

**REVIEW AND USE OF PATIENT-GENERATED HEALTH DATA UNDER THE
OFFICE OF CONNECTED CARE**

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy and responsibilities for Department of Veterans Affairs (VA) staff who have access to review and use patient-generated health data (PGHD) submitted by Veterans through the Office of Connected Care (OCC) mobile health applications.

2. SUMMARY OF CONTENT: This directive:

a. Defines PGHD that is submitted by Veterans and stored in OCC's PGHD database and provides background on how it is collected, accessed and used, and by whom.

b. Establishes expectations for how providers will communicate with Veterans about PGHD.

c. Describes provider responsibility for documenting any agreed upon plans, as were agreed to by the Veteran, for access and use of PGHD.

3. RELATED ISSUES: VA Handbook 6300.5, Procedures for Establishing and Maintaining Privacy Act Systems of Records, dated August 3, 2017; VHA Directive 1058.03, Assurance of Protection for Human Subjects in Research, dated September 17, 2020; VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019; VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019; VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016; VHA Directive 1605.02, Minimum Necessary Standard for Access, Use, Disclosure and Requests for Protected Health Information, dated April 4, 2019; VHA Directive 1907.01, VHA Health Information Management and Health Records, dated April 5, 2021; VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, dated March 9, 2009; and VHA Memorandum 2020-06-35, Ethical Principles for Access to and Use of Veterans Data, dated June 24, 2020.

4. RESPONSIBLE OFFICE: The Office of Connected Care (12CC) is responsible for the content of this directive. Questions may be addressed to VHA12CCConnectedCareAction@va.gov.

5. RESCISSIONS: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of April 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

April 19, 2021

VHA DIRECTIVE 6506

**BY DIRECTION OF THE OFFICE OF
THE UNDER SECRETARY FOR HEALTH:**

/s/ Steven Lieberman, MD, MBA
Acting Deputy Under Secretary for Health

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publication Distribution List on April 22, 2021.

CONTENTS

**REVIEW AND USE OF PATIENT-GENERATED HEALTH DATA UNDER THE
OFFICE OF CONNECTED CARE**

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS..... 3

4. POLICY 4

5. RESPONSIBILITIES 4

6. SUBMISSION AND USE OF PATIENT-GENERATED HEALTH DATA..... 6

7. TRAINING 7

8. RECORDS MANAGEMENT..... 7

9. REFERENCES..... 7

REVIEW AND USE OF PATIENT-GENERATED HEALTH DATA UNDER THE OFFICE OF CONNECTED CARE

1. PURPOSE

a. This Veterans Health Administration (VHA) directive establishes policy and responsibilities for Department of Veterans Affairs (VA) staff that may have access to review or use patient-generated health data (PGHD), submitted by Veterans through the Office of Connected Care (OCC) mobile health applications, as part of their duties for the agency and in accordance with VA and VHA policy for use of Personally identifiable information (PII) and Protected Health Information (PHI). VA staff may be authorized to view or use PGHD for purposes such as enhancing individual Veteran's care, identifying Veterans at risk or in need of particular services, identifying segments of the Veteran population that could benefit from pro-active outreach, population level analysis and other quality improvement (QI) and research studies.

b. Additionally, this directive establishes standards for relevant VA staff to discuss with Veterans how and when PGHD will be viewed, used and documented. The scope of this directive is limited to the use of electronically created PGHD that is stored in OCC's PGHD database and made available to authorized providers, clinical leaders and researchers; this directive does not address other Veteran PGHD collected at VHA. **AUTHORITY:** 5 U.S.C. § 552a; 38 U.S.C. § 7301(b); 45 C.F.R. parts 160 and 164.

2. BACKGROUND

a. OCC's PGHD database stores Veteran's PGHD from a variety of sources as noted in paragraph 3.c. The PGHD database contains data collected from devices and software that have claims for medical use and have been cleared by the Food and Drug Administration (FDA) for medical applications. Other data in OCC's PGHD database may not be cleared for medical applications by the FDA but still support wellness applications (e.g., activity). Some of these devices may be personal devices owned by a Veteran and others may be supported by VA resources. As new technologies become available to Veterans, it is possible that OCC's PGHD database will expand to include additional data sources.

b. PGHD is stored in OCC's PGHD database which meets all Federal and VA requirements for security and privacy. This data is governed by its own Privacy Act System of Records Notice (SORN) "VA Mobile Application Environment (MAE)-VA", 173VA005OP2. PGHD is not part of the Veteran's official health record unless a provider adds the data into the electronic health record (EHR). Any data that is added into the EHR by a provider becomes part of the official VHA health record and subject to all rules associated with the Privacy Act SORN, "Patient Medical Records-VA", 24VA10A7.

c. While it is now common practice to monitor patient health through glucometers and other devices, there is not yet a mature evidence base regarding use of PGHD for

the purposes of clinical diagnosis or prognosis. However, the intent of VA's PGHD efforts is threefold:

(1) **Veteran Self-Care.** PGHD provides individual Veterans with the ability to manage their own care through data such as graphs, charts and dashboards in the mobile health applications where the Veteran enters their data. By using mobile health applications, Veterans are also sharing PGHD with health care staff in order to augment providers' understanding of the individual Veteran and as compared to other Veterans.

(2) **Clinical Care.** PGHD offers the potential of providing individual Veteran health data at the point of care to providers in consumable formats such as graphs, charts and dashboards that can then be used to support clinical decision-making and the delivery of care. In addition, analytics may be performed on individual or population-level PGHD to identify meaningful trends such as possible digital biomarkers that can help explain or predict health-related outcomes and offer other clinically useful insights. The intent of using this curated data is to augment providers' understanding of the individual Veteran. Using PGHD provides a breadth and depth of understanding on how the Veteran is functioning between encounters with the health care system thus supporting a more continuous model of care with real world evidence. **NOTE:** *Data submitted by Veterans and stored in OCC's PGHD database are displayed to providers through provider-facing software applications.*

(3) **Healthcare Analytics, including Population Health, Quality Improvement and Research.** Aggregating and performing analytics on PGHD provides insights into larger Veteran cohorts, thus supporting broader population health, research initiatives and QI efforts.

(a) Population health is focused on improving health outcomes for large groups of people through the identification and monitoring of individual patients within those groups. Population health management tools can help clinicians and healthcare systems aggregate and analyze data to create a full and actionable clinical understanding of each patient. See the Office of the National Coordinator (ONC) for Health Information Technology (IT) Playbook at <https://www.healthit.gov/playbook/population-public-health/> for more information. Typically, providers, researchers or clinical leaders utilizing this Veteran cohort population-level PGHD for research, or for enhancing clinical programs, will not be seeing the Veteran at the point of care.

(b) QI is focused on improving the effectiveness of VA healthcare by examining potential changes that may have a positive effect on healthcare delivery. In the case of PGHD, QI initiatives could include but are not limited to identifying effective strategies to promote adoption of mobile health applications among Veterans as well as determining how best to incorporate PGHD from such applications into VA clinical care.

(c) Research in VA focuses on enhancing the well-being of Veterans and the Nation through discovery and innovation. The strategic priorities of VA Research are designed to make the best use of current and planned resources, including the program's unique

position as part of VA's integrated health care system. The overarching goal is to achieve the broadest and most meaningful positive impacts possible on the health of Veterans. In the context of PGHD, research could include but is not limited to testing novel interventions that leverage use of mobile health applications to improve physical and psychosocial outcomes among Veterans.

3. DEFINITIONS

a. **Electronic Health Record.** EHR is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. **NOTE:** *The purpose of this definition is to adopt a short general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

b. **Office of Connected Care Patient-Generated Health Data Database.** The OCC PGHD database is a database of PGHD collected through OCC's portfolio of virtual tools that include but are not limited to OCC developed mobile applications and personal or VA-issued wearable devices where the Veteran has opted to share that data through a secure OCC mobile application. The OCC PGHD database is a secure Health Insurance Portability and Accountability Act (HIPAA)- compliant cloud database with a VA issued Authority to Operate indicating it meets all the VA standards for privacy and security. This database is not part of the official VHA health record.

c. **Patient-Generated Health Data.** For purposes of this directive, PGHD are health data created, recorded or gathered electronically by or from Veterans, beneficiaries or their authorized delegates outside the clinical health care setting to help address a health concern. PGHD is created, recorded or gathered by or from Veterans from a variety of sources, including but not limited to mobile health applications (e.g., Annie, My VA Images, Mobile Kidney), wearables (e.g., Fitbit, Garmin, Apple Watch) through VA Sync My Health Data application and online patient portals (My HealthVet, EHR). As new technologies become available to Veterans, it is possible that OCC's PGHD database will expand to include additional data sources.

d. **Solicited Data.** Solicited data is PGHD that the VA provider requests from the Veteran.

e. **Unsolicited Data.** Unsolicited data is PGHD that is provided by a Veteran without a request from the VA provider.

f. **VA Provider.** For purposes of this directive, a VA provider is defined as a full-time, part-time or intermittent VA employee (including contractors), that includes but is not limited to a Doctor of Medicine (MD), Doctor of Osteopathic Medicine (DO), nurse practitioner (NP), registered nurse (RN), physician assistant (PA), clinical social worker (LCSW), clinical psychologist (PhD or PsyD), marriage and family therapist (LMFT),

professional clinical counselor (LPCC), clinical associate, clinical pharmacy specialist or other health care professionals, as well as any employee serving in the capacity of case manager or Vet Center team leader and counselor.

g. **Veteran Cohort.** A Veteran cohort is any group of Veterans who share something in common. A Veteran cohort may include but is not limited to a VA provider's panel, a group of Veterans with a certain medical condition, a certain treatment, a certain sociodemographic trait or traits or other such commonalities.

h. **Veteran Self-Care.** Veteran self-care or self-management is the set of behaviors, decisions and routines in which a patient engages to maximize the state of their health in the context of medical conditions. Veteran self-care is interconnected with health literacy, patient activation and health resource access. Examples of self-care behaviors include but are not limited to adhering to prescribed medications, managing diet and exercise regimens and forgoing risky activities such as alcohol and tobacco usage.

4. POLICY

It is VHA policy to maintain standards on the use of PGHD as an important component to supplement other clinical data and offer more comprehensive information to potentially improve Veterans' health and health care and promote Veteran self-care.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health.** The Deputy Under Secretary for Health is responsible for supporting OCC with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **Chief Officer, Office of Connected Care.** The Chief Officer, OCC is responsible for:

(1) Ensuring implementation of this directive and disseminating guidance across VHA to assist clinical staff in complying with this directive.

(2) Developing and making available educational resources, guidelines and other materials to support the use of PGHD as part of the VHA mission.

e. **Veterans Integrated Services Network Director.** The VISN Director is responsible for ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

f. **VA Clinical Leader.** For purposes of this directive, a clinical leader is any VA staff member who is in a leadership position that may have need to access PGHD for purposes of peer review, program management, or for establishing, modifying or discontinuing specific capabilities or clinical services under their authority. Generally, clinical leadership will be looking at PGHD for operational purposes and not one-on-one with Veterans for purposes of care. Each VA clinical leader is responsible for understanding what PGHD is and the responsibilities for their subordinate staff. **NOTE:** *Peer review includes peer review for quality management (see VHA Directive 1190, Peer Review for Quality Management, dated November 21, 2018) as well as other QI activities.*

g. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and that appropriate corrective action is taken if non-compliance is identified.

(2) Ensuring that VA providers are aware of this directive, understand how PGHD can be incorporated into their relationships with Veterans, how to talk to Veterans about PGHD and how to complete required documentation as described under paragraph 5.h.

h. **VA Provider.** The VA provider is responsible for:

(1) Using OCC educational materials to inform and discuss with Veterans how they can share and receive PGHD with VA on mobile applications and devices, the planned or potential uses of PGHD, potential benefits or burdens of allowing use of their data, expectations about if and when the provider will review that data and the need for the Veteran to make the provider aware of situations in which they believe that they may be experiencing a medical issue or need medical attention based on their PGHD. See paragraph 6 for more information.

(2) Viewing PGHD using a VA application or platform (e.g., VA's Virtual Care Manager (VCM)) or displaying PGHD to the Veteran during an encounter, as needed.

(3) Documenting in the EHR a summary of PGHD discussions with the Veteran, including expectations for provider review of the Veteran's PGHD and agreed-upon communication of how and for what purposes PGHD will be shared.

(4) Documenting in the EHR all instances in which a licensed independent provider uses PGHD in making medical decisions. **NOTE:** *The change in the plan of care and a copy of or a narrative description of PGHD that led to the change in care must be documented in the EHR.*

6. SUBMISSION AND USE OF PATIENT-GENERATED HEALTH DATA

a. **Categories of Patient-Generated Health Data.** For the purpose of clinical care, the review and use of PGHD falls into two primary categories:

(1) **Solicited Data.** If the VA provider explicitly requests that the Veteran collect and share PGHD, then the provider has a responsibility to discuss PGHD use and implications with the Veteran (see paragraph 5.h.(1)). The key aspects of the provider-Veteran understanding that is reached regarding the collection, monitoring and use of that Veteran's PGHD for treatment purposes must be documented in a note within the EHR. There is no explicit requirement beyond what is agreed to between the Veteran and the provider for viewing PGHD or taking any specific action based on viewing the PGHD. The collection and review of PGHD should complement standard medical care but is not intended to replace standard care.

(2) **Unsolicited Data.** If the Veteran chooses to share their PGHD with VA without that data being explicitly requested by a VA provider, then the provider has no responsibility to view or act on that data until the provider becomes aware of its existence. Once aware that the Veteran is sharing PGHD, then the provider has the same responsibility to discuss PGHD with the Veteran as outlined in paragraph 5.h.(1) above.

b. If the provider reviews PGHD and takes specific actions that impact an individual Veteran, or groups of Veterans' plan(s) of care, then the provider must document that change in the EHR and what PGHD was viewed that resulted in that change.

c. In order for electronic PGHD to come into OCC's PGHD database, the Veteran must consent to an electronic terms of use agreement for any application that will send PGHD to the PGHD database, thereby giving VA permission to use the data. Providers must make Veterans aware that their PGHD can be shared and how sharing might benefit their health care. This may involve educating Veterans on technologies available to them that include PGHD features or connecting the Veteran to another VA staff member who can offer such education. Regardless of whether the data is solicited or unsolicited, the Veteran always has the option to share or stop sharing at any time. The Veteran has the option to decline the terms and not share their data. The Veteran is not required to share electronic PGHD from VA-issued wearable devices or medical devices. If a device cannot be used without sharing of data, then accommodations will be made for the Veteran to receive equivalent services via another device or modality that honors that preference.

d. Inclusion of PGHD in OCC's PGHD database does not preclude the requirement for all involved parties to adhere to all applicable standards for data access and use including, but not limited to requirements to obtain informed consent for participation in research.

e. Use of PGHD should align to VA's Principles for Veteran Data Access and Use whenever possible. See VHA Memorandum 2020-06-35, Ethical Principles for Access

to and Use of Veterans Data, dated June 24, 2020:

<https://vaww.va.gov/vhapublications/publications.cfm?Pub=3>. **NOTE:** This is an internal VA website that is not available to the public.

7. TRAINING

There are no formal training requirements associated with this directive. OCC will develop and make available educational resources, guidelines and other materials for providers and clinical leaders in the implementation of this directive and for Veterans to support their understanding of the use of PGHD.

8. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

9. REFERENCES

- a. 5 U.S.C. § 552a.
- b. 38 U.S.C. § 7301(b).
- c. 45 C.F.R. parts 160 and 164.
- d. VHA Directive 1190, Peer Review for Quality Management, dated November 21, 2018.
- e. VHA Memorandum 2020-06-35, Ethical Principles for Access to and Use of Veterans Data, dated June 24, 2020:
<https://vaww.va.gov/vhapublications/publications.cfm?Pub=3>. **NOTE:** This is an internal VA website that is not available to the public.
- f. Office of the National Coordinator for Health Information Technology (ONC). Health IT Playbook. 2020: <https://www.healthit.gov/playbook/population-public-health/>.