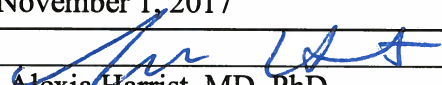


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Policy Title:	PVP: Fraud and Abuse	
Policy Number:	IMM-002	
Effective Date:	November 1, 2017	
Approval:	 Alexia Harrist, MD, PhD State Health Officer Public Health Division	10/18/17 Date

Purpose: As vaccines become more expensive and immunization programs more complex, the Public Vaccine Programs (PVP) managed by the Wyoming Department of Health (WDH) become more vulnerable to fraud and abuse. The intention of this policy is to establish a process for the prevention, identification, investigation, and resolution of suspected cases of fraud and abuse

Scope: This policy applies to primary healthcare providers enrolled in any PVP.

Policy:

1. Definitions

- a. "Public Vaccine Program (PVP)" refers to the state or federally funded programs that provide vaccines to enrolled providers at no cost to be administered to eligible patients at little to no cost to the patient.
- b. "Fraud and Abuse" is consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, the following definitions will be used:
 - i. "Fraud" refers to 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.
 - ii. "Abuse" refers to 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 healthcare. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

2. Examples of Fraud and Abuse

Fraud or abuse can occur in many ways. Some examples of potential fraud and abuse include, but are not limited to, the following:

- a. Providing publicly-supplied vaccine to ineligible patients;
- b. Selling or otherwise misdirecting publicly-supplied vaccine;
- c. Billing a patient or third party for publicly-supplied vaccine;
- d. Charging more than the established maximum regional charge for administration of a publicly-supplied vaccine to an eligible patient;
- e. Denying eligible patients publicly-supplied vaccine because of patient's inability to pay for the administration fee;
- f. Failing to implement provider enrollment requirements of the PVP;
- g. Failing to screen for and document eligibility status at every visit;
- h. Failing to maintain PVP records and comply with other requirements of the PVP;
- i. Failing to fully account for publicly-supplied vaccine, also known as dose-by-dose accountability;
- j. Failing to properly store and handle publicly-supplied vaccine;
- k. Ordering publicly-supplied vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering public doses of vaccine; and
- l. Waste of publicly-supplied vaccine

3. Oversight Personnel

- a. Compliance Specialists employed by the Department, make the decision to refer an incident to the VFC Coordinator for further investigation. This decision is based on the results of a Compliance Site Visit or Assessment.
- b. The VFC Coordinator will conduct the initial investigation and in cooperation with the Immunization Unit Manager determine whether immediate referral to the Medicaid Integrity Group is necessary or if educational intervention and follow-up are adequate.
 - i. If internal resolution is pursued, official notification is sent to the provider that is signed by the State Health Officer.
 - ii. If referral to the Medicaid Integrity Group is necessary, the VFC Coordinator will complete the referral and notify CDC.

4. Prevention

- a. When providers enroll in a PVP, they agree to comply with all of the requirements of the specific program(s) in which they enroll. The following is completed in order to assist in the prevention of fraud and abuse:
 - i. Enrolled providers and their staff are required to complete the Vaccine Coordinator Training Program immediately upon initial enrollment and annually thereafter. This training includes online modules which provide education on program requirements to ensure the provider and the provider's staff receive the information needed to avoid potential fraud and abuse;
 - ii. Quick Reference Guides, which detail appropriate billing and administration practices, are available on the Immunization Unit website;
 - iii. Compliance Visits take place at least every other year for every enrolled provider which consist of audits, one-on-one training, and education on requirements;
 - iv. Immunization Unit staff receive annual training on how to prevent, identify, and follow up on situations of non-compliance or fraud and abuse;

- v. Immunization Unit staff review the List of Excluded Individuals/Entities (LEIE) monthly to identify providers that have been excluded from participating in federally funded healthcare programs; and
- vi. PVP information is monitored on an ongoing basis to identify failures to comply and potential fraud and abuse patterns. Information monitored includes Provider Profiles, vaccine ordering, site visits, and vaccine inventory.

5. Detection

- a. Provider and Public Referrals
 - i. Any individual wishing to make a referral for a Fraud and Abuse investigation may do so by calling the Immunization Unit at 307-777-7952, 1-800-599-9754, or by completing and submitting the Fraud and Abuse Referral Form located on the Wyoming Immunization Unit website at www.immunizewyoming.com.
- b. Compliance Visits and Assessments
 - i. Most instances of fraud and abuse are identified while Immunization Unit Compliance Specialists are conducting annual Compliance Site Visits or Assessments.

6. Return or Disposal of Wasted Vaccine

- a. All wasted/expired vaccine must be returned to the CDC's centralized vaccine distributor within six (6) months of the vaccine being wasted/expired.
 - i. Any vaccine that is dropped/spilled/broken or a multi-dose vial that has been used at least once is not eligible for return and must be appropriately disposed of.
- b. All vaccine returns are to be submitted in the Immunization Information System (IIS) adopted by WDH. Returns are processed monthly by the Provider Support Specialist. Upon processing, the provider will receive a shipping label via email to return the wasted/expired vaccine.

7. Facts Gathering/Investigation

- a. The investigation of potential fraud and abuse will vary based on the type of fraud and abuse identified but may consist of the following:
 - i. Review of data in the IIS or the provider's electronic health record (EHR) system;
 - ii. An audit of billing transactions;
 - iii. An audit of patient records;
 - iv. Review of provider's public vaccine inventory in the IIS; or
 - v. Review of previous accounts of fraud and abuse, if applicable.

8. Resolution

- a. Resolution of fraud and abuse will vary based on the type of fraud and abuse identified and includes, but is not limited to the following:
 - i. Refund of funds paid by patients or insurers that were in excess of the allowable administration fee;
 - ii. Refund of funds paid by patients or insurers for publicly-supplied vaccines;
 - iii. The replacement of vaccine administered to ineligible patients within ninety (90) days of notification;

- iv. Education and corrective action plan;
- v. Probation period;
- vi. Removal of publicly-supplied vaccines; or
- vii. Termination from the program(s).

9. Allegation and Referral Database

- a. The Immunization Unit maintains a database to monitor and document all actions taken on allegations related to fraud and abuse of the PVP requirements, including actions taken to address identified situations.
- b. At a minimum, the following data elements are collected for monitoring, tracking, and reporting:
 - i. Subject's name (Medicaid ID if known);
 - ii. Address;
 - iii. Source of allegation;
 - iv. Date allegation reported to program;
 - v. Description of suspected misconduct;
 - vi. Specific VFC requirements violated;
 - vii. Specific dates and actions taken with provider (specific follow up activities: education, site visit, suspension, removal of vaccine, or other actions taken prior to disposition);
 - viii. Value of vaccine involved if available;
 - ix. Success of educational intervention; and
 - x. Disposition (closed, referred, entered into educational process) of case and date of disposition.

10. Appeals Process

- a. If a provider disagrees with the determination of fraud and abuse, the provider may submit a written appeal to the State Health Officer within ten (10) business days of receiving formal notification of fraud and abuse.
- b. Fraud and abuse appeals must be signed by the Responsible Physician listed on the PVP Provider Agreement. Upon receipt of the appeal, the Immunization Unit will convene a review committee to review the appeal, the circumstances of the incident(s) in question, and any other relevant information. Providers who appeal the determination will receive written notification regarding the outcome of the appeal within thirty (30) calendar days of receipt of the appeal request. Fraud and abuse activities will be on hold and the provider may remain in a PVP during the appeal review period as long as there is no further risk to vaccine accountability.

Contacts:

Immunization Unit Main Line 307-777-7952
 Immunization Unit Manager 307-777-6001
 WyIR Coordinator 307-777-5773

Forms:

PVP Provider Agreement
 Vaccine Coordinator Checklist

References:

Wyo. Stat. Ann. § 21-4-309
 WDH Immunization Program Administrative Rules and Regulations
 WY PVP Policies and Procedures