PRIVACY IMPACT ASSESSMENT (PIA)

For the

Optifill Pharmacy Automated Dispensing Solution (OPADS)

Department of the Navy - TMA DHP Funded System

SECTION 1: IS A PIA REQUIRED?

a. Will this Department of Defense (DoD) information system or electronic collection of information (referred to as an "electronic collection" for the purpose of this form) collect, maintain, use, and/or disseminate PII about members of the public, Federal personnel, contractors or foreign nationals employed at U.S. military facilities internationally? Choose one option from the choices below. (Choose (3) for foreign nationals).

☐ (1) Yes, from members of the general public.

☐ (2) Yes, from Federal personnel* and/or Federal contractors.

☒ (3) Yes, from both members of the general public and Federal personnel and/or Federal contractors.

☐ (4) No

* "Federal personnel" are referred to in the DoD IT Portfolio Repository (DITPR) as "Federal employees."

b. If "No," ensure that DITPR or the authoritative database that updates DITPR is annotated for the reason(s) why a PIA is not required. If the DoD information system or electronic collection is not in DITPR, ensure that the reason(s) are recorded in appropriate documentation.

c. If "Yes," then a PIA is required. Proceed to Section 2.
SECTION 2: PIA SUMMARY INFORMATION

a. Why is this PIA being created or updated? Choose one:

- [ ] New DoD Information System
- [ ] New Electronic Collection
- [x] Existing DoD Information System
- [ ] Existing Electronic Collection
- [ ] Significantly Modified DoD Information System

b. Is this DoD information system registered in the DITPR or the DoD Secret Internet Protocol Router Network (SIPRNET) IT Registry?

- [ ] Yes, DITPR
  Enter DITPR System Identification Number

- [ ] Yes, SIPRNET
  Enter SIPRNET Identification Number

- [x] No

c. Does this DoD information system have an IT investment Unique Project Identifier (UPI), required by section 53 of Office of Management and Budget (OMB) Circular A-11?

- [ ] Yes
- [x] No

If “Yes,” enter UPI

If unsure, consult the Component IT Budget Point of Contact to obtain the UPI.

d. Does this DoD information system or electronic collection require a Privacy Act System of Records Notice (SORN)?

A Privacy Act SORN is required if the information system or electronic collection contains information about U.S. citizens or lawful permanent U.S. residents that is retrieved by name or other unique identifier. PIA and Privacy Act SORN information should be consistent.

- [x] Yes
- [ ] No

If “Yes,” enter Privacy Act SORN Identifier

DoD Component-assigned designator, not the Federal Register number.
Consult the Component Privacy Office for additional information or access DoD Privacy Act SORNs at: http://www.defenselink.mil/privacy/notices/

or

Date of submission for approval to Defense Privacy Office
Consult the Component Privacy Office for this date.
e. Does this DoD information system or electronic collection have an OMB Control Number?

Contact the Component Information Management Control Officer or DoD Clearance Officer for this information.

   This number indicates OMB approval to collect data from 10 or more members of the public in a 12-month period regardless of form or format.

☐ Yes

Enter OMB Control Number

Enter Expiration Date

☒ No

f. Authority to collect information. A Federal law, Executive Order of the President (EO), or DoD requirement must authorize the collection and maintenance of a system of records.

(1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be the same.

(2) Cite the authority for this DoD information system or electronic collection to collect, use, maintain and/or disseminate PII. (If multiple authorities are cited, provide all that apply.)

   (a) Whenever possible, cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.

   (b) If a specific statute or EO does not exist, determine if an indirect statutory authority can be cited. An indirect authority may be cited if the authority requires the operation or administration of a program, the execution of which will require the collection and maintenance of a system of records.

   (c) DoD Components can use their general statutory grants of authority (“internal housekeeping”) as the primary authority. The requirement, directive, or instruction implementing the statute within the DoD Component should be identified.


Medical and dental care in the DoD are authorized by Chapter 55 of Title 10 U.S.C., section 1071 - 1106. The provision of a pharmacy benefit is part of the medical care benefit.
g. Summary of DoD information system or electronic collection. Answers to these questions should be consistent with security guidelines for release of information to the public.

1) Describe the purpose of this DoD information system or electronic collection and briefly describe the types of personal information about individuals collected in the system.

OPADS is a high-volume automated prescription dispensing fulfillment system designed to meet the extreme productivity demands of mail order and central fill dispensing pharmacies. OPADS is a unique, patented pharmacy automation system designed to fulfill and process patient-specific prescription orders. The system automates the filling of oral solid prescriptions, and coordinates the workflow of technicians and pharmacists involved with the filling and checking of all prescriptions. Included in OPADS is the automatic bottle filling machine (OptiFill-II machine), conveyor system, and a small network of computer terminal(s) with proprietary software, installed within a private Virtual Local Area Network (VLAN) behind a Navy-owned and maintained managed switch. The automatic bottle filling machine (OptiFill-II) is comprised of up to five filling modules containing up to 128 drug canisters each, with 64 canisters on each side of a module. The OptiFill-II machine automatically labels the bottle, dispenses the requested prescription drug, captures an image of the bottle’s contents, caps the bottle and collates it with sibling bottles belonging to the same order. Once an order is complete, the bottles within that order are automatically released into a tote and the conveyor system is used to route the tote/order through the remaining prescription processing areas (Manual Picking, Bulk etc) and eventually to the Pharmacist Checking and Packing areas. Barcode technology is used throughout the system to identify the order for routing or processing (filling, checking, packing etc). Automed’s Prescription Processing System (PPS) Software receives customer prescription information from the pharmacy’s Host Management System (example: CHCS B2K), provides users with the necessary application interfaces to perform pharmacy fulfillment, checking and processing functions, and monitors and controls the entire pharmacy automation system.

The types of PII collected in the system include name, prescription number, social security number of sponsor and prefix of patient and gender.

2) Briefly describe the privacy risks associated with the PII collected and how these risks are addressed to safeguard privacy.

All systems are vulnerable to "insider threats." Pharmacy managers are vigilant to this threat by limiting system access to those individuals who have a defined need to access the information. There are defined criteria to identify who should have access to OPADS. These individuals have gone through extensive background and employment investigations.

h. With whom will the PII be shared through data exchange, both within your DoD Component and outside your Component (e.g., other DoD Components, Federal Agencies)? Indicate all that apply.

☒ Within the DoD Component.

Specify. The authorized pharmacy staff will have access to PII as part of their duties. Vendor authorized personnel will have access to the system to perform support and maintenance.

☐ Other DoD Components.

Specify. 

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Other Federal Agencies.
Specify: DEA

State and Local Agencies.
Specify:

Contractor (Enter name and describe the language in the contract that safeguards PII.)
Specify: AutoMed. The vendor for OPADS has a business associate agreement associated with their Federal Supply Schedule (FSS) for procurement and support that stipulates any employee who will have access to protected health information will receive at least annual privacy and security awareness training in accordance to the HIPAA protection laws and regulations.

The BAA is with the VA as their FSS is managed by the VA and all federal agencies buy their products off of the FSS managed by the VA.

Other (e.g., commercial providers, colleges).
Specify:

i. Do individuals have the opportunity to object to the collection of their PII?

☐ Yes ☒ No

(1) If "Yes," describe method by which individuals can object to the collection of PII.

(2) If "No," state the reason why individuals cannot object.

OPADS does not collect PII directly from the patient - it is not the source system.

j. Do individuals have the opportunity to consent to the specific uses of their PII?

☐ Yes ☒ No

(1) If "Yes," describe the method by which individuals can give or withhold their consent.
(2) If “No,” state the reason why individuals cannot give or withhold their consent.

OPADS does not collect PII directly from the patient - it is not the source system.

k. What information is provided to an individual when asked to provide PII data? Indicate all that apply.

☐ Privacy Act Statement  ☐ Privacy Advisory

☐ Other  ☒ None

Describe each applicable format.

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NOTE:

Sections 1 and 2 above are to be posted to the Component’s Web site. Posting of these Sections indicates that the PIA has been reviewed to ensure that appropriate safeguards are in place to protect privacy.

A Component may restrict the publication of Sections 1 and/or 2 if they contain information that would reveal sensitive information or raise security concerns.