIP and Kansas VFC providers will not use VFC-funded vaccines for non-VFC eligible children except on a rare emergency basis.

- Providers will be required to assess their CHIP population to determine if their profile has changed, and does this change impact the amount of CHIP vaccine needed.
- Providers who have patterns of excessive borrowing will be contacted by a program field nurse to assess the issues and develop a plan of correction.
- KIP will continue to assist and educate providers at annual site reviews, educational visits, community meetings, the annual immunization conference, and during one-on-one meetings. This education will consist of information about vaccine funding sources, accuracy of provider profiles, and correct

reporting of doses administered to assure accountability for the vaccine resources provided with federal and state monies.

The attached sheet shows provider vaccine ordering scenarios and the reporting expected to assure the CDC's approved plan is adhered to so that only VFC-eligible children are immunized with VFC-funded vaccines. Providers must screen and document the child's eligibility at every immunization visit and report doses administered, and on-hand inventory by funding sources (VFC, CHIP, 317, state).

All orders will be processed as VFC unless a provider can use full boxes of CHIP vaccine. The provider will have to complete a CHIP order along with a VFC order when CHIP doses are needed. NOTE: CHIP doses may not be needed with every VFC order, order CHIP only when needed.

All providers will order vaccine between the 1st and 15th of the month beginning January 1, 2014. One order per month is allowed. The following conditions must be met to submit an order:

- 1) Monthly reconciliations must have been completed within seven days of the order;
- 2) Temperature logs must be current and complete;
- 3) Current monthly borrowing and wasted vaccine reports must be submitted.

Small providers (those using less than a full box of CHIP vaccine in a 12 month period) can do one of the following:

- Borrow and once a full box has been administered, place a CHIP order to replace the borrowed doses; or
- Request a split order by contacting Fiscal Manager Jackie Strecker.

Providers found to be abusing the borrowing policy or those not conducting and documenting eligibility screening will be contacted by a program nurse, provided additional education, advised of the potential consequences and/or disenrolled if processes are not corrected. KIP is responsible for the integrity of the VFC program in Kansas and providers have always been accountable for assuring the child is eligible to receive a program supplied vaccine. This process has to be followed for KIP to be in compliance with the agreed upon modification arrangement approved by the CDC. The CDC can rescind their approval of this plan at any time. Providers who have separated their vaccine stock are encouraged to continue this as it will assist them in accounting for all program supplied vaccines. KIP knows each VFC provider has been, and will continue to be, good stewards of these vaccine resources. Thank you!

If your clinic has questions, please contact Martha Froetschner at: mfroetschner@kdheks.gov or 785-925-1990.

Modified Kansas Immunization Program Vaccine Order Process

Hospital or Adult Providers

Orders 317 Vaccine between the 1st and 15th of the month

Accepts vaccine shipment as 317

Reports doses administered and on-hand inventory

Private and LHD Providers

Orders VFC vaccine between the 1st and 15th of the month

CHIP orders are separate & require order to be full box of vaccine (no splits)

All orders are VFC unless CHIP is requested by provider

Provider reports doses administered & on-hand inventory by CHIP and VFC*.

*Child's eligibility determines funding source of vaccine used and reported.

Borrowing

Borrowing will be allowed on a *Rare, Emergency basis only.*

All borrowed doses must be documented on the borrowing form and submitted by the 10th of the following month

Vaccine Funding Streams

VFC is Federally Eligible:

Medicaid (Title 19) only

Uninsured

AI/AN

Underinsured at FQHC/RHC/Deputized LHD only

CHIP is Title 21 only:

Not VFC-eligible. CHIP buys the vaccines

317 is Birth Dose Hep B and Special Adult Projects

State is for Disease Outbreaks

SMALL: LESS THAN A FULL BOX OF CHIP Vaccine Used in 12 month period

Provider contacts Fiscal Manager to open Split Order:

1. Provider chooses vaccines to be split and amounts (9/1; 7/3; etc.); OR
2. Provider borrows VFC and orders CHIP once full box is needed

Split orders are very infrequent. Only providers serving less than 10 children combined in the 0-6 or 7-18 age cohorts need split shipments.

Providers are encouraged to share full boxes of CHIP vaccine with other providers in close proximity to them.

NOTIFICATION OF CHANGE IN VFC CONTACT
KANSAS IMMUNIZATION PROGRAM

Pin Number: _____

Date contact changed: _____ **Changed: Primary**_____ **Backup**_____ **Both**_____

Clinic Name: _____

Name of New Contact (Primary) _____

New Primary Contact E-mail Address: _____

Telephone # _____

VFC Contact (Backup): _____

Telephone# _____

The Kansas Immunization Program, Vaccines for Children, requires new Primary and Backup contacts to submit certificates of completion to the Kansas Immunization Program for the two learning modules listed below within 30 days of being assigned the VFC responsibilities.

- 1) Vaccines for Children (VFC);*
- 2) Vaccine Storage and Handling.*

You can find the learning modules at: <http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>

Submit the certificates of completion to:

Jackie Strecker

P: 785-296-2199

F: 785-296-6510

jstrecker@kdheks.gov

Please notify the Nurse Consultant of this change.

Rev. December 5, 2013

Kansas Immunization Program Vaccine Management

The Vaccines for Children (VFC) Program requires the Kansas Immunization Program (KIP) ensure that VFC provider vaccine management practices are consistent with sound immunization, fiscal, business and medical practices, and do not result in unnecessary costs to the program due to excessive wastage or unaccounted for VFC vaccines. The Centers for Disease Control and Prevention (CDC) have established minimum guidelines detailing the steps of proper vaccine storage and handling. This toolkit is found at: <http://www.cdc.gov/vaccines/recs/storage/interim.htm>

Kansas VFC providers are diligent in their practices to ensure sound vaccine management practices. The Kansas Immunization Program appreciates these efforts. These vaccine management policies are designed to help assure continuation of the VFC program for Kansas children by:

- a. assisting each provider clinic in quality improvements in VFC vaccine management practices;
- b. reducing wasted vaccines;
- c. ensuring vaccines are stored appropriately so they are stable;
- d. decreasing and/or eliminating unaccounted for vaccines.

Clinic policies and procedures are fluid and shall be reviewed and updated annually. Program staff will review each clinic's policies and procedures annually at the VFC site visit and/or unannounced visits. VFC providers must have policies and procedures to address management of VFC vaccines in each of the following areas.

Storage and Handling:

Appropriate vaccine storage ensures vaccines are stable and will protect against disease.

1. Vaccines must be handled and stored in accordance with the Food and Drug Administration (FDA) approved package insert that is shipped with each product.
2. Refrigerated vaccines must be stored between 35-46 degrees F (2-8 degrees C).
3. Frozen vaccine must be stored at 5 degrees or less F (-15 degrees C).
4. The storage units for any VFC vaccine may not be a "dorm-style/bar-style" unit.
5. Refrigerated units must be at least large enough to hold the year's largest inventory on the second or lower shelf plus water bottles to stabilize temperature.
6. Storage units should be stand-alone refrigerators and freezers and preferably a vaccine or biological grade unit.
7. Household type units currently in use must have separate doors for the refrigerator and freezer, and each unit must have separate temperature controls. Household units with a single door and/or single temperature control are not acceptable unless the unit is only used for refrigerated vaccine.
8. A "Do Not Unplug" warning sign must be placed next to the electrical outlets for each vaccine storage refrigerator and freezer and on the electrical breaker that services these outlets. Tamper proof plugs are also recommended.
9. A calibrated certified digital thermometer with a minimum and maximum reading capacity and the temperature probe in glycol must be used for every unit storing VFC vaccine. The calibration certification must be current. All calibration certifications must be kept on file for the period of the certification.
10. The data logger KIP provides meets these calibration certification specifications.
11. The temperature of the refrigerator and freezer where the vaccines are stored must be checked and recorded on a temperature log at least twice daily: in the AM when clinic opens and in the PM just before closing. Alarm systems are strongly recommended as back-up for notification of out of range temperatures.
12. If there is a refrigerator or freezer malfunction or power outage, the time interval of the outage needs to be determined as this is critical to determine the stability of the vaccines. Backup generators are strongly encouraged.
13. VFC providers must develop contingency plans to assure vaccine viability in the case of natural disasters, power outages, or other emergencies. Such contingency plans might be a back-up generator or moving vaccines to another location which has a generator. Templates for routine storage, handling and emergency procedures are attached to this policy.

14. Any incident which may call into question the vaccine stability, including incidents of improper vaccine storage and handling, must be reported to KIP and the vaccine manufacturers. The report must include vaccine antigens and length of time and temperature at which vaccine was stored. Not all vaccines are non-viable if the temperature excursion and time factors were minimal. Mark vaccines DO NOT USE and leave refrigerated or frozen until the manufacturer and KIP have been notified. Frozen vaccines are more sensitive to warm temperatures just as refrigerated vaccine is most sensitive to cold temperatures.
15. Once the vaccines are determined to be non-viable, place them in a container and mark DO NOT USE. Complete the KIP Wasted Vaccine Form and document the wasted doses on the KSWebIZ inventory reconciliation. Fax the Wasted Vaccine form to KIP at 785-296-6510 each month with other monthly immunization reports and request a vaccine return shipping label.

Vaccine Ordering:

Vaccine ordering is more than placing the orders. It is an analysis of the number of children served and their insurance or eligibility status over a 12 month period that assist clinics in determining the vaccine manufacturer and presentation needed. Assessing vaccine storage capacity and having written vaccine storage and handling policies that are communicated to, and followed by staff is important.

1. Ordering the appropriate amount of each vaccine at the correct interval is an important component of vaccine accountability.
2. Providers need to calculate their vaccine needs based on the number of children served in each age cohort and eligibility (fund) type. Contact one of our program nurse consultants for assistance. *Check your order! Be sure you order the correct vaccine and number of doses!*
3. Effective January 1, 2014, all VFC providers may order vaccine during the first 15 days of each month. Providers should have a five week supply of vaccine on hand and only order once each month.
4. Vaccine management includes deciding which vaccine manufacturer and presentation to use. This helps improve staff knowledge of the vaccines administered, decreases errors in vaccine administration and streamlines inventory. This decreases wastage and unaccounted for vaccines.
5. Providers must count all VFC vaccine inventory at least monthly and within 7 days of any vaccine order. If large vaccine stores are kept on hand, it is recommended that these counts be done more frequently to assist in identifying discrepancies in vaccine counts early.
6. Designate one person and at least one back up person to be responsible for ensuring vaccine shipments are received, stored and handled properly.
7. A Routine Vaccine Storage and Handling Plan Worksheet will assist in documenting and training staff on the importance of vaccine management.
8. Open shipments immediately and store appropriately.
9. Enter new inventory information immediately by funding source. Keep all program supplied vaccine separate from privately purchased vaccine.
10. Separate new vaccine shipments from those currently in stock. Use stock with the earliest expiration date first.
11. If a provider receives vaccines they did not order, contact KIP and McKesson at once. Providers who order the wrong vaccine are responsible for those doses.
12. Excessive overstocking of vaccines result in waste. Order what is needed.
13. Providers may place excess doses on the KIP Redistribution List if the vaccine has a minimum of 90 days and a maximum of 365 days before the vaccine expiration date. The ordering provider is responsible for any doses which expire on the redistribution list that have not been accepted for transfer by another VFC provider. Providers accepting vaccine from the redistribution list are responsible for using the doses once they are transferred. KIP encourages providers to only accept doses they can administer before the expiration date. The transferring and receiving providers will document doses on their monthly MIR/reconciliation reports as transferred vaccines by the funding source. Vaccine funding sources will be included on the redistribution list.

Vaccine Storage Units:

There are several manufacturers of vaccine storage units. Samples of these are found on the KIP website at:

<http://www.kdheks.gov/immunize/storageandhandling>

KIP does not endorse any product. The examples are only for demonstration purposes. Each provider is responsible for the terms and conditions of any purchase made.

Program specific documents and policies are found in the Immunization Program Manual at: <http://www.kdheks.gov/immunize>

Kansas Immunization Program Wasted VFC Vaccine Policy

The Kansas Immunization Program (KIP) is charged with reducing Vaccines for Children (VFC) vaccine losses due to wasted vaccines. Thousands of doses are wasted annually with values exceeding hundreds of thousands of dollars. This is a needless waste of federal and state tax dollars and adversely impacts the numbers of eligible children who could receive immunizations.

The Centers for Disease Control & Prevention (CDC) strengthened the VFC Program non-compliance processes beginning in 2009. In 2012, the Office of Inspector General (OIG) mandated the CDC become increasingly focused on stopping needless vaccine waste, improve storage and handling of vaccines, and increase program and provider accountability for vaccine resources. All state immunization programs implemented wasted vaccine policies aimed at identifying and preventing waste, poor vaccine management processes, and/or fraud or abuse in the VFC program. Vaccine management processes, including documentation, proper vaccine storage and handling, reporting vaccine usage, determining VFC eligibility, temperature monitoring, and preventing avoidable waste, are critical to this compliance program.

KIP's goal is to educate and assist providers in identifying mechanisms to prevent wasted vaccines and improve overall vaccine management processes. This policy is one component of these processes.

Provider Processes:

1. Complete or submit these documents by the 10th of the month following the month of service:

- a. Monthly vaccine inventory reconciliation in KSWebIZ;
- b. Temperature logs or data logger downloads;
- c. Wasted vaccine report- November 2013 version only;
- d. Borrowed vaccine logs are to be completed and submitted (see Borrowed Vaccine Policy).

By the 30th of the month, missing reports will result in the suspension of vaccine orders until the documents are received.

2. Vaccine Waste is categorized as avoidable or unavoidable. Unavoidable waste occurs due to an act of nature that could not have been avoided (i.e., tornados, floods). Avoidable waste is under the control of the provider and is preventable. Avoidable waste includes, but is not limited to:
 - a. Refrigerator/freezer left open;
 - b. Temperatures out of range and no action taken, or data logger not downloaded when alarm indicates a problem;
 - c. Vaccine left out overnight;
 - d. Excessive vaccine ordering as compared to provider profile;
 - e. Failure to notify KIP 3 months in advance of vaccine expiration date when provider will be unable to use all the doses on hand. This will allow KIP to place the vaccine doses on the redistribution log. KIP will not list vaccines with expiration dates longer than 365 or less than 90 days. Listing vaccines on the redistribution log **does not** absolve the provider of responsibility. Providers who have excess vaccine should contact other VFC providers to determine if they could use the vaccine. Providers might share a box of vaccine with another provider versus ordering quantities they do not need and then wasting the doses;
 - f. Failure to properly package vaccines when shipping to another provider resulting in waste (i.e., shipping without adequate cold/frozen packs);
 - g. Vaccines with longer expiration dates administered prior to vaccines with shorter expiration dates;
 - h. Patterns of client eligibility not determined prior to administering vaccination;
 - i. Patterns of vaccine drawn but not used.

Policy:

1. Avoidable vaccine waste is excessive and will require provider take corrective action.
2. Providers with avoidable wasted vaccine will be expected to replace the wasted vaccine on a "dose for dose" basis. The provider shall replace the wasted vaccine within 90 days of the waste and shall submit a paid invoice showing the replacement of the wasted doses.
3. Providers are requested to specifically identify internal mechanisms to avoid future wastage and to submit these plans to KIP along with their wasted vaccine reports monthly. Examples for avoidable wasted vaccine that will need a plan of action may be:
 - a. expired vaccines;
 - b. improper storage and handling;
 - c. equipment failures;
 - d. staff education on vaccine management practices (i.e., stock rotation);
 - e. ordering patterns (inventory on-hand versus monthly/quarterly use).
4. Providers with ongoing avoidable wasted vaccine may be placed on vaccine hold or may be dis-enrolled from the VFC program should the patterns of wastage continue.
5. Unavoidable wasted vaccines shall be monitored by KIP. Unavoidable waste includes vaccines lost due to natural disasters or equipment failure when the provider has followed their written vaccine emergency policies, including relocating the vaccines to safe storage in a timely manner. Providers who have insurance which covers these situations will be expected to replace all VFC wasted doses with the payment from the insurance company within 90 days of the incident. The provider will be asked to submit the paid invoice for the wasted vaccine. Federal law prohibits financial gain from VFC vaccines.
6. Providers repay avoidable wasted vaccine with privately purchased vaccine on a "dose for dose" basis. A submitted paid invoice must be received by KIP within 90 days of the waste showing this replacement. The Centers for Disease Control have implemented this dose for dose repayment method effective 2014 (see cover letter for 2014 policy).
7. Any unusable vaccine occurring from waste, expiration, or other event must be reported and submitted on the VFC Wasted Vaccine Form in the month of the waste. The November 2013 Wasted Vaccine Form is the acceptable reporting form for wasted vaccines.
8. Providers who receive short-dated vaccines (less than 6 months to the expiration date from McKesson Distributors) are asked to report this to KIP immediately. Only in special circumstances are short-dated vaccines shipped. Good faith efforts to use short-dated vaccines will not be billed if wasted, unless the waste is due to gross negligence.
9. VFC providers who accept redistributed vaccine will not be billed for waste so long as the receiving provider has made a good faith effort to use all the vaccines prior to their expiration date.
10. All VFC providers will be monitored for patterns of waste.

Rev: December 5, 2013

Wasted Vaccine Return Procedure

The Kansas Immunization Program (KIP) has established a procedure for the handling and return of wasted vaccines received through the Vaccines for Children Program (VFC). According to the terms of the provider contract and stipulations of the National Childhood Vaccine Injury Act, covered vaccines which cannot be administered because of improper refrigerator or freezer storage, improper handling during shipment, destruction, expiration, or any other event which results in the return of the vaccine to the manufacturer (other than for resale) will be eligible for a Federal Excise Tax credit. These excise tax credits are monies returned to the federal VFC program to purchase more vaccines. This procedure is applicable only to vaccines that are purchased with VFC, State or 317 Program funds.

VFC providers shall not destroy wasted or expired vaccines, but shall return them to McKesson Distribution Center for return to the appropriate manufacturer. These vaccines may be returned to McKesson packed in a box or in one of the foam shipping containers in which the provider originally received their shipment. The following is the procedure for returning wasted vaccine:

1. The provider calls KIP at 785-296-5591 or emails to: vaccine@kdheks.gov to request a wasted/expired vaccine pick-up. The wasted vaccine form must be submitted to KIP before requesting a return label;
2. KIP notifies McKesson of this request;
3. McKesson will send a shipping label to the provider in an envelope;
4. Once the label arrives, the provider shall send the wasted vaccine to McKesson and include a copy of the wasted vaccine form;
5. All VFC wasted vaccines must be returned to McKesson within six months of the date of waste.

Note: The Wasted Vaccine Form (attached) must be submitted with the provider's monthly immunization and temperature reports.

Exceptions to returned vaccines are:

- 1) Vaccine which was drawn up in a syringe to be administered;
- 2) Broken vials;
- 3) Pre-filled syringes with needles attached;
- 4) Open multi-dose vials.

Mark these types of wasted vaccines on the Wasted Vaccine Form and document them in the KSWebIZ reconciliation, but do not return them.

Vaccine storage and handling, including opening shipments as soon as they are received, is critical to maintaining the stability of the vaccines. Providers must open vaccine shipments immediately upon arrival, compare the packing list with the vaccines in the container, and check the ColdMark to be sure the temperatures are in range.

Wasted Vaccine Return Procedure

- A. Store the vaccines immediately in the correct storage unit;
- B. If there are any shipping issues or if the temperatures are not within range, contact McKesson within 2 hours of the time you sign the receipt for the shipment. Place the vaccine in the refrigerator or freezer and mark **Do Not Use**;
- C. Contact KIP at 855-896-7337 if there are any compromised vaccines;
- D. Remember, you must store the vaccines in the correct cold storage unit even if they are compromised. Contact McKesson at: 877-836-7213 or KIP at 855-896-7337.

If the vaccine is determined to be nonviable at the time of delivery, you must contact McKesson within 2 business days to arrange pick-up of the product and the ColdMark temperature monitor for return to McKesson. Failure to return vaccines in a timely fashion could be construed as fraud by the Vaccines for Children (VFC) Program. McKesson will ship a replacement order to you if these timelines are followed.

Rev. December 2013

**STATE OF KANSAS
VACCINES FOR CHILDREN
WASTED VACCINE RETURN FORM**

MONTH REPORTED ON MIR:
VFC PIN#:
PROVIDER NAME:
CONTACT NAME/PHONE NUMBER:
EMAIL ADDRESS:
CHECK IF REQUESTING RETURN LABEL: ☐
CHECK IF ON A REGULAR UPS ROUTE: ☐

Note: Please DO NOT return opened vials or syringes unless they are pre-filled by manufacturer.

DATE	VACCINE	NDC	LOT	EXP DATE	# DOSES	FUND TYPE	REASON FOR WASTE (Listed Below)

- | | |
|--|---|
| 1. Expired | 5. Broken Vial/Syringe |
| 2. Improper Storage | 6. Vaccine Drawn, Not Administered |
| 3. Improper Handling During Transport | 7. Open Vial not All Doses Administered |
| 4. Destroyed (Must Certify Occurrence/Witnessed) | 8. Other (Describe) |

FUND TYPES: **VFC** **317** **STATE** **CHIP**

Complete this form for all wasted and/or expired vaccines and submit a copy to the Kansas Immunization Program (KIP) in the month of the waste. Fax or Email "Wasted Vaccine Return Form" to the KIP (See info below).

Vaccine Returns: Call or email KIP to notify them when the vaccine is ready to be picked up. KIP will process the return through VTrckS and request a shipping label. KIP will email a return authorization form to be placed inside the box. If you indicated that your clinic is on a regular UPS route, the driver will bring the label, if not, the label will be mailed to you via US Postal Service. UPS should pick up the return within 3-5 business days. A Wasted Vaccine Return Form can be obtained on our website at: www.kdheks.gov/immunize.

EMAIL: vaccine@kdheks.gov

PHONE: 855-896-7337

FAX: 785-296-6510

Rev. November 4, 2013

Kansas Immunization Program Monitoring and Reporting Borrowing of VFC Vaccine Guidance

"Effective January 1, 2014: Program Supplied Vaccine may be borrowed on a Rare Emergency Basis Only. All borrowed vaccines must be documented on the borrowing form and submitted to KIP monthly by the 10th of the month following service."

The federal VFC program requires the Kansas Immunization Program (KIP) to monitor and report the number of doses and frequency of VFC and all state funded vaccine doses borrowed. The CDC VFC Borrowing Report (attached) describes how this documentation is completed.

Beginning October 1, 2013, the CDC stipulated that VFC-funded vaccine may not be borrowed for any reason without the express written permission from the CDC. Borrowing VFC-funded vaccines should never occur. However, KIP presented an alternative plan to the CDC which was approved: Borrowing may occur on a rare, emergency basis only to prevent a child from not being immunized. Borrowing may not occur due to inadequate private vaccine being stocked. Borrowing reports must be submitted monthly to KIP along with other monthly reports. All borrowing will be reviewed to assess borrowing practices.

Please send a copy of all borrowing forms to KIP monthly. This will help KIP and your clinic document the use of vaccine in all funding categories. Please submit the borrowing forms to: www.vaccines@kdheks.gov or fax to: 785-296-6510.

KIP staff is available to assist the practice in review of vaccine ordering to help eliminate or decrease borrowed vaccines. Contact your nurse consultant or the Topeka office at: 785-296-5591.

Rev: January 1, 2014

VFC Vaccine Borrowing Report

"Effective January 1, 2014, Program Vaccine may be borrowed on a rare, emergency basis only."

Guidance:

VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. The provider must assure that borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing would occur only when there is lack of appropriate stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly. The reason cannot be provider planned borrowing from either the private stock or the VFC stock.

Directions for use of this form:

When a provider has borrowed vaccine from one stock to administer to a child who is only eligible to receive vaccine from the other stock, this form must be COMPLETELY FILLED OUT for each borrowing occurrence. **Each vaccine a child receives must be listed on a separate row.** As soon as the borrowed doses of vaccine are replaced to the appropriate vaccine stock that date must be entered on this form. These borrowing reports must be kept as part of the VFC program records and be made available to the VFC staff during the VFC Site Visit.

Vaccine Borrowed	Patient Name/Patient Identifier/ Insurance status (VFC or private)	DOB	Date Borrowed	Reason no appropriate stock vaccine was available (circle one)	Date vaccine returned to appropriate stock
				1.Private stock order delayed 2.Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	
				1.Private stock order delayed 2.Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	
				1.Private stock order delayed 2. Private stock non-viable on arrival 3. VFC order delayed 4.VFC order non-viable on arrival 5. other (specify)	
				1.Private stock order delayed 2.Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	
				1.Private stock order delayed 2.Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.

Provider Name: _____

Provider Signature: _____

Date: _____

Rev. January 1, 2014

SAMPLE COMPLETED VFC Vaccine Borrowing Report

"Effective January 1, 2014, Program Vaccine may be borrowed on a rare, emergency basis only."

Guidance:

VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. The provider must assure that borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing would occur only when there is lack of appropriate stock vaccine (VFC or provider-purchased) due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly. The reason cannot be provider planned borrowing from either the private stock or the VFC stock.

Directions for use of this form:

When a provider has borrowed vaccine from one stock to administer to a child who is only eligible to receive vaccine from the other stock, this form must be COMPLETELY FILLED OUT for each borrowing occurrence. **Each vaccine a child receives must be listed on a separate row.** As soon as the borrowed doses of vaccine are replaced to the appropriate vaccine stock that date must be entered on this form. These borrowing reports must be kept as part of the VFC program records and be made available to the VFC staff during the VFC Site Visit.

Vaccine Borrowed	Patient Name/Patient Identifier/ Insurance status (VFC or private)	DOB	Date Borrowed	Reason no appropriate stock vaccine was available (circle one)	Date vaccine returned to appropriate stock
DTaP	Shirley Temple VFC	08/01/2007	10/19/2007	1. Private stock order delayed 3. <u>VFC order delayed</u> 5. other (specify)	2. Private stock non-viable on arrival 4. VFC order non-viable on arrival 10/21/2007
IPV	" "	" "	" "	1. Private stock order delayed 3. VFC order delayed 5. other (specify)	2. Private stock non-viable on arrival 4. VFC order non-viable on arrival 10/21/2007
DTaP	Mickey Rooney private	08/15/2007	10/19/2007	1. Private stock order delayed 3. VFC order delayed 5. other (specify)	2. <u>Private stock non-viable on arrival</u> 4. VFC order non-viable on arrival 10/21/2007
IPV	Mickey Rooney private	08/15/2007	10/19/2007	1. Private stock order delayed 3. VFC order delayed 5. other (specify)	2. Private stock non-viable on arrival 4. VFC order non-viable on arrival 10/21/2007
				1. Private stock order delayed 3. VFC order delayed 5. other (specify)	2. Private stock non-viable on arrival 4. VFC order non-viable on arrival

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.

"Provider Name: Dr. Sam Who

Provider Signature: Dr. Sam Who

Date: 02/21/2009

Routine Vaccine Storage and Handling Plan Worksheet

Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit. See the CDC's [Vaccine Storage and Handling Plans](http://www2a.cdc.gov/vaccines/ed/shtoolkit/) (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>) for details.

Checklist of Resources for the Routine Vaccine Storage and Handling Plan

- ☐ Up-to-date contact information
 - ☐ Primary and backup vaccine coordinators
 - ☐ State and local health department immunization program
 - ☐ Manufacturers of the vaccines in your inventory
 - ☐ Refrigerator and freezer maintenance and repair company(ies)
 - ☐ Vaccine storage unit alarm company (if applicable)
 - ☐ Sources for packing materials and certified calibrated thermometers
- ☐ Descriptions of the roles and responsibilities of the primary and backup vaccine coordinators
- ☐ Summaries of the storage requirements for each vaccine and diluent in your inventory
- ☐ Protocols for vaccine storage unit temperature monitoring
- ☐ Protocols for vaccine storage equipment maintenance
- ☐ Protocols for the correct placement of vaccine(s) within storage units
- ☐ Protocols for responding to vaccine storage and handling problems
- ☐ Protocols for vaccine inventory management
- ☐ Protocols for transporting and receiving vaccine shipments
- ☐ Policies for preparing vaccine for administration
- ☐ Protocols for proper disposal of vaccines (expired/wasted/used) and supplies
- ☐ Samples of the forms used in your vaccination program

Vaccine Coordinators

Vaccine Coordinators	Title	Telephone Numbers
Primary		
Backup		

Resources Contact List

Resources	Contact Person (Title)		Telephone Numbers
State Health Department Immunization Program			
Local Health Department Immunization Program			
Emergency Resources	Company Name	Contact Person	Telephone Numbers (home, cell, beeper)
Electric Power Company			

Emergency Resources	Company Name	Contact Person (Title)	Telephone Numbers (home,cell,beeper)
Generator Repair Company (if applicable)			
Generator Fuel Source (if applicable)			
Refrigeration Repair Company			
Temperature Alarm Monitoring Company if Applicable			

Packing Materials

Insulated Containers or Coolers			
Fillers (e.g., crumpled paper, bubble wrap)			
Refrigerated/Frozen Packs			
Dry Ice Vendor (if inventory includes varicella-containing vaccines)			
Certified Calibrated Thermometers			

Roles and Responsibilities

1) Accepts Vaccine Deliveries, Unpacks & Stores Vaccine

Name	Title	Telephone Number
Primary		
Backup		

2) Monitors and Records Twice Daily Temperatures & Maintain Temperature Log Files

Name	Title	Telephone Number
Primary		
Backup		

3) Conducts Monthly Inventory; Orders Vaccines; Labels for use; Rotates stock

Name	Title	Telephone Number
Primary		
Backup		

4) Reviews & updates clinic policies & procedures; Assures equipment working order/certifications current

Name	Title	Telephone Number
Primary		
Backup		

VACCINE STORAGE AND EMERGENCY RESPONSE PLAN

Post on outside of refrigerator for all staff

Practice Name: _____	
Primary Person Responsible: _____	Phone: _____
Secondary Person Responsible: _____	Phone: _____
Person with 24-hour access: _____	Phone: _____

For a Power Outage: If you do not have a generator, identify at least one location with a generator (hospital, 24-hour store, etc.). Before transporting, call the back-up location site to ensure that their generator is working.

#1 Location & Contact's Name _____ Ph# _____
#2 Location & Contact's Name _____ Ph# _____

How will you be notified of an outage? _____

Vaccines must be transported in an insulated cooler with a barrier separating the vaccines from the ice/cold packs. Varicella, MMRV and zoster **must** be transported with frozen gel packs..

If your emergency back up location is more than 30 minutes away and you have a large quantity of vaccine, consider renting a refrigerated truck to transport your vaccine.

Refrigeration company _____ Ph# _____

OTHER RESOURCES:

Local Health Department _____ Ph# _____

PREVENT LOSS FROM EXPIRED VACCINES!!

Check and rotate your stock to assure shortest dated vaccine is used first. (Post vaccine expiration date table.)

Notify the state Immunization Program if vaccines are going to expire within 3-6 months.

CHECK AND RECORD REFRIGERATOR AND FREEZER TEMPERATURES TWICE A DAY

- Once in the am when the practice opens;
- Once in the afternoon to allow for adjustments prior to the time the practice closes.

What to do if a power failure occurs, the refrigerator door was left open, the temperature was too cold, the refrigerator plug was pulled, or any other situation which would cause improper storage conditions:

1. Close the door and/or plug in the refrigerator/freezer;
2. Record the current temperature of the refrigerator/freezer;
3. Store the vaccines at appropriate temperatures. Make sure that the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not automatically throw out the affected vaccine;
4. Collect essential data on the reverse side of this sheet and notify the state health department;
5. **Call all manufacturers of affected vaccine(s) (see table on the backside) and ask to speak to the medical advisor.**

Turn over for Emergency Response Worksheet

EMERGENCY RESPONSE WORKSHEET

Current temperature of refrigerator: _____ Max/min temperature reached: _____
Current temperature of freezer: _____ Max/min temperature reached: _____
Amount of time temperature was outside normal range: refrigerator _____ freezer: _____

REFRIGERATOR

Vaccine and Lot #	Expiration Date	Amount of Vaccine

FREEZER

Vaccine and Lot #	Expiration Date	Amount of Vaccine

CALL ALL MANUFACTURERS(S) OF AFFECTED VACCINE(S):

Manufacturer	Telephone Number
Sanofi Pasteur	1-800-822-2463
Merck	1-800-609-4618
GlaxoSmithKline	1-888-825-5249
Wyeth	1-800-999-9384
Novartis	1-800-244-7668
MedImmune	1-877-633-4411
Kansas Immunization Program	1-785-296-5591

KANSAS IMMUNIZATION PROGRAM
Thermometer Data Logger User Agreement

Provider Name: _____

Pin#: _____

The Centers for Diseases Control (CDC) Vaccines for Children (VFC) program requires twice daily monitoring and recording of refrigerator and freezer temperatures, and monthly reporting of those readings to the Kansas Immunization Program (KIP).

Data loggers collect vaccine storage unit temperature data 24 hours a day, 7 days a week. Data loggers allow for improved temperature accountability and will assist in decreasing the amount of wasted VFC vaccine due to unknown storage unit temperatures.

This Provider User Agreement describes the terms and conditions for use of the program supplied data logger.

KIP shall:

1. Provide a maximum of two (2) TempTale®4 USB Multi-Alarm Monitors (data loggers) per calibration period. Calibration period is typically for one year from the date of shipment and is found on the calibration certificate of each monitor.
2. Educate Provider on installation and use of the data logger.
3. Assist Provider with ongoing education and use of the data loggers.
4. Contract with Sensitech for a maximum of two (2) standard downloads per month.

Provider shall:

1. Install, complete the setup, and use data loggers as directed by Sensitech and KIP.
2. Record refrigerator or freezer temperature twice daily on paper temperature logs and maintain the paper logs for three (3) years as stipulated by the CDC.
3. Download temperature data monthly, by the 10th of the following month, to KIP.
4. Maintain program-supplied data loggers in a manner to prevent damage, theft or destruction.
5. Replace damaged, destroyed, or stolen data loggers at a cost of \$100.00 each.

This Agreement may be terminated upon 14 days' notice by either KIP or Provider. In the event of termination, the Provider shall return program-supplied data loggers to KIP.

Provider's Authorized Signature: _____

Date: _____

Kansas Immunization Program VFC Provider Education Policy

Clinic VFC primary and back-up coordinators must complete an educational training prior to re-enrollment each calendar year. The educational training must cover all VFC requirements and the proper vaccine storage and handling of VFC vaccine.

At a minimum, the VFC Providers' primary and back-up coordinators must complete the "**Vaccines For Children (VFC)**" and the "**Vaccine Storage and Handling**" modules to meet the provider educational requirement. The modules certificate of completion must be kept on file in the clinic for a minimum of 3 years. The VFC Reviewer will request a copy of the completion certificates during the VFC Provider Compliance Site Visit. The 2014 VFC Re- Enrollment Form will be approved only if the "box" on the Provider Agreement indicates that the VFC primary and back-up clinic coordinators have completed the annual training requirement, and the certificates are submitted with the re-enrollment.

The education modules are found at: <http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>

New VFC Coordinator Appointment

VFC Providers must appoint a primary and a secondary VFC clinic coordinator that will fulfill assigned vaccine management responsibilities at all times. In the event a new person is appointed to replace the primary VFC clinic coordinator, the Kansas Immunization Program must be notified no later than 15 days after the new VFC Coordinator is appointed. The new VFC coordinator must submit to the Kansas Immunization Program's VFC Manager, a certificate of completion for the education modules within 30 days after their appointment. A Change of Contact Form is attached for your use.

Initial VFC Provider Enrollment

The Kansas Immunization Program will not enroll any new clinic in the VFC program until the primary and back-up VFC Coordinators have completed and submitted, to the Kansas Immunization Program, a certificate of completion for both the "**Vaccines For Children (VFC)**" and the "**Vaccine Storage and Handling**" modules. This component of the enrollment process must be completed prior to finalizing enrollment and activation of the VFC PIN number. This activity will meet the educational requirement for that years' annual enrollment period.

Rev. December 11, 2013

McKesson Specialty Care Dist.
4100 Quest Way
Memphis, TN 38115

Packing Slip

This is not an invoice

Page 1 of 2

Ship-to:

CORSICANA NAVARRO CO PHD
618 N MAIN
CORSICANA, TX 75110
(903) 874-6711

Awardee:

TEXAS DEPT OF HEALTH
IMMUNIZATION PROGRAM
1100 WEST 49TH STREET
AUSTIN, TX 78756
(512) 458-7111

Provider PIN: TXA030003
Delivery Number: 201186745
Quality Check Date: 09/24/2013
Customer Contact: EMILY CARROLL

Internal use only



NDC	Customer P.O.	Material Description Manufacturer	MFR Lot#	Exp. Date	VFC Doses	317 Doses	State Doses	CHIP Doses	Order Qty	Ship Qty	Unit Price	Extended Price
66019-0110-10	0503965322	FLU; SPRAYER; 10-pack MedImmune Vaccines Inc	AJ2025	11/30/2014	20	5	3	2	30	30	\$17.30	\$519.00
Total									30	30		\$519.00

This vaccine was purchased with public (state, local, and/or federal) funds and may be administered only to patients eligible to receive publically-funded vaccine.

If you have questions about your order, or to retrieve a pedigree document for Rx product received on this packing list, please contact your Immunization Program for assistance.

McKesson Specialty Care Dist.
4100 Quest Way
Memphis, TN 38115

Packing Slip

This is not an invoice

Page 2 of 2

Ship-to: CORSICANA NAVARRO CO PHD

Awardee: TEXAS DEPT OF HEALTH

Provider PIN: TXA030003
Delivery Number: 201186745
Customer Contact: EMILY CARROLL

VFC Doses - Federally funded vaccine - Vaccines For Children Program - Only children 0-18 years of age, Uninsured, Medicaid, Underinsured* or American Indian or Alaskan Native are eligible.

317 Doses - Federally funded vaccine - administer only to patients eligible to receive.

State Doses - State and Local funded vaccine - administer only to patients eligible to receive.

CHIP Doses - Separate Children's Health Insurance Program - administer only to patients eligible to receive.

For questions about patient eligibility please contact your Immunization Program for assistance.

*A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccine (eligible for non-covered vaccines only). VFC vaccine is eligible only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.

IMPORTANT

Never reject vaccine delivery or discard vaccine shipments without first contacting your state/local immunization program.

Please carefully review this Packing Slip to make sure doses shipped match information stated on the slip.

SHIPMENT DISCREPANCIES - If an excess or shortage is noted, please contact your state/local immunization program listed above under "Awardee." Your state/local immunization program will work with McKesson to correct the issue.

Please have the following information ready when you call your state/local immunization program.

- Product name and description, Item NDC#, Excess or shortage amount, Delivery Number, Provider PIN #

APPENDIX B: KEY INFORMANT INTERVIEW/INFORMED CONSENT

INFORMED CONSENT

Kansas Health Institute – Vaccines for Children Study

The Kansas Health Institute (KHI), on behalf of Immunize Kansas Kids (IKK), is conducting a study on Vaccines for Children (VFC) participation in the state of Kansas. The purpose of this study is to provide a comprehensive description of the VFC program in Kansas. The study will include background information on VFC, barriers to participation and identified best practices that may address those barriers.

Your participation in this interview is voluntary, and we anticipate it will take about one hour of your time. The information you provide us will help us to understand how VFC is working in Kansas and to identify areas for improvement. Your responses will be strictly confidential, and any information you provide will be reported in the aggregate. If there are any questions that you do not wish to answer, please let us know, and we will move on.

To ensure accuracy of information and subsequent analysis, we will take notes during the interview. These notes will be kept confidential, with access limited to KHI staff working on the project. Please initial here _____ if you agree to these terms.

If you have any questions about this study, you may contact Sheena Smith at (785) 233-5443. By your signature below, you agree to participate in this study. You will be given a copy of this form.

Signature

Date

KEY INFORMANT INTERVIEW QUESTIONNAIRE

VFC Program Clinic Interviews

Clinic Staff

This study will focus on participation in VFC, barriers to participation and best practices of VFC providers in Kansas. This information will be given to IKK partners and potentially used to help dispel myths.

Participating Clinics

- When did your clinic become a VFC Provider?
- Why did your clinic enroll in VFC?
- Do you track immunization rates for VFC?
 - If so, did you experience any changes in immunization rates after enrolling? Please explain.
 - If not, why might that be?
- Did you receive any training on VFC? If so, what kind? From whom?
- Does the state do any monitoring of VFC administration at your clinic? Please explain.
- What practices have worked well in your administration of VFC vaccine?
- Could these practices be replicated in other Kansas clinics?
 - If so, how?
 - If not, why might that be?
- What are the main challenges you experience with being a VFC Provider, if any?
- What improvements could be made regarding VFC, if any?

Non-participating Clinics

- Have you ever attempted becoming a VFC provider?
 - If so, were you a provider?
 - When?
 - Why is the clinic no longer a provider?
 - If not, why did you decide not to become a provider?

- What are the main challenges you experienced in attempting to become a provider?
- What improvements could be made regarding VFC, if any?
 - If improvements were made, would you re-consider becoming a provider?

Is there anything else you would like to add regarding VFC participation in Kansas?

