

Sullivan County Department of Public Health

<u>Title:</u> Immunization Program	Original Approval: 7/18
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<u>Page Number:</u> 1 of 2	

Statement/ Purpose:

To follow appropriate immunization guidelines

Authority:

Immunize.org; cdc.gov/vaccines;

Application:

Terminology:

Responsible Party:

Public Health Director

Cross-Reference:

Medical Waste and Sharps Transport and Disposal

Procedure:

I. Immunization Clinics

1. Adult and Childhood Immunizations Clinics: are held once per month on a selected date from 2 PM until 4PM. Individual appointments can be made based on the schedule and availability of clinical staff. (Changes to this may occur due to Holidays or inclement weather).
 - a. Appointments are necessary for all scheduled clinics and individual vaccinations.
 - b. Children under 18 years old are to be accompanied by their parent or legal guardian.
 - c. A written authorization may be accepted from the Parent and will be verified by phone.
 - d. The child must be with an adult to receive the vaccine.
 - e. College students are asked to bring the immunization request from the school they attend or plan to attend.
 - f. There are no monetary charges for immunizations required by the state for public school attendance for any child 18 years of age and under with Medicaid or those without health insurance. An administration fee may be charged based on a sliding scale.
 - g. All client's must provide their immunization history for SCDPH to use to determine necessary vaccines.
 - h. A copy of the client's immunization history is requested and copied for SCDPH records.
 - i. All previous valid immunizations are transcribed by clerical / clinical staff onto the "SCDPH Immunization Record" form.
 - j. The record is prescreened by clerical / clinical staff for eligibility and VIS forms are given for the client to review for each vaccine they may receive.

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- k. The nurse reviews the record and is the sole individual responsible for the vaccines given or withheld based on appropriate intervals and age eligibility.
 - l. The nurse verifies the signature for consent and the appropriate VIS has been read and understood by the client or Parent/Guardian.
 - m. The nurse verifies the answers to medical screening questions and acts accordingly based upon the answers.
 - n. The nurse answers any questions regarding immunization.
 - o. The nurse administers the vaccine(s) according to ACIP/NYSDOH/CDC recommendations, using the appropriate syringe and recommended sites.
 - p. The nurse monitors for acute adverse reaction from the recipient.
 - q. The nurse completes the immunization record to include the manufacturer, expiration date, lot number, site given, date given and administering nurse's signature and title.
 - r. The nurse makes a copy of the immunization record for the client Parent/Guardian.
 - s. Appropriate timing for follow-up is discussed with the client Parent/Guardian.
 - t. All 'SCDPH Immunization Record' forms will be filed by date of birth and alphabetically in the records file of SCDPH.
 - u. All eligible immunizations will be entered into NYSIIS by SCDPH clerical / clinical staff.
2. Community Clinics: are held at a site determined by the SCDPH clinical staff as deemed appropriate for safety, parking, security needs and estimated attendance.
- a. No appointments are necessary, unless advertised as such when scheduling the clinic.
 - b. Children under 18 years old are to be accompanied by their parent or legal guardian.
 - c. All clients must sign in at the registration area.
 - d. All clients are seen on a first come- first served basis, unless the clinic has appointment times.
 - e. Appropriate immunization forms are completed by the Client/Parent/Guardian.
(*E.g. NYSDOH Influenza form, Spanish translation forms, etc.*)
 - f. The record is prescreened by clerical / clinical staff for eligibility and VIS forms are given for each vaccine possible for the client to review.
 - g. The nurse reviews the record and is the sole individual responsible for the vaccines given or withheld based on appropriate intervals and age eligibility.
 - h. The nurse verifies the signature for consent and the appropriate VIS has been read and understood by the client or Parent/Guardian.
 - i. The nurse verifies the answers to medical screening questions and acts accordingly based upon the answers.
 - j. The nurse answers any questions regarding immunization.
 - k. The nurse administers the vaccine(s) according to ACIP/NYSDOH/CDC recommendations, using the appropriate syringe and recommended sites.
 - l. The nurse monitors for acute adverse reaction from the recipient.
 - m. The nurse completes the immunization record to include the manufacturer, expiration date, lot number, site given, date given and administering nurse's signature and title.
 - n. A copy of the immunization information is given to the Client/Parent/Guardian.
 - o. Appropriate timing for follow-up is discussed with the Client/Parent/Guardian.
 - p. All 'SCDPH Immunization Record' forms will be filed by date of birth and alphabetically in the records file of SCDPH.
3. Special Needs Population Clinics: are held as deemed necessary and viable and as determined by SCDPH clinical

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staff as deemed appropriate for safety, parking, security needs and estimated attendance.

- a. Procedure is the same as Community Clinic Procedure above.

Staff Trainings: All nurses administering vaccines must maintain, and have on file with SCDPH, a current CPR certification. Immunization staff receives annual retraining on the correct storage of vaccine, acceptable temperature ranges, administration techniques, updated CDC and NYSDOH schedules, and emergency procedures.

II. Non-Patient Specific Standing Orders: Immunizations

1. Non-patient specific standing orders are modeled after the guidelines provided by the NYSDOH Immunization Program, NYS Dept. of Education, the Centers for Disease Control (CDC) and the Advisory Committee on Immunization Practices (ACIP).
 - a. Signed by the 'Medical Consultant', a currently licensed physician, who also is a member of the SCDPH Health Services Advisory Board.
 - b. In effect for one full year and are renewed annually.
 - c. Specific for each vaccine medication administered by SCDPH staff.
 - d. Used in lieu of a licensed medical practitioner being present during every clinic held by SCDPH.
 - e. Non-Patient Specific Standing Orders may be revised in the event of a modification in recommendations from NYSDOH or as new vaccines are introduced.
 - f. Non-Patient Specific Standing Orders for the vaccines being administered must be present and readily available at all clinics regardless of location.
 - g. Original Non-Patient Specific Standing orders will be kept in a binder in the DSI office. The binder will be on a shelf in the front vestibule of the DSI suite.
 - h. A copy of pertinent standing orders will be kept in a binder in each clinic bag taken to Off-site clinics.
 - i. Emergency Standing Orders: A copy of the emergency standing orders will include an emergency response protocol (i.e. Benadryl and Epinephrine) in the event of a serious adverse reaction and will be present and readily available at all clinics regardless of location.

III. Immunization Clinic Staffing

1. Adult and Childhood Immunization Clinics held at SCDPH:
 - a. One to three nurses and one to two clerical staff. A Spanish language interpreter will be scheduled on an as needed basis. Use of the language line will be available for other needed languages.
 - b. The senior RN will be designated the clinic manager and perform the duties of this position as stated below:
 - c. Clinic Manager: This position is designed to be a resource for all questions regarding immunizations. The C.M. is responsible for assisting with the review of records, timing intervals, and to offer advice to those immunizing. They will screen clients with the clerical staff and Spanish interpreter when clinic is busy. They will offer assistance to clients in the waiting room to assist with forms or general questions. They will immunize if needed to expedite clinic wait time. They will run 'errands' for the clinic such as copies, additional supplies, frozen vaccine retrieval, etc.
2. Community and Special Needs Clinics:
 - a. This type of clinic will be staffed by a Registered Nurse and clerical staff as deemed necessary by the size of the clinic expected. Larger clinics will have a Clinic Manager and this will be determined by the Immunization Coordinator or the Clinical staff organizing the clinic.

IV. Clinic Supplies

1. All supplies for each clinic will be provided by SCDPH. Nurses are responsible for the set-up and breakdown of their own vaccination station. Supplies that are required include:

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- a. 2x2 gauze
 - b. Bandages
 - c. Alcohol prep pads
 - d. Clean field drape
 - e. Gloves
 - f. IM/ subcutaneous syringes
 - g. Emergency Kit
 - h. Waterless hand sanitizer
 - i. Sharps container
 - j. Vaccine (packed to maintain the cold chain)
2. Clerical staff will be responsible for the set-up and breakdown of their registration area. Supplies that are required:
- a. Vaccination forms
 - b. Clip boards
 - c. Pens
 - d. VIS sheets
 - e. Locked money box (as needed)
 - f. Sign-in sheet
 - g. Receipts/ proof of immunization forms

A single clerical staff member will be responsible for the locked money box that may be required at in house, community and Special needs clinics. This money box will have the cash available for change. This clerical staff member will be responsible for the disbursement of all receipts and monies collected.

Translation staff will be available to assist with all materials required for adequate translation of clinic procedures and vaccinations. Should translation staff be unavailable The Language Line will be utilized.

V. Documentation of Records and Reports

1. All forms must be completed in their entirety.
2. All vaccines administered require a copy of the most recent Vaccine Information Statement (VIS) be given to the patient or parent/ guardian and listed on the immunization form. The most recent versions of all VIS forms are available online through the website www.immunize.org or www.cdc.gov/vaccines .
3. All immunization documentation must contain the injection site, lot number, manufacturer, expiration date, date administered, and nurse's signature.
4. Prior to vaccination the following must be completed:
 - a. All health screening
 - b. All forms must have a signature consent
 - c. Patients or parent/ guardian must receive a SCDPH Bill of Rights
 - d. Patients or parents/ guardians must complete "Eligibility Screening Record"
5. All immunizations given by the SCDPH will be recorded on the "SCDPH Immunization Record" unless a NYS approved form (i.e. influenza, COVID, Jynneos) is available. The NYS form will be used in lieu of the SCDPH Immunization Record.
6. All reports required for the administration of the Immunization program will be completed by the designated 'Program Coordinator'. These will include vaccine inventory, vaccine usage, vaccine wasted, clinic sites, and number of people immunized, eligibility requirements, and any other data considered to be germane to the implementation of the Immunization program. They will be completed by the 15th of every month and submitted to the appropriate local and state administrators.

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VI. Emergency Kits

1. Emergency kits are required for all clinics and the RN is responsible for making sure that the supplies in each kit are up to date. The kits are required to contain the following items:
 - a. PO Diphenhydramine (pill/ liquid)
 - b. Epinephrine (EPI pen)
 - c. Emergency treatment guidelines
 - d. Stethoscope
 - e. CPR mask or barrier
 - f. O2 saturation monitor
 - g. Ammonia inhalants
 - h. Bandages
 - i. Alcohol prep pads
 - j. Non-latex gloves
 - k. BP Cuff- Adult and Pediatric
2. Emergency Standing Orders: A copy of the emergency standing orders will include an emergency response protocol (i.e. diphenhydramine and epinephrine) in the event of a serious adverse reaction. Orders will be present and readily available at all clinics regardless of location.
3. Emergency kits are located in the vaccine storage room. They should be readily available for use by the RN working the clinic.

VII. Immunization Registry

1. All individuals aged 18 and under will be enrolled in the New York State Immunization Registry (NYSIIS). SCDPH will maintain the NYSIIS registry according to the NYS Provider Agreement which can be located in the NYSIIS homepage.
2. All individuals 19 and older will be entered into either the NYSIIS registry once written or verbal consent is obtained at time of vaccine administration.

VIII. Vaccine Handling

1. Vaccine is stored in the refrigerator/ freezer located in the clinic service area.
2. All off site clinic vaccine will be packed on the day of the clinic by the nurse designated to work it. If more than one RN is to work a clinic one individual will be designated as the nurse responsible for packing the vaccine. It is the responsibility of the nurse to return the vaccine to the refrigerator/freezer at SCDPH the same day.

Varicella vaccine may only be taken to an offsite clinic when the exact number of immunizations has been verified on the day of the clinic. Varicella vaccine removed from the freezer must be kept cold as with other vaccines and used within 72 hours or then wasted. It can NEVER be returned to the freezer after having been stored at temperatures above 5 degrees Fahrenheit.

Handling Vaccine

- a. Maintain a daily temperature log for both the refrigerator and freezer; check unit temperature (Fridge-Tag 2L Data Logger) two times per day (AM & PM) with minimum / maximum temperatures recorded in AM. Record results on a temperature log sheet taped directly to the refrigerator/freezer.
- b. Open and store vaccine shipments immediately upon arrival.
- c. Monitor inventory monthly.
- d. Rotate vaccine according to expiration dates; those with shortest expiration dates should be used first. e. Securely close and lock refrigerator and freezer doors.

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- f. Personnel in charge of vaccine will have 24-hour access to the building and storage location.
- g. The refrigerators are plugged into an outlet designated for emergency power in the event of a power outage (red outlet). The temperature in the refrigerator is monitored electronically as well and connected to an alarm service that notifies staff on call in the event of a change of temperature beyond the recommended guidelines.
- h. Department of Public Works provides maintenance and repair in the event of power outage or if the unit breaks down.

Storing Vaccine

- a. Vaccine should be stored in a refrigerator/freezer unit. *It should not be a refrigerator unit that utilizes a freezer tray, such as a dormitory style, as they do not maintain temperature.*
- b. The unit should be capable of maintaining a temperature between 35-46 degree F (2-8 degree C) in the refrigerator section and 5 degree F (-15 degree C) in the freezer. The Ultra-Cold Freezer is to maintain temperature in the range of (-60 to -90 degrees Celsius)
- c. A warning label must be visible at the outlet and the associated circuit breaker to ensure neither has power removed without first informing appropriate personnel.
- d. A thermometer (Digital Data Logger) is located in both the refrigerator and the freezer units.
- e. An alarm system should be integral to monitor for both temperature and possible tampering.
- f. The doors or storage location are secured with a locking mechanism with the key available in the DSI office.
- g. The unit has back-up generator power in case of an outage.
- h. Vaccine is to be stored in labeled bins and/or in areas designated by the Immunization and Program Coordinator.
- i. Never store food or beverages in the same unit as vaccine.
- j. Avoid opening and closing the unit as much as possible in order to maintain a constant temperature.
- k. Storing bottled water and gel packs in the units may help in regulating the space temperature and maintaining the temperature during a short power outage.

Transporting Vaccine

In order to transport vaccine appropriately, it is imperative that the following shipping materials are available: Specially designed Vaccine Transport Cooler or Freezer Units. In place of these items, and to transport smaller units of vaccine: Plastic hard sided cooler, ice packs, cardboard sheeting and sheets of bubble or foam wrap. All transport materials are found in the vaccine storage room at SCDPH. All vaccines must be transported with a continuous digital data logger. Temperatures are to be monitored by SCDPH staff transporting the vaccine.

- a. When Transporting with the Vaccine Transport Cooler/ Freezer Pack:
 - a. Remove coordinating ice packs from the ice pack storage freezer on the counter in the vaccine storage room. Leave ice packs on the counter for approximately 20 minutes so that they can warm up before placing in the transport cooler. Wipe down ice packs to remove condensation before placing in the cooler.
 - b. Line the cooler with bubble wrap.
 - c. Place digital data logger probe inside of the cooler and place the data logger unit in a pocket on the outside of the transport cooler storage case to protect the data logger during transport.
 - d. Once temperature in the cooler is within range for the vaccine place necessary vaccine in the cooler.
 - e. Ensure vaccine is secure in the container and close and seal the lid.
 - f. Place a vaccine temperature monitoring log in the pocket with the data logger and record temps hourly.
- b. When transporting with a hard-sided plastic cooler
 - a. Place ice packs in the bottom of the plastic cooler
 - b. Place cardboard sheeting on top of the ice packs.

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- c. Place bubble wrap or foam wrap on top of cardboard sheeting (vaccine should not come in direct contact with ice packs).
- d. Place vaccine in container
- e. Insert temperature monitor (Digital Data Logger probe) near the center of the vaccine.
- f. Place more bubble wrap or foam on top of the vaccine.
- g. Place cardboard sheeting
- h. Place another ice pack on top of the cardboard sheeting.
- i. Ensure vaccine is secure in the container and close the lid.

VIII. Equipment Failure Protocol

Sensophone notification to on call DSI staff- Vaccine refrigerator/ freezer for temperature maintenance and control of vaccine.

1. All vaccine and/or testing solutions that require cold chain are kept in the DSI Clinic refrigerator and/or freezer located in the DSI suite.
2. The immunization refrigerator and freezer have thermometers that are connected to a Sensophone within SCDPH facility; this Sensophone is programmed and monitors the temperature of both the refrigerator and the freezer in compliance with NYSDOH VFC Immunization guidelines.
3. The Sensophone is located on the wall in the DSI Vaccine Storage room where the refrigerator & freezer are located.
4. In the event that the temperature deviates from the required temperature (either higher or lower), the SCDPH answering service will receive a telephone alert/alarm from the Sensophone.
5. The SCDPH answering service is responsible to notify the On-Call DSI staff of the Sensophone Alarm and give a detailed report with the Sensophone information.
6. Ex. Zone 1, Freezer 1, High temp alarm exists; temp too high;
7. Report of the actual Temperature (degrees) from the Sensophone is to be given to the DSI on Call staff by the answering service personnel reporting the alarm.
8. The on Call DSI staff will take the report and record all information reported by the SCDPH answering service.
9. The DSI on call staff will then call the Sensophone @ # 845-513-2260 X's three in ten-minute intervals and retrieve a report of the current temperature reported on each call to the Sensophone.
10. After each call to the Sensophone, when prompted the DSI on call staff will dial 555; this tells the Sensophone that the informational message has been delivered/acknowledged.
11. In the event that the refrigerator or freezer temperature is not in the acceptable temperature range after the third call to the Sensophone; the DSI on call staff is responsible to come into the agency and check for the problem.
12. Should an equipment failure occur during the hours for which SCDPH is not 'open for business'; the DSI Staff on Call would be alerted to a temperature excursion occurring in either the vaccine refrigerator or vaccine freezer by the Sensophone alert system via the SCDPH answering service.
13. In the event that all systems for refrigeration fail at Sullivan County Public Health, vaccines will be transported via cold chain custody for short term storage to the Pharmacy @ Garnet Health Medical Center, 68 Bushville Road, Harris, New York. The following steps are to be followed:
 - a. Contact with the Pharmacist on duty at Garnet Health Medical Center before transporting. The Pharmacy phone number is 845-794-3300, ext. 2019.
 - b. A complete inventory of vaccines is to be done prior to transport to Garnet Health Medical Center Pharmacy;
 - c. A copy of the inventory is to be kept on file at SCDPH and provided to Garnet Health Medical Center Pharmacist.
 - d. Vaccine is to be transported per cold chain custody.

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- e. Provide Garnet Health Medical Center Pharmacy upon vaccine transport the appropriate number of bins for consolidation of the vaccine to be stored.
 - f. Provide proper labels for each vaccine to be stored AND mark on label of vaccine where it is to be stored, i.e. refrigerator or freezer.
14. If situation requires, portable vaccine refrigerator / freezer (to be found in Vaccine Storage room) and digital data logger can be utilized to hold vaccine at a separate location temporarily.
 15. Transportation of the vaccine will be done in the manner described contained in this plan.
 16. If vaccine reaches temperatures outside of the recommended range, immediately store it in a location at the appropriate temperature and clearly mark and separate it from other vaccines so that it may be checked later. Don't assume that it is spoiled; depending on the recommendations of the manufacturer the vaccine may still be viable.
 17. Contact the manufacturer for guidance regarding the status of the vaccine. Do not discard spoiled or expired vaccine. Contact the NYSDOH and return vaccine accordingly.

IX. Medical Waste and Sharps Transport and Disposal

1. Unused and new sharps containers for clinic use are kept in the locked supply room in the clinic area.
2. Sharps containers, when 3/4 full, are to be closed tightly and given to an individual in the DSI Room who has keys to the clinic area utility room for disposal between 8am-5pm, Monday-Friday. If there is no one available in the DSI room do not leave them. Return with the container when an appropriate person is available to receive them.
3. Transporting of Sharps by nurses: Used sharps shall be transported only in closed red sharps containers carried in the trunk of the County vehicle.
4. Disposal of medical waste and sharps: All full Sharps containers will be stored in the utility closet of the clinic area. They will be placed in the area behind the door under the counter and disposed of on an as needed basis.
 - a. A designated DSI staff member will monitor the storage of medical waste and is responsible to contact the SCDPH waste disposal company to schedule waste pick up. The Principle Account Clerk or the Administrative Assistant will be notified that arrangements have been made for disposal.
5. Medical Waste: All medical waste (i.e.: alcohol swabs, gauze pads, Band-Aid wrappers) that results due to normal function of scheduled clinics or use of the clinic room is placed in a standard garbage receptacle.