



Centers for Disease Control and Prevention Announces Interim Storage and Handling Guidelines:

CDC's storage and handling guidance has been updated. The key issues addressed in the interim guidance are:

- Temperature Excursion Definitions
- Temperature Excursion Corrective Actions
- Updated Temperature Monitoring Equipment Recommendations
- Updated Refrigerator/Freezer Equipment Recommendations

If you would like to access the information on CDC's website, you will find these documents at:

<http://www.cdc.gov/vaccines/recs/storage/interim.htm>

This interim guidance is a very important first step to improving storage and handling practices. Please read it carefully and share with your staff.

Thank you for working with us to strengthen this critically important public health program and ensure proper storage and handling practices are in place.

Adult 317 Vaccine Guidance

The NJ Vaccines for Children Program (NJVFC) provides vaccines through two primary funding sources. These two sources are VFC and Section 317 funds (only used at FQHCs, Local Health Departments and not-for-profits and primarily used for the adult population). Section 317 of the Public Health Services Act authorizes funds for State immunization grants to support the reduction of vaccine-preventable disease through the maintenance of high immunization coverage rates. Historically, the NJVFC Program has supported the immunization of those adults who are at risk for vaccine-preventable disease and who are not otherwise insured or able to pay for the vaccines in question. Section 317 funded vaccine use is based on guidance provided to the States by the Centers for Disease Control and Prevention (CDC). The NJVFC Program is under increased scrutiny to ensure accountability for 317 funded vaccines. The CDC has issued specific guidance for use of 317 funded vaccines which is attached to this newsletter for your review. Please take note that section 317 funded vaccines may not be used for insured individuals.

SCHIP CHILDREN

As a reminder/follow-up, there are strict guidelines in place for vaccinating NJ FamilyCare B, C and D children with NJVFC-provided vaccines. Please visit the NJIIS Bulletin Board for complete details on how these children may receive their vaccines through the VFC Program.

NJVFC Fully Integrated with CDC's VTrckS Vaccine Management System

The NJVFC Program is now fully operational and compliant with the CDC's vaccine management system (VTrckS). VTrckS is being deployed to all 64 CDC project areas world wide to ensure accurate vaccine accountability measures are in place and provides real time vaccine data to projects and the CDC. NJVFC, due to its robust online inventory management system, was able to integrate VTrckS "behind the scenes" so that providers would not have to learn an additional inventory system. However, it is critical for providers to enter immunization data accurately and in a timely fashion. Care also needs to be taken in ensuring EMR/EHR systems are properly decrementing inventory. Excessive inventory would result in delays in vaccine availability to providers.

NJVFC Contact Information

Phone Number – (609) 826-4862

Fax Number – (609) 826-4867 or
(609) 826-4868

Email address –
vfc@doh.state.nj.us

2012 VIS Updates

There are updated Vaccine Information Sheets for Td/Tdap, MMR, HPV, Hep B, Influenza are available at:

www.cdc.gov/vaccines/pubs/vis

Don't Forget to Enter Your Comments!!

Do you recall seeing the comment section at the bottom of the online Order Form? When an order is in review status, the Comments Section lets you send a comment to NJVFC Customer Service. Let the program know if your office is planning a special clinic or vaccination "catch-up." Comments allow us to process your order without delay. The online temperature log also has a Comment Section at the bottom of the page as well. When a temperature goes out of range, it is important to note the corrective action in the comment section.



Keep Vaccines Exposed to Out of Range Temperatures Refrigerated, Label and "DO NOT USE"

Some sites remove vaccine from the refrigerator before confirming the vaccine is unusable. Both Pharmaceutical companies and the NJVFC Program must be contacted to obtain viability information. The pharmaceutical company will send studies which document if vaccine exposed to too warm or too cold temperatures is useable. Depending on the incident, vaccines may be useable, unusable, or have a shortened expiration date. Pharmaceutical company data must be consulted and followed.

2012-2013 Influenza Vaccine

The 2012-2013 season marks the earliest NJVFC has been able to make influenza vaccine available to providers. Providers were able to order influenza vaccine on August 24, 2012. As of October 25, 2012 NJVFC has distributed 300,000 doses of influenza vaccine. NJVFC would like to congratulate its providers on this monumental task. We would like to remind providers to vaccinate through May 2013 to ensure there is availability of vaccine through the entire influenza season.



DID YOU KNOW?



- One vaccine can have two or more lot numbers assigned to it. Use the lot number on the packing list, which is the lot number on the outside of the box. The lot number on the vials may be different. Keep combination vaccines in the box to avoid confusion.
- Diluent and vaccine can have different expiration dates. Order only enough vaccine to last until your next scheduled ordering month. Ordering excess doses puts vaccines & diluent at risk of expiration.
- Ensure that your vaccine shipment is handed to a staff member. Check if a signature was left 'on-file' with FedEx. Signature 'on-file' permits FedEx to leave a delivery when the office is closed or no staff are present. Remove permission to leave shipments without a signature.
- VFC vaccines must remain in the office where they are received. One provider with multiple offices may not transfer vaccines to the other offices which are not enrolled in the VFC program. To receive vaccines at other offices, enroll these offices in the VFC program.
- If an office closes for a period of time after an order is placed, the order may arrive while you're away. Orders returned to McKesson in good condition will be reshipped and will take longer to arrive. Orders that spoil due to the office closure may be the financial responsibility of the practice.

Who Should I Contact?

The NJVFC Program fields many calls regarding various inventory related issues. Here are some tips on who to contact with questions regarding inventory....

NJVFC Customer Service can assist you with general information and questions specific to vaccines provided by the Program (i.e., orders, temperature logs, change of address, enrollment and NJIMODS questions).

NJ Helpdesk can assist you with information technology (IT) related issues such as EMR/EHR concerns, data transfer issues and other technical support related questions.

NJIIS Trainers can assist you with registry related questions and issues such as basic and advanced NJIIS trainings, inventory problems with the registry and trouble shooting registry data.

Borrowing Form

NJVFC Program will discontinue borrowing as of January 1, 2013. CDC no longer promotes this activity due to abuse, promotion of poor inventory control and use of borrowing replacing proper eligibility screening practices. Please contact the NJVFC Program with any questions.

Helpful Contact Info

NJIIS Help Desk:

Phone: (609) 984-0224

Fax: (609) 341-2720

Email:

helpdesk@doh.state.nj.us

NJIIS Trainers - please visit:

<https://njiis.nj.gov/njiis/jsp/trainingschedule.jsp>

to locate the trainer assigned to your county

Use of Vaccine Purchased with 317 Funds Question and Answer Bank

General Policy Guidance

1. What is the role of the Section 317 Immunization Program? What will its role be after Affordable Care Act implementation?
2. Does this policy change mean that CDC is changing the Section 317 program to only serve adults?
3. Why is CDC putting this policy into effect now?
4. With ACA upheld, is this policy still moving forward?
5. Does the CDC have the authority to implement this policy?

Use of 317 Vaccine Funds General Guidance

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7. What is the CDC definition of under- and fully-insured?
8. Can we use 317 vaccine for underinsured children?
9. We do not have third-party billing in place, can we use 317 vaccine funds until we do?
10. Does CDC have any information on when "grandfathered" insurance plans will lose their "grandfather" status and how many of such plans still exist?
11. We have developed a transition plan and are working diligently to be in compliance but have specific hurdles that we are having trouble overcoming. What should we do?

Fully Insured Guidance

12. What if my state has a mandate requiring vaccination of all individuals including fully insured (other than school entry requirements)?
13. Many individuals coming to our clinics do not know if they are fully-insured for immunization. How do we handle that?

14. Some of our fully insured clients have very high deductibles, can we use 317 vaccine funds to immunize them if they have not met their deductible?

Specific Population Exception Guidance

15. We use 317 vaccine funds for birth doses of Hepatitis B, can we continue that?
16. Can American Indian and Alaska Native Adults be vaccinated with 317 vaccine?
17. Tdap vaccine is not a covered service for adults on Medicaid in my state. Can I vaccinate adults on Medicaid with 317-funded Tdap?
18. Zoster vaccine is not covered by Medicare Part B. May I vaccinate adults on Medicare Part B with 317 funded Zoster? What if Zoster vaccine is not covered by Medicare Part D?
19. Can we continue funding our Tdap cocooning programs with 317 dollars?
20. Can we continue funding our school-located influenza vaccine clinics with 317 dollars?
21. Can we use our influenza purchased with 2012 317 funds to vaccinate fully insured individuals in upcoming influenza outreach clinics, even if they fall after the October 1 deadline?
22. Can we use 317 vaccine funds for non-Medicaid covered vaccines?
23. Can we use 317 vaccine funds for immigrants and refugees?
24. Can I use 317 to "front load" vaccines ordered for SCHIP children and then replenish those vaccines with my State dollars?

1. What is the role of the Section 317 Immunization Program? What will its role be after Affordable Care Act implementation?

The Section 317 Immunization Program plays a critical role in achieving national immunization coverage targets and reductions in disease. Behind every vaccine given to a child, adolescent, or adult in the United States are public health systems and experts that are essential to a successful immunization program that will continue to be critical following the implementation of the health insurance reforms of the Affordable Care Act. While the Affordable Care Act expands insurance coverage for immunization services, other important public health functions are necessary to assure that the right vaccines get to the right people at the right time to protect their health and the health of their communities and prevent resurgences of life-threatening diseases. The Section 317 Immunization Program is needed to support those functions.

2. Does this policy change mean that CDC is changing the Section 317 program to only serve adults?

It will no longer be appropriate for Section 317 vaccine to be used for routine vaccination of children, adolescents, and adults who have public or private insurance that covers vaccination. Section 317 vaccine is a precious national resource that will continue to be used to fill critical public health needs, such as providing routine vaccination for those with no insurance and responding to outbreaks of vaccine-preventable diseases.

Most importantly, the immunization systems and experts that are supported by the Section 317 Immunization Program *will continue* to be the backbone for the U.S. childhood immunization program -- regardless of the payer for the vaccine given -- by ensuring that childhood vaccination is accessible, safe and effective, and used most successfully to protect our most precious national resource.

3. Why is CDC putting this policy into effect now?

The 317 program has evolved over time to fill gaps and address priorities in our vaccine programs. As ACA is implemented, more individuals will have coverage for vaccines through both public and private insurance, and nearly *all* children will be covered through VFC or private insurance. While childhood vaccination coverage is at record highs, there are many gaps in uninsured adults. With the changes in insurance coverage it is time to allow 317 to evolve once again to best address the needs of the individuals served by our vaccine programs. Responsible stewardship of vaccine programs and the federal funds used to support them mean that these resources must be allocated to areas of greatest need and not subsidize private insurers.

4. With ACA upheld, is this policy still moving forward?

Yes. This policy goes into effect beginning October 1, 2012. The 317 vaccine

funding policy is not dependent on ACA, although improvements in vaccine coverage mandated by the ACA will facilitate implementation. This policy is to ensure that we are all doing our part to ensure responsible fiscal management of public resources.

5. Does the CDC have the authority to implement this policy?

Yes. CDC has the authority as well as the responsibility for the administration of 317 funds under the enacting legislation and 45 CFR 92. Given this responsibility, CDC is implementing this policy in our continued effort to ensure fiscal accountability for these funds.

6. What can 317 vaccines be used for? What can they NOT be used for?

The clarification of the 317 vaccine policy, generally, focuses on ensuring that insured individuals receive their vaccinations through their insurance provider network, and are not subsidized through federal funding.

Grantees may not administer Section 317 vaccines to fully insured children or adults, except in limited circumstances described below. An underinsured child may receive Vaccines for Children (VFC) funded vaccine if the child is seeking vaccinations in a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under approved deputization agreements.

In circumstances other than “exceptions” specified in the policy, 317 vaccines **may not** be used to vaccinate:

- Fully insured children and adults seen in public clinics
- Fully insured children and adults seen in private provider offices
- Adults with Medicare Part B
- Adults with Medicaid coverage for vaccines
- Fully insured adults seen in STD/HIV clinics or drug treatment centers
- Fully insured parents of newborn infants participating in Tdap cocooning projects
- Fully insured adults at high risk for acquiring Hepatitis A
- Fully insured children and adults with a high co-pay or deductible
- Fully insured students receiving vaccines for college entry at Public Health Clinics or College health facilities
- Fully insured children and/ adults in low medical access areas
- Fully insured adults in LTCs/eldercare
- Fully insured children in school-based health centers or clinics
- Fully insured “high risk” occupational groups (e.g. EMS, first responders, health care workers) for hepatitis A or B or other diseases
- Fully insured adults and children receiving vaccines as part of a community wide outreach event (including mobile vans and health fairs)

- Children who are insured by SCHIP standalone programs

Exceptions: 317 vaccine funds may be used to vaccinate the following:

- Newborns receiving the birth dose of hepatitis B prior to hospital discharge that are covered under bundled delivery or global delivery package (no routine services can be individually billed) that does not include hepatitis B vaccine
- Fully Insured infants of hepatitis B infected women and the household or sexual contacts of hepatitis B infected individuals
- Uninsured or underinsured adults
- Fully insured individuals seeking vaccines during public health response activities including:
 - Outbreak response (regardless of insurance status)
 - Post-exposure prophylaxis
 - Disaster relief efforts
 - Mass vaccination campaigns or exercises for public health preparedness
 - Individuals in correctional facilities and jails (except as outlined in VFC Operations Guide)

7. What is CDC definition of under- and fully-insured?

The terms “underinsured” and “fully insured” are defined as follows:

- **Underinsured:** A person who has health insurance, but the coverage does not include vaccines or a person whose insurance covers only selected vaccines. Children who are underinsured for selected vaccines are VFC-eligible for non-covered vaccines only. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputization agreement.
- **Fully Insured:** Anyone with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan’s deductible had not been met.

8. Can we use 317 vaccine for underinsured children?

Underinsured children who are seeking services in an FQHC or under a deputization arrangement are considered VFC eligible and therefore 317 vaccines may not be used. However, if the vaccines are being given at a health care facility that is neither an FQHC nor has it been deputized, then 317 funded vaccines can be used.

9. **We do not have third-party billing in place; can we use 317 vaccine funds until we do?**

No. We encourage Grantees to incorporate third-party billing as part of their vaccination program and there are a number of Grantees working towards this in a variety of ways. Grantees exploring third-party billing should consider reaching out to other Grantees to understand options that will help facilitate this transition.

10. **Does CDC have any information on when “grandfathered” insurance plans will lose their “grandfather” status and how many of these plans still exist?**

According to a presentation given by the AMA at the Adult Immunization Summit earlier this year, approximately 50% of plans had grandfathered status in 2011 with half of those expected to lose that status in 2012. Small plans are likely to lose grandfathered status quicker than large plans and it is estimated that 90% of grandfathered plans will lose their grandfathered status by 2014.

11. **We have a developed a transition plan and are working diligently to be in compliance but have specific hurdles that we are having trouble overcoming. What should we do?**

Grantees that have been working diligently to meet the October 1, 2012 deadline, but have specific issues that make compliance difficult can contact their CDC project officer to request technical assistance. Prior to requesting technical assistance, grantees should be sure to:

- Have a plan identifying all the steps necessary to reach compliance
- Updated the status of each of the action items showing efforts made
- Identify issues within the plan that will require assistance, type of assistance, etc.

12. **What if my state has a mandate requiring vaccination of all individuals including fully insured (other than school entry requirements)?**

The CDC has reached out to most of the Grantees and has not found state mandates that specifically require vaccination “for all” through federally purchased vaccine. Some states have guidance that **if funding is available**, this type of vaccination program should be pursued. 317 vaccine is not available for “vaccination of all.” Individuals with insurance must obtain their vaccinations through their insurer’s provider network.

13. **Many individuals coming to our clinics do not know if they are fully-insured for immunization. How do we handle that?**

Each Grantee needs to develop policies that best fit their practices and their populations. However, the CDC recommends patient communications regarding this policy in the months leading up to the October 1st deadline to give individuals time to research and understand their insurance status. Recommended communications can include:

- Talking points for staff and clinicians
- Signage or video in patient waiting rooms, etc.
- Handouts

It is the provider's responsibility to conduct diligent screening to ensure fully insured individuals are not receiving 317 vaccine. It is the individual's responsibility to understand their insurance status and identify in network providers. It is our responsibility to communicate this to individuals effectively and ahead of the October 1st deadline to ensure they have the opportunity to understand their individual status.

14. Some of our fully insured clients have very high deductibles; can we use 317 vaccine funds to immunize them if they have not met their deductible?

No. Section 317 vaccine may not be used to routinely vaccinate any fully-insured individual. 317 vaccine may be used to vaccinate under-insured individuals whose insurance does not cover vaccination.

It should be noted that research done by the Kaiser Family Foundation indicates that individuals with high deductible health plans (HDHP) are a very small proportion of the insured population. Additionally, the study states that many HDHPs routinely cover preventative services without requiring the deductible is met. The CDC encourages grantees to contact insurers to determine their specific HDHP policies and benefits. The majority of covered workers with a deductible are in plans where the deductible does not have to be met before certain services, such as physician office visits, preventive care, or prescription drugs, are covered. Specifics from the report include:

- Roughly 84% of covered workers with general plan deductibles in HMOs, POS plans (68%), and PPOs (74%) are enrolled in plans where the deductible does not have to be met before physician office visits for primary care are covered
- Higher shares of covered workers do not have to meet the deductible before preventive care is covered in HMOs (96%), PPOs (93%), POS plans (88%), and HDHP/SOs (94%)

The full report can be found at: <http://ehbs.kff.org/pdf/2011/8225.pdf>

The CDC recommends clear and consistent communication regarding the Section 317 vaccine policy to affected individuals in order to provide these individuals the time necessary to understand their specific insurance policy and plan for the future.

15. We use 317 vaccine funds for birth doses of Hepatitis B. Can we continue that?

VFC and Section 317 may be used for the birth dose of hepatitis B. The CDC wants to ensure that important strides made in vaccination coverage are not compromised. Grantees may decide to use 317 vaccines for vaccinating fully insured newborns

with the birth dose of hepatitis B; however grantees should also be aware that CDC may change this guidance and disallow this use at a later time.

16. Can American Indian and Alaska Native Adults be vaccinated with 317 vaccine?

American Indian and Alaska Native adults whose only source of health care is provided by an Indian Health Service, Tribal or Urban health care organization that does not provide an ACIP-recommended vaccine can receive 317 funded vaccine if the vaccine is otherwise not available because they are not insured. In addition, it is CDC's understanding that the IHS Chief Medical Officer plans to send out a memo stating that IHS considers provision of all ACIP recommended vaccines to be a basic standard of care, and strongly encourage all sites to provide all routinely recommended vaccines.

17. Tdap vaccine is not a covered service for adults on Medicaid in my state. Can I vaccinate adults on Medicaid with 317 funded Tdap?

Yes. If Medicaid does not cover Tdap or another vaccine for adults, the adult is considered underinsured for that vaccine and may receive 317 funded vaccines.

18. Zoster vaccine is not covered by Medicare Part B. May I vaccinate adults on Medicare Part B with 317 funded Zoster? What if Zoster vaccine is not covered by Medicare Part D?

Medicare Part B does not cover certain vaccines, including Zoster, Tdap or Td. However, all Medicare Part D plans are required to cover ACIP-recommended vaccines not covered under Medicare Part B. Thus if the individual has both Medicare Part B and Part D, he/she is considered fully insured for vaccines and may not receive 317 funded vaccines. If the individual does not have Medicare Part D coverage, then he/she is considered underinsured for those vaccines and may receive 317 funded vaccines.

19. Can we continue funding our Tdap cocooning programs with 317 vaccine?

No. Tdap cocooning programs may not be funded with 317 vaccines. Vaccination of pregnant women and contacts of young infants, if part of pertussis outbreak response, may be conducted with 317 vaccine.

20. Can we continue using 317 vaccines for our school-located influenza vaccine clinics?

For the 2012-2013 influenza season, we have indicated that 317 vaccine funds may be used to support mass vaccination clinics, and 317 vaccine can be used to respond to disease outbreaks. It is important to clarify however, that we do not expect 317 vaccine funds will be used routinely for other school-based vaccination efforts.

21. Can we use our influenza vaccine purchased with 2012 317 funds to vaccinate fully insured individuals in upcoming influenza outreach clinics, even if they fall after the October 1 deadline?

Grantees are encouraged to use their FY 2012 Section 317 influenza vaccine for fall influenza outreach clinics even if they fall after the October 1 deadline.

22. Can we use 317 vaccine for non-Medicaid covered vaccines?

If Medicaid does not cover a vaccine for adults, the adult is considered underinsured for that vaccine and may receive 317 funded vaccines.

23. Can we use 317 vaccine for immigrants and refugees?

Many immigrants and refugees lack health insurance, making it hard for them to get the care they need. However, some refugees are eligible for SCHIP, Medicaid, or other special programs such as Refugee Medical Assistance. Grantees are encouraged to contact their State Refugee Program to determine their state policies on immigrant and refugee health care benefits. If the state does not provide immigrants and refugees with medical benefits through these programs and the individuals do not have employer sponsored health insurance, then they are considered uninsured and may be vaccinated with 317 funded vaccines.

24. Can I use Section 317 vaccines to “front load” vaccines ordered for SCHIP children and then replenish those vaccines with my State dollars?

Yes. Grantees that are moving towards purchasing vaccines off of the federal contracts for fully insured SCHIP children may use their Section 317 vaccines to provide a stock of vaccine for those children, as long as those vaccines are replenished with state funds in accordance with our policy. Please note that this only applies to non-direct ship vaccines.