### CONTRACT, LEASE, AGREEMENT CONTROL FORM

Date:

02/22/2021

Contract/Lease Control #: C20-2952-BCC

Procurement#:

<u>NA</u>

Contract/Lease Type: <u>AGREEMENT</u>

Award To/Lessee:

OKALOOSA COUNTY HEALTH DEPARTMENT

Owner/Lessor:

OKALOOSA COUNTY

Effective Date:

08/07/2020

Expiration Date:

03/31/2021

Description of:

CARES ACT MEMORANDUM OF UNDERSTANDING

Department:

<u>BCC</u>

Department Monitor: <u>HOFSTAD</u>

Monitor's Telephone #: 850-651-6136

Monitor's FAX # or E-mail: JHOFSTAD@MYOKALOOSA.COM

Closed:

Cc: BCC RECORDS

# PROCUREMENT/CONTRACT/LEASE INTERNAL COORDINATION SHEET

Procurement/Contract/Lease Number:
Procurement/Contractor/Lessee Name: Okalocsa Contractor/Lessee Nam
Purpose: Renal
Date/Term: 3-31-2CC1 1. ☐ GREATER THAN \$100,000
Department #: 2. GREATER THAN \$50,000
Account #: 3.  \$50,000 OR LESS
Amount:
Department: BCC Dept. Monitor Name: HC/81Cd
Purchasing Review
Procurement or Contract/Lease requirements are met:
Purchasing Manager or designee Jeff Hyde, DeRita Mason, Jesica Darr, Angela Etheridge
Approved as written:
Grants Coordinator
Risk Management Review
Approved as written:
Risk Manager or designee Lisa Price
Approved as written:  County Attorney  Sel Mail attack  Date:
County Attorney Lynn Hoshihara, Kerry Parsons or Designee
Department Funding Review
Approved as written:  Date:
Duic.
IT Review (if applicable)
Approved as written:
Date:

### **DeRita Mason**

From: Lynn Hoshihara

Sent: Thursday, February 18, 2021 1:11 PM

To: DeRita Mason
Cc: 'Parsons, Kerry'
Subject: Re: C20-2952-BCC

Attachments: 1st renewal to C20-2952-BCC 2.18.21.docx

DeRita,

See my changes attached. With these changes, this renewal is approved as to legal sufficiency.

Lynn

Lynn M. Hoshihara County Attorney Okaloosa County, Florida

Please note: Due to Florida's very broad public records laws, most written communications to or from County employees regarding County business are public records, available to the public and media upon request. Therefore, this written e-mail communication, including your e-mail address, may be subject to public disclosure.

From: DeRita Mason

Sent: Wednesday, February 17, 2021 2:54:23 PM

To: Lynn Hoshihara Cc: 'Parsons, Kerry' Subject: C20-2952-BCC

Good afternoon,

Please review and approve the attached.

They have invoice's that need to be paid and the contract expired in December.

Thank you,

#### DeRita Mason



DeRita Mason, CPPB Senior Contracts and Lease Coordinator Okaloosa County Purchasing Department

CONTRACT#: C20-2952-BCC
OKALOOSA COUNTY HEALTH DEPARTMENT
CARES ACT MEMORANDUM OF UNDERSTANDING
EXPIRES: 03/31/2021



# FIRST RENEWAL TO THE MEMORANDUM OF UNDERSTANDING BETWEEN OKALOOSA COUNTY, FLORIDA AND STATE OF FLORIDA DEPARTMENT OF HEALTH, OKALOOSA COUNTY HEALTH DEPARTMENT CONTRACT NO: C20-2952-BCC

This First Renewal to the Memorandum of Understanding between Okaloosa County, a political subdivision of the State of Florida (the "County"), and State of Florida Department of Health, Okaloosa County Health Department, executed this 2011 day of Feb Oury, 2021, is made a part of the original Agreement dated August 7, 2020, Contract No. C20-2952-BCC (the "original Agreement"), incorporated herein by reference. The parties hereby agree as follows:

- 1. **OPTION TO RENEW.** The parties hereby wish to exercise their option to renew the original Agreement for an additional one (1) year term. The initial term was based on the term of the Cares Act Funding, which has since been extended to June 30, 2021.
- EFFECTIVE DATE OF RENEWAL TERM. The Effective Date of this Amendment shall be retroactively dated to begin December 31, 2020 and shall terminate no later than March 31, 2021.
- 3. **COMPENSATION.** Compensation for this renewal term of the Agreement shall:

Stay the same as set forth in the original Agreement ("Compensation") and/or any amendments thereto.

- OTHER PROVISIONS REMAIN IN EFFECT. Except as specifically modified herein, all terms and conditions of the original Agreement between the parties, dated August 7, 2020 and any amendments thereto, shall remain in full force and effect.
- CONFLICTING PROVISIONS. The terms, statements, requirements, or provisions contained
  in this Amendment shall prevail and be given superior effect and priority over any conflicting or
  inconsistent terms, statements, requirements or provisions contained in any other document or
  attachment.

(Remainder of Page Intentionally Left Blank)



IN WITNESS WHEREOF, the parties hereto have executed this Amendment on the day and year first written above.

### STATE OF FLORIDA DEPARTMENT OF HEALTH, **OKALOOSA COUNTY HEALTH DEPARTMENT:**

Karen A. Chapman, Chapman MD, MPH

Dr. Karen Chapman, MD, MPH, Director

### OKALOOSA COUNTY, FLORIDA

BY: Digitally signed by John Hot Date: 2021.02.22 14:14:40

John Hofstad, County Administrator

### CONTRACT, LEASE, AGREEMENT CONTROL FORM

Date: 08/24/2020

Contract/Lease Control #: C20-2952-BCC

Procurement#: NA

Contract/Lease Type: <u>AGREEMENT</u>

Award To/Lessee: OKALOOSA COUNTY HEALTH DEPARTMENT

Owner/Lessor: OKALOOSA COUNTY

Effective Date: 08/07/2020

Expiration Date: <u>12/30/2020</u>

Description of: CARES ACT MEMORANDUM OF UNDERSTANDING

Department: BCC

Department Monitor: HOFSTAD

Monitor's Telephone #: 850-651-6136

Monitor's FAX # or E-mail: JHOFSTAD@MYOKALOOSA.COM

Closed:

Cc: BCC RECORDS

#### Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis Governor

Scott A. Rivkees, MD State Surgeon General

Vision: To be the Healthiest State in the Nation

October 29, 2020

John Hofstad Okaloosa County Administrator 1250 Eglin Parkway, Suite 100 Shalimar, FL 32579

Dear Mr. Hofstad:

The State of Florida Department of Health, Okaloosa County Health Department (OCHD) is respectively asking to reconfigure the approved staffing plan as outlined in the CARES ACT Memorandum of Understanding (Contract No. C20-2952-BCC) that was fully executed August 7, 2020.

Regional COVID IMT staff have been supporting OCHD testing functions. Their support will end on October 30, 2020. OCHD can retain some of the experienced IMT staff by hiring them into Countyfunded COVID OPS positions. One of which is a Licensed Practical Nurse (LPN). OCHD currently has two County-funded LPN positions but would need a third to accommodate this IMT LPN.

Please consider the changes summarized on the following page. If approved, the changes will allow us to staff these high priority functions while staying within the staffing plan included in the CARES ACT Memorandum of Understanding.

If you have any questions, please feel free to contact me at (850)833-9245.

Sincerely,

Karen A. Chapman, MD, MPH

Director

Okaloosa County Health Department

Approved By

John Hofstad

John

Digitally signed by John Hofstad Date: 2020.10.29 15:27:50 -05'00"

Hofstad

Okaloosa County Administrator

CONTRACT#: C20-2952-BCC

OKALOOSA COUNTY HEALTH DEPARTMENT CARES ACT MEMORANDUM OF UNDERSTANDING

EXPIRES: 12/30/2020

in OKALOOSA COUNTY 221 Hospital Dr. NE, Ft Walton Beach, FL 32548 PHONE: 850/833-9240 • FAX 850/833-9252 www.healthyokaloosa.com



### FDOH-OKALOOSA PROPOSED STAFFING CHANGES

						CUR	RENT			
CURREI FUNCTION OPS WORKING TITLE GTY	Π CHANGE	UPDATED QTY START DATE	BU NAME H	IDGETED IOURLY	Hours	Salary	Fringe @ 28%	Total	Hours Salary Fringe 97285 Total	(DECREASE)
Registered Nurse Registered Nurse	11 -	1 10 11/6/2020 V	acant	25:00	288.00	79,200.00	22,176,00	101,376.00		(9,216,00)
Licensed Practical Nurse Licensed Practical Nurse	2	1 3 <b>11/6/2020</b> V	acant	20.00	288.00	11,520.00	3.225.60	14,745.60		7,372.80
	13	0 13		I		90,720.00	25,401.60	116,121.60	1,505,846,160,160,000,000,000,000,000,000,000,00	(1,843.20)

ESTIMATED

#### Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis Governor

Scott A. Rivkees, MD State Surgeon General

Vision: To be the Healthiest State in the Nation

October 2, 2020

John Hofstad Okaloosa County Administrator 1250 Eglin Parkway, Suite 100 Shalimar, FL 32579 CONTRACT#: C20-2952-BCC
OKALOOSA COUNTY HEALTH DEPARTMENT
CARES ACT MEMORANDUM OF UNDERSTANDING
EXPIRES: 12/30/2020

Dear Mr. Hofstad:

The State of Florida Department of Health, Okaloosa County Health Department (OCHD) is respectively asking to reconfigure the approved staffing plan as outlined in the CARES ACT Memorandum of Understanding (Contract No. C20-2952-BCC) that was fully executed August 7, 2020.

Originally, the State of Florida Department of Health (FDOH) approved and provided funding to the OCHD for thirty OPS COVID response positions. As of September 17,2020, the FDOH put a freeze on hiring these positions. At the time of the freeze, twenty-four of the thirty positions were filled. The OCHD lost the six vacant positions and their corresponding funding. The functions of the lost positions are integral to the OCHD's COVID response activities.

We also have a need for a lead worker within the Contract Tracer function and two additional Epidemiologists. These changes are also included in our staffing reconfiguration request.

Please consider the changes summarized on the following page. If approved, the changes will allow us to staff these high priority functions while staying within the staffing plan included in the CARES ACT Memorandum of Understanding.

If you have any questions, please feel free to contact me at (850)833-9245.

Sincerely,

Karen A. Chapman, MD, MPH

Director

Okaloosa County Health Department

Approved

John Hofstad Hofstad Date: 2020.10.12

Digitally signed by John Hofstad Date: 2020.10.12 09:25:33 -05'00'

John Hofstad

Okaloosa County Administrator



### FDOH-OKALOOSA PROPOSED STAFFING CHANGES

							ESTIMATED								
							CURRENT								
FUNCTION	OPS WORKING TITLE	CURRENT QTY CHAN	UPDATEI GE QTY	START DATE	NAME	BUDGETED HOURLY	Hours	Salary	Fringe @ 28%	Total	Hours	Striary	Fringe # 28%	Total	(INCREASE)/ DECREASE
Call Center Operator	Government Operations Consultant I	18	-5 1	3 10/2/2020	VACANT	22.00	488.00	193.248.00	54 109 44	247.357.44				MALE NEWS	[68,710.40]
17 Help Desk	Government Operations Consultant I	1	-1	0 10/2/2020	VACANT	22.00	488.00	10,736.00	3,006.08	13,742.08					(13,742.08)
Data Clerk	Senior Clerk	6	2	8 10/2/2020	VACANT	15.00	488.00	43,920.00	12,297.60	56,217.60		***********		Activities (1)	18,739.20
Epidemiologists	Biological Scientist IV	0	2	2 10/2/2020		22.50	***************************************	M. M. M. When it comments in incomments.		one en regione de sons à sons à la sons des entrement	1984486				28,108.80
Licensed Practical Nurse	Licensed Practical Nurse	0	2	2 10/2/2020	11 11 11 11 11 1 1 1 1 1 1 1 1 1 1 1 1	20.00									24,985.60
Health Educator	Health Educator	6	-3	3 10/2/2020	VACANT	16.50	488.00	48,312.00	13,527.36	61.839.36		hookikx, ::::::::::::::::::::::::::::::::::::		All the second second	(30,919.68)
Contact Tracers	Biological Scientist III	10	2 1	2 10/2/2020	VACANT	21.00	488.00	102,480.00	28,694.40	131,174.40	18294 17185 3344 4475 454		gardenja ju destitutus siiridentiisi		26,234,88
Contact Tracers Lead	Biological Scientist IV	0	1	1 10/2/2020	/ A COLON CO. C. C. APPROX AN CA.	22.50		AAA AA	**********************	a	1111	indicate and services	Maria de la composição de	THE PERSONAL PROPERTY.	14.054.40
		41	0 4	1				398,696.00	111,634.88	510,330.88	nkiran likusi				(1,249.28)

#### Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis Governor

Scott A. Rivkees, MD State Surgeon General

Vision: To be the Healthiest State in the Nation

September 11, 2020

John Hofstad Okaloosa County Administrator 1250 Eglin Parkway, Suite 100 Shalimar, FL 32579 CONTRACT#. C20-2952-BCC
OKALOOSA COUNTY HEALTH DEPARTMENT
CARES ACT MEMORANDUM OF UNDERSTANDING
EXPIRES: 12/30/2020

Dear Mr. Hofstad:

The State of Florida Department of Health, Okaloosa County Health Department is respectively asking to redirect funding outlined in the CARES ACT Memorandum of Understanding (Contract No. C20-2952-BCC) that was fully executed August 7, 2020.

As of August 31, 2020, the Okaloosa County Health Department has an estimated lapse of OPS Salary & Fringe in the amount of \$259,901. We are requesting to redirect a portion of this lapse to purchase refrigerator/freezer storage equipment needed to accommodate COVID-19 vaccine temperature specifications. CDC vaccine storage requirements include temperature monitoring equipment which is included in the redirect. It is listed as Security Installation in the estimated cost below. The attached document from CDC Vaccine Storage and Handling Toolkit (January 2020) Chapter 3 outlines the requirements for temperature monitoring.

Freezer/Refrigerator						
Description	QTY	Price	Total Price			
Ultra Low 18.6 CF pharmacy freezer		1 \$11,006.00	\$11,006.00			
Standard upright pharmacy freezer 21 CF		1 \$5,759.00	\$5,759.00			
Pharmacy Refrigerator 26CF, Vaccine Glass Door		2 \$2,930.82	\$5,861.64			
Security installation		1 \$2,294.2	L \$2,294.21			
Total Cost			\$24,920.85			

The following page includes the estimated lapse calculation and purchase justification.

If you have any questions, please feel free to contact me at (850) 833-9075.

Sincerely,

County Administrator Approval requested

John Hofstad Date: 2020.09.14 10:47:16

Karen A. Chapman, MD, MPH

Director

Okaloosa County Health Department

Attachment 1

Fiorida Department of Health in OKALOOSA COUNTY 221 Hospital Dr. NE, Ft Wallon Beach, FL 32548 PHONE: 850/833-9240 • FAX 850/833-9252 www.healthyokaloosa.com



OPS Per	sonnel	COVID OPS ESTIMATES								
Function	Class Tille	Hourly ROP	Lapsed Hours 8/7 - 8/31	Salary	Fringe &	Total by Position	Qty	Total		
Call Center Operator/										
IT Help Desk	GOCT	22.00	106	2,992.00	837.76	3,829.76	82. 9.94	84,254.72		
Call Center Team Leads	GOC II	22.50	1.39	3,060,00	856.80	3,916,80	0.00	7.833.60		
Data Clerk	Senior Clerk	15.00	136	2,040,00	571.20	2.611.20	9.58	18,278,40		
Registered Nurses/	Nursing Program Specialist/Biological									
<b>Epidemiologist</b>	Scientist IV	25.00	14. 18.5	3,400.00	952.00	4,352,00	55.00	95,744,00		
Health Educator	Health Educator	16.50	11.50	2,244.00	628.32	2,872,32	51. 在建榜	17,233.92		
Contact Tracers	Biological Scientist III	21.00		2,856.00	799.68	3,655.68	1020	36,556,80		
Grand TOTAL - ESTIMATED	LAPSE thru 8/31/20		•			:	69.00	259,901.44		

#### Purchase Justification:

Vaccines are required to be stored at certain temperatures to maintain their viability and effectiveness when administered. CDC guidelines specify minimum and maximum temperature ranges for refrigerated vaccine between 2° C and 8° C (36° F and 46° F). Freezers for frozen vaccine should maintain temperatures between -50° C and -15° C (-58° F and +5° F). Planning assumptions for COVID-19 vaccine include preparing for refrigerated/frozen/ultra-cold temperature storage capacity. The units on page 1, meet these planning assumptions.

Temperature monitoring for these units and all units at DOH-Okaloosa follow CDC and the State of Florida Immunization guidelines. This includes temperature monitoring devices (TMD) such as digital data logger (DDL) which records current temperature reading at per determined intervals. This provides detailed information on all temperatures recorded at these preset intervals and is helpful to determine vaccine viability if temperature excursions occur. Additionally, all units at DOH-Okaloosa are connected to our remote alarm system should temperatures fall out of range after hours. Our security monitoring company notifies an on-call person who responds to any out of range temperatures and takes action, such as moving the vaccine to an operational unit in order to prevent vaccine loss



# Vaccine Storage and Handling Toolkit



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Disclaimer: This document provides best practices and Centers for Disease Control and Prevention (CDC) recommendations on storage, handling, and transport of vaccines and diluents. It also provides information on vaccine storage and handling requirements related to the Vaccines for Children program. Use of trade names and commercial sources in this toolkit is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), or CDC.

### Introduction

Proper vaccine storage and handling are important factors in preventing and eradicating many common vaccine-preventable diseases. Yet, each year, storage and handling errors result in revaccination of many patients and significant financial loss due to wasted vaccines. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in inadequate immune responses in patients and poor protection against disease. Patients can lose confidence in vaccines and providers if they require revaccination because the vaccines they received may have been compromised.

This toolkit provides information, recommendations, and resources to assist you in properly storing and handling your vaccine supply. The Centers for Disease Control and Prevention (CDC) Vaccine Storage and Handling Toolkit brings together best practices from the <u>Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization</u>,\* product information from vaccine manufacturers, and results of scientific studies. Implementing these best practices and recommendations will help protect your patients, safeguard your vaccine supply, and avoid the unnecessary costs of revaccinating patients and replacing expensive vaccines.

For specific, detailed storage and handling protocols for individual vaccines, always refer to the manufacturers' product information and <u>package inserts</u>,\* or contact the manufacturer directly.

### **Vaccines for Children Program**

The Vaccines for Children (VFC) program provides vaccines at no cost to eligible children. VFC providers are important partners in making sure VFC-eligible children receive viable, properly handled vaccine.

This toolkit provides general background information on many of the VFC storage and handling requirements and illustrates best practices essential to safeguarding the public vaccine supply.

If you are a VFC provider or receive other vaccines purchased with public funds, consult your state or local immunization program (referred to throughout this document as "immunization program"\*) to ensure you are meeting all mandatory storage and handling requirements that are specific or tailored to your jurisdiction.

You may see vendors use terms such as "VFC-compliant," "CDC-compliant," or "satisfies VFC requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC or the VFC program has independently assessed and verified the quality of these products. CDC/VFC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that neither CDC nor the VFC program has validated any product or service for compliance with CDC or VFC program requirements or standards.

\*ACIP recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html

Manufacturers' package inserts: www.immunize.org/packageinserts/

Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

### Introduction

### How to Use the Vaccine Storage and Handling Toolkit

This toolkit outlines CDC recommendations for vaccine storage and handling.

This list shows the icons you will see throughout the toolkit and their meanings:

### ICON DESCRIPTION



CDC Recommendation - CDC recommends this as a minimal action to protect your vaccine supply.



CDC Best Practice - CDC recommends best practices as additional actions, practices, and procedures to enhance protection of your vaccine supply.

Additional CDC vaccine storage and handling information is available at:

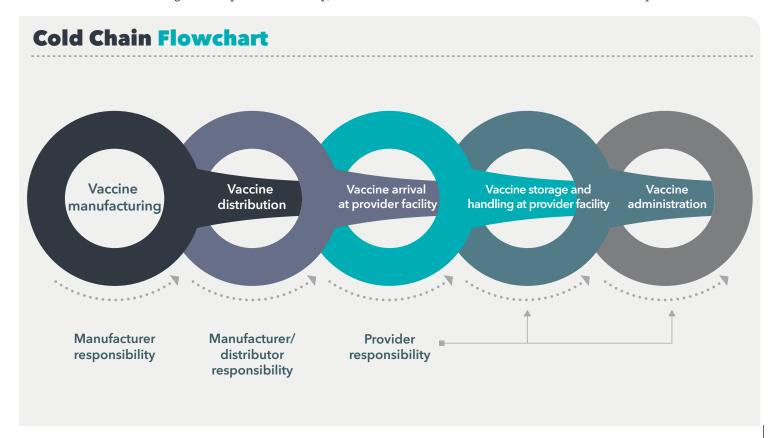
- Vaccine storage and handling home page: <u>www.cdc.gov/vaccines/recs/storage/default.htm</u> (sign up for notifications about updates)
- Educational webinars and continuing education for health care providers: www.cdc.gov/vaccines/ed/courses.html
- Contact information for state/local immunization programs: www.cdc.gov/vaccines/imz- managers/awardee-imz-websites.html
- E-mail specific questions to CDC: <u>NIPInfo@cdc.gov</u>

## **SECTION ONE:** Vaccine Cold Chain

Proper vaccine storage and handling play critical roles in efforts to prevent vaccine-preventable diseases. Vaccines exposed to storage temperatures outside the recommended ranges may have reduced potency, creating limited protection and resulting in the revaccination of patients and thousands of dollars in wasted vaccine.

### Proper storage and handling begin with an effective vaccine cold chain.

A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and correct storage at the provider facility, and ends with administration of the vaccine to the patient.



### If the cold chain is not properly maintained, vaccine potency may be lost, resulting in a useless vaccine supply.

Vaccines must be stored properly from the time they are manufactured until they are administered. Potency is reduced every time a vaccine is exposed to an improper condition. This includes overexposure to heat, cold, or light at any step in the cold chain. Once lost, potency cannot be restored.

Exposure to any inappropriate conditions can affect potency of any refrigerated vaccine, but a single exposure to freezing temperatures (0° C [ $32^{\circ}$  F] or colder) can actually destroy potency. Liquid vaccines containing an adjuvant can permanently lose potency when exposed to freezing temperatures.

### **SECTION ONE:** Vaccine Cold Chain

#### When the cold chain fails

Assuring vaccine quality and maintaining the cold chain are shared responsibilities among manufacturers, distributors, public health staff, and health care providers.

An effective cold chain relies on three main elements:

- » A well-trained staff
- » Reliable storage and temperature monitoring equipment
- » Accurate vaccine inventory management

Results of a cold chain failure can be costly.<sup>1,2,3</sup> ACIP's General Best Practice Guidelines for Immunization states, "vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated."<sup>4</sup>

A break in the cold chain can mean extra doses for patients, increased costs for providers, and damage to public confidence in vaccines.

More importantly, patients refusing revaccination can remain unprotected from serious, vaccine-preventable diseases.

Vaccine appearance is not a reliable indicator that vaccines have been stored in appropriate conditions. For example, inactivated vaccines—even when exposed to freezing temperatures—may not appear frozen, giving no indication of reduced or lost potency.

By following a few simple steps and implementing CDC-recommended storage and handling practices, providers can ensure patients receive high-quality vaccine that has not been compromised.

- 1. Department of Health and Human Services, Office of Inspector General. Vaccines for Children Program: Vulnerabilities in Vaccine Management, June 2012, oig.hhs.gov/oei/reports/oei-04-10-00430.asp.
- 2. Gazmararian JA, Oster NV, Green DC, Schuessler L, Howell K, et al. Vaccine storage practices in primary care physician offices: assessment and intervention. Am J Prev Med 2002;23(4):246-53.
- 3. Bell KN, Hogue CJR, Manning C, Kendal AP. Risk factors for improper vaccine storage and handling in private provider offices. *Pediatrics* 2001;107(6):1–5.
- 4. Centers for Disease Control and Prevention. ACIP's General Best Practice Guidelines for Immunization, <a href="https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html">https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html</a>.

# SECTION TWO: Staff and Training

Vaccine storage and handling practices are only as effective as the staff that implements them. Staff that is well-trained in general storage and handling principles and organization-specific storage and handling standard operating procedures (SOPs) is critical to ensuring vaccine supply potency and patient safety.

### **Staff Training**

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and be familiar with your facility's storage and handling SOPs. If you are a VFC provider or have vaccines purchased with public funds, contact your <a href="mmunization program">immunization program</a>\* for specific state requirements related to training, policies, and procedures.

### **Online Training Resources**

CDC's <u>You Call the Shots: Vaccine Storage and Handling</u><sup>†</sup> is a free, online training module focused on storage and handling requirements.

Check with your <u>immunization program</u>\* and professional organizations to see what vaccine storage and handling training resources they offer.

### Storage and Handling SOPs

CDC recommends your facility develop and maintain clearly written, detailed, and up-to-date storage and handling standard operating procedures (SOPs). SOPs will help your facility stay organized, serve as a reference and training tool, and assure proper vaccine management. SOPs help ensure proper procedures are followed and problems are identified, reported, and corrected. SOPs should also provide guidance for emergencies such as equipment malfunctions, power failures, or natural disasters.

Storage and handling plans and SOPs should contain plans and information for three major areas (see the <u>Vaccine</u> Storage and Handling SOP Worksheet):

- General information—include contact information for vaccine manufacturers, equipment service providers, and important facility staff, as well as job descriptions, regularly used forms, and staff training requirements
- Routine storage and handling SOPs—include information for all aspects of vaccine inventory management, from ordering to monitoring storage conditions
- Emergency vaccine storage, handling, and transport SOPs—outline steps to be taken in the event of equipment malfunctions, power failures, natural disasters, or other emergencies that might compromise vaccine storage conditions

Worksheets to assist you in developing your organization's routine and emergency SOPs are located in the resources section.

- Train staff on routine vaccine storage and handling and emergency SOPs. Keep SOPs near vaccine storage units and make sure staff knows where to find them. Document all training completed with dates and participant names.
- Storage and handling training should be completed:
  - As part of new employee orientation
  - · Annually as a refresher for all staff involved in immunization and vaccine storage and handling activities
  - · Whenever new vaccines are added to inventory
  - · Whenever recommendations for storage and handling of vaccines are updated

\*Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

<sup>†</sup>You Call the Shots: Vaccine Storage and Handling: <a href="www.cdc.gov/vaccines/ed/youcalltheshots.html">www.cdc.gov/vaccines/ed/youcalltheshots.html</a>

### **SECTION TWO:** Staff and Training

#### **Vaccine Coordinator Recommendations**



Designate a primary vaccine coordinator. This person will be responsible for ensuring all vaccines are stored and handled correctly and should be an expert on your facility's storage and handling SOPs.

Coordinator responsibilities should include:

- Ordering vaccines
- · Overseeing proper receipt and storage of vaccine
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording minimum/maximum temperatures at start of each workday<sup>‡</sup>
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
- Removing expired vaccine from storage units
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all documentation, such as inventory and temperature logs
- · Organizing vaccine-related training and ensuring staff completion of training
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport (when necessary) per SOPs
- Overseeing emergency preparations per SOPs:
  - Tracking inclement weather conditions<sup>§</sup>
  - Ensuring appropriate handling of vaccines during a disaster or power outage

Coordinator responsibilities may be completed by the coordinator or delegated to appropriate staff. Ensure the coordinator has trained the delegate(s) and documented competency for the specific task(s) assigned.



### Staff Training and **SOP Best Practices**

- » Review and update SOPs annually.
- » Appoint an alternate vaccine coordinator to act in the absence of the primary coordinator.
- » The alternate coordinator, like the primary coordinator, should be an expert in routine and emergency SOPs.

<sup>‡</sup>This is a VFC provider requirement.

\*The Federal Emergency Management Agency (FEMA) offers a wide range of information on disaster preparedness: www.fema.gov/. The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/.

The National Oceanic and Atmospheric Administration (NOAA) provides up-to-date information on U.S. weather conditions: www.weather.gov/ www.goes.noaa.gov/

It is important your facility has proper storage and monitoring equipment that is set up correctly, maintained appropriately, and repaired as needed. This equipment protects patients from inadvertently receiving compromised vaccine and your facility against costs of revaccinating patients, replacing expensive vaccines, and losing patient confidence in your practice.

### Vaccine Storage Units: Refrigerator and Freezer Recommendations

There are several types of vaccine storage units available. <u>Purpose-built units</u> are specifically designed to store vaccines. However, household-grade units are also an acceptable option for vaccine refrigeration under the right conditions.

Use purpose-built or pharmaceutical-grade units designed to either refrigerate or freeze. These units can be compact, under-the-counter style or large.

Purpose-built units, sometimes referred to as "pharmaceuticalgrade," are designed specifically for storage of biologics, including 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.

Household-grade units can be an acceptable alternative to pharmaceutical-grade vaccine storage units. As the name implies, these units are primarily designed and marketed for home use. However, the freezer compartment of this type of unit is not recommended to store vaccines and there may be other areas of the refrigerated compartment that should be avoided as well. If your facility provides frozen vaccine, a separate freezer unit is necessary.

# Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.

These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing vaccines, even when used for temporary storage. (Note: Not all small storage units are dormitory- or bar-style units. Compact, purpose-built units for biologics can be used to store vaccines.)

### Storage unit doors

A door that is not sealed properly or left open unnecessarily not only affects the temperature in a unit, it also exposes vaccines to light, which can reduce potency of some vaccines. Consider using safeguards to ensure the doors of the unit remain closed—for example, self-closing door hinges, door alarms, or door locks.



### **Storage Unit Best Practices**

To fully ensure the safety of vaccines, equipment should include a recommended unit with enough space to accommodate your maximum inventory without crowding.

### Storage Unit Placement

Good air circulation around the outside of the storage unit is important. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover of the motor compartment. The unit should be firm and level, with the bottom of the unit above the floor. Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. If not secured properly, unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find most units work best when placed in an area with standard indoor room temperatures, usually between 20° C and 25° C (68° F and 77° F). Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

You may see vendors use terms such as "VFC-compliant," "CDC-compliant," or "satisfies VFC requirements" in their marketing materials or on their websites. In this context, "compliance" and related terms may lead consumers to incorrectly believe that CDC or the VFC program has independently assessed and verified the quality of these products. CDC/VFC is not authorized to assess, validate, verify, or endorse the products or services of private companies. Should you encounter this type of language in vendor marketing materials, please keep in mind that neither CDC nor the VFC program has validated any product or service for compliance with CDC or VFC program requirements or standards.

### Stabilizing Temperatures in New and Repaired Units

It may take two to seven days to stabilize the temperature in a newly installed or repaired refrigerator and two to three days for a freezer.

Before using a unit for vaccine storage, check and record the minimum and maximum temperatures each workday for two to seven days. If temperatures cannot be recorded digitally, check and record temperatures a minimum of two times each workday. Once you have two consecutive days of temperatures recorded within the recommended range, your unit is stable and ready for use.

### **Temperature Ranges**

Refrigerators should maintain temperatures between  $2^{\circ}$  C and  $8^{\circ}$  C ( $36^{\circ}$  F and  $46^{\circ}$  F). Freezers should maintain temperatures between  $-50^{\circ}$  C and  $-15^{\circ}$  C ( $-58^{\circ}$  F and  $+5^{\circ}$  F). Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

Consult the owner's manual for instructions on how to operate the thermostat. Thermostats are marked in various ways and, in general, show levels of coldness rather than temperatures. The only way to know the temperature where vaccines are stored is to measure and monitor it with a temperature monitoring device.

### Temperature Monitoring Device (TMD)

Every vaccine storage unit must have a TMD. An accurate temperature history that reflects actual vaccine temperatures is critical for protecting your vaccines. Investing in a reliable device is less expensive than replacing vaccines wasted due to the loss of potency that comes from storage at out-of-range temperatures.

© CDC recommends a specific type of TMD called a "digital data logger" (DDL). A DDL provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range (referred to as a "temperature excursion"). Unlike a simple minimum/maximum thermometer, which only shows the coldest and warmest temperatures reached in a unit, a DDL provides detailed information on all temperatures recorded at preset intervals.

Many DDLs use a <u>buffered temperature probe</u>, which is the most accurate way to measure actual vaccine temperatures. Temperatures measured by a buffered probe match vaccine temperatures more closely than those measured by standard thermometers, which tend to reflect only air temperature.

Temperature data from a DDL can either be downloaded to a computer using special software or retrieved from a website. The software or website may also allow you to set the frequency of temperature readings. Reviewing DDL data is critical for vaccine viability, so it is important to decide whether independent software or a website program works best for your facility.

Weep the data for three years so it can be analyzed for long-term trends and/or recurring problems. Those receiving public vaccine may need to keep records longer as required by state regulations.

### Use a DDL or other appropriate TMD for:

- Each vaccine storage unit
- Each transport unit (emergency or non-emergency)

Have at least one backup TMD in case a primary device breaks or malfunctions.

### Use DDLs with the following features:

- Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol, glass beads, sand, or Teflon®)†
- Alarm for out-of-range temperatures
- Low-battery indicator<sup>†</sup>

Probes that are permanently embedded in a buffer are acceptable as long as the temperature monitoring system for the entire unit can be calibration-tested.

†Since these devices are typically battery-operated, have a supply of extra batteries on hand.

- Current, minimum, and maximum temperature display
- Recommended uncertainty of +/-0.5° C (+/-1° F)
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes

Use DDLs with a current and valid Certificate of Calibration Testing.

### **Certificate of Calibration Testing**

Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards.

### A DDL's Certificate of Calibration Testing should include:

- Model/device name or number
- · Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument is in tolerance)
- Recommended uncertainty of +/-0 .5° C (+/-1° F) or less

To determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- Performed by a laboratory accredited by <u>International Laboratory Accreditation Cooperation (ILAC) Mutual</u> <u>Recognition Arrangement (MRA) signatory body</u>
- Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- Meets specifications and testing requirements for the <u>American Society for Testing and Materials (ASTM)</u> <u>Standard E2877 Tolerance Class F or higher</u>
- Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points
- Calibration testing should be done every one to two years or according to the manufacturer's suggested timeline. TMDs can experience a "drift" over time, affecting their accuracy. This testing ensures the accuracy of the device continues to conform to nationally-accepted standards.

Mishandling a TMD can affect its accuracy. If a TMD is dropped, hit against the side of a storage unit, or is potentially damaged in any way, its accuracy should be checked against another calibrated TMD. If there is any question about accuracy, the device should be replaced or sent for calibration testing.

#### Monitoring Vaccine Temperature and Vaccine Equipment

Monitoring vaccine storage equipment and temperatures are daily responsibilities to ensure the viability of your vaccine supply and your patients. Implementing routine monitoring activities can help you identify temperature excursions quickly and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients.

Certain types of TMDs have significant limitations and should not be used to measure temperatures in a vaccine storage unit. These devices can be difficult to read and, because they only show the temperature at the exact time they are checked, may fail to detect temperatures outside the recommended range.

### CDC does not recommend the following TMDs:

- » Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
- » Bimetal stem TMDs
- » TMDs used for food
- » Chart recorders
- » Infrared TMDs
- » TMDs that do not have a current and valid Certificate of Calibration Testing

**Please note:** Some devices sold in hardware and appliance stores are designed to monitor temperatures for household food storage. They are not calibrated and not accurate enough to ensure vaccines are stored within the correct temperature range. Using these devices can pose a significant risk of damaging vaccines.

\*Battery changes may affect temperature accuracy and may warrant checking against a known, calibrated TMD. Check with the device's manufacturer for specific information on battery changes.

### **Power Supply**

Even with appropriate equipment and temperature monitoring practices in place, power disruption can result in destruction

Food and beverages should never be stored in the unit with vaccines.

of the entire vaccine supply. Precautions should always be taken to protect the storage unit's power supply.

- Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that turns the power off.
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.
- Post "DO NOT UNPLUG" warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units.
- Label fuses and circuit breakers to alert people not to turn off power to a storage unit.
- ☑ Use caution when using power outlets that can be tripped or switched off and avoid using:
  - Built-in circuit switches (may have reset buttons)
  - · Outlets that can be activated by a wall switch
  - Multioutlet power strips

If built-in circuit switches or power strip surge protection must be used, make sure the power strip is rated to carry the maximum current as specified by the manufacturer of the refrigerator or freezer. Contact the unit manufacturer for any additional questions or guidance regarding circuit switches, power strips, or surge protection.

If the entire storage unit is affected by a temperature excursion because of a power supply issue or unit malfunction, refer to your facility's emergency SOPs.

### Organizing and Storing Vaccine

Correctly organizing and placing vaccines in a storage unit helps prevent conditions that could reduce vaccine potency or cause vaccine failure.



### Temperature Monitoring

Regular checks provide an opportunity to inspect the storage unit, reorganize any misplaced vaccines, and remove any expired vaccines. Check the temperature each time vaccines are accessed in the unit.

Review storage unit temperature readings and review continuous DDL software or website information weekly for changes in temperature trends that might require action.

If there appears to be any fluctuation in temperature, troubleshoot the problem based on additional information provided in this toolkit, manufacturer manuals, and/or your office storage and handling SOPs.

- Store vaccines in their original packaging with lids closed until ready for administration. Vials and manufacturer-filled syringes should always be stored in their original packaging. Loose vials or syringes may be exposed to unnecessary light, potentially reducing potency, and may be more difficult to track for expiration dates. They may also impact inventory management and increase the risk of administration errors because they may be confused with other vaccines. For certain purpose-built units, it is recommended that vaccine be stored outside of the packaging. If this is the case, follow the manufacturer's quidance for vaccine storage.
- Check and record storage unit minimum and maximum temperatures at the start of each workday. If your TMD does not read min/max temperatures, then check and record the current temperature a minimum of 2 times per workday (at the start and end of the workday).

#### Record:

- Minimum/maximum temperature
- Date
- Time
- · Name of person who checked and recorded the temperature
- · Any actions taken if a temperature excursion occurred
- · If a reading is missed, leave a blank entry in the log.

#### **Temperature Excursions**

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges in the manufacturers' package inserts\* is considered a temperature excursion. In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out of range, as well as information about the vaccine in question, to determine whether a vaccine is likely to still be viable.

### ODC recommends the following steps in the event of a temperature excursion:

- 1. Any staff who hears an alarm or notices a temperature excursion on the DDL should notify the primary or alternate vaccine coordinator immediately or report the problem to their supervisor.
- 2. Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a seperate container apart from other vaccines (do not discard these vaccines).



### Organizing and Storing Vaccine

To confirm vaccines are stored correctly and to minimize the risk of administration errors, implement the following practices:

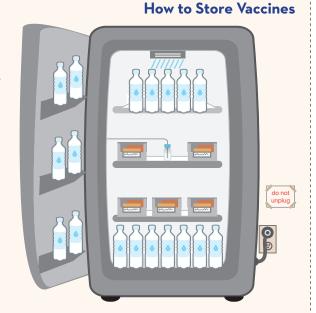
- » Store each type of vaccine or diluent in its original packaging and in a separate container.
- » Position vaccines and diluents two to three inches from the unit walls, ceiling, floor, and door. If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow, such as directly under cooling vents, in deli, fruit, or vegetable drawers, or on refrigerator door shelves. The instability of temperatures and air flow in these areas may expose vaccines to inappropriate storage temperatures.
- » Label shelves and containers to clearly identify where each type of vaccine and diluent is stored.
- » Store vaccines and diluents with similar packaging or names or with pediatric and adult formulations on different shelves.
- » Whenever possible, store diluent with the corresponding refrigerated vaccine. Never store diluent in a freezer.
- » Avoid placing or storing any items other than vaccines, diluents, and water bottles inside storage units.
  - If other medications and biological products must be stored in the same unit as vaccines, they must be clearly marked and stored in separate containers or bins from vaccines.
    - —Potentially contaminated items (e.g., blood, urine, stool) should be properly contained and stored below vaccines due to risk of contamination from drips or leaks.
    - —The freezer of a household-grade unit may be used for non-vaccine, medical storage, so long as the use does not compromise the temperature range within the refrigerator compartment where vaccine is stored.
- » Arrange vaccines and diluents in rows and allow space between them to promote air circulation.
- » Place vaccines and diluents with the earliest expiration dates in front of those with later expiration dates.

<sup>\*</sup>Manufacturers' vaccine package inserts: www.immunize.org/fda/



Place water bottles on the top shelf and floor and in the door racks. Putting water bottles in the unit can help maintain stable temperatures caused by frequently opening and closing unit doors or a power failure.

Water bottles are not recommended for use with certain pharmaceutical-grade and purpose-built units. For such units, follow the manufacturer's guidance.



- 3. The vaccine coordinator, supervisor, or if necessary, the person reporting the problem should begin to document the event with the following information<sup>s</sup>:
  - a. Date and time of the temperature excursion
  - b. Storage unit temperature as well as room temperature, if available (including minimum/maximum temperatures during the time of the event, if available)
  - c. Name of the person completing the report and description of the event":
    - General description of what happened
    - The length of time vaccine may have been affected, if using a DDL
    - Inventory of affected vaccines
    - List of items in the unit (including water bottles) other than vaccines
    - Any problems with the storage unit and/or affected vaccines before the event
    - Other relevant information
- 4. Implement your facility SOPs to adjust unit temperature to the appropriate range. At a minimum, check the TMD to make sure it is appropriately placed in the center of the vaccines.
- 5. Contact your immunization program and/or vaccine manufacturer(s) per your SOPs for further guidance on whether to use affected vaccines and for information about whether patients will need to be recalled for revaccination. Be prepared to provide documentation of the event (e.g., temperature log data) to ensure you receive the best guidance.
- 6. Complete your documentation of the event, including:
  - a. Action taken
    - What you did with vaccine and how long it took to take action
    - Whom you contacted and instructions received
    - What you did to prevent a similar future event
  - b. Results
    - Final disposition of affected vaccines (e.g., shortened expiration date per manufacturer, discarded, or returned)
    - Other comments

The Immunization Action Coalition has developed a <u>Temperature Monitoring Log</u> and a <u>Vaccine Storage Troubleshooting Record</u> to support these activities.

Responses from vaccine manufacturers to events depend on information given by the provider to the manufacturer. If different information about the same event is provided to the same manufacturer, this can lead to different recommendations on whether vaccine can be used or whether patients need to be revaccinated. In addition, each event is unique, and manufacturer recommendations based on existing stability data cannot be applied to future events that may appear to be similar.

### Regular Maintenance of Vaccine Storage Units and Temperature Monitoring Devices

Storage units and TMDs need regular maintenance to ensure proper operation.

Never allow vaccines to remain in a malfunctioning unit for an extended period of time. If you believe your your unit has failed, implement your emergency SOPs.

# Conduct routine maintenance for all vaccine storage units and related equipment so that your equipment functions at maximum efficiency.

- · Check seals and door hinges.
- Clean coils and other components per manufacturer direction.
- Defrost manual-defrost freezers when the frost exceeds either 1 cm or the manufacturer's suggested limit. Follow the manufacturer's instructions. While defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures.
- Clean the interior of each unit to discourage bacterial and fungal growth. Do so quickly to minimize the risk of a temperature excursion.
- Test any backup generator quarterly and have it serviced annually.

### **Troubleshooting Equipment Problems**

#### Adjusting Storage Unit Temperatures

Storage unit temperatures may need to be adjusted over time. In some situations, thermostats may need to be reset in summer and winter, depending on room temperature.

Temperature adjustments should:

- Be made by the primary or alternate vaccine coordinator, based on information from the TMD and temperature monitoring log.
- Be done at a time that is not during a busy workday when the unit door is being frequently opened and closed.

Remember that temperatures within any storage unit will vary slightly, even with normal use. Therefore, before making any adjustment:

- Confirm the unit is securely plugged into a power source.
- · Check the temperature inside the storage unit.
- Wait 30 minutes, without opening the door, to allow the temperature to stabilize and then check it again to determine if the thermostat should be adjusted.

If you believe there could be an issue with your TMD, use your backup device to confirm the temperature.

If you confirm that an adjustment is needed:

- 1. Refer to the owner's manual for detailed instructions.
- 2. Make a small adjustment toward a warmer or colder setting by turning the thermostat knob slowly to avoid going outside the correct temperature range.
- 3. Once the adjustment is made, allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
- 4. Recheck the temperature.
- 5. Repeat these steps as needed until the temperature has stabilized between 2° C and 8° C (36° F and 46° F) for a refrigerator or between -50° C and -15° C (-58° F and +5° F) for a freezer.
- 6. Consider placing additional water bottles in the unit to help improve temperature stability.

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at high risk. Use your SOPs to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

If you are using a combination storage unit, note that adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen vaccines in the refrigerator.

### Repeated Alarm Alerts

If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause. Do basic checks of the unit door, power supply, and thermostat settings. If the alarm continues to trigger or the temperature remains out of range, transfer vaccines to a backup unit as directed by your SOPs. A repair technician should check your equipment to determine the need for repair or replacement.

# **SECTION FOUR:** Vaccine Inventory Management

Proper vaccine inventory management is essential for appropriate vaccine ordering and stock rotation, and ensures your facility has the vaccines your patients need. Vaccines are expensive, so making sure they are unpacked, stored, prepared, administered, and transported correctly is critical.

Never leave a vaccine shipping container unpacked and unattended. If vaccines and diluents get too warm, they cannot be used. Be sure all staff knows that vaccine deliveries require immediate attention.

#### Vaccine Delivery

### Scheduling and Receiving Deliveries

Maintaining the cold chain is the first step in vaccine inventory management. Staff members who might accept vaccine deliveries should be trained to immediately notify the vaccine coordinator or alternate coordinator when deliveries arrive. Vaccines must always be immediately checked and stored properly upon arrival.

### **Unpacking Deliveries**

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately after they arrive. Do not place an unopened and/or unpacked shipment box in a vaccine storage unit because the cool packs shipped with the vaccine may make the packaged vaccine too cold if placed inside the storage unit.

- Immediately examine shipments for signs of damage and to guarantee receipt of the appropriate vaccine types and quantities.
  - Examine the shipping container and vaccines for signs of physical damage.
  - Check the contents against the packing list to be sure they match.
    - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
  - If the shipment includes lyophilized (freeze-dried) vaccines, make sure they came with the correct type and quantity of diluents.
  - Immediately check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
  - Immediately check the <u>cold chain monitor (CCM)</u>, a device used to monitor vaccine temperatures during transport, if one was included, for any indication of a temperature excursion during transit.

### **Vaccine Inventory Accounting**

#### **Stock Counts**

Stock records are used to determine the type and amount of vaccines your facility should stock to meet the needs of your patients. At least once a month and before placing any vaccine order, count all vaccine and diluent doses to make sure the number of doses in the storage unit matches the number of doses documented in the stock record. Always check expiration dates while counting stock and remove any expired doses immediately.



#### **Stock Records**

Use a stock record to account for and document every dose of vaccine. This record will help you keep track of your inventory and can be in either paper or electronic form. This record should be updated weekly and include the vaccine delivery information below:

- » Date of delivery and initials of the person who unpacked the box
- » Vaccine and diluent name and manufacturer
- » Number and expiration date for each lot
- » Number of doses received
- » Condition of each vaccine and diluent upon arrival
- » CCM reading if included in the shipping container
- » Number of doses used
- » Balance of remaining doses after subtracting the amount used

**Note:** State and local programs that have an immunization information system (IIS) with vaccine inventory accounting functions will require VFC providers to use the IIS to track their inventory.

### **SECTION FOUR:** Vaccine Inventory Management

### **Tally Sheets**

Tally sheets can help keep stock records up to date. Place tally sheets outside the storage unit door (or another easily accessible location), and have staff use tick marks to keep a count of every dose removed from the unit.

If the numbers in the storage unit do not match the doses documented in the stock record, enter the correct number based on your count on a separate line below the old balance on your stock record. Make a note next to the new entry indicating that your count confirmed the new balance and sign it. Use the corrected balance for calculating stock quantities in the future.

If you receive multiple doses of the same vaccine in the same <u>presentation</u> from the same lot with the same expiration date, you can document these doses as one entry

on the stock record. Indicate the total number of doses received, regardless of how many vials or syringes the doses came in. For example, if you receive 10 single-dose vials of the same vaccine with the same lot number and expiration date, you can make a single entry on the stock record, noting that 10 doses were received.

If there are discrepancies between the contents and the packing list or other concerns about the contents, immediately notify the vaccine manufacturer. If you are a VFC provider or receive vaccines purchased with public funds, contact your immunization program.\*

Diluents should be documented on a separate stock record and should equal quantities of corresponding vaccines.

At the end of each month, determine the total number of vaccine and diluent doses used that month and the amount of stock still available. At the end of each year, use your stock record to determine the number of doses received for the year and add up your monthly dose counts to get a total number of doses used. This information will help you determine your facility's needs and guide you in ordering so you can minimize future waste and reduce the need for transfer and transport of vaccines. It will also help to make sure you have a sufficient supply to meet your patients' needs.

### **Vaccine Ordering**

### Order and stock only enough vaccine to meet patient needs.

Storing a larger volume than your facility needs can increase the risk of wasting vaccines if they expire before they can be used or they are compromised in some way (e.g., due to mechanical failure of a storage unit).

Most facilities should also reorder based on patient needs after checking stock count. Vaccine orders usually arrive within one to two weeks, but there can be delays. When possible, avoid placing last-minute or rush orders to lessen the risk of running out of vaccines.



### Arranging your stock

The vaccine coordinator (or other designated person) should rotate vaccine and diluent stock at least once a week, as well as each time your facility receives a vaccine delivery. This will ensure that vaccines expiring sooner are used first.

#### Stock Rotation and Removal

Vaccine stock should be rotated and checked for expired doses regularly. Any expired vaccines and diluents should be removed immediately to avoid inadvertently administering them. Arrange stock for each vaccine type so that doses with the earliest expiration dates are placed in front of those with later expiration dates.

Contact your <u>immunization program</u>\* to find out if expired vaccines purchased with public funds can be returned.

Contact your immunization program for details about specific state or local regulations impacting this activity.

An adequate supply of vaccine varies for most providers, facilities, or immunization programs. It is recommended that reordering is done when stock has been reduced to a four week inventory.

## **SECTION FOUR:** Vaccine Inventory Management

### **Understanding Expiration Dates**

Determining when a vaccine or diluent expires is a critical step in maintaining proper storage and handling. Understanding vaccine expiration dates can help save your practice time and money.

When the expiration date has only a month and year, the product may be used up to and including the last day of that month. If a day is included with the month and year, the product may only be used through the end of that day.

In some instances, such as the examples for beyond use date (BUD) below, vaccines must be used before the expiration date on the label.

### **Beyond Use Dates**

Some vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first entered and the storage information in the package insert. If the vaccine has no BUD, use the expiration date provided by the manufacturer.

The BUD replaces the manufacturer's expiration date and should be noted on the label along with the initials of the person making the calculation. Examples of vaccines with BUDs include:

**Reconstituted vaccines** have a limited period for use once the vaccine is mixed with a diluent. This period or BUD is listed in the package insert.

**Multidose vials** might have a specified period for use once they have been entered with a needle. For example, the package insert may state that the vaccine must be discarded 28 days after it is entered. If the vial is entered on 06/01/2019, the BUD is 06/29/2019. The vaccine should not be used after the BUD.

Manufacturer-shortened expiration dates may apply when vaccine is exposed to inappropriate storage conditions. The manufacturer might determine the vaccine can still be used, but will expire on an earlier date than the date on the label.

### Vaccine Disposal

General vaccine disposal guidelines for:

- Expired or compromised vaccine—sometimes unused vaccine and diluent doses, unopened vials, expired vials, and potentially compromised vaccine may be returned for credit, even if they must be discarded. Contact your <a href="immunization program">immunization program</a>\* and/or the vaccine manufacturer for vaccine-specific information.
- Open and broken vials and syringes, manufacturer-filled syringes that have been activated, and vaccine predrawn by providers—these cannot be returned and should be discarded according to your state requirements.
- **Empty vaccine vials**—most are not considered hazardous or pharmaceutical waste and do not require disposal in a biomedical waste container. However, check and comply with your state requirements regarding disposal.

Medical waste disposal requirements may vary from state to state because they are set by state environmental agencies. Contact your <u>immunization program</u>\* or state environmental agency for guidance to ensure your facility's vaccine disposal procedures comply with state and federal regulations.

<sup>\*</sup>Contact your immunization program for details about specific state or local regulations impacting this activity.

<sup>&</sup>quot;While vials are not usually considered hazardous or pharmaceutical waste, an empty RV dispensing tube or oral applicator is considered medical waste and should be disposed of in a medical waste container.

### **SECTION FIVE: Vaccine Preparation**

### **Preparing Vaccine for Administration**

Vaccine preparation is the final step in the cold chain before administration. Handling vaccines with care is equally as important as storing them properly.



### **Vaccine administration**

- » Prepare vaccines in a designated area away from any space where potentially contaminated items are placed.
- » Only prepare vaccines when you are ready to administer them.
- » Always check expiration dates and confirm that you have selected the correct vaccine.
- » Only administer vaccines you have prepared. This is a quality control and patient safety issue and a best practice standard of medication administration.

#### Reconstitution of Vaccine

Lyophilized (freeze-dried) vaccines are in either powder or pellet form and must be mixed with a liquid (diluent) in a process known as "reconstitution" before being administered.

Diluents vary in volume and composition and are specifically designed to meet volume, pH balance, and the chemical requirements of their corresponding vaccines. Refer to the manufacturer's <u>package insert</u> for guidance on storage and handling.

### **SECTION FIVE:** Vaccine Preparation

### Diluents are not interchangeable unless specified by the manufacturer.

• Some diluents contain an antigen or an adjuvant needed for vaccine effectiveness. Even if the diluent is composed of sterile water or saline, use only the diluent supplied with the vaccine to reconstitute it.

Always check expiration dates on both diluents and vaccines before reconstituting them.



Never use a stock vial of sterile water or normal saline to reconstitute vaccines.

### Never administer vaccine reconstituted with the wrong diluent.

 If an incorrectly reconstituted vaccine has already been administered, contact your <u>immunization program</u>\* or the vaccine manufacturer for revaccination guidance.

### **Predrawing Vaccine**

Predrawing vaccines can result in waste if more are drawn up than needed.

Once vaccines only at the time of administration.
Once vaccines are inside syringes, it is difficult to tell them apart, which can lead to administration errors.
However, there may be rare instances when the only

Predrawn syringes must be stored at the manufacturerrecommended temperatures throughout the clinic day. If vaccines must be predrawn:

option is to predraw vaccine.

- Set up a separate administration station for each vaccine type to prevent medication errors.
- Draw up vaccines only after arriving at the clinic site or mass vaccination event. Drawing up doses days or even hours before administering them is not a best practice because general-use syringes are not designed for storage.
- Each person administering vaccines should draw up no more than one MDV or 10 doses at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Predraw reconstituted vaccine into a syringe only when
  you are ready to administer it. If a predrawn vaccine
  is not used within 30 minutes of being reconstituted,
  follow manufacturer guidance for storage conditions and
  time limits. A manufacturer may specify that an unused
  reconstituted vaccine can only be stored in the vial for a
  specified amount of time.
- Discard any remaining vaccine in predrawn syringes at the end of the workday.

Never transfer predrawn reconstituted vaccine back into a vial for storage.

As an alternative to predrawing vaccines, use manufacturerfilled syringes for large vaccination clinics.

<sup>\*</sup> Immunization programs: www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html

<sup>†</sup> If you are a VFC provider or have other vaccines purchased with public funds and must transfer vaccine to another facility so it can be used before it expires, contact your immunization program\* for guidance on vaccine transport.

### **SECTION SIX:** Vaccine Transport

Transport, as described in this section, involves the movement of vaccine between providers or other locations over a shorter distance and time frame and is appropriate for events such as an emergency, off-site clinic, or to ensure vaccines that are about to expire can be used rather than wasted.

### **Vaccine Transport Situations**

Vaccine transport to off-site or satellite facilities is different from both shipping and emergency transport. Shipping usually involves a professional carrier and a longer distance and time frame for moving vaccines between locations. Emergency transport usually involves relocating vaccines to protect them when a facility's ability to store vaccines is compromised (e.g., because of power loss). Depending on the situation, some transport recommendations may be the same, but there are also some differences.

#### **Vaccine Transport**

Vaccines from your supply should not be routinely transported. In instances where the transport of vaccine from your supply is necessary, take appropriate precautions to protect your supply. Vaccines should only be transported using appropriate packing materials that provide the maximum protection.

### Protecting your vaccine supply

- » Vaccine that will be used at an off-site or satellite facility should be delivered directly to that facility.
- » If delivery to the specific site is not possible, then vaccine can be transported in a stable storage unit and monitored with a TMD. If the facility doesn't have the capacity to refrigerate the vaccines, then a portable vaccine storage unit or qualified container and packout may be used with a DDL.
- » Develop an emergency plan or SOPs for transporting vaccines and include procedures and protocols for packing and transport.

Partially used vials cannot be transferred between providers OR across state lines.

- The total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
- Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution.
- Your facility should have a sufficient supply of materials needed for vaccine transport of your largest annual inventory. Appropriate materials include:
  - Portable vaccine refrigerator/freezer units (preferred option)
  - · Qualified containers and packouts
  - Hard-sided insulated containers or Styrofoam<sup>™</sup> (Use in conjunction with the <u>Packing Vaccines for Transport</u> <u>during Emergencies</u><sup>†</sup> tool. This system is only to be used in an emergency.)
  - Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to  $4^{\circ}$  C to  $5^{\circ}$  C
  - · Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container
  - TMDs for each container

Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers because most are poorly insulated and likely to be affected by room or outdoor temperatures.

The same shipping materials the vaccines were initially shipped in should rarely, if ever, be used as they are not meant for reuse. This could put the cold chain and, ultimately, the viability of the vaccine, at risk.

<sup>\*</sup> Contact your immunization program for details about specific state or local regulations impacting this activity.

<sup>†</sup> Packing Vaccines for Transport during Emergencies: <a href="www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf">www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf</a>

### **SECTION SIX:** Vaccine Transport

### **Transport of Vaccines**

It is always safest to have vaccines delivered directly to a facility with a vaccine storage unit ready to receive the shipment, but this is not always possible. If necessary, vaccines may be transported using a portable vaccine refrigerator with a temperature monitoring device placed with the vaccines. If a portable vaccine refrigerator is not available, qualified containers and packouts with a TMD in each container can be used. For transport to an off-site clinic, bring only what is needed for the workday.

### **Transport System Recommendations**

	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System <sup>†</sup>	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

### **Coolants for Transport**

PCMs at  $4^{\circ}$  C- $5^{\circ}$  C (39° F- $41^{\circ}$  F) can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions<sup>‡</sup> for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be "sweating."

In emergency situations, a system using conditioned water bottles can be used. Manufacturers' original shipping containers may also be used as a last resort in an emergency situation.

The <u>Packing Vaccines for Transport during Emergencies</u><sup>†</sup> tool describes a system in which properly conditioned frozen water bottles can be used as a coolant when transporting vaccine during emergency situations.

#### Transport Planning and Preparation

Improper packing for transport is as risky for vaccines as a failed storage unit.

Include vaccine packing and transport protocols in your routine and emergency storage and handling SOPs. At a minimum, include the following procedures and protocols:

### For all staff-facilitated transport:

- Identify trained staff to pack vaccines as well as primary and backup vehicles and drivers for transport in advance.
- Consider renting a refrigerated truck if you have a large quantity of vaccines or need to transport vaccines an extended distance.
- Take an inventory of your vaccines and record actions to protect the vaccines during transport.
- Open unit doors only when necessary and only after completing all preparation for packing and moving vaccines.

### **Emergency Transport**

In addition to the actions outlined in Transport Planning and Preparation, during an emergency also:

- » Contact the alternative vaccine storage facility before packing any vaccine to confirm it can accept your vaccines for storage.
- » Note any protective measures in place at the time of the event (water bottles, battery-powered TMD, transport to alternative facility, etc.).
- » Only open the unit door when you are ready to pack or power has been restored.
- » If an emergency can be anticipated (e.g., weather event), suspend vaccination activities before the onset of emergency conditions to allow more time for packing and transport.

 $^{\dagger} Packing \ Vaccines \ for \ Transport \ during \ Emergencies: \\ \underline{www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf}$ 

\*Manufacturers' vaccine package inserts: www.immunize.org/fda/

### **SECTION SIX:** Vaccine Transport

- If using a company or personal vehicle, only transport vaccines inside the passenger compartment (not in the trunk or bed of a truck, which may be too hot or too cold).
- Move transport containers directly to a vehicle that is already at a comfortable temperature, neither too hot nor too cold.
- · Avoid leaving containers in areas where they are exposed to direct sunlight.
- Check vaccine temperature upon arrival at the alternative vaccine storage facility and store vaccines at recommended temperatures immediately.
- Check with your <u>immunization program</u><sup>s</sup> for additional guidance and resources on emergency transport of vaccines, particularly in major emergencies.

### **Transporting Opened Multidose Vials**

If absolutely necessary, a partially used vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained. However, a partially used vial cannot be transferred from one provider to another or across state lines.

### **Transporting Diluents**

Transport diluents with their corresponding vaccines so there are always equal amounts of vaccines and diluents for reconstitution. Follow the manufacturer's guidance<sup>‡</sup> for specific temperature requirements.

If diluents stored at room temperature (20° C to 25° C [68° F to 77° F]) are going to be transported with refrigerated vaccines, they should be refrigerated in advance for as long as possible so they do not raise the container temperature when placed with refrigerated vaccines.

### Never freeze diluents—not even during transport.

Place an insulating barrier like bubble wrap between the diluents and conditioned water bottles or phase change materials.

### **Transporting Frozen Vaccines**

☑ If frozen vaccines must be transported, use a portable vaccine freezer unit or qualified container and packout that maintains temperatures between -50° C and -15° C (-58° F and +5° F).

Follow these steps for transporting frozen vaccines:

- Place a TMD (preferably with a buffered probe) in the container as close as possible to the vaccines.
- Immediately upon arrival at the destination, unpack the vaccines and place them in a freezer at a temperature range between -50 $^{\circ}$  C and -15 $^{\circ}$  C (-58 $^{\circ}$  F and +5 $^{\circ}$  F). Any stand-alone freezer that maintains these temperatures is acceptable.
- Record the time vaccines are removed from the storage unit and placed in the transport container, the temperature during transport, and the time at the end of transport when vaccines are placed in a stable storage unit.

Do not use dry ice, even for temporary storage. Dry ice might expose the vaccines to temperatures colder than -50° C (-58° F).

### **Temperature Monitoring During Transport**

Use a continuous TMD, preferably a DDL, for monitoring and recording temperatures while transporting vaccines:

- The TMD should have an accuracy of  $\pm$ -0.5° C ( $\pm$ -1° F).
- Place buffered probe material in a sealed vial directly with the vaccines.
- · Keep the TMD display on top of vaccines so you can easily see the temperature.

 $<sup>^{8}</sup>$ Immunization programs:  $\underline{www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html}$ 

<sup>\*</sup>Manufacturers' vaccine package inserts: www.immunize.org/fda/

# **SECTION SIX:** Vaccine Transport

### **Temperature Monitoring After Transport**

- Immediately upon arrival at the destination, vaccines should be stored in an appropriate storage unit with a **TMD.** Be sure to follow these guidelines for monitoring and recording storage unit temperature:
  - If the device displays min/max temperatures, this information should be checked and recorded.
  - If the device does not display min/max temperatures, then the current temperature should be checked and recorded a minimum of two times (at the start and end of the workday).

If vaccines cannot be stored in an on-site storage unit, they should be kept in the portable vaccine storage unit using the following guidance:

- Place a TMD (preferably with a probe in a thermal buffer) as close as possible to the vaccines, and check and record temperatures hourly.
- · Keep the container closed as much as possible.
- For off-site clinic use, remove only one multidose vial or 10 doses at a time for preparation and administration by each person administering vaccines.

# SECTION SEVEN: Emergency Vaccine Storage and Handling

Emergencies like equipment failures, power outages, severe weather conditions, or natural disasters usually happen without warning and may compromise vaccine storage conditions. In addition to vaccine transport planning, you should make additional plans to prepare for emergencies.\*

**Emergency Equipment Backup Options** 

### **Alternative Storage Facility**

No piece of vaccine storage equipment is infallible. At some point, equipment will fail because of a power outage, breakdown, or normal wear and tear.

Establish a working agreement with at least one alternative storage facility even if you have a generator as backup equipment. Make sure you have 24-hour access to this facility. Hospitals, long-term care facilities, state depots, the Red Cross, fire stations, packing plants, and commercial pharmacies are some of the facilities that may be able to assist you.

Your facility may also choose to have a backup storage unit so that vaccine may not have to be packed and/or moved to an alternative storage facility if the primary storage unit fails.

### **Accessing Your Building after Hours**

Emergency situations can arise outside of normal business hours, so maintain a relationship with your facility's building manager and/or security staff. Ensure all staff members are familiar with emergency SOPs, including after-hours roles and responsibilities. Your facility's storage and handling SOPs should include instructions for accessing your vaccine storage units when the building is closed with a building map/diagram and locations of:

- Spare batteries
- · Flashlights
- Keys
- Locks
- Circuit breakers
- · Emergency transport equipment and materials

Keep information on after-hours building access and security procedures with the SOPs, with building management and security staff, if appropriate, and also make sure relevant staff has copies of this information available at home.

Vaccines may remain inside a nonfunctioning unit as long as appropriate temperatures are maintained. Monitor your DDL to determine when additional action should be taken.

### Generators and backup battery power sources

Having an on-site generator(s) prevents the need to transport vaccines to an alternative storage facility during a power outage.

- » Keep sufficient fuel on hand to continuously run the generator for at least 72 hours.
- » A generator should be tested quarterly and serviced annually.

A backup battery power source can be used in lieu of a generator.

- » Backup battery power sources should be tested quarterly and serviced annually.
- » Check the manufacturer's guide for testing procedures and maintenance schedules.

### If an alternative vaccine storage facility is not available

If you cannot find an alternative vaccine storage facility within a reasonable distance, or if you cannot reach your alternative facility, you can use qualified containers and packouts and portable vaccine refrigerator/freezer units (if power source is available) using the <u>Packing Vaccines for Transport during Emergencies system</u>. Always place a TMD with the vaccines and carefully monitor the TMD to ensure vaccines remain within the appropriate temperature range. Temporary storage containers should remain closed, and vaccines can only be stored safely for as long as the containers are validated to maintain proper storage temperatures.

The Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) offers information concerning the storage and use of temperature-sensitive biological products that have been involved in a temporary electrical power failure or flood conditions: <a href="https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm">www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ProductSecurity/ucm147243.htm</a>.

# SECTION SEVEN: Emergency Vaccine Storage and Handling

### **Power Outages**

### Monitoring Unit Temperature during a Power Outage

If your storage unit has an external temperature monitoring display that you can check without opening the unit door, take the following steps:

- Record room temperature (if possible) and the temperature inside the unit as soon as the power goes out.
- Record minimum and maximum temperatures reached inside the unit during the outage.
- Temperature excursions should be avoided, if possible, by using emergency plans and SOPs for transport and alternative storage. However, if temperatures have fallen outside of the recommended range, follow your procedures for temperature excursions.

If you cannot monitor the temperature inside the unit without opening the door and you do not have an alternative facility with power where the vaccines can be stored or other emergency vaccine storage SOPs, wait until power is restored and then take the following steps:

- Record the room temperature (if possible) and the temperature inside the unit.
- If using a DDL, document the length of time the power was off and the minimum and maximum temperatures during that period.
- If temperatures inside the unit have already fallen outside of the recommended range, follow your procedures for temperature excursions. Even if an excursion has occurred, move your vaccines to an alternative storage unit or location where they can be stored at appropriate temperatures, if possible. Make sure to separate and mark these vaccines "Do NOT Use" until a decision can be made about whether the vaccines can still be used.

During a power outage, only open the storage unit door if:

- » Power is restored.
- » It is determined that the vaccines need to be packed in separate storage containers and/or transported to an alternative storage facility.

### Buffered temperature probe

Temperature probe designed to prevent false readings by protecting the thermometer from sudden changes in temperature that can occur when opening a refrigerator door. A probe is "buffered" by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon®, aluminum).

### Beyond use date (BUD)

The date or time after which a vaccine should not be administered, stored, or transported. The BUD should never exceed the manufacturer's original expiration date.

### **Calibration**

Professional measurement of the accuracy of a temperature monitoring device's readings against nationally accepted standards.

### Cold chain monitor (CCM)

Generally, a single-use device that monitors the temperature inside a vaccine shipping container. CCMs should be thrown away after being checked. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer).

### Conditioned water bottles

Frozen water bottles that have been submerged under lukewarm water until the ice block inside can spin freely.

### Digital data logger (DDL)

An electronic device that records data digitally over time or in relation to location either with a built-in or external instrument or sensor.

### Diluent

A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration. Manufacturers of these vaccines also supply the matching diluent.

### Dormitory-style (bar-style) storage unit

A combination refrigerator/freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. These units have been shown to pose a significant risk of freezing vaccines, even when used for temporary storage.

### Fan-forced air circulation

Technology using powerful fans or multiple cool air vents inside the unit that promote uniform temperature and fast temperature recovery.

### Household-grade storage unit

 $\ensuremath{\mathsf{A}}$  storage unit that is primarily sold for home use.

### Lyophilized

Freeze-dried; usually referring to a vaccine that is freeze-dried into a powder or wafer.

### Minimum/maximum temperature

A vaccine storage unit's coldest and warmest temperature readings during a set period of time.

## Glossary

Phase change materials (PCMs) Engineered packing supplies to

Engineered packing supplies that help control container temperatures during vaccine transport or shipping.

Portable Vaccine Storage Unit

A type of powered refrigerator or freezer unit specifically designed for use during vaccine transport. These are passive units that require a power source to function. Please note that some active units are "qualified" to maintain desired temperatures for a set amount of time in the event of a power loss.

**Potency** 

A vaccine's strength or effectiveness; in the context of this toolkit, potency refers to a vaccine's response to environmental conditions.

Presentation

Type of packaging for a vaccine (e.g., single-dose vial, multidose vial, manufacturer-filled syringe, etc.).

Purpose-built /pharmaceutical-grade units

Units that are specifically designed to store vaccines.

Qualified container and packout

A type of container and supplies specifically designed for use when packing vaccines for transport. They are passive containers that do not require a power source and are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.

Standard operating procedures (SOPs)

A set of step-by-step instructions compiled by an organization to help workers carry out complex routine or emergency operations. SOPs aim to achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and preventing failure to comply with industry regulations and best practices.

Stand-alone storage unit

A storage unit that operates independently of any other device or system for its desired function (i.e., a refrigerator that only functions as a refrigerator or a freezer that only functions as a freezer).

Temperature excursion

Any temperature reading that is outside the recommended range for vaccine storage as defined by the manufacturer's package insert.

**Tolerance** 

Compliance with nationally accepted standards for the calibration limits of temperature monitoring equipment. The equipment can either be considered "in" or "out" of tolerance.

**Traceability** 

An unbroken chain of measurements and associated uncertainties.

Uncertainty

The quantification of the doubt about the measurement result.

# **REFERENCE:** Purpose-Built Vaccine Storage Units

Numerous vaccine storage units have entered the market that are designed specifically for the storage of vaccines. These units can take many physical forms. Some look like traditional stand-alone units, while others can take the form of dispensing or vending units, either with or without doors. Although these units may be similar to pharmaceutical-grade or medical-grade units, they are unique in that they are designed and tested to keep vaccines in appropriate storage conditions. If you are a VFC provider, your immunization program determines which purpose-built units meet VFC program requirements. Always check with your immunization program before purchasing any unit that will be used to store VFC vaccines. Features and considerations related to these types of units include the following:

### **VFC Vaccine Management**

- » Purpose-built units must have the ability to allow the user to separate public and private vaccine stock physically or virtually
- » If stock is separated virtually, an inventory printout must be accessible upon request.
- » If unable to physically remove expired vaccine from a purpose-built unit immediately, the unit must be able to make expired vaccine inaccessible.

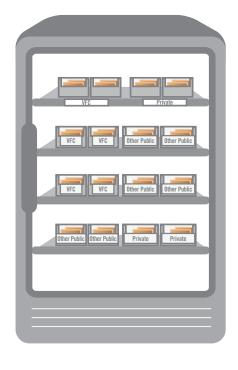
'The inventory printout should be used to answer storage and handling and inventory sections of the site visit reviewers guide.

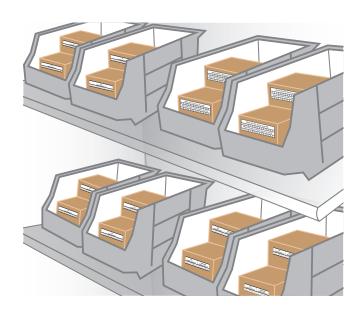
### **Temperature Monitoring**

- Many purpose-built units have multiple temperature probes or sensors. It is important that these probes or sensors have current Certificates of Calibration.
- Many of the purpose-built closed or doorless units may utilize air sensors (non-buffered probes). Since these units have very limited exposure to ambient air, the use of a buffered probe is not essential.
- Many purpose-built units will have built-in digital data loggers with electronic interfaces that will allow you to track
  the continuous temperatures and/or provide min/max temperatures. If you are a VFC provider, always check to make
  sure that these satisfy the VFC program data logger requirements.

### Vaccine Storage

- Many purpose-built units have undergone testing and temperature mapping so that the probe is in the most appropriate location.
- Although purpose-built units can have multiple temperature probes, a backup DDL is still needed for transport to a backup facility in an emergency.
- Many purpose-built units do not need water bottles to serve as thermal ballast.





Complete the following checklist and forms and store this information in an easily accessible area near the vaccine storage unit.

#### **CHECKLIST OF GENERAL INFORMATION**

- » Up-to-date contact information
  - · Primary vaccine coordinator
  - · Alternate vaccine coordinator
  - · Additional staff to assist in emergencies
  - Immunization program
  - · Vaccine manufacturers
  - Refrigerator and freezer maintenance and repair companies
  - Temperature monitoring device (TMD) companies
  - Utility/power company
  - Vaccine storage unit alarm company (if applicable)
  - Generator repair company (if applicable)
  - Sources for qualified containers and packouts

- » Descriptions of the roles and responsibilities of the primary and alternate vaccine coordinators
- » Information for each storage unit, including serial number, links to equipment websites, installation dates, and routine maintenance and repair records
- » Samples of all vaccine-related forms used in your facility
- » Protocols for staff education and training

### CHECKLIST FOR ROUTINE STORAGE AND HANDLING

- » Protocols for:
  - · Ordering and accepting vaccine deliveries
  - · Unpacking deliveries
  - Managing inventory
  - · Storing each vaccine and diluent
  - · Placing vaccines and diluents in storage units
  - · Handling vaccines prior to administration

- Disposing of vaccines and supplies
- Monitoring storage unit and temperature
- Maintaining storage equipment and TMDs
- · Responding to storage and handling problems
- Transporting vaccines to off-site/satellite facilities

### CHECKLIST FOR EMERGENCY VACCINE STORAGE, HANDLING, AND TRANSPORT

- All contact information in Checklist for General Information as well as up-to-date contact information for:
  - · Alternative vaccine storage facility (one or more)
  - Transportation of vaccines
- » Vaccine storage unit specifications (type, brand, model number, serial number)
- » Diagram of facility showing important elements, including doors, flashlights, packing materials, batteries, circuit breakers
- » Keep a copy of emergency SOPs with emergency supplies and at multiple off-site locations such as homes of vaccine coordinator and alternate coordinator and with building manager, security staff, and alternative storage facility.

- » Protocols for:
  - Monitoring vaccines during a power outage
  - Packing vaccines and diluents for emergency transport
  - Transporting vaccines to and from an alternative vaccine storage facility
  - Assessing whether vaccine can be used after an emergency
  - Accessing your building and facility after hours

Store emergency information with emergency supplies.

	STAFF CON	TACT LIST	
Name	Title	Telephone Numbers home/cell/other	E-mail Address
	Primary Vaccine Coordinator		
	Alternate Vaccine Coordinator	•	

	EMERO	GENCY STAFF CONTACT LIST
Name	Title	Telephone Numbers home/cell/other E-mail Address
	Title	Home/cen/other E-mail Address
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		

List contacts in order of preference. Determine whether all or certain persons on the list should be contacted or if the first person reached is sufficient.

	GENERAL RESO	URCES CONTACT LIST	
Resources	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
Local Health Department Immunization Program			
State Health Department Immunization Program			
Vaccine Manufacturers			
Refrigerator Repair Company			
Freezer Repair Company			
Utility/Power Company			
Temperature Monitoring Device Company			
Vaccine Storage Unit Alarm Company (if applicable)			
Generator Repair Company (if applicable)			

	ALTERNATIVE VA	CCINE STORAGE FACILITIES	
Alternative Vaccine Storage Facility Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address
1.			
2.			
3.			
4.			

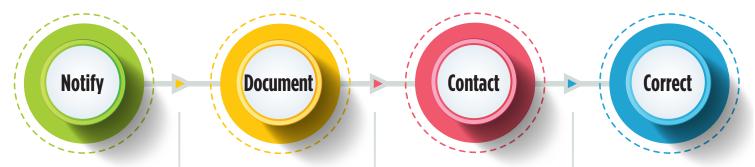
TRANSPORTATION TO ALTERNATIVE VACCINE STORAGE FACILITIES										
Emergency Resources Name/Address	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address							
Refrigeration Company										
Refrigeration Company (alternative)										
Private Vehicle										
Private Vehicle (alternative)										

PACKING MATERIAL SUPPLIERS CONTACT LIST									
Emergency Resources	Company Name	Contact Person Name/Title	Telephone Numbers home/cell/other	E-mail Address					
Portable vaccine refrigerator/freezer units									
Qualified containers and packout materials									
Qualified containers and packout materials (alternative)									
Packing materials									
Packing materials (alternative)									

VACCINE STORAGE UNIT SPECIFICATIONS										
Type of Unit (Refrigerator or Freezer)	Brand	Model Number	Serial Number							
1.										
2.										
3.										
4.										
5.										
6.										
7.										
8.										
9.										
10.										

# Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



- » Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.
- » Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.
- » Document details of the temperature excursion:
  - · Date and time
  - Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
  - Room temperature, if available
  - Name of the person completing the report
  - General description of the event (i.e., what happened)
  - If using a digital data logger (DDL), determine the length of time vaccine may have been affected
  - Inventory of affected vaccines
  - List of items in the unit other than vaccines (including water bottles)
  - Any problems with the storage unit and/or affected vaccines before the event
  - Other relevant information

- » Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).
- » Be prepared to provide the immunization program or manufacturer with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:							
Dynavax	1-844-375-4728						
GlaxoSmithKline	1-888-825-5249						
Massachusetts Biological Labs	1-888-825-5249						
MedImmune	1-877-633-4411						
Merck	1-800-672-6372						
Pfizer	1-800-438-1985						
Sanofi Pasteur	1-800-822-2463						
Seqirus	1-855- 358-8966						

- » If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- » Check the basics, including:
  - Power supply
  - Unit door(s)
  - Thermostat settings
- » If the excursion
  was the result of a
  temperature fluctuation,
  refer to the section,
  "Vaccine Storage and
  Temperature Monitoring
  Equipment," in CDC's
  Vaccine Storage and
  Handling Toolkit for
  detailed guidance on
  adjusting storage unit
  temperature to the
  appropriate range.
- » If you believe the storage unit has failed, implement your emergency vaccine storage and handling SOPs. Never allow vaccines to remain in a nonfunctioning unit following a temperature excursion.



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

# Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

۰F	۰C	۰F	°C	۰F	°C	•C	۰F	۰C	۰F
-22	-30	21	-6.1	64	17.8	-30	-22	13	55.4
-21	-29.4	22	-5.6	65	18.3	-29	-20.2	14	57.2
-20	-28.9	23	-5	66	18.9	-28	-18.4	15	59
-19	-28.3	24	-4.4	67	19.4	-27	-16.6	16	60.8
-18	-27.8	25	-3.9	68	20	-26	-14.8	17	62.6
-17	-27.2	26	-3.3	69	20.6	-25	-13	18	64.4
-16	-26.7	27	-2.8	70	21.1	-24	-11.2	19	66.2
-15	-26.1	28	-2.2	71	21.7	-23	-9.4	20	68
-14	-25.6	29	-1.7	72	22.2	-22	-7.6	21	69.8
-13	-25	30	-1.1	73	22.8	-21	-5.8	22	71.6
-12	-24.4	31	-0.6	74	23.3	-20	-4	23	73.4
-11	-23.9	32	0	75	23.9	-19	-2.2	24	75.2
-10	-23.3	33	0.6	76	24.4	-18	-0.4	25	77
-9	-22.8	34	1.1	77	25	-17	1.4	26	78.8
-8	-22.2	35	1.7	78	25.6	-16	3.2	27	80.6
-7	-21.7	36	2.2	79	26.1	-15	5	28	82.4
-6	-21.1	37	2.8	80	26.7	-14	6.8	29	84.2
-5	-20.6	38	3.3	81	27.2	-13	8.6	30	86
-4	-20	39	3.9	82	27.8	-12	10.4	31	87.8
-3	-19.4	40	4.4	83	28.3	-11	12.2	32	89.6
-2	-18.9	41	5	84	28.9	-10	14	33	91.4
-1	-18.3	42	5.6	85	29.4	-9	15.8	34	93.2
0	-17.8	43	6.1	86	30	-8	17.6	35	95
1	-17.2	44	6.7	87	30.6	-7	19.4	36	96.8
2	-16.7	45	7.2	88	31.1	-6	21.2	37	98.6
3	-16.1	46	7.8	89	31.7	-5	23	38	100.4
4	-15.6	47	8.3	90	32.2	-4	24.8	39	102.2
5	-15	48	8.9	91	32.8	-3	26.6	40	104
6	-14.4	49	9.4	92	33.3	-2	28.4		
7	-13.9	50	10	93	33.9	-1	30.2		
8	-13.3	51	10.6	94	34.4	0	32		
9	-12.8	52	11.1	95	35	1	33.8		
10	-12.2	53	11.7	96	35.6	2	35.6		
11	-11.7	54	12.2	97	36.1	3	37.4		
12	-11.1	55	12.8	98	36.7	4	39.2		
13	-10.6	56	13.3	99	37.2	5	41		
14	-10	57	13.9	100	37.8	6	42.8		
15	-9.4	58	14.4	101	38.3	7	44.6		
16	-8.9	59	15	102	38.9	8	46.4		
17	-8.3	60	15.6	103	39.4	9	48.2		
18	-7.8	61	16.1	104	40	10	50		
19	-7.2	62	16.7			11	51.8		
17							0		

Doses

Forward (In Doses)

#### STOCK RECORD

**Instructions:** Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock record every month, listing at the top the previous month's balance as the new month's starting balance.

Vaccine Type: PPSV23

Date

. Month and Year: <u>August 2018</u>

or Usage Tallied	Receiving Shipment*	Arrival Condition**	or Diluent Name	Manufacturer	(SDV, MDV, MFS)***	Lot Number	Expiration Date	Date After Reconstitution	Balance Forward	Doses Used <sup>†</sup>	Balance (Doses) <sup>††</sup>
08/02/18			BEGIN	INING BALANC	E FOR THE	MONTH			2	N/A	2
08/09/18										1	1
08/15/18	LST	G	PPSV23	Merck	MDV	03958	02/15/19	N/A	5	3	3
08/23/18							·			1	2
08/29/18										0	2
** G = vac	cines/diluent	s arrived in go	od conditio			•		Vaccine Totals	7	5	2
imm	? = condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.								Physical St Check (In I		2
*** SDV = Single-dose vial  MDV = Multidose vial  MFS = Manufacturer-filled syringe								Difference ("Balance" Physical St	minus	0	
	es number of doses administered, wasted, unusable, expired, or transferred.								Balance Ca	arried	_

Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact program staff for information. If stock records are not available from your state or local health department or an immunization information system (IIS), this stock record may be used.

### **TALLY SHEET**

**Instructions:** Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet.

Week: August 19-23, 2018 (Week 3)

Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."

Storage Location (R or F)*	Vaccine or Diluent Name	Doses Administe		Doses Wasted	Doses Expired	Doses Unusable**	Doses Transferred (Viable)***	Total
F	VAR	<del>    </del>	(8)					8
R	DTaP	<del>    </del>	(12)					12
R	НерВ	<del>         </del>	(12)					12
R	IPV	<del>         </del>	(12)		II			14
R	HepA (pediatric)	II	(2)					2
R	PPSV23	I	(1)					1

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an immunization information system (IIS), this tally sheet may be used.

<sup>\*</sup> R = Refrigerator F = Freezer

<sup>\*\*</sup> Some unusable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

<sup>\*\*\*</sup> Viable vaccine doses transferred to your state or local health department immunization program or another facility.

## Stock Record

the actual (physical count) balance next to the previous recorded balance. Note the cause of the discrepancy or if it is unknown. Start a new stock end of each month, count inventory in storage unit(s) and compare with recorded balance. If physical count and recorded balance are different, record Instructions: Use the monthly stock record to document inventory from new vaccine/diluent shipments and track weekly accounts of doses used. At the record every month, listing at the top the previous month's balance as the new month's starting balance

? = condition of vaccines/diluents questionable and state and local health department program and vaccine manufacturer(s) contacted. Document details/outcome on re record.  *** SDV = Single-dose vial  MDV = Multidose vial  MFS = Manufacturer-filled syringe  † Includes number of doses administered, wasted, unusable, expired, or transferred.  †* Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."	* The initials of the person who unpacked and ch ** G = vaccines/diluents arrived in good condition			Vaccine Type:  Date Received or Usage Tallied	
? = condition of vaccines/diluents questionable and state and local health department immunization program and vaccine manufacturer(s) contacted. Document details/outcome on reverse side of stock record.  **SDV = Single-dose vial  **MDV = Multidose vial  **MFS = Manufacturer-filled syringe  Includes number of doses administered, wasted, unusable, expired, or transferred.  **Enter the sum of "Total Doses Received/Balance Forward" minus "Total Doses Used."	The initials of the person who unpacked and checked the vaccines/diluents upon arrival G = vaccines/diluents arrived in good condition			Person Receiving Shipment*	
/diluents ques manufacturer( syringe s administered oses Received	who unpacked in good c			Arrival Condition**	
s) contacted. [s] s) wasted, unud/Balance For	d and checked		BEGINNI	Vaccine or Diluent Name	
tate and local Document det Document det sable, expired ward" minus "	d the vaccines,		BEGINNING BALANCE FOR THE MONTH	Manufacturer	
health depart ails/outcome of ails/outcome of ails/outcome of rotal Doses Us	/diluents upor		E FOR THE	Vial Type (SDV, MDV, MFS)***	
on reverse sid on reverse sid d.	n arrival		HTNOM	Month and Year:  Lot Ex  Number	-
e of stock				ear: Expiration Date	
	Vaccine Totals			Expiration Date After Reconstitution	
Physical Stock Check (In Doses)  Difference ("Balance" minus Physical Stock)  Balance Carried Forward (In Doses)				Doses Received/ Balance Forward	
Balance" al Stock) ied Joses)			N/A	Doses Used <sup>†</sup>	
				Balance (Doses) <sup>††</sup>	

program staff for information. If stock records are not available from your state or local health department or an immunization information system Some state or local health department immunization programs have developed their own stock record for immunization providers. Contact (IIS), this stock record may be used.

diluent names and indicate the storage location (refrigerator = R, freezer = F). Make a tick mark in the appropriate box for each dose of vaccine/diluent vaccine/diluent and update the totals on the appropriate stock record. File the completed tally sheet and replace with a new sheet. removed from the unit (i.e., each dose administered, wasted, unusable, expired, or transferred). At the end of the week, add the tick marks for each **Instructions:** Place a copy of this sheet on or near the refrigerator and freezer doors. Record the week (by date or week number). Write the vaccine/

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							Storage Location (R or F)*
							Vaccine or Diluent Name
							Doses Administered
							Doses Wasted
							Doses Expired
							Doses Unusable**
							Doses Transferred (Viable)***
							Total

R = Refrigerator F = Freezer

Some state or local health department immunization programs have developed their own tally sheets for immunization providers. Contact program staff for information. If tally sheets are not available from your state or local health department immunization program or an immunization information system (IIS), this tally sheet may be used

Some unusable doses (VFC vaccines or other vaccines purchased with public funds) may need to be returned to your state or local health department immunization program.

<sup>\*\*\*</sup> Viable vaccine doses transferred to your state or local health department immunization program or another facility.

# REFRIGERATOR Store vaccines between 2°C and 8°C (36°F and 46°F)

# **FREEZER** Store vaccines between -50°C and -15°C (-58°F and +5°F)

- » Keep your storage units and vaccines within the appropriate temperature ranges.
- » Check and record storage unit min/max temperatures at start of each workday. If your device does not display min/max temperatures, then check and record current temperature a minimum of 2 times (at start and end of workday). Also check current temperature before accessing and administering vaccine.
- » Take immediate action if temperatures are out of range.
- » Keep vaccines in their original packages.
- » Many vaccines should be protected from light (consult manufacturer's product information).
- » Check expiration dates and rotate your vaccine stock to keep most recent expiration dates at the front.





## WARNING LABELS: Do Not Adjust Freezer Controls



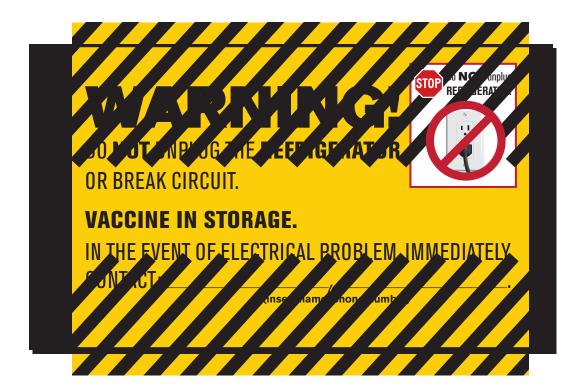


# **WARNING!**

VACCINE IN STORAGE
DO NOT STOP POWER TO CIRCUIT BREAKER
IN THE EVENT OF ELECTRICAL PROBLEM, IMMEDIATELY
CONTACT

AT

# WARNING LABELS: Warning! Do Not Unplug Refrigerator









# REFRIGERATE

**UPON ARRIVAL** 

PERISHABLE NO DELAY!

DO NOT FREEZE | KEEP FROM HEAT

# **FREEZE**

**UPON ARRIVAL** 

PERISHABLE NO DELAY!

DO NOT REFRIGERATE | KEEP FROM HEAT



**OPEN IMMEDIATELY** 

FREEZE
UPON RECEIPT

OI ON INLULII I

**DO NOT REFRIGERATE** 

# TRANSPORT LABELS: Fragile: Handle with Care







# CARES ACT MEMORANDUM OF UNDERSTANDING BETWEEN OKALOOSA COUNTY AND THE STATE OF FLORIDA DEPARTMENT OF HEALTH, OKALOOSA COUNTY HEALTH DEPARTMENT

- 1. Florida Department of Health
- Department of Health's DUNS number (see 2 C.F.R. § 200.32 "Data Universal Numbering System (DUNS) number"): 364215061
- 3. Federal Award Identification Number (FAIN):
- 4. Federal Award Date (see 2 C.F.R. § 200.39 "Federal award date"):
- 5. Period of Performance:

Effective Date: Date MOU is fully executed Termination Date: December 30, 2020

- 6. Amount of Federal Funds Obligated by this action: \$2,205,389.00
- 7. Total Amount of Federal Funds Obligated to the Department of Health: \$2,205,389.00
- Total Amount of the Federal Award Subject to this Agreement: \$2,205,389.00
- 9. Federal award project description: Coronavirus Aid, Relief, and Economic Security Act (CARES Act) must be used for necessary expenditures incurred due to the public health emergency with respect to the Coronavirus Disease 2019 (COVID-19) between March 1, 2020, to December 30, 2020.
- Name of Federal awarding agency, pass-through entity and contact information for awarding official;

Federal Awarding Agency - The Department of the Treasury

Pass Through Entity – Florida Division of Emergency Management then Okaloosa County, Florida

Contact Information for Awarding Official of Pass-Through Entity-John Hofstad, County Administrator 1250 North Eglin Parkway, Suite 102 Shalimar, FL 32579 managerinfo@myokaloosa.com 850-651-7515

- 11. CFDA Number and Name: 21.019 Coronavirus Relief Fund: Note: funding is considered "Other Financial Assistance".
- 12. Identification of whether the award is for research and development (R&D): No
- 13. Indirect cost rate for the Federal award (including whether the de minimis rate is charged per 2 C.F.R. § 200.414 "Indirect (F&A) costs"): Not applicable

THIS CARES ACT MEMORANDUM OF UNDERSTANDING (hereinafter referred to as "MOU" or "Agreement") is entered into by and between OKALOOSA COUNTY, a political subdivision of the State of Florida, whose primary address is 1250 North Eglin Parkway, Suite 102, Shalimar, FL 32579 (hereinafter referred to as the "County") and the STATE OF FLORIDA, DEPARTMENT OF HEALTH, OKALOOSA COUNTY HEALTH DEPARTMENT, whose address is 221 Hospital Dr NE, Ft Walton Beach, FL 32548 (hereinafter referred to as "Department of Health"), to provide guidance and understanding related to the financial assistance to the Department of Health made available through certain CARES Act Funding Agreements between the County and the State of Florida Division of Emergency Management (hereinafter referred to as "FDEM"). Collectively, the County and the Department of Health shall be referred to as "Parties" or individually as a "Party."

WHEREAS, the Coronavirus Disease 2019 ("COVID-19") is an infectious acute respiratory illness capable of spreading rapidly among humans and capable of causing severe illness and death; and

WHEREAS, on March 11, 2020, the World Health Organization declared COVID-19 a pandemic; and

WHEREAS, on or about March 27, 2020, the President of the United States signed into law the Coronavirus Aid, Relief, and Economic Security Act, Public Law 116-136, (hereinafter referred to as the "CARES Act") to facilitate the provision of federal assistance and relief in response to the COVID-19 pandemic; and

WHEREAS, Title V of the CARES ACT established the "Coronavirus Relief Fund" and appropriated \$150 billion in such fund for Fiscal Year 2020 to provide direct assistance to state, tribal, territorial, and local governments to fund certain necessary and allowable expenses incurred due to the public health emergency with respect to COVID-19; and

WHEREAS, utilizing a population-based formula described in the CARES Act, the State of Florida was allocated \$8.328 billion, of which amount 55% (\$4.58 billion) was reserved for the state and 45% (\$3.747 billion) was reserved for direct payments to eligible local government jurisdictions that exceed 500,000 in population; and

WHEREAS, on June 10, 2020, the Governor of the State of Florida announced that the State would disburse up to \$1.275 billion in Coronavirus Relief Funds to counties with a population below 500,000 using a phased approach through FDEM; and

WHEREAS, on or about July 8, 2020 the County and FDEM entered into FDEM CARES Act Funding Agreement No. Y2276 providing 25% of the County's total Coronavirus Relief Fund allocation directly to the County and pursuant to which the County may provide for the award of such funds to eligible entities, including the Department of Health; and

WHEREAS, the County anticipates entering into one or more future amendments with FDEM providing for the remainder of the County's Coronavirus Relief Fund allocation to be provided to the County on a reimbursement basis; and

WHEREAS, the purpose of this Agreement is to provide for the sub-award of a portion of the financial assistance obtained by County under FDEM CARES Act Funding Agreement No.Y2276 and which the County anticipates receiving under future amendments with FDEM to assist Department of Health with funding such necessary expenses incurred due to the COVID-19 public health emergency as are described in this Agreement and the attachments hereto, subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the promises and the mutual benefits to be derived here from, the County and the Department of Health do hereby agree as follows:

### **SECTION 1. RECITALS.**

The above recitals are true and correct and are hereby incorporated herein by reference and made a part of this Agreement.

### SECTION 2. GENERAL.

In performing under this Agreement, the Department of Health does hereby agree to fully comply with the terms and conditions set forth in this Agreement and all attachments and exhibits hereto. FDEM CARES Act Funding Agreement No. 2276, a copy of which is attached as Attachment A, and all future amendments and/or agreements entered into between the County and FDEM governing distribution of the County's Coronavirus Relief Fund allocation (collectively, such agreements shall hereinafter be referred to as the "FDEM Agreements"), Title V of the CARES Act and all implementing rules, regulations, and all other applicable federal, state, and local laws, rules, regulations, and guidance.

### SECTION 3. TERM.

- A. This Agreement shall begin upon execution by both Parties (the "Effective Date") and shall remain in effect until December 30, 2020 (the "Termination Date") unless extended by the County or terminated earlier in accordance with the provisions of this MOU hereof, except that the provisions contained within Sections related to record keeping, auditing and indemnification shall survive the termination of this Agreement.
  - B. All references to days herein shall refer to calendar days unless otherwise indicated.

## SECTION 4. ALLOCATION; ELIGIBLE COSTS; SUPPORTING DOCUMENTATION.

A. The County shall allocate up to the maximum amount of \$2,205,389.00 for uses as submitted in a Department of Health request to the County or as otherwise approved in writing by the County Administrator. The request is dated July 13, 2020 and is attached hereto as Attachment B. The funding requested is planned to be used by the Department of Health for equipment and reimbursement needs as a result of the impacts of COVID in accordance with the CARES Act funding provided to the County through the Florida Department of Emergency Management, a

copy of which is attached hereto as Attachment "A". Equipment and supplies within the Department of Health request will be purchased through the County on behalf of the Department of Health, or the County may direct the Department of Health to purchase said equipment and supplies. The parties currently work through these issues today and will work together in an expedited manner to determine who will lead in procurements.

- B. Department of Health funds allocated under this MOU shall be used by the Department of Health solely to cover eligible and allowable costs that:
- 1. are necessary expenditures incurred due to the public health emergency with respect to the COVID-19;
- 2. were not accounted for in the Department of Health's budget most recently approved as of March 27, 2020;
- 3. were incurred during the Covered Period, as defined under the CARES Act; and
- 4. are otherwise in accordance with the terms and conditions of this Agreement, the FDEM Agreements, Title V of the CARES Act, and all other applicable laws, rules, regulations, and guidance.

Costs that do not satisfy all of the above-required conditions shall be ineligible for reimbursement under this Agreement.

- C. Any funds which shall be provided to the Department of Health under the allocation shall be on a cost reimbursement basis for eligible and allocable cost incurred by the Department of Health in the implementation of the projects and/or activities described in Attachment "B" or authorized approved in writing by the County Administrator as adjustments to Attachment B. The Department of Health shall be responsible for reporting all costs to the County by November 30, 2020, including the projected costs through December 2020.
- D. All reimbursement requests shall be submitted to the County through the Office of Management and Budget Department, Grants Division, every two weeks preferably prior to the 15 and 30<sup>th</sup> of each month. To be eligible for reimbursement under this Agreement, Department of Health shall also submit sufficient documentation to the satisfaction of the County demonstrating that Subrecipient meets the standard of the federal Cares Act to include the FDEM Agreement (Attachment A) and is within its request approval (Attachment B) to include any approved request modifications thereafter All reimbursement requests must include a certification, signed by an official who is authorized to legally bind the Subrecipient, that reads as follows:

By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729–3730 and 3801–3812).

- E. All requests for reimbursement under this Agreement shall be submitted in detail sufficient for a proper pre-audit and post-audit thereof. All costs must be incurred on or before December 30, 2020, and a final payment request should be submitted to the County no later than such date to ensure the County and FDEM have adequate time to process the request. For a cost to have been considered "incurred," performance or delivery must occur during the Covered Period but payment of funds need not be made during that time (though payment shall occur within 90 days of a cost being incurred). For instance, in the case of the lease of equipment or other property, irrespective of when payment occurs, the cost of a lease payment shall be considered to have been incurred for the period of the lease that is within the Covered Period, but not otherwise. Furthermore, in all cases it must be necessary that performance or delivery take place during the Covered Period.
- F. The County requires detailed documentation of all costs for which reimbursement is sought under this Agreement ("Supporting Documentation"). The minimum requirements regarding such Supporting Documentation are set forth in Attachment C, Supporting Documentation Requirements. Each payment request submitted by the Department of Health shall be accompanied by sufficient Supporting Documentation substantiating all costs incurred for which reimbursement is sought, to the satisfaction of the County. In the event the County determines the Supporting Documentation submitted by the Department of Health is insufficient to enable it to evaluate the allowability and eligibility of costs, the Department of Health shall furnish additional Supporting Documentation to the satisfaction of the County.
- G. Processing of Reimbursement Requests. No more frequently than twice every month, the Department of Health may request reimbursement from the County for costs incurred by Department of Health under this Agreement for which actual payment has been made. All payment requests shall be submitted using the Payment Request Form made available by the County and shall be accompanied by sufficient Supporting Documentation (collectively the Payment Request Form and any Supporting Documentation shall hereinafter be referred to as the "Payment Request"). Additionally, at the time of each Payment Request, Department of Health shall submit a "Progress Report" utilizing a form for same made available by the County, which shall describe the nature of the projects and/or activities being funded.
- H. Within ten (10) days after receipt of the Payment Request, the County shall, in its sole discretion, determine if the Payment Request, or any portion thereof, is acceptable and in strict compliance with the terms of this Agreement. If it is determined there are any errors in the Payment Request or if additional Supporting Documentation is required, the County shall notify the Subrecipient within fifteen (15) days of receipt of such Payment Request. The Department of Health shall submit a revised Payment Request within ten (10) days of receipt of notice from the County. The County reserves the right to delay or deny any Payment Request containing errors or lacking sufficient Supporting Documentation until such deficiencies are corrected to the satisfaction of the County.

I. Upon determination by the County that the Payment Request is sufficient, the County shall reimburse the Subrecipient directly and seek reimbursement through FDEM.

### SECTION 5. ACCOUNTING: DUPLICATION OF BENEFIT.

- A. Accounting. The Department of Health's accounting and financial management system shall be sufficient to permit the preparation of reports required in connection with this Agreement and the tracing of funds to a level of expenditures adequate to establish that such funds have been used pursuant to the terms of this Agreement.
- B. <u>Duplication of Benefit</u>. The Department of Health hereby certifies and affirms that the projects and/or activities to be funded under this Agreement shall not result in a prohibited duplication of the benefits obtained by the Department of Health. It is the Department of Health's responsibility and obligation to implement processes and procedures to select and subsequently monitor all sub-subrecipients, individuals, and entities receiving funds under this Agreement to ensure compliance with this paragraph. The Department of Health acknowledges and agrees that it has an affirmative obligation to promptly identify and report any duplication of benefits to the County. In the event that the Department of Health recovers costs incurred under this Agreement and reimbursed by the County from another source, the Department of Health shall reimburse the County for all recovered funds originally provided under this Agreement. Interest on any refund shall be calculated based on the prevailing rate used by the State Board of Administration. Interest shall be calculated from the date(s) the payment(s) are recovered by the Department of Health to the date repayment is made to the County by the Department of Health.
- D. Funding Accountability and Transparency Act. Because of the federal funds awarded under this Agreement, the County must comply with the Funding Accountability and Transparency Act of 2006 ("FFATA"). FFATA requires that information on federal awards (federal financial assistance and expenditures) be made available to the public via a single, searchable website, www.USASpending.gov. Grant recipients awarded a new Federal grant greater than or equal to \$25,000 awarded on or after October 1, 2010, are subject to FFATA. The Department of Health agrees assist the County in providing the information necessary, over the life of this Agreement, for the County to comply with its reporting obligations under FFATA.
- D. Nonconsumable and/or nonexpendable personal property or equipment that costs \$1,000 or more purchased by the Department of Health is subject to the requirements set forth in Chapter 274, F.S., Chapter 69I-73, F.A.C., and 2 C.F.R. Part 200 (for equipment in excess of \$5,000), as applicable. The Department of Health shall be responsible for maintaining appropriate property that include the purchase of equipment as part of the delivery of services. The Department of Health shall comply with this requirement and ensure its subcontracts issued under this Agreement, if any, impose this requirement, in writing, on its subcontractors.

### SECTION 6. COORDINATION MEETINGS.

The Parties shall try to meet regularly near the first of each month for the duration of this contract to coordinate the take down of funds, documentation/payment issues, facility and technology issues, any necessary funding changes, additional needs beyond allocated funding, the reuse of any under-utilized funds by the County, and other similar issue to ensure a good working relationship related specifically to this request and allocated CARES Act Funding.

### **SECTION 7. SOVEREIGN IMMUNITY.**

It is specifically agreed by and between the Parties that, in accordance with section 768.28 Florida Statutes, neither Party waives any defense of sovereign immunity.

### SECTION 8. DEFAULT; TERMINATION.

### A. Termination for Cause.

- 1. By County. The County may terminate this Agreement for cause at any time if any covenant, warranty, or representation made by the Department of Health in this Agreement, or in any application materials for funding submitted to the County in connection with this Agreement shall at any time be false or misleading in any respect, or in the event of the failure of the Department of Health to comply with the terms and conditions of this Agreement. Prior to termination, the County shall provide fifteen (15) days written notice of its intent to terminate and shall provide the Department of Health an opportunity to consult with the County regarding the reason(s) for termination.
- B. <u>Termination for Convenience</u>. This Agreement may be terminated for convenience by either Party upon providing the non-terminating Party with ten (10) days written notice.
- C. <u>Termination due to Unavailability of Funds</u>. In the event the FDEM Agreements are terminated by FDEM or the funding contemplated under the FDEM Agreements is either reduced or eliminated for any reason, this Agreement may be terminated by the County immediately upon providing written notice to the Department of Health.
- D. <u>Effect of Termination.</u> Costs incurred by the Department of Health after termination of this Agreement shall not be reimbursable unless expressly authorized by the County prior to the effective date of termination.

### SECTION 9. REMEDIES; FINANCIAL CONSEQUENCES.

A. In the event that a task, deliverable, or activity to be performed under this Agreement is deemed unsatisfactory by the County, the Department of Health shall re-perform same, at no additional cost to the County, within twenty (20) days of being notified of the unsatisfactory task, deliverable, or activity, or within such other timeframe as is specified in writing by the County. If such task, deliverable, or activity is not satisfactorily performed within the specified timeframe, the County may, in its sole discretion, terminate this Agreement for cause in accordance with Section 6 hereof.

- B. If the Department of Health materially fails to comply with the terms and conditions of this Agreement, including any federal or state statutes, rules, policies, or regulations, applicable to this Agreement, the County may, in its sole discretion, take one or more of the following actions:
- 1. Temporarily withhold cash payments to the Department of Health pending correction of the deficiency by the Department of Health or take general common law contract actions, such as terminating the contract or suing for relief.
- 2. Disallow (i.e. deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.
  - 3. Wholly or partly suspend or terminate this Agreement.
- 4. Initiate suspension or debarment proceedings as authorized under 2 C.F.R. Part 180 or other applicable federal regulations (or recommend such a proceeding be initiated by FDEM or the Department of the Treasury).
- 5. Withhold future requests for reimbursement to the Department of Health under any other Agreement between the Parties providing for the subaward of funds from the Coronavirus Relief Fund.
- 6. Demand a refund, either in whole or in part, of the funds provided to the Department of Health under this Agreement where such funds were improperly provided to the Department of Health due to non-compliance with the material terms of this Agreement. The Department of Health, upon such written notification from the County shall refund, and shall forthwith pay to the County, the amount of money demanded by the County if the Department of Health does not challenge the claim of default and demand. The Department of Health retains its right to challenge this claim of default and demand. Interest on any refund shall be calculated based on the prevailing rate used by the State Board of Administration. Interest shall be calculated from the date(s) the original payment(s) are received from the County by the Department of Health to the date repayment is made by the Department of Health to the County.
  - 7. Take any other remedy that may be available to the County at law or equity.
- 8. Costs of the Department of Health resulting from obligations incurred by the Department of Health during a suspension or after termination of the Agreement are not allowable unless the County expressly authorizes them in the notice of suspension or termination. Other Department of Health costs during suspension or after termination that are necessary and not reasonably avoidable are allowable if the following apply:
- a. The costs result from obligations which were properly incurred by the Department of Health before the effective date of suspension or termination, are not in anticipation of it, and in the case of termination, are non-cancellable; and

- b. The cost would be allowable if the Agreement were not suspended or expired normally at the end of the funding period in which the termination takes place.
- C. <u>CARES Act-Specific Remedies for Noncompliance</u>. In addition to the remedies available in the paragraphs above, the Department of Health is subject to any CARES Act-specific remedies for noncompliance outlined in the CARES Act and any implementing laws, rules, regulations, and guidance.
- D. State and Federal Clawbacks. In the event FDEM, Department of the Treasury, or such other state or federal entity having jurisdiction at any time demands the return of funds paid to the Department of Health pursuant to this Agreement following a state or federal audit or otherwise for any reason, including but not limited to situations where costs paid with such funds were determined to be ineligible or unallowable, the Department of Health shall be solely liable for any such amounts and shall return the full amount of the funds in question to the County promptly upon demand. If the Department of Health fails to comply with its obligation to return funds pursuant to this paragraph, the County may withhold future requests for reimbursement to the Department of Health under this Agreement or any other Agreement between the Parties providing for the award of Coronavirus Relief Funds or pursue any other remedy described in paragraph (B) above or available at law or in equity.

### SECTION 10. LOBBYING PROHIBITION; CONFLICTS OF INTEREST.

The Department of Health agrees to comply with the following provisions:

- A. The Department of Health certifies that no Federal appropriated funds have been paid or will be paid, by or on behalf of the Department of Health, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
- B. The Department of Health certifies that no funds provided under this Agreement have been used or will be used to engage in the lobbying of the Federal Government or in litigation against the United States unless authorized under existing law.
- C. Pursuant to 2 C.F.R. §200.450 and 2 C.F.R. §200.454(e), the Department of Health is hereby prohibited from using funds provided by this Agreement for membership dues to any entity or organization engaged in lobbying activities.
- D. If any funds other than federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Department of Health shall complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities."

E. <u>Hatch Act</u>. In accordance with the provisions of the Hatch Act (5 U.S.C. 1501-1508 and 7324-7328), no funds provided, nor personnel employed under this Agreement, shall be in any way or any extent engaged in the conduct of political activities.

### SECTION 11. COMPLIANCE WITH LAWS.

The Department of Health shall comply with all applicable federal, state and local laws, rules, and regulations, including but not limited to, the Agreement between FDEM and the County, attached as Attachment A and the Federal Requirements Attached as Attachment D, and County policies and regulations in performing under this Agreement, including but not limited to the federal laws, regulations rules, policies, and executive orders. The failure of this Agreement to specifically reference a particular federal or state law or regulation, or policy or regulation shall not excuse the Department of Health from compliance with same to the extent such law, regulation, or policy is applicable to the Department of Health's performance under this Agreement.

### SECTION 12. NOTICE.

All notices and written communication between the Parties shall be sent by electronic mail, U.S. Mail, a courier delivery service, or delivered in person. Notices shall be considered delivered when reflected by an electronic mail read receipt (or when receipt is otherwise acknowledged), a courier service delivery receipt, other mail service delivery receipt, or when receipt is acknowledged by recipient. This Section shall not preclude routine communication by the Parties by other means.

### SECTION 13. CONTACTS.

All notices required or permitted under this Agreement shall be directed to the following contact persons:

### County

Okaloosa County
Attn: Craig Coffey, Deputy County Administrator
1250 North Eglin Parkway, Ste 100
Shalimar, FL 32579
ccoffey@myokaloosa.com
850-651-6136

Kerry Parsons, Assistant County Attorney Nabors, Giblin & Nickerson 1500 Mahan Drive, Ste 200 Tallahassee, FL 32308 kparsons@ngnlaw.com

### The Department of Health

Florida Department of Health Okaloosa County Attn: Susan Wagner, PHFM Operations Manager 221 Hospital Drive NE Ft. Walton Beach, FL 32548-5066

Either Party may change the above-described contact information by giving notice of such change to the other party Pursuant to Section 10 hereof.

### SECTION 14. RECORDS; ACCESS TO RECORDS AND PERSONNEL.

- A. The Department of Health shall retain all records generated under this Agreement in accordance with 2 C.F.R. § 200.333.
- B. The Department of Health shall comply with the Florida Public Records Law, codified at Chapter 119, F.S. Records made or received in conjunction with this Agreement are public records under Florida law. The Department of Health shall keep and maintain public records generated by the Department of Health in association with its performance of this Agreement.
- C. This Agreement may be unilaterally canceled by the County for refusal by the Department of Health to either provide to the County upon request, or to allow inspection and copying of, all public records made or received by the Department of Health in conjunction with this Agreement and subject to disclosure under Chapter 119, F.S.
- D. IF THE DEPARTMENT OF HEALTH HAS QUESTIONS REGARDING THE APPLICATION OF CHAPTER 119, FLORIDA STATUTES, TO THE DEPARTMENT OF HEALTH'S DUTY TO PROVIDE PUBLIC RECORDS RELATING TO THIS AGREEMENT, CONTACT THE COUNTY'S CUSTODIAN OF PUBLIC RECORDS BY TELEPHONE AT OKALOOSA COUNTY RISK MANAGEMENT DEPARTMENT 302 N. WILSON ST., CRESTVIEW, FL 32536 PHONE: (850) 689-5977 riskinfo@myokaloosa.com.
- E. The Department of Health acknowledges and agrees that the County, FDEM, the U.S. Department of Treasury, the Treasury Office of Inspector General, the Comptroller General of the United States (Government Accountability Office (GAO)), or their authorized representatives, shall have timely and unrestricted access to any pertinent books, documents, papers, and records, whether written, printed, recorded, produced, or reproduced by any electronic, mechanical, magnetic, or other process or medium, in order to make audits, inspections, investigations, excerpts, transcripts, or other examinations as authorized by law. This also includes timely and reasonable access to the Department of Health's personnel for the purpose of interview and discussion related to such documents. In the event any work is subawarded or subcontracted,

the Department of Health shall similarly require each sub-subrecipient and subcontractor to maintain and allow access to such records for audit purposes.

- F. The County, FDEM, the U.S. Department of Treasury, the Treasury Office of Inspector General, the Comptroller General of the United States (GAO), or their authorized representatives shall have the right during normal business hours to conduct announced and unannounced onsite and offsite physical visits of the Department of Health and their subcontractors corresponding to the duration of their records retention obligation for this Agreement.
- G. The rights of access in this Section are not limited to the required retention period for the applicable records but last as long as the records are retained.
- H. The Department of Health agrees that if any litigation, claim, or audit is started before the expiration of the record retention period established above, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

### SECTION 15. DEBARMENT/SUSPENSION.

In accordance with Presidential Executive Order 12549, Debarment and Suspension (2 C.F.R. Part 180), the Department of Health agrees and certifies that neither it, nor its principals, is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency; and, that the The Department of Health shall not enter into any lower tier contract, or other covered transaction, with a person who is similarly debarred or suspended from participating in this covered transaction. The Department of Health is responsible for reviewing the status of all proposed subcontractors and subawardees in the System for Award Management (SAM) at https://sam.gov/SAM/ before entering into any subcontract or sub-award under this Agreement. The Department of Health shall include language incorporating the requirements of this Section in all subcontracts or lower tier agreements executed under this Agreement.

### SECTION 16. REAL PROPERTY; EQUIPMENT.

A. The Department of Health acknowledges that any equipment purchased in accordance with the provisions of this MOU shall be for the benefit and titled in the name of the County and shall be turned over to the County upon the expiration of the Public Health Emergency as demonstrated by the withdrawal of the Federal Emergency Declaration. If Department of Health acquires an interest in real property utilizing funds under this Agreement, Department of Health acknowledges and shall comply with 2 C.F.R. § 200.311 and other applicable laws, rules, and regulations, including, but not limited to CARES Act guidance issued by the Department of the Treasury. Pursuant to same, except as otherwise expressly authorized by the County, real property acquired under this Agreement must be used for the originally authorized purpose as long as needed for that purpose, during which time the Department of Health entity must not dispose of or encumber its title or any other interest therein.

B. Department of Health's acquisition, use, management, and disposition of equipment under this Agreement shall be in compliance with 2 C.F.R. §§ 200.313 and 200.439 and other applicable laws, rules, and regulations, including, but not limited to CARES Act guidance issued by the Department of the Treasury.

### SECTION 17. UNAUTHORIZED EMPLOYMENT.

The employment of unauthorized aliens is considered a violation of Section 274A(e) of the Immigration and Nationality Act. If the Subrecipient/subcontractor knowingly employs unauthorized aliens, such violation shall be cause for unilateral cancellation of this Agreement. The Department of Health shall be responsible for including this provision in all subcontracts with private organizations issued as a result of this Agreement.

### **SECTION 18. MISCELLANEOUS.**

- A. <u>Assignment</u>. No assignment, delegation, transfer, or novation of this Agreement, or any part hereof, may be made unless in writing and signed by both Parties.
- B. Execution in Counterparts. This Agreement, and any Amendments or Change Orders thereto, may be executed in multiple counterparts, each of which together shall be deemed an original, but all of which together shall constitute one and the same instrument. In the event that any signature is delivered by facsimile transmission or by email delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the Party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.
- C. <u>Interpretation; Severability</u>. This Agreement shall be construed in accordance with the laws of the State of Florida. Wherever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.
- D. Entire Agreement; Joint Preparation. This Agreement represents the entire agreement of the Parties. Any alterations, variations, changes, modifications or waivers of provisions of this Agreement shall only be valid when they have been reduced to writing, duly signed by each of the Parties hereto, and attached to the original of this Agreement, unless otherwise provided herein. The Parties represent and agree that they have jointly negotiated this Agreement and have had the opportunity to consult with and be represented by their own competent counsel. This Agreement is therefore deemed to have been jointly prepared by the Parties and no part hereof shall be construed more severely against one of the Parties than the other.
- E. <u>Venue</u>. Venue for any litigation arising from this Agreement shall be in Okaloosa County, Florida.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed, the day and year last written below.

OKALOOSA COUNTY	STATE OF FLORIDA, DEPARTMENT OF HEALTH, OKALOOSA COUNTY HEALTH DEPARTMENT				
By: CALL	By: Karan a. a. Cec una				
John Hofstad, County Administrator Print Name and Title	Dr. Karen Chapman, MD, MPH, DirectorPrint Name and Title				
Date: 7 August 2020	Date: 6 August, 2020				

# Attachment A COUNTY-FDEM CARES ACT Grant Agreement

# Attachment B Department of Health Request Dated July 13, 2020 (Subsequently Approved by the BOCC on July 21st)

### ATTACHMENT C SUPPORTING DOCUMENTATION REQUIREMENTS

The Department of Health should prepare a cover page on their letterhead with the date of the reimbursement request and amount with the required certification as noted in this agreement. The cover page should be signed by person authorized to obligate the subrecipient.

An Excel spreadsheet will be provided to the subrecipient to prepare a reimbursement request summary. Each line should have a unique sequence number which will correlate to the supporting documentation. That unique number should appear on the supporting documentation pages.

The minimum documentation should include: Vendor payments: Check copy Invoice copy

Procurement:
Small purchase up to \$
Justification of procurement method

Payroll:

Payroll register with check number; check date; employee name and total hours worked; total fringe benefits

Timesheet

Fringe Benefit rate calculation

In-house equipment:

Description of equipment; record of usage; time used; equipment rate

Equipment rate basis

Costs incurred on or before September 30 must be submitted by October 5.

### ATTACHMENT D

### FEDERAL PROVISIONS APPLICABLE TO THIS MOU

The Project subject to this Agreement is fully or partially funded by Federal grants and therefore, the Subrecipient will be required to comply with the following provisions:

- 1. Drug Free Workplace Requirements: All Subrecipients and contractors entering into Federal funded contracts over the simplified acquisition threshold (as defined at 41 U.S.C. § 134) must comply with the Drug Free Workplace Act of 1988 (41 U.S.C. 8102), which requires the Subrecipient to take certain actions to provide a drug-free workplace.
- 2. Davis-Bacon Act: If applicable, the Subrecipient agrees to comply with all provisions of the Davis Bacon Act as amended (40 U.S.C. §§ 3141-3144 and 3136-3148), and to require all of its contractors performing work under this Agreement to adhere to same. The Subrecipient and its contractors are required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor. In addition, the Subrecipient and its contractors are required to pay wages not less than once a week. If the grant award contains Davis Bacon provisions, the Subrecipient shall place a copy of the current prevailing wage determination issued by the Department of Labor in the solicitation documents. The decision to award a contract shall be conditioned upon the acceptance of the wage determination. The Subrecipient shall must report all suspected or reported violations of the Davis Bacon Act to the County.
- 3. Copeland Anti Kick Back Act: Subrecipient and its contractors shall comply with all the requirements of the Copeland Anti-Kickback Act (18 U.S.C. § 874 and 40 U.S.C. § 3145, as supplemented by Department of Labor regulations at 29 CFR Part 3), which are incorporated by reference to this Agreement. Subrecipient and its contractors are prohibited from inducing by any means any person employed in the construction, completion or repair of public work to give up any part of the compensation to which he or she is otherwise entitled.
- 4. Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 3701–3708): Where applicable, all contracts awarded in excess of \$100,000 that involve the employment of mechanics or laborers must be in compliance with 40 U.S.C. §§ 3702 and 3704, as supplemented by Department of Labor regulations (29 CFR Part 5). Under 40 U.S.C. § 3702 of the Act, each contractor is required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than one and a half times the basic rate of pay for all hours worked in excess of 40 hours in the work week. The requirements of 40 U.S.C. § 3704 are applicable to construction work and provide that no laborer or mechanic must be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

5. Debarment and Suspension (Executive Orders 12549 and 12689): A contract award (see 2 CFR 180.220) must not be made under this Agreement to parties listed on the government wide exclusions in the System for Award Management (SAM), in accordance with the OMB guidelines at 2 CFR part 180 that implement Executive Orders 12549 (3 CFR part 1986 Comp., p. 189) and 12689 (3 CFR part 1989 Comp., p. 235), Debarment and Suspension. SAM Exclusions contains the names of parties debarred, suspended, or otherwise excluded by agencies, as well as parties declared ineligible under statutory or regulatory authority other than Executive Order 12549. The contractor shall certify compliance. The Subrecipient further agrees to include a provision requiring such compliance in its lower tier covered transactions and subcontracts, which shall read as follows:

Applicants or bidders for a lower tier covered transaction (except procurement contracts for goods and services under \$25,000 not requiring the consent of the County and/or the applicable state or federal entity) are subject to 2 C.F.R. Part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)." In addition, applicants or bidders for a lower tier covered transaction for a subaward, contract, or subcontract greater than \$100,000 of Federal funds at any tier are subject to relevant statutes, including among others, the provisions of 31 U.S.C. 1352, as well as the common rule, "New Restrictions on Lobbying," published at 55 FR 6736 (February 26, 1990), including definitions, and the Office of Management and Budget "Governmentwide Guidance for New Restrictions on Lobbying," and notices published at 54 FR 52306 (December 20, 1989), 55 FR 24540 (June 15, 1990), 57 FR 1772 (January 15, 1992), and 61 FR 1412 (January 19, 1996)

- 6. Byrd Anti-Lobbying Amendment (31 U.S.C. § 1352): Subrecipients that apply or bid for an award exceeding \$100,000 must file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. § 1352. Each tier must also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the non-Federal award. The contractor shall certify compliance.
- 7. 501(c)(4) Entities. The Lobbying Disclosure Act of 1995, as amended (2 U.S.C. §1601 et seq.), prohibits any organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities, from receiving federal funds, including through an award, grant, and/or subgrant. Subrecipient shall ensure that its contractors and sub-awardees comply with this requirement.
- 8. Federal Changes: Subrecipient shall comply with all applicable Federal agency regulations, policies, procedures and directives, including without limitation those listed directly or by reference, as they may be amended or promulgated from time to time during the term of the contract.

- 9. Safeguarding Personal Identifiable Information: Subrecipient and its contractors and subawardees will take reasonable measures to safeguard protected personally identifiable information and other information designated as sensitive by the awarding agency or is considered sensitive consistent with applicable Federal, state and/or local laws regarding privacy and obligations of confidentiality.
- 10. Energy Policy and Conservation Act (43 U.S.C. §6201): Contracts shall comply with mandatory standards and policies relating to energy efficiency, stating in the state energy conservation plan issued in compliance with the Energy Policy and Conservation act. (Pub. L. 94 163, 89 Stat. 871) [53 FR 8078, 8087, Mar. 11. 1988, as amended at 60 FR 19639, 19645, Apr. 19, 1995].
- 11. Right to Inventions Under Federal Grants. If applicable, Subrecipient shall comply with the requirements of 37 C.F.R. part 401, "Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," and any implementing regulations issued by the awarding agency.