Vaccinator required pre-clinic training		
Training (click title to be directed to training PDF or website)	**Type of Training**	**Page number**
POD Vaccination Clinic Overview	PDF	2
POD Role Description	PDF	18
Complete COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers	Web training	Web
Moderna - CDC's COVID-19 Vaccine: What Healthcare Professionals Need to Know	Web training	Web
Moderna's EUA Factsheet for providers	PDF	23
Moderna's EUA Factsheet for recipients	PDF	45
Review of information on Moderna's website	Webpage	Web
Review of CDC's information on Moderna vaccine	Webpage	Web
Moderna COVID-19 Vaccine; Vaccine Preparation and Administration Summary	Webpage	Web
Pfizer - CDC's COVID-19 Vaccine: What Healthcare Professionals Need to Know	Web training	Web
Pfizer's EUA Factsheet for providers	PDF	50
Pfizer's EUA Factsheet for recipients	PDF	80
Pfizer-BioNTech COVID-19 Vaccine; Vaccine Preparation and Administration Summary	Webpage	Web
Review CDC's information on Pfizer's vaccine	Webpage	Web
Health Department's Immunization Protocol	PDF	86
Health Department's Medical Orders for COVID-19 Vaccines	PDF	89
Health Department's Bloodborne Pathogen Plan and Appendices 2, 4, 5 & 6	PDF	93
Health Department's Emergency Care and Adverse Event Guidelines	PDF	111
Health Department's Epinephrine Medical Order	PDF	116
VAMS Sheet for Healthcare Providers and video attached to email	PDF	118
When I Work Training	PDF	119
Agency of Human Services HIPAA Awareness Training	PDF	132
Review CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination.	Webpage	Web
Review Preventing and Managing Adverse Reactions General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)	Webpage	Web
Review the Immunization Action Coalition's Medical Management of Vaccine Reactions in Adults in a Community Setting	Webpage	Web
Review Vaccine Safety Information on COVID-19 vaccine on CDC's Website	Webpage	Web
Review V-Safe information on CDC's Website	Webpage	Web
Be familiar with CDC's Pre-Vaccination Checklist for COVID-19 Vaccines o Pfizer o Moderna	Webpages	Web
Total estimated training time = 2-3 hours		



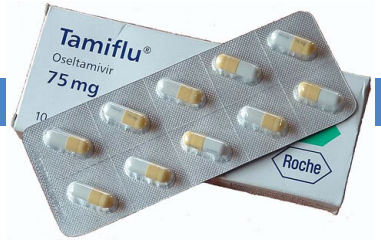

COVID-19 Vaccination
POD Overview Training

VERMONT
DEPARTMENT OF HEALTH

January 2021

What is a POD?

What is a POD?

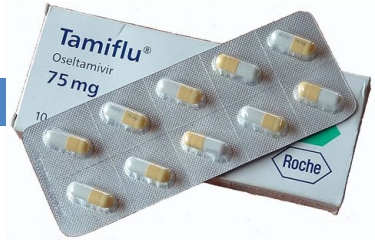


A "POD" is a *Point of Distribution*

Points of Distribution are sites located around the state which have agreed to assist the Vermont Department of Health (VDH) in quickly and efficiently distributing medications and/or vaccines in the case of a public health emergency.

POD sites are designed for ***worst case*** scenarios and are intended to provide prophylaxis to affected individuals within a predetermined time period.

What is a POD?



VDH manages two types of PODs:

- **Open PODs:**
  - PODs open to the general public and are staffed by VDH staff and Medical Reserve Corps Volunteers.
  - Plans for these PODs are managed by VDH staff.
- **Closed PODs:**
  - PODs only open to a pre-identified population to administer medications to an agency's internal staff and their family members.
  - Staffed by employees of the individual agency.
  - Plans for these PODs are managed by agency staff.

This training will focus primarily on Open PODs, but the concepts can be applied to Closed PODs as well.

POD Planning

POD Planning Documents

PODs require a significant amount of pre-planning prior to actual operations. VDH maintains various documents which assist in the overall operation of a POD site.

POD Planning and Support

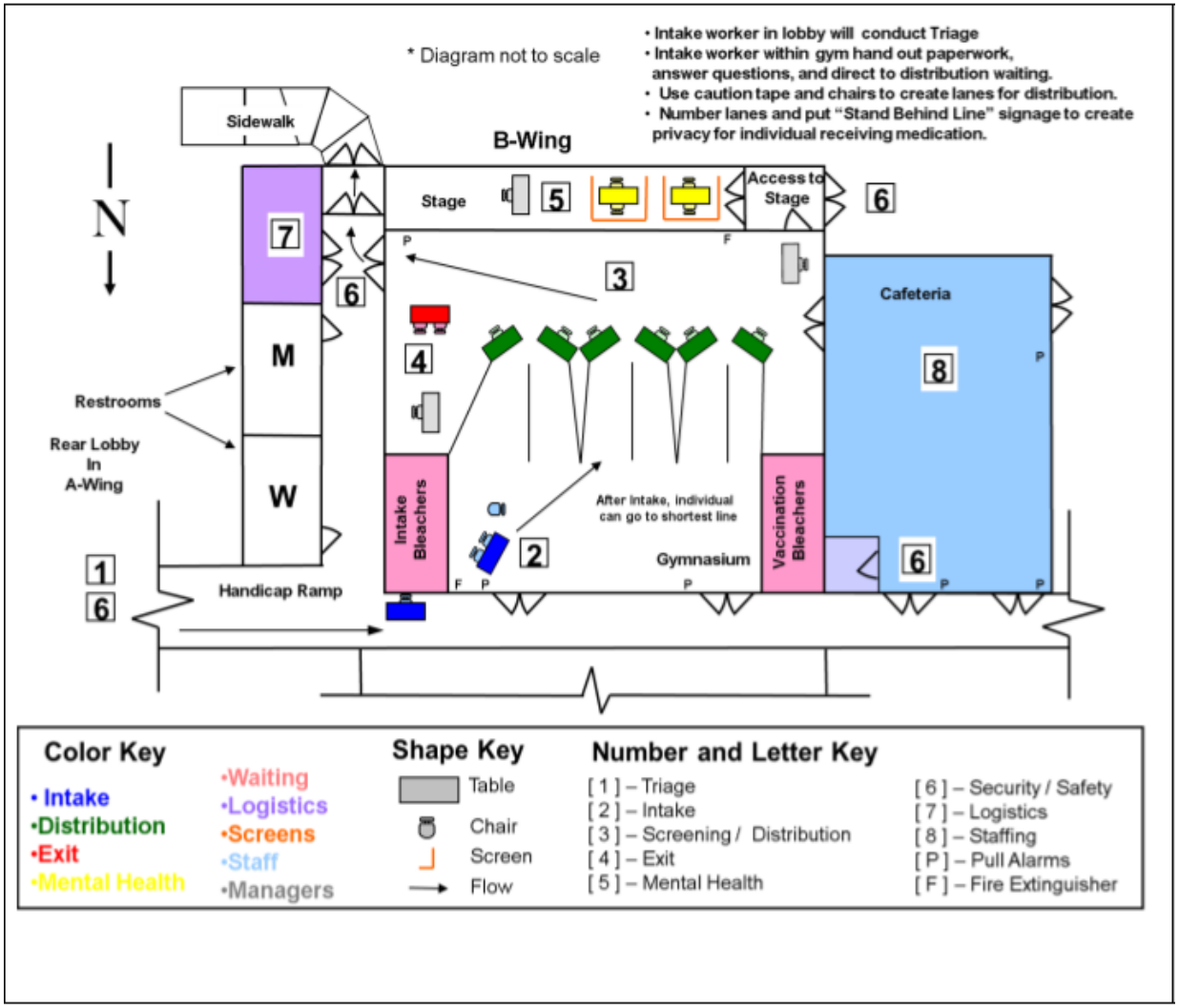
The Health Operations Center (HOC) is a VDH facility setup to coordinate response efforts during a public health emergency.

The HOC:

- Participates in calls with the CDC to assess situations
- Requests activation of POD sites
- Assists in coordination and support of POD sites (staffing, equipment, supplies, etc)
- Coordinates media outreach messaging
- Collects, creates, and communicates Event Specific Information (ESI) which may include:
    - Modifications to POD layouts
    - Medical orders
    - Staffing plans
    - Specific task sheets
    - Other pertinent event-specific information

POD Setup

POD Site Setup



This is an example of a POD site set up.

POD Stations:

- Triage
- Intake
- Distribution
- Exit

POD Site Stations

Triage

- Determines if an individual is symptomatic
- Provides special needs assistance
- Directs to next stations

Intake

- Checks people in
- Assists in form completion
- Provides flow control/ direction

Exit

- Provides special needs assistance
- Provides assistance leaving facility
- Provides assistance with making appointment for second dose

Distribution

- Reviews forms
- Provides correct medications or vaccination
- Provides information on medication or specimen

POD Staffing

Who staffs an Open POD?

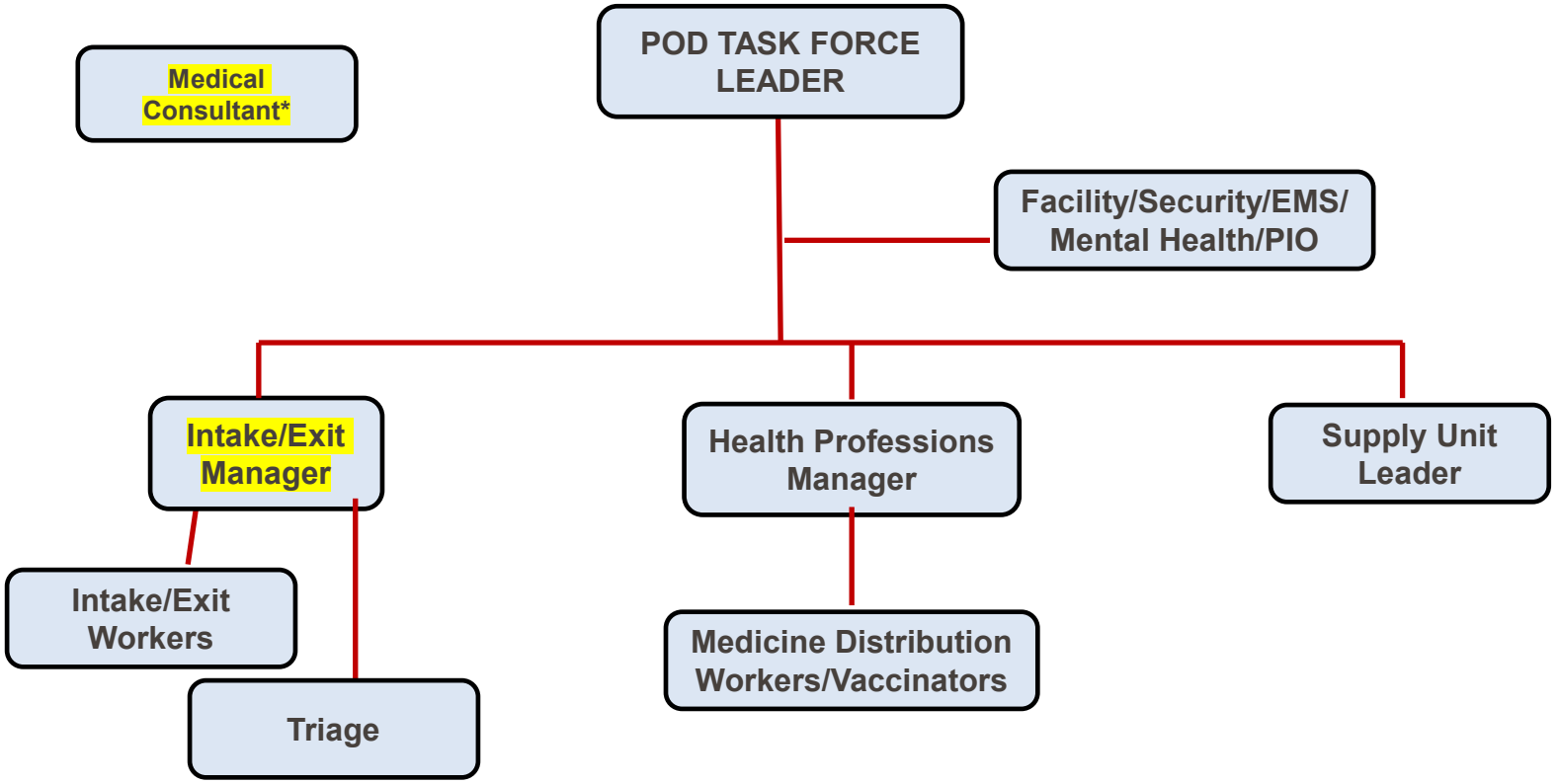
- **VDH**
  - For COVID-19 Vaccination Clinics Provides, at minimum, 4 “key positions” requiring additional oversight of running the clinic:
    - POD Task Force Leader
    - Health Professions Manager
    - Intake/Exit Worker Manager
    - Supply/Inventory Unit Leader
    - *Public Information Officer - as needed to deal with media on site*
- **EMS, State of Vermont Employees, Medical Reserve Corp, possibly others**
  - Triage Workers
  - Intake Workers
  - Medical Distribution Workers/Vaccinator
  - Exit Workers
- **Others Involved** – as needed
  - Facility Manager, Security (Law Enforcement), Mental Health Services

Incident Command System

POD structures follow the Incident Command System (ICS) which is a part of the National Incident Management System (NIMS).

In ICS, each individual in a POD reports to someone else. It is important that you know who you report to when you are working in a VDH COVID-19 Vaccination Clinic.

POD Organizational Structure



Job Action Sheets (JAS)/ Task Sheets

Job Action Sheet

Support Manager (logistics)

Position Assigned to: _____

You report to: **POD Task Force Leader** _____

Mission: Responsible for Point of Distribution (POD) set up, break down and supply/logistics functions. Assures that POD staff have the needed supplies and provides basic supports for staff. Oversees POD logistics staff. Performs miscellaneous duties as required by the POD Task Force Leader.

Immediate:

- ☐ Receive appointment from the POD Task Force Leader.
- ☐ Obtain briefing from the POD Task Force Leader; develop initial action plan for staffing and supply needs with Intake/Exit Manager and Health Professions Manager. Set time for next meeting.
- ☐ Arrange for clinical space, as determined by the POD Task Force Leader.
- ☐ Determine and arrange for signage as requested by Intake/Exit Manager, Mental Health Manager, Volunteer Manager and Health Professions Manager.
- ☐ Obtain, organize and maintain adequate inventory of office and clinic supplies by first utilizing District Office supplies, rental supply agreements, and systems in place, including the POD Set-Up Kits. Notify Division Supervisor of need for additional supplies.
- ☐ Develop records to list/record materials used and personnel staffing the POD.
- ☐ Arrange for on-site communication technology (e.g. cell phones, walkie-talkies, laptops etc.).
- ☐ With staff, set up the clinic—post signage, distribute supplies, display handouts, etc.
- ☐ Provide additional administrative support as needed (e.g. photocopy, assemble information packets, order supplies).
- ☐ Orient, train and supervise all team staff.

Vigilant Guard
July 28, 2016
Brattleboro Area Middle School

Role: Support Manager/Worker

Responsibilities:

Before the POD:

_____ Set up POD according to flow diagrams

_____ Set up POD signage (indicated in pink bold) according to flow diagrams

During the POD:

_____ Provide a "heads up" to SNS 10 minutes before medicine needs to be ready for dispensing

_____ Stay visible

_____ Resupply stations as requested and complete required Inventory Management or Items Acquired from the POD site forms

_____ Meet lunch delivery staff. Instruct them to unload at door #13, to the left of the main entrance.

Job Action Sheets (JAS)/Task Sheets

- Job Action Sheets and Task Sheets contain specific information for each role within the POD such as:
  - Who they report to
  - Roles and responsibilities during all stages of operation
  - Recommended or required skills or prerequisites

- Both JAS and Task Sheets will be given to you before each clinic.

Medical Distribution Worker – Vaccinator

PPE:
Required: Surgical/Procedure Mask, Face Shield or Goggles
Optional: Gloves

Note - Gloves will be changed and hands sanitized between every attendee without exception. All other PPE can remain on without changing unless contaminated. PPE should be removed if leaving the clinic area for breaks.

Responsibilities:
During Set Up

- Assist in setting up vaccination station
- Read all forms in the Just-In-Time Training (JITT) Packet
- Test WiFi, tablets and access to VAMS
- Review other materials as needed
- Check in with the Health Care Professions Manager

Vaccination Clinic Procedures

- Ensure communication chain with Health Profession's Manager (HPM)
  - Interpreter Services Instructions and use of cell phones
  - Assistance needed with vaccination or questions
  - Use ***Red Card*** for assistance
  - Use ***Blue Card*** for additional supplies as needed

Vaccination Process

- Ensure you have all the materials you need to vaccinate
- Pre-draw one multi-use vaccine vial at the vaccine supply station following appropriate vaccine EUA prescribing information and dosage. As soon as you dilute the Pfizer vaccine or puncture the top of the Moderna vial, mark the vial with the date and time. This must be done even if you are drawing up the entire vial. Both of those vaccines are only viable for 6 hours after they are drawn up.
  - If using Pfizer vaccine, be aware that it is a .3ml dose.
- Bring syringes to the vaccination station.
- Near end of clinic check with HPM before pre-drawing vaccine to ensure that we limit unused vaccine.

- Refer to the appropriate vaccine EUA prescribing information to ensure correct procedure and dosage for drawing up vaccine. A copy of the vaccine EUA prescribing information should be on the vaccine supply station.
- Log into VAMs
- Call the next individual over to your vaccination station
- Greet the individual, verify their name and DOB, verify their information is in Vaccine Administration Management System (VAMS)
- Review vaccine pre-screening form "CDC's Pre-Vaccination Checklist for COVID-19 Vaccines" answers. If any concerns with responses or contraindications noted, discuss with Healthcare Professions Manager
- Ask them if they have any questions and answer any questions they may have
- Explain the vaccination procedure *(Ex: I am going to clean the site on your arm, then give you the vaccination, then document that I have given you the vaccination)*
- Explain what they should expect including risks and benefits *(you should expect a little pain at the site, the most common post-vaccination reactions are. . . I will give you a copy of todays vaccination for your records)*
- Ask them if they have any other questions and provide education or support prior to administration
- Verify that they want to be vaccinated
- Confirm their name and DOB again
- Prepare site and give vaccination
- Complete the VAMS Administration section. Refer to the lot # and Exp Date
- Complete the COVID-19 vaccine card and give it to them for their records
- Give them V-Safe information and encourage them to sign up
- Direct participant to the post vaccine and waiting area
- Remind them to wait 15 minutes in the waiting area
- Inform them they need to sign up for an appointment for their second dose while they wait (only applicable for first dose clinics)

Demobilization

- **ALL** non-porous items in the clinical area get wiped down with virucidal wipes or cleaner
- Package all items in distribution area in boxes and bins for return to district office
- Assist in the takedown of stations and packaging of waste
- PPE should be removed last after all activities for demobilization have been completed. Face shields are wiped down with virucidal wipes or disinfected and collected for sterilization and reuse. All other PPE is discarded at end of shift

Vaccination Station Supply List

Vaccination Station Supplies

- Pens
- Hand Sanitizer
- Wire Basket- to place forms in
- Education Packets
- Red & Blue Flag Card – *to indicate you need assistance during clinic. The color of the cards may differ.*
- Trash Bucket & Trash Bag
- Gloves
- Band Aids
- 2X2 gauze
- Alcohol Swabs
- Sharps Container
- Red Infectious Waste Bag
- Clear Shoe Boxes – *optional for transporting syringes from vaccine supply station to vaccination stations.*
- Vaccine Administration Cards

Signs

- Table Signs
- Station Signs

Vaccinator Training Requirements:

- Review of POD/Clinic Overview PowerPoint
- Completion of the CDC's COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers
- Review of vaccine specific information
    - Moderna:
        - CDC's COVID-19 Vaccine: What Healthcare Professionals Need to Know
        - Moderna's EUA Fact Sheet for Providers
        - Moderna's EUA Fact Sheet for Recipients
        - Review of information on Moderna's website and CDC's information on Moderna's vaccine, https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

        - Moderna COVID-19 Vaccine; Vaccine Preparation and Administration Summary
    - Pfizer-BioNTech:
        - CDC's COVID-19 Vaccine: What Healthcare Professionals Need to Know
        - Pfizer's EUA Fact Sheet for Providers
        - Pfizer's EUA Fact Sheet for Recipients
        - Pfizer-BioNTech COVID-19 Vaccine; Vaccine Preparation and Administration Summary
        - Be familiar with CDC's information on Pfizer's vaccine, https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
- Review Health Department's Immunization Protocol
- Review Health Department's Medical Orders for COVID-19 Vaccines
- Review Health Department's Blood Bourne Pathogen Plan and Appendices 2, 4, 5 & 6
- Review Health Department's Emergency Care and Adverse Event Guidelines
- Review Health Department's Epinephrine Medical Order
- Review VAMS Sheet for Healthcare Providers
- Review When I Work Training
- Health Insurance Portability and Accountability Act (HIPAA) training
- Review CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination.
- Review Preventing and Managing Adverse Reactions General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)
- Review the Immunization Action Coalition's Medical Management of Vaccine Reactions in Adults in a Community Setting
- Review Vaccine Safety Information on COVID-19 vaccine on CDC's Website
- Review V-Safe information on CDC's Website

- Be familiar with CDC's Pre-Vaccination Checklist for COVID-19 Vaccines
  - Pfizer
  - Moderna

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **MODERNA COVID-19 VACCINE,** for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS
Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR THE MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling
The storage and handling information in this Fact Sheet supersedes the storage and handling information on the vial and carton labels.

Storage Prior to Use

As Displayed on the Vial Labels and Cartons

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25º to -15ºC (-13º to 5ºF). Store in the original carton to protect from light.

Additional Storage Information Not Displayed on the Vial Labels and Cartons

Do not store on dry ice or below -40ºC (-40ºF).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours.

Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration.

If either of these conditions exists, the vaccine should not be administered.
- Each dose is 0.5 mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

Administration
Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,
- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

CONTRAINDICATION
Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

WARNINGS
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS
Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. *(See Full EUA Prescribing Information)*

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

USE WITH OTHER VACCINES

There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Moderna COVID- 19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

    *Serious adverse events are defined as:
    - Death;
    - A life-threatening adverse event;
    - Inpatient hospitalization or prolongation of existing hospitalization;
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - A congenital anomaly/birth defect;
    - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.
Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

ADDITIONAL INFORMATION
For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES
There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA
The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

COUNTERMEASURES INJURY COMPENSATION PROGRAM
The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are

specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Patent(s): www.modernatx.com/patents
Revised: 12/2020

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA)
PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION
2.1 Preparation for Administration
2.2 Administration
2.3 Dosing and Schedule
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Management of Acute Allergic Reactions
5.2 Altered Immunocompetence
5.3 Limitations of Vaccine Effectiveness
6 OVERALL SAFETY SUMMARY
6.1 Clinical Trials Experience
8 ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS REPORTING REQUIREMENTS AND INSTRUCTIONS
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20 PATIENT COUNSELING INFORMATION
21 CONTACT INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain

white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.

- Each dose is 0.5mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Moderna COVID-19 Vaccine is administered as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse

reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.3 Limitations of Vaccine Effectiveness

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID- 19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White,10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were Other, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected using standardized diary cards for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose by subject are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		**Placebo[a]**	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Local Adverse Reactions				
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3[b]	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/tenderness, Grade 3[b]	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25 mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3[c]	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25 mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)
Erythema (redness), Grade 3[c]	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)
Systemic Adverse Reactions				
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade 3[d]	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Headache, Grade 3[f]	219 (1.9)	553 (5.0)	162 (1.4)	129 (1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade 3[d]	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade 3[d]	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3[g]	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3[h]	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade 3[i]	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade 4[j]	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use of antipyretic or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

[f] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[g] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[h] Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

[i] Grade 3 fever: Defined as ≥39.0 – ≤40.0°C / ≥102.1 – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Local Adverse Reactions				
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3[b]	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/tenderness, Grade 3[b]	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25 mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3[c]	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25 mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3[c]	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions				
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade 3[d]	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade 3[e]	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade 3[d]	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade 3[d]	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3[f]	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Nausea/vomiting, Grade 3[g]	4 (0.1)	10 (0.3)	4 (0.1)	3 (<0.1)
Nausea/vomiting, Grade 4[h]	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade 3[i]	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade 4[j]	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use of antipyretic or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).
[a] Placebo was a saline solution.
[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.
[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.
[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.
[e] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
[f] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
[g] Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.
[h] Grade 4 Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.
[i] Grade 3 fever: Defined as ≥39.0 – ≤40.0°C / ≥102.1 – ≤104.0°F.
[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 2 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-Diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included

lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible

for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of multisystem inflammatory syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines

received within one month prior.

2. In Box 18, description of the event:
    a. Write “Moderna COVID-19 Vaccine EUA” as the first line
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider’s office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary
All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically

recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development or postnatal development were reported in the study.

11.2 Lactation

Risk Summary
Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use
Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use
Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age *[see Clinical Trial Results and Supporting Data for EUA (18)]*. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants *[*see *Clinical Trials Experience (6.1*)*]*.

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

A Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older is ongoing in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set), included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were white, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

<u>Efficacy Against COVID-19</u>

COVID-19 was defined based on the following criteria: The participant must have experienced

at least two of the following systemic symptoms: fever (≥38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model

The subgroup analyses of vaccine efficacy are presented in Table 4.

Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per- Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)*
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS, (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple-Dose Vials are supplied as a carton of 10 multiple-dose vials (NDC 80777-273-99).

Store frozen between -25º to -15ºC (-13º to 5ºF). Store in the original carton to protect from light. Do not store on dry ice or below -40ºC (-40ºF).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most resent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

Patent(s): www.modernatx.com/patents
Revised: 12/2020

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?
Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?
- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Patent(s): www.modernatx.com/patents
Revised: 12/2020

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **Pfizer-BioNTech COVID-19 Vaccine**, for active immunization to prevent COVID-19 in individuals 16 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.3 mL each) 3 weeks apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF). Vials must be kept frozen between -80ºC to -60ºC (-112ºF to -76ºF) and protected from light until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Vials After Dilution

- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Any vaccine remaining in vials must be discarded after 6 hours.
- Do not refreeze.

Dosing and Schedule

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

Prior to Dilution

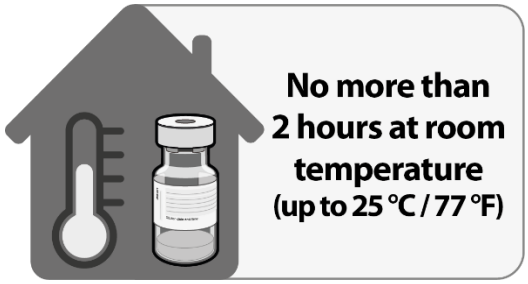
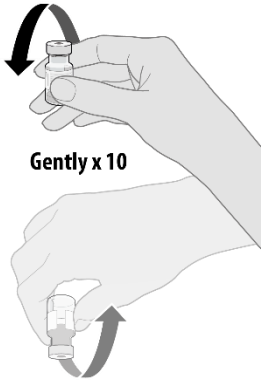
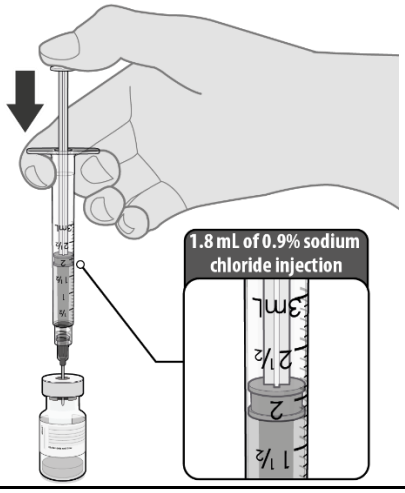
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)] *(see Storage and Handling)*.
- Refer to thawing instructions in the panels below.

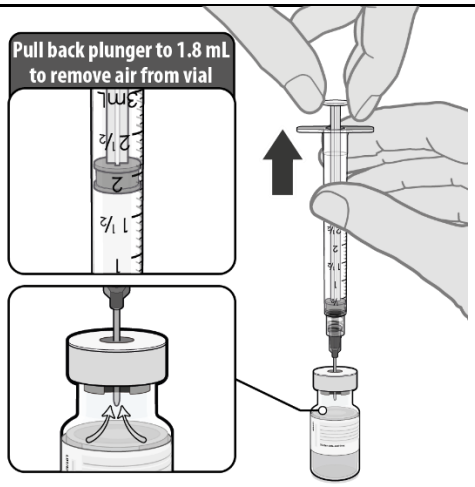
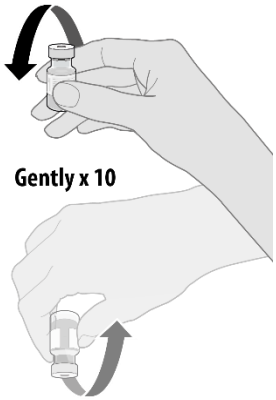
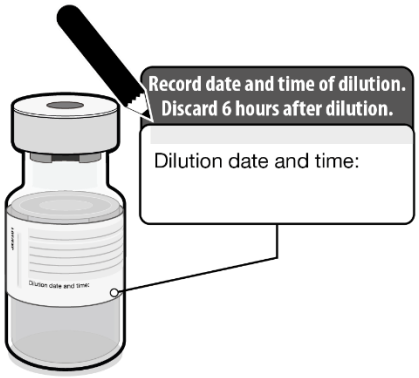
Dilution

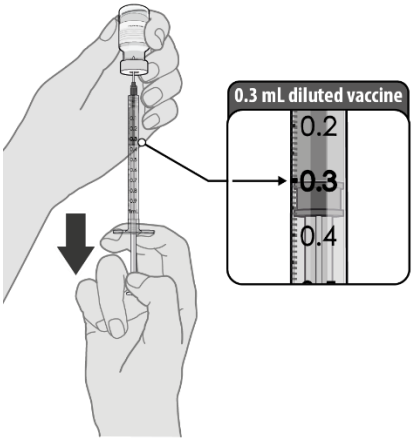
Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent.

After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Fact Sheet regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: ○ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). ○ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	• Before dilution invert vaccine vial gently 10 times. • <u>Do not shake</u>. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

Warnings

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs

following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy *(see Full EUA Prescribing Information)*.

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine.

Use with Other Vaccines

There is no information on the co-administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.cvdvaccine.com to obtain the Fact Sheet) prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Pfizer-BioNTech COVID-19 Vaccine.

Provide the v-safe information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 16 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting

to VAERS call 1-800-822-7967. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

* Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND PFIZER INC.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

ADDITIONAL INFORMATION

For general questions, visit the website or call the telephone number provided below.

To access the most recent Pfizer-BioNTech COVID-19 Vaccine Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The Secretary of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 pandemic. In response, FDA has issued an EUA for the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization against COVID-19 in individuals 16 years of age and older.

FDA issued this EUA, based on Pfizer-BioNTech's request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Pfizer-BioNTech COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

The Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the Pfizer-BioNTech COVID-19 Vaccine used to prevent COVID-19, visit www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1450-4.0

Revised: January 2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

PFIZER-BIONTECH COVID-19 VACCINE

FULL EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION: CONTENTS*

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* Sections or subsections omitted from the full emergency use authorization prescribing information are not listed.

FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

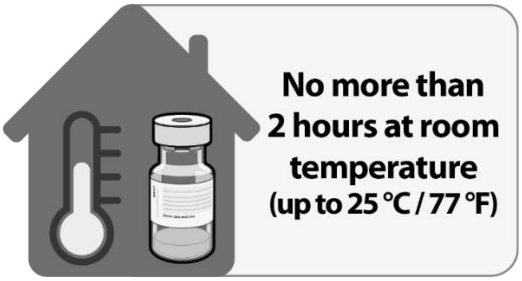
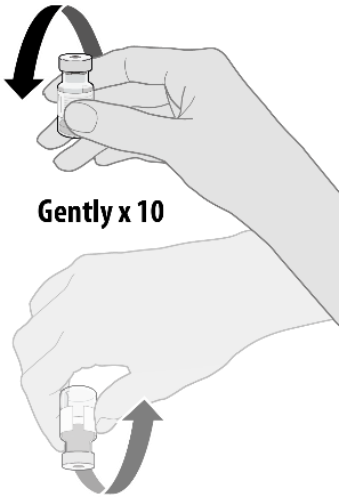
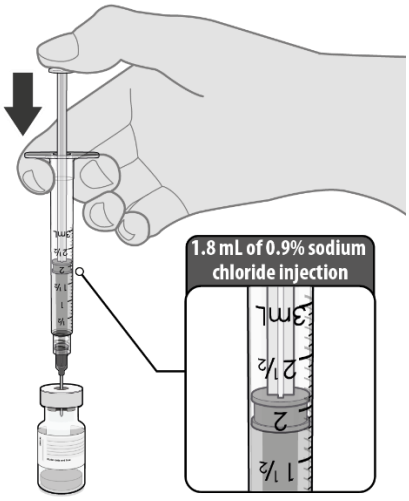
2.1 Preparation for Administration

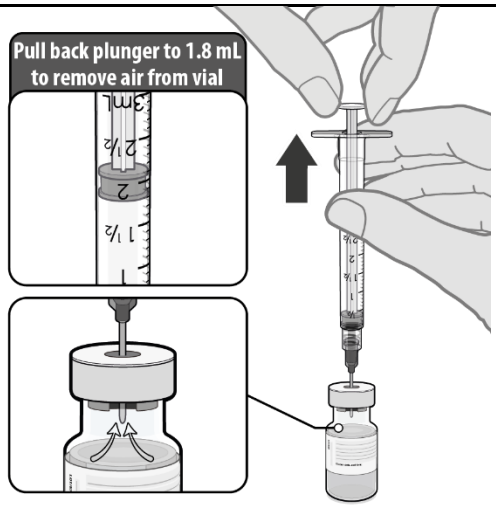
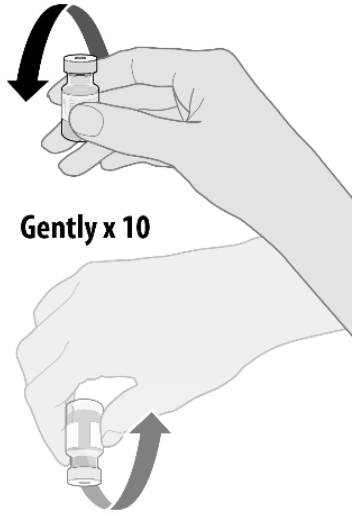
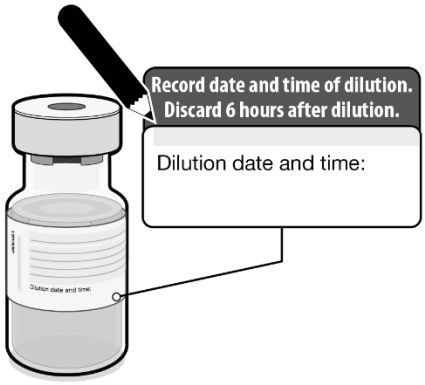
Prior to Dilution

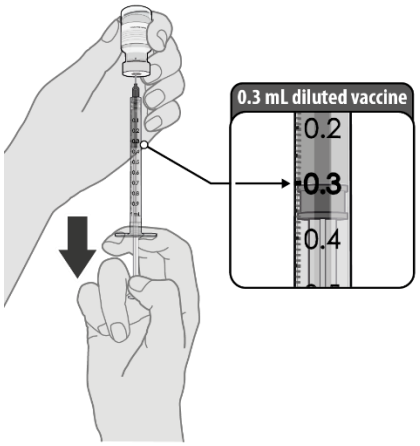
- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)] *[see How Supplied/Storage and Handling (19)]*.
- Refer to thawing instructions in the panels below.

Dilution

- Dilute the vial contents using 1.8 mL of 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. Do not add more than 1.8 mL of diluent.
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.
- Refer to dilution and dose preparation instructions in the panels below.

THAWING PRIOR TO DILUTION	
	• Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: o Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). o Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
	• Before dilution invert vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using low dead-volume syringes and/or needles. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

2.2 Administration Information

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

2.3 Vaccination Schedule for Individuals 16 Years of Age and Older

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Pfizer-BioNTech COVID-19 Vaccine is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/).

5.2 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.

5.3 Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Pfizer-BioNTech COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to Pfizer Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Pfizer Inc.

In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of Pfizer-BioNTech COVID-19 Vaccine was evaluated in participants 16 years of age and older in two clinical studies conducted in the United States, Europe, Turkey, South Africa, and South America. Study BNT162-01 (Study 1) was a Phase 1/2, two-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age. Study C4591001 (Study 2) is a Phase 1/2/3, multicenter, multinational, randomized, saline placebo-controlled, observer-blind, dose-finding, vaccine candidate-selection (Phase 1) and efficacy (Phase 2/3) study that has enrolled approximately 44,000 participants, 12 years of age or older. Of these, approximately 43,448 participants (21,720 Pfizer-BioNTech COVID-19 Vaccine; 21,728 placebo) in Phase 2/3 are 16 years of age or older (including 138 and 145 adolescents 16 and 17 years of age in the vaccine and placebo groups, respectively).

At the time of the analysis of Study 2 for the EUA, 37,586 (18,801 Pfizer-BioNTech COVID-19 Vaccine and 18,785 placebo) participants 16 years of age or older have been followed for a median of 2 months after the second dose of Pfizer-BioNTech COVID-19 Vaccine.

The safety evaluation in Study 2 is ongoing. The safety population includes participants enrolled by October 9, 2020, and includes safety data accrued through November 14, 2020. Participants 18 years and older in the reactogenicity subset are monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination].

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received Pfizer-BioNTech COVID-19 Vaccine and those who received placebo. Overall, among the total participants who received either the Pfizer-BioNTech COVID-19 Vaccine or placebo, 50.6% were male and 49.4% were female, 83.1% were White, 9.1% were Black or African American, 28.0% were Hispanic/Latino, 4.3% were Asian, and 0.5% were American Indian/Alaska Native.

Local and Systemic Adverse Reactions Solicited in the Study 2

Table 1 and Table 2 present the frequency and severity of solicited local and systemic reactions, respectively, within 7 days following each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo in the subset of participants 18 to 55 years of age included in the EUA safety population who were monitored for reactogenicity with an electronic diary.

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of each dose of Pfizer-BioNTech COVID-19 Vaccine and placebo for participants 56 years of age and older.

Across both age groups, the mean duration of pain at the injection site after Dose 2 was 2.5 days (range 1 to 36 days), for redness 2.6 days (range 1 to 34 days), and for swelling 2.3 days (range 1 to 34 days) for participants in the Pfizer-BioNTech COVID-19 Vaccine group.

Solicited reactogenicity data in 16 and 17 year-old participants are limited.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age‡ – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Redness[c]				
Any (>2 cm)	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2)	10 (0.5)	0 (0.0)
Swelling[c]				
Any (>2 cm)	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0.0)
Pain at the injection site[d]				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

‡ Eight participants were between 16 and 17 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 18-55 Years of Age‡ – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Fever				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0.0)	2 (0.1)	1 (0.0)	0 (0.0)
Fatigue[c]				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Headache[c]				

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=2291 n[b] (%)	Placebo Dose 1 N[a]=2298 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=2098 n[b] (%)	Placebo Dose 2 N[a]=2103 n[b] (%)
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321 (15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Chills[c]				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0.0)
Vomiting[d]				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0.0)	1 (0.0)	4 (0.2)	0 (0.0)
Diarrhea[e]				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0.0)	4 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
New or worsened joint pain[c]				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0.0)	20 (1.0)	4 (0.2)
Use of antipyretic or pain medication[f]	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.
f. Severity was not collected for use of antipyretic or pain medication.
‡ Eight participants were between 16 and 17 years of age.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Redness[c]				
Any (>2 cm)	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Swelling[c]				
Any (>2 cm)	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0.0)	3 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2 cm)	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	125 (7.6)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0.0)	8 (0.5)	0 (0.0)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
b. n = Number of participants with the specified reaction.
c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.
d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.
* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)
Fatigue[c]				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Pfizer-BioNTech COVID-19 Vaccine Dose 1 N[a]=1802 n[b] (%)	Placebo Dose 1 N[a]=1792 n[b] (%)	Pfizer-BioNTech COVID-19 Vaccine Dose 2 N[a]=1660 n[b] (%)	Placebo Dose 2 N[a]=1646 n[b] (%)
Headache[c]				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Chills[c]				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0.0)	1 (0.1)	17 (1.0)	0 (0.0)
Vomiting[d]				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0.0)	1 (0.1)	0 (0.0)
Severe	0 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Diarrhea[e]				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
New or worsened joint pain[c]				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

a. N = Number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention.

Unsolicited Adverse Events

Serious Adverse Events

In Study 2, among participants 16 to 55 years of age who had received at least 1 dose of vaccine or placebo (Pfizer-BioNTech COVID-19 Vaccine = 10,841; placebo = 10,851), serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported by 0.4% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.3% of placebo recipients. In a similar analysis, in participants 56 years of age and older (Pfizer-BioNTech COVID-19 Vaccine = 7960, placebo = 7934), serious adverse events were reported by 0.8% of Pfizer-BioNTech COVID-19 Vaccine recipients and by 0.6% of placebo recipients who received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine or placebo, respectively. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. Appendicitis was reported as a serious adverse event for 12 participants, and numerically higher in the vaccine group, 8 vaccine participants and 4 placebo participants. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

Non-Serious Adverse Events

Overall in Study 2 in which 10,841 participants 16 to 55 years of age received Pfizer-BioNTech COVID-19 Vaccine and 10,851 participants received placebo, non-serious adverse events from Dose 1 through up to 30 days after Dose 2 in ongoing follow-up were reported in 29.3% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 13.2% of participants in the placebo group, for participants who received at least 1 dose. Overall in a similar analysis in which 7960 participants 56 years of age and older received Pfizer-BioNTech COVID-19 Vaccine, non-serious adverse events within 30 days were reported in 23.8% of participants who received Pfizer-BioNTech COVID-19 Vaccine and 11.7% of participants in the placebo group, for participants who received at least 1 dose. In these analyses, 91.6% of study participants had at least 30 days of follow-up after Dose 2. The higher frequency of reported unsolicited non-serious adverse events among Pfizer BioNTech COVID-19 Vaccine recipients compared to placebo recipients was primarily attributed to local and systemic adverse events reported during the first 7 days following vaccination that are consistent with adverse reactions solicited among participants in the reactogenicity subset and presented in Tables 3 and 4. From Dose 1 through 30 days after Dose 2, reports of lymphadenopathy were imbalanced with notably more cases in the Pfizer-BioNTech COVID-19 Vaccine group (64) vs. the placebo group (6), which is plausibly related to vaccination. Throughout the safety follow-up period to date, Bell's palsy (facial paralysis) was reported by four participants in the Pfizer-BioNTech COVID-19 Vaccine group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. No cases of Bell's palsy were reported in the placebo group. Currently available information is insufficient to determine a causal relationship with the vaccine. There were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Pfizer-BioNTech COVID-19 Vaccine.

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for MANDATORY reporting of the listed events following Pfizer-BioNTech COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in children and adults
- Cases of COVID-19 that result in hospitalization or death

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of the Pfizer-BioNTech COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Pfizer-BioNTech COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Pfizer-BioNTech COVID-19 Vaccine EUA" as the first line.
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.

3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Emergency Use Authorization of Pfizer-BioNTech COVID-19 Vaccine in adolescents 16 and 17 years of age is based on extrapolation of safety and effectiveness from adults 18 years of age and older. Emergency Use Authorization of Pfizer BioNTech COVID-19 Vaccine does not include use in individuals younger than 16 years of age.

11.4 Geriatric Use

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy *[see Overall Safety Summary (6.1) and Clinical Trial Results and Supporting Data for EUA (18.1)]*. Of the total number of Pfizer-BioNTech COVID-19 Vaccine recipients in Study 2 (N=20,033), 21.4% (n=4,294) were 65 years of age and older and 4.3% (n=860) were 75 years of age and older.

13 DESCRIPTION

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy in Participants 16 Years of Age and Older

Study 2 is a multicenter, multinational, Phase 1/2/3, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV).

In the Phase 2/3 portion approximately 44,000 participants 12 years of age and older were randomized equally and received 2 doses of Pfizer-BioNTech COVID-19 Vaccine or placebo separated by 21 days. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

The population for the analysis of the primary efficacy endpoint included, 36,621 participants 12 years of age and older (18,242 in the Pfizer-BioNTech COVID-19 Vaccine group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. Table 5 presents the specific demographic characteristics in the studied population.

Table 5: Demographics (population for the primary efficacy endpoint)[a]

	Pfizer-BioNTech COVID-19 Vaccine (N=18,242) n (%)	**Placebo (N=18,379) n (%)**
Sex		
Male	9318 (51.1)	9225 (50.2)
Female	8924 (48.9)	9154 (49.8)
Age (years)		
Mean (SD)	50.6 (15.70)	50.4 (15.81)
Median	52.0	52.0
Min, max	(12, 89)	(12, 91)
Age group		
≥12 through 15 years	46 (0.3)	42 (0.2)
≥16 through 17 years	66 (0.4)	68 (0.4)
≥16 through 64 years	14,216 (77.9)	14,299 (77.8)
≥65 through 74 years	3176 (17.4)	3226 (17.6)
≥75 years	804 (4.4)	812 (4.4)
Race		
White	15,110 (82.8)	15,301 (83.3)
Black or African American	1617 (8.9)	1617 (8.8)
American Indian or Alaska Native	118 (0.6)	106 (0.6)
Asian	815 (4.5)	810 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)
Other[b]	534 (2.9)	516 (2.8)
Ethnicity		
Hispanic or Latino	4886 (26.8)	4857 (26.4)
Not Hispanic or Latino	13,253 (72.7)	13,412 (73.0)
Not reported	103 (0.6)	110 (0.6)
Comorbidities[c]		
Yes	8432 (46.2)	8450 (46.0)
No	9810 (53.8)	9929 (54.0)

a. All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window, have no other important protocol deviations as determined by the clinician, and have no evidence of SARS-CoV-2 infection prior to 7 days after Dose 2.

b. Includes multiracial and not reported.

c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease
- Chronic lung disease (e.g., emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma
- Significant cardiac disease (e.g., heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)
- Obesity (body mass index ≥ 30 kg/m^2)
- Diabetes (Type 1, Type 2 or gestational)
- Liver disease
- Human Immunodeficiency Virus (HIV) infection (not included in the efficacy evaluation)

Efficacy Against COVID-19

The population in the primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 to 55 years of age and 56 years of age and older began enrollment from July 27,2020, 16 to 17 years of age began enrollment from September 16, 2020 and 12 to 15 years of age began enrollment from October 15, 2020.

The vaccine efficacy information is presented in Table 6.

Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=18,198 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=18,325 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	8 2.214 (17,411)	162 2.222 (17,511)	95.0 (90.3, 97.6)[f]
16 to 64 years	7 1.706 (13,549)	143 1.710 (13,618)	95.1 (89.6, 98.1)[g]
65 years and older	1 0.508 (3848)	19 0.511 (3880)	94.7 (66.7, 99.9)[g]
First COVID-19 occurrence from 7 days after Dose 2 in participants with or without evidence of prior SARS-CoV-2 infection			
Subgroup	**Pfizer-BioNTech COVID-19 Vaccine N[a]=19,965 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=20,172 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI)**
All subjects[e]	9 2.332 (18,559)	169 2.345 (18,708)	94.6 (89.9, 97.3)[f]
16 to 64 years	8 1.802 (14,501)	150 1.814 (14,627)	94.6 (89.1, 97.7)[g]
65 years and older	1 0.530 (4044)	19 0.532 (4067)	94.7 (66.8, 99.9)[g]

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. No confirmed cases were identified in participants 12 to 15 years of age.
f. Credible interval for VE was calculated using a beta-binomial model with a beta (0.700102, 1) prior for $\theta=r(1-VE)/(1+r(1-VE))$, where r is the ratio of surveillance time in the active vaccine group over that in the placebo group.
g. Confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

19 HOW SUPPLIED/STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) or 195 multiple dose vials (NDC 59267-1000-2). After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information in this Full EUA Prescribing Information regarding the number of doses per vial after dilution supersedes the number of doses stated on vial labels and cartons.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and store in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF). Vials must be kept frozen between -80ºC to -60ºC (-112ºF to -76ºF) and protected from light, in the original cartons, until ready to use.

If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage within this temperature range is not considered an excursion from the recommended storage condition.

Thawed Vials Before Dilution

Thawed Under Refrigeration
Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature
For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.cvdvaccine.com.

Manufactured by
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Revised: January 2021

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?
Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?
FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD <u>NOT</u> GET THE PFIZER-BIONTECH COVID-19 VACCINE?
You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?
The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?
The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in **v-safe. V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?
It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?
Currently, there is no approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?
No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-2.0

Revised: December 2020

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

VERMONT
DEPARTMENT OF HEALTH

Protocol for COVID-19 Vaccine Administration			
Date Created:	December 2020	Last Revision Date:	January 2021
Author:	Robinson, Margaret		
Division:	All		

PURPOSE

Public Health Nurses and other professionals working for the Vermont Department of Health who are licensed to administer immunizations in Vermont will safely administer immunizations according to current department medical orders, adhering to practice standards and CDC recommendations.

PROCEDURE

1. Before administering vaccinations, staff should review CDC's vaccine administration training, COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers

A. Assessment

1. Review and be familiar with the appropriate Standing Medical Orders for COVID-19 vaccinations.
2. Become familiar with the Emergency Care/Management of Vaccines and CDC's Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination.
3. Become familiar with the Epinephrine medical order and protocol.
4. Be aware of COVID-19 vaccine specific information, including contraindications and message to give should someone be contraindicated for the vaccine.

B. Preparation & Verification

1. Read the current medical order for each vaccination to be administered.
2. Review Immunization Precautions and Contraindications.
3. Prepare the clinic area prior to immunization appointment. Clean all surfaces as appropriate. Prepare work area and waste disposal for sharps and any hazardous waste.

4. Assure there is access to a phone should you need to call for help.

5. Review epinephrine indications, instructions for use, and assure that no products have expired.

6. Review the epinephrine administration order.

7. Read the vaccine package insert for vaccine specific information.

8. Review the Vaccine Administration Management System (VAMS) and be familiar with how to use it and what you will need to complete in it.

9. Call the client over to your station. Introduce yourself to the client and review the procedure to be done, including the steps you will take and which vaccines you will give.

10. Verify the identity of the client and the parent/guardian if needed.

11. Assess if the client will need privacy for the immunization and provide it when possible.

12. Review and collect vaccine screening form.

13. Review risks and benefits, possible reactions, and site aftercare recommendations and answer any remaining questions.

C. Administration

2. Prepare the equipment needed to administer the immunization. This includes but is not limited to:
    - Soap and water
    - Hand sanitizer if no soap and running water
    - Correct size syringe and needle when injecting
    - Isopropyl alcohol prep pads
    - Gloves (if needed)
    - Bandages
    - Gauze
    - Sharps container
    - Vaccine
    - Diluent (as needed)
    - Epinephrine kit

3. Verify the client's identity again and explain how the immunization administration.

4. Determine the site the immunization will be given.

5. Have the client be seated or reclining during the immunization. If client is a minor review how parent should hold and comfort the child during the immunization.

6. Before vaccination, the client should remove any food or gum in their mouth.

7. Perform appropriate hand hygiene and don gloves if needed.

8. Prepare the site.

9. Prepare vaccine for immunization follow the guidance provided in the CDC vaccine administration training, COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Healthcare Providers

10. Administer vaccine using appropriate technique for the immunization being given.

11. Appropriately dispose of the syringe, vial and other medical waste.

12. Apply bandage as necessary.

13. Perform appropriate hand hygiene.

14. Document the immunization appropriately and offer a vaccine administration card to the client and/or parent/guardian.

15. Appropriately document immunization in VAMS.

16. Answer any additional questions from the client, refer them to the VIS as needed and ask them to wait the appropriate interval before leaving the clinic. Wait time is based on specific vaccine being given and the clients medical information shared in the screening form.

17. Clean up the area used for the immunization administration.

Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:

- No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, a second dose of the same brand should be administered.
  - This vaccine is administered in a 2-dose series. Separate doses by at least 28 days.*
- Moderna COVID-19 Vaccine should not be administered at the same time as other vaccines. Separate Moderna COVID-19 Vaccine from other vaccines by 14 days before or after the administration of Moderna COVID-19 vaccine.
- Moderna COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindication
    - Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine for both Pfizer-BioNTech and Moderna COVID-19 vaccines. For a list of vaccine components, see the Emergency Use Authorization (EUA).
  - Precautions
    - Severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous)
    - Moderate to severe illness
- Provide all recipients with a copy of the current federal Emergency Use Authorization (EUA) Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine.
  - Choose the correct needle gauge, needle length, and injection site for persons:
    - 18 years of age: 1-inch needle is recommended.
    - 19 years of age and older: See table below.
  - Follow the manufacturer's guidance for storing/handling punctured vaccine vials.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site†
Female or male fewer than 130 lbs	22–25	⅝§–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* If the second dose of Moderna COVID-19 Vaccine was given as early as 24 days after the first dose, then do not repeat a second dose.

† Alternatively, the anterolateral thigh also can be used.

§ Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

Moderna COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

- Administer 0.5 mL Moderna COVID-19 Vaccine by intramuscular (IM) injection.
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - Immunization information system (IIS): Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at https://www.modernatx.com/.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
    - Persons with a history of any anaphylaxis: 30 minutes
    - All other persons: 15 minutes
  - Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 epinephrine prefilled syringes or autoinjectors, H1 antihistamine, blood pressure cuff, and stethoscope and timing device to assess pulse.
  - For more information, please see:
    - **Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html**
    - CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/generalrecs/adverse-reactions.html
    - **Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf**
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    - Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - Serious AEs (irrespective of attribution to vaccination)
    - Multisystem inflammatory syndrome (MIS) in adults or children
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the Vermont Department of Health Clincs effective 12/22/2020 until rescinded or until the vaccine is no longer being used under an EUA.

Medical director (or other authorized practitioner) J. Reams MD, DEC 23, 2020

Adapted from Immunization Action Coalition Standing Orders templates. These templates for routinely recommended vaccines can be found at https://www.immunize.org/standing-orders/. We thank the Immunization Action Coalition for the use of their resources.

Pfizer-BioNTech COVID-19 Vaccine

Standing Orders for Administering Vaccine to Persons 16 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state or local health department or the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

- Assess persons 16 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria: No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, the second dose of the same brand should be administered.
  - This vaccine is administered in a **2-dose** series. Separate doses by at least 21 days.*
  - Pfizer-BioNTech COVID-19 Vaccine should not be administered at the same time with other vaccines. Separate Pfizer-BioNTech COVID-19 Vaccine from other vaccines by 14 days before or after the administration of COVID-19 vaccine.
- Screen for contraindications and precautions.
  - Contraindications
    - Severe allergic reaction (e.g., anaphylaxis) to a previous dose of Pfizer-BioNTech COVID-19 Vaccine or to a component of the vaccine.
  - Precautions
    - Severe allergic reaction (e.g., anaphylaxis) to a previous dose of any vaccine (not including Pfizer-BioNTech COVID-19 Vaccine).
    - Severe allergic reaction (e.g., anaphylaxis) to a medication that is injectable
    - Moderate to severe acute illness
- Provide Emergency Use Authorization (EUA) patient information.
  - Provide all recipients with a copy of the current federal EUA Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine.
  - Choose the correct needle gauge, needle length, and injection site for persons:
    - 16 through 18 years of age: 1-inch needle is recommended, administered in the deltoid muscle of the arm.
    - 19 years of age and older: See table below.

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site**
Female or male fewer than 130 lbs	22–25	⅝***–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs	22–25	1-1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1-1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* If the 2nd dose Pfizer vaccine was given as early as 17 days after the 1st dose, then do not repeat a 2nd dose.

** Alternatively, the anterolateral thigh also can be used.

*** Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

- Mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine.

- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.Document vaccination.
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., Immunization Information System) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - Immunization information system: Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
    - Persons with a history of a any anaphylaxis: 30 min
    - All other persons: 15 minutes
  - Be prepared to manage a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For more information, please see:
    - CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html.
    - Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    - Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - Serious AEs (irrespective of attribution to vaccination)
    - Multisystem inflammatory syndrome (MIS) in adults or children
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the Vermont Department of Health Clincs effective 12/17/2020 until rescinded or until the vaccine is no longer being used under an EUA.

Medical director (or other authorized practitioner)
Jennifer Reas MD December 17, 2020

Adapted from Immunization Action Coalition Standing Orders templates. These templates for routinely recommended vaccines can be found at https://www.immunize.org/standing-orders/. We thank the Immunization Action Coalition for the use of their resources.

VERMONT
DEPARTMENT OF HEALTH

BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN (BBPECP)			
Date created:	2008	Last revision date:	August 2019
Author:	Margaret E Robinson, Director of Public Health Nursing		
Divisions:	All		

PURPOSE

In accordance with the OSHA Regulations (Standards - 29 CFR) Bloodborne Pathogens - 1910.1030, Appendix A (Federal Register 01/18/01), Compliance Directive CPL 2-2.44D (11/5/99), and the VOSHA Safety and Health Standards for General Industry (29CFR1910), this exposure control plan has been developed, including the Appendices listed at the end of this document.

At a minimum, this document will be reviewed annually by the Director of Public Health Nursing or designee and updated as appropriate.

DEFINITIONS

DisCide – Ultra Disinfecting Towelettes, MSDS Sheet: http://portal.ecolab.com/servlet/PdfServlet?sid=914400&cntry=US&langid=en-US&langtype=RFC1766LangCode&locale=en_US&pdfname=DISCIDE+ULTRA+DISINFECTING+TOWELETTES

OPIM - Other Potentially Infectious Materials;

OSHA – Occupational Safety and Health Administration, https://www.osha.gov/

Standard Precautions - Standard Precautions include a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered. These include: hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; and safe injection practices. Also, equipment or items in the patient environment likely to have been contaminated with infectious body fluids must be handled in a manner to prevent transmission of infectious agents (e.g., wear gloves for direct contact, contain heavily soiled equipment, properly clean and disinfect or sterilize reusable equipment before use on another patient).

The application of Standard Precautions during patient care is determined by the nature of the healthcare worker patient interaction and the extent of anticipated blood, body fluid, or pathogen exposure. See Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007 found at http://www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf for more specifics.

Body fluids to which standard precautions apply are blood, semen, vaginal secretions, breast milk, synovial fluid, cerebrospinal fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

Regulated Waste - Regulated waste is liquid or semi-liquid blood or other potentially infectious materials; contaminated items that release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

LMS – AHS Learning Management System

VOSHA – Vermont Occupational Safety and Health Administration, http://labor.vermont.gov/vosha/

PROCEDURE

Exposure Determination

Appendix 2 lists positions at the Vermont Department of Health that have been identified as Having potential occupational exposure. Appendix 2 also lists tasks and procedures in which occupational exposures may take place. By performance of the tasks and duties listed, it may reasonably be anticipated that an employee may be occupationally exposed to blood or OPIM by one or more of the following routes: Skin, eye, mucous membrane and parenteral exposure.

Practice Controls

Annually, the Director of Public Health Nursing or designee will review the use of engineering controls, consider new technologies that have become available, and review any "Deviation from Standard Clinical Practice forms" for patterns. Assessment of possible need for redesign of workplace practices and/or adoption of alternate safety products will be conducted with changes implemented when determined appropriate.

A. Prevention remains the primary strategy for reducing occupational bloodborne pathogen infections. Hepatitis B Vaccination is available at no cost to all employees who are reasonably anticipated to have skin, eye, mucous membrane, or parenteral exposure.

B. Hand Hygiene - "Hand hygiene has been cited frequently as the single most important practice to reduce the transmission of infectious agents in healthcare settings and is an essential element of Standard Precautions. The term "hand hygiene" includes both hand washing with either plain or antiseptic-containing soap and water, and use of alcohol-based products (gels, rinses, foams) that do not require the use of water. In the absence of visible soiling of hands, approved alcohol-based products for hand disinfection are may be used

over antimicrobial or plain soap and water. http://www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html). Hand sanitizers should contain 60-90% isopropyl solution or ethanol alcohol in foam, gel, or rinse.

- Hand hygiene is required before and after contact with each client and between clients.
- Employees shall perform hand hygiene immediately or as soon as possible after removal of gloves.
- It is important to perform hand hygiene after removing gloves and before touching anything, including pens, light switches, faucets, and door knobs.
- Failure to adhere to this instruction necessitates that all contaminated items and surfaces be cleaned with a 1:10 bleach solution.

C. Safety Devices - Safety syringes, retractable lancets, and safety venipuncture equipment are to be used by Health Department employees to carry out carry out their clinical responsibilities. Safety equipment will be used according to equipment instructions.

D. Personal Protective Equipment – Regulations (Standard - 29CFR) bloodborne pathogens 1910.1030d(3)(I)Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, or other ventilation devices.

Personal protective equipment will be considered 'appropriate' for protection against BBP only if it does not permit blood or potentially infectious material to pass through to reach the employee's work clothes, street clothes, undergarments, skin eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

E. Gloves – The Vermont Department of Health requires that gloves be worn at all times when coming in contact with blood or OPIM.

- Gloves shall be worn when the employee's hands may have direct skin contact with blood, OPIM, mucous membranes, or non-intact skin.
- Gloves shall also be worn when the employee handles items or surfaces soiled with blood or OPIM.
- Gloves are to be changed between clients.
- Gloves shall be replaced as soon as possible when visibly soiled, torn, punctured, or when their ability to function as a barrier is compromised.

- Gloved hands that have had contact with clients or specimens are considered soiled.
    - Remove gloves and perform hand hygiene prior to touching ANYTHING, including pens, light switches, faucets, and door knobs.
    - Failure to adhere to this instruction necessitates that all contaminated items and surfaces be cleaned with a the appropriate disinfection solution.

- Gloves are optional when administering intramuscular or subcutaneous injections as long as bleeding is not anticipated.

- Gloves are <u>not</u> optional when the health care professional has scratches, cuts, or other breaks in skin integrity to his/her hands.

- Gloves are **<u>always required</u>** for phlebotomy, lead screening and invasive hemoglobin screening.

F. <u>Other Protective Measures</u> - Employees administering immunizations, tuberculin skin testing or preforming phlebotomy tests will not wear open toe shoes. Eating, drinking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a potential for occupational exposure. Food and drink will not be stored in refrigerators, freezers, or cabinets where blood or OPIM are stored or in other areas of possible contamination. All procedures involving blood or OPIM will be performed in such a manner as to minimize splashing, spraying, and aerosolization of OPIM substances.

<u>Sharps Containers and Safe Disposal of Sharps</u>

Sharps consist of, but are not limited to, needles, syringes, lancets, HemoCues® cuvettes, venipuncture equipment, and sharp cutting objects that come into contact with client's body fluids. They should be considered as potentially infective after use and be handled with extraordinary care to prevent accidental injuries. Immediately after use, sharps should be placed directly into sharps containers for safe storage.

Sharps containers shall be easily accessible to personnel and located in the immediate area of use. Sharps containers shall be replaced routinely and should be closed and locked when the box is ¾ full. When filled containers are awaiting shipping, they should be stored in a box clearly labeled with the biohazard stickers. Do not store filled containers on top of refrigerators or on the top shelves of storage areas.

Immediately after use, sharps should be placed directly into sharps containers for safe storage.

See Appendix 4, "Safe disposal of vaccines, sharps containers and Regulated Waste".

<u>Safe Disposal of Medical and Regulated Waste (non-sharps)</u>

Dispose of any blood contaminated non-sharp item used in the procedure (disposable gloves, gauze, Band-Aid®, alcohol swab, etc.) in a plastic-lined wastebasket. Double bagging and

incineration are not necessary. However, the contaminated materials should be disposed of either at the clinic site (covered trash container) or returned to the Health Department for disposal.

If the contaminated items are soaked/caked in blood or OPIM, it is considered "regulated waste" and must be disposed of in an labeled bag in an appropriate manner. See Appendix 4, "Safe disposal of vaccines, sharps containers and Regulated Waste" for details on how to appropriately dispose of Regulated Waste.

Broken glassware, which may be contaminated, shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dustpan, or forceps. Broken glassware once cleaned up should be safely disposed in a manner to avoid creating any potentially hazardous situations.

Cleaning Clinic Work Surfaces & Non-Porous Equipment

Dental Hygienists working for the Vermont Department of Health may use DisCide products to clean all surfaces in the clinic area. All other Health Department staff should use Oxivir to clean all clinic work surfaces and equipment. Oxivir will be ordered through the Health Department standard supply ordering process.

- All clinic work surfaces and equipment shall be wiped clean with Oxivir or DisCide between clients if contaminated with blood or OPIM.

- Work surfaces must be cleaned when they become visibly contaminated.
  - First, the visible spill must be wiped up with a paper towel.
  - Then the paper towel must then be properly disposed.
  - Next, wipe the surface down with the solution.

- Work surfaces and equipment shall be wiped clean with Oxivir or DisCide when employees leave the area for lunch or breaks and at the end of the clinic day.

Communication of Hazards/Transportation of Hazards

1. Communication of Hazards - Warning labels shall be affixed to containers of infectious waste, refrigerators and freezers containing blood and OPIM, and other containers used to store or transport blood or OPIM. Use adhesive-backed labels supplied for this purpose. Labels shall be fluorescent orange or orange-red with letters or symbols in a contrasting color.

2. Transportation of Hazards – See Appendix 4.

Training - All employees with potential occupational exposure will participate in BBPEC training at the time of their initial employment. Training will occur at least annually thereafter and whenever there is a change in work practices or procedures involving potential exposure of employees to bloodborne pathogens or chemical hazards. It is recommended that support staff receive basic training on bloodborne pathogens to make them aware of the possible

risks in the workplace.

The Supervisor, District Director or designee will conduct the training in each district office following the outline in Appendix 3a. Attendance will be recorded in the AHS Learning Management System and on an attendance sheet. Documentation and training records will be kept in the either the employees District Office or their Division for 5 years from the date on which the training occurred.

Vermont Department of Health BBPEC Training is outlined in Appendix 3a. Components contained in the training must include:

1. Information about the location of the written Bloodborne Pathogen Exposure Control Plan as well as any applicable VOSHA standards.
2. An explanation of this Bloodborne Pathogens Exposure Control Plan, including an explanation of applicable chemical hazards (bleach).
3. Information about the hepatitis B vaccine, including information on its efficacy, safety, and the benefits of being vaccinated.
4. Information about the appropriate actions to take and persons to contact in the event of an emergency.
5. An explanation of the procedures to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available.
6. An explanation of the hazardous labels used in the department.
*****7. A general explanation of the epidemiology and symptoms of bloodborne diseases.
*****8. An explanation of the modes of transmission of bloodborne pathogens.
*****9. An explanation of the appropriate methods for recognizing tasks and activities that may involve exposure to blood and OPIM.
*10. An explanation of the use and limitations of practices that can prevent or reduce exposure, including appropriate engineering controls, work practices, and personal protective equipment.
*****11. An explanation of the basis for selection of personal protective equipment.

***** *Items 7–11 above are covered in the OSHA-approved training DVD. Three copies of the DVD are available and will circulate between district offices.*

Emergency Actions

All incidents involving exposure to blood or OPIM are considered emergencies and are to be reported immediately by the exposed or potentially exposed employee to his/her supervisor. The Supervisor/District Director will assist staff involved in the incident to follow the procedures currently in place.

Blood or OPIM Exposure - See also Appendix 8 and 9 for more information
The employee must immediately wash or flush (depending on site) the affected area with soap and water. Caustic substances such as bleach must not be used. If an employee **does not need additional medical services**, complete the State Employee Injury Reporting form at http://bgs.vermont.gov/workers_comp/injury .

If an employee is **injured and additional medical services are needed**, the employee should immediately seek medical care and the employees Supervisor can coordinate with the employee to assure that the State Employee Injury Reporting form is completed within 24hours.

The Director of Public Health Nursing and the Division Director should be notified about any incident on the day that it happens or as soon as feasible thereafter.

Provide the following information to the health care provider in the ED who will evaluate the exposed employee:

a. Partially completed "Checklist for Needle stick/ Sharps Injury" (BBP Appendix 5) if applicable

b. Partially completed "Employee's Claim and Employer First Report of Injury form" (AHS intranet)

c. "ED Report of Post-Exposure Incident" (BBP Appendix 6)

Supervisors of Employees at risk for BBP Exposure, or other designated Health Department staff who may be in positions of authority during a possible BBP exposure are responsible for the following:

- Informing staff of appropriate procedures in place for emergency situations.
- Complete the supervisor's section of the AHS Incident/Injury form and assures that it is submitted electronically to AHS Personnel. There is no need to obtain the employee's current hepatitis B, hepatitis C, or HIV status (baseline testing is recommended on the day of the incident at the Emergency Department if the incident involved Blood or OPIM exposure or possible exposure).
- Referencing the employee's documented hepatitis B vaccination titer history from Health Department records if possible exposure to blood or OPIM occurred.
- Assuring that a medical evaluation of the employee by a health care provider is arranged immediately by calling the local Emergency Department. The injured employee should proceed promptly to local Emergency Department for evaluation and treatment. Possible testing and HIV PEP may be determined necessary by the Emergency Department physician.
- Understanding that all evaluations, procedures, vaccinations, and post exposure management will be provided at no cost to the employee and will follow the current recommendations from the U.S. Public Health Service or other current authority, including evaluation for HIV post exposure prophylaxis (see Appendix 8).
- Source client (exposure source) bloodwork for HIV and Hepatitis B and C may be drawn at the District Office, with the individual's signed Informed Consent or it may be done at the individual's provider office. Source client's results shall be

sent only to the source's health care provider. All efforts to get the source client to complete a consent form to have their primary care provider share health information with the employees primary care provider should be made. The source client should be counseled not coerced into completing the consent form.

- Notification of the Director of Public Health Nursing and/or the Division Director of the exposure incident and sending a copy of AHS Employee Incident/Injury Report. The Director of Public Health Nursing may conduct an assessment of potential work practice changes.

Healthcare Provider:
Healthcare providers should be encouraged to collect blood specimen for baseline testing of the exposed employee. If blood tests for hepatitis B, hepatitis C, and/or HIV are not done initially, the provider must request that the laboratory maintain the employee's blood sample for 90 days in case the employee changes his or her mind about testing. As part of the employee's medical evaluation, the following resources should beconsulted for the latest information on post exposure prophylaxis and general management.

- **National Clinicians Post exposure Hotline**: 888-448-4911 (staffed by physicians 24 hours/7 days per week)
- **FAHC Infectious Disease practice:** (802) 847-4594. One of the doctors is always on call when the office is closed.

The Healthcare provider should counsel the employee about the incubation period, methods of transmission, and prevention of transmission of hepatitis B, hepatitis C, and HIV. Review results of the exposure source's lab work when obtained from the exposed employee's primary health care provider (if source individual has signed informed consent). Confidentiality shall be maintained with respect to the source individual's identity and test results. Exposure source's name will not be recorded with the exposed employee's records.

The physician or healthcare provider seen needs to complete two forms.

1. Complete the "ED Report of Post-Exposure Incident form" and return to the employee who should give it to their Supervisor and
2. Complete the Medical section of the "Employee's Claim and Employer First Report of Injury form".

Recordkeeping
Confidentiality of related records will be maintained in accordance with State of Vermont policies. The requirement to handle the employee health record in a fashion that is compliant with HIPAA and other applicable state and federal regulations should be a priority. Authorization for release of the health records contained in the record to the assessing/treating health care professional should be required and documentation or the authorization (or its refusal) should be retained in the record. A record will be established and maintained for each employee with an occupational BBP exposure. It will be stored in the District Office's or Divisions' centralized records of employee health, consistent with the Recordkeeping provisions of State Personnel Policy #17.5. These records shall be kept separate from the employee's

official personnel file for at least the duration of employment plus 30 years in accordance with VOSHA requirements. These records shall include:

a. Employee name and date of birth
b. A copy of the employee's hepatitis B vaccination/titer status (including dates) and/or a copy of the Hepatitis B Vaccine Declination form.
c. A copy of the health care professional's written opinion of evaluation following an exposure incident (ED Report of Post Exposure Incident form).
d. Results of any examinations, medical testing, and follow-up procedures in accordance with post-exposure evaluation and follow-up.
e. Copies of information given to the health care professional to include: a copy of the federal regulations on BBP, a description of the exposed employee's duties relating to the exposure incident, documentation of the route and circumstances under which the incident occurred, results of the source individual's blood testing if available, and all relevant medical records regarding the treatment of the employee.

Information regarding the circumstances of the exposure incident (AHS Incident/Injury Report and the Deviation from Standard Clinical Practice form) will be maintained separately by Vermont Department of Health's Director of Public Health Nursing.

FURTHER INFORMATION

Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001;50(No. RR-11); http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf

Centers for Disease Control and Prevention. Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for Postexposure Prophylaxis. MMWR 2005;54(No. RR-9); http://www.cdc.gov/mmwr/PDF/rr/rr5409.pdf

Department of Labor Occupational Safety and Health Administration, https://www.osha.gov/law-regs.html

Vermont Department of Health
Bloodborne Pathogens Exposure Control Plan (BBPECP) Training

The following Bloodborne Pathogens Exposure Control Plan (BBPECP) annual training is a VOSHA requirement for some employees (see Appendix 1). It must be conducted during orientation and repeated annually. It is recommended that staff review BBPECP prior to an employee being assigned to clinical activities. An attendance sheet must be used to record attendees of every Bloodborne Pathogens (BBP) training. Any Health Department BBP training must contain 4 major components:

1) Review of all areas of BBPEC. This can be done by watching the OSHA approved DVD, *Bloodborne Pathogens in Healthcare Facilities* (Marcom) or Bloodborne Pathogens in Healthcare Facilities by Atlantic Training.

2) Supervisor or trainer should provide information on the unique and specific aspects of BBPECP in the setting employees will be working in. They should at a minimum review:
   - The location of the written BBPECP (including all Appendices) in the Clinical Procedure Manual.
   - The following key components of the plan:
     - Prevention of BBP exposure such as vaccination, safety devices and hand hygiene.
     - Reporting and medical follow-up plan for exposure incidents.
     - Recordkeeping and documentation of incidents/injuries.

3) Each employee will read/review the BBPECP and all Appendices (1–9).

4) Employees will take the Competency Evaluation (Appendix 3). Answers to this evaluation can be found in the BBPEC policy and in Appendix 3a. The evaluation should be used as time for discussion of BBPEC so that the employee develops an understanding of BBP. After Supervisor or trainer feels employee has successfully completed the evaluation, the Supervisor or trainer will initial sign the employee's evaluation form and hold it on file.

Safe Disposal of Vaccines, Sharps Containers, and other Regulated Waste			
Date created:		Last revision date:	06/11/2019
Author:	Margaret E. Robinson, Public Health Nursing Director		
Division:	All		

PURPOSE

To provide safe and clear guidance on disposal of vaccines, sharps containers and regulated waste.
The following guidance should be followed for safe disposal of vaccines, sharps containers, and other regulated waste in any clinic or clinic activity during daily functions and emergency events.

PROCEDURE

Disposal Training for Staff

The Biohazardous Waste Training thru Stericycle is required for anyone who handles or transports waste or sharps to the Vermont Department of Health Department Lab (VDHL). This online training is free, but you do have to register. The training takes about 60 minutes to complete. Individuals will need to register through MyStericycle at http://mystericycle.com/register. To register, a person will need the VDHL's account information: Account #8059035 and address: 359 S Park Dr, Colchester, VT 05446. Once registered for the site, participants need to go to the Online Training Center to see the available courses. Individuals must take the Biohazardous Waste Training. Once registered, individuals should receive an email. There is a post-test after the training that must be passed with at least 80%. Individuals can take the exam over until they get at least 80%.
In the training section of the MyStericycle.com there is a Scores and Certificates tab that will allow a person to view and print the certificate and grades which will need to be filed in their training file. If you have a large group, it is possible to do a group class instead of having individuals do it online. If the training is done by a group, please use a sign in sheet that includes the date of the training as well as printed and signed names for individuals participating. Completed certificates must be scanned and sent to Joyce Oetjen at the VDHL. She will need to sign the certificate and then will send it back for the individual to keep on file. Group training should scan the certificate and the sign in sheet and send to Joyce Oetjen and include a note regarding that a group training occurred. This training must be done every calendar year.

Vaccine Disposal – In Vermont, live or attenuated vaccines are considered regulated medical waste. To help assure that appropriate disposal of empty vials occurs please dispose of **all** empty vaccine vials in regular waste/trash bags. Opened expired vials of vaccine should be disposed of in medical waste bags. **No vaccine vials should be put into sharps containers for disposal.**
Surplus and outdated vaccines should NOT be discarded as regulated waste. Please follow Immunization Program guidelines for removal of outdated or compromised vaccine.

Epinephrine Vial Disposal - Full and partially full epinephrine vials should be disposed of in medical waste bags.

Expired Sharps Disposal - All expired sharps (needles, syringes or blood collection sets) need to be taken out of their packaging and appropriately placed in sharps containers before being transported to the VDHL for disposal.

Sharps Containers and Autoclave Bags of Regulated Waste Disposal - Full sharps containers and regulated waste bags can be disposed of via the VDHL. The following steps are **required** when sending sharps containers and bags of regulated waste to VDHL:

1. The VDHL requires advance notice before materials are sent to them. Inform the Lab at 802-338-4724. That number will be answered by the front desk. You need to ask to speak to someone who can authorize the delivery of sharps for disposal.

2. All syringes, needles, lancets, cuvettes, blood drawing holders, and sharp cutting objects should be in rigid containers (preferably red sharps containers). Use packing tape to secure lid to container after locking the opening.

3. All medical waste bags should be transported in a box or other firm packaging. If leakage is possible a second container, that is closable and would contain all contents and prevent leakage during handling, storage, transport, or shipping is required.

4. Non-sharp items that are expired but unused, may be permissible to transport for disposal in the original packaging. The original packaging must be secured to prevent any leakage during handling, storage and transport.

5. All materials being shipped to the lab for disposal must be labeled as outlined below
    - Date sent
    - Contents
    - District Office of origin
    - Contact person at District Office and phone number
    - Expected and Estimated arrival time at the VDHL
    - Biohazard label

It is permissible for employees to transport regulated waste to the lab for disposal.

Transportation of materials to be properly disposed of by any non-Health Department source requires consultation with VDHL to assure delivery and they must adhere to the Vermont Agency of Natural Resources' Disposal of Regulated Medical Waste guidelines.

Guidelines for Transportation by a Health Department Employee:

1. Waste will be in a closed container; sharp containers will be taped shut.
2. Containers will be placed in a second container or box which can be securely closed.
3. The inner and outer container should be labeled with a biohazard sticker.

4. When transporting non-regulated waste, the weight of one or more inner packaging's, may not contain more than 0.5 kg (1.1 lbs.) or 0.5 L (17 ounces), and an outer packaging containing not more than 4 kg (8.8 lbs.) or 4 L (1 gallon); or a single inner packaging containing not more than 16 kg (35.2 lbs.) or 16 L (4.2 gallons) in a single outer packaging.[2]
5. When transporting regulated medical waste, a combination packaging must consist of one or more inner packaging's, each of which may not contain more than 4 kg (8.8 lbs.) or 4 L (1 gallon), and an outer packaging containing not more than 16 kg (35.2 lbs.) or 16 L (4.2 gallons).[2]
6. Container for transport should be put in the trunk of a car or in a location in the car that the material can be secured. Material should be placed in a location that will not impair driving.
7. Employees transporting regulated waste will have read this document, be familiar with the Health Departments BBPEC plan, be aware of what material they are transporting and have taken the Stericycle Biohazardous Waste Training.
8. Employees transporting regulated waste will be offered the protections of Division's Exposure Control Plan under 1910.1030 of the VOSHA Bloodborne Pathogen Rule.
9. When dropping off at VTHL use the loading dock entrance. Once at the loading dock you will need to pick up the phone there which will ring costumer service. Once you explain why you were there, they should forward the call to someone who can meet you take the container(s) from you for disposal.

References:

1. Disposal of Regulated Medical Waste: Vermont Agency of Natural Resources, https://dec.vermont.gov/sites/dec/files/wmp/SolidWaste/Documents/RegulatedMedicalWasteProcedures2018.pdf

2. § 173.6 Materials of trade exceptions: https://www.law.cornell.edu/cfr/text/49/173.6

When transported by motor vehicle in conformance with this section, a material of trade (see § 171.8 of this subchapter) is not subject to any other requirements of this subchapter besides those set forth or referenced in this section.
(4) A Division 6.2 material, other than a Category A infectious substance, contained in human or animal samples (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or is a biological product or regulated medical waste. The material must be contained in a combination packaging. For liquids, the inner packaging must be leakproof, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging (sharps container) must be constructed of a rigid material resistant to punctures and securely closed to prevent leaks or punctures, and the outer packaging must be securely closed to prevent leaks or punctures. For solids, liquids, and sharps, the outer packaging must be a strong, tight packaging securely closed and secured against shifting, including relative motion between packages, within the vehicle on which it is being transported.

(i) For other than a regulated medical waste, the amount of Division 6.2 material in a combination packaging must conform to the following limitations:

(A) One or more inner packagings, each of which may not contain more than 0.5 kg (1.1 lbs.) or 0.5 L (17 ounces), and an outer packaging containing not more than 4 kg (8.8 lbs.) or 4 L (1 gallon); or

(B) A single inner packaging containing not more than 16 kg (35.2 lbs.) or 16 L (4.2 gallons) in a single outer packaging.

(ii) For a regulated medical waste, a combination packaging must consist of one or more inner packagings, each of which may not contain more than 4 kg (8.8 lbs.) or 4 L (1 gallon), and an outer packaging containing not more than 16 kg (35.2 lbs.) or 16 L (4.2 gallons).

(4) The operator of a motor vehicle that contains a material of trade must be informed of the presence of the hazardous material (including whether the package contains a reportable quantity) and must be informed of the requirements of this section.

(e)Other exceptions. A material of trade may be transported on a motor vehicle under the provisions of this section with other hazardous materials without affecting its eligibility for exceptions provided by this section.

Combination packaging

Combination packaging means a combination of packaging, for transport purposes, consisting of one or more inner packagings secured in a non-bulk outer packaging. It does not include a composite packaging.

Vermont Department of Health
Checklist for Needlestick/Sharps Injuries

EMPLOYEE: _____ Date: _____

___ 1. Wash/flush injured area with soap and water thoroughly for several minutes

___ 2. Notify supervisor

___ 3. Get informed consent to draw specimen from source patient for immediate diagnostic testing (with Informed Consent—see Appendix 7):

Source patient information:

HIV status:	+	-	Unknown
HBV status:	+	-	Unknown
HCV status:	+	-	Unknown

___ HIV antibody (if status is unknown or hx of negative)
___ HBsAg (HBV antibody, if status is unknown or hx of negative)
___ HCV antibody (EIA or Elisa, if status is unknown or hx of negative)

Supervisor's assessment of relative risk of source patient if status not known by the patient.

___ high risk
___ no known risk category
___ unknown/not determined

___ 4. Obtain HBV vaccine/titer status from employee's records and record here:

Dates of 3-dose hepatitis B immunization series:
___/___/___, ___/___/___, ___/___/___

Date of hepatitis B titer: ___/___/___ Titer result: _____

Appropriate baseline blood specimens on the employee will be collected at the medical evaluation appointment.

___ 5. Contact local Emergency Department to notify them that a Health Department employee is coming in for evaluation of bloodborne pathogen exposure.

___ 6. **The injured employee should proceed promptly to local ED** for evaluation and treatment of the needle stick injury, testing, and possible HIV PEP (to be started within 1-2 hours of the incident, or as soon as possible thereafter).

___ 7. A follow-up appointment within 72 hours of the initial evaluation needs to be scheduled with the employee's primary provider and consultation with an HIV specialist at UVMMC or DHMC or directly with one of the HIV specialists is recommended to discuss evaluation and treatment needs.

___ 8. Follow CDC recommendations for post exposure testing.

Take a <u>copy</u> of this form to your medical evaluation on the day of the exposure.

Emergency Department Report of Post-Exposure Incident

Exposed Person's Name: _____

Date of visit: _____

Health Care Facility Address:

_____
_____
_____

Health Care Facility Phone: _____

As Required under the OSHA Bloodborne Pathogen Standard:

- The person named above has been informed of the results of the post-exposure medical evaluation.
- The person named above has been told about any medical conditions resulting from exposure to blood or any other potentially infectious materials that require further evaluation or treatment.

Recommendation for Post-Exposure prophylaxis:

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Please continue recommendations on a separate page if more space is required.

Printed name of Health Care Provider: _____

Signature of Health Care Provider: _____

Date of Signature: _____

VERMONT
DEPARTMENT OF HEALTH

Emergency Care due to an Adverse Event Protocol			
Date Created:		Last Revision Date:	August 2020
Author:	Margaret E Robinson, Public Health Nursing Director		
Division:	Entire Department		

PURPOSE

To ensure that healthcare professionals working for the Vermont Department of Health are prepared to manage adverse events during clinical operations in a way that is consistent with current standards of practice. *Prevention is the primary objective*. If an adverse event occurs during any clinic or following any clinical procedure, Health Department staff will follow emergency guidelines.

PROCEDURE

1. **Preparation of Clinic Area**
    a. Staff will ensure that current emergency phone numbers are posted next to each phone
    b. Staff will know how to call local emergency medical system and will know how to provide clear directions to their exact clinic location
    c. A First Aid Kit, an epinephrine kit (containing a vial of epinephrine, appropriate needles/syringes and epinephrine dosing requirements) and blood pressure equipment are available in the clinical area
    d. Current CPR instructions should be posted in all clinical areas

2. **Preparation and Screening of Client**
    a. To minimize adverse reactions, clients will be carefully screened for precautions and contraindications, including a history of previous reactions or allergies
    b. The client will be questioned about any history of a severe (anaphylactic) latex allergy
    c. If there is any contraindication to giving a vaccine or performing a clinical procedure, refer the client to their Primary Care Provider for further discussion and follow up
    d. Staff will review applicable Health Department medical orders and procedures relevant to the procedure that will be preformed

3. **Vaccine Adverse Events**
    a. Based on ACIP recommendations, observe the client for 15-20 minutes after vaccination to observe for adverse events
    b. If there is an adverse event, complete necessary paperwork as outlined under Documentation

Table A
Possible Adverse Reactions from Vaccine Administration or other Clinical Procedures

Reaction	Symptom	Management
Localized/Minor Reaction	Soreness, redness, itching or swelling at the injection site	Apply a cold compress to the injection site. Refer client to physician for recommendations on taking any analgesics.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place a thick layer of gauze pads over the site and maintain direct and firm pressure. Raise the bleeding injection site above the level of the client's heart. Call 911 if bleeding persists
Fright	Fright before injection is given	Have client sit or lie down for the vaccination or procedure if possible.
Syncope	Extreme paleness, sweating, light-headedness, weakness, coldness in hands and feet	Have client lie flat or sit with head between knees for several minutes. Loosen tight clothing and maintain open airway. Apply cool, damp cloth to client's face and neck.
	Fall, without loss of consciousness	Examine the client to determine if injury is present prior to moving the client. Monitor vital signs if applicable. Place client flat on back with feet elevated. Call 911 if nurse determines they are needed.
	Loss of consciousness	Check the client to determine if injury is present before moving the client. Place client flat on back with feet elevated. Call 911 Monitor vital signs every 5 minutes until emergency services arrive.

Reaction	Symptom	Management
Hyperventilation Syndrome	Lightheadedness, weakness, anxiety, numbness/tingling of hands, feet or around mouth, rapid breathing or sighing. May end in fainting	Have client sit down and provide reassurance to calm anxiety. Counsel/coach client to breath slowly through nose. Call 911 if client does not recover immediately. Monitor vital signs every 5 minutes until emergency services arrive.
Seizure Abnormal activity of brain cells.	Symptoms may include some or all of the following: • Temporary confusion • Staring spell • Uncontrollable jerking movements of the arms or legs • Loss of awareness • Loss of consciousness • Loss of muscle control • Incontinence Symptoms will vary depending on the type of seizure.	**Assure that the client does not become injured.** This may include but is not limited to: • Loosen anything around the neck that may make breathing difficult. • Lay client on floor if possible and remove objects that might cause injury. Put something flat and soft, like a folded jacket, under the client's head for protection against a head injury. If possible, turn the client gently onto one side to keep the airway clear. Stay with the person until the seizure ends naturally. Record the length of time the person seizes and symptoms. If someone experiences a seizure or you think they may be experiencing a seizure call 911.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or hives; swelling of the lips, face or throat; severe bronchospasm; shortness of breath; shock; abdominal cramping; cardiovascular collapse	Call for help from another staff person. A nurse should stay with the client to monitor airway, breathing, circulation and level of consciousness. If possible send a second person to call 911. <u>Administer epinephrine as outlined in the VDH Medical Orders for epinephrine administration.</u> Monitor client's vital signs every 5 minutes until EMS arrives.

Reaction	Symptom	Management
Cardiopulmonary Arrest	Client is unconscious, has no pulse and no respirations	Establish unresponsiveness and assess cardiopulmonary status. Call for help. A nurse or another staff member certified in CPR should administer CPR while another person calls 911. Continue CPR until EMS arrives or pulse and respirations resume.

4. Documentation

Depending on the nature of the event, the following forms may need to be completed. If unsure about which form(s) to complete, please contact the Public Health Nursing Director.

BGS Incident Report
Submit this report when there is an event or an occurrence that is not ordinary in nature. This includes all incidents that may be potentially violent or may result in a critical situation. This form is filled out by the Office of Local Health District Office and sent to the State of Vermont Building and General Services (BGS) via electronic submission. A copy of this form will also be submitted electronically by the Office of Local Health District Office to the Public Health Nursing Director who sits in the Vermont Department of Health Central Office.

Vaccine Adverse Event Reporting System Report (http://vaers.hhs.gov)
Submit this report when there is any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. If a VAERS report is completed the Office of Local Health District Office must notify the Immunization Program Chief who sits in the Vermont Department of Health Central Office.

VDH Report of Deviation from Standard Clinical Practice (Found in the Clinical Procedure Manual)
Complete this form for all incidents resulting from a deviation from standard practice, even if no harm results to the individuals involved. This form must be completed and sent electronically from the Office of Local Health District Office and/or clinic leads to the Director of Public Health Nursing at the Vermont Department of Health's Central Office.

Adverse Medicine Administration; FDA's MedWatch
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Go to the website and submit a report whenever an incorrect administration of medication occurs.

5. Additional Guidance when the Vermont Department of Health's Health Operation Center is Activated.

When the Health Department's Health Operation Center (HOC) is activated and that activation requires Health Department run clinics, the HOC Safety Officer may provide guidance and required documentation beyond this protocol.

References/ Resources:

i. American Academy of Pediatrics. Red Book: 2019 Report of the Committee on Infectious Disease. 31st ed. Elk Grove Village, IL: American Academy of Pediatrics.
ii. CDC. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hamborsky J., Kroger A, Wolfe, S., eds. 13th ed. Washington DC: Public Health Foundation, 2015.
iii. American Academy of Neurology. www.aan.com
iv. Immunization Action Coalition. Medical Management of Immunizations. http://www.immunize.org/clinic/administering-vaccines.asp

VERMONT
DEPARTMENT OF HEALTH

Standing Order for Administering Epinephrine to Children and Adults

Purpose: To be prepared for possibility of adverse reactions: Even with careful screening, unforeseen reactions may occur. Reactions can vary from inconvenient to life threatening. Staff need to be prepared to administer epinephrine if anaphylactic shock occurs.

Policy: Under these standing orders, nurses and other healthcare professionals working for the Vermont Department of Health as allowed by state law may provide epinephrine to children and adults who experience a severe allergic reaction or anaphylactic shock following or during a clinical procedure.

Procedure:

1. Review and be familiar with the Vermont Department of Health's protocol for Emergency Care & Adverse Event Protocol located in the Clinical Procedure Manual.

2. If anaphylactic shock occurs administer aqueous epinephrine 1:1000 dilution (i.e., 0.01 mg/kg) intramuscularly preferably in the lateral aspect of the thigh; the standard dose is 0.01mg/kg body weight.[1] If agent causing anaphylactic shock was given by injection, epinephrine should be injected into the same site to slow absorption. *(AAP, 2015, p.67 table 1.14)*

Dosing by body weight.

Weight (lb)	Weight (kg)	Epinephrine Dose
9-15	4-7	0.05mg (.05mL)
15-24	7-11	0.1mg (0.1mL)
24-37	11-17	0.15mg (0.15mL)
37-51	17-23	0.2mg (0.2mL)
51-77	23-35	0.3mg (0.3mL)
77-99	35-45	0.4 mg (0.4 mL)
99+	45+	0.5mg (0.5 mL)

3. Have someone call 911 and monitor the patient closely until EMS arrives.

4. A second dose of epinephrine may be administered 5-15 minutes following the first dose *(AAP, 2015, p. 66)* based on patient's status (still exhibiting symptoms of a severe

allergic reaction or anaphylactic shock) and EMS has not arrived. The dose administered would be the same as the initial dose.

5. A third dose of epinephrine may be administered 5-15 minutes following the second dose based on patient's status (still exhibiting symptoms of a severe allergic reaction or anaphylactic shock) and EMS has not arrived.

6. No more than 3 doses of epinephrine should be given. *(AAP, 2015, p.67 table 1.14)*

7. Perform cardiac resuscitation (CPR) if necessary.

8. Keep patient in supine position unless he/she is having breathing difficulty. If patient is having breathing difficulties, elevate the patients head.

9. Monitor vital signs (pulse, respirations and, if possible, blood pressure) every 5 minutes until EMS arrives.

10. Record all vital signs and medication administered to the patient. Include time, dose given, patient response, and the name of the medical personnel who administered the medication.

11. Following the incident make sure to notify your Supervisor, and the Director of Public Health Nursing.

12. Make sure to complete all required documentation post-emergency.

This standing order shall remain in effect until rescinded or until May 31, 2021.

Jennifer Read MD — May 22, 2018

Signature: Jennifer S. Read, MD — Effective Date

References

1. American Academy of Pediatrics. Passive Immunization. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2015 Report of Committee of Infectious Diseases.* 30th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2015: 66-68.

2. de Caen AR, Berg MD, Chameides L, Gooden CK, Hickey RW, Scott HF, Sutton RM, Tijssen JA, Topjian A, van der Jagt E, Schexnayder SM, Samson RA. 2015, American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care; *Circulation.* 132(suppl 2): S526–S542.

VAMS Vermont Help Desk
802-863-7428
ahs.vdhophpvams@vermont.gov

VERMONT
DEPARTMENT OF HEALTH
healthvermont.gov

VAMS Quick Reference Guide – Healthcare Professional/Medicine Distribution Worker

Before proceeding
Make sure you have activated your account in VAMS (follow the prompts in your registration email from **vams@cdc.gov to complete this step).*

Access and Review Recipients' Records (Log into your clinic account.)

□ Select the **Manage Recipients** tab.

□ Select recipient or search for recipient by name or email address. Partial searches will not work.

□ Click the recipient's name to access their records.

□ Confirm their identity and review **Recipient Details**. Edit any information as needed.

□ Review any **Notes** and the recipient's **Medical Information**.

Add Notes as applicable to record

□ Select New Note in the upper right corner of the recipient's page.

□ Enter your note, select Done.

Log vaccination

□ Select the **Vaccine Administration** tab.

□ Select **Log Vaccination**.

□ Answer the question on the **Assess Recipient Condition** page. Select **Next**. (Selecting **No** will stop the vaccination.)

□ Enter the vaccine information either manually or by scanner. **NOTE:** please verify that this information matches the vaccine barcodes. Some internet browsers may save previous entries and autofill.

□ Select the **site** where you administered the vaccine from the dropdown and verify the **Vaccination Date** is correct. Select **Next**.

□ On the following pages, follow the prompts and record any vaccine waste as needed.

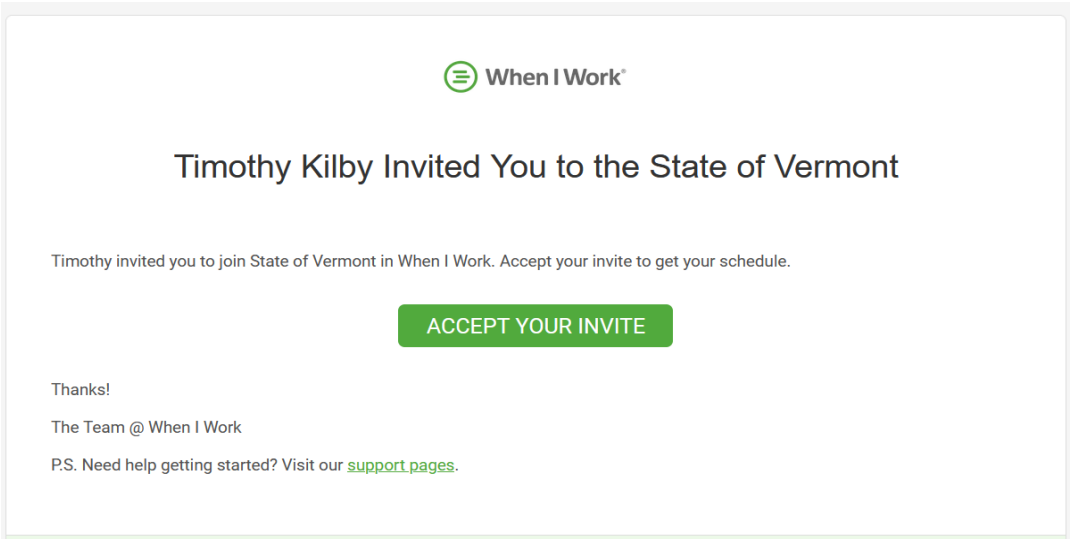
□ Let the recipient know when they can get their next dose.

Troubleshooting Tips:

Website isn't loading – Internet Explorer is not supported. Try another browser. If you are not using Internet Explorer, reach out to the Help Desk.

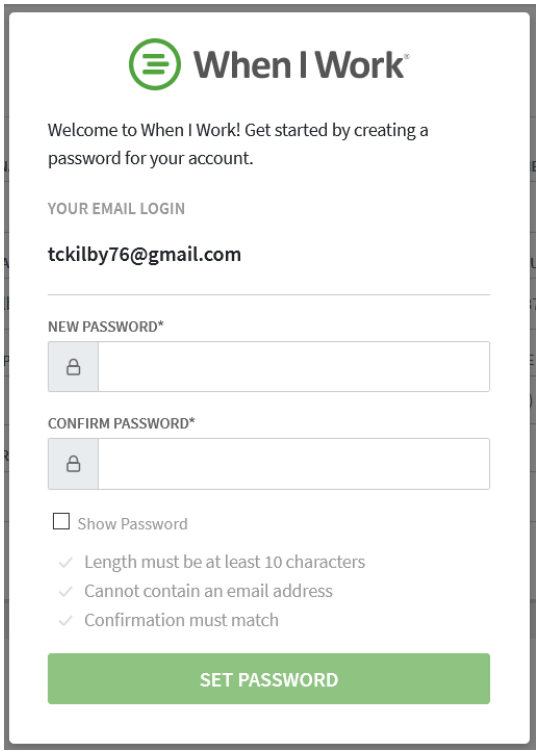
Initial invite:

You will receive an email from noreply@wheniwork.com. Click the "Accept Your Invite" button to start setting up your profile. There is also an app that can be downloaded to your iPhone and Android phones. Please note WIW is used to abbreviate When I Work.



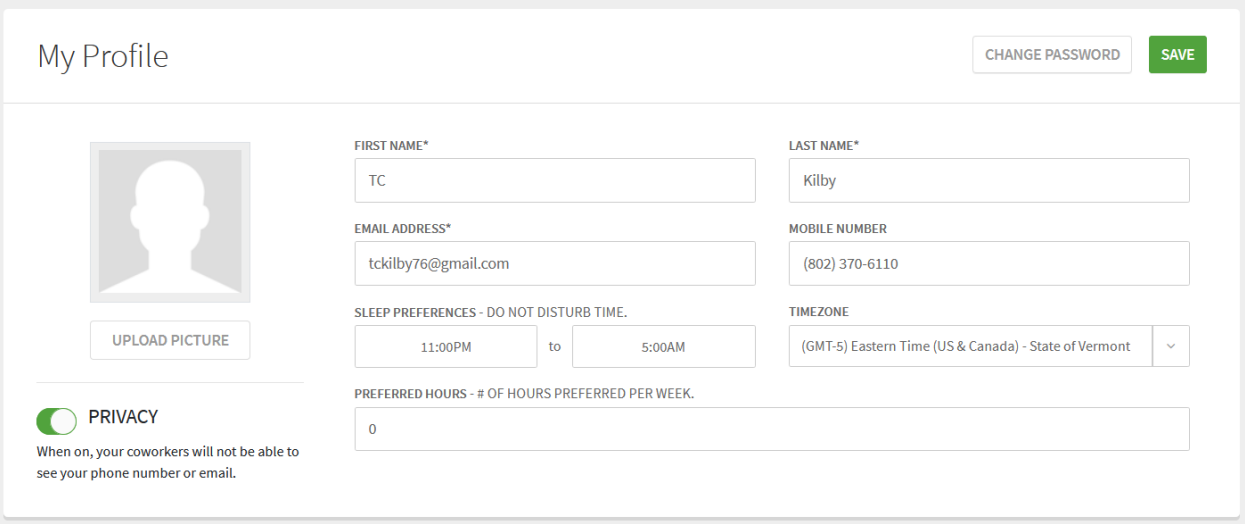
Setting up password:

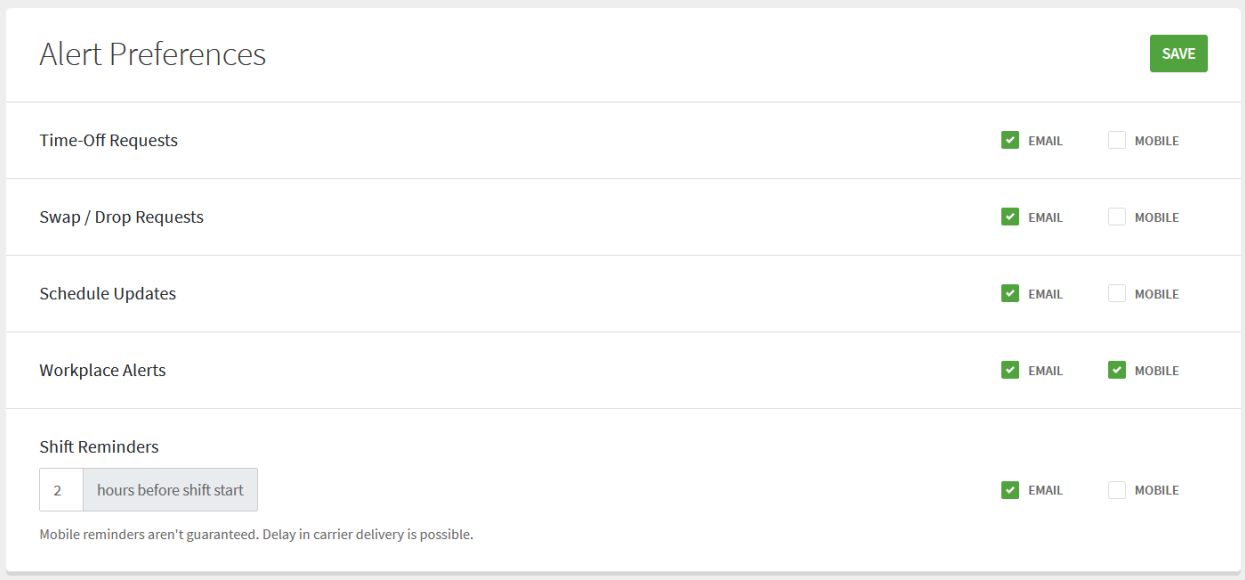
Upon clicking the button you will be taken to a new webpage and asked to set your password for your account.



Profile setup:

Once you set your password you will be taken to your profile page. Here you can set your preferred number of hours and alert preferences. It defaults to email alerts and you can add mobile alerts if you are using the app on your phone. Once you have made any changes click the "Save" button at the top of each box.



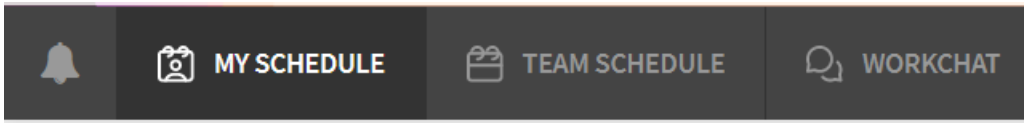


Now your profile and password are set you can start using When I work. When you receive your invite, you should have been assigned a position.

Checking out When I Work (WIW):

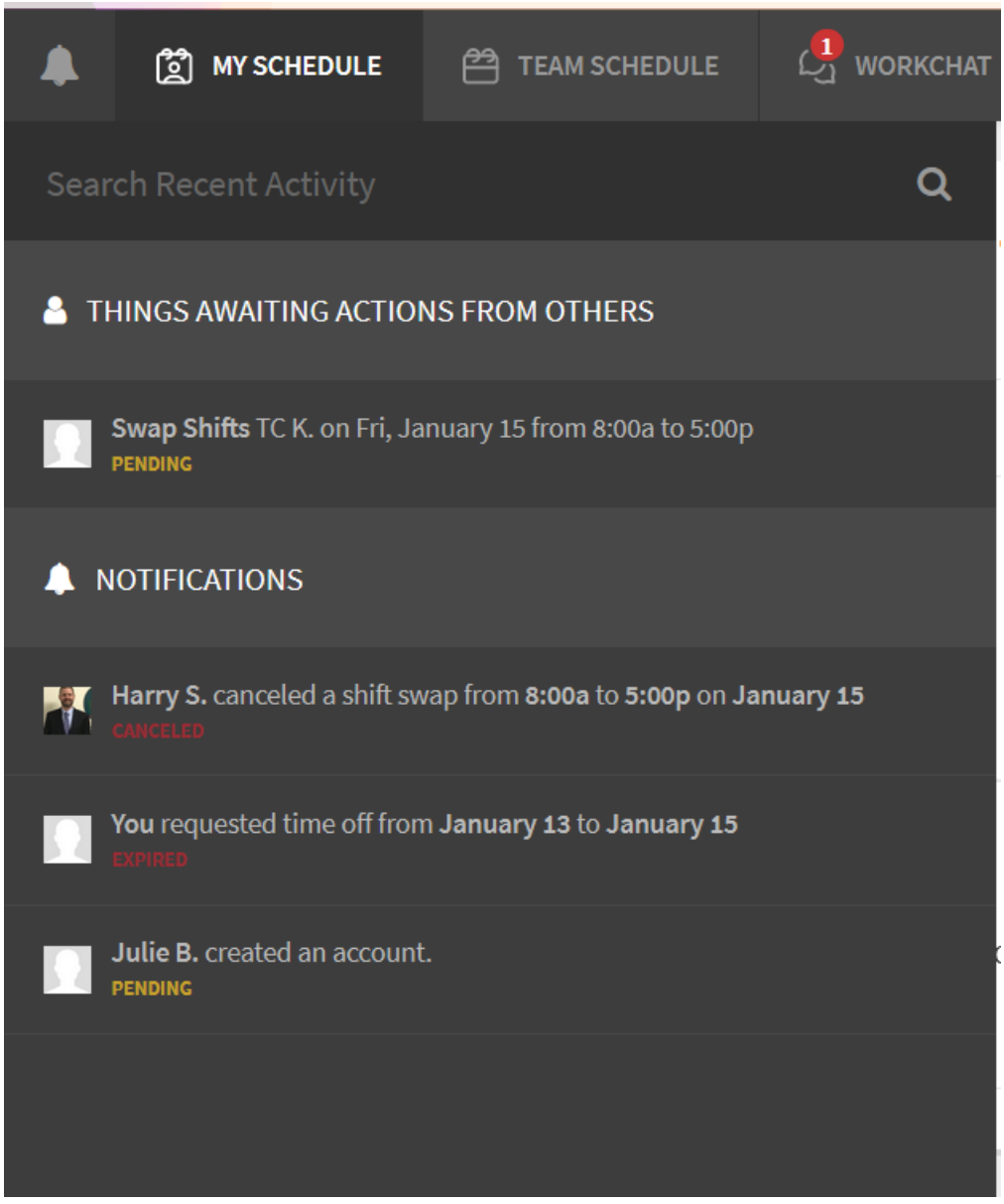
At the top of the pages in WIW is a dark colored bar with multiple options to click on.

On the left side:



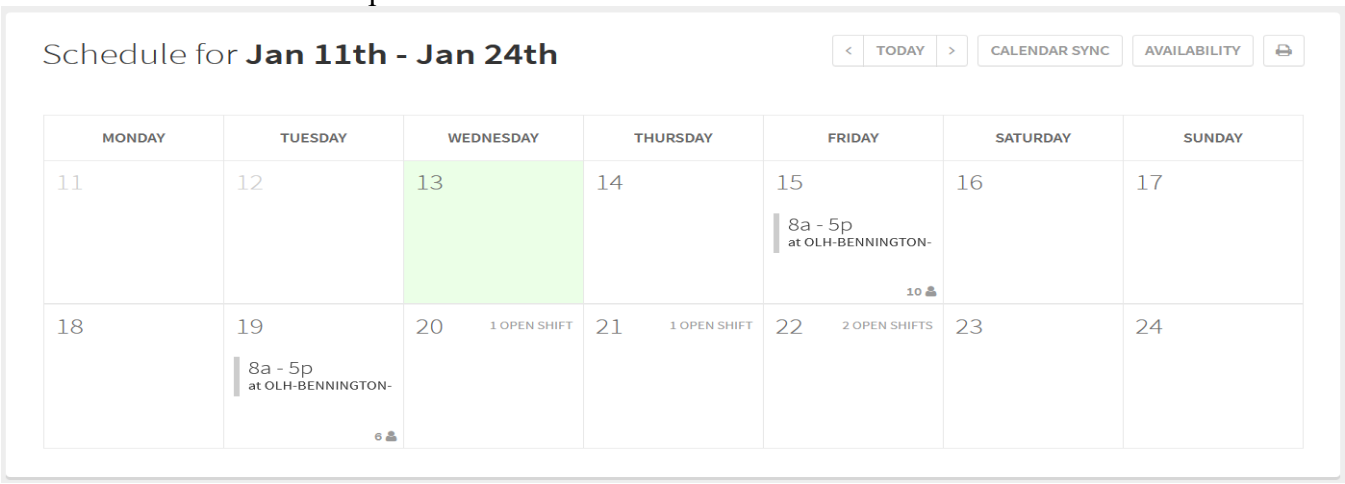
Notifications:

Bell shaped icon, if you click on it a side bar opens showing any notifications applicable to you.



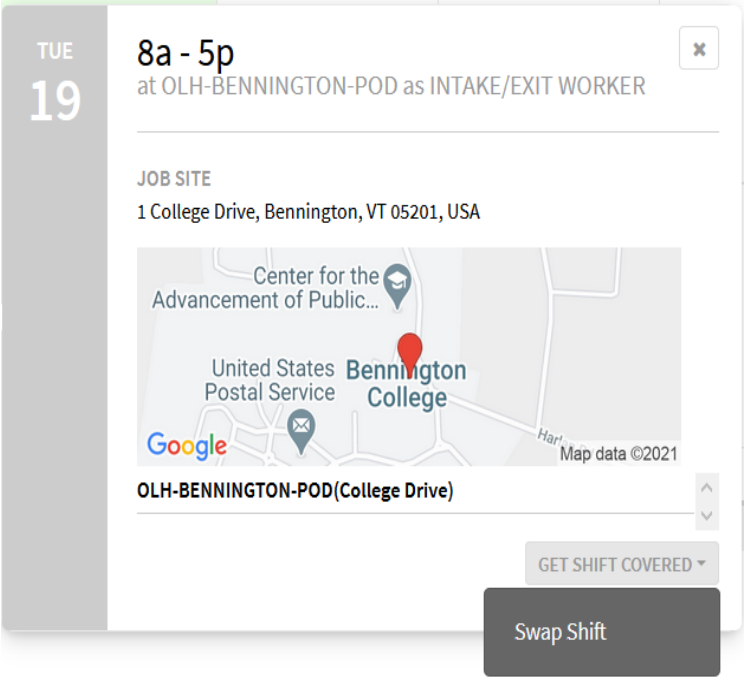
My Schedule:

When you click this will take you to a page showing your schedule for a two week period at the top of the screen. This calendar shows the date, hours, and location you are scheduled for. It also shows if there are any open shifts available. If you click on one of your scheduled shifts you will get a popup showing the details and a small google map. From here you can also initiate a shift swap, go to page 9 for more information on swaps.

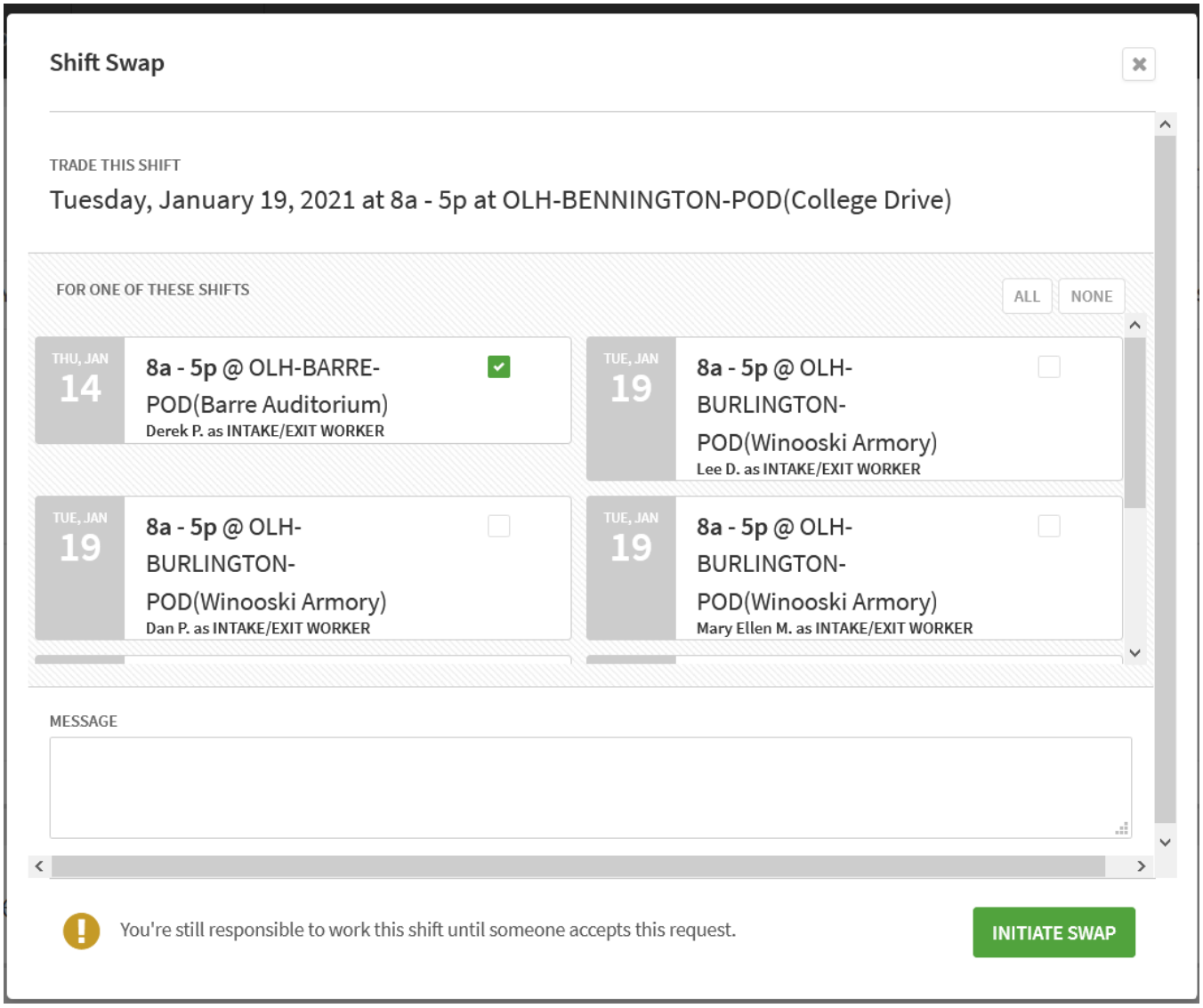


Shift swap:

Click on the shift you want to swap to get the details popup. Bottom right of the popup is a button that says, “GET SHIFT COVERED”, click that and a new button appears saying, “Swap Shift”. Click it and you get a new popup.

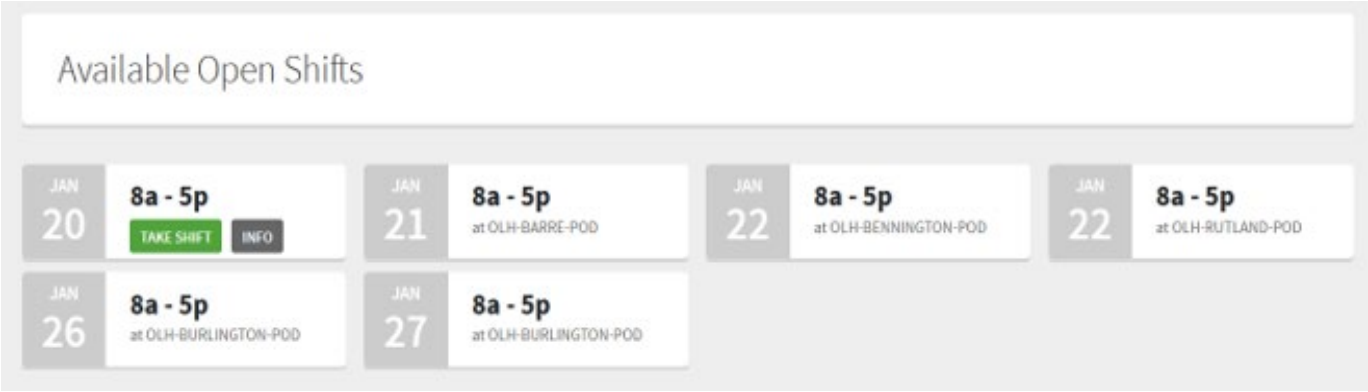


In this new popup select the shift or shifts want to swap, check box on right side of shift details. There is a message box for providing details on why you want to swap. Once completed click “INITIATE SWAP”. Take note of the warning at the bottom next to the button, that until the swap is accepted and approved by a supervisor you are responsible for covering that shift

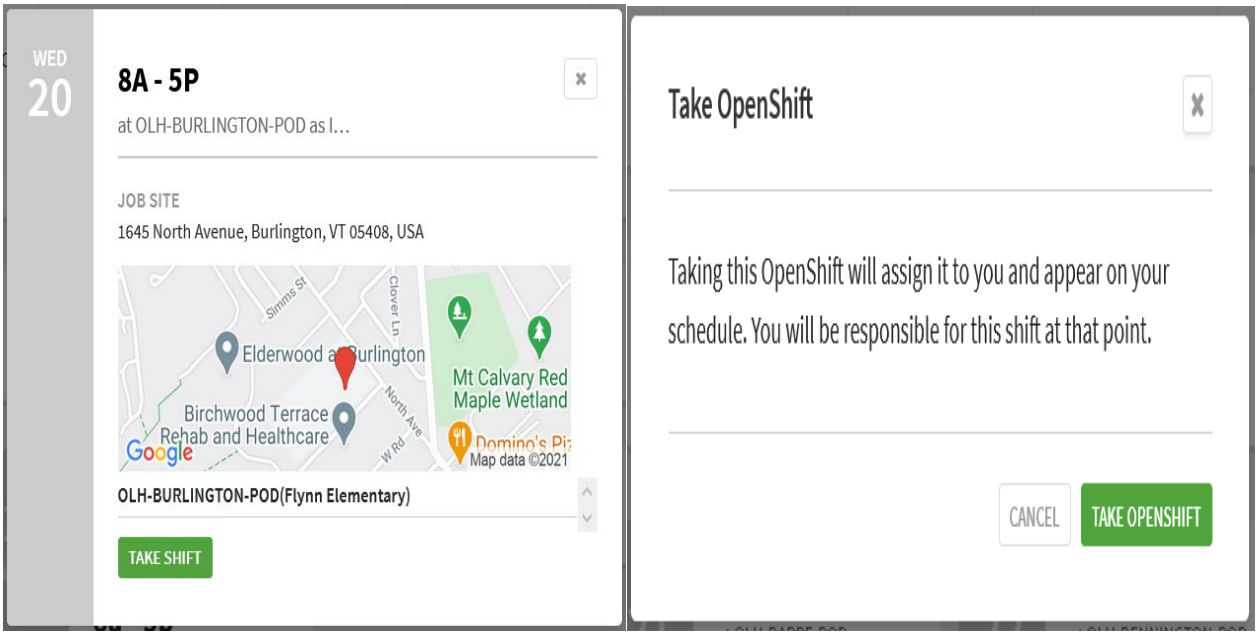


Once the swap has been sent a notification will appear in the Notification pane and it can be seen in the “Shift Requests” page. (Hover over Requests icon and select Shift Requests.)

The bottom half of the page shows available shifts for your position and locations you are assigned to. You can hover on any available shift and two buttons will appear, “Take Shift” and “Info”.



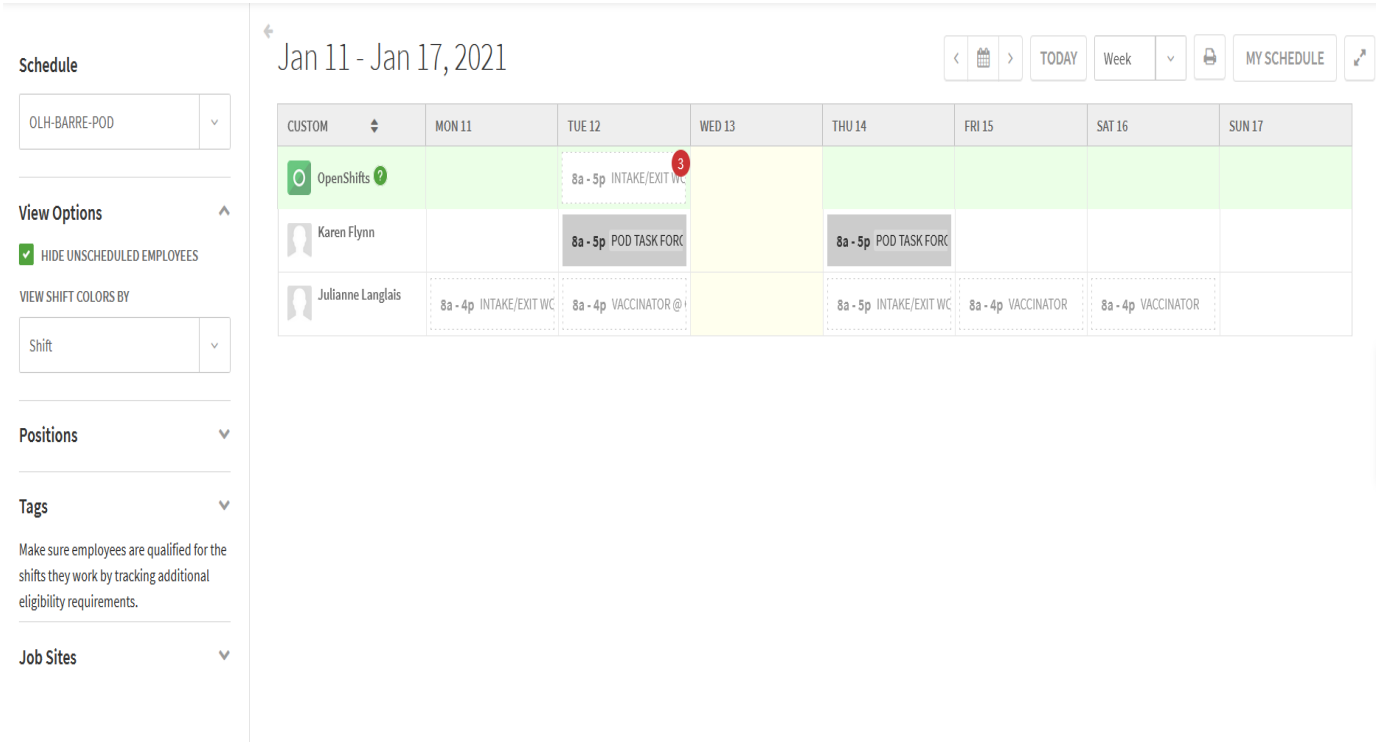
If you click “INFO” you will get a popup showing details on the shift and a Google map of the location. At the bottom of the popup the “TAKE SHIFT” button is available. Whether you click the take shift button on the Available shifts page or in the popup you will get a new popup, “Take OpenShift”. This popup reminds you that if you take the shift you are responsible for covering it. You can click “Cancel” or “TAKE OPENSHIFT”.



Team schedule:

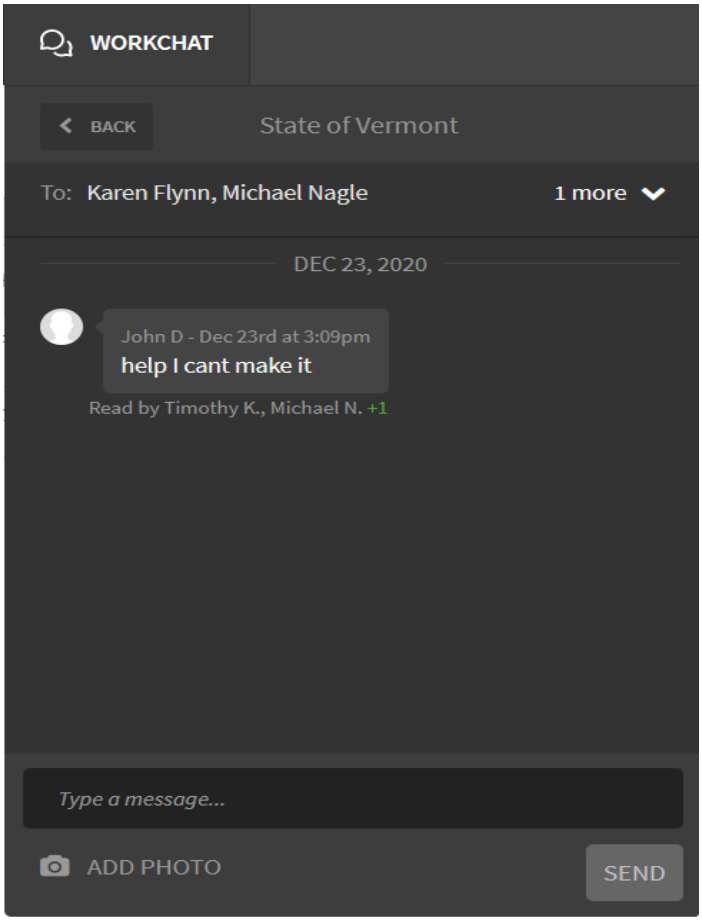
This page shows the schedule for the team(s) you are assigned too. On the left side is filter options for checking the team schedules; Schedule allows you to choose with POD schedule you want to view. If you are only assigned to one POD then there will be no other options. You can adjust shift colors by Shift, Position, or job site. You can filter to view only certain positions or by Tags (if there are any assigned).

Top right you can change the calendar to view by day, week, 2 weeks and the time period.



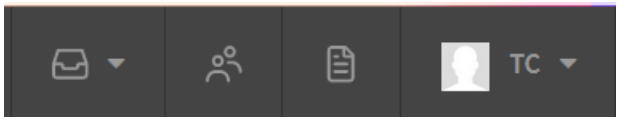
Work Chat:

When you click on this button it drops down a chat box. You can choose to chat with individuals or on of the channels. If chat using a channel it goes to all users for that channel in WIW. Multiple channels can be setup. Channels will be setup by Managers.



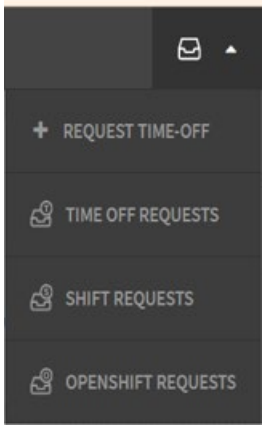
Right side of screen buttons:

Requests, Coworkers, Documents, and your account options drop down.



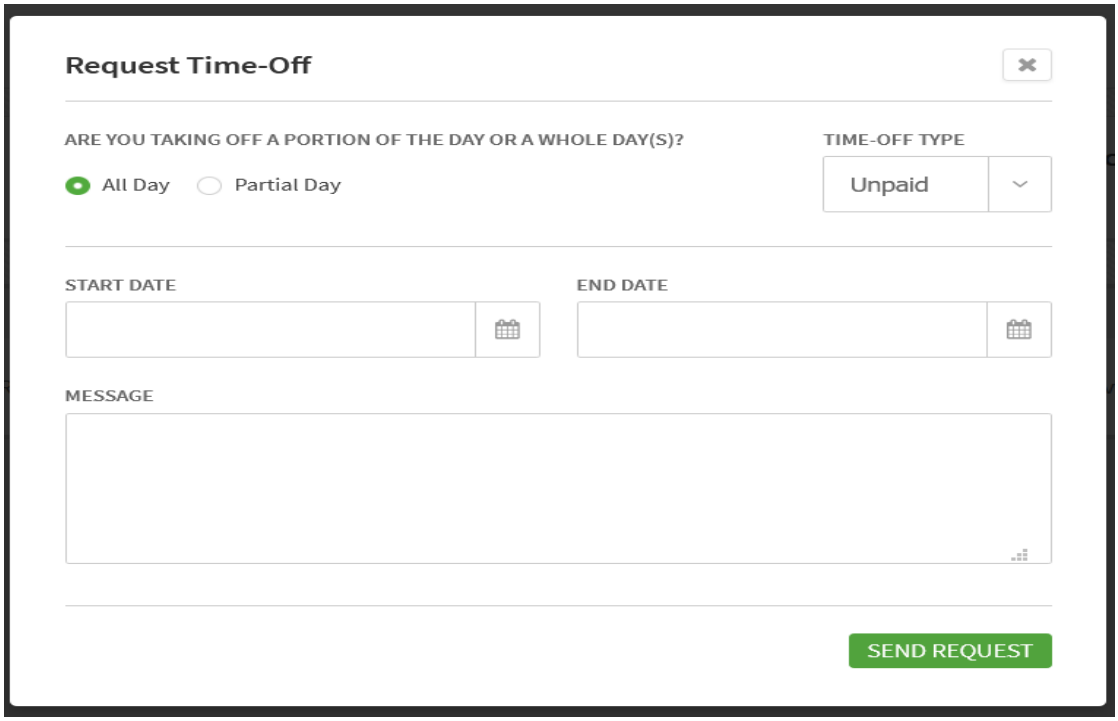
Requests:

The first button is a drop down for making time off requests and seeing shift requests in the system, like shift swaps.



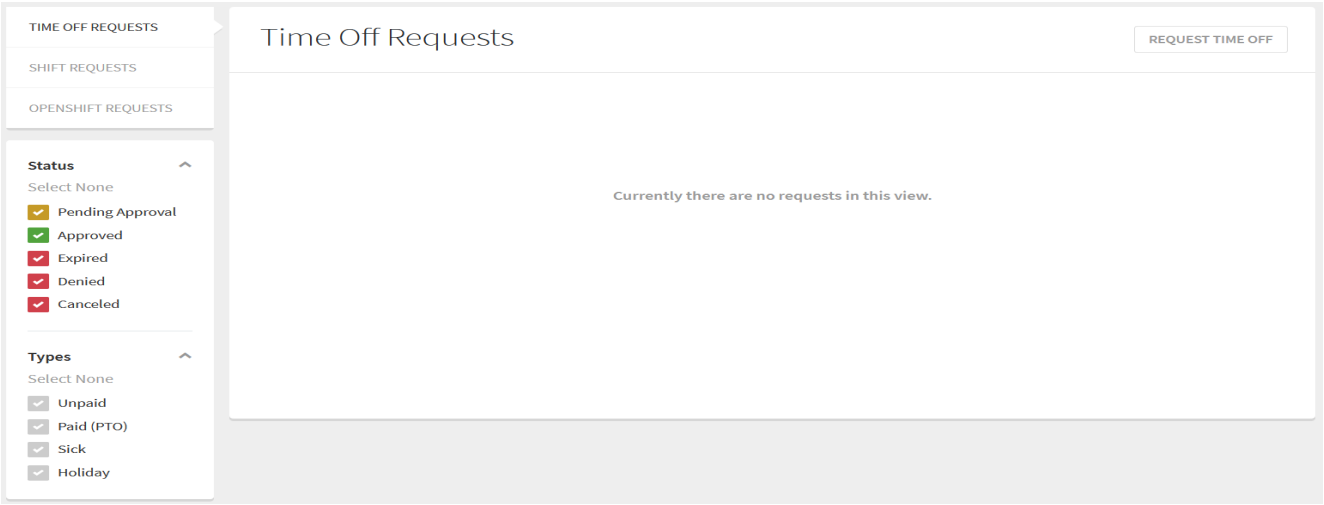
Request time-off:

When you click this you will get a popup for you to provide information on the requested time off. Fill in the information and send the request. Will go to your supervisor in the PODs for approval.



Time off requests:

If you click this it brings you to a page showing all the current requests for time off. On the left is filter options. You can also on this page select to see shift requests and openshift requests. If you choose shift requests or openshift requests from drop down it will also bring you to this page.

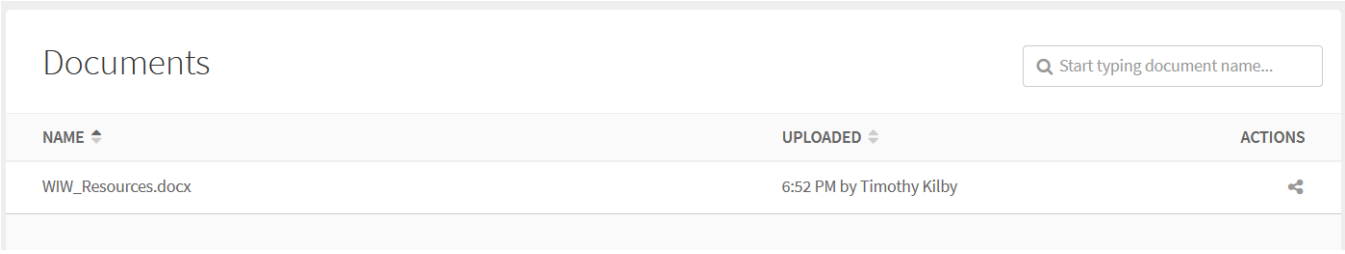


Coworkers:

Clicking on this brings you to a page showing your coworkers in WIW. These are the people assigned to the same POD(s) as you.

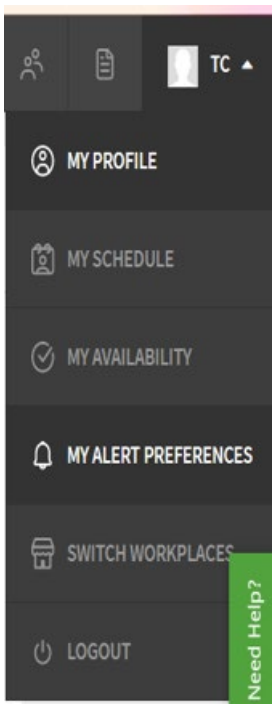
Documents:

When you click on this icon it will bring you to a page showing the documents that have been uploaded to WIW. Employees can view any document uploaded but only supervisors or managers can upload documents



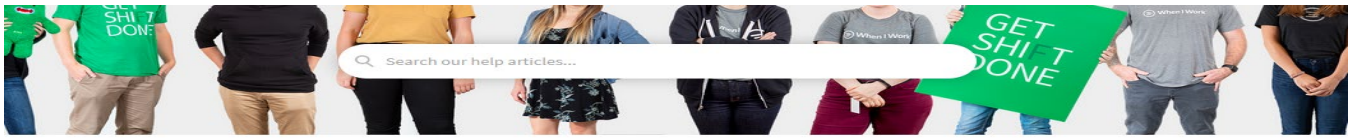
Your account options:

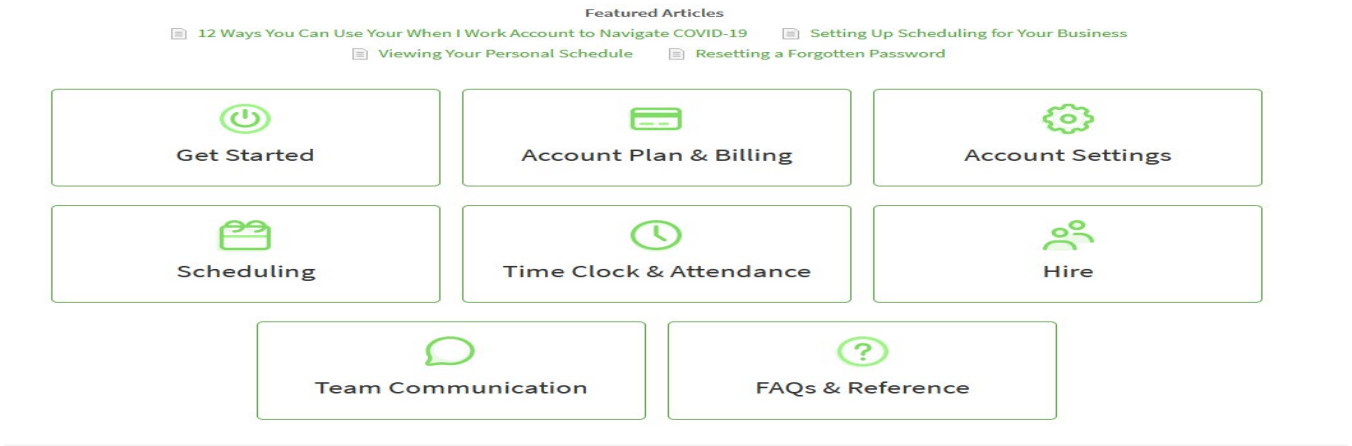
When you hover over this you will get a drop down showing several options. You can go to your profile and alerts (page 2), schedule (page 4), availability (next page) or logout.



Help button:

This is located at the bottom of the page and as a green tab on the right side of webpage, “NEED HELP?”. When you click on this it will open a new webpage. On this page near the top is a search bar to search through their articles and farther down they have “Featured Articles” and some general topic areas you can select.



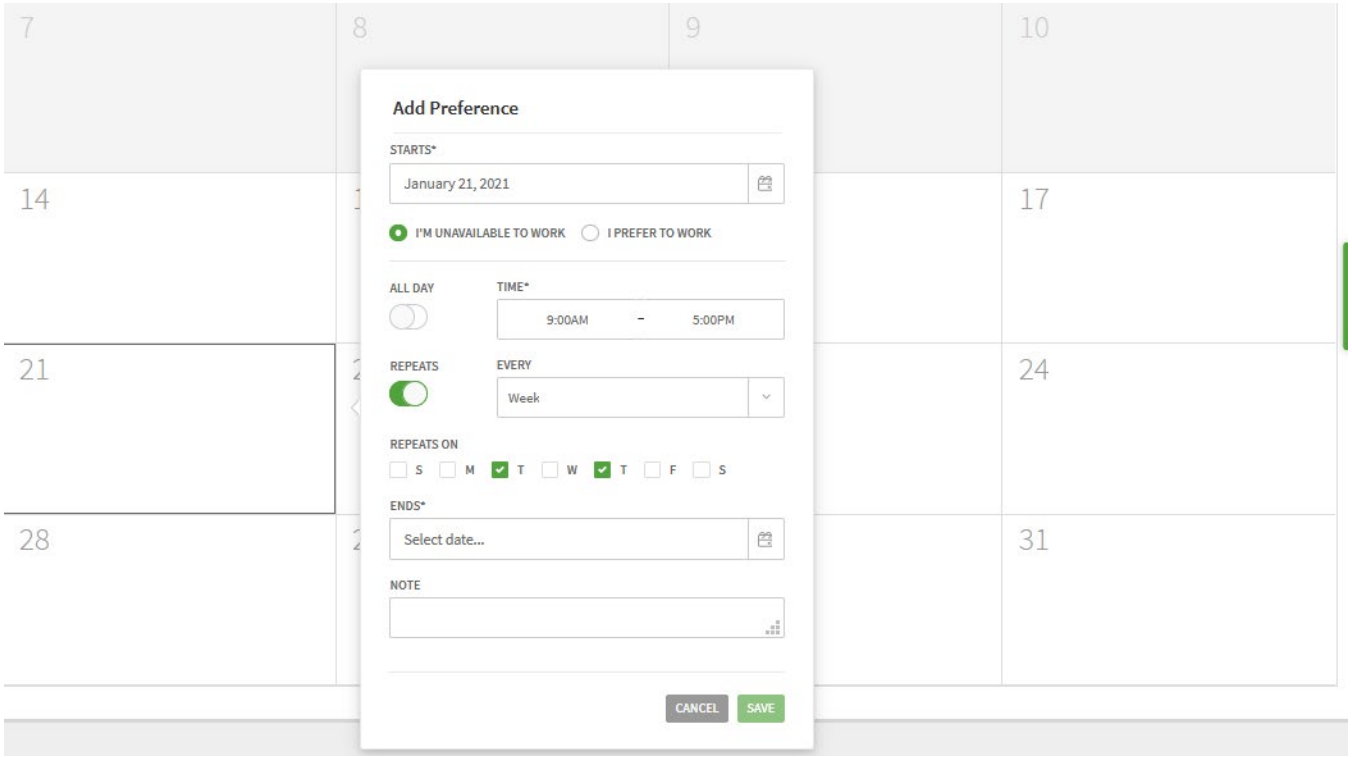


My availability:

This feature is important in setting your schedule preferences. When you click the icon, it opens a page showing a calendar and defaults to current month. Can use option buttons at the top right to change the view.

It is from here that you can mark days or hours you are unavailable to work. Including setting up a recurring preference. Click on any day and you will get a pop up, “Add Preference”. You can select that you are unavailable to work or if you prefer to work this day. Select the entire day or certain hours. You can make this a repeat occurrence; if you are unavailable to work on Tuesdays and Thursdays check those days. Can choose an end date for this preference and add a note to it.

There is also a button at the top right above the calendar that looks like a trash can, if you click this it will reset all your future availability options. You do get a warning popup if you click it to verify you wish to do this



When I work resources

Websites:

Employee training video to familiarize oneself with When I Work (WIW)
https://help.wheniwork.com/training/employee-training/

Employee resources guide. Instruction on setting up account and navigating app.
https://help.wheniwork.com/articles/employee-training-resources/

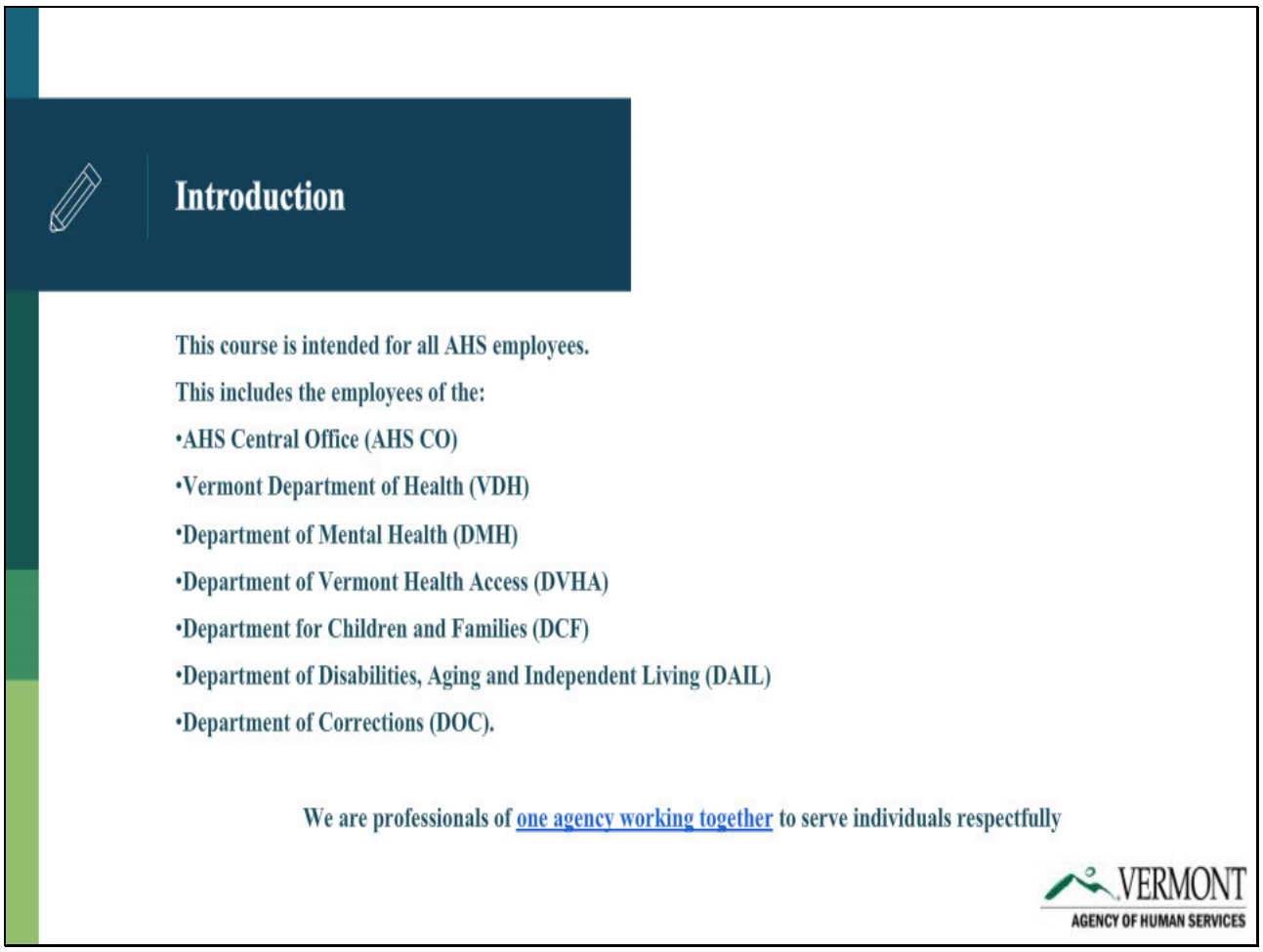
Videos, tutorials, tips and tricks for employees
https://help.wheniwork.com/videos/#employees

Videos, tutorials, tips and tricks for management
https://help.wheniwork.com/videos/#management

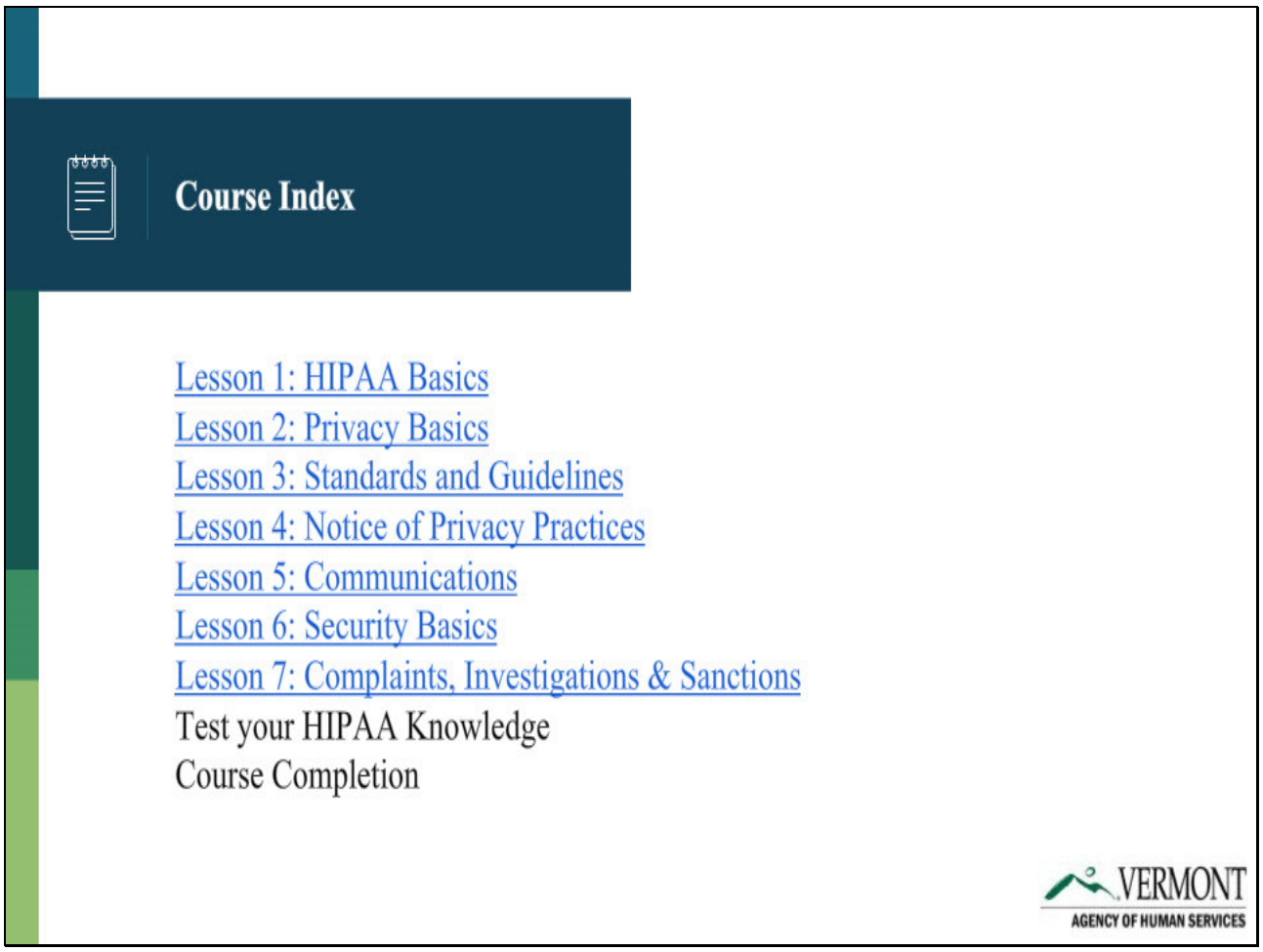
When I work YouTube channel
https://www.youtube.com/c/Wheniwork-Employee-Scheduling/videos

Slide 1 - AHS HIPAA Awareness Training

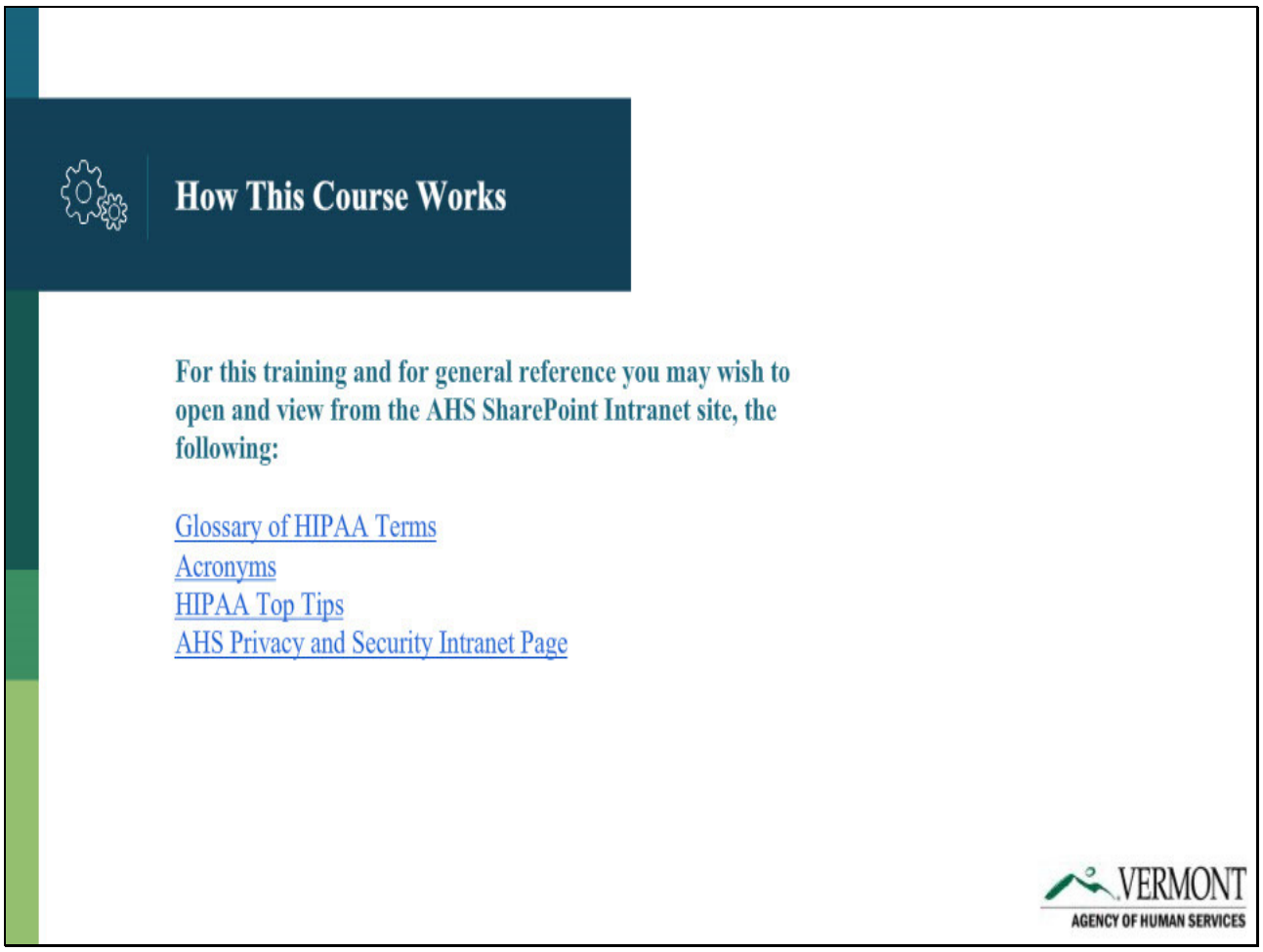
Slide 2 - Introduction



Slide 3 - Course Index



Slide 4 - How This Course Works



Slide 5 - What Is The Purpose Of This Course?

What Is The Purpose Of This Course?

The purpose of this course is to train AHS employees to keep private and secure the health information of the individuals we serve. Because of the very nature of our work, human services, we all come across sensitive information, even if "health information" is not our focus or responsibility.

This course focuses on the federal Health Insurance Portability and Accountability Act of 1996, known as "HIPAA," and its federal regulations, known as "the HIPAA Privacy Rule" and "the HIPAA Security Rule." This course is required by law. For those employees of departments that regularly handle health information, this electronic course may be accompanied by more in-depth and job-specific HIPAA training.

If you have questions about how HIPAA applies to your job duties, talk with your supervisor and/or HIPAA Departmental Liaisons. You can visit the HIPAA Site on the AHS Intranet to find more resources, forms and links to HIPAA related information.

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Slide 6 - Why Should AHS Employees Be Concerned About The Privacy And Security Of Health Information?

Why Should AHS Employees Be Concerned About The Privacy And Security Of Health Information?

Almost daily, there are stories in the news about the mistaken disclosure of personal information by state agencies, non-profit organizations, or private businesses.

The individuals we serve trust us with highly personal information about themselves and their families. We must be deserving of their trust and keep their information private. This is a basic tenet that guides our work and ensures that we work together to serve individuals respectfully.

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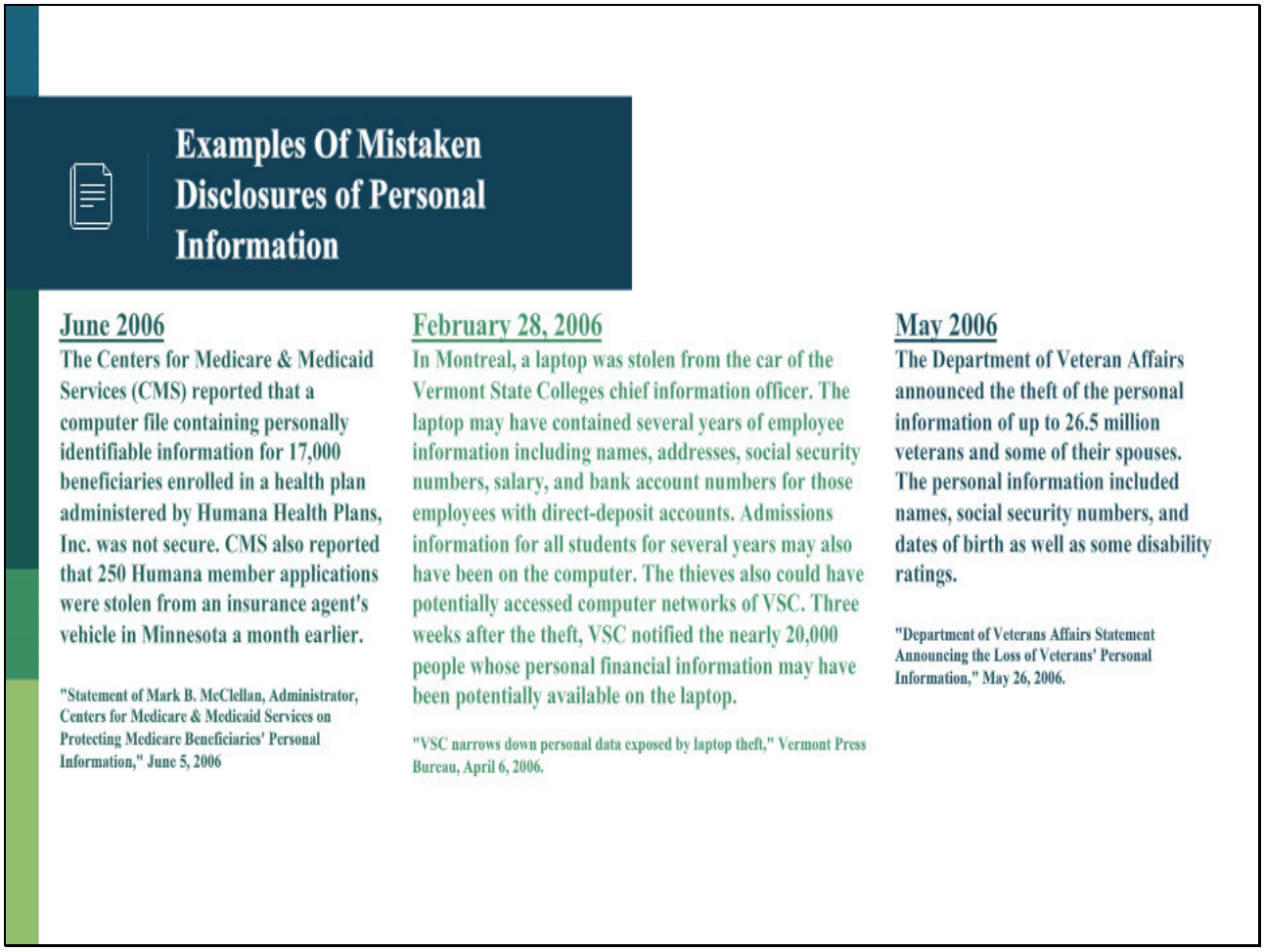
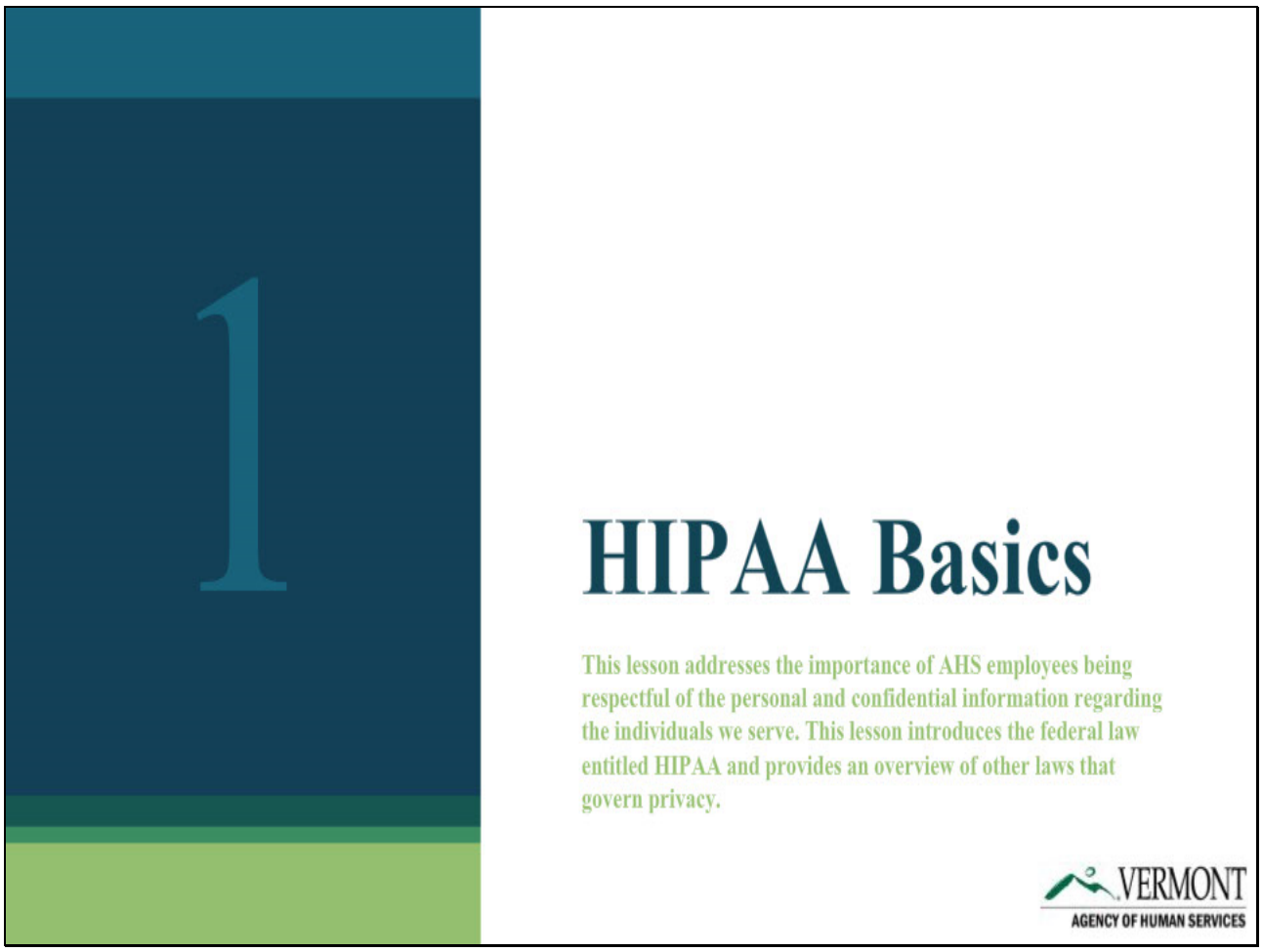
Slide 7 - Examples Of Mistaken Disclosures of Personal Information

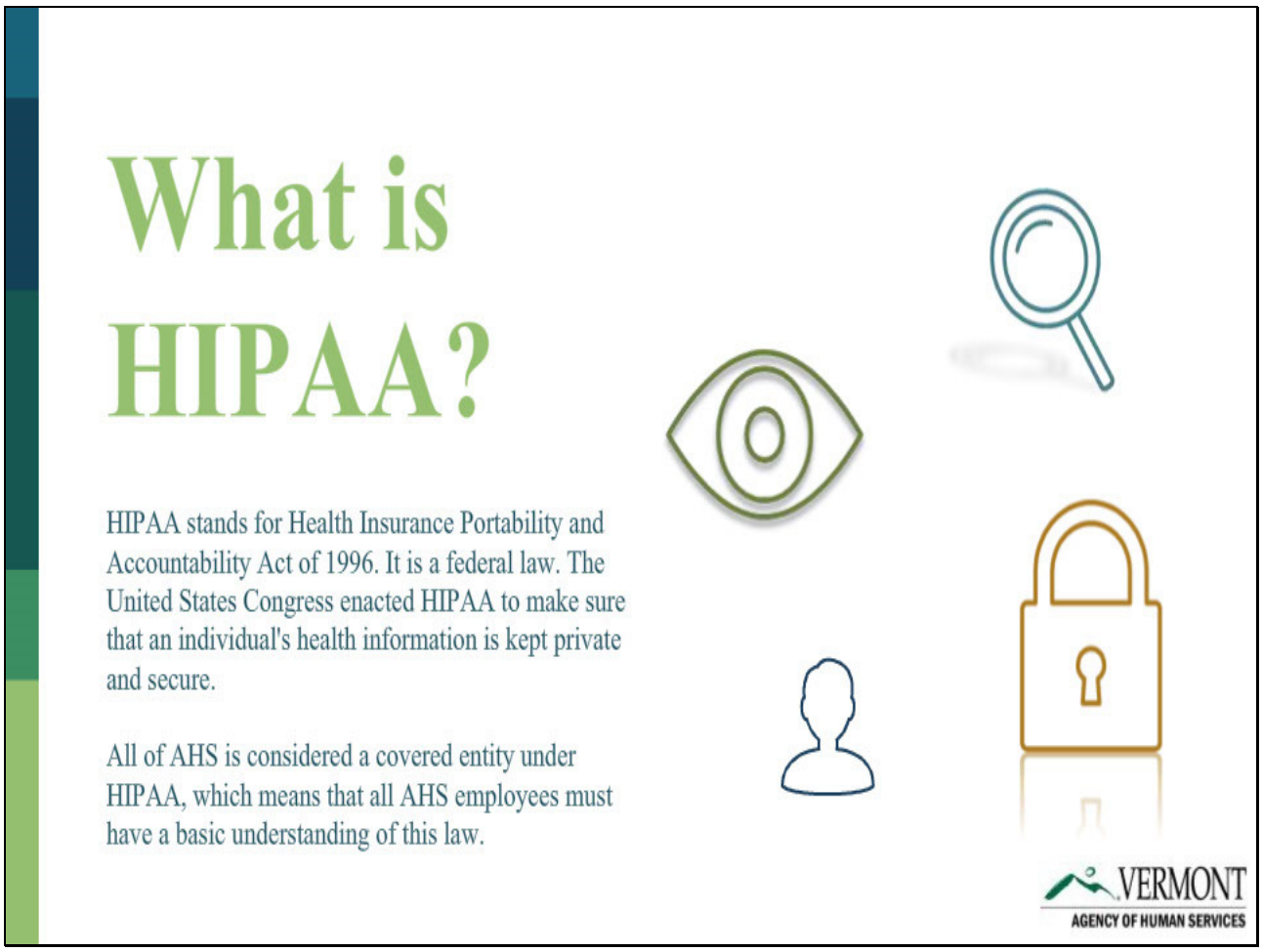


Slide 8 - HIPAA Basics

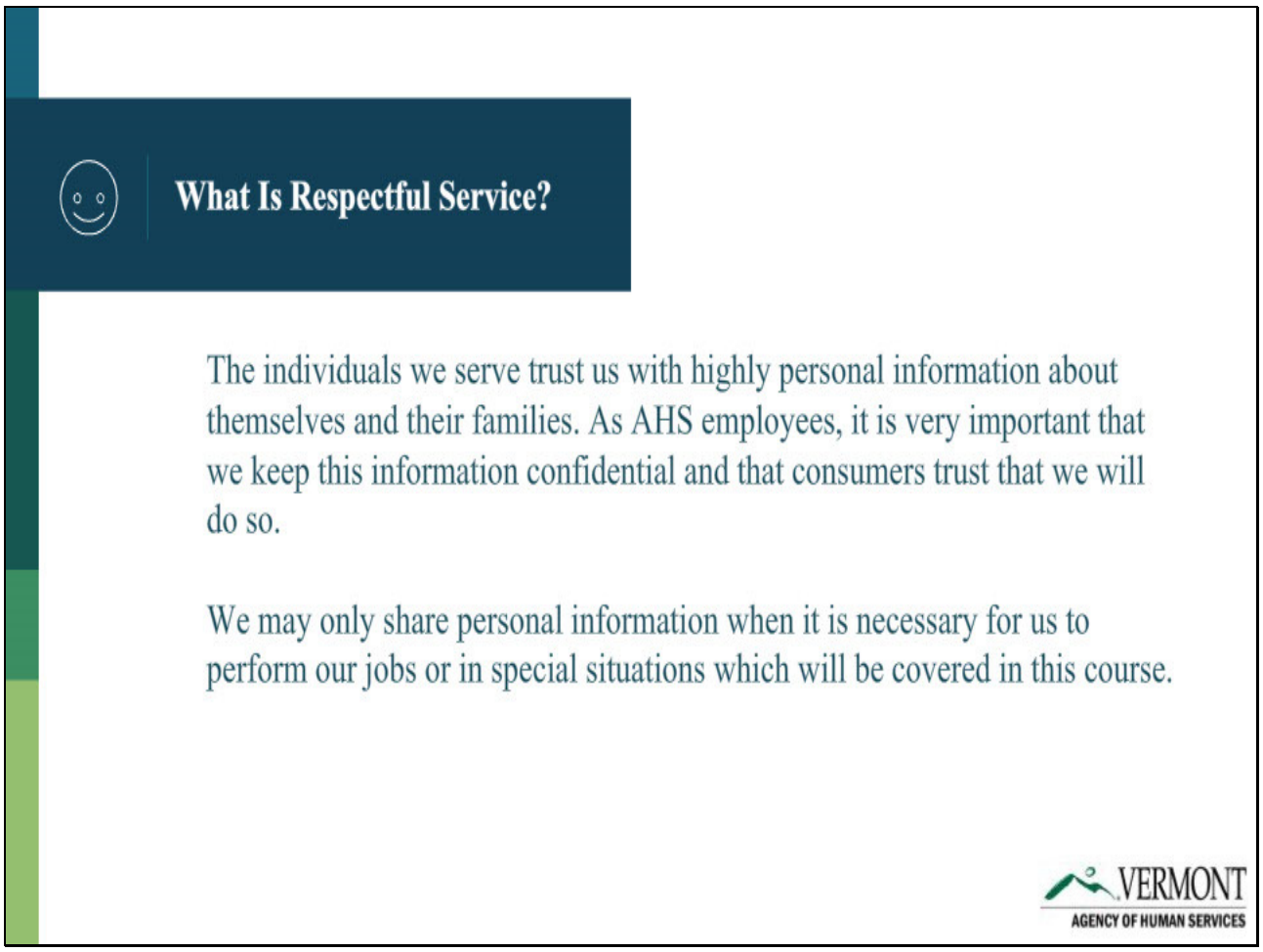


Slide 9 - Slide 9

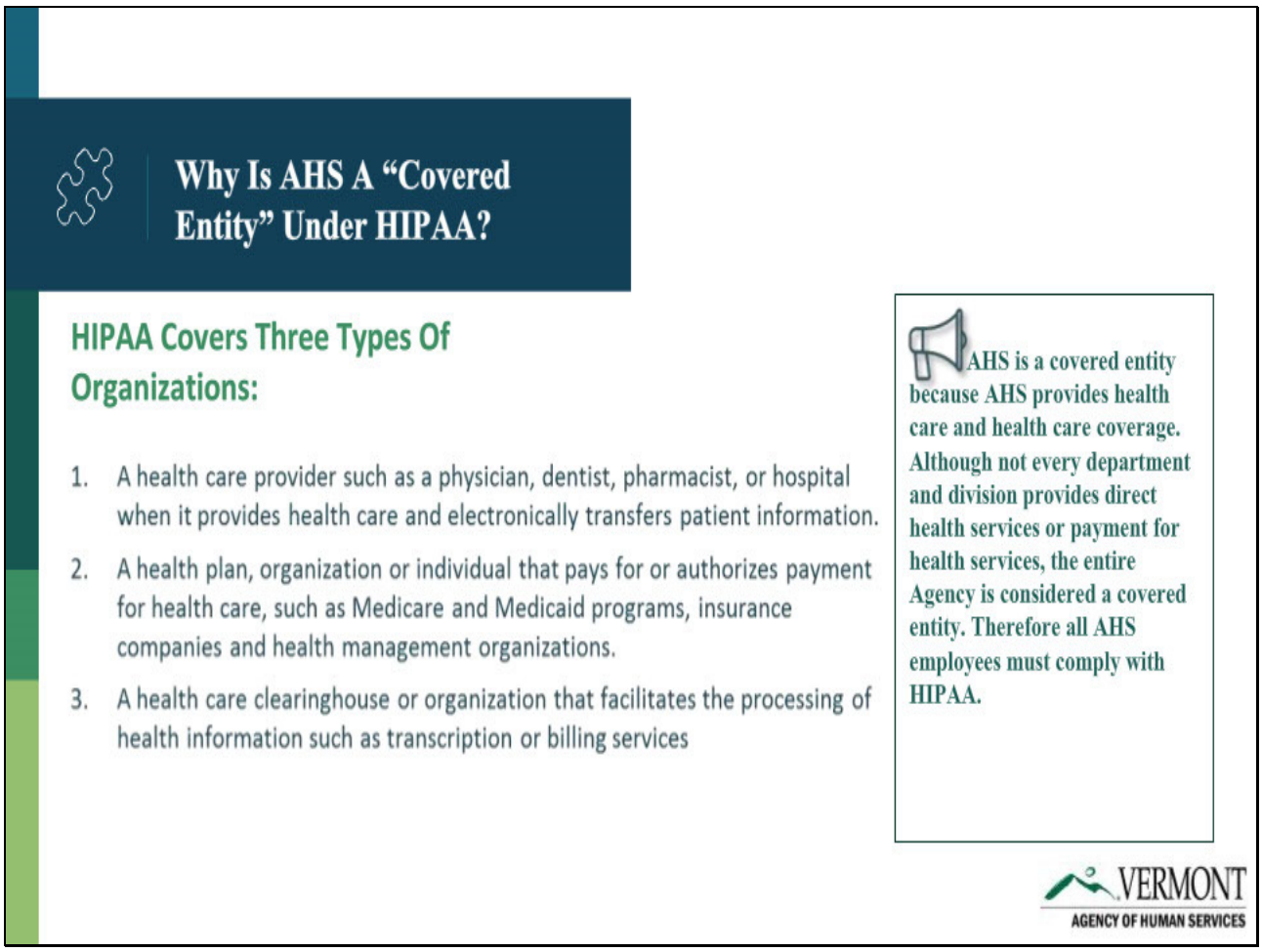
Slide 10 - What is HIPAA?



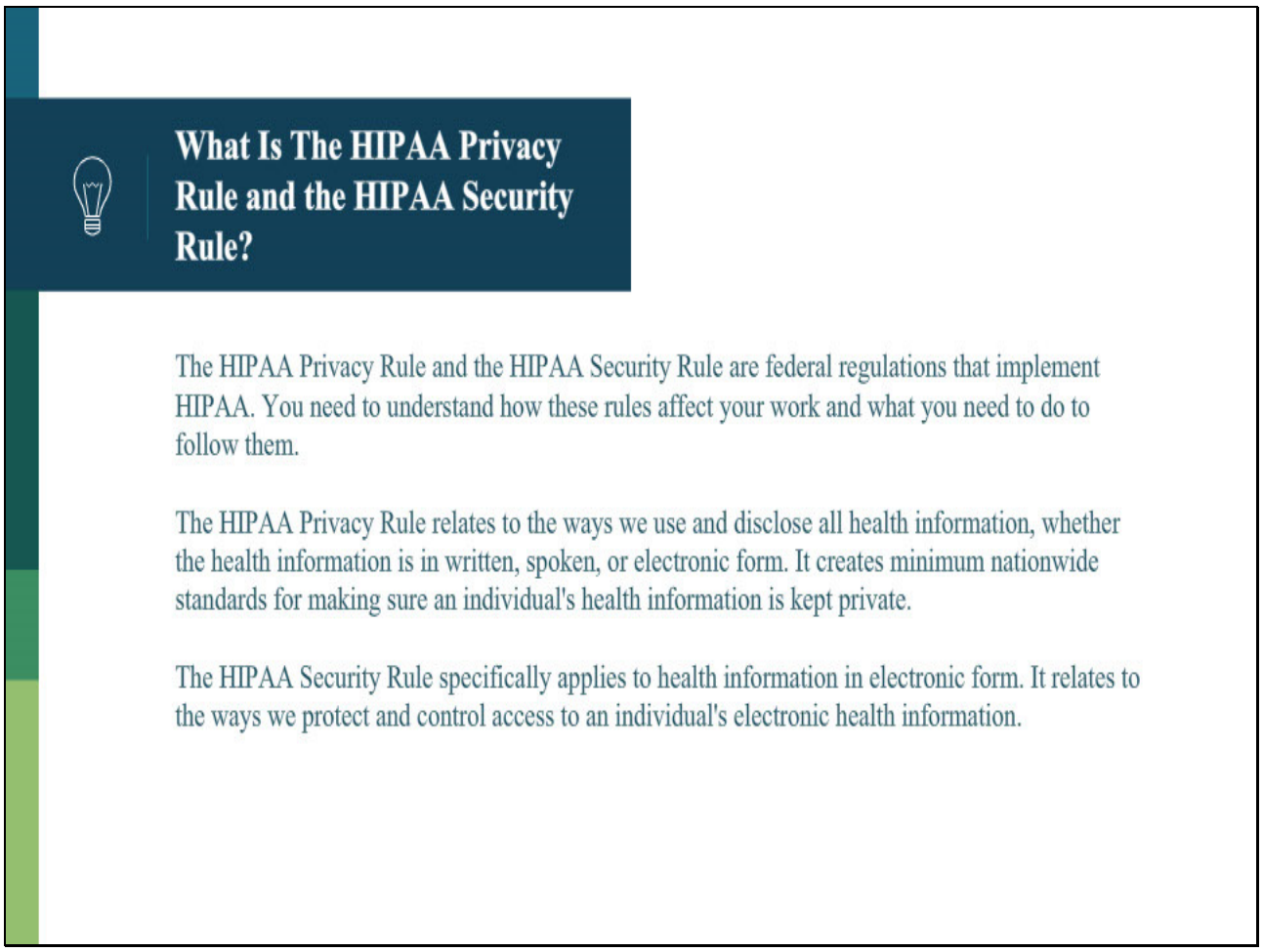
Slide 11 - What Is Respectful Service?



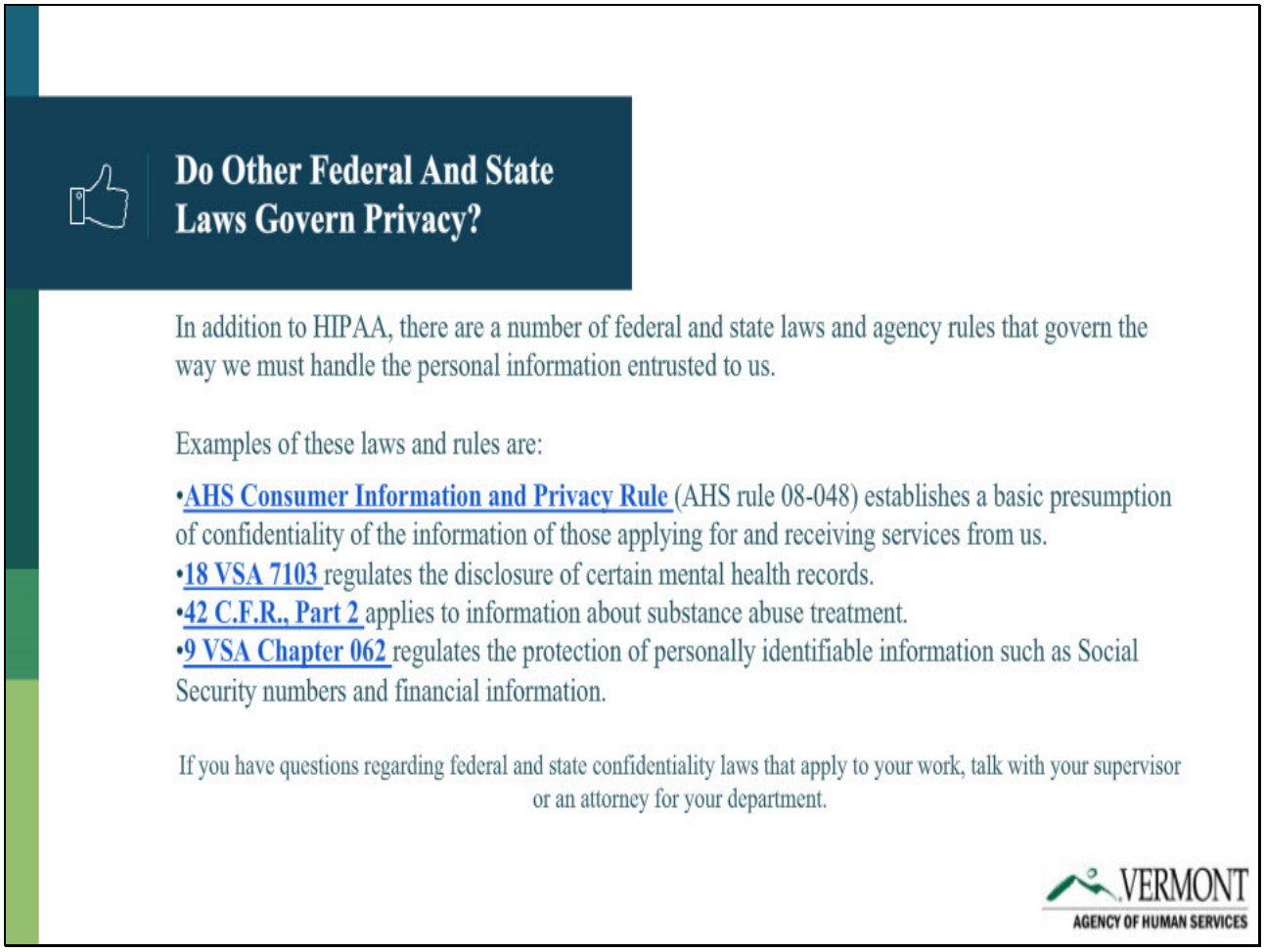
Slide 12 - Why Is AHS A "Covered Entity" Under HIPAA?



Slide 13 - What Is The HIPAA Privacy Rule and the HIPAA Security Rule?



Slide 14 - Do Other Federal And State Laws Govern Privacy?



Slide 15 - What Happens When Other Federal Or State Laws Are More Protective Of An Individual's Privacy Than HIPAA?

What Happens When Other Federal Or State Laws Are More Protective Of An Individual's Privacy Than HIPAA?

When Vermont or federal law is stricter than HIPAA in protecting the privacy of an individual's health information, we need to follow the stricter law. That is to say, we need to follow the law that affords more privacy protections for an individual's health information.

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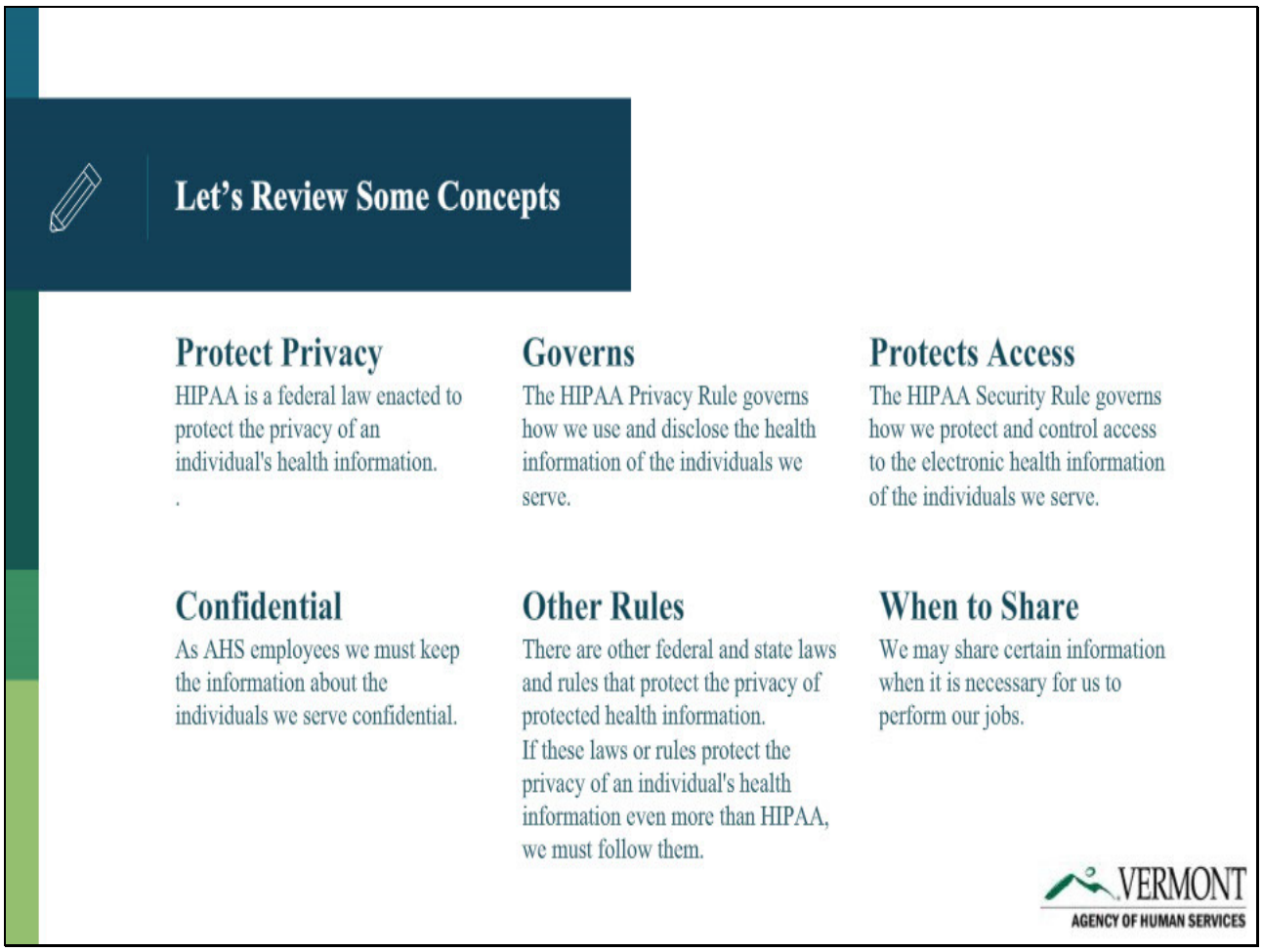
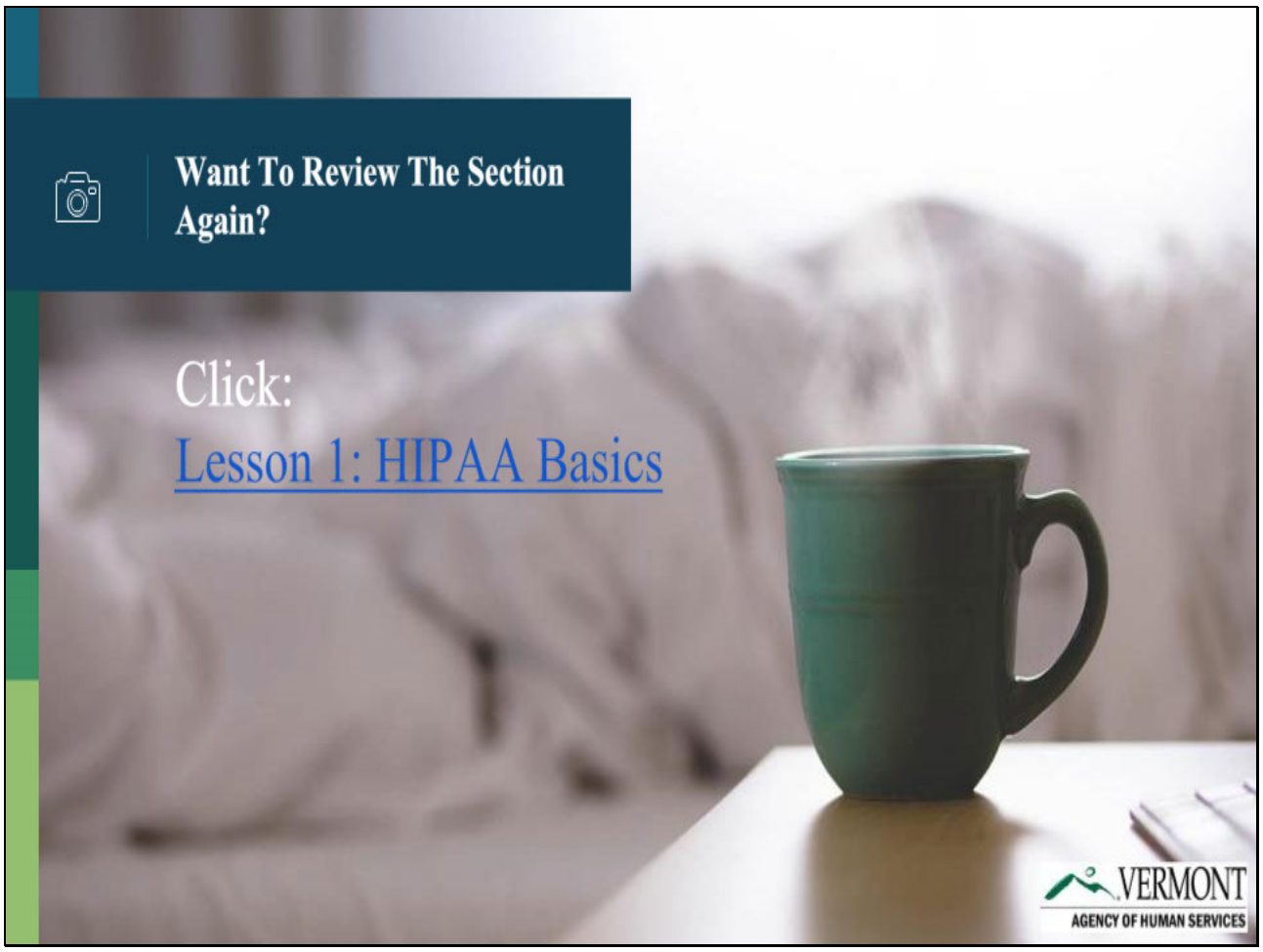
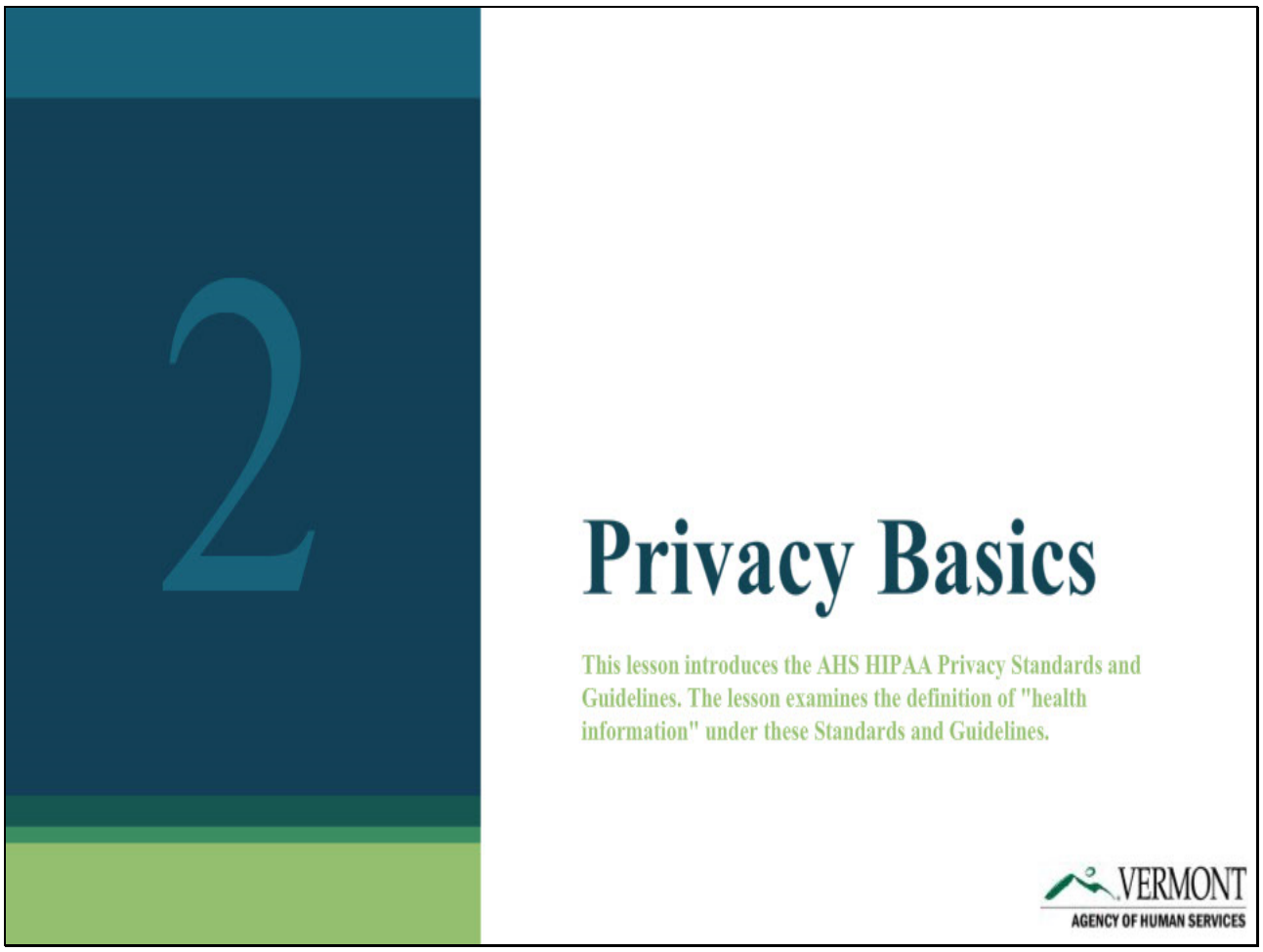
Slide 16 - Let's Review Some Concepts



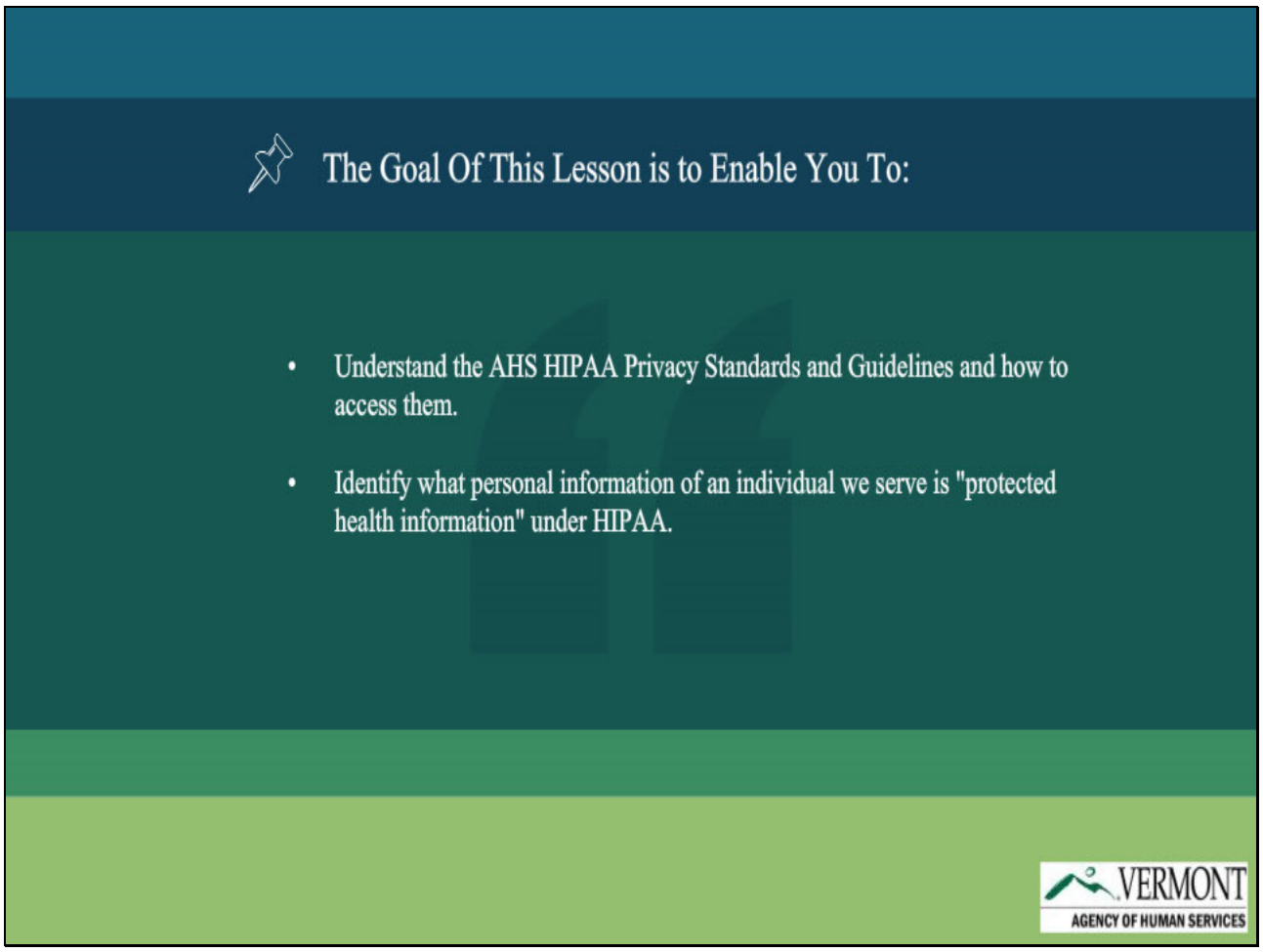
Slide 17 - Want To Review The Section Again?



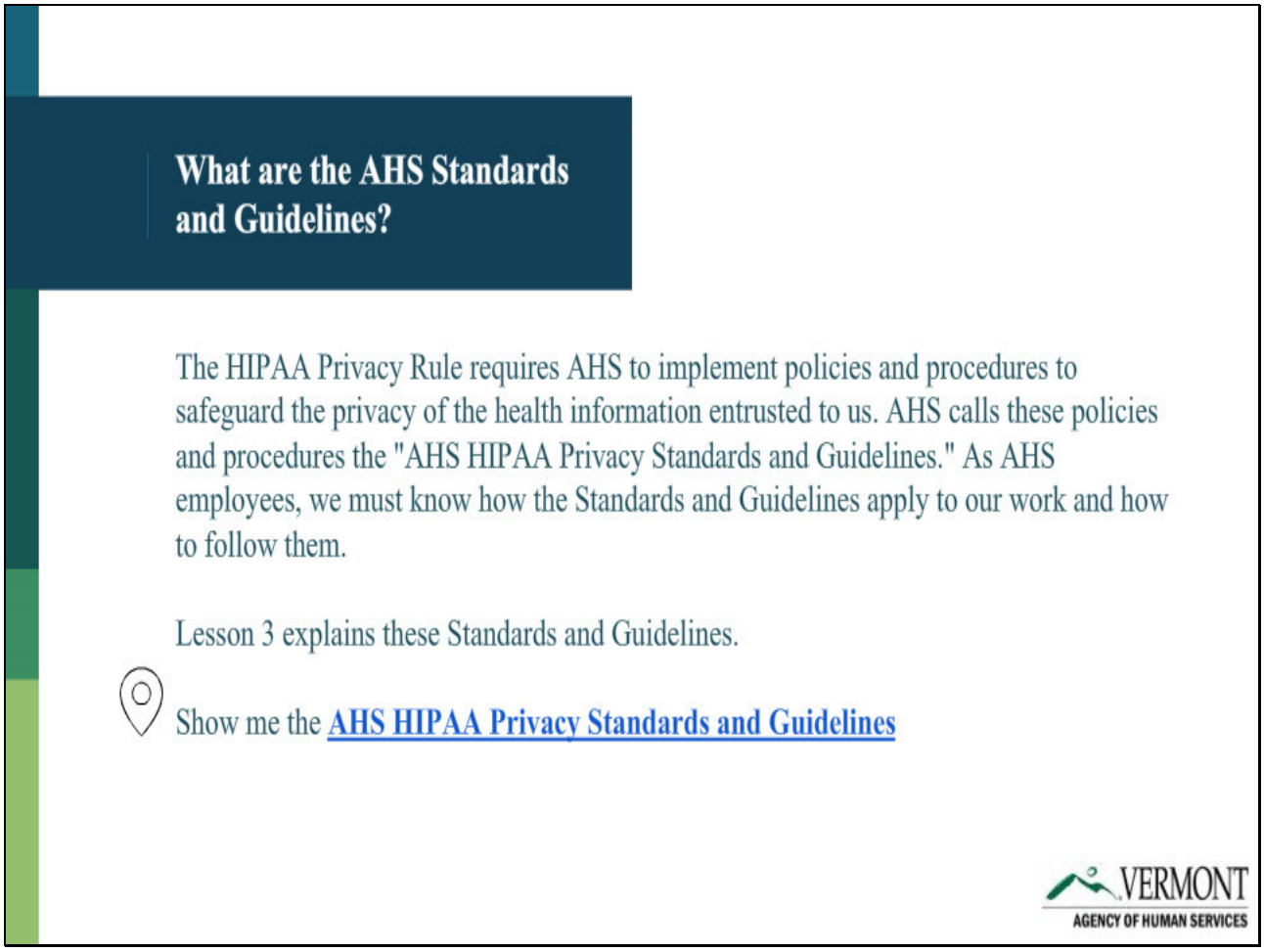
Slide 18 - Privacy Basic



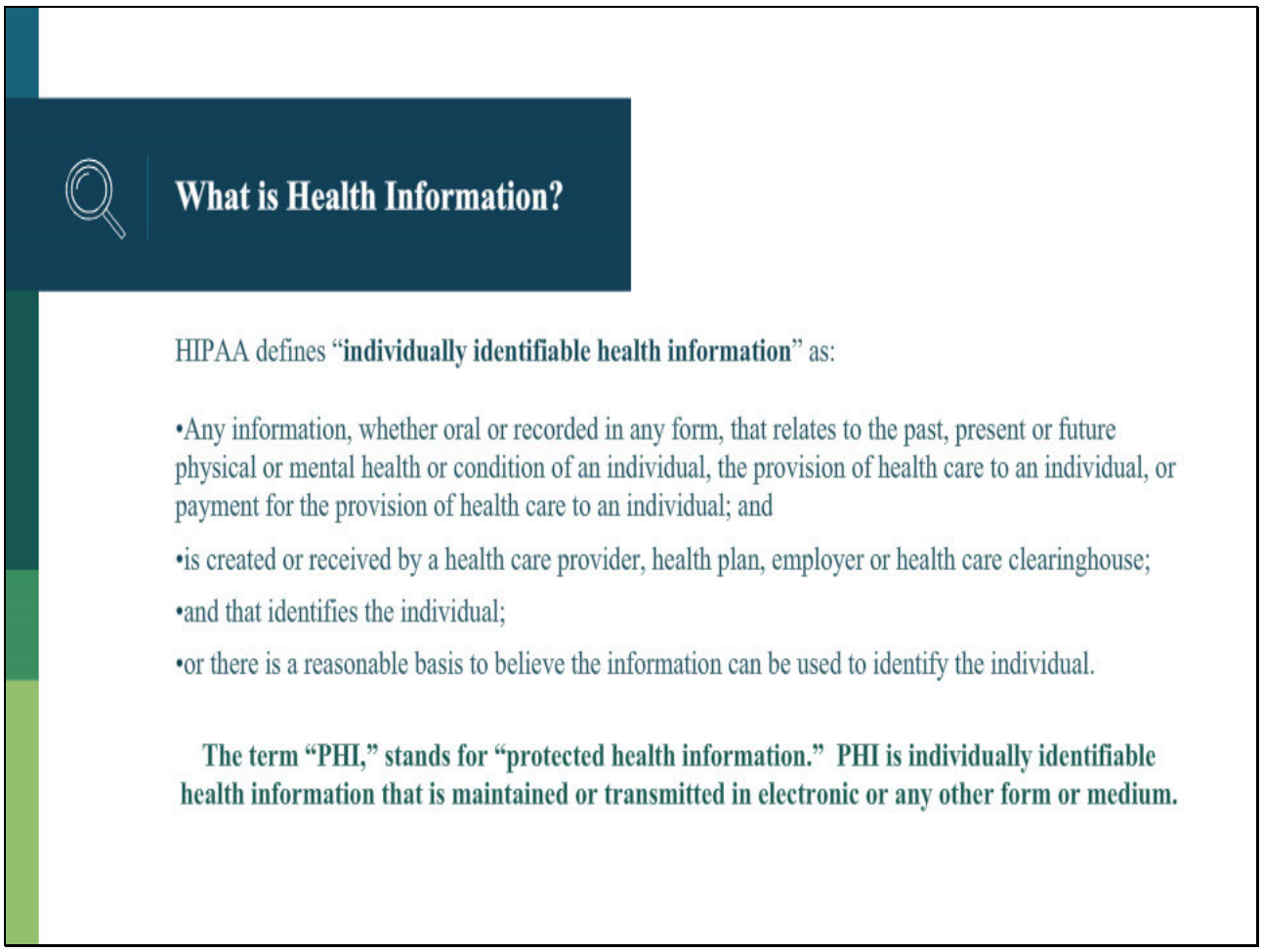
Slide 19 - Slide 20



Slide 20 - What are the AHS Standards and Guidelines?



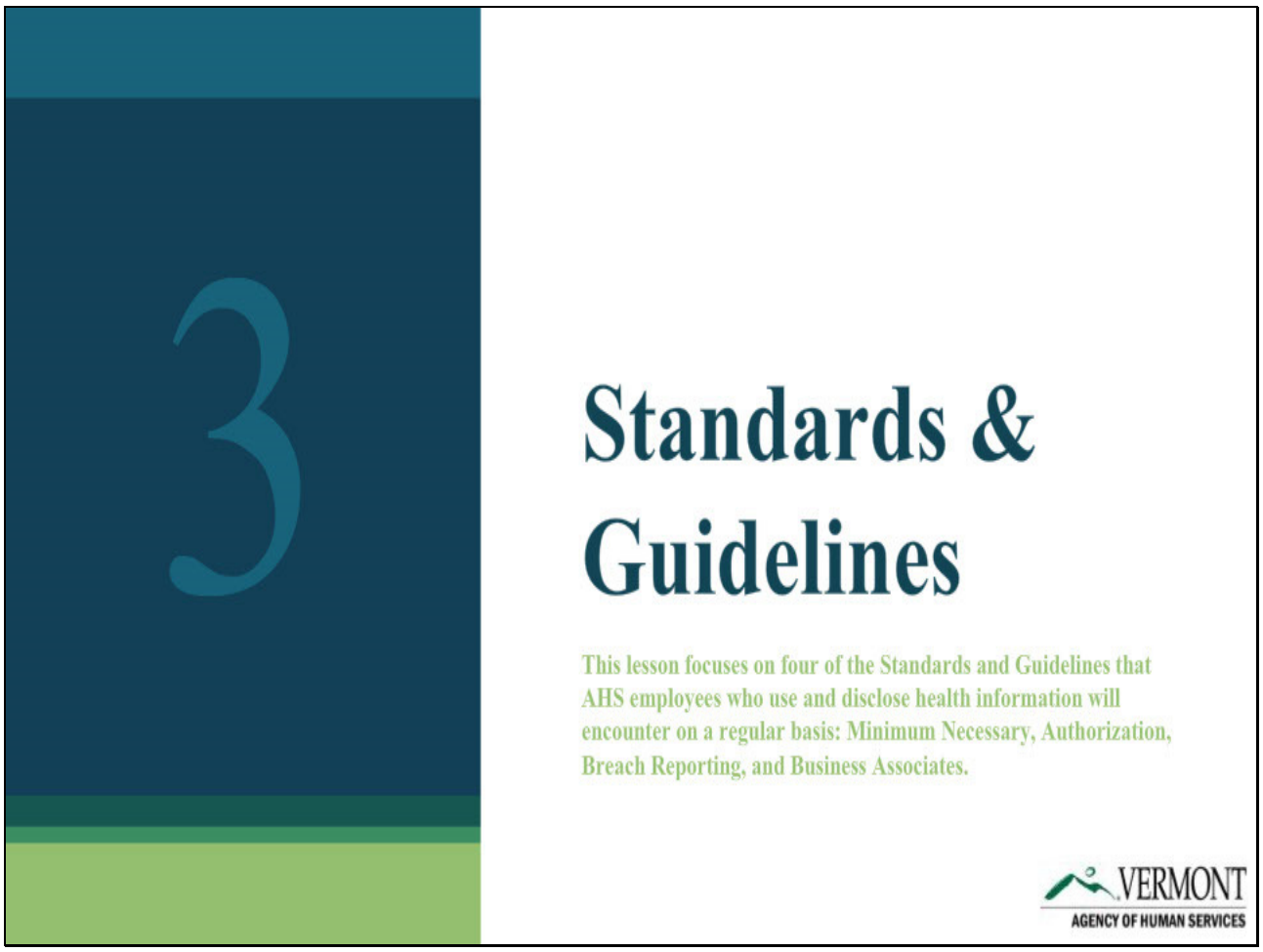
Slide 21 - What is Health Information?



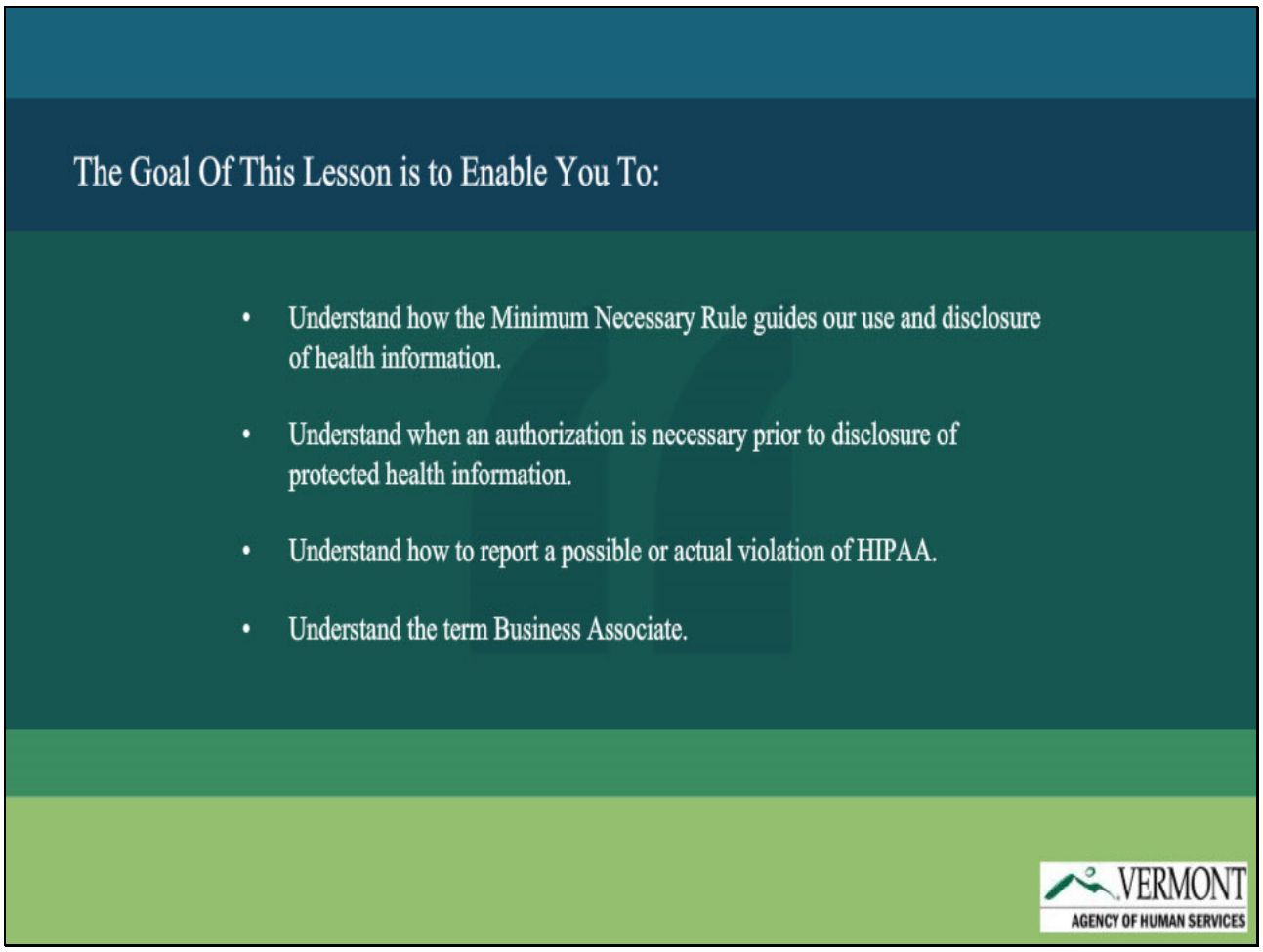
Slide 22 - Let's review some concepts

Slide 23 - Want to Review the Section Again?

Slide 24 - Standards & Guidelines



Slide 25 - Slide 26



Slide 26 - What Is Minimum Necessary?

What Is Minimum Necessary?

The Minimum Necessary Rule requires that AHS employees make reasonable efforts to use, disclose or request only the minimum amount of health information that is necessary to accomplish the purpose of the use, disclosure, or request. This rule does not apply when the disclosure is to a health care provider for the purpose of providing treatment, or when the use or disclosure is authorized in writing by the individual.

You should only use, disclose, or request health information that you need to perform your job duties.

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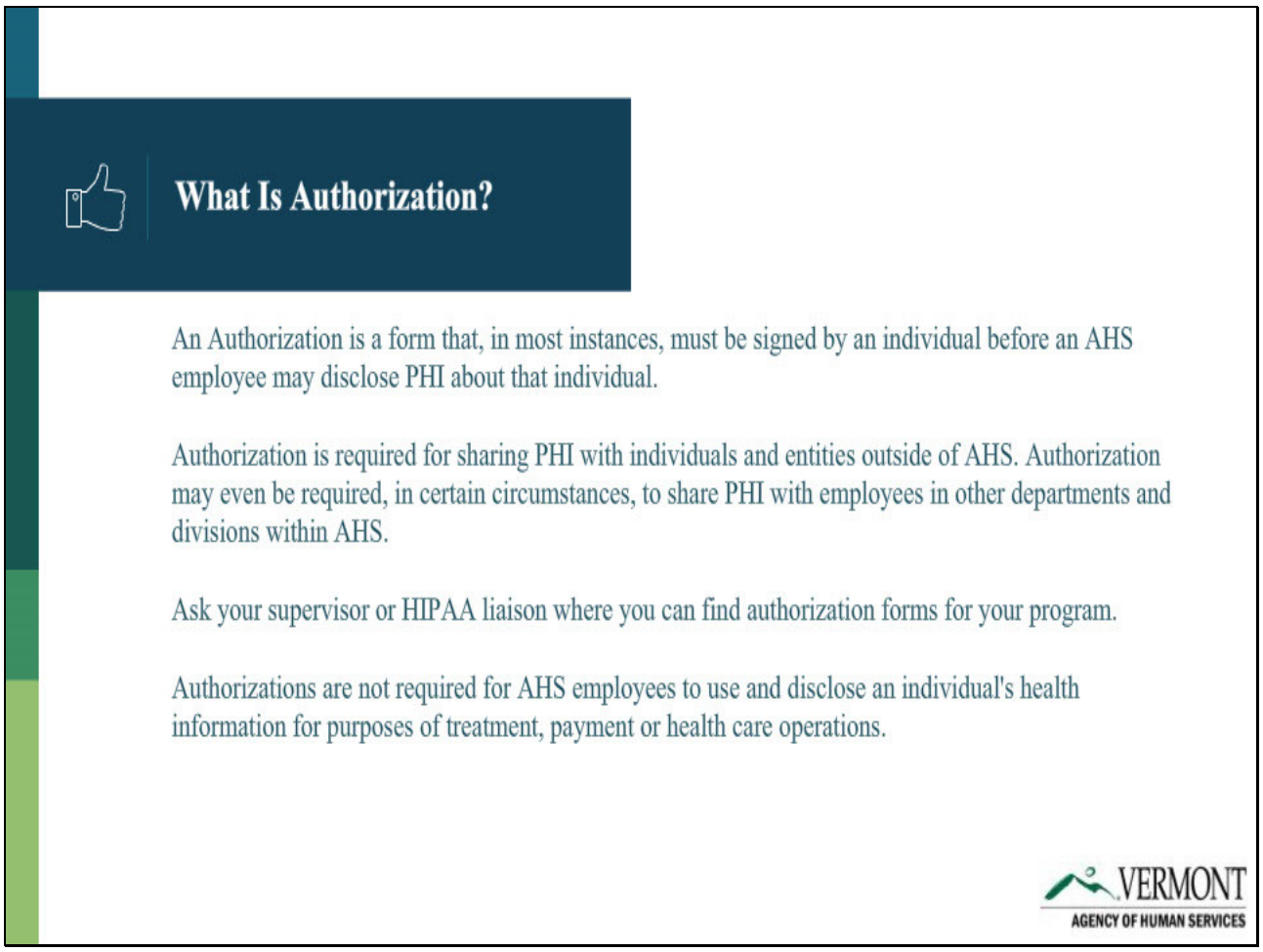
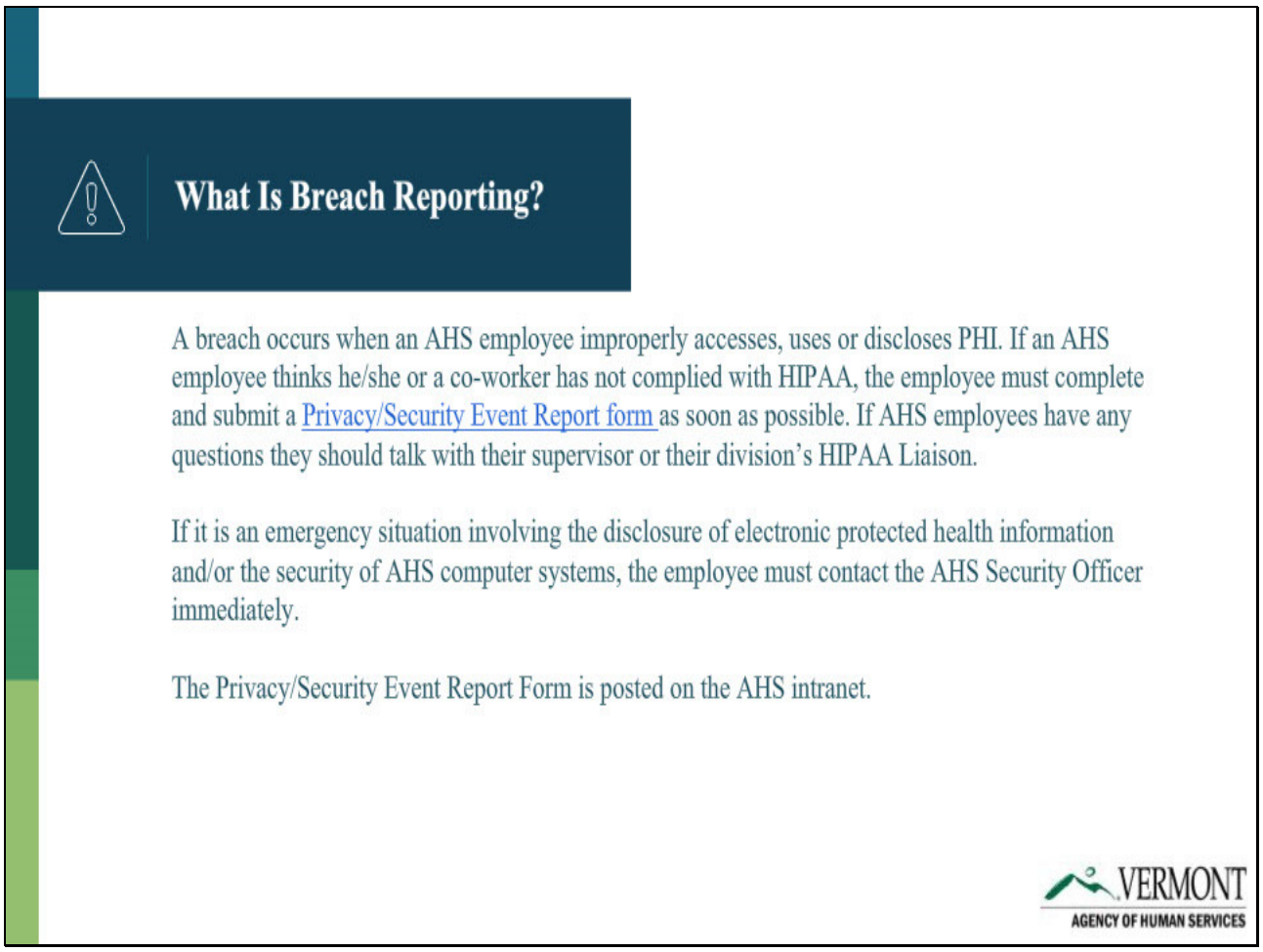
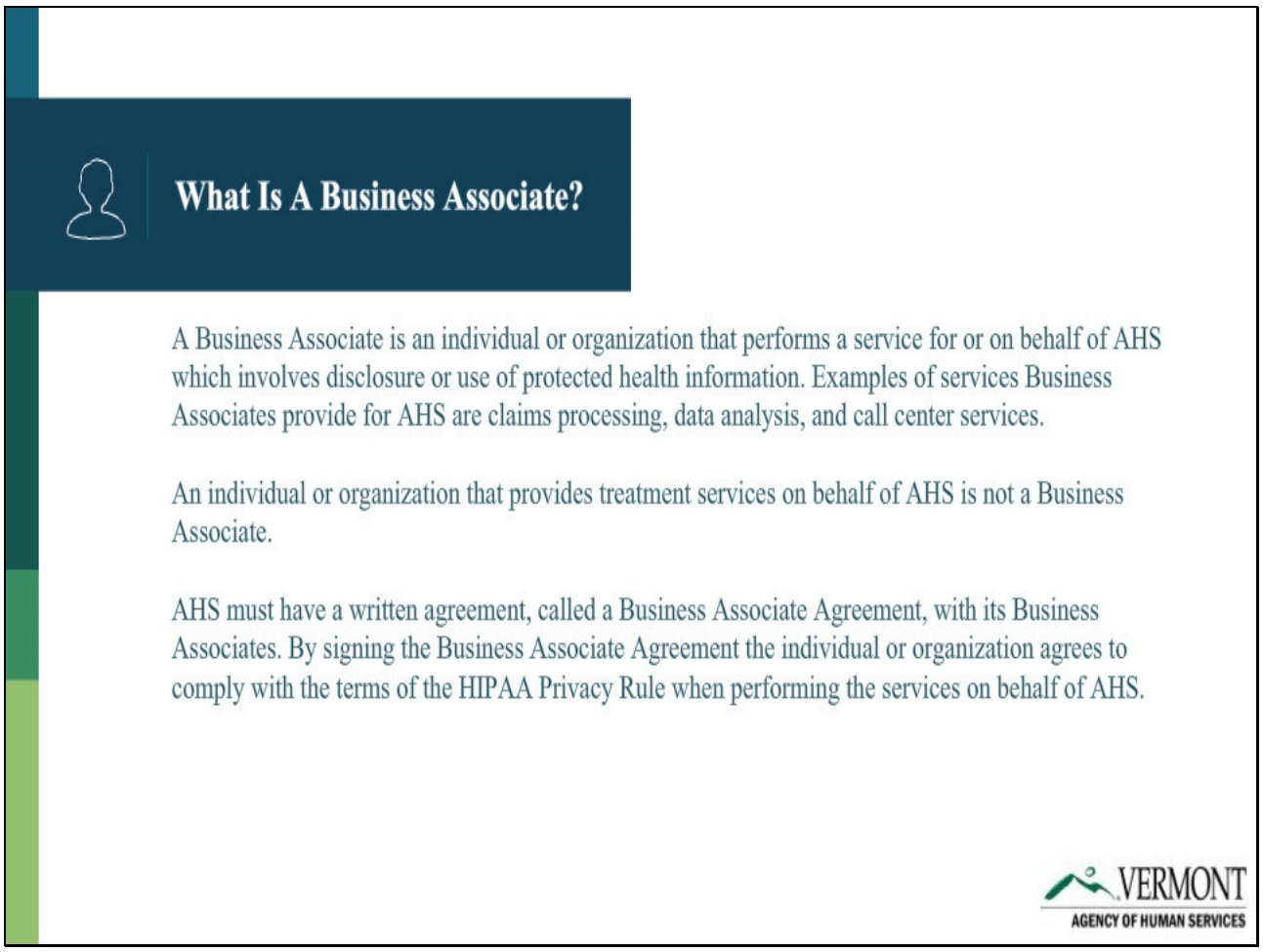
Slide 27 - What Is Authorization?



Slide 28 - What Is Breach Reporting?



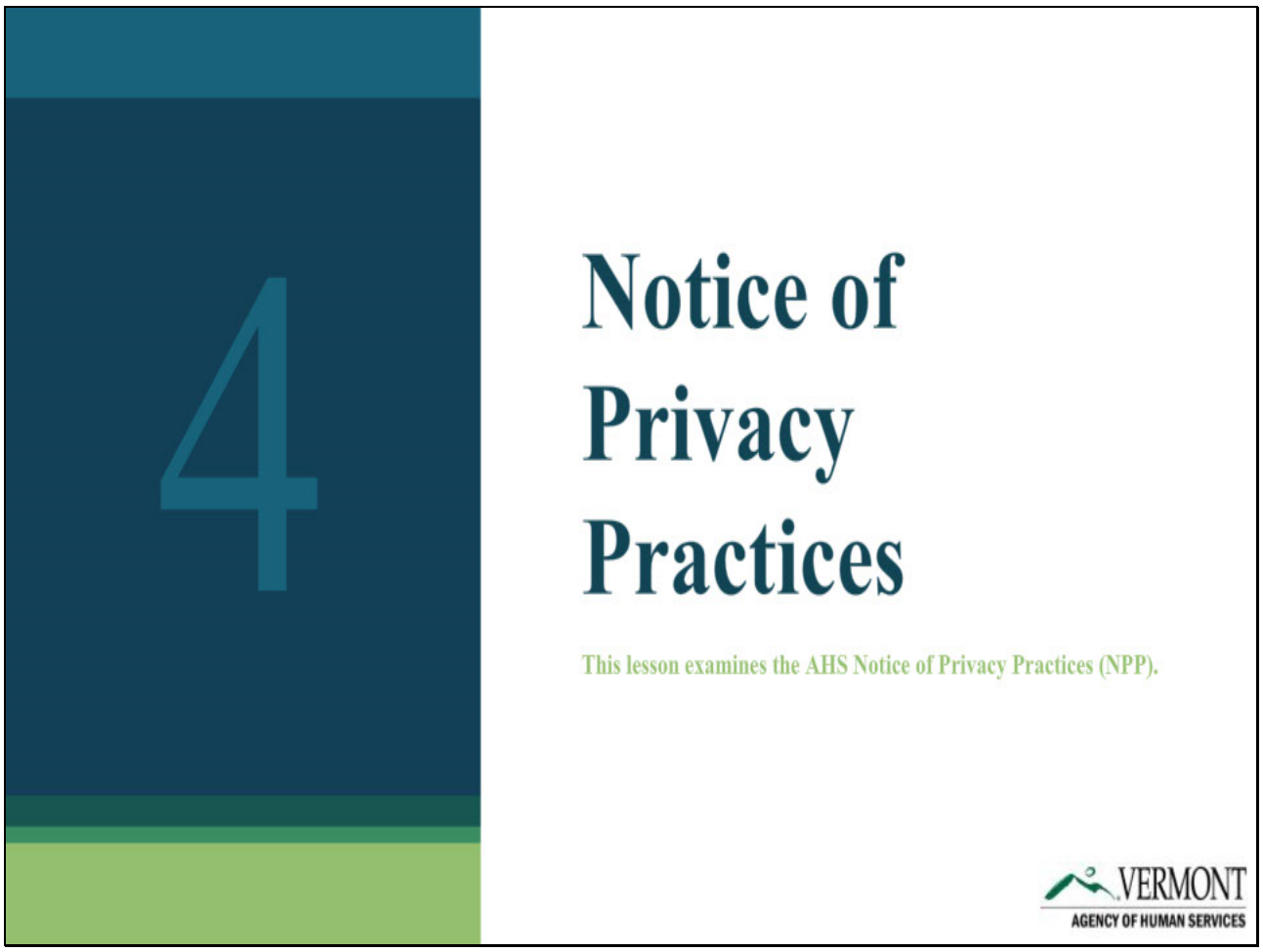
Slide 29 - What Is A Business Associate?



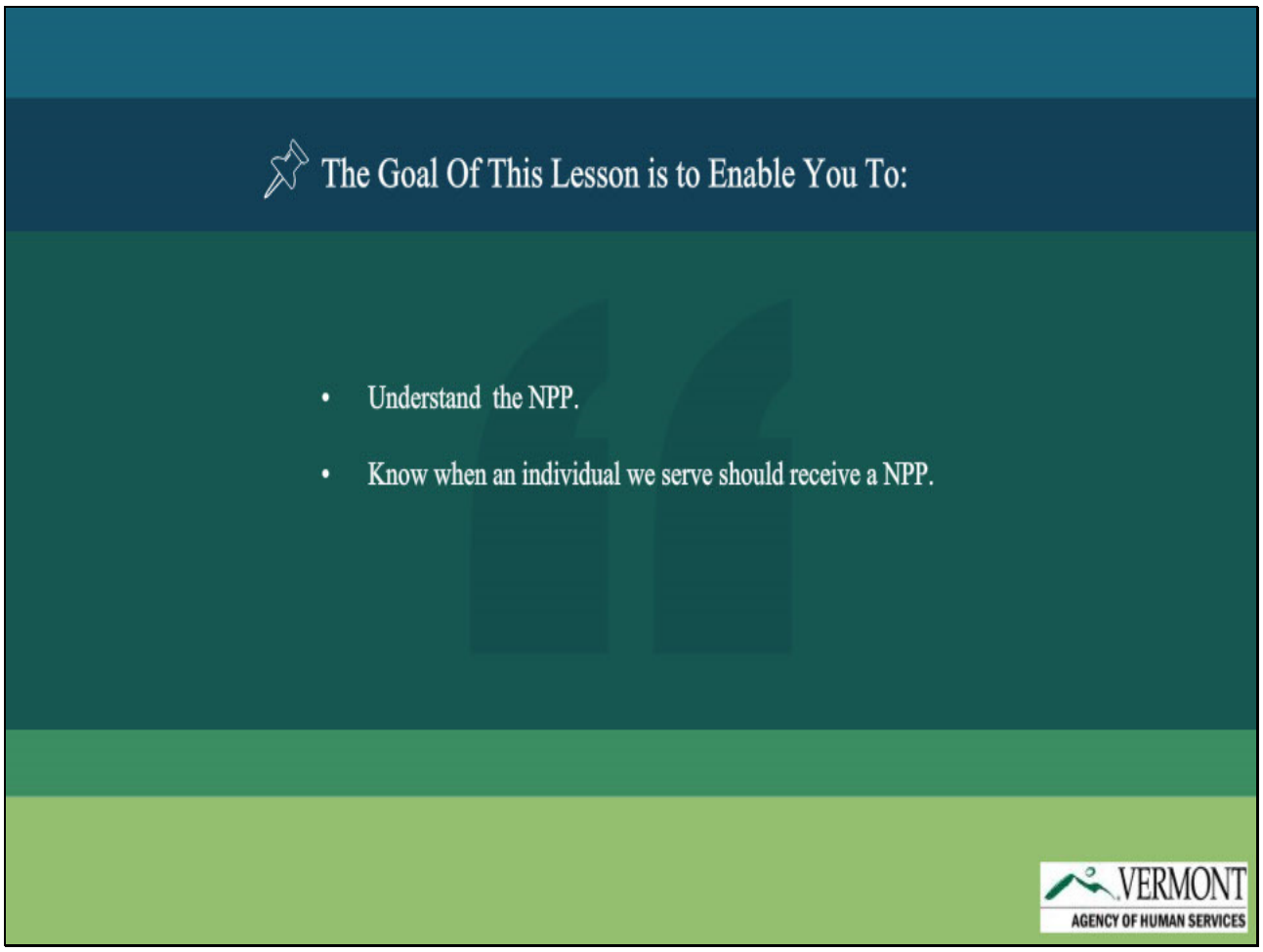
Slide 30 - Let's Review Some Concepts

Slide 31 - Want to Review the Section Again?

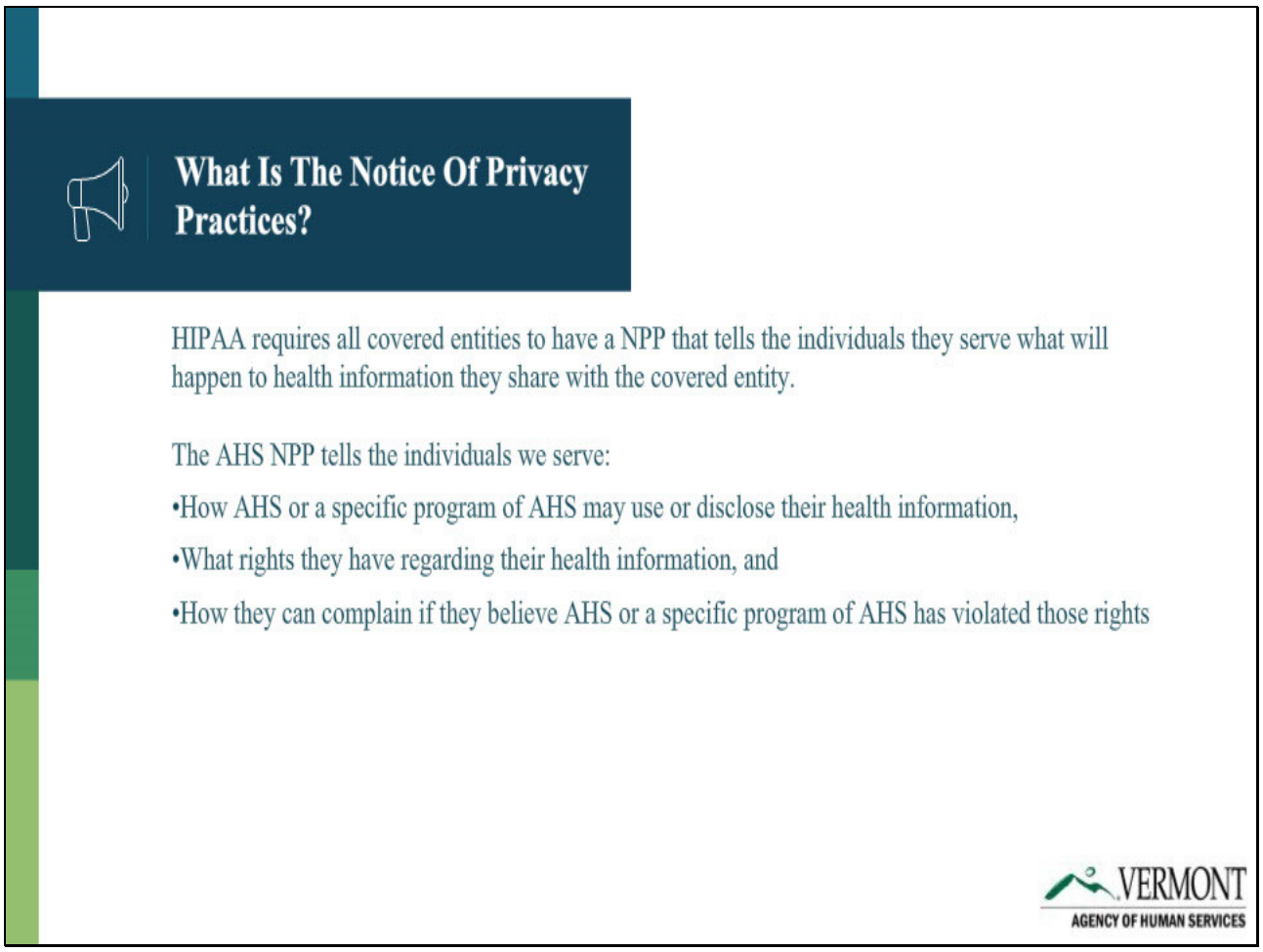
Slide 32 - Notice of Privacy Practices



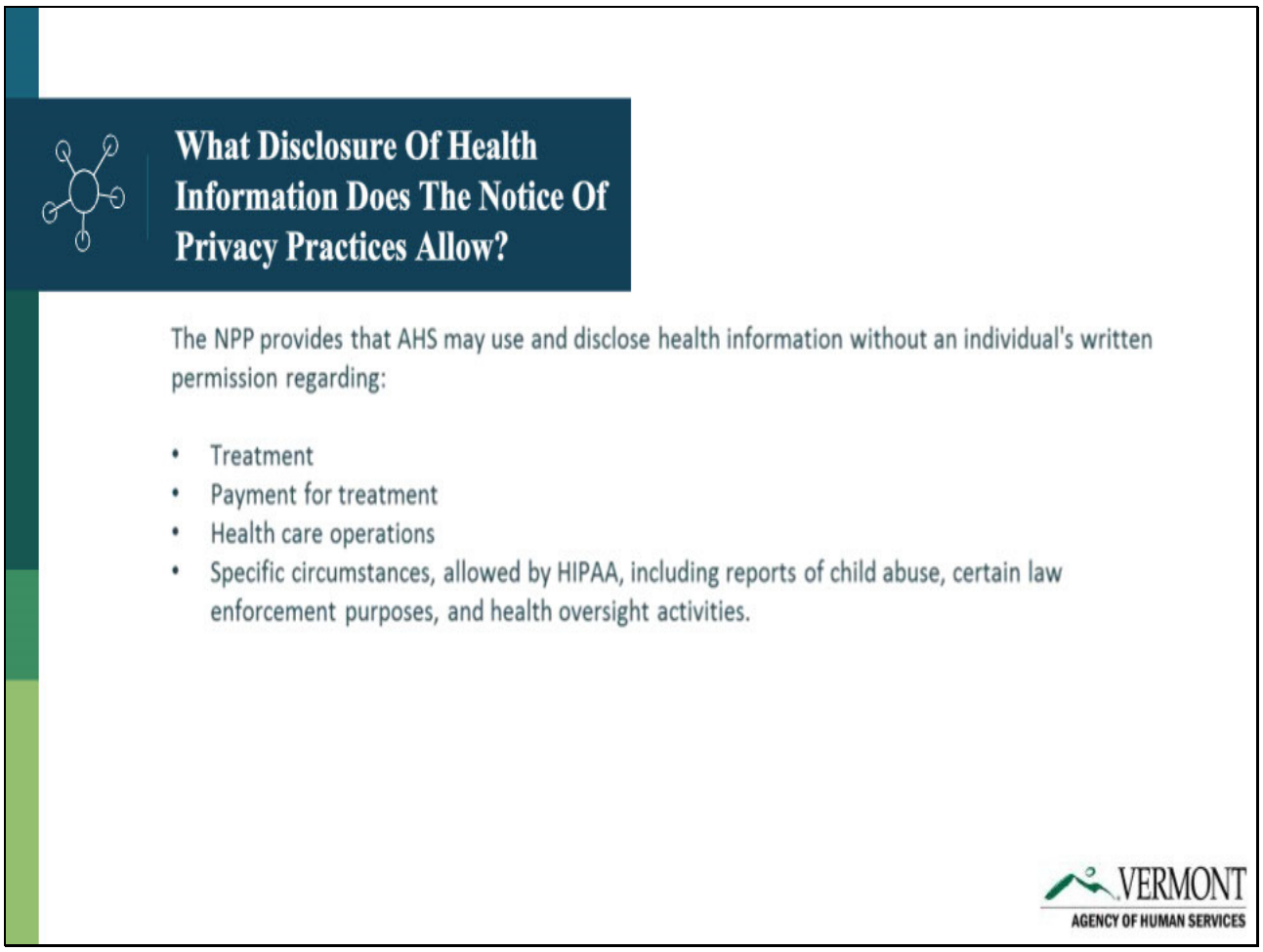
Slide 33 - Slide 34



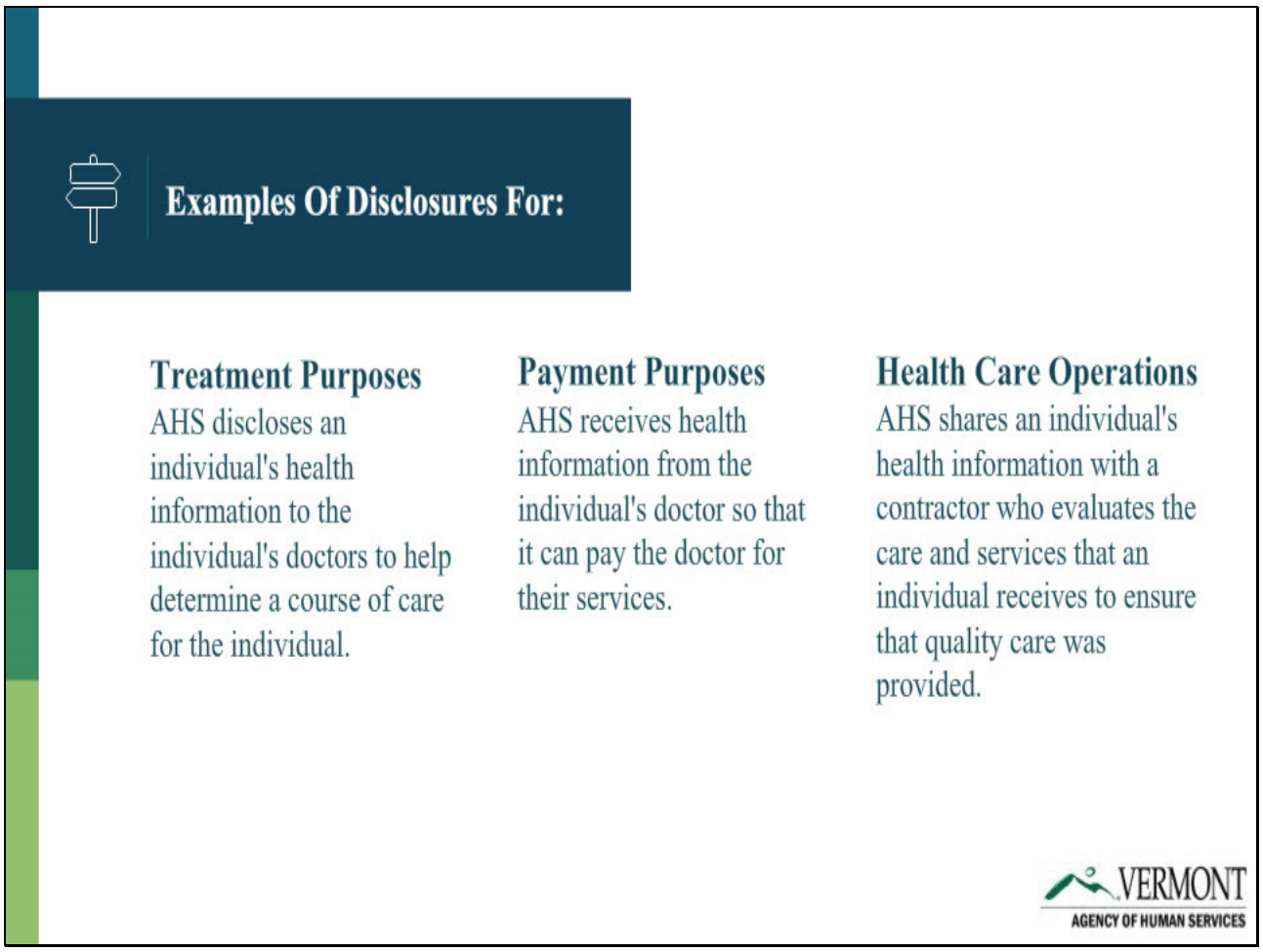
Slide 34 - What Is The Notice Of Privacy Practices?



Slide 35 - What Disclosure Of Health Information Does The Notice Of Privacy Practices Allow?



Slide 36 - Examples Of Disclosures For:



Slide 37 - What Rights Do Individuals Have Regarding Health Information Under NPP?

What Rights Do Individuals Have Regarding Health Information Under NPP?

The notice informs individuals of their rights with respect to their health information such as:

- Reviewing their health information
- Obtaining an accounting of disclosures of their health information by AHS
- Written notification in the event of a breach of their health information.

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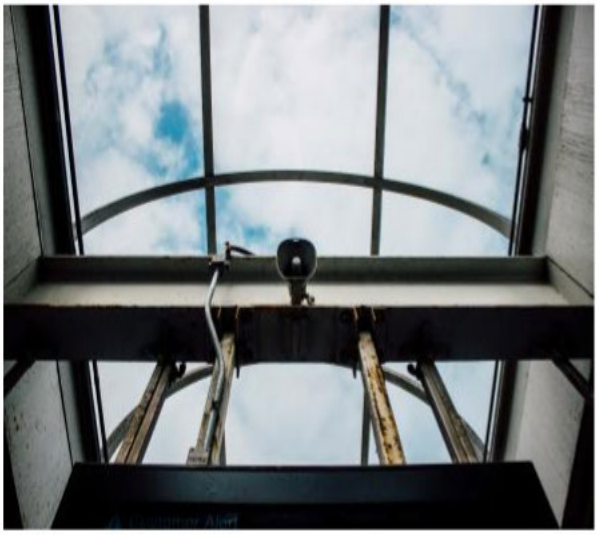
Slide 38 - Does The NPP Include A Process For Filing A Complaint If An Individual Believes AHS Has Violated His/Her Rights?

Does The NPP Include A Process For Filing A Complaint If An Individual Believes AHS Has Violated His/Her Rights?

The NPP explains the process for filing a complaint with the Agency of Health and Human Services, Office of Civil Rights (OCR) if an individual believes AHS has violated his/her rights.



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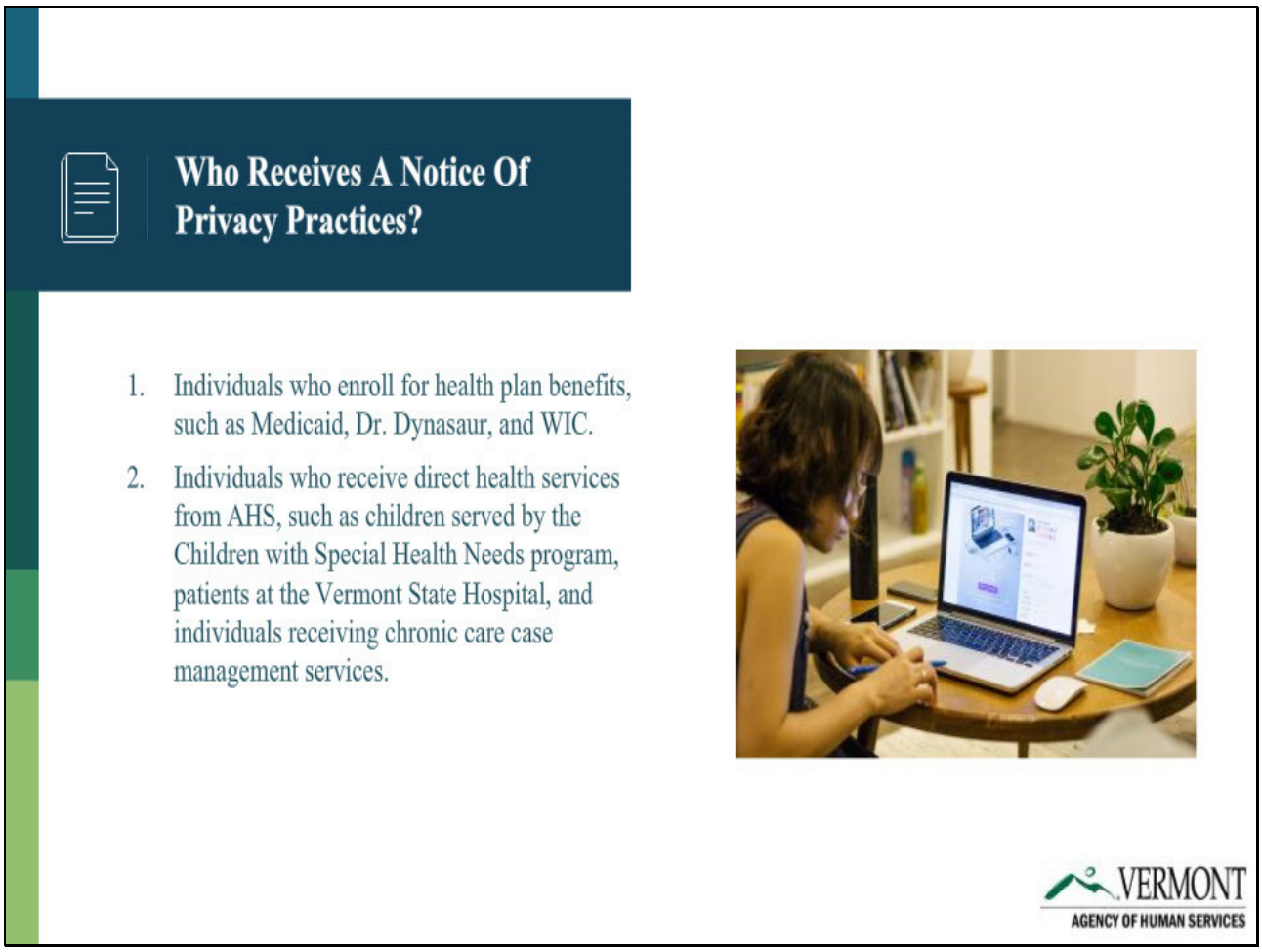
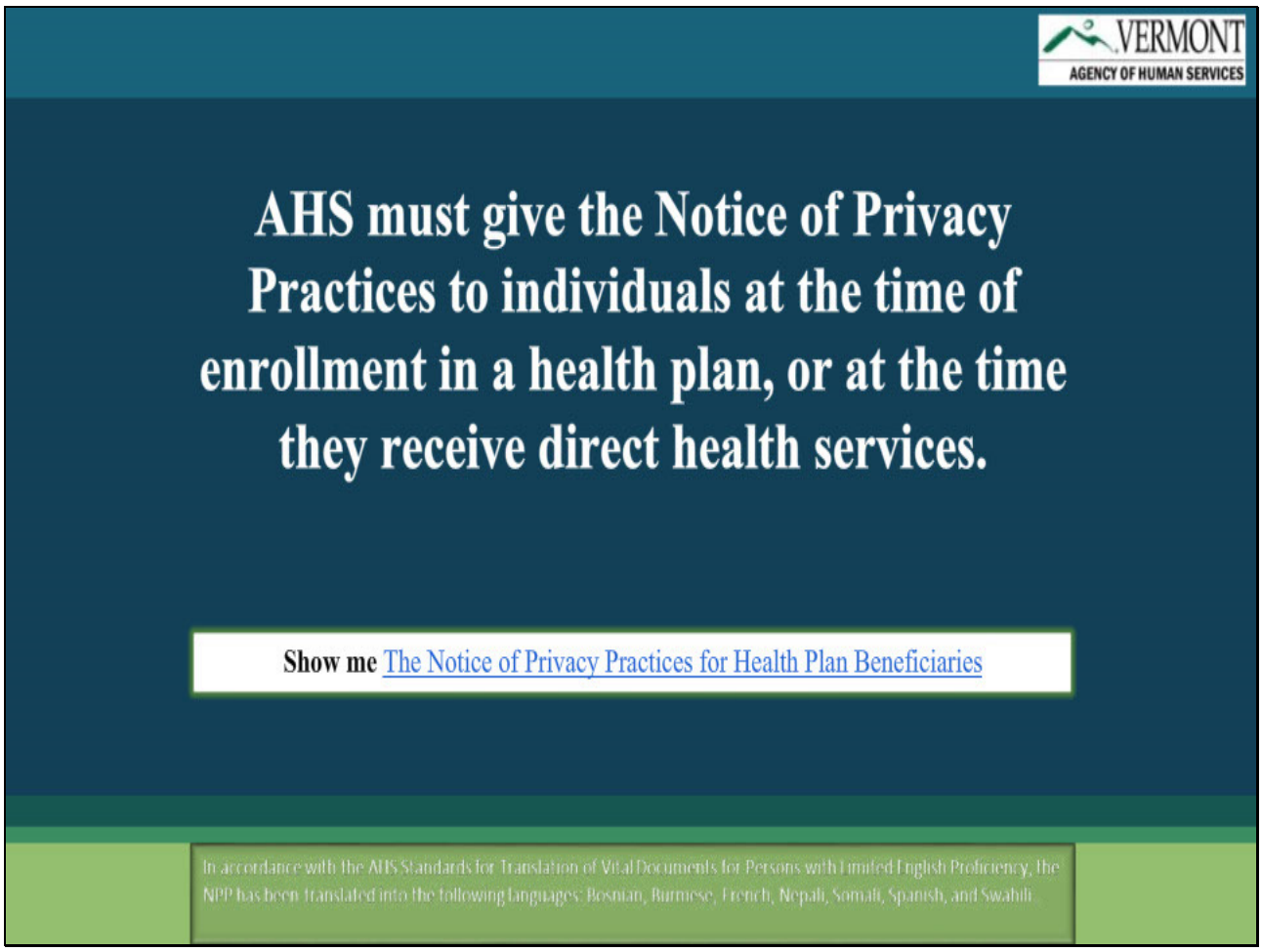
Slide 39 - Who Receives A Notice Of Privacy Practices?

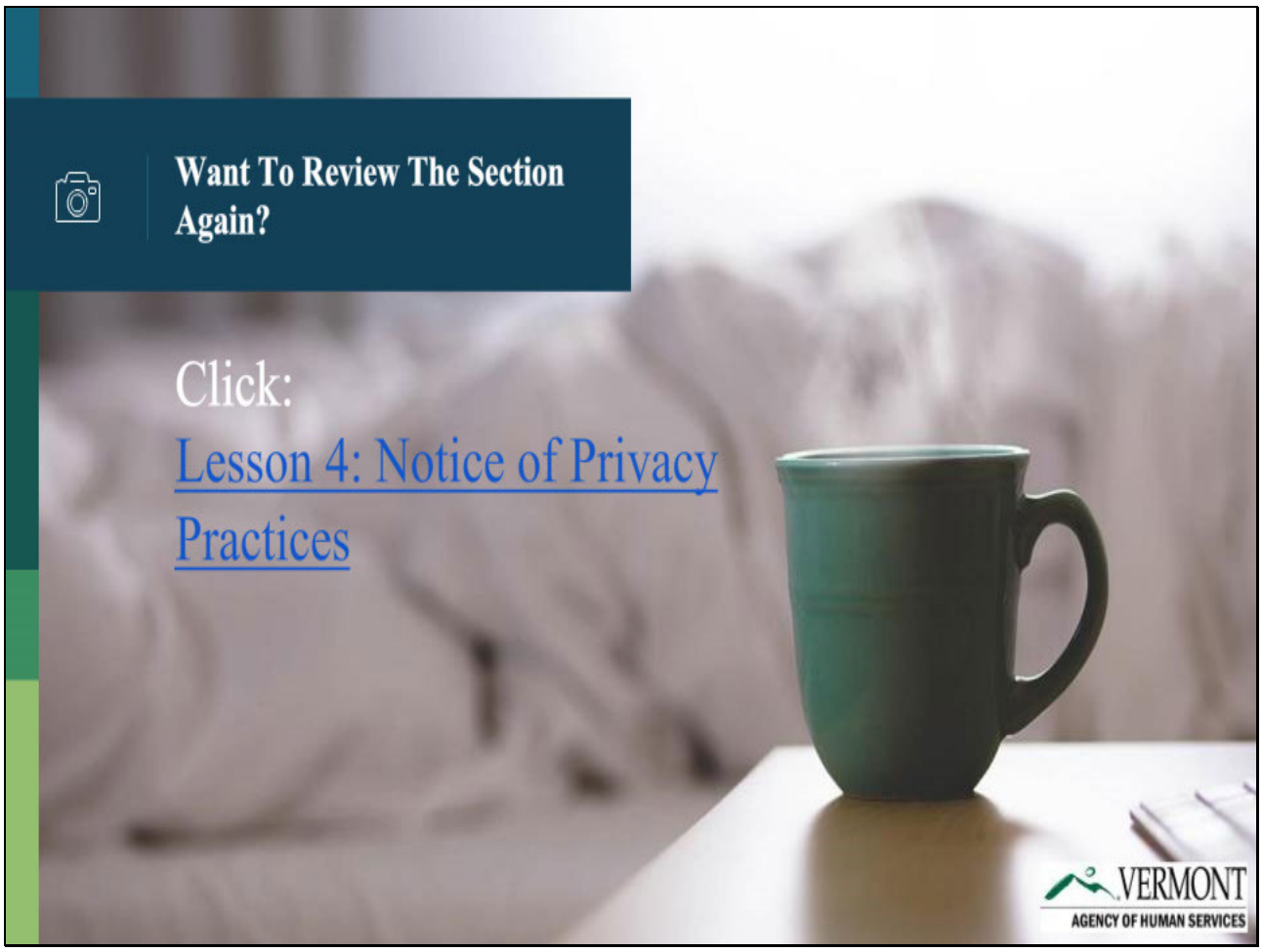


Slide 40 - Slide 41

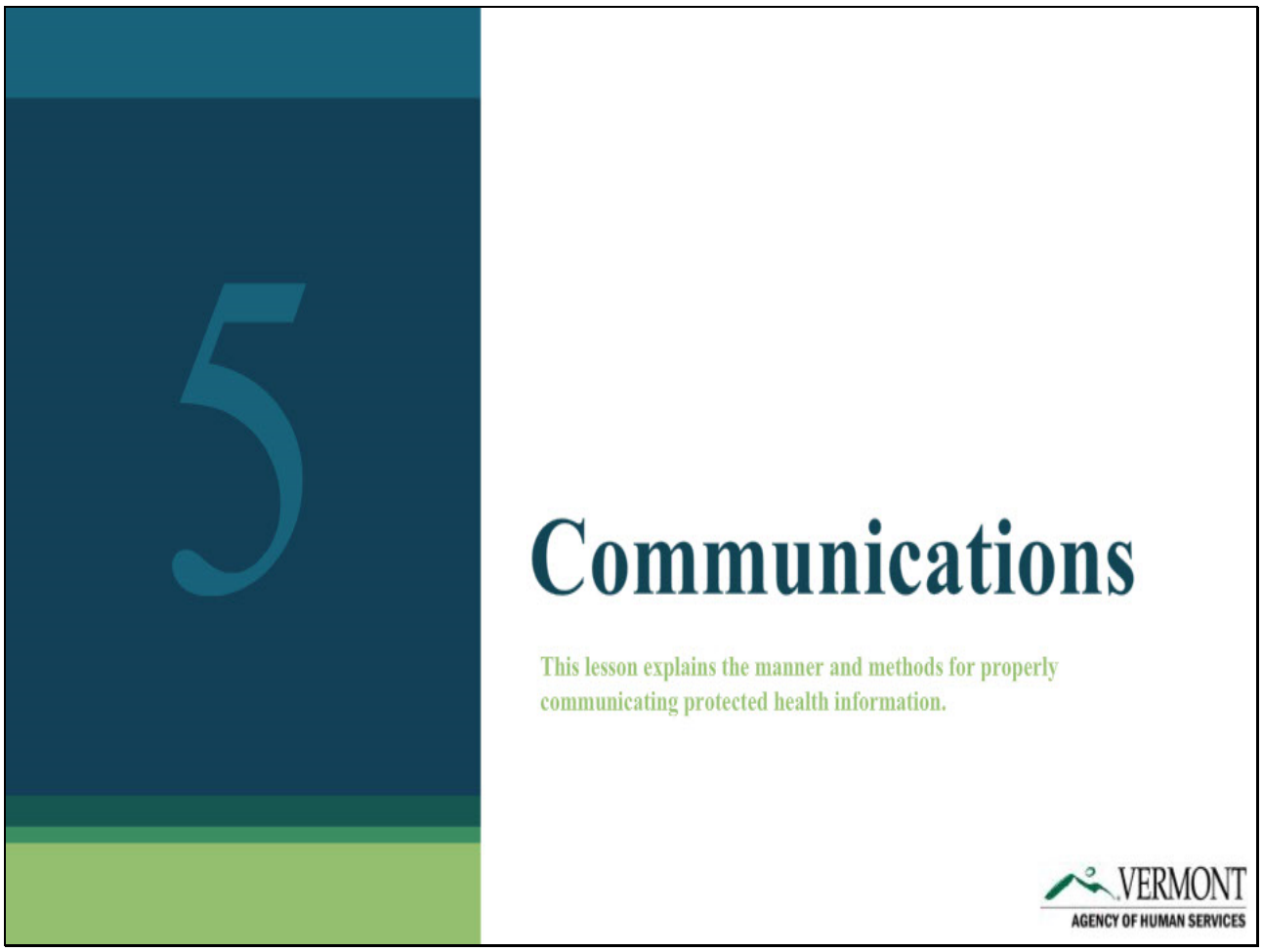


Slide 41 - Let's Review Some Concepts

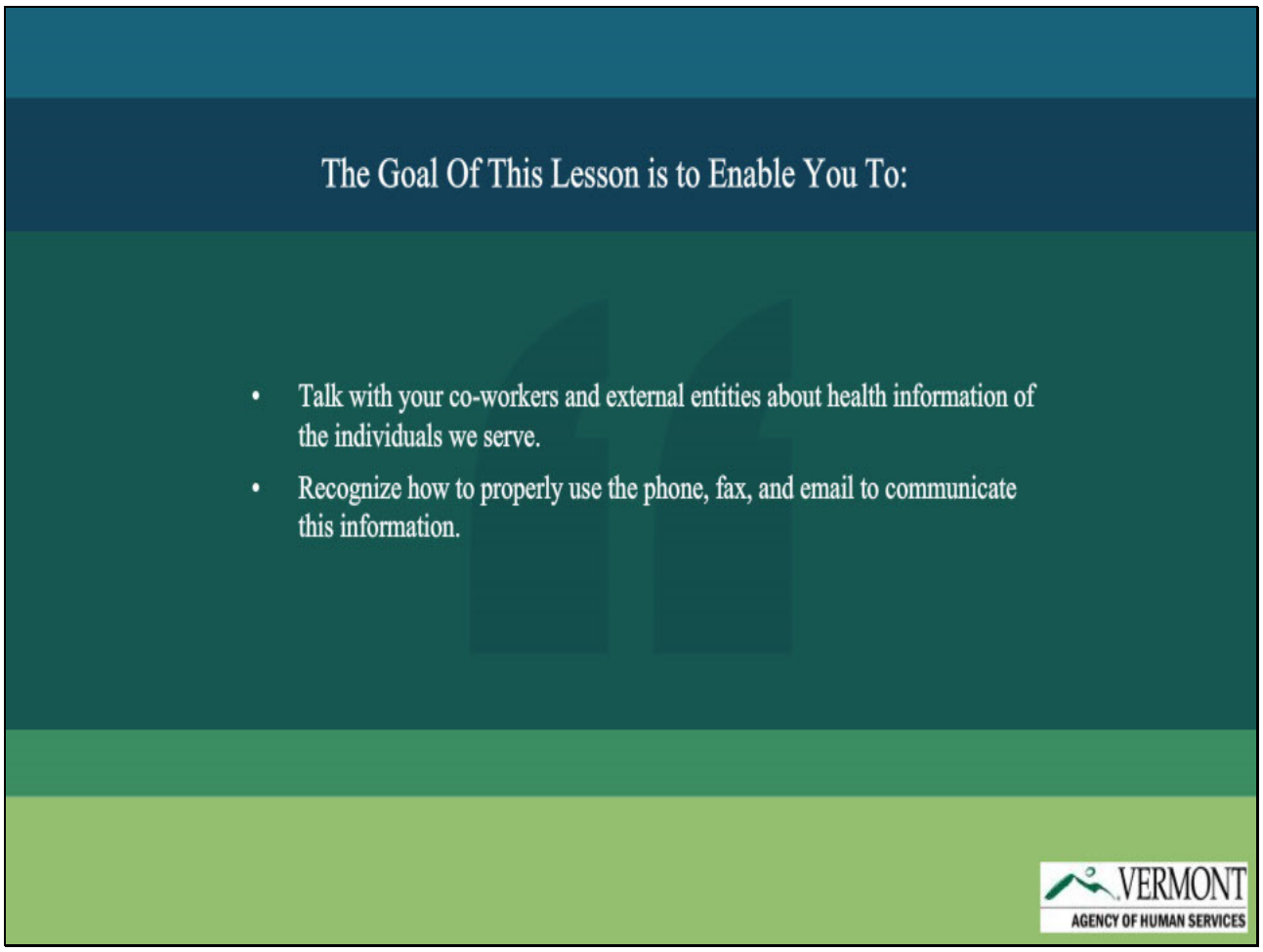
Slide 42 - Want To Review The Section Again?



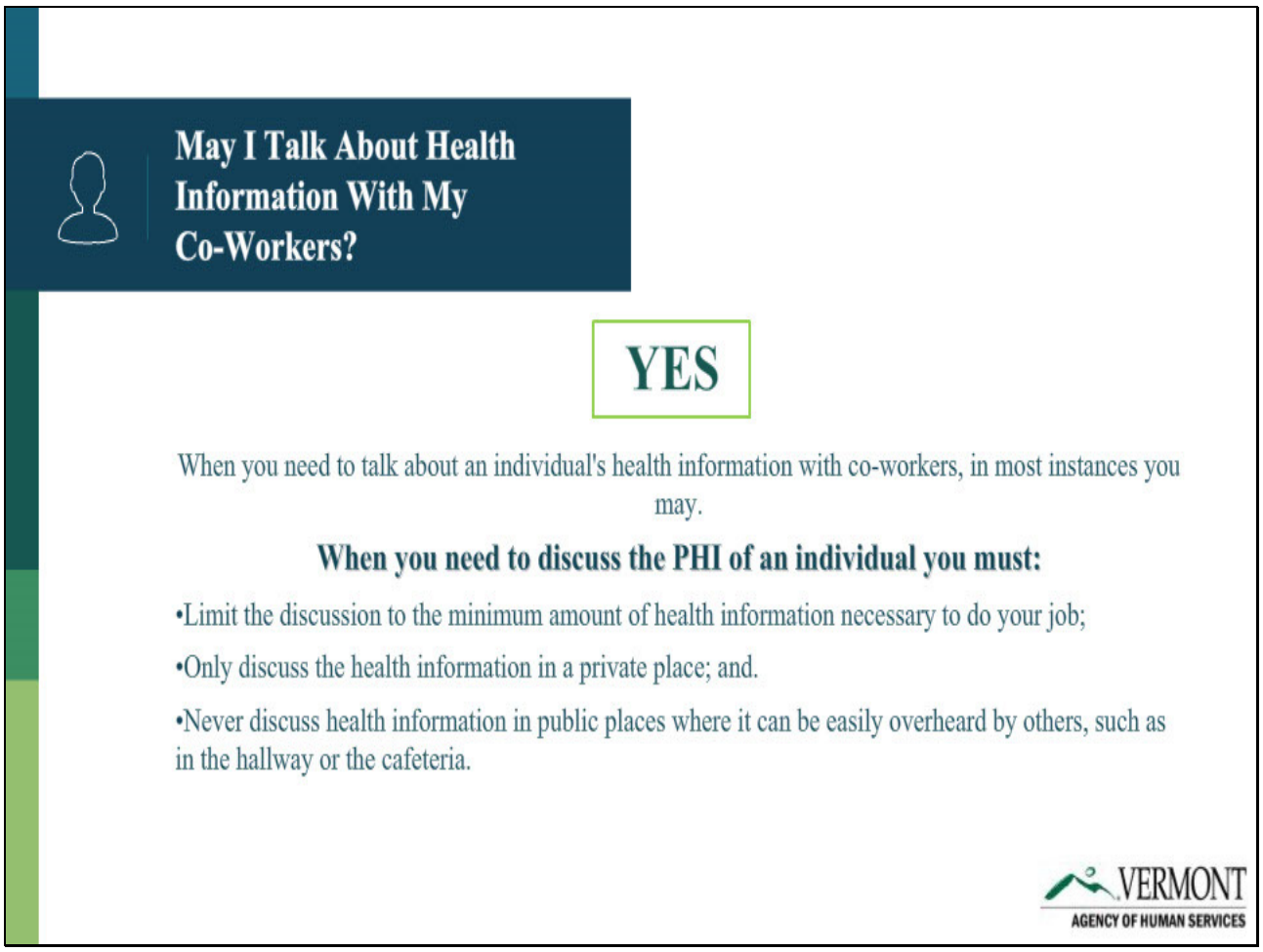
Slide 43 - Communications



Slide 44 - Slide 45

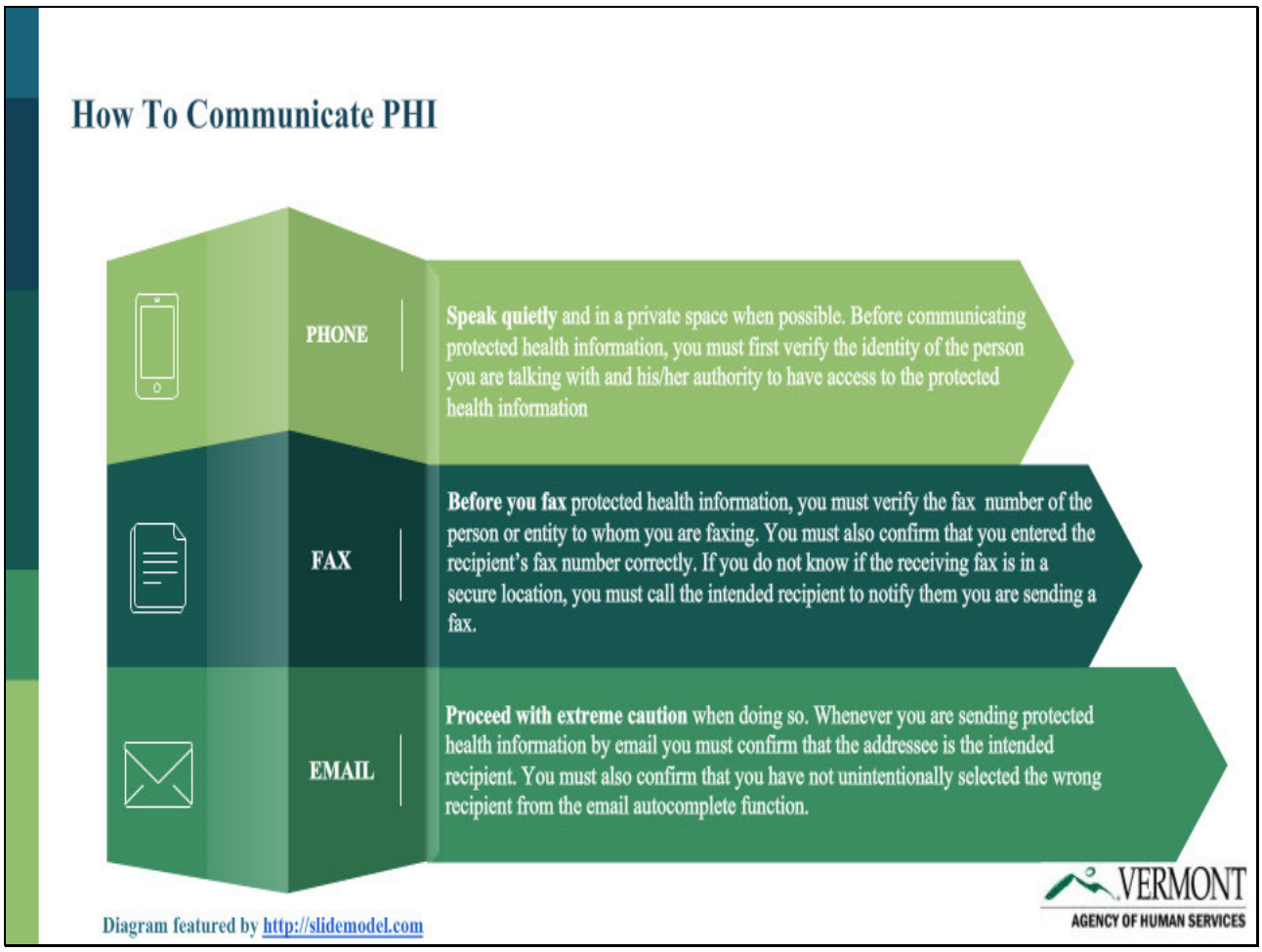


Slide 45 - May I Talk About Health Information With My Co-Workers?



Slide 46 - May I Communicate PHI By Phone, Fax, Or Email?

Slide 47 - How To Communicate PHI



Slide 48 - What Should I Do If I Have An Accidental Disclosure?

What Should I Do If I Have An Accidental Disclosure?

Accidental disclosures of protected health information can occur when you use the phone, fax, or email.

If you believe you have accidentally disclosed protected health information, you must contact your Department's HIPAA liaison and complete a HIPAA Privacy / Security Event Form found on the AHS SharePoint site.

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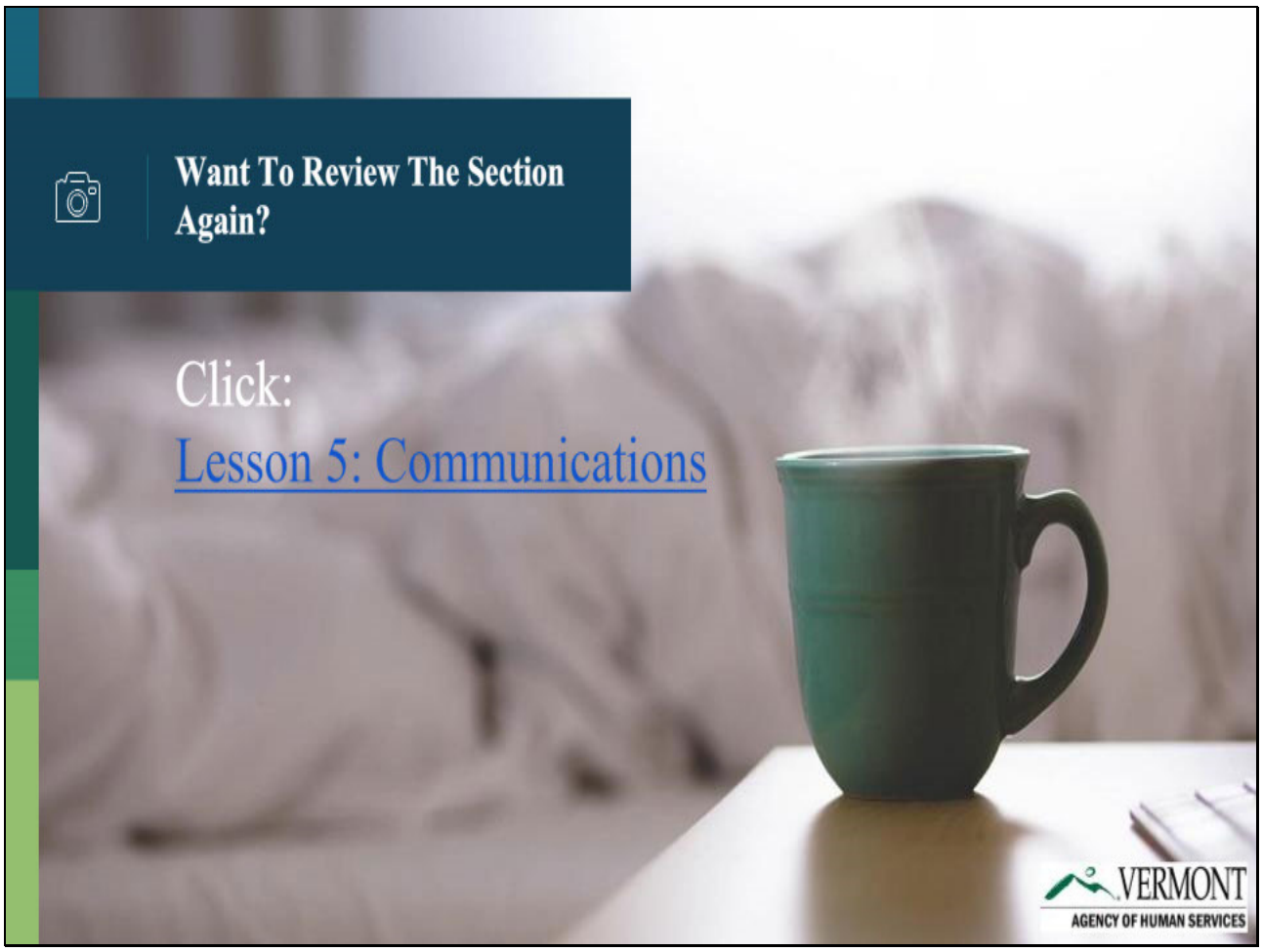
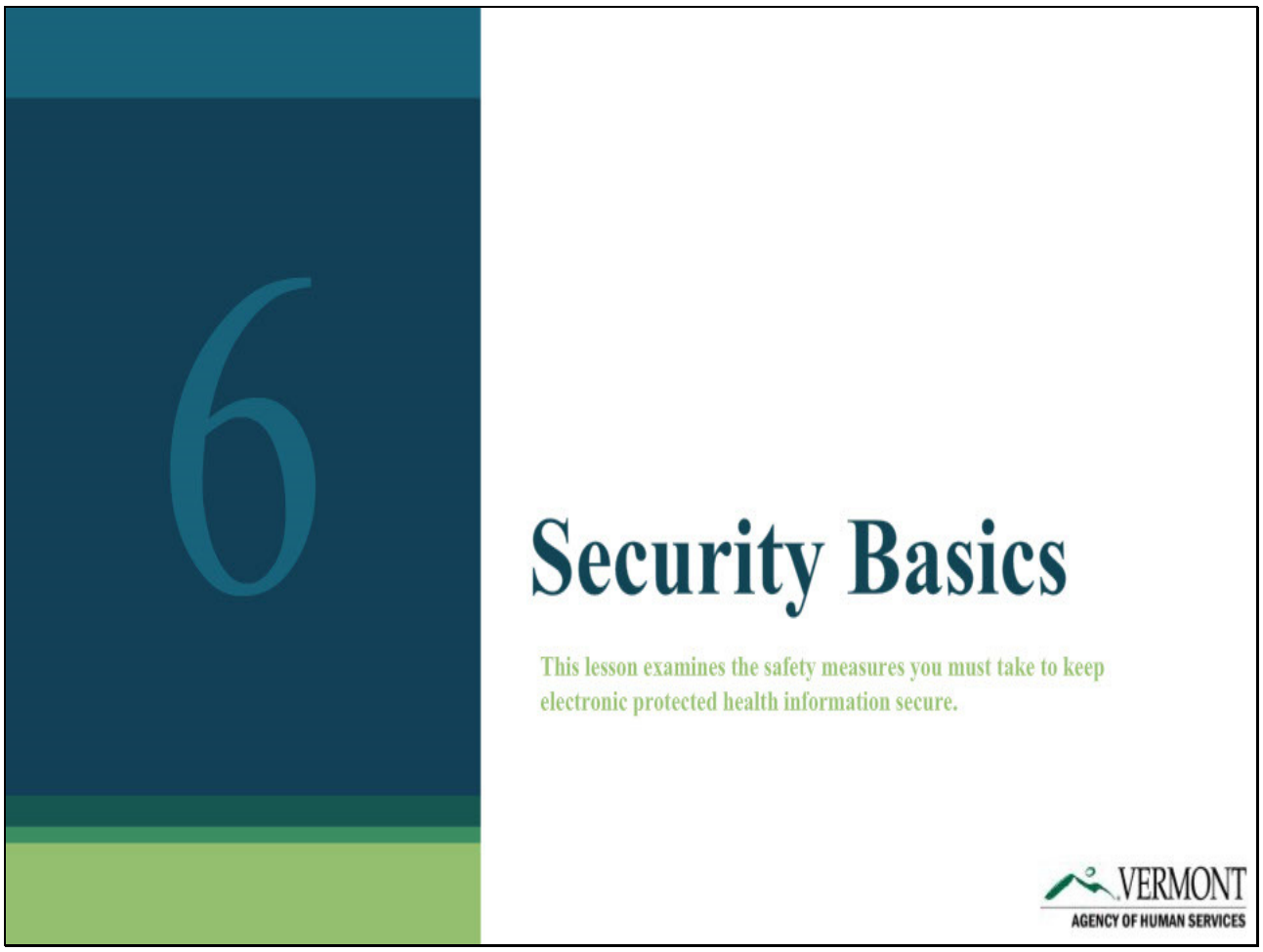
Slide 49 - Let's Review Some Concepts

Slide 50 - Want To Review The Section Again?



Slide 51 - Security Basics

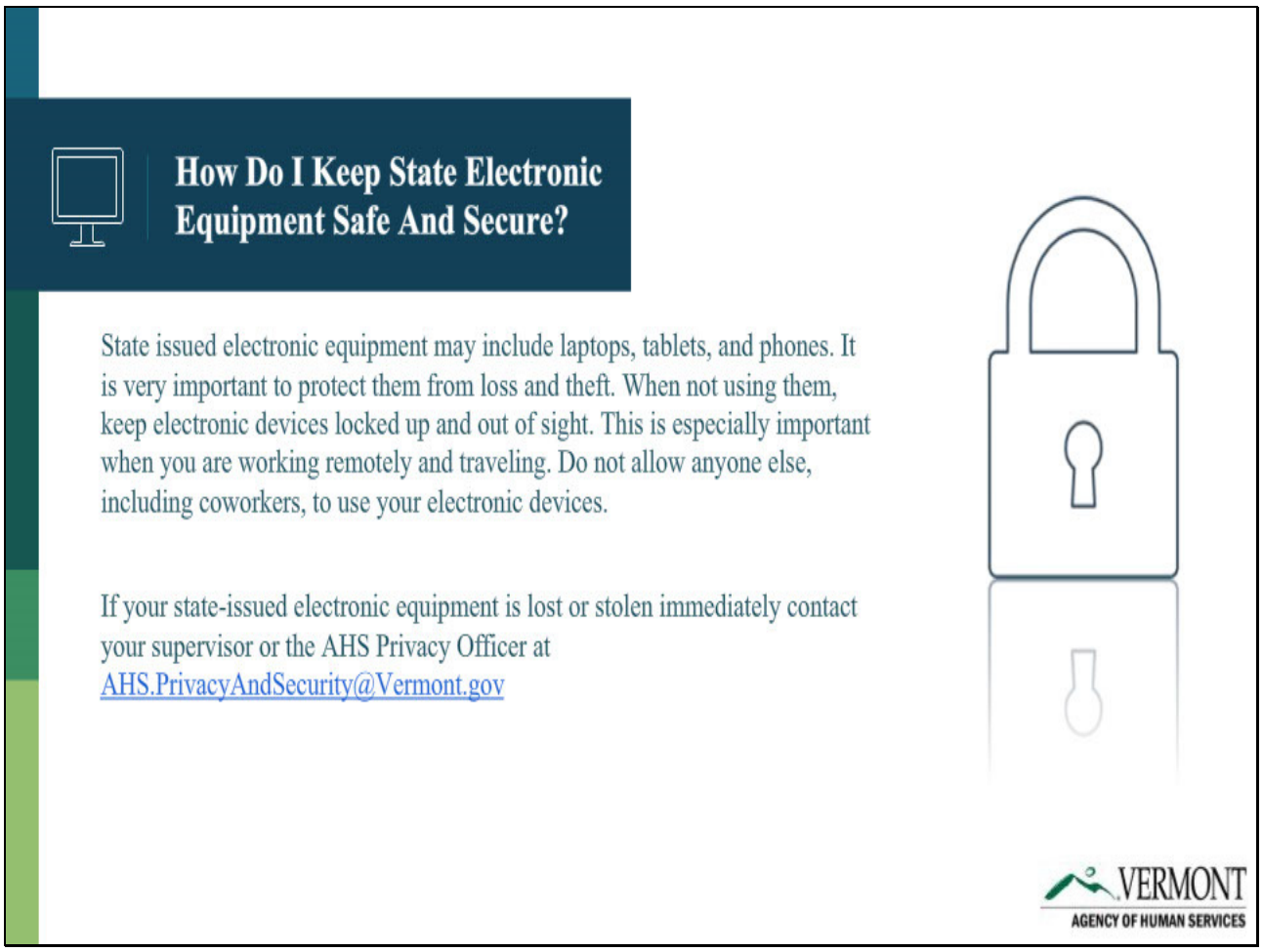


Slide 52 - Slide 53

Slide 53 - What Safety Measures Should I Take To Protect My Computer Workstation?

Slide 54 - Slide 55

Slide 55 - How Do I Keep State Electronic Equipment Safe And Secure?



Slide 56 - What Precautions Must I Take To Protect Against Viruses And Other Malicious Software?

What Precautions Must I Take To Protect Against Viruses And Other Malicious Software?

Malicious software or "malware" is used as a catch-all term to refer to any software that causes damage to a single computer, server, or computer network. Malware might expose or alter confidential information; delete or remove important files; disable your and other AHS network computers; email everyone in your email address book; and/or spread quickly to other machines.

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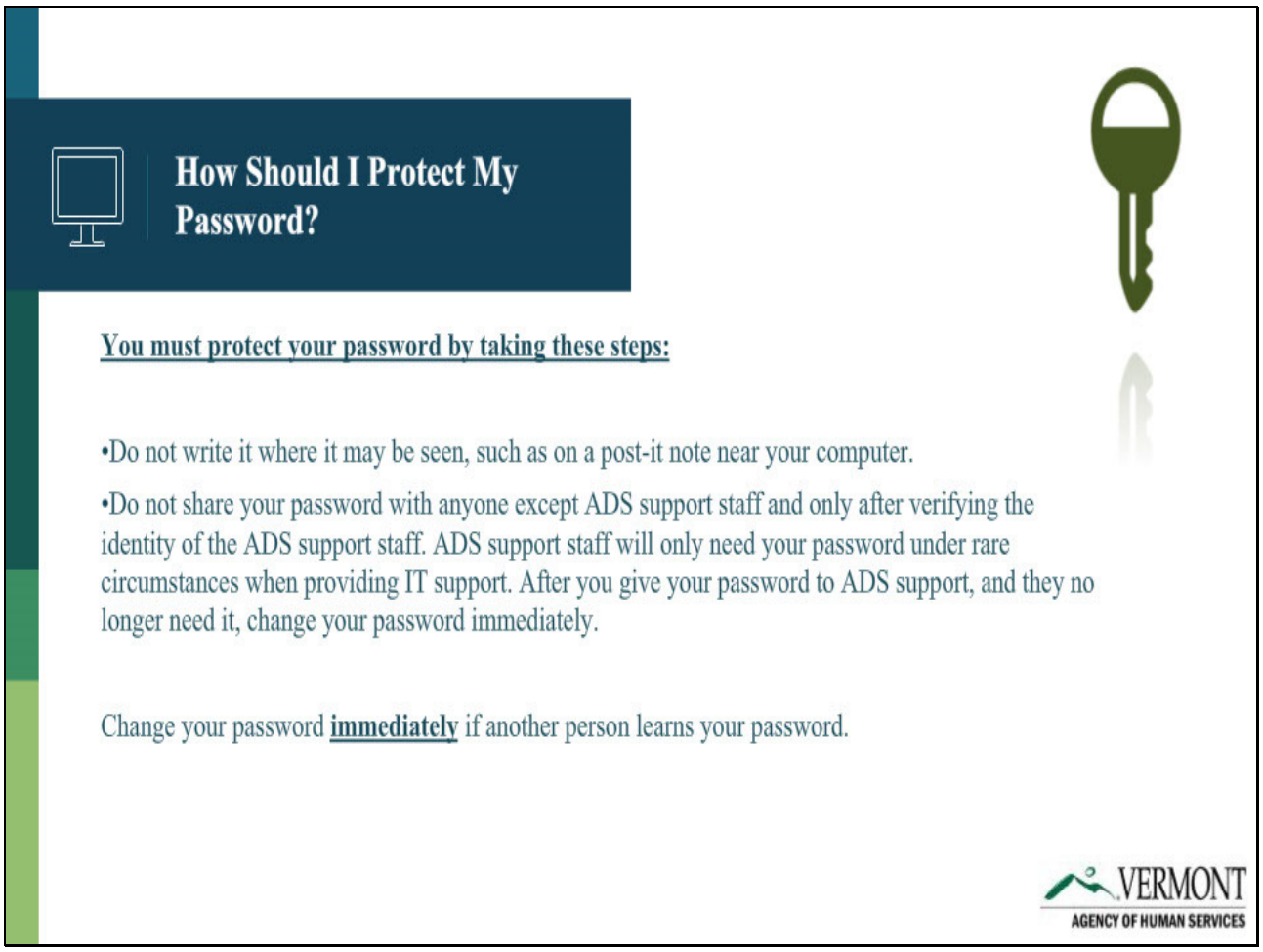
Slide 57 - Slide 58

Slide 58 - How Should I Protect My Password?



Slide 59 - When I Use Email, How Can I Safeguard Protected Electronic Health Information?

When I Use Email, How Can I Safeguard Protected Electronic Health Information?

You may only use state email to conduct AHS business. Sometimes email will contain protected health information.

AHS internal email is secure and encrypted. If you are emailing outside of AHS, email is not automatically secure. When sending protected health information to an external entity you must use the secure method approved by ADS. Click here to review the approved ADS secure email method.

For additional instructions about the approved method to safeguard this information, contact your supervisor of AHS Privacy and Security Staff at: AHS.PrivacyAndSecurity@Vermont.gov

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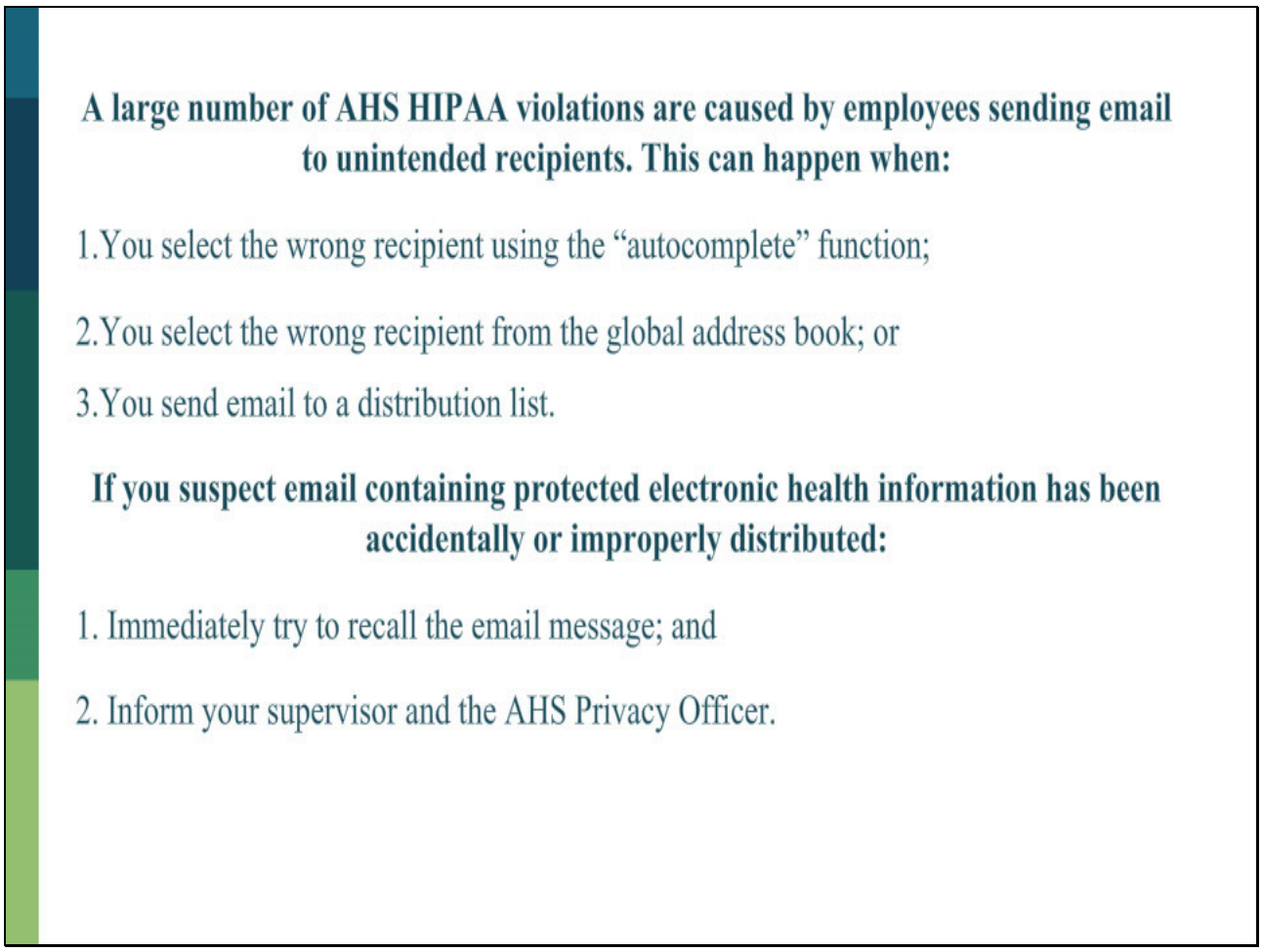
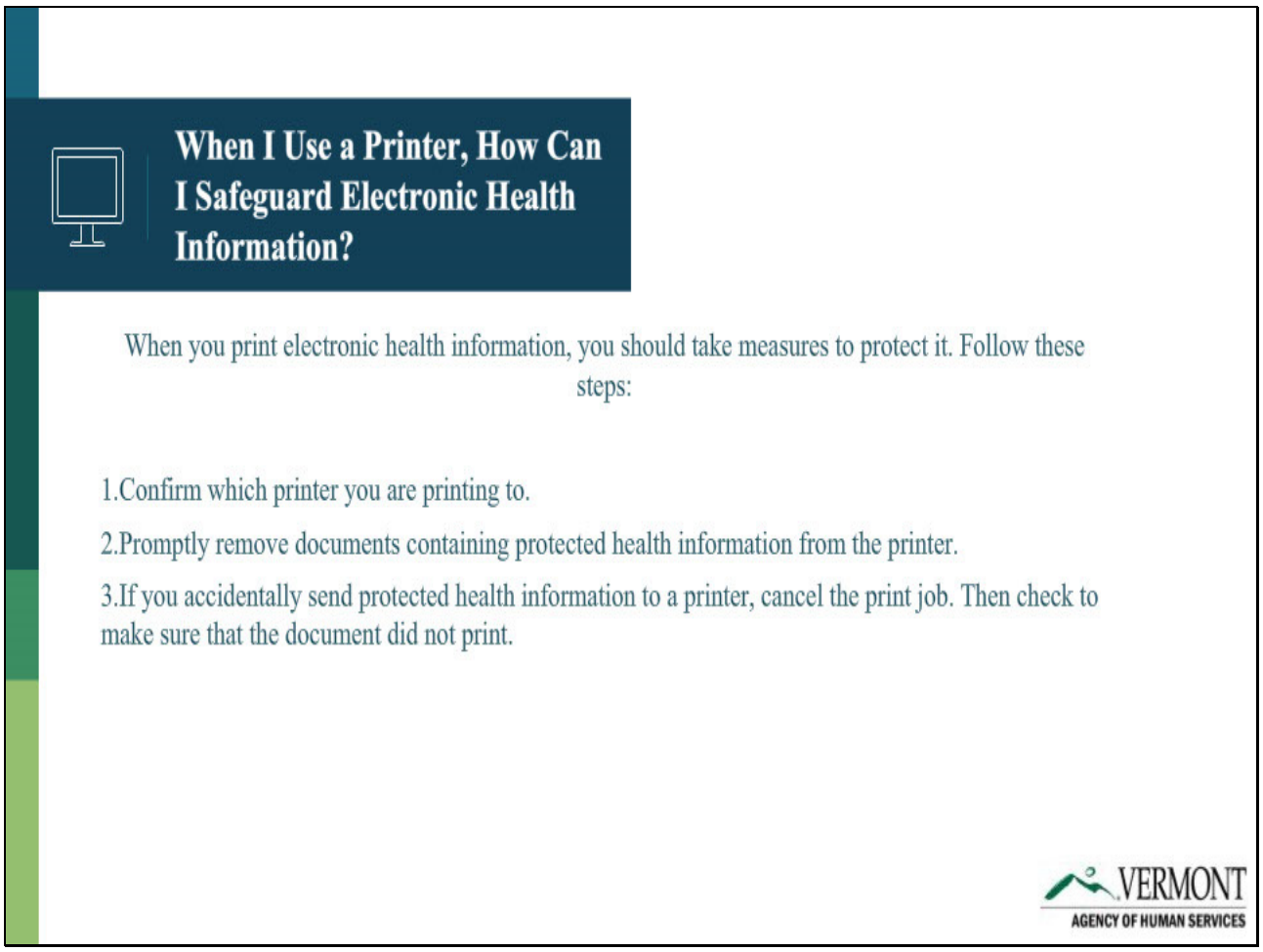
Slide 60 - Slide 61



Slide 61 - When I Use a Printer, How Can I Safeguard Electronic Health Information?



Slide 62 - Let's review some concepts

Slide 63 - Want To Review The Section Again?

Slide 64 - Complaints, Investigations & Sanctions

Slide 65 - Slide 66

Slide 66 - What Procedure Do I follow If I Think I Have Violated HIPAA, Or Another AHS Employee Has Violated HIPAA?

What Procedure Do I follow If I Think I Have Violated HIPAA, Or Another AHS Employee Has Violated HIPAA?

If you think that you have violated HIPAA or another AHS employee has violated HIPAA, **you must inform** your supervisor, your department's HIPAA liaison, or the AHS Privacy Officer. If you are a supervisor, you must inform your department's HIPAA liaison or the AHS Privacy Officer.

When you or your supervisor are reporting a HIPAA violation use the HIPAA Privacy and Security Event Form to report the event.

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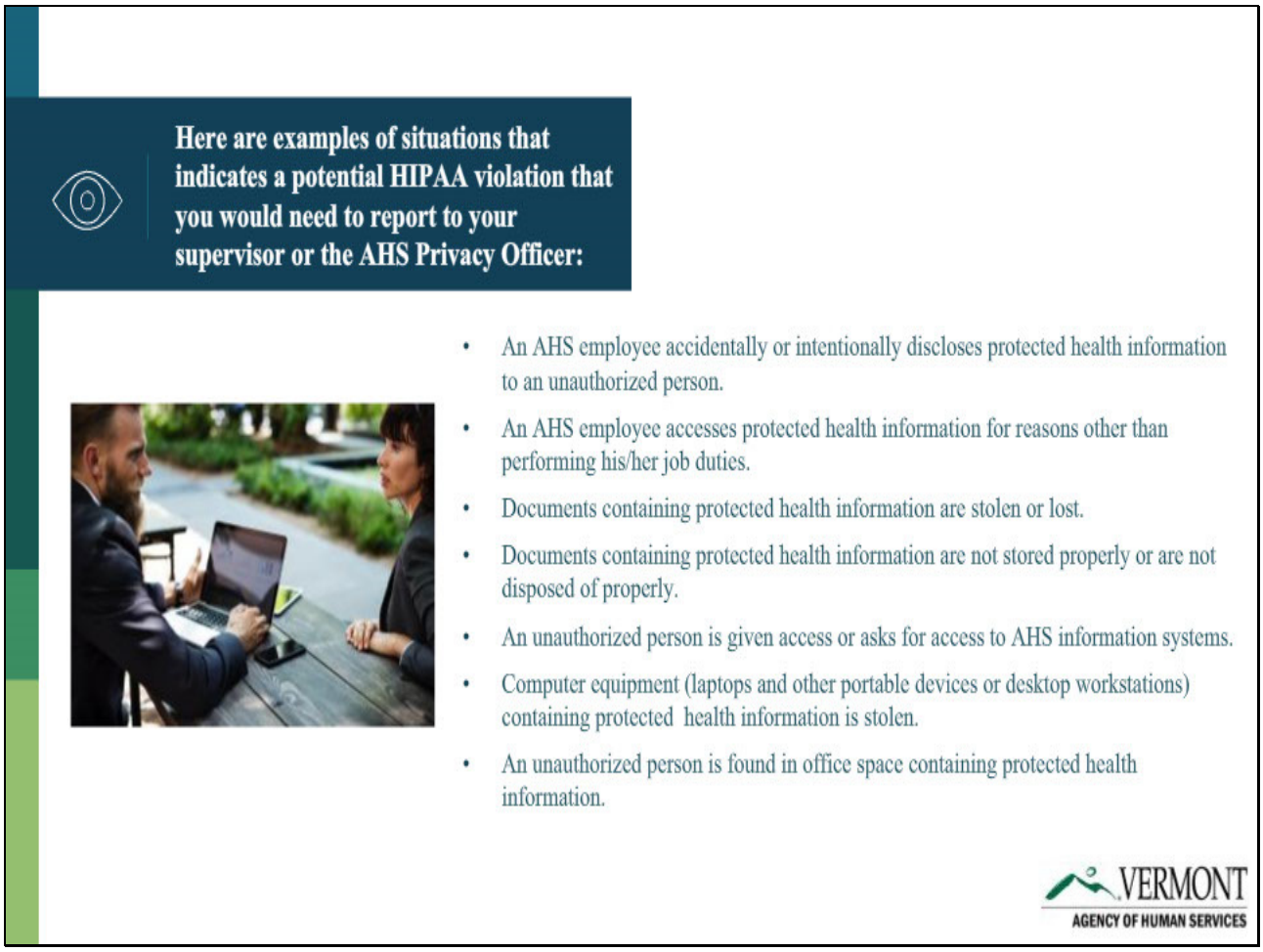
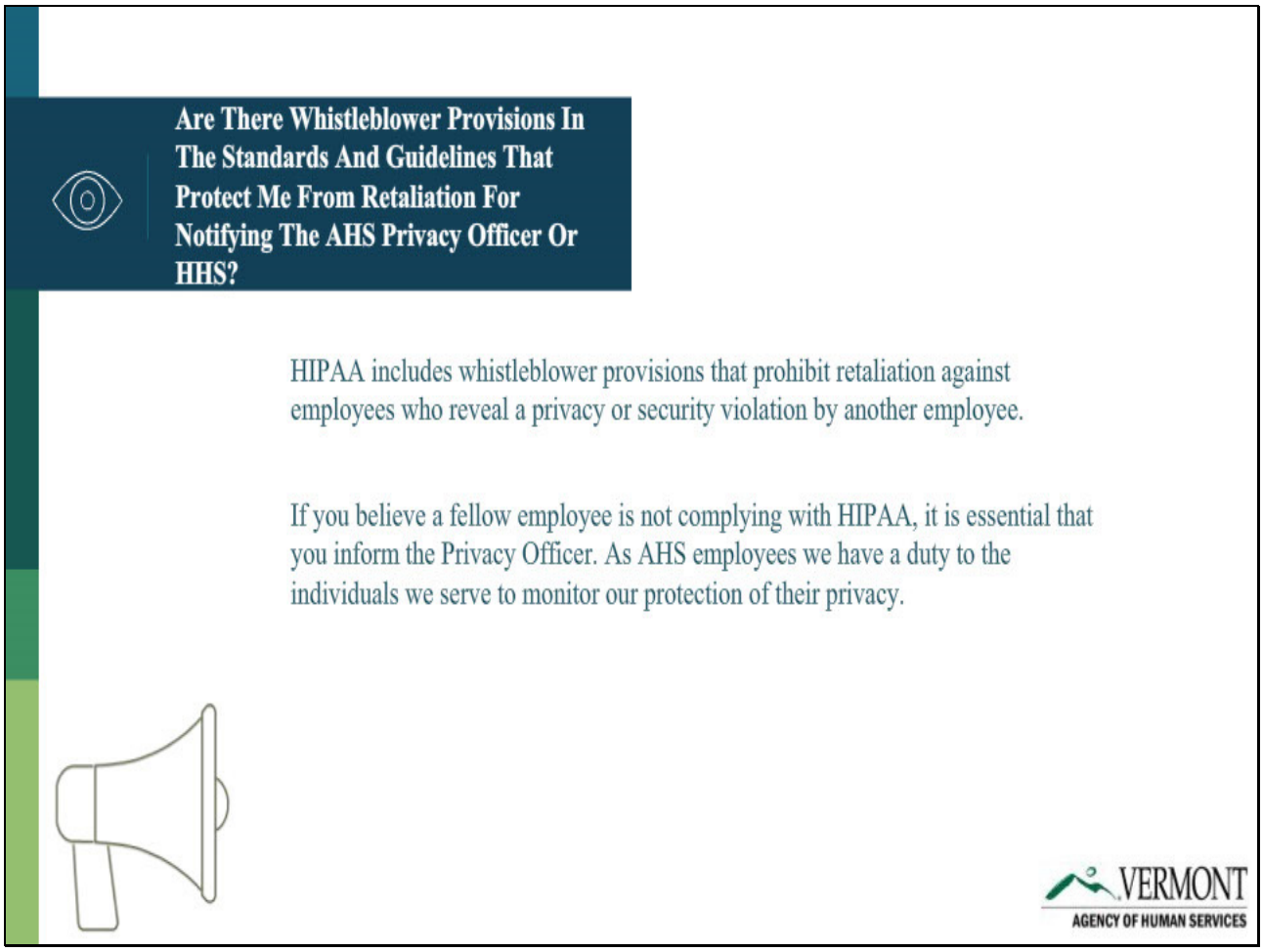
Slide 67 - Here are examples of situations that indicates a potential HIPAA violation that you would need to report to your supervisor or the AHS Privacy Officer:



Slide 68 - Are There Whistleblower Provisions In The Standards And Guidelines That Protect Me From Retaliation For Notifying The AHS Privacy Officer Or HHS?



Slide 69 - Can Members Of The Public File A Complaint When They Believe Their HIPAA Privacy Rights Have Been Violated?

Can Members Of The Public File A Complaint When They Believe Their HIPAA Privacy Rights Have Been Violated?

Members of the public can file a complaint by using the AHS Health Information Privacy Complaint Form or by letter, email, or phone. Members of the public can locate the privacy complaint form and information on how to file a complaint on the AHS website.

Members of the public can also file a complaint with HHS. Members of the public can locate information about how to file a complaint on the HHS website.

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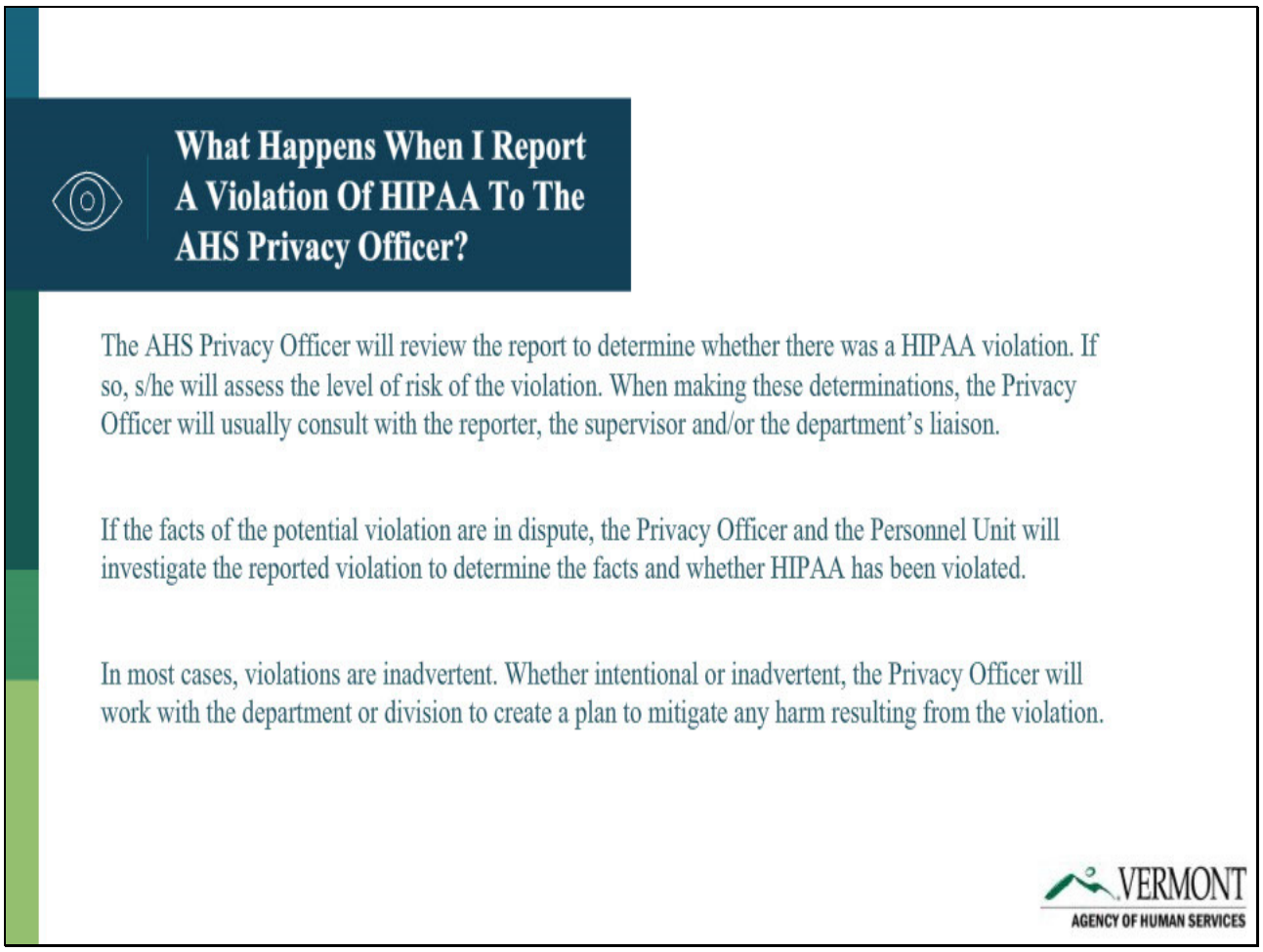
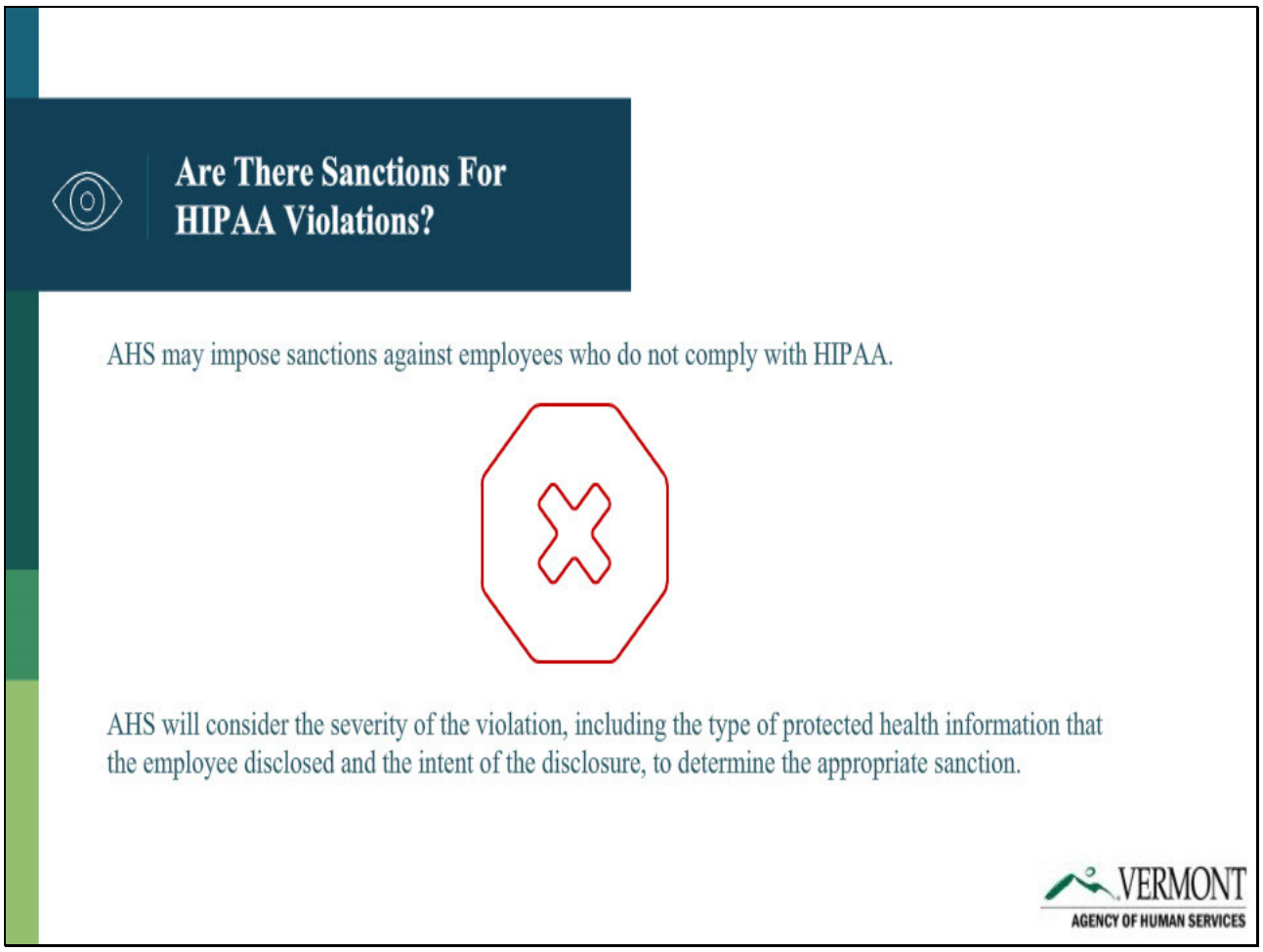
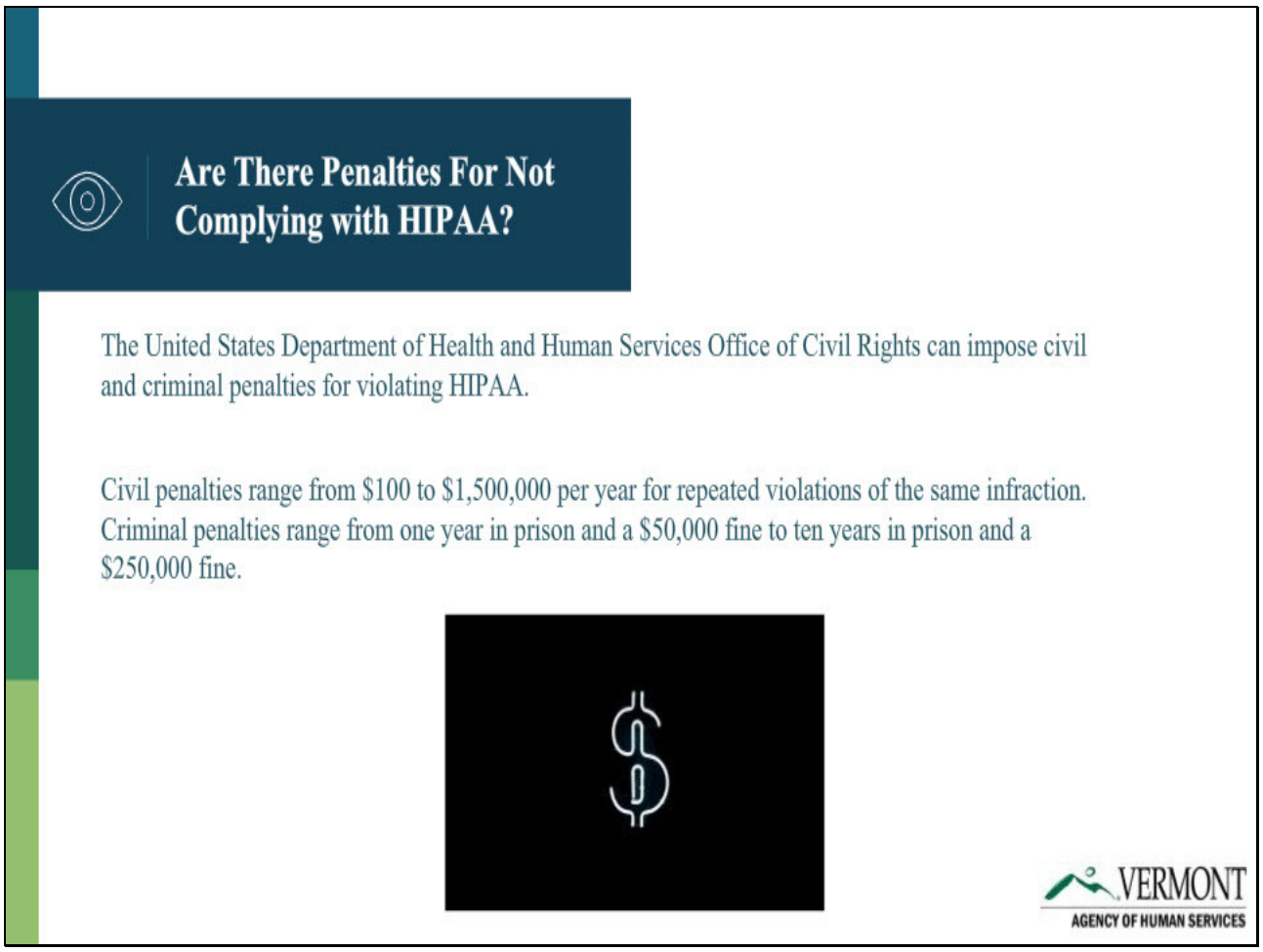
Slide 70 - What Happens When I Report A Violation Of HIPAA To The AHS Privacy Officer?



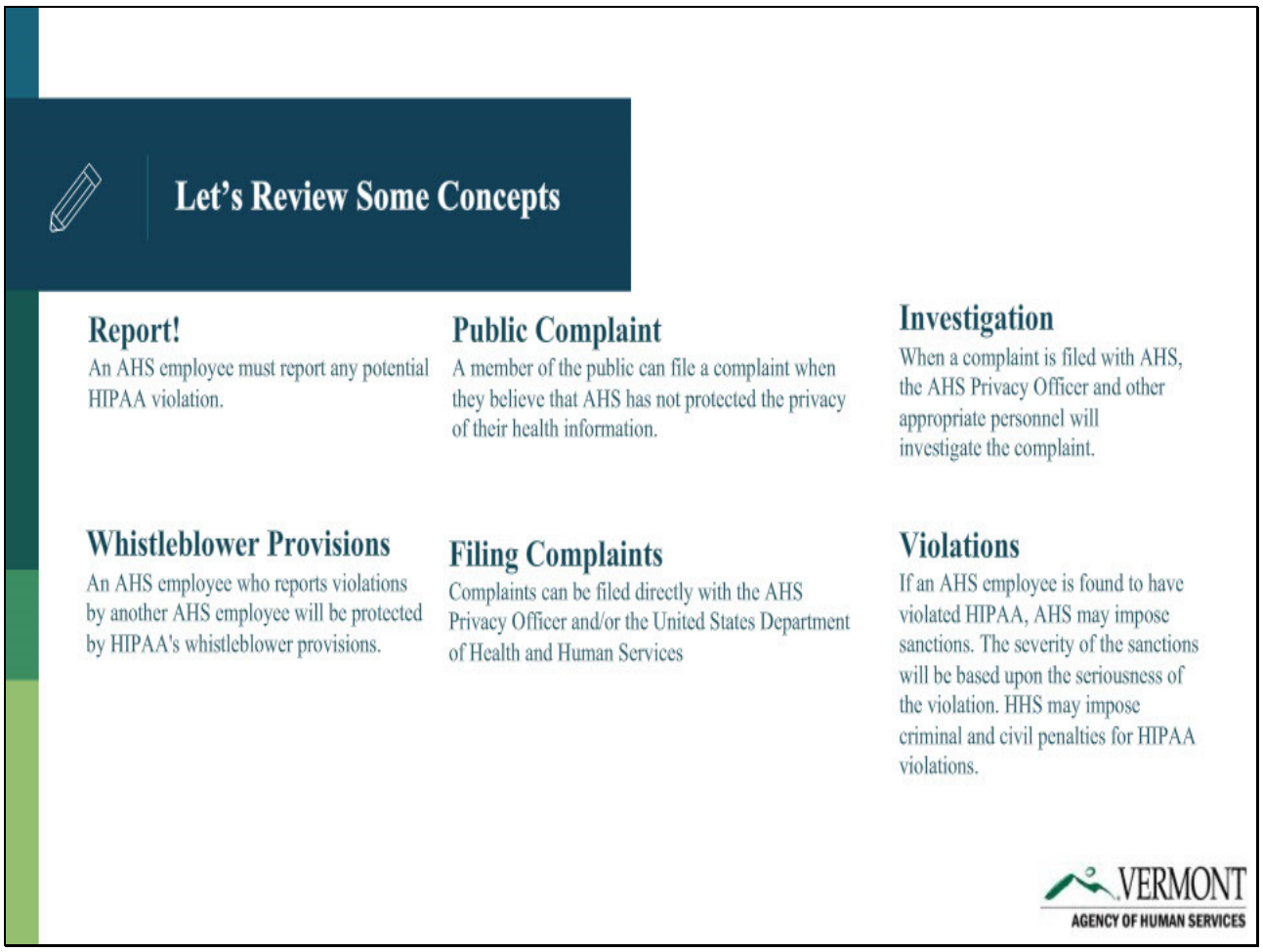
Slide 71 - Are There Sanctions For HIPAA Violations?



Slide 72 - Are There Penalties For Not Complying with HIPAA?



Slide 73 - Let's Review Some Concepts



Slide 74 - Want To Review The Section Again?

Slide 75 - Test Your HIPAA Knowledge