FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen 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 receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine 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 Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

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. Common 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 JANSSEN COVID-19 VACCINE?

The Janssen 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 Janssen 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 JANSSEN 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 JANSSEN COVID-19 VACCINE?

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

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

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

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

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

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

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

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

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

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

There is a remote chance that the Janssen 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 Janssen 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.

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks following vaccination. Most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen 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 "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

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

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

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 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 JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen 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 JANSSEN 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 JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Janssen 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 JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

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. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

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

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: Apr/23/2021

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

Barcode Date: 02/2021

HAWAII IMMUNIZATION REGISTRY INFORMATION

INFORMATION CONTAINED IN THE REGISTRY

- Immunization information including but not limited to vaccine type, date of vaccine administration, vaccine administration site and route, lot number, expiration date, patient's history of vaccine preventable diseases, contraindications, precautions, adverse reactions, and/or comments regarding vaccinations.
- Personal information including but not limited to an individual's first, middle, and last name, date of birth, gender, mailing address, phone number, parent/guardian name, parent/guardian relationship to the individual, their contact information, and mother's maiden name.

CONFIDENTIALITY AND PRIVACY INFORMATION

All authorized users and the Department of Health Immunization Branch acknowledge that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (PL 104-191 and 45 CFR Parts 160 and 164, "Standards for Privacy of Individually Identifiable Health Information") governs the use and disclosure of individually identifiable information by entities subject to the Privacy Rule. Although HIPAA standards for privacy were used as a guide to assist in the development of the Registry Confidentiality and Privacy policies, the Registry and the Department of Health Immunization Branch are not "covered entities" under HIPAA. Providers, health plans and other covered entities who are authorized users must comply with the HIPAA Privacy Rule.

Registry information will be entered by and available to authorized users for authorized purposes only. All authorized users will be required to safeguard the privacy of patient participants by protecting confidential information in the Registry in accordance with the Hawaii Immunization Registry Confidentiality and Privacy Policy, the Hawaii Immunization Registry Security Policy, as well as all applicable State and Federal Laws.

AUTHORIZED USERS

Authorized users of the Registry may include individuals and/or entities that require regular access to patient immunization and other individually identifiable health information to provide immunization services to specific patients, maintain a computerized inventory of their public and private stock of vaccines, assess immunization status to determine immunization rates, and/or ensure compliance with mandatory immunization requirements. All authorized users are required to sign a Hawaii Immunization Registry Confidentiality and Security Statement indicating that they have received a copy of the Hawaii Immunization Registry Confidentiality and Privacy Policy and the Hawaii Immunization Registry Security Policy, understand the terms, including penalties for violation of the policies, and agree to comply with the policies.

The Department of Health Immunization Branch is responsible for oversight of the Registry and therefore will be designated as an authorized user.

USES OF REGISTRY INFORMATION (AUTHORIZED PURPOSES)

Registry immunization data and other individually identifiable health information shall be utilized by authorized users for the purposes of:

- Consolidating, maintaining, and accessing computerized immunization records;
- Consolidating and maintaining vaccine inventory information;
- Determining the immunization history of individuals and delivering health care treatment accordingly;
- Generating notices for individuals who are due or overdue for immunizations and in the event of a vaccine recall;
- Staying abreast of the complex immunization schedule by utilizing registry-supplied immunization forecasting tools;
- Assessing the immunization rate of their patient population (or subsets thereof);
- Generating official immunization records (e.g. Student's Health Record);
- Ensuring compliance with mandatory immunization requirements;
- Recording the distribution of prophylactic and treatment medications administered or dispensed in preparation for and in response to a potentially catastrophic disease threat;
- Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures; and
- Other purposes determined at the discretion of the Department of Health Immunization Branch.

Registry immunization data and other individually identifiable health information shall be utilized by the Department of Health Immunization Branch for the following public health purposes including but not limited to:

- Ensuring compliance with mandatory immunization requirements;
- Performing Quality Improvement/Quality Assessment activities;
- Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures;
- Preventing and managing outbreaks of vaccine-preventable diseases and other public health emergencies;
- Producing immunization assessment reports to aid in the development of policies and strategies to improve public health;
- Managing and maintaining the Registry system; and
- Other purposes determined at the discretion of the Department of Health Immunization Branch.

AVAILABILITY OF IMMUNIZATION RECORD INFORMATION

An individual's immunization data and other individually identifiable health information in the Registry will be made available to the individual's immunization provider, the Department of Health, and other Registry authorized users for authorized purposes only.

OPT-OUT

Individuals may choose not to include their or their child's immunization data in the Registry ("opt-out"). Individuals must opt-out in writing by completing a "Hawaii Immunization Registry Opt-Out Form" which is available from the individual's immunization provider or the Department of Health Immunization Branch. The Registry will retain only core demographic information necessary to identify the individual has chosen to opt-out of the Registry. This information is necessary to enable the Registry to filter and refuse entry of immunization information for the individual. Core demographic data will be for Hawaii Department of Health use only and will be non-displaying to all other Registry authorized users. An individual's decision not to authorize the inclusion of immunization data in the Registry will not affect whether or not they receive immunizations.

REVOCATION

An individual may revoke their decision to opt-out of the Hawaii Immunization Registry at any time. Revocations must be made in writing by completing a "Hawaii Immunization Registry Reauthorization Form" obtained from the individual's immunization provider or the Department of Health Immunization Branch.

RIGHT TO INSPECT, COPY, CORRECT OR AMEND PERSONAL AND IMMUNIZATION INFORMATION

Individuals may inspect, copy, correct or amend their or their child's immunization record information via their or their child's immunization provider or the Department of Health Immunization Branch. For information on how to inspect, copy, correct or amend your or your child's information, please speak with your doctor, call the Department of Health Immunization Branch at 586-4665 (Oahu) or 1-888-447-1023 (neighbor islands), or e-mail your request to RegistryHelp@doh.hawaii.gov.

QUESTIONS?

If you have any questions about the Registry, please speak with your doctor, call the Department of Health Immunization Branch at 586-4665 (Oahu) or 1-888-447-1023 (neighbor islands), e-mail your question to RegistryHelp@doh.hawaii.gov, or visit our website at: http://hawaii.gov/health/Immunization/HIR.html.

Rev. 07/06/2012

NOTICE OF PRIVACY PRACTICES

02/14/2017

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

As part of the federal Health Insurance Portability and Accountability Act of 1996, known as HIPAA, the Practice has created this Notice of Privacy Practices (Notice). This Notice describes the Practice's privacy practices and the rights you, the individual, have as they relate to the privacy of your Protected Health Information (PHI). Your PHI is information about you, or that could be used to identify you, as it relates to your past and present physical and mental health care services. The HIPAA regulations require that the Practice protect the privacy of your PHI that the Practice has received or created.

This Practice will abide by the terms presented within this Notice. For any uses or disclosures that are not listed below (Including Psychotherapy Notes, Marketing and Selling of PHI), the Practice will obtain a written authorization from you for that use or disclosure, which you will have the right to revoke at any time, as explained in more detail below. **The Practice reserves the right to change the Practice's privacy practices and this Notice.**

HOW THE PRACTICE MAY USE AND DISCLOSE YOUR PHI

The following is an accounting of the ways that the Practice is permitted, by law, to use and disclose your PHI.

Uses and disclosures of PHI for Treatment: We will use the PHI that we receive from you to fill your prescription and coordinate or manage your health care.

Uses and disclosures of PHI for Payment: The Practice will disclose your PHI to obtain payment or reimbursement from insurers for your health care services.

Uses and disclosures of PHI for Health Care Operations: The Practice may use the minimum necessary amount of your PHI to conduct quality assessments, improvement activities, and evaluate the Practice workforce.

The following is an accounting of additional ways in which the Practice is permitted or required to use or disclose PHI about you without your written authorization.

Uses and disclosures as required by law: The Practice is required to use or disclose PHI about you as required and as limited by law.

Uses and disclosure for Public Health Activities: The Practice may use or disclose PHI about you to a public health authority that is authorized by law to collect for the purpose of preventing or controlling disease, injury, or disability. This includes the FDA so that it may monitor any adverse effects of drugs, foods, nutritional supplements and other products as required by law.

Uses and disclosure about victims of abuse, neglect or domestic violence: The Practice may use or disclose PHI about you to a government authority if it is reasonably believed you are a victim of abuse, neglect or domestic violence.

Uses and disclosures for health oversight activities: The Practice may use or disclose PHI about you to a health oversight agency for oversight activities which may include audits, investigations, inspections as necessary for licensure, compliance with civil laws, or other activities the health oversight agency is authorized by law to conduct.

Disclosures to Individuals Involved in your Care: The Practice may disclose PHI about you to individuals involved in your care.

Disclosures for judicial and administrative proceedings: The Practice may disclose PHI about you in the course of any judicial or administrative proceedings, provided that proper documentation is presented to the Practice.

Disclosures for law enforcement purposes: The Practice may disclose PHI about you to law enforcement officials for authorized purposes as required by law or in response to a court order or subpoena.

Uses and disclosures about the deceased: The Practice may disclose PHI about a deceased, or prior to, and in reasonable anticipation of an individual's death, to coroners, medical examiners, and funeral directors.

Uses and disclosures for cadaveric organ, eye or tissue donation purposes: The Practice may use and disclose PHI for the purpose of procurement, banking, or transplantation of cadaveric organs, eyes, or tissues for donation purposes.

Uses and disclosures for research purposes: The Practice may use and disclose PHI about you for research purposes with a valid waiver of authorization approved by an institutional review board or a privacy board. Otherwise, the Practice will request a signed authorization by the individual for all other research purposes.

Uses and disclosures to avert a serious threat to health or safety: The Practice may use or disclose PHI about you, if it believed in good faith, and is consistent with any applicable law and standards of ethical conduct, to avert a serious threat to health or safety.

Uses and disclosures for specialized government functions: The Practice may use or disclose PHI about you for specialized government functions including; military and veteran's activities, national security and intelligence, protective services, department of state functions, and correctional institutions and law enforcement custodial situations.

Disclosure for workers' compensation: The Practice may disclose PHI about you as authorized by and to the extent necessary to comply with workers' compensation laws or programs established by law.

Disclosures for disaster relief purposes: The Practice may disclose PHI about you as authorized by law to a public or private entity to assist in disaster relief efforts and for family and personal representative notification.

Disclosures to business associates: The Practice may disclose PHI about you to the Practice's business associates for services that they may provide to or for the Practice to assist the Practice to provide quality health care. To ensure the privacy of your PHI, we require all business associates to apply appropriate safeguards to any PHI they receive or create.

OTHER USES AND DISCLOSURES

The Practice may contact you for the following purposes:

Information about treatment alternatives: The Practice may contact you to notify you of alternative treatments and/or products.

Health related benefits or services: The Practice may use your PHI to notify you of benefits and services the Practice provides.

Fundraising: If the Practice participates in a fundraising activity, the Practice may use demographic PHI to send you a fundraising packet, or the Practice may disclose demographic PHI about you to its business associate or an institutionally related foundation to send you a fundraising packet. No further disclosure will be allowed by the business associates or an institutionally related foundation without your written authorization. You will be provided with an opportunity to opt-out of all future fundraising activities.

FOR ALL OTHER USES AND DISCLOSURES

The Practice will obtain a written authorization from you for all other uses and disclosures of PHI, and the Practice will only use or disclose pursuant to such an authorization. In addition, you may revoke such an authorization in writing at any time. To revoke a previously authorized use or disclosure, please contact Kerri Okamura / Director of Pharmacy to obtain a *Request for Restriction of Uses and Disclosures*.

YOUR HEALTH INFORMATION RIGHTS

The following are a list of your rights in respect to your PHI. Please contact Kerri Okamura / Director of Pharmacy for more information about the below.

Request restrictions on certain uses and disclosures of your PHI: You have the right to request additional restrictions of the Practice's uses and disclosures of your PHI. The Practice is not required to accommodate a request, except that the Practice is required to agree to a request to restrict disclosures to health insurance plans related to products and services you pay out-of-pocket for.

The right to have your PHI communicated to you by alternate means or locations: You have the right to request that the Practice communicate confidentially with you using an address or phone number other than your residence. However, state and federal laws require the Practice to have an accurate address and home phone number in case of emergencies. The Practice will consider all reasonable requests.

The right to inspect and/or obtain a copy your PHI: You have the right to request access and/or obtain a copy (Paper or Electronic) of your PHI that is contained in the Practice for the duration the Practice maintains PHI about you. There may be a reasonable cost-based charge for photocopying documents. You will be notified in advance of incurring such charges, if any.

The right to amend your PHI: You have the right to request an amendment of the PHI the Practice maintains about you, if you feel that the PHI the Practice has maintained about you is incorrect or otherwise incomplete. Under certain circumstances we may deny your request for amendment. If we do deny the request, you will have the right to have the denial reviewed by someone we designate who was not involved in the initial review. You may also ask the Secretary, United States Department of Health and Human Services ("HHS"), or their appropriate designee, to review such a denial.

The right to receive an accounting of disclosures of your PHI: You have the right to receive an accounting of certain disclosures of your PHI made by the Practice.

The right to receive additional copies of the Practice's Notice of Privacy Practices: You have the right to receive additional paper copies of this Notice, upon request, even if you initially agreed to receive the Notice electronically

Notification of Breaches: You will be notified of any breaches that have compromised the privacy of your PHI.

REVISIONS TO THE NOTICE OF PRIVACY PRACTICES

The Practice reserves the right to change and/or revise this Notice and make the new revised version applicable to all PHI received prior to its effective date. The Practice will also post the revised version of the Notice in the Practice.

COMPLAINTS

If you believe your privacy rights have been violated, you may file a complaint with the Practice and/or to the Secretary of HHS, or their designee. If you wish to file a complaint with the Practice, please contact Kerri Okamura / Director of Pharmacy.

You may also file a complaint with the U.S. Department of Health and Human Services Office for Civil Rights by sending a letter to 200 Independence Avenue, S.W., Washington, D.C. 20201, calling 1-877-696-6775, or visiting www.hhs.gov/ocr/privacy/hipaa/complaints/.

The Practice will not take any adverse action against you as a result of your filing of a complaint.

CONTACT INFORMATION

If you have any questions on the Practice's privacy practices or for clarification on anything contained within the Notice, please contact:

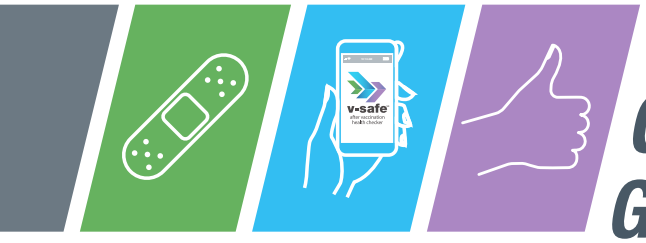
Puna Plantation Hawaii, Ltd.

Kerri Okamura / Director of Pharmacy

50 E. Puainako Street

Hilo, HI 96720

(808) 959-2849



Get vaccinated. Get your smartphone. Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2pm local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

v-safe℠
after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

12/01/20

How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the ***v-safe*** website using one of the two options below:

Use your smartphone's browser to go to

vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in ***v-safe*** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, ***v-safe*** will start your initial health check-in around 2pm that day. If you register after 2pm, ***v-safe*** will start your initial health check-in immediately after you register—just follow the instructions.

   You will receive a reminder text message from ***v-safe*** when it's time for the next check-in—around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a ***v-safe*** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- ***V-safe*** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe