

VACCINES FOR CHILDREN LOST / WASTED / EXPIRED POLICY DEFINITIONS

a) Abuse:

42 CFR 455.2 defines abuse as “provider practices that are inconsistent with sound fiscal, business or medical practices, those practices that result in unnecessary costs to the Medicaid program, or reimbursement or requests for reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for administration of health care.” Information concerning a provider who engages in abuse of the VFC Program shall be reviewed on a case-by-case basis and may result in dismissal from participation.

b) Administered:

A vaccine is administered if it is provided to the patient to prevent a medical illness or condition.

c) Borrowed Vaccine:

A vaccine dose is “borrowed” if a VFC vaccine dose is substituted for a private stock vaccine dose. This type of substitution shall occur only under exceptional circumstances and substitution of a private stock vaccine dose with a VFC vaccine dose shall not be the general practice of a provider. All doses shall be tracked in the MCIR VIM and it is noted that all doses shall be replaced with the same antigen (e.g., if one dose of VFC ActHIB vaccine is substituted, one dose of private stock ActHIB shall be used for replacement).

d) Breakage:

A vaccine dose is subject to breakage if the vaccine is determined to be unfit for administration due to the vaccine becoming non viable [child kicked the vaccine from the hand, vaccine is dropped on the floor or counter, or issues with the integrity of the vaccine’s vial (seal, top, etc.)]. The provided list of examples is not exhaustive. Breakage of a vaccine dose by a provider is considered waste for purposes of this policy.

e) Drawn But Not Used:

A vaccine dose is drawn but not used if the vaccine is prepared for administration and the dose is subsequently not administered. Circumstances in which this may occur include the parent of a child withdraws consent to administer a vaccine, a nurse or parent determines that a child has previously received the vaccine antigen, a child is determined to be unable to be vaccinated due to illness, discarding of pre-filled vaccine syringes at the conclusion of an immunization clinic and failure to timely administer a vaccine(s). The provided list of examples is not exhaustive. Vaccine that is drawn but not used by a provider is considered waste for purposes of this policy.

f) *Expiration-Pending Vaccine:*

An expiration-pending vaccine is one in which the vaccine will achieve or exceed its expiration date within 90 days.

g) *Expired Vaccine:*

A vaccine dose is considered to have expired if the date of expiration printed on the vaccine vial by the manufacturer has been exceeded. The value of a vaccine dose which has expired shall be reimbursed to the Division.

h) *Extraordinary Circumstances:*

A crisis involving the storage, handling or administration of a vaccine in which a significant novel force or occurrence is experienced and results in the departure from the routine, accepted course of business.

i) *Federal Contract Price:*

CDC vaccine contracts are established for the purchase of vaccines by immunization programs that receive CDC immunization grant funds (i.e., state health departments, certain large city immunization projects, and certain current and former U.S. territories).

j) *Fraud:*

42 CFR 455.2 defines "Fraud" as "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." Information concerning a provider who engages in fraud concerning the VFC Program shall be reviewed on a case-by-case basis and may result in dismissal from participation.

k) *Inadequate Refrigeration:*

Refrigeration is inadequate if the temperature within the interior of a refrigeration device fails to maintain temperatures within specified bounds set by the vaccine manufacture for appropriate storage (Refrigerator - typically 2-8 degrees Celsius or 35–46 degrees Fahrenheit / Freezer – typically -15 degrees Celsius or 5 degrees Fahrenheit). Inadequate refrigeration can result from human, mechanical, and natural occurrences. Vaccine that becomes non-viable due to inadequate refrigeration is considered waste for purposes of this policy.

l) *Loss:*

Loss is the generic term for a vaccine dose that has become non-viable (waste, expiration, lost).

m) *Lost Vaccine:*

A vaccine dose is lost if a provider is unable to account for the dose.

n) *Mechanical Failure:*

The inability of a device to effectively operate due to wear or other circumstances affecting performance.

o) *Medical Error:*

A medical error occurs when a vaccine has been administered improperly (incorrect vaccine, wrong age group, improper administration, using non-viable vaccine, etc.). A medical error involving administration of a vaccine by a provider is considered waste for purposes of this policy.

p) *Misrepresentation:*

Misrepresentation occurs when a provider manifests by words or other means information that is incorrect according to the facts that the circumstances provide. Information concerning a provider who engages in misrepresentation concerning the VFC Program shall be reviewed on a case-by-case basis and may result in dismissal from participation.

q) *Natural Disaster:*

A natural disaster is the occurrence of a natural phenomenon which manifests in a limited space and time that disrupts the typical patterns of life, causing, human, material and economic loss. Examples of natural disasters include hurricanes, tornados, storms, high water, wind, driven water, earthquakes, lightening, blizzards, and snow storms. The provided list of examples is not exhaustive. A vaccine which has become non-viable due to a natural disaster is considered waste for purposes of this policy. However, instances in which waste occurs due to a natural disaster will be reviewed on a case-by-case basis for purposes of reimbursement.

r) *Non-Viable Vaccine:*

A vaccine dose is non-viable if the vaccine has become unfit for administration. Circumstances in which a vaccine may become non-viable include expiration, vaccine handling errors, storage and handling errors or damage incurred during shipping. The provided list is not exhaustive. A vaccine which has become non-viable is considered waste for purposes of this policy.

s) *Power Outage:*

A disruption in the provision of electrical energy to a provider's or LHD's office for a period of time sufficient to cause potential or actual damage to vaccine doses.

t) *Provider:*

An actively practicing physician enrolled in the VFC Program.

u) *Received:*

A vaccine dose is received by a provider or LHD when the benefits and burdens of ownership have been shifted from McKesson to the receiving provider or LHD.

v) *Reimbursement:*

A monetary payment provided to the Division by a provider or LHD to address a vaccine dose(s) which has been lost, wasted or has expired under circumstances which are not excusable.

w) *Replaced:*

A VFC vaccine dose is replaced when a private stock vaccine dose is used to offset a dose of VFC vaccine. The private stock vaccine dose and VFC vaccine dose should be an exact match regarding antigen, amount and presentation.

x) *Short-Dated Vaccine:*

A vaccine dose is "short-dated" if the vaccine has been assigned a shortened expiration date by the manufacturer due to an out-of-range temperature excursion. Vaccine of this type cannot be re-distributed to another provider unless the receiving provider is notified of the circumstances surrounding the temperature excursion and agrees to accept the vaccine. If a receiving provider is unable to administer the short-dated vaccine prior to expiration, the original provider shall be responsible for all costs associated with reimbursement. A short-dated vaccine which is not able to be administered is considered waste for purposes of this policy.

y) *Storage and Handling Errors:*

Occur when a vaccine dose is rendered non-viable due to exposure to temperatures which are outside of the specified temperature range set by the vaccine manufacturer for appropriate storage. This also includes circumstances in which a vaccine dose is rendered non-viable due to reconstitution errors or exceeding time limitations, exposure to light and temperatures which are outside specified parameters set by the vaccine manufacturer. The provided list is not exhaustive. A vaccine dose which becomes non-viable due to storage and handling errors is considered waste for purposes of this policy.

z) *Timely Reimbursement:*

Reimbursement is considered to have been timely submitted by a provider if received by the Division within timeframes agreed to by the Division, LHD and provider.

aa) *Waste:*

A vaccine dose is considered to be waste if the vaccine is: i) rendered non-viable due to breakage; ii) drawn but not used; iii) subject to expiration; iv) subject to inadequate refrigeration; v) subject to a medical error; vi) rendered non-viable due to natural disaster; and vii) rendered non-viable due to storage and handling errors. The provided list is not

exhaustive. A vaccine dose which has been identified as waste is subject to reimbursement to the Division by a LHD or provider.

January 2009