Provider Operations Manual

Adult Safety Net (ASN) Program

TEXAS
Health and Human Services

Texas Department of State
Health Services

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Adult Safety Net (ASN) Provider Operations Manual Introduction

I. ASN Provider Operations Manual Information

The purpose of the Adult Safety Net (ASN) Program Provider Operations Manual is to consolidate ASN Program policies and information into one source. You may consult the manual as needed for the handling and management of ASN Program vaccines. Throughout the year, the Texas Department of State Health Services (DSHS) Immunization Section will announce new policies via official policy letters and memorandums. This manual will undergo a comprehensive review annually. Manual updates can be found on the DSHS Immunization Section website. Consultations on the policies in this manual are conducted routinely with the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), DSHS, and other organizations.

II. Establishment of the ASN Program

The ASN Program began in 2003 as a Hepatitis B initiative. In its 23 years of service, the ASN Program has expanded its vaccination services for uninsured and vulnerable adults 19 years of age and older in Texas and has evolved into one of the major efforts to increase access to vaccines for this population across the state. Funding for the Program is appropriated through Texas General Revenue (GR) and Section 317 of the Public Health Service Act, which authorizes the federal purchase of vaccines to vaccinate adults.

The ASN Program is supported through a network provided by DSHS, DSHS Public Health Regions (PHRs), and contracted Local Health Departments (LHDs). These organizations serve as Responsible Entities (REs) to ensure compliance with state and federal standards and to support effective vaccine distribution. ASN-enrolled sites should contact the RE for more information on Program requirements. In addition, the ASN Program is supported by Adult Immunization Coordinators (AIC) situated in PHRs to assist PHR managers in overseeing ASN providers. AICs perform outreach regarding adult uptake, compliance, program implementation, and preparedness. In addition, AICs, with the help of DSHS Central Office, will promote adult immunization initiatives.

III. Vision and Mission of the DSHS Immunization Section

Vision

To create a Texas free of vaccine-preventable diseases.

Mission

To remove barriers to complete and timely vaccination, increase vaccination coverage, and reduce the burden of vaccine-preventable diseases for all Texas infants, children, adolescents, and adults.

IV. Goals of the Immunization Section

The goals of the DSHS Immunization Section are to:

- Raise and sustain vaccine coverage levels for infants and children.
- Improve adolescent vaccine coverage levels.
- Improve adult vaccine coverage levels.
- Prevent and reduce cases of vaccine-preventable diseases.
- Maintain and improve public health preparedness.
- Promote and practice the safe handling of vaccines and ensure the accountability of all program components.

V. Goals of the ASN Program

The goals of the ASN Program are to:

- Eliminate vaccine cost as a barrier to immunizations and increase access to vaccines for adult populations.
- Improve vaccine coverage for uninsured adults.
- Provide a vaccine delivery system that is both efficient and effective for enrolled sites.
- Reduce vaccine waste among ASN providers.
- Provide accessible, organized resources that will support the DSHS Immunization Section, all partners, and providers.
- Establish and strengthen partnerships between the DSHS Immunization Section and external partners.
- Conduct site visits and reviews to expand awareness, education, and implementation of the adult immunization standards.

Chapter One: ASN Site Eligibility and Enrollment

I. Signing Clinician Eligibility Requirements

To be eligible to enroll in the ASN Program, signing clinicians must be one of the following.

- Medical Doctor (MD)
- Doctor of Osteopathy (DO)
- Nurse Practitioner (NP)
- Certified Nurse Midwife (CNM)
- Physician Assistant (PA)
- Registered Pharmacist (RPh)

The following organizations are eligible to participate in the ASN Program, but may not be limited to:

- DSHS Public Health Regions (PHRs)
- Local Health Departments (LHDs)
- Federally Qualified Health Centers (FQHCs)
- Rural Health Clinics (RHCs)
- Federally Recognized Indian Tribes

With few exceptions, all DSHS PHRs and contracted LHDs must be enrolled in the TVFC and ASN Programs.

II. Enrollment Requirements

A. Specific Terms of Agreement

To participate in the ASN Program, each signing clinician must agree to follow all program requirements and sign the ASN Annual Provider Agreement. The signing clinician, office staff, and all practitioners associated with the medical site agree to:

- Submit a profile representing populations served by the facility at initial enrollment, annually during re-enrollment, and more frequently if the status of the facility changes, and when patient populations change.
- Screen for and document ASN-eligibility of all adults at each immunization encounter.
- Administer ASN Program vaccines to all adults 19 years of age and older who meet the established eligibility criteria.

- Comply with appropriate vaccination schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP), unless deemed medically inappropriate or contrary to state law.
- Maintain all records related to the ASN Program for at least five years, and upon request, make these records available for review.
- Immunize eligible adults with publicly supplied vaccines at no charge to the patient for the vaccine.
- Not charge an administration fee above $25.00 per vaccine dose.
- Not deny administration of an ASN Program vaccine to an eligible adult because of the inability to pay the administration fee.
- Not send a patient to collections or charge additional fees for non-payment of an ASN Program administration fee.
- Provide a copy of the most current Vaccine Information Statement (VIS) for each vaccine at the time of administration.
- Comply with the ASN Program requirements for vaccine management, including ordering and proper storage and handling practices.
- Operate within the ASN Program in a manner intended to avoid fraud and abuse.
- Participate in ASN Program compliance site visits, including unannounced visits and other educational opportunities, as required.
- Vaccines supplied through the ASN Program will only be at the facility listed in this agreement and will not be transferred to another facility without prior approval from DSHS. The provider site may be required to purchase a new refrigerator, freezer, or temperature-monitoring equipment if the equipment at the facility is deemed inappropriate for vaccine storage or unable to maintain appropriate temperatures.
- Identify a primary and backup vaccine coordinator at your facility who is authorized to order vaccines. Inform DSHS of all changes in status of current staff members or representatives who are no longer authorized to order vaccine(s), or the addition of new staff authorized to order vaccine(s).
- Complete and submit the TVFC/ASN Program Provider Satisfaction Survey annually.
- Acknowledge that the DSHS Immunization Section may terminate the agreement at any time for failure to comply with established requirements. If the agreement is terminated, the office or facility agrees to return all ASN Program vaccines.

In jurisdictions where mass vaccinators are enrolled, or when the enrolled provider is not directly providing services and other parties are administering the vaccines, all parties involved in running the clinics, including the signing clinician and other groups directly administering the vaccine, must sign an agreement. There must be a written agreement attached to the ASN Annual Provider Agreement that clearly outlines each party’s responsibilities.

B. Site Coordinator Responsibilities

The ASN Program requires the signing clinician to designate a primary vaccine coordinator at the site who will ensure all vaccines are stored and managed correctly. It is also required that a second staff member (the backup vaccine coordinator) at the facility be named as the alternate in the event of the primary coordinator's absence. Both coordinators must be physically based out of the clinic site and fully trained in routine and emergency policies and procedures. At least one coordinator must be on site during operating hours.

Each site must designate a unique primary vaccine coordinator and a unique backup vaccine coordinator. Both coordinators are required to provide unique email addresses for each user to ensure security and reliable contact. ASN-enrolled sites with non-overlapping operating hours or days may share coordinators.

The primary and backup vaccine coordinators must do the following to implement, oversee, and monitor the ASN Program requirements:

- Ensure only ASN-eligible patients receive ASN Program vaccines.
- Ensure vaccine is stored and handled appropriately to safeguard vaccine viability.
- Ensure that all staff are trained in properly storing and handling vaccines.
- Setup data loggers in storage units.
- Ensure staff are familiar with the operations of the data loggers, including how to download the data (recommended weekly, on Mondays).
- Monitor and record the temperatures of the units (refrigerator and freezer) two times each workday.
- Read and record the minimum and maximum temperatures at the beginning of each workday.
- Reset the minimum and maximum temperatures at the beginning of each workday.
- Review and analyze temperature data at least weekly to identify shifts in temperature trends.
- Respond to out-of-range temperature excursions or respond in the event of an emergency (unit failure, power outage, disaster, etc.).
- Monitor the operation of storage equipment and systems.
- Oversee proper receipt and storage of vaccines deliveries.
- Organize vaccines to monitor expiration dates.
- Remove expired vaccine from storage units and document the loss.
- Maintain all documentation, such as vaccine inventory and temperature logs.

- Document ASN Program vaccine inventory information.
- Place orders for additional ASN Program vaccines in the Vaccine Allocation and Ordering System (VAOS).
- Track and document doses administered.
- Report vaccine activities monthly in VAOS.
- Oversee proper vaccine transport when necessary (i.e., during an emergency).
- Notify RE of staff changes (primary and backup vaccine coordinators and signing clinicians).
- Maintain access to all IT systems involved with ASN Program management (e.g., VAOS, ImmTrac2, Syntropi, IAMOnline).

In the event a primary or backup vaccine coordinator is removed from a site, providers must notify the RE of the staffing change immediately with a "Changes to Enrollment Form," stock no. 11-15224. Once the notification is received, the site will have 10 business days to designate and onboard a replacement coordinator and submit a "Changes to Enrollment Form", stock no. 11-15224. If a new coordinator is not onboarded (including completion of all required training) by the end of the 10th business day, the site will be suspended until a new coordinator is designated.

C. Initial Enrollment

To join the ASN Program, the ASN Annual Provider Agreement must be completed. If you need assistance, you should contact your RE or the DSHS Immunization Section at the phone number listed on the agreement form. The ASN Annual Provider Agreement is available on the DSHS Immunization portal at Syntropi - IDx Management System.

The ASN Annual Provider Agreement includes basic information about the facility and outlines the signing clinician's responsibilities. The signed agreement must be received and processed by the DSHS Immunization Section before the clinic receives state and federally funded vaccines.

All licensed health care staff (MD, DO, NP, CNM, PA, or RPh) at the facility who have prescribing authority must be listed on the ASN Annual Provider Agreement form. The listing must also include the signing clinician's information.

Information required for all licensed health care staff includes the following:

- Name
- Title
- Texas Medical/Nursing/Pharmacy License Number and

- National Provider Identification (NPI)

If the signing clinician leaves the practice, the ASN Annual Provider Agreement must be updated and signed by a new signing clinician. The profile section of the ASN Annual Provider Agreement requires information about the site's patient population, including projections and identification of clients the clinic will serve in the upcoming year.

New sites must provide accurate data from the previous 12-months and must also include the number of insured patients served by the site. These numbers must be specific to the clinic site and not combined with other clinics' patient numbers.

Data sources may come from the following:

- Immunization registry
- Benchmarking
- Client encounter data

The RE will assist the staff through the enrollment process. Two staff members at each site must be designated as primary and backup vaccine coordinators. The two staff members will be educated by the RE on how to complete the two required CDC "You Call the Shots" training modules 10 and 16, the most current "TVFC/ASN Provider Policy Training" module, and "Vaccine Allocation and Ordering System (VAOS) Training" upon initial enrollment.

After completing the modules, the "Certificates of Completion" must be electronically uploaded to the ASN Program enrollment system, Syntropi. The RE will provide education by conducting an initial enrollment visit with the primary and backup vaccine coordinators.

To participate in the ASN Program, sites must enroll in the Texas Immunization Registry (ImmTrac2). Upon completion of enrollment with ImmTrac2, the site will receive an ImmTrac2 organization code. DSHS recommends that all medical providers report all immunizations administered to clients 18 years of age or older to ImmTrac2 within 30-days of administration. The RE will provide the necessary education on ImmTrac2.

The RE will submit the required paperwork including the ASN Annual Provider Agreement, data logger certificate(s), and training certificates to the DSHS Immunization Section. The DSHS Immunization Section checks the Office of the Inspector General's (OIG) "List of Excluded Individuals or Entities" to ensure that all licensed health care professionals listed on an enrollment form are eligible to participate in the ASN Program.

Once the forms are approved by the DSHS Immunization Section, a Provider Identification Number (PIN) is issued. The PIN will be the clinic's vaccine account number for the duration of the clinic's enrollment in the ASN Program.

The PIN must be included on all ASN Program forms and communications. Sites must enter their ASN PIN into their ImmTrac2 organization account.

Information regarding ImmTrac2 may be found in Chapter Seven: Documentation Requirements and on the ImmTrac2 webpage. The enrolled site will be contacted by the RE to schedule additional visits/contacts.

D. ASN Enrollment Visit

All new sites to the ASN Program must receive an enrollment visit prior to receiving vaccines. When the RE visits the new site, a review of all storage units is conducted to ensure only approved, adequate storage units are used. A certified and calibrated data logger must be in all units that store ASN Program vaccines, and temperatures must be documented twice daily for seven operational days before any ASN Program vaccine is received. Training for new clinics is conducted on the ASN Program's policies to ensure the program policies are understood and followed. The initial enrollment visit typically takes a minimum of three hours. The primary and backup vaccine coordinators must both be available to meet with the RE for the duration of the initial enrollment visit. Information for new sites is available at dshs.texas.gov/immunizations/health-departments/overview.

Training for new sites will include the following:

- Review and confirmation that staff understand and will implement all ASN Program requirements.
- Confirmation of the following:
    - Proper equipment is available to store ASN Program vaccine(s).
    - Staff understands how to properly store, handle, and monitor ASN Program vaccine(s).
    - Staff know who to contact if problems arise.

Verification of the following:

- Facility information provided on the initial enrollment form includes:
    - Shipping address;
    - Phone numbers;
    - Email address of signing clinician (must not exceed 40 characters); and

    - Medical license numbers and NPI for all listed licensed health care professionals.
- A primary and backup vaccine coordinator has been identified.
- A plan for routine and emergency vaccine management is in place.
- There are adequate water bottles in the refrigerator and frozen water bottles in the freezer unless the manufacturer's manual states water bottles could impair the unit's function. Vaccine storage units that conform to NSF/ANSI Standard 456 (which have been rigorously tested for vaccine storage) do not require water bottles.
- Vaccine storage units have enough storage space to accommodate the maximum capacity of vaccine throughout the year.

Review the following forms:

- Vaccine Choices
- "Vaccine Management Plan," stock no. E11-14498

Training also includes a review of the following:

- "Provider Operations Manual: Adult Safety Net," stock no. 11-13602
- Vaccine ordering and accounting in VAOS
- Proper vaccine storage and handling
- "Vaccine Quarantine Bag"
- Immunization guidelines and schedules
- Texas' Immunization Registry, ImmTrac2 forms and literature
- Vaccine Information Statements (VIS)
- Reporting adverse events to the Vaccine Adverse Events Reporting System (VAERS)
- Vaccine safety and other resources
- "Standards for Adult Immunization Practices"
- Vaccine types
- Administering vaccines
- Schedule and intervals of vaccines
- Anatomic site
- Needle sizes

E. ASN Site Setup

Once temperature charts are logged twice daily for seven operational days and temperatures are within the required range, the RE begins the ASN Program site

setup process and performs the following activities to ensure that vaccines are stored and handled appropriately:

- Check the equipment to include the following:
  - Placement of data loggers, probes, and calibration certificates; and
  - Verifies placement of or installs plug guards.
- Train the staff on essential processes:
  - Vaccine choice options;
  - Establishing maximum stock levels (MSL);
  - Online vaccine management in VAOS;
  - Setting up an initial order;
  - Completion of a "Vaccine Management Plan;" and
  - Completion of a "Temperature Recording Form," stock no. EC-105.
- Ensure the following signage is displayed prominently within the clinic:
  - "Vaccine Management - Recommendations for Storage and Handling of Selected Biologicals" poster, stock no. 6-26P (if available);
  - "How to Administer Vaccinations" (Anatomic Sites for Immunizations) poster, stock no. 6-27P;
  - "Giving All the Doses" Chart, stock no. 11-12155;
  - "Refrigerator Warning Signs," stock no. 6-180; and
  - "Do Not Unplug" stickers on wall outlet and at the circuit breaker, included in the "Refrigerator Warning Signs," stock no. 6-180.
- Provide immunization schedules, catch-up schedules, resource lists, and other materials. If any of the items above were not provided to you as a new ASN-enrolled site, contact your RE.

F. Vaccine Accountability

Vaccine accountability is a cornerstone of the ASN Program and a top priority for the DSHS Immunization Section. When a site enrolls in the Program, the staff agree to the accountability requirements as a condition of participation.

All ASN-enrolled sites must ensure the following:

- ASN Program vaccines are administered only to ASN-eligible clients.
- Vaccine loss and waste are minimized and documented.
- Fraud and abuse (as defined in Chapter Six: Fraud and Abuse) do not occur.
- ASN Program vaccine inventory, vaccine uses, and documents are accurately reported monthly.

- Patients are screened at all immunization encounters for ASN Program eligibility.

G. Provider Identification Number

A PIN is assigned to new sites upon initial enrollment into the ASN Program. The PIN is the clinic's vaccine account number for the duration of the clinic's enrollment in the ASN Program.

The PIN must be included on all ASN Program forms and communications. PINs are associated with site visits, vaccine ordering, vaccine shipments, and overall program operations. As a result, separate PINs will be created for sites in different physical locations, even if they are supported by the same clinic staff.

The ASN Program PIN must be entered in the site's ImmTrac2 user account. Information regarding ImmTrac2 may be found in Chapter Seven: Documentation Requirements and on the ImmTrac2 website.

H. Provider Change of Information

Staff at ASN-enrolled sites are responsible for notifying the RE of any changes to site information. To notify an RE, staff should fill out a "Changes to Enrollment Form," stock no. 11-15224, when the following changes occur:

- Facility shipping address (Complete sections A and B)
- Facility shipping hours (Complete sections A and C)
- Signing clinician (Complete sections A and D)
- Patient population data change (Complete sections A and F)
- Primary or backup vaccine coordinator (Complete sections A and E)

The completed form must be emailed to the RE. If there is a change in primary or backup vaccine coordinator(s), also attach the following training certificates for the coordinators being updated:

- The CDC's "You Call the Shots" Module 10: Vaccine Storage & Handling
  - Register for the "Immunization: You Call the Shots-Module Ten-Storage and Handling-2026 (Web Based) - WB5004," hosted through TRAIN, at the following link: train.org/texas/course/1133532/details
- The CDC's "You Call the Shots" Module 16: Vaccines for Children Program
  - Register for the course "Immunization: You Call the Shots-Module Sixteen-Vaccines for Children Program-2026 (Web Based) - WB5005", hosted through TRAIN, at the following link: train.org/texas/course/1133869/details.

- The most current "TVFC/ASN Provider Policy Training," located on the TX TRAIN Platform: train.org/texas. Register for the "TVFC/ASN Provider Policy Training" modules here: train.org/texas/course/1133007/compilation
- The VAOS Training: dshs.texas.gov/immunizations/providers/training and quiz: survey.alchemer.com/s3/6801123/Vaccine-Allocation-and-Ordering-System-Quiz

Depending on the changes indicated on the form, the DSHS Immunization Section may have site staff complete additional steps. Failure to properly update current clinic information may result in vaccine delays and possible negligent vaccine loss. Facility name, facility address, and prescribing authorities must be updated through an ImmTrac2 renewal. During annual re-enrollment, all changes to a facility's information will be updated when completing the ASN Annual Provider Agreement.

I. Annual Re-Enrollment

The ASN Program re-enrollment takes place annually in September to prepare for the following year. The ASN Program requires that the ASN Annual Provider Agreement and profile be updated annually, as these forms are required for continued enrollment in the ASN Program. ASN-enrolled sites that are a FQHC or a RHC must submit a copy of the CMS letter designating the sites as such.

The assigned primary and backup vaccine coordinators are required to complete the most current "TVFC/ASN Provider Policy Training" module and an online re-enrollment form each year. Certificates of completion for the CDC "You Call the Shots" and VAOS training modules are required for re-enrollment but may be reused from previous years. Certificates of Completion for the most current "TVFC/ASN Provider Policy Training" module, CDC "You Call the Shots" modules 10 and 16, and the VAOS training certificate of completion for both primary and backup vaccine coordinators must be uploaded electronically during the re-enrollment process.

Clinics must be enrolled in ImmTrac2 to re-enroll in the ASN Program. Staff who do not know their ImmTrac2 organization code should contact the RE for assistance. Information regarding ImmTrac2 may be found in Chapter Seven: Documentation Requirements, the Texas Immunization Registry (ImmTrac2), and on the DSHS ImmTrac2 webpage ImmTrac.dshs.texas.gov.

Sites that fail to complete re-enrollment may not be eligible to continue participation in the ASN Program for the upcoming year. All sites that do not complete re-enrollment by the deadline are subject to withdrawal and must undergo a new enrollment process, following all necessary approval steps, to

participate in the program for the upcoming year. Vaccine shipments may be interrupted for sites that do not have current enrollment information on file.

NOTE: For sites that are also enrolled in the TVFC Program, the provider site must sign the TVFC Annual Provider Agreement and TVFC Addendum in addition to the ASN Annual Provider Agreement

III. Suspension from the ASN Program

If it is determined that the ASN Annual Provider Agreement or accountability requirements have been violated, the enrolled site may temporarily lose program privileges. Suspension is dependent upon the severity of the non-compliance issues or the failure to complete the required corrective action plans for the ASN Program.

ASN Program corrective action plans are set in place to correct failures in vaccine management and non-compliance issues, including, but not limited to:

- Failure to complete re-enrollment in a timely manner.
- Failure in vaccine management.
- Failure of required patient eligibility screening.
- Improper storage and handling practices.
- Failure to complete monthly reporting requirements.

Staff at suspended sites may be required to complete additional training as part of a corrective action plan.

IV. Withdrawal from the ASN Program

The RE and Adult Immunization Coordinators (AIC) must be contacted if an ASN-enrolled site wants to withdraw from the ASN Program. Prior to withdrawal, clinic staff must complete a "Provider Withdrawal Form," stock no. F11-11443 and submit it to the RE. The RE will coordinate to arrange to pick up ASN Program vaccine(s), document doses administered, vaccine losses, doses transferred and ensure that the provider's vaccine inventory is zeroed out in VAOS.

When withdrawing providers from the ASN Program, the REs will coordinate to collect state-issued data loggers, state-issued room-temperature thermometers, docking stations, state vaccines, and accompanying certificates of calibration from withdrawing providers.

V. Termination from the ASN Program

A site may be terminated from the ASN Program for continued non-compliance with ASN Program requirements, such as failure to complete required corrective actions associated with non-compliance. An enrolled ASN Program provider that has not ordered vaccines in the past 12-months may be terminated. A site may also be terminated for instances of fraud and abuse, as described in Chapter Six: Fraud and Abuse, of this manual. All sites will be notified of termination from the ASN Program via a signed letter from the DSHS Immunization Section Director.

VI. Re-enrollment after Termination from the ASN Program

In the event a terminated site is approved for re-enrollment in the ASN Program, completion of the most current "TVFC/ASN Provider Policy Training" module, CDC "You Call the Shots" Module 10 and 16, and VAOS training is required. Staff must participate in on-site education and confirm that any outstanding issues have been resolved through a focused site review and assessment.

Sites terminated for instances of fraud and abuse may be considered for re-enrollment after one year, the signing clinician must be actively enrolled in Medicaid and is not listed on OIG's "List of Excluded Individuals and Entities (LEIE)." The DSHS Immunization Section has the authority to determine whether a site is eligible to re-enroll in the ASN Program.

Chapter Two: ASN Patient Eligibility and Screening

I. Patient Eligibility Requirements

Adults 19 years of age and older who are uninsured are eligible to receive ASN Program vaccines. Those with medical insurance, including Medicare or Medicaid, are not eligible to receive ASN Program vaccines. Adults with private insurance that covers any vaccines are not eligible to receive ASN Program vaccines from ASN-enrolled sites.

Some ASN facilities may see patients who participate in the Healthy Texas Women (HTW) Program. HTW is a limited benefit package program and is not considered insurance. Adults enrolled in HTW who have no other insurance, including Medicaid, are eligible to receive vaccines under the ASN Program. HTW covered benefits include a range of immunization services, including all ASN Program vaccines and the respective administration fee.

Adults who are enrolled in the Medical Access Program (MAP) are eligible to receive vaccines from ASN-enrolled sites.

An LHD, FQHC, or RHC that provides comprehensive health care services to adults with private insurance may continue to serve as the medical home for their privately insured patients. However, private stock vaccine must be purchased to vaccinate privately insured adults. Immigration or residency status does not affect an uninsured adult's eligibility for the ASN Program.

II. Patient Eligibility Screening Record

Screening for patient eligibility is the foundation of the ASN Program's accountability. Screening all adults at every immunization encounter and documenting eligibility screening at every visit is the only way to ensure that ASN Program vaccine is used only for ASN-eligible adults. As such, full compliance with screening for eligibility is required. If improper screening results in the administration of ASN Program vaccine(s) to a non-ASN-eligible adult, staff are responsible for documenting the error on a "Vaccine Borrowing Form," stock no. EF11-14171, and immediately replacing the improperly used ASN Program vaccine with private stock. Please refer to Chapter Three: Vaccine Borrowing for more information.

Eligibility screening must be completed or updated for all adults at every visit, including adults with a previous record on file. An adult's eligibility must be documented at every visit prior to vaccine administration.

The "Adult Safety Net (ASN) Patient Eligibility Screening Form," stock no. F11-12842, may be used, or staff may electronically store patient demographic information in the site's Electronic Medical Record (EMR).

The screening form must be completed by the individual, guardian, or a healthcare provider and is a self- declaration. Verification of the patient's or guardian's response is not required.

Eligibility screening must include all the following elements:

- Date of screening;
- Patient's name;
- Patient's date of birth;
- Clinic name;
- Sex;
- Service member status; and
- Eligibility status for each visit.

Eligibility screening records must be kept on file with the patient's record for a minimum of five years after the last date of service to the patient and must be easily retrievable.

It is also acceptable for sites to use an EMR system to capture and store information from the patient's eligibility screening record provided the EMR captures all required eligibility elements.

Chapter Three: Vaccine Management

I. Approved Vaccines

The following vaccines and toxoids recommended by ACIP are available to enrolled clinics through the ASN Program:

- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Hepatitis A-Hepatitis B (HepA-HepB)
- Measles, mumps, and rubella (MMR)
- Meningococcal serogroups A, C, W, Y (MCV4)
- Tetanus, diphtheria, and acellular pertussis (Tdap)
- Tetanus and diphtheria (Td)

It may be necessary for the DSHS Immunization Section to update the ASN vaccine list based on available funding. Official information will be distributed to all ASN-enrolled sites if changes to the vaccine formulary are necessary.

II. Vaccine Ordering

A. Vaccine Choice

Some ACIP-recommended vaccines for adults are available to enrolled clinic sites through the ASN Program. Clinics participating in the ASN Program are recommended to offer the adult ACIP-recommended vaccines listed on the ASN formulary to eligible populations the clinic serves. All DSHS PHR and contracted LHD clinics must offer all adult ACIP-recommended vaccines on the current ASN formulary.

House Bill 448 from the 81st Texas Legislature provides ASN-enrolled sites' staff with the opportunity to select preferred brands and presentations of vaccines from available formularies. The signing clinician at ASN-enrolled sites may choose vaccine brands and presentations. For new clinics enrolling in the ASN Program, the RE and the staff will have the opportunity to select their desired vaccine brands and presentations in VAOS. Changes or adjustments to specific vaccine brands and presentations within each vaccine "family" (i.e., Hep A) can be made, or sites can decide to take no action, which will maintain the current selections. Staff at ASN-enrolled sites are encouraged to review their programmatic vaccine choice selections frequently.

A site's primary or backup vaccine coordinator may update vaccine choices in VAOS at any time; however, the signing authority must be consulted and must agree to the selected vaccine presentations.

Only vaccines supplied by the CDC to the ASN Program will be available for selection from the vaccine choice menu in VAOS.

If a chosen vaccine is not available, the ASN Program has the authority to replace the unavailable vaccine(s) with a comparable substitution until the provider's preferred vaccine becomes available.

NOTE: Vaccine choice does not apply in the event of a disaster or public health emergency, terrorist attack, hostile military or paramilitary actions, or any other extraordinary law enforcement emergency.

B. Patient Population Profile Estimate

The patient population profile estimate captures the number of ASN-eligible adults served in each facility. Information reported on the patient profile must represent the population served during the most recent 12-months. During initial enrollment and annual re-enrollment, DSHS requires all enrolled sites to complete the patient profile.

This data is used to ensure that vaccine orders are in the appropriate amounts and that each site properly maintains its vaccine inventories. Patient population data is used during the first year of a site's ASN Program participation to calculate Maximum Stock Levels (MSLs) and establish suggested order quantities. This data should be collected by using one or a combination of any of the following sources:

Benchmarking – Process whereby providers maintain logs in which they record all vaccines administered by type and number of doses and patients eligible for the ASN Program, e.g., one to three months. This data is used to project the vaccine needs over 12-months and to assess the appropriateness of vaccine requests.

Immunization Information System/Registry Data – Data submitted to ImmTrac2, a secure and confidential database, that safely consolidates and stores immunization records from multiple sources in one centralized system.

Doses Administered – Data collected each time vaccine doses are administered for patients. Data collected using this method should be deduplicated.

Encounter Data – Data that counts each patient encounter once. This data is deduplicated from the total number of patient visits for each patient.

Billing System – The site's method of billing patients for services. Data collected using this method should be deduplicated to ensure accuracy.

Other Methods (including forecasting) – Any method not listed above, including future predictions based on current patient populations.

When there is a change in the population, the "Changes to Enrollment Form," stock no. 11-15224, must be submitted to the RE. REs will ensure the form is routed to the DSHS Immunization Section.

MSLs may be lowered at sites that consistently order below the suggested quantity. MSLs may be increased at sites that place multiple large orders during a given month. The final determination is made based on the frequency and duration of the ordering patterns.

Changes to the patient profile data will impact population-based MSLs.

C. Vaccine Inventory Plan and Maximum Stock Levels

The vaccine inventory plan requires all enrolled sites to maintain a 75-day supply of vaccine inventory. Staff at ASN-enrolled sites are recommended to place vaccine orders monthly. DSHS recommends placing a vaccine order when a four-week supply of vaccine is available at the site to ensure there is sufficient vaccine in stock to accommodate any potential delays.

DSHS also recommends smaller, more frequent orders rather than larger orders to minimize vaccine loss in the event an incident occurs during shipment or storage. Additional orders may be placed during the month.

Although vaccine orders are not required each month, it is best practice for providers to place an order frequently enough to maintain a 75-day supply of vaccine.

Current inventory and unit storage capacity must be considered when placing vaccine orders to ensure adequate storage is available for all vaccines.

Exceptional circumstances may occasionally permit MSL adjustments.

Staff at ASN-enrolled sites must request a review and obtain permission from the RE prior to ordering more than their suggested MSL quantity.

For the first 12-months at an ASN-enrolled site, MSLs are calculated based on the patient population reported during enrollment. Population-based MSLs are

monitored and can be revised by adjusting the patient profile in Syntropi. Newly enrolled sites may have MSLs reassessed by the RE after 6-months of enrollment in the ASN Program.

After the first year, MSLs are recalculated on the first of each month based on the previous 12-months of VAOS administration data.

See Chapter Three: Reporting Requirements for more details on the monthly reporting requirements.

D. Increasing and Decreasing Maximum Stock Levels

MSLs may be increased or decreased at any time if the number of ASN-eligible patients changes or if there are any applicable changes to the status of the facility that might impact vaccine usage. Staff at ASN-enrolled sites must notify the RE if a change is needed. The DSHS Immunization Section may also make changes based on the data gathered during the calendar year.

MSLs may be lowered at sites that consistently order below the suggested quantity. MSLs may be increased at sites that place multiple large orders during a given month. The final determination is made based on the frequency and duration of the ordering patterns.

E. Short-Dated Vaccine

Short-dated vaccines are those that are within 90-days of expiration. Placing vaccine orders according to the established MSLs and rotating vaccines so that short-dated vaccines are used first will help to prevent losses due to expiration. Clinic staff must note vaccine expiration dates when physically counting inventory at the end of the month. Short-dated vaccines must be used first. A vaccine surplus kept in inventory increases the risk of vaccine expiration and increases the amount of loss in the event of unit failure. When vaccines are ordered, staff must have no more than the designated MSL in stock, including the order. Each site is required to notify the RE at least 90-days prior to the expiration of vaccine(s). If the vaccine cannot be administered prior to expiration, the RE may assist with moving the vaccine to another site provided another site is willing to accept the vaccine.

Vaccine diluent, the liquid mixed with a freeze-dried vaccine to reconstitute, must be managed in the same manner as vaccines. The expiration date of diluents must be checked prior to every reconstitution. The diluent must be rotated to use the shortest expiration date first.

If vaccines expire, they are considered non-viable and must be placed in a "Vaccine Quarantine Bag," clearly labeled "Do Not Use," and removed from storage units.

F. Storage Capacity for Vaccine Orders

Sites must have adequate refrigeration or freezer space to accommodate a maximum order based on MSLs throughout the year. Space needed for private or TVFC vaccine stock must be taken into consideration when calculating storage capacity.

G. Vaccine Ordering in the Vaccine Allocation and Ordering System (VAOS)

The ASN Program uses VAOS for vaccine ordering. VAOS allows ASN-enrolled sites to manage vaccine inventory online. All vaccine orders must be placed in VAOS unless internet access is unavailable. Sites may be held responsible for vaccine loss that is a result of erroneous information entered into VAOS. Prior to placing a vaccine order, the following information must be up to date in VAOS:

- Verification of days and hours of operation that the staff at the ASN-enrolled sites are available to receive vaccine orders;
- Clinic's delivery address;
- Contact information for primary and backup vaccine coordinators;
- "Temperature Logs;"
- "Doses Administered;"
- Physical inventory;
- Receipt of vaccine shipments (if applicable);
- Vaccine transfers (if applicable);
- Vaccine loss (if applicable);
- If applicable, all doses that will expire within the next 90-days; and
- All scheduled clinic closures (including holidays) must be noted in the comments section of the vaccine request.

Each site establishes the hours available to accept vaccine shipments during enrollment and confirms the accuracy of the order when each order is placed in VAOS. Submit a "Changes to Enrollment Form," stock no. 11-15224, to the RE to update hours of operation and shipment address.

Vaccine shipments will be delivered within the hours of operation to the address on file at the time the order was placed. Updates made using a "Changes to Enrollment Form," stock no. 11-15224, will apply to subsequent orders. The signing clinician is

responsible for ensuring that the "ASN Provider Agreement" contains accurate and complete information as incomplete or erroneous information can result in vaccine loss.

Monthly reporting in VAOS is required for all ASN-enrolled sites between the first and seventh of each month, regardless of whether a vaccine order has been placed. Additionally, reporting up to the current date is required each time an order is placed.

All orders placed in VAOS will be reviewed and approved by the RE after the completion and submission of the required monthly reporting and resolution of outstanding issues. Incomplete or inaccurate online orders will be placed "On Hold" pending corrections which may cause vaccine orders to be delayed. Each site must abide by established MSLs when placing vaccine requests. VAOS uses the ASN-enrolled site's MSLs and current on-hand inventory to determine a suggested quantity of vaccine on the "Input Order" tab. Any order placed over the established MSL during a vaccine allocation event is subject to being reduced to the suggested quantity unless a valid reason for deviation is provided during the ordering process.

Vaccine coordinators can view vaccine order status on the "Vaccine Requests" page in VAOS (Table 2-1).

PENDING	Indicates the order has not been approved, pending the review of a Vaccine Loss Report (VLR), the need for additional documentation, or other identified issues.
ON HOLD	Indicates the order has been placed on hold by the RE, pending additional documentation, or other identified issues that must be addressed before the order is approved.
APPROVED	Indicates the order is ready to be sent to the distributor for shipment after the order is placed and approved by the RE.
SENT TO VTRCKS	Indicates the order is with the distributor.
SHIPPED	Indicates the order is in transit or a transfer has been conducted in VAOS.
RECEIVED	Indicates the vaccine order has been received.
DENIED	Indicates the vaccine order was not approved for processing.

Table 2-1 Vaccine Order Status in VAOS

If a discrepancy is found between the orders placed, the packing list, or the doses received, staff at ASN-enrolled sites must immediately contact the RE to resolve it. Sites should expect to receive their approved orders approximately two to three weeks after placing the online vaccine request in VAOS, depending on the quantity and type of vaccines requested.

All vaccines must be appropriately stored immediately upon receipt, regardless of any errors in the order.

H. Vaccine Ordering for Sites Without Internet Access

ASN-enrolled sites without internet access must contact the RE to place a vaccine order. The RE will enter the ASN Program vaccine order in VAOS after reviewing the provided documentation and completing the required reporting for the provider.

The ASN-enrolled site must submit the following paper forms to the RE to place a vaccine order:

- "Monthly Biological Report," available in VAOS and provided by RE; and
- "Temperature Recording Form," stock no. EC-105.

The vaccine coordinator(s) at the ASN-enrolled site must inform the RE of the internet outage and request a blank copy of the "Monthly Biological Report," which can be exported by the RE from the enrolled site's VAOS account. The provider should indicate vaccine usage from the last reported month up to the current date on the blank "Monthly Biological Report," including the vaccine received, doses administered, vaccine transferred, vaccine loss, and on-hand physical count. The provider must return the completed "Monthly Biological Report" to the RE for transcription to the provider's VAOS account. If discrepancies arise during reporting to VAOS, the RE will collaborate with the provider to find the source of the discrepancy and correct the data in VAOS during the internet outage. Calculations must be accurate, and all corrections will be reported to the staff at the ASN-enrolled site, allowing the records to be corrected before ordering.

Once the required reporting is completed, the RE may submit the provider's vaccine order on their behalf in VAOS using the most up-to-date vaccine order form provided by the TXVaccineOrders@dshs.texas.gov inbox upon request.

The "Physical and Tally" report may assist vaccine coordinators in documenting vaccine management procedures. The "Physical and Tally" report should be exported from VAOS by the RE and supplied to the provider during the internet outage.

Provider sites also enrolled in the ASN Program are required to distinguish between pediatric and adult vaccines. Provider sites must order and report the TVFC Program pediatric vaccines separately from the ASN Program adult vaccines.

I. Vaccine Ordering for Newly Enrolled ASN Sites

Newly enrolled sites in the ASN Program are setup for vaccine ordering in VAOS following completion of new provider training with the RE. The vaccine order is placed by the site staff after receipt of VAOS login information and assignment of a

PIN as part of the second visit/contact. The RE will collect and review the "Temperature Recording Form," stock no. EC- 105, prior to assisting the staff with placing the initial vaccine order. DSHS restricts VAOS access to primary and backup vaccine coordinators.

III. Vaccine Distribution

A. Vaccine Distributors

All ASN Program vaccine is shipped refrigerated through the third-party distributor, McKesson Specialty.

If frozen vaccine(s) are made available through the ASN Program, the central distributor and/or the manufacturer will ship frozen vaccines directly to ASN-enrolled sites.

B. Receiving Vaccine Orders

The ASN Program requires that vaccine shipments must be accepted and never refused or returned without specific instructions from the RE or the DSHS Immunization Section.

The staff at ASN-enrolled sites must ensure that the clinic address and delivery hours are entered accurately in Syntropi during enrollment, re-enrollment, or whenever time changes are made. Submit a "Changes to Enrollment Form," stock no. 11-15224, to the RE to update hours of operation and shipment address, as needed. Updates made using a "Changes to Enrollment Form," stock no. 11-15224, will apply to subsequent orders. The signing clinician is responsible for ensuring that the "ASN Provider Agreement" contains accurate and complete information, as incomplete or erroneous information can result in vaccine loss.

For sites to receive vaccine shipments, appropriate staff must be on-site and available at least one day a week, excluding Mondays, and for at least four consecutive hours between 8:00 a.m. to 5:00 p.m.

It is essential to recognize and store vaccine shipments immediately upon receipt to ensure vaccine viability. All staff at ASN-enrolled sites are required to train other clinic staff on what a vaccine shipment looks like and must maintain a completed "Vaccine Management Plan" in place to ensure the vaccine is stored promptly and correctly upon arrival.

The following steps are required when a vaccine shipment arrives:

- Check vaccines against the packing list to verify all vaccines have been received.
- Inspect the vaccines and check the temperature strip or other temperature reading device.
- If the shipment arrives with a temperature monitoring device or strip, follow the provided instructions.
- Ensure an adequate amount of diluent is included for vaccines that require reconstitution (e.g., MMR II).
- Appropriately store all vaccines immediately upon receipt, regardless of any quantity, shipping, or transport errors.
- Check expiration dates and rotate stock to ensure short-dated vaccines are used first.
- Immediately accept receipt of the vaccine shipment in VAOS using the "Reporting and Ordering" module.

Immediately contact the RE when:

- The appropriate quantity and type of vaccine or diluent is not received, or
- Vaccines have been received in error, or
- Vaccines appear to be compromised (e.g., broken vial, temperature excursion)

If staff suspect that the cold chain has been compromised, they must immediately follow the instructions in Chapter Three, Subsection E: Vaccines Received Warm or Questionable.

Staff at ASN-enrolled sites must mark vaccine shipments as "received" in VAOS upon delivery and after reviewing the vaccine to maintain an accurate online vaccine inventory. When accepting an order in VAOS, providers are required to report both "Doses Passing Inspection" and "Doses Failed Inspection." Any vaccine received in error, damaged, or with questionable viability should be reported to the RE and the DSHS Immunization Section within 24-hours and before electronically accepting a shipment in VAOS.

C. Manufacturer and Distributor Maintenance of the Cold Chain

The manufacturer and distributor pack the vaccine using qualified pack-outs and containers that have been tested to maintain appropriate temperatures. Refrigerated vaccine is packed to maintain the cold chain for 72-hours. The vaccine will be shipped using high-quality cardboard boxes with Styrofoam inserts.

Packages from McKesson are imprinted with "Temperature Sensitive Product" and include stickers reading "Refrigerate upon Arrival" to alert clinic staff to refrigerate contents immediately.

Additionally, temperature monitors (TagAlert) are now being used in refrigerated shipments from McKesson. Upon opening the box, providers should immediately press the blue Stop and Start Button until the Stop Icon appears, then read the indicator status to determine whether the appropriate temperature was maintained during transit. Each shipment includes a flyer attached with directions and pictures to assist staff responsible for receiving the vaccines.

In the event that frozen vaccine is made available through the ASN Program, frozen Merck products are shipped with a one-, two-, or four-day pack-out. If the frozen vaccine shipment arrives within the date range on the packing slip, then the vaccine is viable. Staff must immediately place all vaccines in proper storage. If the vaccine arrives outside of the prescribed pack-out date, the staff must immediately place the vaccine in a "Vaccine Quarantine Bag," store the vaccine properly, notify the RE, and contact the manufacturer.

D. Cooler Return

McKesson

Refrigerated shipments from McKesson will arrive in either a smaller red KoolTemp cooler or a larger green EcoFlex cooler, depending on shipment size. The EcoFlex coolers must be returned to McKesson for reuse. The KoolTemp coolers do not need to be returned to McKesson and can be discarded.

Refrigerated and frozen TagAlerts do not need to be returned to McKesson and can be discarded.

The following steps must be followed to return the EcoFlex coolers to McKesson:

- These coolers have an attached UPS shipping label on the inner box flap.
- Open the cooler and remove the top Phase Change Material (PCM) gel pack(s).
- Remove the product(s) from the inner corrugated box.
- Ensure the inner corrugated box is back in the EcoFlex shipping system.
- Place the top PCM gel pack(s) back on top.
- Fold in the original outer flaps. Fold in the remaining flaps with return.
- Schedule a pickup with UPS by phone or by email.

UPS Phone Number:

1-800-377-4877

7:00AM – 9:00PM EST

Monday – Friday

7:30AM – 6:00PM EST

Saturday

UPS Email:

Healthcaresupport@UPS.com

7:00AM – 9:00PM EST

Monday – Friday

7:30AM – 6:00PM EST

Saturday

Website: UPS.com/healthcare

Provide the McKesson Account Number: 20V8R9

Merck

Frozen shipments from Merck arrive in Reusable Shipping Containers that must be returned for reuse.

The following steps must be followed to return the Reusable Shipping Containers to Merck:

- Open the shipping container and unfold the flaps to reveal the top protective panel. After, remove the top protective panel.
- Remove the ice pack on top of the corrugated box. Then, remove the corrugated box, take out the products, and store them in the appropriate temperature-controlled environment.
- Put the ice pack back into the container. Replace the top protective panel, keeping the refrigerants and packing material in place.
- Close the inner flaps so that the resealing instructions are visible.
- Close flap 1 and remove the protective cover from the adhesive strip on flap 2 to seal and close. Be sure the return shipping label to AeroSafe, Merck's reusable container manufacturer, is visible.
- Put the shipping container where UPS normally comes to your facility. UPS will return the shipping container to AeroSafe, which will inspect and certify it for reuse.

  Merck Box Return Hotline: 585-760-2830.

Pfizer

Refrigerated shipments from Pfizer arrive in reusable shipping containers without an electronic temperature monitor and must be returned to AeroSafe for reuse. The AeroSafe containers come in 8L, 18L, and 59L sizes, and pickup is coordinated directly with AeroSafe.

AeroSafe Return Hotline: 855-551-4919.

Frozen shipments from Pfizer may arrive in one of three container sizes: Sonoco small, Softbox medium, or Softbox large ULT (LTL only). The smallest container is for one-time use, while the medium and large containers must be returned with the included data logger to Controlant.

Controlant Return Hotline: 855-442-6687.

Container	Return Data Logger	Return Shipper	Return To
Sonoco Small	✓	✗	Controlant
Softbox Medium	✓	✓	Controlant
Softbox Large ULT	✓	✓	Controlant

E. Vaccines Received Warm or Questionable

Vaccines must always be stored properly, even if viability is questionable since it cannot be determined visually.

If ASN-purchased vaccines arrive warm, damaged, or in otherwise questionable condition, you must immediately contact your RE and the DSHS Immunization Section at TXVaccineOrders@dshs.texas.gov.

Questionable vaccines must be placed in a "Vaccine Quarantine Bag" and separated in proper storage until viability can be determined.

If reporting a viability concern or temperature excursion outside of business hours (9:00 a.m. – 5:00 p.m.), contact the distributor's customer support immediately. Direct contact with the distributor(s) should only occur when there is questionable temperature during shipment.

Examples of questionable (potentially non-viable) vaccines are below:

- Vaccine shipment received with a temperature indicator strip or TagAlert showing out of range;
- Vaccine is warm to the touch;
- Ice/gel packs are melted;
- Ice/gel packs are missing; or
- Vaccine is received damaged.

If vaccine viability is questionable upon receipt:

- Place the probe of the backup data logger in the questionable shipment, near the vaccine, and replace the lid to gain the current temperature. Temperatures must be checked frequently to determine when they stabilize.
- Separate the questionable vaccine in a "Vaccine Quarantine Bag" and place the questionable vaccines in the refrigerator or freezer, as applicable, until viability can be determined. Do not write on the vaccine itself.
- Contact the RE on the same day the vaccine arrived. If the RE is unavailable, contact the distributor(s) to determine if a shipping issue has occurred. Direct contact with the distributor(s) should only occur when there is a questionable temperature during shipment.
- Inform the RE regarding the viability determination of the vaccine.
- Vaccine(s) must be kept quarantined until instructions for replacement, reporting loss, etc., are received.

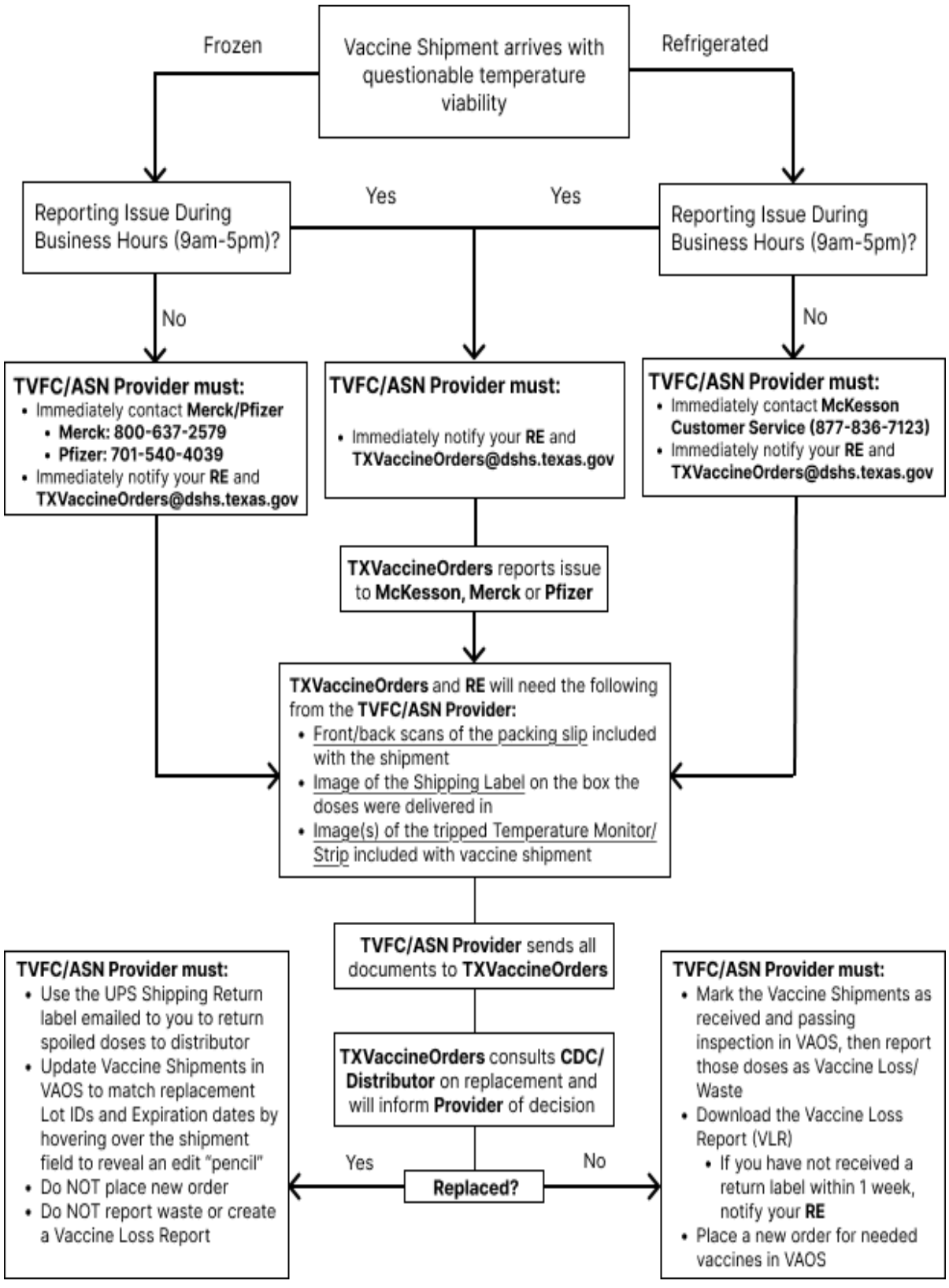


Figure 3-1 Decision tree for when a provider receives a vaccine shipment with questionable temperature viability.

F. Vaccines Received in Error

The RE must be contacted immediately upon receipt of vaccines that are received in error. Staff at the ASN-enrolled site may choose to keep the vaccine if storage capacity is sufficient and the vaccine doses will be administered. If the vaccine was ordered incorrectly by the site, it is the site's responsibility to keep the vaccine(s). If the site cannot absorb the vaccine due to storage capacity, the RE may assist with redistributing the vaccine to other sites to prevent vaccine waste.

IV. Vaccine Loss

A. Expired, Soiled, and Ruined/Wasted Vaccine

The ASN Program requires all vaccine loss be documented on a Vaccine Loss Report (VLR) in VAOS within one business day of the incident date*. All spoiled, expired, unopened, intact, and untampered vials or syringes of vaccines should be returned to McKesson within six months of expiration or the date the loss occurred. Vaccines considered waste should not be returned to McKesson.

Staff must not discard viable ASN-purchased vaccines unless specifically directed to do so by the RE or the DSHS Immunization Section and after correctly reporting the inventory removal in VAOS. The DSHS Immunization Section will communicate exceptions to this rule on a case-by-case basis. Staff at ASN-enrolled sites must notify the RE of vaccine cold chain failure events or vaccine waste incidents involving ASN Program vaccines as soon as the loss occurs.

Enrolled sites that have lost vaccine because of improper storage temperature must assess how long the vaccines were stored improperly and how many adults may have received the affected vaccines. The signing clinician determines whether the adults will need to be recalled and revaccinated. In such circumstances, the ASN Program will not provide the vaccine to revaccinate patients. The clinic will assume all financial responsibility for the cost of vaccines for recalls. Clinic staff must contact the RE with the determination from the signing clinician.

*Notify the RE immediately of extenuating circumstances that could prevent reporting vaccine loss within the required timeframe.

Spoiled or Expired Vaccine

An expired or spoiled vaccine is any non-viable vaccine in its original container, such as a vial or syringe.

This may include expired vaccines or vaccines that have been spoiled because of the following:

- Natural disaster or power outage;
- Refrigerator temperature is too warm (greater than 46°F or 8°C) or too cold (less than 36°F or 2°C);
- Freezer temperature is too warm (greater than +5°F or -15°C);
- The vaccine was not stored properly upon receipt;
- The vaccine was spoiled in transit due to a provider error;
- Vaccine was spoiled in transit due to shipper error; no replacement will be sent;
- Mechanical failure of a refrigerator or freezer unit; or
- Other, including:
    - Seasonal De-Authorization;
    - Beyond Use Date Exceeded; or
    - Spoiled.

Expired or spoiled vaccines must be removed from the storage unit, labeled "Do Not Use," and stored pending return to the distributor. All vaccines that are not considered waste must be returned to McKesson within 6-months of the loss. Expired diluents do not need to be returned.

Vaccines Considered Waste

Any nonviable vaccine that cannot be returned to McKesson is considered waste. The corresponding vaccine loss must be reported to VAOS in the VLR but should never be returned to McKesson. Vaccines considered waste should be disposed of properly by the provider after documentation in VAOS, in accordance with their medical waste procedures. The following are examples of vaccines considered waste:

- Broken vial/syringe;
- Vaccine drawn up into syringe but not administered;
- Lost or unaccounted for vaccine;
- Open multi-dose vial, but all doses were not administered; or
- Incorrect diluent was drawn or used for vaccine reconstitution.

B. Procedures for Vaccine Loss

Documentation

Every dose of vaccine lost due to expiration, spoilage, or waste must be reported electronically to the ASN Program via a VLR in VAOS within one business day after the incident or loss date. VLRs are generated automatically and available to download as a PDF after submitting the vaccine loss to VAOS in the "Enter Vaccine Loss" page.

Staff must follow the procedures listed below when a vaccine loss occurs:

- Report the vaccine loss in VAOS to generate a VLR within one business day after the date of the incident or loss. The following sections are required to be filled out on a VLR:
  - Clinic demographics;
  - Date loss was discovered or occurred;
  - Type of loss;
  - Reason for the loss;
  - Corrective action taken to avoid recurrence; and
  - List of vaccines by antigen, manufacturer, lot number, expiration date, and number of doses lost.
- Remove expired or spoiled vaccines from the vaccine storage unit and place them in a "Vaccine Quarantine Bag" labeled "Do Not Use."
- Contact the RE immediately with the following information:
  - Antigen;
  - Lot number;
  - Expiration date;
  - Reason for the loss; and
  - Number of doses.

If the storage unit was compromised, provide the RE with the amount of time the product was out of range and the highest and lowest temperatures recorded (this information may be gathered by performing a download of the data logger).

The VLR must be printed and signed by medical personnel with the prescribing authority listed on the site's enrollment form. The report must be available for the RE's review. Sites are not allowed to use signature stamps on the VLRs, as the signing authority is expected to be fully aware of the loss in the clinic.

Spoiled or Expired Vaccine Returns

All vaccines that are not considered waste must be returned to McKesson within 6-months of the loss. Vaccines considered waste or expired diluents do not need to be returned and can be discarded in accordance with local regulations after proper documentation in VAOS.

Following proper documentation and RE notification, the primary vaccine coordinator will receive a shipping label via email from pkginfo@UPS.com within seven business days of reporting the waste in VAOS to return expired or spoiled vaccine to McKesson. Depending on the number of doses returned, multiple shipping labels may be received. Shipping labels expire after 30-days. If a provider receives a shipping label and UPS has not picked up the package within 30-days, staff must contact the RE for a new shipping label. Staff must adhere to the following:

- Ensure all vaccines listed on the VLR are included in the box for return. Do not return broken vials or syringes with needles attached.
- If more than one box is used to return spoiled or expired vaccine, staff must print the VLR and indicate on the form the number of the box in which the vaccine is being shipped (e.g., "Box 1 of 2," "Box 2 of 2," etc.). Each box used to return the vaccine must not weigh more than 70 pounds.
- Vaccines considered waste should be marked through with a single line on a printed VLR, as they must not be included in the box for return.

Staff must wait until UPS returns to the ASN-enrolled site with the next delivery to pick up the expired or spoiled vaccine. Calls to UPS to schedule a pickup for expired or spoiled vaccines will be subject to a fee set by UPS. McKesson will not schedule pickups on behalf of ASN-enrolled sites unless the DSHS Immunization Section makes special arrangements.

C. Negligent Vaccine Loss

Signing clinicians at ASN-enrolled sites are responsible for negligent vaccine losses.

The following are examples of vaccine negligence:

- Prepared the vaccine dose and the patient refused.
- Prepared the wrong vaccine including:
  - The vaccine was mixed with the wrong diluent; or
  - Only diluent was administered.
- Dropped vaccine dose resulting in:
  - Damage to the vial integrity or sterility; or

    - Compromised vial.
- Expired vaccine and the site did not notify the RE at least 90-days before expiration.
- Failure to store vaccine properly, including:
    - Vaccines that were left out of appropriate storage;
    - Improper monitoring of unit temperatures; or
    - Not stored properly upon receipt.
- Storage temperature too cold.
- Storage temperature too warm, including:
    - Unit was unplugged accidentally or intentionally, and a plug guard was not used; or
    - Unit door left open.
- Temperatures were not documented or monitored improperly.
- Vaccine was spoiled in transit due to clinic staff error including:
    - Vaccine transfers;
    - Refused vaccine shipment; or
    - Vaccine was delivered when the clinic was closed and the closure was not documented in VAOS. ASN-enrolled sites may be required to reimburse the DSHS Immunization Section for vaccine losses that occur due to negligence.

D. Non-negligent Vaccine Loss

Non-negligent vaccine losses include the following:

- Damaged needle or seal, particulate in the vial, or discolored product.
- Expired and the clinic staff notified the RE 60- to 90-days before expiration and the RE was unable to coordinate a transfer.
- Mechanical failure of the refrigerator or freezer.
- Natural disaster or power outage.
- Unable to transfer opened multi-dose vial .
- Vaccine spoiled in shipment due to a shipping error.

E. Vaccine Disposal

The CDC advises providers to dispose of vaccines in accordance with local regulations. DSHS follows the Texas Commission on Environmental Quality's (TCEQ) guidance on proper medical waste disposal of wasted vaccine. TCEQ and DSHS define medical waste as special waste from healthcare-related facilities (25 TAC 1.132[46] and 30 TAC 326.3[23]) which includes treated and untreated animal

waste, bulk human blood, and body fluids, microbiological waste, pathological waste, and sharps.

Following TCEQ's guidance on medical waste disposal, needles and associated vials should be disposed of in a clearly labeled sharps container, treating it as a contaminated biohazardous waste container. Wipe down and sanitize work areas. After disposing of the vaccine, remove and dispose of gloves, and thoroughly wash your hands with soap and water for at least 20 seconds, or use an alcohol-based hand sanitizer that contains at least 60% alcohol.

Additional information on local regulations for treating and disposing of medical waste in Texas can be found on the TCEQ's website or by emailing info@tceq.texas.gov.

V. Vaccine Storage and Handling

Proper receipt and storage of a vaccine delivery is essential to maintain the vaccine cold chain. The cold chain, or temperature monitoring, begins with the cold storage unit at the manufacturing plant, extends through the transport of vaccines to the distributor, and continues through delivery to and storage at the enrolled facility, ending with the administration of the vaccine to the patient. Exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of potency.

Failure in the cold chain can be costly. If there is a failure in the cold chain, the result can mean extra doses for patients, increased costs for sites, and damage to public confidence in vaccines. A loss of public confidence in vaccines can lead patients to refuse revaccination, leaving them unprotected from serious vaccine-preventable diseases. Maintaining the vaccine cold chain will avoid incurring additional costs associated with losing and replacing vaccines, as well as the need to recall patients for revaccination.

All ASN Program vaccines are shipped refrigerated and should be stored under appropriate refrigeration conditions. If a frozen vaccine is made available through the ASN Program, provider sites must store it under the appropriate freezer conditions outlined in this manual.

A. Refrigerator and Freezer Requirements

ASN-enrolled sites are required to have appropriate equipment that can store the vaccine and maintain proper conditions. Refrigerator and freezer units must be large enough to hold the facility's largest inventory without crowding. The DSHS

Immunization Section recommends the following types of units, listed in preferential order:

- Pharmaceutical or purpose-built units.
- Vaccine storage units that conform to NSF/ANSI Standard 456 (which have been tested rigorously to be used for the storage of vaccines).
- Stand-alone, single-purpose refrigerator and stand-alone single-purpose freezers.
- Combination household units:
    - Providers enrolled after July 1, 2024, may store refrigerated vaccine in the refrigerator compartment of a combination household unit only.
    - Providers enrolled after July 1, 2024, are not allowed to use the freezer compartment of a household combination unit. Frozen vaccine must be stored in a stand-alone freezer.
    - Any provider enrolled before July 1, 2024, using both compartments of a household combination unit and consistently maintains the required temperature ranges, may continue using the combination unit. The provider must discontinue using the combination unit if temperature excursions occur that cannot be attributed to another cause (e.g., power outage).

Dorm-style and small combination refrigerator and freezer units with a single external door are never allowed for the storage of ASN vaccine.

Refrigerators with solid glass shelves are approved for use.

The refrigerator compartment must maintain temperatures between 36°F and 46°F (2°C and 8°C) for vaccine viability. The refrigerator temperature should be set at 40°F (4°C). The freezer compartment must maintain temperatures between -58°F and 5°F (-50°C and -15°C) for vaccine viability.

An alarm system and backup power system are recommended to help reduce vaccine loss in the event of unexpected temperature fluctuations.

For Auto-Dispensing Units

DSHS has approved the use of auto-dispensing or doorless units to store ASN Program vaccines. This type of unit is purposely built to store vaccines. Loading vaccines into this type of unit is the only time vaccines should be kept outside of their original packaging; however, providers must retain all the original vaccine packaging in case the vaccine needs to be transported outside of the unit.

A service record is required for auto-dispensing units if a certificate of calibration is not available. Servicing must be completed on auto-dispensing units as specified by the manufacturer. Monthly temperature logs must be recorded and submitted on the seventh of each month. As with other cold storage units, ensure that temperature logs are posted on the unit.

New or Repaired Units

Prior to using a new or newly repaired unit to store vaccines, the ASN Program requires seven operational days of refrigerator or freezer temperature recordings (twice daily) on a "Temperature Recording Form," stock no. EC-105, using a certified calibrated data logger.

Minimum and maximum temperatures must be recorded once daily, at the beginning of each business day, to ensure temperatures are within appropriate ranges.

Submit the recordings to the RE for review and approval, before placing vaccine in the storage unit. Minimum and maximum temperature readings must be reset from the day before at the end of each business day (if the device requires this function).

If adjustments to a unit's temperature control are necessary, read the instructions carefully and verify that the temperatures did not change overnight. Some manufacturers recommend resetting the controls in the summer and winter. If so, post instructions on the unit door.

B. Vaccine Storage Requirements

Refrigerators and freezers storing vaccines must be plugged directly into a wall outlet with a plug guard installed to prevent accidental or intentional unplugging.

Storage units containing ASN Program vaccines must not be plugged into a multi-strip power outlet, surge protector, or extension cord.

In addition, units must not be plugged into an outlet controlled by a wall switch or GFI outlets.

NOTE: You may see vendors use terms such as "VFC-Compliant," "CDC-Compliant," or "satisfies VFC Requirements" in their marketing materials or on websites. If this type of language in vendor marketing materials are encountered, remember that the ASN Program has not validated any product or service for compliance with ASN Program requirements or standards.

Each refrigerator and freezer must contain a sufficient number of water bottles to help maintain proper storage temperature during peak usage of the unit or during a power outage. Peak usage is when there is frequent opening and closing of the unit.

Water bottles serve as a physical barrier to prevent placing vaccines in areas where there is greater risk for temperature excursions.

The following cooling materials must not be used in units containing ASN Program vaccine:

- Gel packs (thawed or frozen);
- Ice packs;
- Coolant packs from vaccine shipments; or
- Any other coolant material that is not allowed by CDC or ASN Program.

NOTE: Water bottles are recommended for household-grade units and are not recommended for use with the majority of pharmaceutical-grade[1] and purpose-built units. For such units, follow the manufacturer's guidance.

[1]Pharmaceutical-grade units are designed specifically for the storage of biologics, which can include vaccines. These units often have:

- Microprocessor-based temperature control with a digital temperature sensor (thermocouple, resistance temperature detector [RTD], or thermistor).
- Fan-forced air circulation with powerful fans or multiple cool air vents promoting uniform temperature and fast temperature recovery from an out-of-range temperature.

Vaccine storage units that conform to NSF/ANSI Standard 456 (which have been tested rigorously to be used for the storage of vaccines) do not require water bottles.

For the refrigerator:

- Ensure the door closes completely.
- Replace crisper bins with water bottles to help maintain a consistent temperature (unless used for other medical equipment or supplies).
- Place water bottles in unit doors carefully so they do not dislodge and prevent the doors from closing or weigh down the door so much that it does not seal tightly.
- Place water bottles on the top shelf of the refrigerator under the fan (if present).
- Do not drink from or remove the water bottles.

- Label water bottles "Do Not Drink."
- Post "Do Not Unplug" signs on the refrigerator, at the electrical outlet, and at the circuit breaker.
- Do not store food or beverages in the refrigerator with vaccines.
- Vaccines must be centrally stored within the unit.
- Leave two to three inches between all vaccines (if possible) and the refrigerator walls.
- Do not use the top shelf for vaccine storage.
- Do not put vaccines in the doors or on the floor of the refrigerator.
- Place vaccines with the earliest expiration dates in front of those with later expiration dates.
- Store each type of vaccine in a separate container.
- Attach labels to shelves and containers to identify where each type of vaccine and diluent is stored.
- Vaccine with diluent must be kept together in the same box. The Merck diluent for MMR, MMRV and VAR vaccines may be stored in the door of the refrigerator, but this diluent does not require refrigeration and must not be frozen.
- Whenever possible, store diluent with the corresponding refrigerated vaccine. Diluents must not be frozen.
- If diluent is stored separately from the corresponding vaccine, label the container where it is stored. Store vaccines and diluents with similar packaging or names (e.g., DTaP and Tdap or Hib and Hep B) or with both pediatric and adult formulations on different shelves to minimize the risk of administration errors.
- Label the formulation "pediatric" or "adult," if applicable.
- Always store vaccines in their original packing with lids closed until ready for use unless vaccines are stored in an auto-dispensing unit that requires vaccines to be removed from the original packing.
- Never store loose vials or manufacturer-filled syringes outside of their packaging.
- Do not pack a storage unit too tightly. This may result in restricted air circulation and impact the unit's temperature.
- Store privately purchased vaccine on different shelves from ASN Program vaccine to minimize the risk of administering ASN Program vaccine to non-eligible patients. ASN Program vaccines must be clearly marked to differentiate them from privately purchased vaccines.
- If enrolled in the TVFC Program, store TVFC Program vaccines on different shelves from ASN Program vaccine to minimize the risk of administering ASN

Program vaccine to pediatric patients. ASN Program vaccines must be clearly marked to differentiate them from TVFC Program vaccines.

For the freezer:

- Ensure the door closes completely.
- Use frozen water bottles to help maintain a consistent temperature. Place water bottles against the walls, in the back, on the floor and on the door racks.
- Place water bottles in the unit doors carefully so they cannot dislodge and prevent the doors from closing or weighing down the door so much that it does not seal tightly.
- Post "Do Not Unplug" signs on the freezer, by the electrical outlet, and at the circuit breaker.
- Do not store food in the freezer.
- Vaccine(s) must be centrally stored within the unit.
- Leave two to three inches between all vaccine(s) and the freezer walls.
- Do not store vaccine(s) in the doors or on the floor of the freezer.
- Avoid storing vaccine(s) in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents or shelves on the door.
- Store each type of vaccine(s) in a separate container.
- Attach labels to shelves and containers to clearly identify each type of vaccine(s).
- Place vaccine(s) with the earliest expiration dates in front of those with later expiration dates.
- Store vaccine(s) with similar packaging or with pediatric and adult formulations on different shelves to minimize the risk of administration errors.
- Clearly label the formulation "pediatric" or "adult," if applicable.
- Always store vaccine(s) in their original packaging with lids closed until ready for administration.
- Never store loose vials or manufacturer-filled syringes outside of their packaging.
- Diluents must not be frozen.
- Do not pack a storage unit too tightly. This can restrict air circulation and impact vaccine(s) temperature.
- Store privately purchased vaccine(s) in a clearly marked container separate from ASN Program vaccine(s) to ensure ASN Program vaccine(s) is not inadvertently administered to a non-eligible patient.

- If enrolled in the TVFC Program, store TVFC Program vaccine(s) in a clearly marked container separate from ASN Program vaccine(s) to ensure ASN Program vaccine(s) are not inadvertently administered to a TVFC patient.

Some vaccines are sensitive to light, and their efficacy could be compromised if exposed to light. The following vaccines are particularly sensitive and must be protected from light at all times: MenB and MMR.

All vaccines, except Varicella and MMRV, are to be stored in the refrigerator and must never be frozen. Varicella and MMRV must be stored in the freezer in a continuously frozen state between -58°F and +5°F (-50°C and -15°C).

Sufficient alternate space to store vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service must be identified.

C. Protective Equipment

The following activities are required to ensure and protect the power supply for vaccine storage:

- Plug unit(s) directly into a wall outlet.
- Plug only one unit into an outlet.
- Plug guards are required to be used on all units that store ASN Program vaccine(s).
- Plug guards are effective tools in preventing accidental or intentional unplugging of equipment.
- A "Do Not Unplug" sign is required to be posted on or near all outlets where units are plugged in.
- A "Do Not Disconnect" sign must be posted on or near each circuit breaker.

Do not use the following for units that contain ASN Program vaccine:

- Extension cords;
- Multi-outlet power strips;
- Power outlets that can be activated by a wall switch;
- Outlets with built-in circuit switches (GFI receptacle); or
- Surge protectors.

D. Data Logger Requirements

A data logger provides accurate and comprehensive monitoring of temperature to ensure that the vaccine is viable and effective. Using a data logger may reduce vaccine loss by providing necessary data during a temperature excursion to determine vaccine viability.

ASN Provider sites are required to monitor all units that contain ASN Program vaccines with a data logger and have at least one backup data logger for the site. Backup data loggers must be readily available in the event the primary data logger cannot be used (e.g., malfunction, currently in use for emergency vaccine transport, or undergoing calibration testing).

The backup data logger must be stored outside the storage unit until needed to avoid vaccine space issues and inconsistent temperature readings, which could lead to confusion.

Data loggers must be accompanied by a centrally located data logger probe with a current and valid Certificate of Calibration Testing, also known as a "Report of Calibration" (see Figure 3-2). Data loggers must be set to record every 30-minutes.

In addition, a room thermometer is required to record the room temperature when a temperature excursion occurs in a vaccine storage unit. This is important for making vaccine viability determinations, if necessary.

When reading the data logger, do not round the numbers up or down; record the numbers on both sides of the decimal point (ex. 40.5°F or 6.3°C).

NOTE: 35.9°F or 46.1°F (1.9°C or 8.1°C) indicates a temperature excursion. If a temperature excursion occurs, ASN Program providers must contact the vaccine manufacturer to obtain guidance on the viability of the vaccine.

Temperatures must not be converted from Fahrenheit to Celsius or Celsius to Fahrenheit. It is recommended that staff download the data from their data loggers at least once per week, on Mondays, to ensure that any excursions are identified and addressed in a timely manner. ASN-enrolled sites that use data loggers must still comply with the requirements for twice daily temperature recordings and once daily minimum and maximum recordings.

The following are requirements for data loggers:

- An active temperature display that can be easily read by all staff from outside of the unit, without having to open the door.
- The data logger must have functionality that does not require a computer password to access the temperature display.
- The display must remain active for temperature readings (i.e., must not have sleep mode turned on).
- An alarm for out-of-range temperatures.

- A display that shows the current temperature and minimum and maximum temperatures.
- A low battery indicator.
- Accuracy of +/-1°F (+/-0.5°C).
- Detachable probe in buffered material.
- Memory storage of at least 4,000 readings (device must not rewrite over old data and must stop recording when the memory is full).
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.
- Probes must be in buffered material so that they measure temperatures that are more representative of the temperature of the vaccine(s) in the vial rather than the air temperature of the storage unit.

Examples of buffers include the following:

- A vial filled with liquid (glycol, ethanol, glycerin).
- A vial filled with loose media (sand, glass beads).
- A solid block of material (Teflon®, aluminum).

The ASN Program does not allow the following temperature monitoring devices for vaccine storage units:

- Alcohol or mercury thermometers, even if placed in a fluid-filled bio-safe liquid vial;
- Bi-metal stem temperature monitoring devices;
- Food temperature monitoring devices;
- Household mercury temperature monitoring devices;
- Chart recorders; or
- Infrared temperature monitoring devices.

These devices can have significant limitations, can be difficult to read, and generally only provide information on the temperature at the precise time they are read. Therefore, temperature fluctuations outside the recommended range may go undetected.

Placement

The following are requirements for placing data logger probes:

- In the center of the unit;
- As close to the vaccine as possible; and
- Away from walls, ceilings, cooling vents, doors, floor, and back of the unit.

NOTE: In pharmaceutical or purpose-built units, the data logger probe is recommended to be placed in a central location; however, other placements may be suitable because these units maintain more consistent temperatures throughout the unit.

The data logger probe must not be suspended from wire shelves or suspended by tape or other means attached to the inside ceiling of the unit.

Certificate of Calibration

Each data logger that monitors units containing ASN Program vaccine must be calibrated and certified with a "Certificate of Calibration" (see Figure 3-2). All "Certificates of Calibration" must be readily available for review and are recommended to be posted on or near the refrigerator or freezer. Calibration testing is required every two to three years, or according to the manufacturer's recommended schedule.

"Certificates of Calibration" must be submitted during the annual re-enrollment period and not expire through the end of the current calendar year, or risk delaying approval of the ASN-enrollment. Any new "Certificates of Calibration" should be sent immediately to the RE in PDF format. Providers with expired "Certificates of Calibration" will be suspended until updated certificates are received. A continuous-read temperature-recording device does not replace the requirement for a certified data logger. Photos of the data logger do not meet the "Certificate of Calibration" requirements and will not be accepted.

Data logger "Certificates of Calibration" must contain the following:

- Model number;
- Serial number;
- Date of calibration;
- Measurement results that indicate the unit passed the test and the documented uncertainty is within suitable limits (+/-1°F [+/-0.5°C]); and
- Testing laboratory accreditation (one of the following):
    - Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC);

      Mutual Recognition Arrangement (MRA) signatory body
    - A statement indicating that it meets International Organization for Standardization/International Electronic Commission (ISO/IEC) 17025 international standards for calibration testing and traceability;
    - Traceable to the standards maintained by the National Institute of Standards and Technology (NIST);

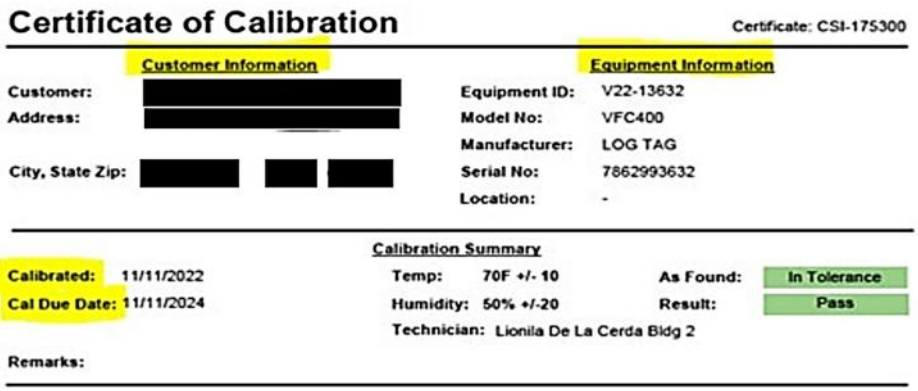
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM); or

  Standard E2877 Tolerance Class F or higher

- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points.

All clinic sites must have at least one backup data logger with a valid and current "Certificate of Calibration." The backup data logger is required to have a different calibration retesting date to prevent having to send both devices for recalibration at the same time. Having different calibration dates for data loggers ensures there will always be one data logger available for use.

Refrigerators and freezers that are manufactured with built-in temperature monitoring capabilities are required to be accompanied by a "Certificate of Calibration," and the thermostat must be capable of being adjusted as needed to maintain proper temperature.



Certificate of Calibration

Certificate: CSI-175300

Customer Information

Customer: [redacted]
Address: [redacted]
City, State Zip: [redacted]

Equipment Information

Equipment ID: V22-13632
Model No: VFC400
Manufacturer: LOG TAG
Serial No: 7862993632
Location: -

Calibration Summary

Calibrated: 11/11/2022
Cal Due Date: 11/11/2024
Temp: 70F +/- 10
Humidity: 50% +/-20
Technician: Lionila De La Cerda Bldg 2
As Found: In Tolerance
Result: Pass

Remarks:

Figure 3-2 Example of a data logger Certificate of Calibration.

E. Temperature Recording

A "Temperature Recording Form," stock no. EC-105, also known as a Temperature Log, must be maintained for all refrigerators and freezers that store ASN-purchased vaccine (including temporary day storage units). A Fahrenheit form (stock nos. EC-105RF and EC-105FF) or Celsius form (stock nos. EC-105RC and EC-105FC) is required to be used to monitor temperatures. Temperatures must not be converted from Fahrenheit to Celsius or Celsius to Fahrenheit.

When reading the data logger, do not round the numbers up or down; record the numbers on both sides of the decimal point (ex. 40.5°F or 6.3°C).

NOTE: 35.9°F or 46.1°F (1.9°C or 8.1°C) indicates a temperature excursion. If a temperature excursion occurs, ASN-enrolled sites must contact the vaccine manufacturer to determine the vaccine's viability.

Maintaining ASN Program temperature recording requirements is mandatory for all ASN-enrolled sites for all units that contain ASN-purchased vaccines. The required steps are listed:

- A "Temperature Recording Form," stock no. EC-105, is required to be located on or near all vaccine storage units that store ASN Program vaccines, including auto-dispensing units.
- Refrigerator and/or freezer temperatures must be recorded manually on the "Temperature Recording Form," stock no. EC-105, using certified, calibrated data logger readings.
    - Current refrigerator and/or freezer temperatures must be recorded and initialed twice daily (once in the morning and once in the afternoon).
    - Minimum and maximum refrigerator and/or freezer temperatures must be recorded once at the beginning of each business day.
- Minimum and maximum temperature readings on the data logger must be reset from the day before at the end of each business day.
- Data loggers must be able to be reset on-site.
- Temperature logs must be maintained for five years and made easily available.

F. Temperature Excursion

If an out-of-range temperature excursion is observed, clinic staff must document the excursion and immediately take the following actions:

- Place vaccines in a "Vaccine Quarantine Bag."
- Store vaccines in a unit where they can be kept under appropriate conditions.
- Generate a report from the data logger for discussion with help from the vaccine manufacturer.
- Contact the vaccine manufacturer that is listed on the box to obtain documentation for the viability of the vaccine.
- Contact the RE to report the manufacturer's vaccine viability determination, submit the manufacturer's determination letter(s) or online validity results.
- Complete the "Vaccine Storage Troubleshooting Record" on page 4 of the "Temperature Recording Form", stock no. EC-105 with the following information:
    - Date and time of event;
    - Storage unit temperature;

- Room temperature;
- Name of person completing the report;
- Description of the event; and
- Action taken, including the instructions and procedures given by the RE and the individual spoken to and the results.

All documentation regarding temperature deviations must be retained for review during ASN compliance site visits and storage and handling site visits.

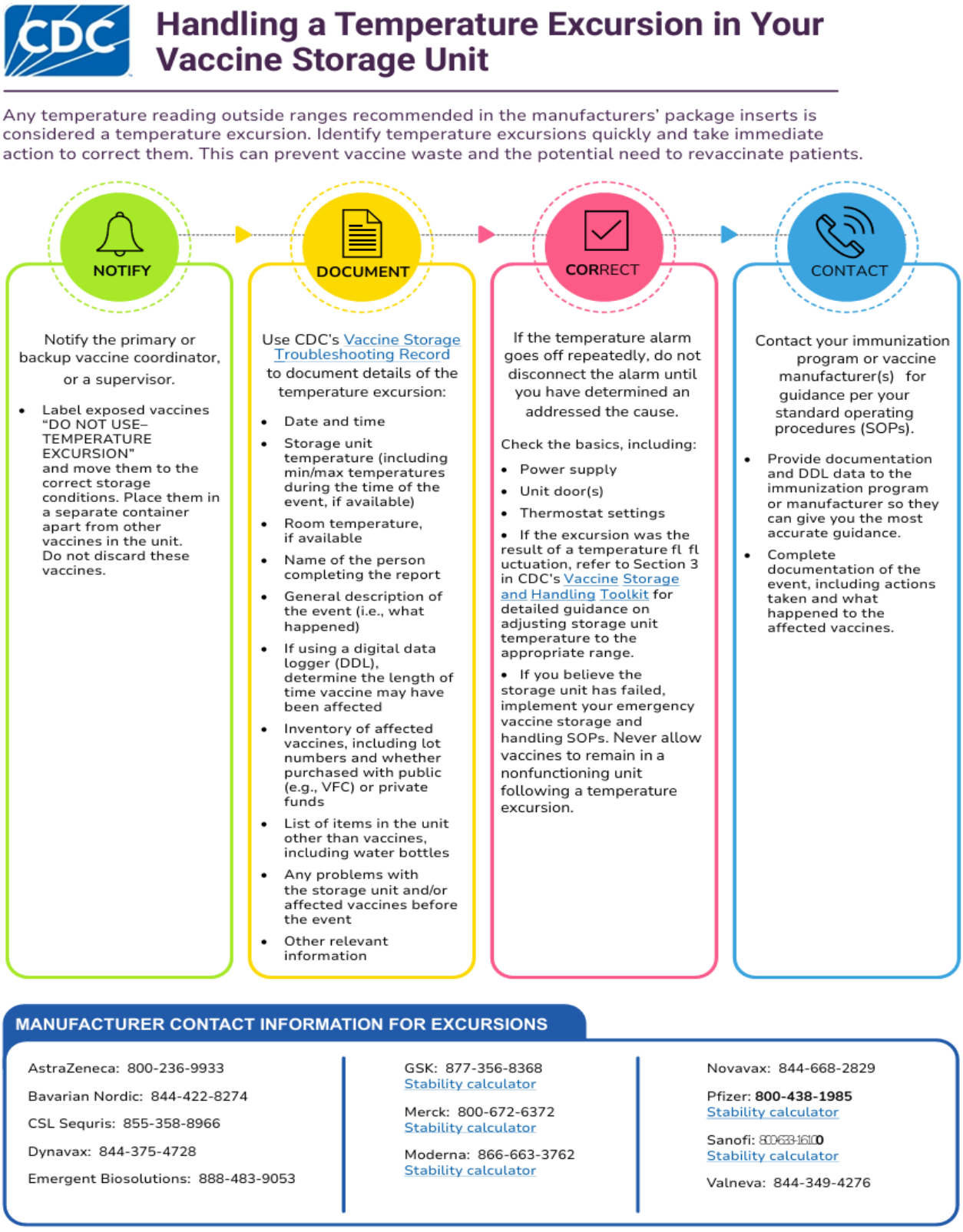


Figure 3-3 Illustrates the steps for handling a temperature excursion in your vaccine storage unit.

G. Personnel

Vaccine viability depends on the knowledge and habits of the clinic staff. All staff who handle the ASN Program vaccine must be trained in proper storage, handling, and administration of the vaccine, and be aware of and familiar with the written procedures for emergency situations to ensure the continued viability of the vaccines. The site must designate a primary and a backup vaccine coordinator to ensure that ASN Program vaccines are handled and stored correctly.

The following are training requirements for vaccine coordinators:

- Primary and backup vaccine coordinators at newly enrolled ASN Program sites must complete the following trainings and provide the certificates of completion to the RE:
  - Most current "TVFC/ASN Provider Policy Training" module located on TX TRAIN;
  - VAOS Training and Quiz; and
  - CDC "You Call the Shots" training modules 10 and 16.
- If the primary or backup vaccine coordinators change, replacement coordinators must complete the following trainings and provide the certificates of completion to the RE:
  - Most current "TVFC/ASN Provider Policy Training" module located on TX TRAIN;
  - VAOS Training and Quiz; and
  - CDC "You Call the Shots" training modules 10 and 16.
- During re-enrollment, the primary and backup vaccine coordinators must complete the most current "TVFC/ASN Provider Policy Training" module and upload the certificate of completion to the electronic re-enrollment form. Re-enrolling vaccine coordinators are permitted to use the CDC's "You Call the Shots" and VAOS Training and Quiz certificates of completion from a prior year.

Registration for the "TVFC/ASN Provider Policy Training" module is available at train.org/texas/course/1133007/compilation.

Registration for the "Immunization: You Call the Shots-Module Ten-Storage and Handling-2026 (Web Based) - WB5004" is available at train.org/texas/course/1133532/details.

Registration for the "Immunization: You Call the Shots-Module Sixteen- Vaccines for Children Program-2026 (Web Based) - WB5005" is available at https://www.train.org/texas/course/1133869/details

Location of VAOS Training: dshs.texas.gov/immunizations/providers/training and location of quiz: survey.alchemer.com/s3/6801123/Vaccine-Allocation-and-Ordering-System-Quiz

Additional information and course listings are available at train.org/texas.

H. Routine and Emergency Storage and Handling Plan

All ASN-enrolled sites must have plans for routine and emergency vaccine management. The ASN Program provides templates for the "Vaccine Management Plan" and the "Emergency Vaccine Storage and Handling Plan Checklist," stock no. E11-14498.

The plan and checklist templates contain comprehensive information on best practices and the most current information about the storage and handling of vaccines. Clinics are not required to use these templates, but they are valuable tools that may be used when assistance is needed in developing an emergency plan. If the templates are not used, staff at the site must develop routine and emergency vaccine management plans that include all the information on the templates provided by the ASN Program.

The "Vaccine Management Plan" and the "Emergency Vaccine Storage and Handling Plan Checklist," stock no. E11- 14498, must be reviewed and updated annually. The signature, name, and title of the preparer, as well as the date the documents were reviewed, must be documented.

The following items must be addressed in the "Emergency Vaccine Storage and Handling Plan:"

- Identify a responsible primary and backup person for the contingency plan. Contact information, such as email addresses and home, office, and cell phone numbers, must be included for both the primary and backup person. Contact information must be updated annually or when changes occur.
- Identify an alternative location to take the ASN Program vaccine for storage in the event of an emergency. A location with a backup power system or other alternate source of power, such as a hospital or pharmacy, is preferable. Ideally, the alternate location must be located within a reasonable distance from the ASN-enrolled clinic site and capable of maintaining the cold chain during any period when the ASN-enrolled clinic's refrigerator or freezer is out of service. Additionally, the alternate location should have adequate space to accommodate the ASN-enrolled clinic's largest vaccine inventory.
- It is recommended to review storage unit compliance at backup sites.

- Temperatures for these temporary storage units are required to be monitored and recorded.
- An adequate quantity of supplies sufficient for packing and transporting the entire ASN Program vaccine inventory must be available at the enrolled site, in case of an emergency.
- Contact with staff at the emergency storage location is important to gain their approval before including them as part of the plan. List their contact person(s) and phone number(s) on the plan. An alternative backup location must be considered if the primary alternative location is unavailable or unable to store the vaccine inventory for any reason.
- Due to strict temperature, storage, and monitoring requirements of vaccines, the DSHS Immunization Section does not permit ASN Program vaccines to be stored at a private residence. Private residences include, but are not limited to, the part of a structure used as a dwelling, including, without limitation: a private home, townhouse, condominium, apartment, mobile home, vacation home, cabin, or cottage. The DSHS Immunization Section reserves the right to decline to send vaccine to providers as it deems appropriate.

The most current "Vaccine Management Plan" will be reviewed during ASN Program compliance site visits and storage and handling visits. The plan must be posted on or near the refrigerator or freezer that contains ASN Program vaccine. The clinic staff involved with vaccine management must be aware of this plan.

I. Vaccine Protection in the Event of an Emergency

In the event of an emergency, the RE must be contacted immediately to be informed of the situation.

Staff at enrolled sites must be prepared to provide the following information:

- The temperature of the vaccine;
- The amount of vaccine;
- Expiration dates of the vaccine; and
- The amount of time the vaccine was exposed to inappropriate temperatures.

The following information must be collected when transporting the vaccine to the alternate location:

In the event of an emergency, the RE must be contacted immediately to be informed of the situation.

Staff at enrolled sites must be prepared to provide the following information:

- The temperature of the vaccine;

- The amount of vaccine;
- Expiration dates of the vaccine; and
- The amount of time the vaccine was exposed to inappropriate temperatures.

The following information must be collected when transporting the vaccine to the alternate location:

- Document the time of the emergency or power outage.
- Document the temperature of the refrigerator and freezer before removing any vaccine for transportation.
- Indicate which containers are being used and how the refrigerated vaccine will be packed for transportation (e.g., conditioned water bottles separated from the vaccine by layered packing materials to prevent freezing and damage).
- If frozen vaccine is being transported, indicate whether a portable freezer or cooler will be used and what packing materials will be used.
- Take inventory of the vaccine as it is moved into the transport container, documenting the number of doses of each vaccine and the expiration dates. Use a "TVFC/ASN Vaccine Transfer Authorization Form," which must be completed and uploaded to VAOS.

Ensure the "Vaccine Management Plan" and the "Emergency Vaccine Storage and Handling Plan Checklist," stock no. E11-14498 is available for documenting this process.

J. Cold Chain Management and Vaccine

The ASN Program requires vaccines to be stored properly from when they are manufactured until they are administered. The system used to maintain and distribute vaccines in optimal condition is called the cold chain. Sufficient alternative space to store ASN Program vaccines and maintain the cold chain during any period when the refrigerator or freezer is unavailable must be identified. Adequate supplies for packing and transporting the entire ASN Program vaccine supply or inventory must be available in case of an emergency. Packing supplies must be available to show during the ASN Program compliance site visit. Facilities that do not have packing supplies on hand during the site visit will be contacted by the RE. Follow the below cold chain and vaccine transport requirements:

- Avoid prolonged vaccine(s) temperature exposure inside vehicles by taking the quickest route possible.
- Do not leave vaccine(s) unattended in vehicles.
- Do not place vaccine(s) in the trunk of a vehicle.

- Pack refrigerated vaccines first. If followed, the directions below will help maintain the cold chain for up to eight hours during the transport of refrigerated vaccines.

Refrigerated Vaccine Transport

Assemble Packing Supplies

Portable refrigerator - DSHS recommends transporting refrigerated vaccines in a portable refrigerator that maintains a temperature between 36°F and 46°F (2°C and 8°C). Portable refrigerators may be available for rent. Label the portable refrigerator with the facility name and "Fragile Vaccines – Do not Freeze," and the date and time the vaccine was removed from the permanent storage unit.

NOTE: If a portable vaccine refrigerator unit is used to transport vaccines, follow the manufacturer's requirements regarding the use of packing material, i.e., bubble wrap or cardboard.

If a portable refrigerator is not available, a hard-sided, insulated cooler with at least two-inch walls, a Styrofoam vaccine shipping container, or other qualified container may be used, provided it maintains the recommended temperature between 36°F and 46°F (2°C and 8°C).

Using a hard-sided cooler, Styrofoam vaccine shipping container, or other qualified container requires the following:

- Coolers should be large enough to hold the ASN supply of refrigerated vaccines.
- Label the container with the facility name and "Fragile Vaccines – Do Not Freeze" and the date and time the vaccine was removed from the permanent storage unit.
- NOTE: Do not use soft-sided collapsible coolers for transporting vaccines.

Conditioned frozen water bottles must be used to protect ASN-purchased vaccine(s) from temperature fluctuations during transport, unless the manufacturer specifies otherwise (e.g., portable refrigerator). For conditioned frozen water bottlers:

- Use 16.9-ounce bottles for medium-to-large coolers and 8-ounce bottles for small coolers.
- Before use, condition the frozen water bottles by placing them in a sink filled with several inches of cool or lukewarm water until a layer of water forms near the inner surface of the bottle.
- The bottle is conditioned correctly when the ice block spins freely within the bottle when rotated.

NOTE: Do not reuse coolant packs from original vaccine shipping containers.

Insulating material – two of each of the following layers are needed.

- Corrugated cardboard – two pieces cut to fit the internal dimensions of the cooler(s) and placed between the insulating cushioning material and the conditioned water bottles.
- Insulating cushioning material such as bubble wrap, packing foam, or Styrofoam for a layer at least two inches thick above and below the vaccines. Ensure this layer completely covers the cardboard.

NOTE: Do not use packing peanuts or other lose material that may shift during transport.

- Temperature monitoring device - A data logger with a buffered probe must be used as a temperature monitoring device. To use a data logger with a buffered probe as a temperature monitoring device:
- Prepare the probe by pre-chilling it in the refrigerator for at least five hours prior to transport.
- Ensure the data logger has a current and valid "Certificate of Calibration" testing. Ensure the data logger certificate is documented to be accurate within ±1°F (±0.5°C).
- The data logger currently stored in the refrigerator can be used for transport if there is a device in place to measure the temperature for the remaining vaccines.

Packing for Transport

- To pack the vaccine(s) for transport:
- Line the bottom of the cooler with a single layer of conditioned water bottles.
- Place a sheet of corrugated cardboard over the water bottles.
- Place at least a two-inch insulating layer (i.e., bubble wrap, packing foam, or Styrofoam) over the cardboard.
- Stack boxes of vaccines on top of insulating material.
- When the cooler is halfway full, place the data logger buffered probe in the center of the vaccine(s), but keep the display outside the cooler.
- Cover vaccine(s) with another two-inch layer of insulating material.
- Add the second layer of corrugated cardboard.
- Fill the remaining space in the cooler with conditioned water bottles.
- Close the lid of the cooler securely and attach the data logger display and a "Temperature Recording Form," stock no. EC-105, to the top of the lid to record and monitor the temperature during transport.

- Use the vaccine transport log to record the time and temperature inside of the storage unit at the time the vaccine(s) are removed.
- If vaccine(s) are kept in a transport container for longer than an hour, record the temperatures hourly. As soon as the destination site is reached, check and record the vaccine temperature.
- If the vaccine temperature is between 36°F and 46°F (2°C and 8°C), place it in the refrigerator. If the vaccine is below 36°F (below 2°C) or above 46°F (above 8°C), put it in a quarantine bag in the refrigerator and immediately contact the vaccine manufacturer to determine its viability. Next, contact the RE with the manufacturer's viability determination.

NOTE: Always keep the vaccine properly stored until otherwise instructed by the vaccine manufacturer or the ASN Program.

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

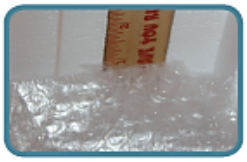
1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

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Centers for Disease Control and Prevention

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Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

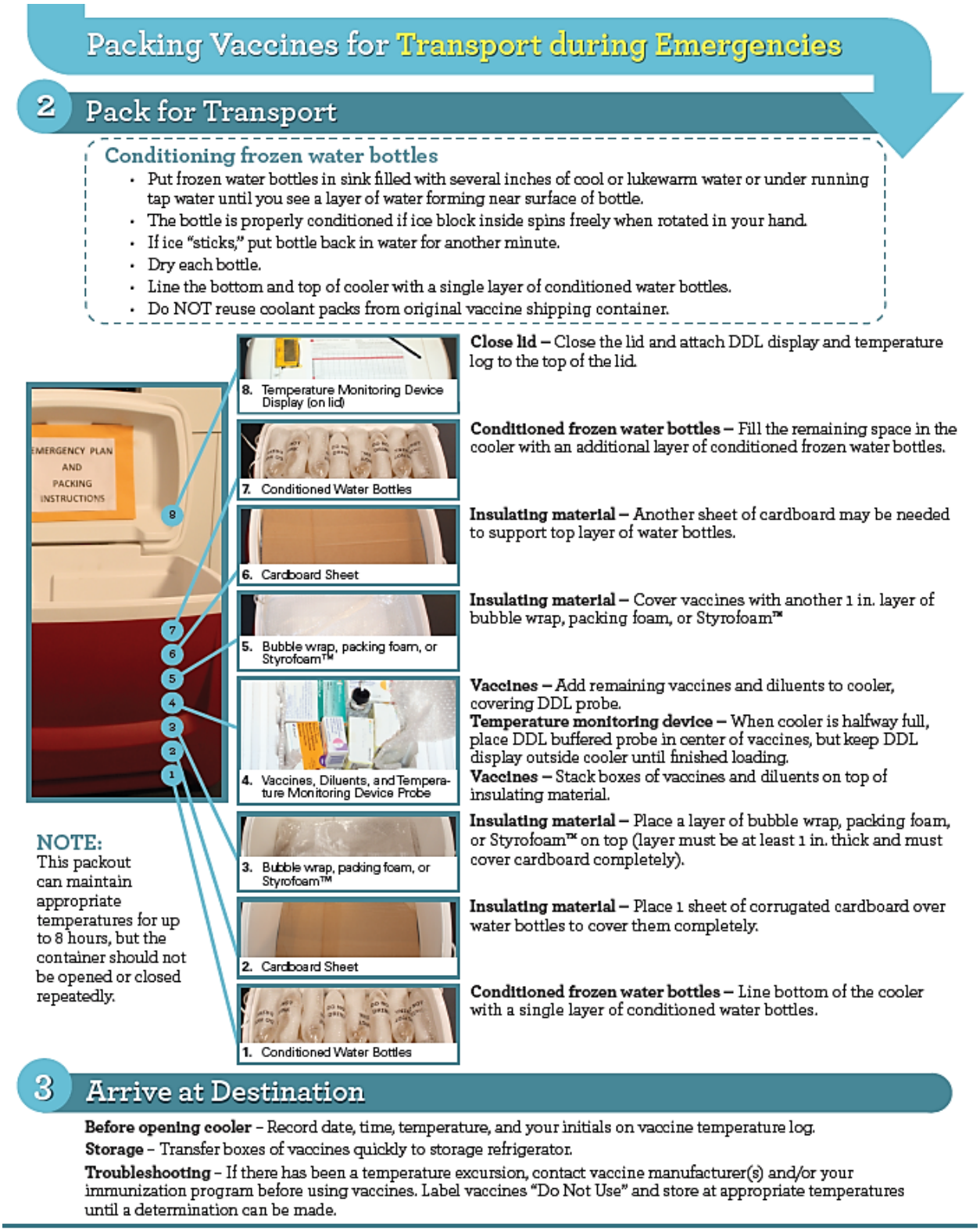

Figure 3-3 Illustrates proper vaccine packing for transport during emergencies when portable refrigerators.

Frozen Vaccine Transport

If the ASN Program makes frozen vaccines available in the future, the following section outlines the steps to transport frozen vaccines. Routine transport of frozen vaccine is not recommended; however, it is allowable in emergency situations.

Assemble Packing Supplies

Portable freezer – DSHS recommends transport with a portable freezer unit that maintains the temperature between - 58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent. Label the portable freezer with the facility name and "Fragile Vaccines – Keep Frozen," and the date and time the vaccine was removed from the permanent storage unit.

NOTE: If a portable vaccine freezer unit is used to transport vaccines, follow the manufacturer's requirements for packing material, e.g., bubble wrap or cardboard.

If a portable freezer is unavailable, a hard-sided insulated cooler with at least 2-inch walls, a Styrofoam vaccine shipping container, or another qualified container may be used if it maintains the recommended temperature range of -58°F to +5°F (-50°C to -15°C).

Using a hard-sided cooler, Styrofoam vaccine shipping container, or other qualified container requires the following:

- Coolers should be large enough to hold the supply of frozen vaccine(s).
- Label the container with the facility name and "Fragile Vaccines – Keep Frozen," and the date and time the vaccine(s) was removed from the permanent storage unit.

NOTE: Do not use soft-sided collapsible coolers for transporting vaccines.

Frozen water bottles must be used in the cooler. Dry ice cannot be used for transporting vaccines, even for temporary storage or emergency transport. Dry ice exposes the vaccine to temperatures colder than -58°F (-50°C).

Insulating material – two layers of insulating cushioning material such as bubble wrap, packing foam, or Styrofoam for a layer at least two inches thick above and below the vaccines.

NOTE: Do not use packing peanuts or other loose material that may shift during transport.

Temperature monitoring device – Use a certified and calibrated data logger with a current and valid "Certificate of Calibration" testing. Prepare the data logger by placing it in a freezer unit at least two hours before packing the vaccine.

Packing for transport:

- Line the bottom of the cooler with a single layer of frozen water bottles.
- Place at least a two-inch layer of insulating material (e.g., bubble wrap, packing foam, or Styrofoam) over the frozen water bottles.
- Stack boxes of vaccines and diluents on top of insulating material.
- When the cooler is halfway full, place the data logger probe in the center of the vaccines, keeping the display out of the cooler.
- Cover the vaccines with another two-inch layer of insulating material.
- Fill the remaining space in the cooler with frozen water bottles.
- Close the lid of the cooler securely and attach the data logger display and a "Temperature Recording Form," stock no. EC-105, to the top of the lid to record and monitor the temperature during transport.
- Use the vaccine transport log to record the time and temperature inside the storage unit at the time the vaccines are removed.
- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly.
- As soon as the destination site is reached check and record the vaccine temperature.
- Place the vaccines in a freezer that maintains a temperature range between -58°F and +5°F (-50°C and -15°C).
- Document the time and temperature at which the vaccine was removed from the transport container and placed in the alternate storage unit.

Immediately contact the vaccine manufacturer for viability data and guidance when the frozen vaccine has been exposed to a temperature above +5°F (-15°C). Do not discard the vaccine without contacting the manufacturer. Viability determination will be made on a case-by-case basis.

Contact the RE with the manufacturer's viability determination.

VI. Vaccine Transfers

ASN Program vaccine transfers are allowed when necessary to avoid vaccine loss (i.e., if a provider's storage unit is overstocked, if the provider withdraws, or if the provider is suspended or terminated from the ASN Program). If a transfer must occur, a "TVFC/ASN Vaccine Transfer Authorization Form," stock no. EC-67, must be completed to receive approval before conducting vaccine transfers. Note that the electronic "TVFC/ASN Vaccine Transfer Authorization Form" must be signed by the

primary coordinator, backup coordinator, or signing clinician. The vaccine transfer can then be approved if the ASN Program PIN of where the vaccine is being transferred to is available. The transfer information must be documented and tracked in VAOS. Once transfer requests are submitted in VAOS, the RE receives the transfer request and the "TVFC/ASN Vaccine Transfer Authorization Form" is available with pre-populated pertinent information for the transfer. Upon approval of a transfer request, the provider is responsible for arranging the physical transfer with the RE and the receiving facility.

Routine redistribution of ASN Program vaccine is not allowed.

Ensure that the vaccine transfer is occurring for one of the following reasons:

- Short-dated vaccine;
- Withdrawal, suspension, or termination of a clinic from the ASN Program; or
- Other (emergency situations).

The primary coordinator, backup coordinator, or signing clinician must complete and sign the "TVFC/ASN Vaccine Transfer Authorization Form," stock no. EC-67 and agree that the vaccine will be transferred in accordance with ASN vaccine storage and handling guidelines.

Each transferred vaccine must be listed on a separate row on the "TVFC/ASN Vaccine Transfer Authorization Form," and must include the following:

- Vaccine type;
- National Drug Code (NDC);
- Lot number;
- Expiration date; and
- Number of doses being transferred.

The completed "TVFC/ASN Vaccine Transfer Authorization Form," stock no. EC-67, must be made available to the RE and retained for a minimum of five years. For emergency situations, contact the RE before uploading the form or performing the transfer in VAOS. The RE may also request that the form be emailed or faxed to them.

The DSHS PHR must approve or deny the transfer as soon as possible. VAOS will automatically deny transfers after two weeks.

The RE must ensure that the vaccine is packaged using proper cold chain procedures as detailed in Chapter Three, Subsection H: Cold Chain Management

and Vaccine Transport, and a certified, calibrated data logger is enclosed with the vaccine.

Include a copy of the "TVFC/ASN Vaccine Transfer Authorization Form" in the transfer packaging. The "TVFC/ASN Vaccine Transfer Authorization Form" can be printed with pre-filled information from VAOS after the transfer request is submitted or accessed from the DSHS Immunization Section website.

After the vaccine transfer has been approved, the receiving provider must download the completed "TVFC/ASN Vaccine Transfer Authorization Form" from VAOS. Alternatively, the "TVFC/ASN Vaccine Transfer Authorization Form," stock no. EC-67, can also be downloaded from the DSHS Immunization website, signed by the receiving provider, and uploaded to VAOS or emailed to the RE.

The ASN-enrolled site taking possession of the vaccine must keep the "TVFC/ASN Vaccine Transfer Authorization Form," stock no. EC-67, on file for at least five years and made readily available, upon request by the RE, site reviewer, or the DSHS Immunization Section.

VII. Vaccine General Information

Vaccine borrowing is the use of ASN Program vaccines as a replacement for meeting the vaccine needs of non-ASN-eligible patients.

The CDC requires that state immunization programs enhance oversight of all vaccine borrowing within ASN Program sites. As such, the ASN Program enforces a policy prohibiting routine vaccine borrowing between ASN-eligible and ineligible patients.

All ASN-enrolled sites are expected to maintain an adequate inventory of vaccine for both ASN-eligible and privately insured patients.

Vaccines supplied by the ASN Program must not be provided to an ineligible patient. Undocumented borrowing and administering ASN Program vaccines to an ineligible patient constitute fraud. ASN Program vaccines must not be used as a replacement system for filling the vaccine needs of a privately insured patient.

A vaccine borrowing form must be completed for the following reasons:

- A dose of TVFC vaccine is administered to a non-TVFC-eligible patient (i.e., any adult or privately insured child).
- A dose of TVFC vaccine is administered to an ASN-eligible adult.

- A dose of ASN vaccine is administered to a non-ASN-eligible patient (i.e., any child or privately insured adult).
- A dose of ASN vaccine is administered to a TVFC-eligible child.
- A dose of privately purchased vaccine is administered to a TVFC-eligible child or an ASN-eligible adult.

To properly document any of the borrowing situations, the following steps must be completed:

- Document the incident by completing the "TVFC/ASN Vaccine Borrowing Form," stock no. EF11- 14171. Each instance of vaccine administered to an ineligible patient must be listed on a separate row on the form.
- Report the incident by faxing or emailing a copy of the "TVFC/ASN Vaccine Borrowing Form," stock no. EF11- 14171, to the RE within 24-hours. Adherence to HIPAA guidelines is mandatory when distributing this form. Do not upload the form to VAOS.
- The "TVFC/ASN Vaccine Borrowing Form," stock no. EF11-14171, must be kept as part of the ASN Program record for a minimum of five years and be made readily available.

If an ASN dose is administered to a privately insured patient, the vaccine must be replaced immediately with a privately purchased vaccine, and the replacement must be accounted for in VAOS.

If a privately purchased dose is administered to an ASN-eligible patient, the vaccine must be replaced immediately with the ASN vaccine, and the replacement must be accounted for in VAOS.

If a TVFC dose is administered to an ASN-eligible patient, or an ASN dose is administered to a TVFC-eligible patient, the dose does not need to be replaced; however, the clinic should review its protocols and retrain staff to ensure this borrowing does not occur again.

Adequate vaccine supply must be maintained in accordance with the clinic's patient population. The ASN Program, TVFC Program, and private vaccine must be kept separate and clearly labeled as such. All vaccine usage must be tracked, and all doses of the ASN Program vaccine must be accounted for in VAOS.

Continued noncompliance with the ASN Program's policies and procedures may constitute fraud and abuse. Referral may be made to the CMS Medicaid Integrity Group (MIG) Field Office.

VIII. Reporting Requirements

A. Vaccine Allocation and Ordering System (VAOS) Reporting

The ASN Program requires the monitoring of refrigerators and freezers containing ASN Program vaccines, vaccine inventory, and vaccine usage. ASN providers are required to distinguish between their adult and pediatric vaccines. They must order and report ASN adult vaccines separately from TVFC pediatric vaccines. All reports should be submitted in VAOS. If internet access is not available, contact your RE and coordinate the report submission.

All records related to the ASN Program must be maintained for five years and made easily accessible.

The following documents must be completed in VAOS between the first and seventh of each month, and each time an order is placed. The following documents must be completed in VAOS or submitted to the RE:

- "Temperature Recording Form," stock no. EC-105;
- Doses Administered: Equivalent to the "Monthly Biological Report," formerly, stock no. C-33;
- Physical Inventory: Equivalent to the "Monthly Biological Report," formerly, stock no. C-33;
- Receipt of Vaccine Shipments (if applicable);
- Vaccine Transfers (if applicable): Equivalent to the "TVFC/ASN Vaccine Transfer Authorization Form," stock no. EC-67;
- Vaccine Loss (if applicable): Equivalent to the "Monthly Biological Report," formerly stock no. C-33; and
- Any other reports or required documents.

Failure to submit required documents will automatically prevent ordering until the documents are uploaded in VAOS. Clinic staff must ensure that all reports are completed and submitted in VAOS by the required due dates.

If internet access is unavailable, required reporting must be submitted to the RE using ASN Program forms. Providers should contact the RE and coordinate the submission of required reports.

B. Uninsured Service Members Report

In accordance with Senate Bill 805 of the 87th Texas Legislature, Regular Session, DSHS must collect and report the number of uninsured service members who receive vaccines under the ASN Program.

By the seventh of each month, all ASN-enrolled sites must document the number of female service members and the total number of all service members who received ASN Program vaccines for the previous month using the "Uninsured Service Members Reporting Form" located online at dshs.texas.gov/immunizations/providers/materials. This online survey is password-protected. Clinic staff must contact the RE to obtain the password for the online survey. If no service members received an ASN Program vaccine the previous month, clinic staff must report zero in the survey.

Chapter Four: Billing and Administration

I. Billing for Invoice

Clinics enrolled in the ASN Program are prohibited from charging any ASN-eligible adult for the cost of vaccines. ASN Program vaccines are provided to clinics at no cost to vaccinate eligible adults. Charging for the cost of vaccines supplied by the ASN Program constitutes fraudulent behavior. Fraud in the ASN Program will be handled in the same manner as Medicaid fraud.

II. Administration Fee

ASN sites may charge an administration fee for administering the ASN Program vaccines to ASN-eligible adults. The maximum administration fee that may be charged is $25.00 per dose. Services must not be denied due to the patient's inability to pay the administration fees. ASN sites that choose to bill a vaccine administration fee after the date of service must issue only a single bill to the patient within 90-days of the administration of the vaccine. ASN patients must not be sent to collections or charged penalties for the inability to pay administration fees.

Sites can continue to bill for other charges, such as office visits or labs. Sites cannot refuse to vaccinate an eligible adult who has unpaid vaccine administration fees.

Chapter Five: Program Evaluation

I. Standards for Adult Immunizations

In 2013, the National Vaccine Advisory Committee (NVAC) revised the "Standards for Adult Immunization Practice." The new standards are aimed at increasing adult immunization rates in the United States. In January 2017, DSHS incorporated the "Standards for Adult Immunization Practices," stock no. 6-252, into ASN site visits. The DSHS Immunization Section highly encourages all ASN-enrolled sites to adopt the adult standards. The "Standards for Adult Immunization Practice" are outlined below.

A. Assess

Assess immunization status for all patients at every clinical encounter. To accomplish this, policies should be implemented to ensure that patients are regularly screened for immunizations and reminded about the vaccines they need.

B. Recommend

Strongly recommend all necessary vaccines. Clinic site staff should stay up to date on information pertaining to adult vaccines to best inform patients. Explain the reasons why a patient should receive the vaccine, as well as address questions and concerns the patient may have. A strong recommendation for a vaccine from a trusted health care professional can make the difference in whether a patient chooses to receive it.

C. Administer or Refer Patients

Administer the vaccines the patient chooses to receive. Vaccines that are currently in stock should be offered. If the patient requests a vaccine that is not in stock or available through the ASN Program, the patient should be referred to local sites that offer the vaccine.

D. Document

All vaccines administered to adults must be documented and included in the patient's medical records. ASN-enrolled clinic sites must participate in ImmTrac2, the Texas Immunization Registry.

The ASN Program captures the aggregate number of doses administered through monthly reports in VAOS. For more information regarding documentation requirements, see Chapter Seven: Documentation Requirements. Visit

cdc.gov/vaccines-adults/hcp/imz-standards for more information regarding the Standards for Adult Immunization Practice.

II. Common Site Visit Structures: Compliance and Storage and Handling

By signing the ASN Annual Provider Agreement, the signing clinician agrees to allow DSHS, PHRs, LHDs, AICs, or DSHS Quality Assurance and Improvement contractors (TMF) to conduct ASN site visits. All ASN-enrolled providers will receive a compliance site visit between 11- to 24-months after their last compliance site visit. Storage and handling site visits may occur at any time and at any frequency.

During an ASN site visit, the reviewer will need access to the following:

- Space to work;
- Power source;
- Internet connectivity (if available);
- Access to patient records;
- "Temperature Recording Forms" or data for the last three months or longer if deficiencies are found;
- "TVFC/ASN Vaccine Borrowing Forms," stock no. EF11-14171 for the previous 12-months;
- The circuit breaker;
- Admitting and billing personnel to clarify eligibility screening and the billing processes; and
- All vaccine storage units where the ASN Program vaccine is stored.

A. ASN Compliance Site Visits

The purpose of the compliance visit is to assess, support, and educate the staff regarding ASN Program policies and procedures, not to critique. This visit consists of a questionnaire and review of ASN storage units.

Clinic sites will be contacted before scheduling the ASN site visit. They will receive a confirmation letter via email or fax that includes the date and time, the materials needed, and a summary of the site visit process. It is required that the signing clinician, primary vaccine coordinator, or backup vaccine coordinator be present at all site visit-related activities.

Components of the ASN Compliance Site Visit

During the ASN compliance site visit, the reviewer and clinic staff will work together to do all the following, but not limited to:

- Review the "Standards for Adult Immunization Practices;"
- Review ASN Program requirements (billing, eligibility screening, borrowing documentation, etc.);
- Review patient immunization records (lot number, manufacturer, date VIS was given to the patient for review, date vaccine was given, clinic name and address, etc.); and
- Review storage and handling practices ("Temperature Recording Form," water bottles, "Vaccine Management Plan," valid calibrated data logger, etc.).

At the end of the compliance site visit, the staff present must print and sign the Acknowledgment of Receipt (AR) form. The AR form attests that a site visit was completed, the visit results were received, and that the vaccine coordinator(s) understand all non-compliance issues identified and the actions necessary to address them.

Electronic Medical Record Review

In recent years, the use of EMRs has become routine, changing how records are reviewed. If an EMR is in use at a site, clinic staff must do one of the following:

- Provide a dedicated staff member to log in to the EMR and sit with the reviewer throughout the record review process to pull up EMR immunization and eligibility records.
- Provide printouts from the EMR of the immunization records and documentation of the adult's eligibility.

NOTE: It is not acceptable for a site staff member to log in and then turn the EMR screens over to the reviewer; the staff member must remain present. Neither the ASN Program nor TMF will pay for or reimburse clinics for copies when staff choose to print immunization records from their EMR system.

ASN Compliance Site Visit Follow-Up

Upon completion of the compliance site visit, the reviewer will discuss the visit's outcomes with the vaccine coordinator(s) or the signing clinician. The discussion will include a review of the site visit findings and a formal follow-up plan with a timeline that addresses non-compliance issues or improvement opportunities.

The RE, DSHS ASN Program staff, or AIC will conduct all required follow-up activities to ensure that the site's staff understand the areas for improvement identified by the reviewer and that corrective actions have been identified and implemented. Follow-up activities are conducted as necessary to address all issues, depending on the severity of the non-compliance issues and the follow-up action plan.

The RE, AIC, or DSHS ASN Program staff will determine the provider site's compliance with the corrective action plans by one or more of the following methods of follow-up:

- Visit the clinic to observe corrective actions.
- Call the vaccine coordinator at the clinic.
- Send a letter to address the deficient items identified during the site visit.
- Determine the staff's compliance with the corrective action plans, if applicable.
- The RE works with clinic staff on non-compliance issues by providing education and guidance regarding corrective actions, including monitoring. If a site exhibits habitual noncompliance and fails to follow corrective actions despite education, its vaccine ordering privileges may be suspended. If noncompliance continues, termination from the ASN Program may be implemented.

B. Announced and Unannounced Storage and Handling Visits

Announced and unannounced storage and handling visits may be conducted to serve as "spot checks" for proper vaccine storage and handling. Announced and unannounced visits focus exclusively on vaccine storage and handling.

Announced visits will be scheduled with the facility by the site reviewer prior to arrival. Providers are not notified prior to receiving an unannounced visit.

The signing clinician, primary vaccine coordinator, or backup vaccine coordinator must attend the announced and unannounced storage and handling site visits.

Vaccine storage and handling issues are identified and addressed immediately during both announced and unannounced storage and handling visits. Staff are expected to make on-site corrections to ensure the vaccine's viability.

At the end of the announced or unannounced storage and handling visit, the signing clinician, primary vaccine coordinator, or backup vaccine coordinator present during the site visit must print and sign their name on an Acknowledgment of Receipt (AR) form following the visit. The AR form confirms that a site visit was completed, the visit results were received, and that the vaccine coordinator understands all noncompliance issues identified and the necessary actions to address them.

III. ASN Provider Satisfaction Surveys

ASN-enrolled providers are the best sources of information for evaluating which aspects of the ASN Program are working or not working as planned. In addition to assessing operational components, surveys are used to gather information on educational needs of enrolled sites or their responses to education provided. Findings may determine which quality improvement projects may be undertaken. Enrolled sites can expect to receive at least two mandatory surveys per year.

A. Annual TVFC/ASN Satisfaction Survey

The Annual TVFC/ASN Satisfaction Survey was created to assess overall satisfaction with the TVFC and ASN Programs and is an annual requirement by DSHS and the CDC. Enrolled provider sites are required to submit an Annual TVFC/ASN Satisfaction Survey during the re-enrollment. A survey link will be sent to providers when it is time to re-enroll in the program(s).

B. ASN Compliance Site Visit Satisfaction Survey

The site visit satisfaction survey is conducted following an ASN compliance visit. An email containing a link to an online survey is sent to the primary vaccine coordinator, the backup vaccine coordinator, or the signing clinician after a site visit. It allows the clinic staff to provide feedback about their experiences during the visit. Please complete only one ASN Compliance Site Visit Satisfaction Survey per facility per visit.

Chapter Six: Fraud and Abuse

I. Fraud and Abuse

As the complexity of immunizations and immunization-related programs grow, sites enrolled in the ASN Program may become more vulnerable to unintentionally committing acts that could be construed as fraud or abuse. Fraud and abuse, whether intentional or not, are subject to all federal fraud and abuse laws.

II. Definitions

A working understanding of what constitutes fraud and abuse is critical for all staff working in the ASN Program. The following are definitions of terms related to fraud and abuse.

Fraud - An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in an unauthorized benefit to himself or another person. It includes any act that constitutes fraud under applicable federal or state laws.

Abuse - Practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the ASN Program, Medicaid, a health insurance company, or a patient, result in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care.

Oversight - The act of training, monitoring, and assisting clinic staff on ASN Program policies and procedures.

Enforcement - Ensuring corrective action is taken once a policy violation has been identified.

Termination - Removal from the ASN Program when a site or signing authority is no longer eligible for the ASN Program due to fraud, abuse, or non-compliance.

Waste - The careless, inefficient, or unnecessary use of ASN Program resources.

III. Examples

Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier to prevent or detect than others. All staff at ASN-enrolled sites should familiarize themselves with the examples below, as they illustrate common practice errors that could lead to allegations of fraud or abuse. The list below provides examples only

and should not be considered an exhaustive list of situations that would constitute fraud or abuse:

- Provide ASN vaccine to ineligible adults.
- Sell or otherwise misdirect ASN vaccine.
- Bill a patient or third party for ASN vaccine (other than administration fees).
- Charge more than $25.00 for administration of a ASN vaccine to an eligible adult.
- Failure to meet licensure requirements for enrolled clinicians.
- Deny ASN-eligible adults an ASN vaccine because of the inability to pay the administration fee.
- Send a patient to collections or charge additional fees for non-payment of the administration fee.
- Failure to implement ASN Program enrollment requirements.
- Failure to screen for and document ASN eligibility at every visit.
- Failure to maintain ASN records for five years.
- Failure to fully account for ASN vaccines.
- Failure to properly store and handle ASN vaccines.
- Order ASN vaccine in quantities or patterns that do not match the site’s population profile or otherwise involve over-ordering of ASN doses.
- Loss of ASN vaccine due to negligence.

IV. Failure to Comply with ASN Program Requirements

Enrolling in the ASN Program constitutes an agreement to comply with all the Program's requirements. Failure to adhere to the ASN Program requirements may result in that site committing fraud or abuse of the ASN Program. Non-compliance with the ASN Program requirements may occur due to an unintentional lack of understanding of the requirements. Behavior may also be intentional. If the non-compliance appears intentional and the clinic staff or signing authority has received financial benefits from the behavior, the situation will result in immediate referral for investigation of suspected ASN Program fraud and abuse.

V. Fraud and Abuse Prevention

The ASN Program actively collaborates with enrolled clinics to help prevent fraud and abuse within the program. The most effective methods to prevent fraud and abuse include strong educational components discussed during the initial enrollment process and during ASN compliance site visits. Both occasions provide the opportunity to identify and prevent situations that may develop into fraud and abuse.

VI. Reporting Fraud and Abuse

Suspected fraud or abuse can be reported to the ASN Program or the RE via email, telephone, fax, or letter. Furthermore, newspaper articles and internet pages that promote potential fraudulent situations are also investigated. The RE and DSHS Quality Assurance and Improvement contractors (TMF) must report all cases of alleged or suspected fraud or abuse. Reports received by the DSHS Immunization Section in any form that merit further investigation may be referred to the CMS, Medicaid Integrity Group (MIG) Field Office. The state Medicaid agency will conduct preliminary investigations and as warranted, refer appropriate cases to the state's Medicaid Fraud Control Unit following the Federal Regulatory scheme at 42 CFR section 455.15 and 42 CFR section 455.23.

Chapter Seven: Documentation Requirements

I. Vaccine Record Keeping Requirement

The 1986 National Childhood Vaccine Injury Act (NCVIA) requires staff nationwide to record the following specific information in the medical record each time a vaccine is administered:

- Name of vaccine administered;
- Date vaccine was administered (month, day, year);
- Date VIS was given;
- Publication date on VIS;
- Name of vaccine manufacturer;
- Vaccine lot number;
- Name and title of the health care professional administering the vaccine; and
- Address of the clinic where the vaccine was administered.

If needed, the DSHS Immunization Section provides immunization records designed to capture all required information when a vaccine is administered. The "Vaccine Information Documentation Form," stock no. C-100, can document immunization records for clinics, and the "Personal Immunization Record Card," stock no. C-102, can document immunization records for clients. Both forms can be ordered free of charge from the DSHS Immunization Section (See Chapter Ten: Ordering Forms and Literature).

The ASN Program recommends the following record-keeping practices:

- Designate an immunization staff member to answer immunization questions for staff and patients.
- File patient records, keeping the immunization record and "Adult Safety Net (ASN) Patient Eligibility Screening Form," stock no. F11-12842, together.
- Place immunization records at the front of each patient's chart and make immunizations a priority.
- Encourage patients to bring their immunization records with them to facilitate complete documentation in the patient's record of previous immunization history.
- If a patient presents with no immunization record, obtain the history through the Texas Immunization Registry (ImmTrac2), or call previous medical facility to obtain the history.

- Empower all staff to become "Immunization Advocates" and have them assess each patient's immunization status at every encounter.
- Give a personal immunization record to each vaccine recipient showing the date (month, day, and year) of when each vaccine was administered.
- Copies of all ASN Program documents must be maintained for five years and made available on request by the ASN Program, the RE, or the DSHS QAI Contractor (TMF).

II. The Texas Immunization Registry (ImmTrac2)

ImmTrac2 is operated by the DSHS Immunization Section and is a key component of Texas' strategy to improve immunization coverage rates. ImmTrac2 is designed to consolidate immunization records from multiple sources throughout the state.

Some benefits of ImmTrac2 include:

- Electronic data exchange with ImmTrac2 from Electronic Health Record (EHR) systems.
- Registered organizations have easy access to immunization records for participating clients.
- Forecast immunizations coming due or past due.
- Various reports available for ImmTrac2 users, including "Reminder", "Recall", and "Benchmarking" capabilities
- DSHS recommends that all medical providers report all immunizations administered to clients 18 years of age or older to ImmTrac2 within 30-days of administration.

ASN providers are strongly recommended to obtain consent at each immunization visit and to report all adult administrations to ImmTrac2, regardless of whether consent is on file.

Parent or guardian consent for ImmTrac2 participation is required for clients younger than 18 years of age. Adults may also consent to ImmTrac2, which stores their immunization information for a lifetime. Individuals who turn 18 years old, and were participating in ImmTrac2 as a minor, must sign an adult consent form by their 26th birthday to keep their immunization information in ImmTrac2. On the patient's 18th birthday, the immunization record stored in ImmTrac2 will be "hidden" from view until an adult consent is signed. If a patient does not sign an adult consent form, the record will be deleted from ImmTrac2 on the patient's 26th birthday.

As a registered user of ImmTrac2, medical professionals can confirm whether a patient is in ImmTrac2 and should gather consent from individuals who wish to participate.

ASN-enrolled sites must register as an authorized organization with ImmTrac2 by completing an online form. Refer to the "ImmTrac2 Site Registration Guide," stock no. 11-15175, and "ImmTrac2 Site Renewal Through Syntropi," stock no. 11-16804, on how to register a new site and renew an agreement.

Call ImmTrac2 Customer Support line at 800-348-9158 or visit the Immtrac2 webpage at ImmTrac.dshs.texas.gov to register or for more information about ImmTrac2.

A. Reporting Vaccine Eligibility in ImmTrac2

Eligibility for the ASN Program must be reported in Immtrac2 using specific vaccine eligibility codes. The following codes must be used when reporting in ImmTrac2 online or by data exchange (HL7):

- TXA04 for Adult, No Insurance: Patient is ≥ 19-years-old.
- TXA06 for Adult, Private Pay/Insurance: Patient is ≥ 19-years-old Underinsured.

B. Reporting Requirements During Disaster Declaration

In the event of a disaster declaration, providers are required to report Antivirals, Immunizations and other Medications (AIM) for disasters and emergencies to ImmTrac2. Disaster-related AIMs are required to be kept in the registry for five years following the end of the disaster declaration. For the information to remain in ImmTrac2 past the initial five years, the client must sign a "Disaster Information Retention (DIR) Consent Form," stock no. F11-12956.

Visit the Texas Administrative Code Title 25 Part 1 Chapter 100 for more information regarding the reporting of AIMS and other immunizations to ImmTrac2.

III. Addressing Vaccine Hesitancy

Maintaining public confidence in immunizations is critical to preventing a decline in vaccination rates that can lead to disease outbreaks. While most adults believe in the benefits of immunization, some have concerns about vaccine safety. These concerns about vaccine safety prevent some adults from getting themselves immunized.

Overcoming barriers requires both knowledge and interpersonal skills on the part of the medical staff. Medical staff who administer vaccines should understand vaccines, be up to date on recommendations, and have reliable resources to direct parents and patients to accurate information. Also, staff must have the skills to address fears and misconceptions about vaccines and to provide a supportive and encouraging environment for patients.

When a patient raises a vaccine concern, address the specific concern and provide information. The VIS provides an outline for discussing vaccine benefits and risks. Reinforce key points for each vaccine, including safety, and emphasize the risks faced by unimmunized adults.

Documenting these discussions in the patient's record might reduce potential liability if a vaccine-preventable disease occurs in an unimmunized patient.

IV. Vaccine Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration (FDA) and the CDC. VAERS aims to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events that occur after the administration of U.S. licensed vaccines.

All staff at enrolled sites are required to report adverse events following vaccine administration. An adverse event can be reported using the VAERS online form at vaers.hhs.gov or the PDF form at the same site. Generally, reporting is also required for events described in a manufacturer's package insert as contraindications to additional doses of vaccine and for acute complications or sequelae, including death.

Clinic staff should use the VAERS Reporting Website to report all adverse events after vaccination directly to VAERS. Be prepared with all information needed for the VAERS reporting form, including patient and provider details, the adverse event description, the outcome, and vaccine details such as the manufacturer, lot number, and injection site.

For a serious adverse event (one that causes life-threatening illness, hospitalization, prolongation of an existing hospitalization, permanent disability, or death), a copy of the VAERS report must be submitted to your RE. This can be completed using the "PDF upload" option on the VAERS website at vaers.hhs.gov.

Chapter Eight: Off-Site, Mobile, and Mass Vaccination Clinics

I. Vaccine Ordering for Off-Site and Mass Vaccination Clinics

Off-site and mass vaccination clinics may be established using ASN-purchased vaccines to reach a large number of patients. Because most temporary mass clinics typically require vaccine transport on the day of the clinic, these temporary clinics require enhanced storage and handling practices. Providers that conduct off-site and mass clinics are not allowed to operate outside of their jurisdiction. Contact the RE if an ASN-enrolled site is unsure about its jurisdictional boundaries. Clinic staff must develop mass vaccination protocols to ensure outreach efforts meet all ASN Program requirements, including the following:

- Showing the established vaccine needs (e.g., provider profile).
- A schedule to include the date, location, and estimated number of vaccines expected to be administered for each off-site clinic.
- A plan for overseeing vaccine ordering for each clinic site to ensure that proper amounts of ASN stock are transported on each clinic day.
- The type of portable storage unit being used.
- How the cold chain will be maintained from the beginning to the end of the mass vaccination clinic. Each site location must document temperatures on the "Temperature Recording Form," stock no. EC-105.
- Documentation of eligibility screening for all ASN doses given during the event.

The RE must review and approve a mass vaccination plan before initiation of the mass vaccination clinics. For mass vaccination sites where the enrolled site is not providing direct services and other parties are involved in administering the vaccines, all parties involved in implementing the clinics, including the signing clinician and other groups directly administering the vaccine, must sign an agreement. A written agreement must be attached to the ASN Annual Provider Agreement detailing the responsibilities of each party involved.

II. Off-Site, Mobile, and Mass Vaccination Clinic Requirements

To ensure proper storage and handling of vaccines for off-site, mobile, and mass vaccination clinics, the following storage and handling practices are required:

- All ASN vaccines must be ordered and shipped directly to a location within the ordering clinic's DSHS PHR.
- The vaccine must be properly transported, not shipped, to local schools or other community sites where the mass vaccination clinics will be held. For more information on vaccine transport, refer to Chapter Three, Subsection J: Cold Chain Management and Vaccine Transport.
- The total time for vaccine transport alone or vaccine transport plus clinic workday must not exceed a maximum of eight hours (e.g., if transport to an off-site clinic is one hour each way, the clinic may run for up to six hours).
- Only amounts of vaccines that are appropriate, based on ASN-eligibility estimates, should be transported to each scheduled clinic.
- Vaccine must be transported to and from the scheduled mass vaccination clinic at appropriate temperatures and must be monitored by a data logger that meets ASN Program requirements as listed in Chapter Three, Subsection D: Data Logger Requirements. The data logger's display must be placed outside the storage unit for continuous monitoring.
- Temperature data must be reviewed and documented every hour during the clinic using a data logger with a digital display and probe in buffered material.
- At the end of the clinic day, temperature data must be assessed prior to placing vaccines back into storage units to prevent future administration of vaccines that may be compromised.
- All remaining vaccines must be taken back to the provider's central vaccine storage unit at the end of the clinic day.

The vaccine being transported must be tracked to maintain accountability for monthly reporting in VAOS. This includes the following:

- Vaccine type(s) and brand name;
- Quantity of each type;
- NDC numbers;
- Lot numbers; and
- Expiration dates.

Upon arrival at the clinic site, ensure the vaccine is stored to maintain the appropriate temperature throughout the clinic day.

Since the vaccine is at a temporary location, temperature data must be reviewed and documented every hour during the clinic using a data logger. The "Temperature Recording Form," stock no. EC-105, may be used to document hourly temperatures.

After each clinic day, a physical count of the remaining vaccine must be conducted, and a temperature assessment must be performed before placing the vaccine back into central storage units to prevent inadvertent administration of vaccine that may have been compromised.

Vaccines exposed to temperature excursions must be separated in a "Vaccine Quarantine Bag" and labeled "Do Not Use" until further information can be gathered from the manufacturer(s). The vaccine should be stored at the appropriate temperature until the viability determination is made.

Chapter Nine: Vaccine Information Statement (VIS)

The National Vaccine Childhood Injury Act (NCVIA-42 U.S.C. 300ss-26) requires all immunization clinic sites to provide a patient, parent, guardian, or other responsible adult with a current VIS of specific vaccines. The appropriate VIS must be given prior to vaccination and must be given prior to each dose of a multi-dose series.

The VIS informs the patient about the benefits and risks of the vaccine the patient is receiving. The most current version of each VIS must be provided. A list of current VIS dates for each vaccine can be found on the DSHS Immunization website at or the Immunization Action Coalition (IAC) website at immunize.org/vis.

A VIS may be provided as a paper copy or in the following ways:

- A permanent, laminated, office copy of each VIS, which must be read prior to vaccination.
- A computer monitor or video display where the VIS can be reviewed.
- As a downloadable document that can be accessed via a smartphone or other electronic device by the client, parent, guardian, or other responsible adult to a smartphone or other electronic device.

The patient must still be offered a copy in one of the formats mentioned above to be read during the immunization visit. A copy (which can be an electronic copy) of each appropriate VIS must be offered to take away following the vaccination.

Reasonable steps must be taken to provide information in the appropriate languages to ensure patients with limited English proficiency are effectively informed. All VIS are available in more than 20 languages and can be downloaded from the IAC website at immunize.org/vis.

NOTE: Providers should not delay use of an ACIP-recommended vaccine because a VIS is unavailable. For any ACIP-recommended vaccine or immunization product that does not yet have a VIS or Immunization Information Statement available, a provider may use the manufacturer's package insert, written FAQs, or any other document to inform patients about the benefits and risks of that vaccine. Once a VIS is available, providers must use it.

Chapter Ten: Ordering Forms and Literature

The DSHS Immunization Section offers various forms, literature, brochures, posters, and VIS free of charge. Forms are available for viewing, downloading, or shipping directly to clinic sites. Allow 10 or more business days for delivery. Visit dshs-imm.specialbee.com/ for a complete list of forms and materials available for ordering.

If internet access is unavailable, clinic sites may send a request for literature directly to the DSHS Immunization Section via email or mail.

When placing orders in writing, include the following elements:

- Stock number or title and requested quantity;
- Physical address for delivery, including department or suite numbers (Cannot deliver to PO Box); and
- Telephone number (including area code).

Handwritten requests may be sent to the following DSHS facility address:

Mail to: Immunization Section
Department of State Health Services
Mail Code-1946
P.O. Box 149347
Austin, Texas 78714-9347

Call the Public Information, Education, and Training (PIET) Department at 800-252-9152 if you have questions regarding publications or the ordering process.

Chapter Eleven: Immunization Resources

CDC Immunization Website	cdc.gov/vaccines/
CDC Immunization Schedules	cdc.gov/vaccines/hcp/imz-schedules/index.html
CDC Vaccine Storage and Handling Toolkit	cdc.gov/vaccines/hcp/downloads/storage-handling-toolkit.pdf
CDC "You Call the Shots" Module 16, Vaccines for Children Program	train.org/texas/course/1133869/details
CDC Module 10, Storage and Handling	train.org/texas/course/1133532/details
ImmTrac2, the Texas Immunization Registry	immtrac.dshs.texas.gov/
Immunization Action Coalition	immunize.org/
Standards for Adult Immunization Practice	cdc.gov/vaccines-adults/hcp/imz-standards/index.html
TVFC/ASN Provider Policy Training	train.org/texas/course/1133007/compilation

Texas DSHS Immunization Website	dshs.texas.gov/immunizations
Texas DSHS Program Information for Providers	dshs.texas.gov/immunizations/provider/overview
Texas DSHS Immunization Materials for Order	dshs-imm.specialbee.com/
Texas TRAIN	train.org/texas
VAOS Training & Quiz	Training: dshs.texas.gov/immunizations/providers/training Quiz: survey.alchemer.com/s3/6801123/Vaccine-Allocation-and-Ordering-System-Quiz

Vaccine Manufacturers Contact List

Vaccine manufacturers should be contacted in the event the vaccine storage experiences a temperature excursion. Refer to the vaccine manufacturer information as listed on the box.

Vaccine Manufacturers Phone Numbers	**GlaxoSmithKline** 888-825-5249 **Astra Zeneca** 800-236-9933 **Merck** 800-672-6372 **Sanofi Pasteur** 800-822-2463

	Seqirus USA Inc 855-358-8966 **Pfizer** 800-438-1985 **Grifols** 888-474-3657
ASN Program Contact Information	
DSHS Immunization Section	800-252-9152 ASNInfo@dshs.texas.gov
Find a TVFC Provider Tool	TVFC Providers Map
Find an ASN Provider Tool	ASN Providers Map
Responsible Entity Contact	
PINs Beginning with Responsible Entity Phone Number	
00 City of San Antonio	**San Antonio Metro Health Department** 210-207-3965
01	**PHR 1** 806-744-3577
02 or 03	**PHR 2/3** 817-264-4500
04 or 05 not in Hardin, Jefferson, or Orange Counties	**PHR 4/5N** 903-595-3585
06 or 05 in Hardin, Jefferson, or Orange Counties	**PHR 6/5S** 713-767-3000
07	**PHR 7** 254-778-6744
08	**PHR 8** 210-949-2000

09 or 10	**PHR 9/10** 915-834-7675
11	**PHR 11** 956-423-0130
25 City of Houston	**Houston Health Department** 832-393-5188

List of Acronyms

ACIP	Advisory Committee for Immunization Practices
AIC	Adult Immunization Coordinator
ASN	Adult Safety Net Program
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
Co-Ag	CDC's Cooperative Agreement
CMS	Centers for Medicare & Medicaid Services
DDL	Digital Data Logger
DSHS	Texas Department of State Health Services
EHR/EMR	Electronic Health [Medical] Record
FQHC	Federally Qualified Health Center
GR	Texas General Revenue
HCP	Healthcare Provider
HHS	United States Department of Health and Human Services
HHSC	Texas Health and Human Services Commission
IQIP	Immunization Quality Improvement for Providers
LHD	Local Health Department

MSL	Maximum Stock Level
PEAR	Provider Education, Assessment, and Reporting
PHR	Public Health Region
PIOS	Texas Pharmacy Inventory and Ordering System
QAI	Quality Assurance and Improvement
RHC	Rural Health Clinic
TAC	Texas Administrative Code
TDH	Texas Department of Health
TIPS	ImmTrac2 Texas Immunization Provider Summary Report Guide
TMF	TMF Health Quality Institute
TVFC	Texas Vaccines for Children Program
USH	Unannounced Storage & Handling Visit
VAOS	Texas Vaccine Allocation and Ordering System
VFC	Federal Vaccines for Children Program
VTrckS	Federal Vaccine Tracking System

Program and Contact Information

Adult Safety Net (ASN) Program
Vaccine Operations Unit
Immunization Section
Texas Department of State Health Services (DSHS)
1100 West 49th Street
PO Box 149347, MC 1946
Austin, Texas 78714-9347

Phone: 888-777-5320

Email: ASNInfo@dshs.texas.gov

Website:
dshs.texas.gov/immunizations/what-we-do/programs

Texas Department of State Health Services
Immunization Section
Adult Safety Net (ASN) Program
Dshs.texas.gov/immunizations

Texas Department of State Health Services
Immunization Section

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