

APPENDIX

7

PROVIDER COMPLIANCE AND MONITORING

Bureau of Immunization-Vaccines for Children Program

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List of Revised Standards for Child and Adolescent Immunization Practices

A. Availability of Vaccines

1. Vaccination services are readily available.
2. Vaccinations are coordinated with other healthcare services and provided in a medical home when possible.
3. Barriers to vaccination are identified and minimized.
4. Patient costs are minimized.

B. Assessment of Vaccination Status

1. Healthcare professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
2. Healthcare professionals assess for and follow only medically indicated contraindications.

C. Effective Communication about Vaccine Benefits and Risks

1. Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

D. Proper Storage and Administration of Vaccines and Documentation of Vaccinations

1. Healthcare professionals follow appropriate procedures for vaccine storage and handling.
2. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
3. Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education.
4. Healthcare professionals simultaneously administer as many indicated vaccine doses as possible.
5. Vaccination records for patients are accurate, complete, and easily accessible.
6. Healthcare professionals report adverse events following vaccination promptly and accurately to the Vaccine Adverse Events Reporting System (VAERS) and are aware of a separate program, the National Vaccine Injury Compensation Program (NVICP).

7. All personnel who have contact with patients are appropriately vaccinated.
8. Systems are used to remind parents/guardians, patients, and healthcare professionals when vaccinations are due and to recall those who are overdue.
9. Office- or clinic-based patient record reviews and vaccination coverage assessments are performed annually.
10. Healthcare professionals practice community-based approaches.

The Standards

A. Availability of Vaccines

1. Vaccination Services Are Readily Available

All healthcare professionals who provide primary care to children and adolescents should always include routinely recommended vaccines as a part of the care that they deliver in the medical home. For some children and adolescents, the main contact with the healthcare system is not in a primary care provider's office; therefore, opportunities for vaccination may be missed. Thus, specialists and health care professionals in settings such as schools and school health clinics, sports physical clinics, family planning clinics, sexually transmitted disease clinics, and substance abuse treatment centers should assess each patient's vaccination status and either offer indicated vaccines or refer for vaccination if necessary. Information on vaccines administered outside the primary care setting should be communicated to the primary care provider.

2. Vaccinations Are Coordinated With Other Healthcare Services and Provided in a Medical Home When Possible

Ideally, vaccines should be given as part of comprehensive healthcare. In primary care settings, vaccination services should be coordinated with routine well-care visits and other visits. Patients who are vaccinated in other settings should be encouraged to receive subsequent vaccines in their primary care setting. Patients without a primary care provider should be assisted with identifying one.

3. Barriers to Vaccination Are Identified and Minimized

Barriers to receiving vaccines include delays in scheduling appointments, requiring a well-care visit, long waiting periods in the office, and lack of culturally and age-appropriate educational materials. A physical examination, although an important part of well care, should

not be required before administering vaccines: simply observing the patient and questioning about the patient's health status, immunization history, and vaccine contraindications are sufficient. In addition, vaccination-only visits should be available. Healthcare professionals should seek advice from parents/guardians and patients to identify ways to make vaccination services easier to use.

4. **Patient Costs Are Minimized**

Out-of-pocket costs—including vaccine, administration, and office visit fees—should be as low as possible for all patients, and no child or adolescent should be denied vaccination because of inability to pay. Resources should be identified to keep patient vaccination costs as low as possible. Free vaccine is available through some public programs, although healthcare professionals who offer these vaccines may charge a reasonable administration fee. Sources of publicly funded vaccines include the Vaccines for Children Program (VFC), Public Health Service Section 317 grants to states, and state or local programs. Children and adolescents should be screened for their eligibility to receive vaccines through these programs. Vaccinations provided through VFC or Section 317 grants may not be denied because of an inability to pay the administration fee, and healthcare professionals should ensure that parents/guardians and patients are aware of this requirement (applies to all vaccines purchased using Centers for Disease Control and Prevention (CDC) contracts, regardless of the setting—private or public—in which the vaccines are administered).

To minimize costs for patients, health plans and insurance plans should include the provision and administration of all routinely recommended vaccines as a covered benefit for all children and adolescents. Furthermore, to minimize costs for health care professionals, purchasers and health plans should reimburse healthcare professionals adequately for delivering vaccines, including the time required for vaccine administration and for communication about vaccine benefits and risks. The CDC maintains a web page about VFC at <http://www.cdc.gov/vaccines/programs/vfc/default.htm>.

B. **Assessment of Vaccination Status**

1. **Healthcare Professionals Review the Vaccination and Health Status of Patients at Every Encounter to Determine Which Vaccines Are Indicated**

Healthcare professionals should review the vaccination status of all patients at all healthcare visits to minimize the number of missed

opportunities to vaccinate. This review should determine whether the patient has received any vaccinations elsewhere or is at high risk for disease or under vaccination. This information should be documented in the patient's chart and preventive health summary. Healthcare professionals who do not offer vaccinations should refer patients to a primary care provider for needed vaccinations.

2. **Healthcare Professionals Assess for and Follow Only Medically Accepted Contraindications**

Withholding vaccinations because of medical concerns that are not contraindications results in missed opportunities for prevention. Healthcare professionals should ask about any condition or circumstance that might indicate that a vaccination should be withheld or delayed and about previous adverse events temporally associated with any vaccination. Healthcare professionals should support their decisions about what constitutes a contraindication or deferral for each vaccine by consulting the *Guide to Vaccine Contraindications and Precautions* published by the CDC (available at: <http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm>); the harmonized recommendations of the ACIP, the AAP, and the AAFP (available at: <http://www.cdc.gov/vaccines/recs/schedules/default.htm>), the AAP's *Red Book* and other relevant recommendations; Vaccine Information Statements; and manufacturers' package inserts. Contraindications and deferrals should be documented in the medical record.

C. **Effective Communication about Vaccine Benefits and Risks**

1. **Parents/Guardians and Patients Are Educated About the Benefits and Risks of Vaccination in a Culturally Appropriate Manner and in Easy-to-Understand Language**

Healthcare professionals should allow sufficient time with parents/guardians and adolescent patients to discuss the benefits of vaccines, the diseases that they prevent, any known risks from vaccines, the immunization schedule and the need to receive vaccines at the recommended ages, and the importance of bringing the patient's hand-held vaccination record to each healthcare visit. Healthcare professionals should encourage parents/guardians and adolescent patients to take responsibility for ensuring that the patient is fully vaccinated.

For all commonly used childhood vaccines, all healthcare professionals are required by federal law to give a Vaccine Information Statement (VIS) to vaccine recipients or their parents/guardians at each visit.

A VIS is a vaccine-specific, 2-page information sheet, produced by the CDC that describes the benefits and risks of a vaccine. If necessary, healthcare professionals should supplement the VIS with oral explanations or other written materials that are culturally and linguistically appropriate. Healthcare professionals should review written materials with patients and their parents/guardians and address questions and concerns.

Healthcare professionals should encourage parents/guardians and adolescent patients to inform the healthcare professional of adverse events after the vaccine to be administered and explain how to obtain medical care, if necessary. (See Standard 13 for a description of the Vaccine Adverse Events Reporting System (VAERS).

General vaccination information for healthcare professionals, parents, and members of the public may be obtained by calling the CDC National Immunization Information Hotline at 1-800-232-2522 (English) or 1-800-232-0233 (Spanish). Information about vaccine risk communication for healthcare professionals can be found at <http://www.cdc.gov/vaccinesafety/basic/history.htm> and in the latest edition of the *Red Book*. VISs are available in English and numerous other languages from state health departments and at <http://www.cdc.gov/vaccines/pubs/vis/> and <http://www.immunize.org/vis/>. Recommendations for national standards for culturally and linguistically appropriate services in healthcare may be found at <http://www.omhrc.gov/assets/pdf/checked/finalreport.pdf>.

D. Proper Storage and Administration of Vaccines and Documentation of Vaccinations

1. Healthcare Professionals Follow Appropriate Procedures for Vaccine Storage and Handling

Vaccines should be handled and stored as recommended in the manufacturers' package inserts; the expiration date for each vaccine should be noted. Temperatures at which vaccines are stored and transported should be monitored and recorded twice daily. Summary information about vaccine storage and handling procedures are also available from state and local health departments and the CDC. Healthcare professionals should monitor vaccine inventory and undertake efforts to reduce wastage and loss. CDC-recommended storage and handling procedures are available from the CDC by calling 404-639-8222.

2. **Up-to-Date, Written Vaccination Protocols Are Accessible at All Locations Where Vaccines Are Administered**

To promote the safe and effective use of vaccines, healthcare professionals should maintain written protocols that detail the following: vaccine storage and handling; the recommended vaccination schedule, vaccine contraindications, and administration techniques; treatment and reporting of adverse events; vaccine benefit and risk communication; and vaccination record maintenance and accessibility. These protocols should be consistent with established guidelines, reviewed frequently, and revised as needed to ensure that they remain up-to-date.

3. **People Who Administer Vaccines and Staff Who Manage or Support Vaccine Administration Are Knowledgeable and Receive Ongoing Education**

Healthcare professionals or others who administer vaccinations should be knowledgeable and receive continuing education in vaccine storage and handling; the recommended vaccine schedule, contraindications, and administration techniques; treatment and reporting of adverse events; vaccine benefit and risk communication; and vaccination record maintenance and accessibility. With appropriate training and in accordance with state law/regulation/policy, people other than physicians and nurses may administer vaccines. In addition, other staff should receive training and continuing education related to their specific roles and responsibilities that affect vaccination services.

The CDC sponsors distance-based training opportunities (e.g., satellite broadcasts, web-based training, videotapes, and self-administered print materials) for healthcare professionals. Information about training is available at <http://www.cdc.gov/vaccines/ed/default.htm>.

4. **Healthcare Professionals Simultaneously Administer as Many Indicated Vaccine Doses as Possible**

Administering vaccines simultaneously (at the same visit), in accordance with recommendations from the ACIP, the AAP, and the AAFP, is safe, effective and indicated. Although the immunization schedule provides age flexibility for administering certain vaccine doses, simultaneous administration decreases the number of visits needed and the potential for missed doses and enables earlier protection. When indicated vaccines are not simultaneously administered, arrangements should be made for the patient's earliest return to receive the needed vaccination(s). Additional information on

the safety of simultaneous vaccination may be found at <http://www.cdc.gov/vaccinesafety/updates/multiplevaccines.htm>.

5. Vaccination Records for Patients Are Accurate, Complete, and Easily Accessible

Vaccination records for patients should be recorded on a standard form in an easily accessible location in the medical record to facilitate rapid review of vaccination status. Accurate record keeping helps to ensure that only needed vaccinations are given. As required by federal law (42 US Code 300aa-25), healthcare professionals should ensure that records contain the following information for each vaccination: the date of administration, the vaccine manufacturer and lot number, the signature and title of the person administering the vaccine, and the address where the vaccine was given. Vaccine refusal should also be documented.

The medical record maintained by the primary care provider should document all vaccines received, including those received at a specialist's office or in another healthcare setting. When a healthcare professional who does not routinely care for a patient vaccinates that patient, the patient's primary care provider should be informed.

All vaccinations administered should be reported to state or local immunization registries, where available, to ensure that each patient's vaccination history remains accurate and complete. Registries also may be useful for verifying the vaccination status of new patients, determining which vaccines are needed at a visit, printing official records, and providing reminders and recalls to parents, guardians, and patients.

Healthcare professionals should ensure that each patient has a hand-held vaccination record that documents each vaccine received, including the date and the name of the healthcare professional who administered the vaccine. Health care professionals should encourage parents/guardians and adolescent patients to bring the patient's hand-held record to each healthcare visit so that it can be updated.

The CDC maintains an Immunization Registry Clearinghouse. Information about this clearinghouse is available at <http://www.cdc.gov/vaccines/programs/iis/default.htm>.

6. **Healthcare Professionals Report Adverse Events After Vaccination Promptly and Accurately to the Vaccine Adverse Events Reporting System (VAERS) and Are Aware of a Separate Program, the National Vaccine Injury Compensation Program (VICP)**

Healthcare professionals should promptly report all clinically significant adverse events after vaccination to the VAERS even if the healthcare professional is not certain that the vaccine caused the event. Healthcare professionals should document in detail the adverse event in the patient's medical record as soon as possible. Providers should be aware that parents/guardians and patients may report to VAERS and that if they choose to do so, they are encouraged to seek the help of their healthcare provider.

The National Vaccine Injury Compensation Program (VICP) is a no-fault system that compensates people of any age for injuries or conditions that may have been caused by a vaccine recommended by the CDC for routine use in children. Health care professionals should be aware of the VICP to address questions raised by parents/guardians and patients.

Because VAERS and VICP are separate programs, a report of an event to VAERS does not result in the submission of a compensation claim to VICP. A brief description and contact information for both programs is provided on each VIS for those vaccines covered by the National Childhood Vaccine Injury Act. Information about VAERS, as well as guidance about how to obtain and complete a VAERS form, can be found at <http://vaers.hhs.gov/> or by calling (800) 822-7967. Information about the VICP is available at <http://www.hrsa.gov/vaccinecompensation/> or by calling (800) 338-2382.

7. **All Personnel Who Have Contact With Patients Are Appropriately Vaccinated**

Healthcare professionals and other personnel who have contact with patients should be appropriately vaccinated. Offices and clinics should have policies to review and maintain the vaccination status of staff and trainees. ACIP recommendations for vaccinating healthcare workers are available at <ftp://ftp.cdc.gov/pub/publications/mmwr/rr/rr4618.pdf>.

E. **Implementation of Strategies to Improve Vaccination Coverage**

1. **Systems Are Used to Remind Parents/Guardians, Patients, and Healthcare Professionals When Vaccinations Are Due and to Recall Those Who Are Overdue**

Evidence demonstrates that reminder/recall systems improve vaccination coverage. Patient reminder/recall interventions inform individuals that they are due (reminder) or overdue (recall) for specific vaccinations. Patient reminders/recalls can be mailed or communicated by telephone; an auto dialer system can be used to expedite telephone reminders. Patients who might be at high risk for not complying with medical recommendations, for example, those who have missed previous appointments, should receive more intensive follow-up. Similarly, provider reminder/recall systems alert healthcare professionals when vaccines are due or overdue. Notices should be placed in patient charts or communicated to health care professionals by computer or other means. Immunization registries can facilitate automatic generation of reminder/recall notices.

2. **Office- or Clinic-Based Patient Record Reviews and Vaccination Coverage Assessments Are Performed Annually**

Evidence shows that assessments are most effective in improving vaccination coverage in a practice when they combine chart reviews to determine coverage with the provision of results to healthcare professionals and staff. Effective interventions also may incorporate incentives or compare performance with a goal or a standard. Coverage should be assessed regularly so that reasons for low coverage in the practice or in a subgroup of patients are identified and addressed. For assistance in conducting vaccination coverage assessments, healthcare professionals should contact their state or local immunization program.

3. **Healthcare Professionals Practice Community-Based Approaches**

All healthcare professionals share in the responsibility to achieve the highest possible degree of community protection against vaccine-preventable diseases. Immunization protects the entire community as well as the individual. No community is optimally protected against vaccine-preventable diseases without high vaccination coverage. Therefore, healthcare professionals should consider the needs of the community (especially underserved populations) as well as those of their patients. Community-based approaches may involve working with partners in the community, including public health departments, managed care organizations, other service providers such as the US

Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), advocacy groups, schools, and service organizations to determine community needs and develop vaccination services that address these needs.

VFC Provider Site Visit Questionnaire

(This form to be completed by the public health official who is conducting the site visit review.)

Date: _____ Reviewer's Name: _____
Provider Site Name: _____
Provider address: _____
Contact person: _____ Telephone: _____
Email: _____ VFC Number: _____

Type of Practice:

- Public Health Dept. Clinic Private Practice FQHC/RHC
 Other Public (specify) _____

Specialty Type for Practice:

- Pediatric Family Practice Internal Medicine
 Multi-specialty Other (specify) _____

SECTION I. VFC COMPLIANCE

Questions 1-15 should be answered by the provider.

1. Does this clinic/practice charge non-Medicaid, VFC-eligible children (VFC-eligible because uninsured, American Indian/Alaskan Native, Under-insured if vaccinated at FQHC/RHC) a vaccine administration fee?
 Yes No (**skip to question 4**)
If so, what is the fee: \$ _____

2. Is the administration fee equal to or below the State fee cap?
 Yes No

3. If a non-Medicaid, VFC-eligible patient is unable to pay the administration fee at the time of visit, which of the following actions does the provider take?
 Waives the administration fee
 Vaccinates the child, patient is responsible for payment at a later date (e.g. payment plan)
 Does not vaccinate the child; he/she is referred to a public health department clinic or a FQHC/RHC

4. VFC eligibility information on each child is maintained for 3 years.
 Yes
 No

5. Which of the following vaccines are **NOT** routinely recommended in this clinic/practice?
- | | | |
|------------------------------------|--|---|
| <input type="checkbox"/> DTaP | <input type="checkbox"/> Varicella | <input type="checkbox"/> Polio |
| <input type="checkbox"/> Hib | <input type="checkbox"/> Hepatitis A | <input type="checkbox"/> Influenza |
| <input type="checkbox"/> MMR | <input type="checkbox"/> Hepatitis B | <input type="checkbox"/> Pneumococcal Conjugate |
| <input type="checkbox"/> Tdap | <input type="checkbox"/> Meningococcal | <input type="checkbox"/> Human Papillomavirus |
| <input type="checkbox"/> Rotavirus | <input type="checkbox"/> Other: _____ | |
6. When does this clinic/practice provide patients with copies of the Vaccine Information Statements (VIS)?
- Every time the patient receives a vaccination
- When the child receives the 1st dose of vaccine within a particular series (e.g. 1st dose of DTaP)
- Never
- Other (specify) _____
7. Does the clinic/practice give the parent a copy of the VIS to keep?
- Yes No
8. Please identify the publication date for each of the VIS currently being used in this clinic/practice and then check the appropriate status for each VIS.

VACCINE*	VIS VERSION BEING USED IN THIS CLINIC/PRACTICE		
	Current	Outdated	None Used
DTaP (5/17/07)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Polio (1/1/2000)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MMR (3/13/08 Interim)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hepatitis B (7/18/07 Interim)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Varicella (3/13/08 Interim)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hepatitis A (3/21/06)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hib (12/16/98)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pneumococcal Conjugate (12/9/08 Interim)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Influenza (updated annually)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Td/Tdap (11/18/08 Interim)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Human Papillomavirus (2/2/07 Interim)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meningococcal (1/28/08)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rotavirus (8/28/08 Interim)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* current VIS publication dates as of June, 2009

If your program requires providers to submit annual provider profiles, please ask question 9. Otherwise skip to question 10.

9. In order to complete the annual provider profile, how do you determine the number of VFC-eligible patients in this practice/clinic?
- Use doses administered data
 - Use benchmarking data
 - Use claims or encounter data
 - Rough estimate based on knowledge of the patient volume in the practice/clinic
 - Other (please describe): _____

10. When does the clinic/practice screen patients for VFC eligibility?
- First immunization visit to the office
 - Every immunization visit
 - Do not screen for VFC eligibility
 - Other (specify) _____

11. Does the clinic/practice have written procedures for vaccine management? (ask to see a copy)
- Yes No **(skip to question 13)**

12. Do the written procedures for vaccine management include the following (check to see if present):

	Yes	No
Proper vaccine storage and handling	<input type="checkbox"/>	<input type="checkbox"/>
Procedures for vaccine relocation in the event of a power failure or mechanical difficulty	<input type="checkbox"/>	<input type="checkbox"/>
Vaccine ordering	<input type="checkbox"/>	<input type="checkbox"/>
Inventory control (e.g. stock rotation)	<input type="checkbox"/>	<input type="checkbox"/>

13. How often is a physical inventory of stored VFC vaccine conducted?
- Never
 - Before placing a vaccine order
 - Once a month
 - Other (specify) _____

14. How often are VFC vaccines ordered?
- Monthly
 - Bi-Annually
 - As Needed
 - Quarterly
 - Other _____

15. Does this clinic/practice always notify the Immunization Program when publicly purchased vaccine has expired or been wasted?
- Yes No

Questions 16-33 should be answered based on a physical review of the provider's refrigerator and freezer.

16. What type of refrigeration unit is used to store your vaccines, including varicella (if appropriate)? (check all that apply)
- Stand alone freezer
 - Stand alone refrigerator
 - Dormitory style refrigerator/freezer
 - Combined refrigerator/freezer with separate refrigerator and freezer doors (e.g. household style appliance)
 - Combined refrigerator/freezer with a single door

17. Are working thermometers placed in a central area of each refrigerator and freezer?

	Yes	Have thermometer but not placed properly	No thermometer
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18. What type of thermometer is used by the practice?

	Standard Fluid Filled	Continuous Recording	Min-Max	Dial	Digital	Other (specify)
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

19. How often are refrigerator and freezer temperatures recorded?

	Once a day	Twice a day	Once a week	Other (specify)
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

20. Record the highest and lowest temperatures logged in the last 3 months:

	Lowest	Highest	Log available for last 3 months?	
Refrigerator			<input type="checkbox"/> Yes	<input type="checkbox"/> No
Freezer			<input type="checkbox"/> Yes	<input type="checkbox"/> No

If the lowest and/or highest temperatures are out of the recommended range then go to question 21. If the temperatures are within the recommended guidelines, then go to question 24.

21. During past 3 months, how many times were the temperatures outside the recommended range?

	Below Guidelines	Above Guidelines
Refrigerator (2-8°C / 35-46°F)		
Freezer (-15°C / 5°F or lower)		

22. When the temperatures were outside the recommended range, what action did the provider take?

(✓ all that apply)

- Adjusted thermostat in refrigerator/freezer
- Measured temperature with different thermometer to check accuracy of original reading
- Moved vaccine to a different refrigerator/freezer maintained at proper temperature
- Called the vaccine manufacturer to determine the potency of the vaccine
- Called the local/state immunization program for assistance
- Did not do anything

23. Did the provider document the action taken (indicated in #21) on the temperature log or elsewhere?

- Yes No

24. Record the current temperatures.

	Practice Thermometer	Reviewer's Thermometer
Refrigerator		
Freezer		

25. Are current temperatures within the guidelines according to the Reviewer's thermometer? (Refrigerator: 2-8°C / 35-46°F, Freezer: -15°C / 5°F or lower) *Please note: if reviewer does not use a thermometer to check the temperature, then refer to the practice's thermometer to answer this question.*

	Yes	No
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>

26. Is food stored with vaccines in the refrigerator and freezer?

	Yes	No
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>

27. Are vaccines stored in the body of the refrigerator and freezer and not in the doors?

	Yes	No
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>

28. Is vaccine stacked with air space between the stacks and side/back of the unit to allow cold air to circulate around the vaccine?

	Yes	No
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>

29. Are bottles of water placed in the refrigerator and ice packs in the freezer to maintain the internal temperatures of the storage area?

	Yes	No
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>

30. Is there a “DO NOT DISCONNECT” sign on the refrigerator/freezer outlet?

	Yes	No
Refrigerator	<input type="checkbox"/>	<input type="checkbox"/>
Freezer	<input type="checkbox"/>	<input type="checkbox"/>

31. Is there a “WARNING – VACCINE STORAGE – DO NOT TURN OFF BREAKER” sign on the circuit breaker?

Yes No

32. Are short-dated vaccines stored in front and used first, rotating stock effectively?

Yes No

33. Can the provider show you how privately purchased vaccine is distinguished from public purchased vaccine?

- Yes
- No, cannot distinguish
- Not applicable, provider does not stock privately purchased vaccine

34. Upon checking the provider’s vaccine supply, did you find any unreported wasted or expired vaccine?

Yes No

Questions 35-37 should be answered based on a review of patient charts.

35. What is the VFC eligibility screening coverage in this clinic/practice?

- VFC screening coverage of 100%
- VFC screening coverage between 99% and 95%
- VFC screening coverage between 90% and 94%
- VFC screening coverage below 90%

36. What methodology was used to determine VFC eligibility screening coverage during this site visit?

- CDC supplied Lot Quality Assurance (LQA) protocol
- CASA
- Project developed methodology
- Other: _____

37. Do all immunization records contain the following documentation required by statute 42 US Code 300aa-25? (*✓ one box per item*)

Required Documentation	Yes	No
Name of vaccine given	<input type="checkbox"/>	<input type="checkbox"/>
Date vaccine was given	<input type="checkbox"/>	<input type="checkbox"/>
Name of vaccine manufacturer	<input type="checkbox"/>	<input type="checkbox"/>
Lot number	<input type="checkbox"/>	<input type="checkbox"/>
Signature and title of person who gave the vaccine	<input type="checkbox"/>	<input type="checkbox"/>
Address of clinic where vaccine was given	<input type="checkbox"/>	<input type="checkbox"/>
Publication date of VIS	<input type="checkbox"/>	<input type="checkbox"/>
Site of vaccination	<input type="checkbox"/>	<input type="checkbox"/>

Questions 38-40 should be answered based on results of the VFC Site Visit.

38. Are corrective actions recommended for this VFC enrolled site?

- Yes
- No (*STOP here*)

39. Please indicate which corrective actions regarding vaccine practices were recommended for this VFC enrolled site. (*✓ all that apply and specify action taken*)

- Administrative practices _____
- Vaccine storage and handling _____
- Other: _____

40. Please indicate your plan for following-up with the site to ensure recommendations were implemented.

- Provided technical assistance at time of site visit, no further follow-up is needed
- Telephone call
- Site visit
- Suspended delivery of VFC vaccine until storage/handling problems resolved
- Other: _____

SECTION II. STANDARDS OF PEDIATRIC IMMUNIZATION PRACTICES

Questions 1-13 should be answered by the provider.

1. Does the clinic/practice have a copy of the most recent version of the following documents?

	Yes	No
<i>Recommended Childhood Immunization Schedule</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Standards for Pediatric Immunization Practices</i>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Contraindications for childhood immunization</i>	<input type="checkbox"/>	<input type="checkbox"/>

2. Does the clinic/practice simultaneously administer all vaccines for which a child is eligible?

Yes No

3. Is a physical exam required before immunizations are given?

Yes No

4. Does the clinic/practice routinely immunize when the child has:

	Yes	No
A "cold"	<input type="checkbox"/>	<input type="checkbox"/>
Low grade fever (e.g. 100.4 °F [38 °C] or lower)	<input type="checkbox"/>	<input type="checkbox"/>
Recently been exposed to infectious illness	<input type="checkbox"/>	<input type="checkbox"/>
Mild diarrhea	<input type="checkbox"/>	<input type="checkbox"/>
Convalescing from an acute illness	<input type="checkbox"/>	<input type="checkbox"/>

5. Does the clinic/practice have VAERS forms and know how to report to VAERS?

Yes No

6. Who gives immunization injections? (✓ all that apply)

MD NP PA
 RN LVN LPN MA

7. What size needles are generally used for intramuscular injections?

5/8" (inch) 1" (inch) Other (specify) _____
 7/8" (inch) Depends on age

8. Does the clinic/practice pre-fill vaccine syringes?

Yes No

9. Does the clinic/practice participate in the Florida State Health Online Tracking System (Florida SHOTS)?

Yes No

10. How does clinic/practice remind patients of their next appointment? (*✓ all that apply*)
- | | |
|---|---|
| <input type="checkbox"/> Mail | <input type="checkbox"/> Written appointment slip given at last visit |
| <input type="checkbox"/> Telephone | <input type="checkbox"/> Does not remind patients of their next appointment |
| <input type="checkbox"/> Verbally at last visit | <input type="checkbox"/> Other _____ |
11. How does clinic/practice contact patients who miss their appointment? (*✓ all that apply*)
- | | |
|--|------------------------------------|
| <input type="checkbox"/> Mail | <input type="checkbox"/> Telephone |
| <input type="checkbox"/> Does not contact patients who missed an appointment | |
| <input type="checkbox"/> Other _____ | |
12. How does clinic/practice identify patients if no appointment is made and vaccinations are due/overdue?
- | |
|---|
| <input type="checkbox"/> Cannot identify patients due/overdue for immunizations |
| <input type="checkbox"/> Immunization registry |
| <input type="checkbox"/> Computer (office based, not connected to a registry) |
| <input type="checkbox"/> Paper based "tickler" system |
| <input type="checkbox"/> Other: _____ |
13. How frequently does this clinic/practice generate recall notices (or phone calls) to patients who are due/overdue for a vaccination?
- | |
|---|
| <input type="checkbox"/> Weekly |
| <input type="checkbox"/> Monthly |
| <input type="checkbox"/> Quarterly |
| <input type="checkbox"/> No regular schedule |
| <input type="checkbox"/> Clinic/practice does not distribute recall notices to patients |

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**Standards for Pediatric Immunization Practices Questionnaire
Florida Vaccines for Children (VFC) Program**

Site: _____ Date: _____ Initials: _____

A. IMMUNIZATION SERVICES ARE READILY AVAILABLE:

1. Immunization services available during the week: Yes No
2. Immunization services available during other times:
Days: _____ Hours: _____
3. Immunization services available at all times other child health services are offered: Yes No
4. Immunization services routine part of primary care to infants and children:
 Yes No

COMMENTS: Previous Review –

B. THERE ARE NO BARRIERS OR UNNECESSARY PREREQUISITES TO THE RECEIPT OF VACCINES:

1. Walk-in immunization services available at all times that the office is open: Yes No
2. Average waiting time for walk-in immunizations:
_____.
3. If physical exams, temperature measurements, or other comprehensive health services are required before children can receive immunizations, how long must the patient wait in order to get an appointment:
_____.
4. Do they delay or impede receipt of vaccines: Yes No
5. Are children getting pre-immunization assessments: Yes No

COMMENTS: Previous Review –

C. IMMUNIZATION SERVICES ARE AVAILABLE FREE OR FOR A MINIMAL FEE:

1. Administration fee per dose of vaccine for VFC patients:
\$ _____
2. VFC vaccine is given to a child even if the adult accompanying the child cannot pay the administration fee: Yes No

COMMENTS: Previous Review –

D. PROVIDERS UTILIZE ALL CLINICAL ENCOUNTERS TO SCREEN FOR NEEDED VACCINES, AND WHEN INDICATED, IMMUNIZE CHILDREN:

1. Children screened for and either offered or referred for immunization when they accompany parents or siblings who are receiving care:
 Yes No
2. Children routinely screened for immunizations when presenting for other reasons: Yes No
3. Child's regular provider notified when immunizations are administered:
 Yes No

COMMENTS: Previous Review –

E. PROVIDERS EDUCATE PARENTS AND GUARDIANS ABOUT IMMUNIZATIONS IN GENERAL TERMS:

1. Parents educated about:
 - a. Importance of immunizations: Yes No
 - b. Diseases they prevent: Yes No
 - c. Need to receive shots on time: Yes No
 - d. Recommended immunization schedules: Yes No
 - e. Importance of bringing their child's immunization record to each visit: Yes No
2. Solicit and answer parents questions: Yes No

3. Educational material provided in appropriate languages and at appropriate reading levels: Yes No

COMMENTS: Previous Review –

F. PROVIDERS QUESTION PARENTS OR GUARDIANS ABOUT CONTRAINDICATIONS AND, BEFORE IMMUNIZING A CHILD, INFORM THEM IN SPECIFIC TERMS ABOUT THE RISKS AND BENEFITS OF THE VACCINE THEIR CHILD IS TO RECEIVE:

1. Question parents about contraindications: Yes No
2. Ask if parents have questions and answer the questions to the parent's satisfaction: Yes No
3. Explain to parents what to do in case of an adverse event: Yes No
4. CHECK: Using appropriate VIS or IIS for each vaccine: Yes No

COMMENTS: Previous Reviews –

G. PROVIDERS FOLLOW ONLY TRUE CONTRAINDICATIONS:

1. Immunize according to the "Guide to Contraindications and Precautions to Immunizations": Yes No

COMMENTS: Previous Review –

H. PROVIDERS ADMINISTER SIMULTANEOUSLY ALL VACCINE DOSES FOR WHICH A CHILD IS ELIGIBLE AT THE TIME OF EACH VISIT:

1. All possible vaccines administered at each visit: Yes No
2. If all possible vaccines aren't administered simultaneously:
 - a. Reasons documented: Yes No
 - b. Record flagged for automatic recall to receive needed dose(s) as soon as possible: Yes No

COMMENTS: Previous Review –

I. **PROVIDERS USE ACCURATE AND COMPLETE RECORDING PROCEDURES:**

1. Provide a personal immunization record card to parents: Yes No
2. When accepting immunization data from parents, confirm the administration of previous doses by either reviewing immunization record cards or contacting former providers: Yes No
3. REVIEW RECORDS: Recording date vaccine was administered, name, manufacturer, and lot number of the vaccine, signature, title and address of the person who administers the vaccine: Yes No
4. REVIEW RECORDS: Maintain eligibility information on each VFC-eligible child for at least 3 years (by using BOI VACCINE USAGE WORKSHEET): Yes No
5. REVIEW PROVIDER'S VFC FOLDER: Properly complete other required forms for participation in VFC Program (vaccine report forms): Yes No

COMMENTS: Previous Reviews –

J. **PROVIDERS CO-SCHEDULE IMMUNIZATION APPOINTMENTS IN CONJUNCTION WITH APPOINTMENTS FOR OTHER CHILD HEALTH SERVICES:**

1. Co-schedule other needed health services with immunization services: Yes No
2. Co-schedule postponed immunization: Yes No

COMMENTS: Previous Reviews –

K. **PROVIDERS REPORT ADVERSE EVENTS FOLLOWING IMMUNIZATION PROMPTLY, ACCURATELY, AND COMPLETELY:**

1. Encourage parents/guardians to inform them of adverse events following immunizations: Yes No
2. Report clinically significant events, including those required by law, in accordance with the National Childhood Vaccine Injury Act: Yes No

COMMENTS: Previous Reviews –

L. PROVIDERS OPERATE A TRACKING SYSTEM:

1. Currently using a system that produces reminders of upcoming immunizations and/or recalls for children who are overdue:
 Yes No
2. Recall system provide reminders on at least a monthly basis:
 Yes No

COMMENTS: Previous Reviews –

M. PROVIDERS ADHERE TO APPROPRIATE PROCEDURES FOR VACCINE MANAGEMENT:

1. At least one person and a backup coordinator assigned to monitor vaccine storage and handling: Yes No

VERIFY THE FOLLOWING: (Can be taken from provider worksheet)

- a. Thermometer in refrigerator: Yes No
- b. Thermometer in freezer: Yes No
- c. Current temperatures:
Refrigerator: _____ Freezer: _____
- d. Daily temperature log for both refrigerator and freezer:
 Yes No
- e. Logged temperatures within recommended/acceptable ranges (refrigerator 35°- 46°F (2°- 8°C); freezer: +5°F (-15°C) or colder]:
 Yes No

COMMENTS: Previous Reviews –

N. PROVIDERS CONDUCT SEMI-ANNUAL AUDITS TO ASSESS IMMUNIZATION COVERAGE LEVELS IN THE PATIENT POPULATION THEY SERVE:

1. Performs assessments to measure:
 - a. Immunization coverage levels: Yes No
 - b. Frequency of missed opportunities: Yes No
 - c. Quality of documentation: Yes No

- d. How often assessments conducted:
 Annually: Semi-annually

COMMENTS: Previous Reviews –

O. PROVIDERS MAINTAIN UP-TO-DATE, EASILY RETRIEVABLE MEDICAL PROTOCOLS AT ALL LOCATIONS WHERE VACCINES ARE ADMINISTERED:

1. Have written protocols covering:
 - a. Vaccine dosages: Yes No
 - b. Vaccine contraindications: Yes No
 - c. Recommended sites and techniques for vaccine administration:
 Yes No
 - d. Adverse events and their emergency management:
 Yes No
2. Protocols specify the following with regards to medical emergencies related to administering immunizations:
 - a. Necessary emergency equipment: Yes No
 - b. Necessary drugs: Yes No
 - c. Appropriate personnel: Yes No
3. If no written protocols, a doctor is present when immunizations are given:
 Yes No

COMMENTS: Previous Reviews –

P. PROVIDERS PRACTICE PATIENT-ORIENTED AND COMMUNITY-BASED APPROACHES:

1. Cooperate with local health officials in their efforts to assure high coverage levels throughout the community: Yes No
2. Publicize their immunization services: Yes No
3. Work with coalitions to increase immunization levels in the community:
 Yes No

4. Conduct community outreach activities: Yes No

COMMENTS: Previous Reviews –

Q. VACCINES ARE ADMINISTERED BY PROPERLY TRAINED INDIVIDUALS:

1. Who administers vaccinations:
 RN MD ARNP PA LPN MA
 OTHER: _____

COMMENTS: Previous Reviews –

R. PROVIDERS RECEIVE ONGOING EDUCATION AND TRAINING ON CURRENT IMMUNIZATION RECOMMENDATIONS:

1. Clinic personnel receive ongoing education and training on current immunization guidelines and recommendations: Yes No
2. Have current:
- a. ACIP General Recommendations: Yes No
 - b. AAP "Red Book": Yes No
 - c. Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book): Yes No
 - d. Standards for Pediatric Immunization Practices: Yes No
 - e. Information regarding state and national immunization goals:
 Yes No

COMMENTS: Previous Reviews –

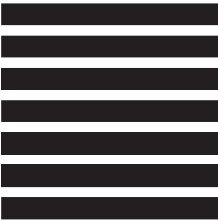
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DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.
- Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
- Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
- and 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
- Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
- Item 13: List ONLY those vaccines given on the day listed in Item 10.
- Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
- Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
- Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
- Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
- Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
- Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
- Item 26: This space is for manufacturers' use only.