



## **Improper vaccine storage and handling procedures occurring in a New Jersey Vaccines for Children (VFC) provider office**

### **Frequently Asked Questions**

**May 9, 2017**

#### **PATIENTS/PUBLIC CONCERNS:**

##### **Why are some of the children who visited Dr. Bleiman's practice being recommended for evaluation for possible revaccination?**

Dr. Bleiman at Southern Ocean Pediatrics and Family Medicine, LLC participates in the NJ Vaccines for Children (NJ VFC) Program and was found to be out of compliance with the Centers for Disease Control and Prevention's (CDC) requirements for vaccine storage and management. Specifically, vaccine that is used as part of the NJ VFC Program may not have been stored at proper temperatures.

##### **Who is affected by this situation?**

Approximately 900 children received potentially compromised vaccines between November 1, 2014 through July 28, 2016 as part of the NJ VFC Program. There are also 38 children who received vaccines after July 28, 2016, who are being notified that the vaccines they received were not stored properly. To identify these children, the New Jersey Department of Health (NJDOH) used the information that Dr. Bleiman recorded in the New Jersey Immunization Information System (NJ IIS) about the doses of VFC vaccine he administered.

##### **What actions have been taken to address the situation with Dr. Bleiman's practice?**

Under the terms of a settlement reached on April 27, 2017, approved by the state Comptroller, Dr. Bleiman is required to pay \$156,220 to the Medicaid Fraud Division. This settlement ends Dr. Bleiman's temporary suspension from the state's Medicaid and NJ FamilyCare programs. Although the suspension from Medicaid was lifted by the Medicaid Fraud Division, Dr. Bleiman remains suspended from the NJ VFC Program.

##### **I have heard that the vaccines administered were proven to be effective. Is this true?**

The NJ VFC Program has no new data regarding the viability of the VFC vaccines stored and/or administered at Dr. Bleiman's office.

##### **Who can I speak with if I have further questions about this situation?**

For your convenience, the NJ Health Hotline has been established to answer general questions. That number is 1-866-448-2432. Educated health professionals are available to answer your questions 24/7. Information in multiple languages is available, and the helpline has resources to assist callers who are deaf or hard of hearing.

For more specific information about whether your child should be revaccinated, please contact a healthcare provider to schedule an appointment to discuss an evaluation.

##### **Who is going to cover the cost of a medical evaluation / revaccination?**

As with any medical visit, questions about billing should be directed to your health plan or insurer.

- Families who participate in the VFC Program can contact their managed care organization using one of the following numbers:
  - Aetna Better Health® of New Jersey  
1-855-232-3596
  - Amerigroup New Jersey, Inc.  
1-800-600-4441
  - Horizon NJ Health  
1-877-765-4325
  - UnitedHealthcare Community Plan  
1-800-941-4647
  - WellCare Health Plans of NJ, Inc.  
1-888-453-2534
- Families who are uninsured may contact one of the Federally Qualified Health Centers (FQHCs) in the area, including:
  - Center for Health Education, Medicine, & Dentistry (CHEMED) in Lakewood  
732-364-6666 (<https://www.chemedhealth.org/>)
  - Ocean Health Initiatives in Lakewood at  
732-363-6655 (<http://ohinj.org/>)
- Families who are insured should contact their primary health insurer.

**I was notified that my child received vaccines that were not stored properly. Does that mean my child is going to get sick?**

Exposure to temperatures outside the range recommended by vaccine manufacturers can make the vaccines less effective. Children who received these vaccines might not be fully protected against vaccine-preventable diseases. A healthcare provider can help you determine whether revaccination is necessary. In general, receiving extra doses of vaccine poses no medical problem.

**Does my child have to repeat all of the vaccines he/she received?**

Not necessarily. In some cases, there may be blood tests that can be done to determine if the vaccines were effective. In some cases, your child might have “aged-out” of the vaccine. This means that your child has reached the age at which the vaccine is no longer recommended. In other circumstances, vaccines may need to be repeated in order for your child to receive the best protection against certain vaccine-preventable diseases. A healthcare provider can help you determine whether revaccination is necessary.

**Is it harmful for my child to receive more than the recommended doses of vaccine?**

In general, receiving extra doses of vaccine poses no medical problem. Children and adults who receive more than the recommended dose of tetanus vaccine (i.e., DTP, DTaP, DT, Tdap or Td), may experience a localized reaction such as fever, redness, swelling or soreness where the shot was given. Please consult with a healthcare provider regarding the need for an appointment to be evaluated for possible revaccination.

**Can blood tests determine if my child needs to be revaccinated?**

Yes, there are certain blood tests, called titers, that can be done to find out if your child is immune (protected) from certain diseases. If your child has a certain level of immunity, he/she may not need to be revaccinated. However, titers are not available for every vaccine-preventable disease. Consult with a healthcare provider for further guidance regarding titers and whether an appointment should be scheduled for an evaluation.

**How do I know if my child needs to be revaccinated or if he/she needs blood tests (titers)?**

A healthcare provider is the best person to assess your individual situation and can determine the best course of action regarding your child’s immunizations. The NJDOH will not know the specifics of each patient and

therefore cannot provide medical guidance.

**How do I know if Dr. Bleiman gave my child NJ VFC vaccines?**

Your healthcare provider can access the password-protected internet-based NJIIS to determine if NJ VFC vaccines were administered from November 1, 2014 through July 28, 2016.

In addition, if your child is 0 to 18 years of age and falls into one of the following categories, your child likely received NJ VFC vaccine:

- Medicaid
- Medicaid managed care (Plan A only)
  - Aetna Better Health® of New Jersey
  - Amerigroup New Jersey, Inc.
  - Horizon NJ Health
  - UnitedHealthcare Community Plan
  - WellCare Health Plans of NJ, Inc
- Uninsured

**What if my child’s name is not in NJIIS but I am certain my child received a VFC vaccine during the specified time period?**

After you have visit a health care provider, if your child’s name is not in the system please be aware of the following:

As a participant in the NJ VFC Program, Dr. Bleiman is required to record all NJ VFC vaccines administered into NJIIS. Furthermore, NJ regulations mandate that all providers who administer vaccines to children less than seven years of age must record these vaccinations in NJIIS within 30 days of administration. However, we cannot confirm that Southern Ocean Pediatrics and Family Medicine, LLC entered all vaccine doses administered by the practice into NJIIS. Additionally, Southern Ocean Pediatrics and Family Medicine, LLC could not account for all the doses that they received from the NJ VFC Program. Therefore, it is possible that a child who received NJ VFC vaccine may not have been recorded in the NJIIS. If you are certain you received NJ VFC vaccine during the time period specified, but this information is not recorded in NJIIS, speak with a healthcare provider to schedule an evaluation to determine if revaccination is necessary.

**I/my child received NJ VFC vaccines during this time period but I did not receive a letter. What should I do?**

If your child received a vaccine at the practice from November 1, 2014 through July 28, 2016, we recommend that you discuss the situation with a healthcare provider. We obtained our information from the New Jersey Immunization Information System (NJIIS). This system contains information entered by Southern Ocean Pediatrics and Family Medicine, LLC. We cannot guarantee that Southern Ocean Pediatrics and Family Medicine, LLC entered all vaccine doses administered by the practice into NJIIS. Anyone who is concerned about their child’s vaccination status should contact a healthcare provider and request an evaluation.

**If the NJDOH has known about this since July 2016, why am I just learning about this now?**

This has been an ongoing investigation. The Department of Health has made referrals to and is working with the Division of Consumer Affairs and the New Jersey Board of Medical Examiners, both in the Attorney General’s Office; the Medicaid Fraud Division in the Office of the State Comptroller; and the Medicaid program in the New Jersey Department of Human Services.

**If my child received vaccines at Dr. Bleiman’s office, is he/she going to be excluded from school or**

**preschool/childcare?**

The NJDOH is not recommending exclusion of these children from school or preschool/childcare. We are leaving the decision for revaccination with the evaluating healthcare provider in consultation with the guardians.

**My child’s vaccines are covered by insurance (not part of the NJ VFC program). How do I know if the vaccines my child received were affected (i.e., how do I know if vaccine used for private patients was stored improperly)?**

Anyone who is concerned about their child’s vaccination status should contact a healthcare provider and request an evaluation. Privately purchased vaccines that are covered by insurance were maintained in a separate storage unit at this office which the NJ VFC Program staff did not have the authority to access; therefore, the NJDOH cannot speak to the storage conditions of vaccines that privately insured patients received. The NJ VFC program only assesses vaccines purchased through the Vaccines for Children Program. Investigation of privately purchased vaccine has been referred to the Board of Medical Examiners (BME).

**Do children in the NJ VFC program receive different/separate vaccines than privately insured children?**

Vaccines available through the NJ VFC Program are those recommended by the Advisory Committee on Immunization Practices (ACIP) and are the same type of vaccines offered to children who are privately insured.

**Where can I get a copy of my child’s vaccination records?**

In order to receive a copy of your child’s vaccination records, you would need to complete the “Request for Copy of NJIIS Immunization Record” (IMM-46) available at <https://njiis.nj.gov/njiis/html/forms.html>. Mail the completed form along with a copy of your driver’s license (or acceptable form of identification) to the New Jersey Vaccine Preventable Disease Program, P.O. Box 369, Trenton, NJ 08625-0369. This information can also be faxed to 609-826-4866.

**My child participates in the NJ VFC program. Where else can my child receive vaccines?**

Please contact your health plan if you need any assistance in locating an in-network provider.

**Managed care organization numbers include:**

- Aetna Better Health® of New Jersey  
1-855-232-3596
- Amerigroup New Jersey, Inc.  
1-800-600-4441
- Horizon NJ Health  
1-877-765-4325
- UnitedHealthcare Community Plan  
1-800-941-4647
- WellCare Health Plans of NJ, Inc.  
1-888-453-2534

If your child is uninsured, you can contact one of the **Federally Qualified Health Centers (FOHCs)** in the area, including:

- Center for Health Education, Medicine, & Dentistry (CHEMED) in Lakewood  
732-364-6666  
(<https://www.chemedhealth.org/>)
- Ocean Health Initiatives in Lakewood at  
732-363-6655  
(<http://ohinj.org/>).

In addition, you can contact **Southern Ocean Medical Center** in Manahawkin at 1-609-978-2111.

## **VACCINES FOR CHILDREN (VFC) PROGRAM:**

### **What is the NJ VFC Program?**

Introduced in 1994 by the CDC, VFC is a federally funded, state operated vaccine supply program that provides pediatric vaccines at no cost to healthcare providers who serve children who might not otherwise be vaccinated because of inability to pay. Healthcare providers may charge office visit and administration fees based on a government fee schedule. There are over 1,000 medical offices enrolled in the NJ VFC Program and most are private providers. The NJ VFC is a program component of the NJDOH, Vaccine Preventable Disease Program.

### **Why did the NJ VFC Program first visit Southern Ocean Pediatric and Family Medicine, LLS, the office of Dr. Michael Bleiman?**

The CDC mandates that providers who participate in the VFC Program receive routine office visits in order to evaluate a provider's compliance with all VFC requirements including: appropriate screening for eligibility, documentation of vaccine administration for each patient, and satisfactory storage and handling of vaccines. The CDC requires that VFC Programs visit approximately half the number of enrolled providers every year. The NJ VFC Program's first visit to Dr. Michael Bleiman was a routine scheduled visit to the office.

### **What is the NJ VFC program doing about this situation?**

The NJ VFC program takes the health of the children and all potential misuse of federally funded vaccines seriously. The NJ VFC Program referred Dr. Bleiman to the Medicaid Fraud Division and to the New Jersey Board of Medical Examiners for investigation.

Southern Ocean Pediatrics and Family Medicine, LLC, the office of Dr. Michael Bleiman, was suspended from Medicaid and NJ FamilyCare from January 27-April 27, 2017. He reached a settlement with the Medicaid Fraud Division and agreed to pay \$156,220.

On January 9, 2017, the State Division of Consumer Affairs in the Attorney General's Office filed a complaint with the State Board of Medical Examiners alleging gross negligence, professional misconduct and other violations by Dr. Bleiman. The investigation by the New Jersey Board of Medical Examiners (BME) is ongoing.

Dr. Bleiman and Southern Ocean Pediatrics and Family Medicine, LLC remain suspended from the NJ VFC Program.

### **When did the problem with temperature monitoring begin?**

Upon review of the temperature logs, it appears that problems started in November 2014.

Dr. Bleiman went into private practice and applied to the NJ VFC Program in June 2014. He had his new provider site visit on July 31, 2014, which includes training. His first compliance visit was on October 29,

2014, and during that visit, he was meeting the vaccine storage requirements of the program.

**What should providers do when they record NJ VFC storage unit temperatures that are outside the range recommended by the vaccine manufacturers and the CDC?**

The provider must immediately stop using any vaccines exposed to temperatures outside the range recommended by the vaccine manufacturers and the CDC. The vaccines must be placed in “quarantine.” The NJ VFC Program must be notified. The provider must contact the manufacturers of the vaccines to determine if the vaccine has been made less effective and if the vaccine should be used. Only after obtaining information supporting the use of the vaccine from the vaccine manufacturers in writing and reporting the findings to the NJ VFC Program should the provider use the vaccine placed in quarantine. Dr. Bleiman continued to administer the vaccines that had been exposed to out-of-range temperatures without taking the recommended steps of contacting the vaccine manufacturers or notifying the NJ VFC Program.

**Why did the provider administer compromised vaccine after July 28, 2016?**

The NJDOH’s priority is to ensure the public health of New Jersey’s children. On July 28, 2016, the NJ VFC Program stressed the importance of proper vaccine storage and handling and indicated to Dr. Bleiman that potentially compromised vaccines are not to be used.