

## HIGH PRIORITY QUESTION KEY

All questions indicated with the ! icon are considered high priority questions. Inappropriate or incorrect responses given to any of these questions require that a corrective action plan be developed with the provider by the staff person conducting the VFC site visit. The newly added “pre-visit” review question was added to incorporate a review of the provider profile related to the provider’s vaccine ordering patterns to identify issues that may need further follow-up. If a reviewer is unable to identify a valid reason for the ordering discrepancy then the situation should be documented as a potential case of fraud and abuse and followed-up based on the grantee’s fraud and abuse policy. The table below is to be used as a key. It outlines the correct response to each of the high risk questions.

#	Question	Response Options	Acceptable	Unacceptable- Requires Corrective Action to be documented in #32 & follow-up in #33
<b>Pre-visit Review</b>	Are vaccine orders consistent with most current provider profile?	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ol>	Yes	<p>No. Conduct further review/research to determine if the provider’s patient population significantly changed in size but the provider profile was not updated. If this is the case, an updated provider profile must be submitted to the immunization program as soon as possible. The VFC staff should follow-up to make sure the revised provider profile is submitted.</p> <p>If no reason can be identified for vaccine orders that are greater than expected based on the current provider profile, the situation should be documented as a potential case of fraud and abuse and, following the grantee’s written policy, be referred for further investigation or education.</p>
<b>1</b>	What is the vaccine administration fee charged to non-Medicaid VFC eligible patients (uninsured, American Indian/Alaska Native, under-insured if vaccinated at FQHC/RHC)?	Open-ended	Within state cap (varies by state)	In excess of state cap. <b>** Universal states may set their administration fee for the non-Medicaid VFC eligible children higher than the listed maximum regional charge but only if the proper protocol was followed and documented. The protocol that must be followed is outlined in the Federal Register, Vol 59, No.190, October 3, 1994</b>

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4	When does this clinic/practice provide patients with copies of the Vaccine Information Statements (VIS) to keep?	<ol style="list-style-type: none"> <li>1. Every time the patient receives a vaccination</li> <li>2. When the child receives the first dose of vaccine within a particular series (e.g. 1<sup>st</sup> dose of DTaP)</li> <li>3. Do not provide</li> <li>4. Other (specify)</li> </ol>	Option 1	Option 2-4
6	When does the clinic/practice screen patients for VFC eligibility?	<ol style="list-style-type: none"> <li>1. First immunization visit to the office</li> <li>2. Every immunization visit</li> <li>3. Do not screen for VFC eligibility</li> <li>4. Not Applicable clinic /practice serves 100% VFC eligible children and has the appropriate Comprehensive Certificate with up to date signature on file.</li> <li>5. Other (specify)</li> </ol>	Option 2,4	Option 1, 3, , 5
7	Does this clinic/practice always notify the immunization program when publicly purchased vaccine has been involved in a cold chain failure, has expired or been wasted?	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ol>	Option 1	Option 2
8	When does the clinic/practice prepare vaccine for administration to patients?	<ol style="list-style-type: none"> <li>1. Immediately before administration</li> <li>2. Other: specify</li> </ol>	Option 1	Option 2

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9	Does the clinic/practice have a written plan for vaccine management? (ask to see a copy)	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ol>	<p>Option 1-Yes</p> <p>All 8 components must be present and content must accurately reflect requirements in Module 6 of VFC Operations Guide(August 2007 release)</p>	<p>No to all 8 components or any combination of Yes and No answer to the components</p> <p>Any component with a "No" response selected must have a corrective action plan developed with the provider by the staff person conducting the VFC site visit for that specific component</p>
10	Please identify the publication date for each VIS currently being used in this clinic/practice and then check the appropriate status for each VIS	<ol style="list-style-type: none"> <li>1. Current</li> <li>2. Outdated</li> <li>3. None Used</li> <li>4. Does not administer</li> </ol>	Options 1 or 4	<p>Options 2 or 3 to any VIS for a VFC vaccine provided within the practice.</p> <p><b>Please note: The VIS dates listed in Question 10 were current at the time the word version of the questionnaire was provided to the grantees. VIS are updated on an as-needed basis so each grantee must have a process to check for new VIS form dates between the annual release of the VFC site visit questionnaire</b></p>
11	What type of storage units does this clinic/practice use to store varicella-containing vaccine?	<ol style="list-style-type: none"> <li>1. Stand-alone freezer</li> <li>2. Stand-alone refrigerator</li> <li>3. Dormitory style refrigerator/freezer</li> <li>4. Combined refrigerator/freezer with separate external refrigerator and freezer doors (e.g. household-style appliance)</li> <li>5. Combined refrigerator/freezer with a single door</li> <li>6. Does not administer vaccines requiring freezer storage</li> </ol>	Option 1,4, 6	Option,2, 3, 5

#	Question	Response Options	Acceptable	Unacceptable- <b>Requires Corrective Action to be documented in #32 &amp; follow-up in #33</b>
11	What type of refrigeration unit is used to store all other vaccines (except varicella containing)? (check all that apply)	<ol style="list-style-type: none"> <li>1. Stand alone freezer</li> <li>2. Stand-alone refrigerator</li> <li>3. Dormitory style refrigerator/freezer</li> <li>4. Combined refrigerator/freezer with separate external refrigerator and freezer doors (e.g. household-style appliance)</li> <li>5. Combined refrigerator/freezer with single door (e.g. household-style appliance)</li> </ol>	Options: 2, 4	Options: 1, 3, 5
12	Are working thermometers placed in a central area of each refrigerator and freezer? <b>See note in right column.</b>	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. Have thermometer but not placed properly</li> <li>3. No thermometer</li> </ol>	Option 1	Options 2, 3 <b>Use of multiple thermometers:</b> Although multiple thermometers are not required within a storage unit, it is recognized that some providers may wish to thoroughly monitor temperatures throughout their storage unit. When a site is using multiple thermometers, it is important that they select only one certified and centrally-located thermometer as their official recorder of temperatures.
13b	For each type of thermometer used by the practice, indicate if the thermometer is certified (check all that apply)? Refer to 13(A) for type of thermometer	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ol>	Option 1- Yes	Option 2- If "No" is selected for any of the storage units, a corrective action plan must be developed even if only one unit does not have a certified thermometer. If any units have both certified and uncertified thermometers located in the unit, the staff must be instructed to use only the certified thermometer to record the temperature on the log sheets.

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14	For each refrigerator and freezer indicate how often temperatures are recorded (check all that apply)	<ol style="list-style-type: none"> <li>1. Once a day</li> <li>2. Less than once a day</li> <li>3. Twice a day</li> <li>4. More than twice a day</li> </ol>	Options 3, 4	Options 1, 2 specify in corrective action section (#32) If Option 4 is selected if the practice monitors the temperatures more than twice a day. It is important to acknowledge to the office that the VFC program appreciates their diligence, but it is not necessary to monitor the temperatures more than twice a day (a.m. & p.m.) and discuss with the practice staff how that time could be used to improve another aspect of vaccine management & document corrective action section.
15	Record highest and lowest temperatures logged in the last 3 months. If no log is available document current temperatures for both highest and lowest. If log is available for all 3 months select, "Yes" for section 3. If no log is available, select "No" for section 3. If log is available for any part of last 3 months, select "Partial" for section 3.	<p>Record lowest &amp; highest temperatures from log. If no log available use current temperatures for both lowest &amp; highest temperatures.</p> <p>Log available? Yes, No, Partial</p>	Record lowest & highest temperatures from available temperatures. If no log available use current temperatures for both lowest & highest temperatures. Correct answer to "Log available for last 3 months?"-"YES"	Log Available? Answer of No or Partial Storage Units temperatures must be recorded twice a day (am & pm) on a log. If log is not available or only available for part of the last 3 months –corrective action plan must be developed
16	During past 3 months, how many times were the temperatures outside the recommended range?	Number of occurrences Unknown: no log is available	0	Anything greater than 0 or documentation that no temperature log is available in question #15. Review responses to question # 17 and #18 to determine if all necessary actions were taken when the temperature was identified as outside the recommended range and actions were documented.

#	Question	Response Options	Acceptable	Unacceptable- Requires Corrective Action to be documented in #32 & follow-up in #33
17 <b>Only if out-of-range temp has been documented</b>	When temperatures were outside the range, what action(s) did the clinic/practice take?	<ol style="list-style-type: none"> <li>1. Adjust thermostat in refrigerator /freezer</li> <li>2. Measure temperature with different thermometer to check accuracy of original reading</li> <li>3. Moved vaccine to a different refrigerator/freezer</li> <li>4. Called the vaccine manufacturer to determine potency of the vaccine</li> <li>5. Called the local/state immunization program for assistance</li> <li>6. Did not do anything</li> <li>7. Not applicable, no temperatures outside range</li> <li>8. Unable to answer, no log available</li> </ol>	Options 1-5  Depending on situation, the most acceptable answer may be a combination of options or selecting all options 1-5 or Option 7-Not applicable, No temperatures outside range	Options 6, 8 or selecting only 1 or 2 of the acceptable options when the situation required further action to safeguard or determine the viability of the vaccine. <b>Reviewers must use their judgment to decide if all necessary steps were taken for identified situation.</b>
18 <b>Only if out-of-range temp has been documented</b>	Does the clinic/practice have written documentation of action taken when the temperatures were outside the recommended range?	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> <li>3. Not applicable, no temperatures outside range</li> <li>4. Unable to answer, no log available</li> </ol>	Option 1- Yes Option 3-Not Applicable no temperatures outside range	Option 2- No or Option 4 <b>All actions must be documented on the back of temperature log or on a separate page attached to log with the date that the temperature was out of range.</b>
20	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)	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ol>	Option 1-Yes to all units	Option 2-No- to any unit If any unit is out of temperature range, the reviewer must assist /instruct the staff on the actions to determine if the vaccine is still viable and how to document actions correctly.
21	Is food stored with vaccines in the refrigerator or Freezer	<ol style="list-style-type: none"> <li>1. Yes</li> <li>2. No</li> </ol>	Option 2- No to all units	Option 1- Yes to any unit Reviewer should instruct on why food should not

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22	Are vaccines stored in the doors of the refrigerator and freezer?	1. Yes 2. No	Option 2-No to all units	Option 1-Yes to any unit Reviewer should instruct/demonstrate how to properly arrange stored vaccine.
23	Is vaccine stored in the middle of the storage unit and stacked with air space between the stacks and side/back of the unit to allow cold air to circulate around the vaccine?	1. Yes 2. No	Option 1- Yes to all units	Option 2-No to any unit Reviewer should instruct/demonstrate how to properly arrange stored vaccine.
24	Is there a "DO NOT DISCONNECT" sign on the refrigerator/freezer electrical outlets?	1. Yes 2. No	Option 1- Yes to all units	Option 2- No to any unit Reviewer should provide warning sign and offer to assist in placing sign in proper location.
25	Is there a "DO NOT DISCONNECT" sign on the circuit breaker?	1. Yes 2. No 3. Don't know	Option 1-Yes to all units	Option 2, 3- No or Don't know to any unit Reviewer should provide warning sign and offer to assist in placing sign in proper location
26	Are short-dated vaccines stored in front and used first, rotating stock effectively?	1. Yes 2. No	Option 1-Yes to all units	Option 2- No to any unit
27	Can the clinic/practice physically differentiate privately purchased vaccine from publicly purchased vaccine? <b>To answer yes, clinic/practice must be able to demonstrate how this is done</b>	1. Yes 2. No 3. Not applicable clinic/practice is located in a universal state, has no private stock 4. Not applicable clinic/practice serves 100% VFC eligible children, has no private stock 5. Other	Options 1, 3*,4,5 Option 1 is acceptable if method allows provider to identify public from private stock. Option 3- universal purchase grantees would select this method and document that provider does not have private stock. Option 4 can only be selected if provider has Comprehensive Certificate on file and the certificate is current.	Option 2- No
28	Upon checking the clinic/practice's vaccine supply, did reviewer find any unreported wasted or expired vaccine?	1. Yes 2. No	Option 2- No	Option 1- Yes