

Standard Operating Procedure Manual

4. Legal Compliance

4.7. Privacy and HIPAA Compliance

Access to PHI

POLICY:

The Pharmacy will give individual's the right of access to inspect and obtain a copy of their protected health information in a designated record set in accordance with the HIPAA Privacy Rule.

PROCEDURE:

General

The phrase "designated record set" is defined in 45 CFR § 164.501. The Pharmacy will document and retain the following for a period of at least ten (10) years from the date of its creation or the date when it last was in effect, whichever is later:

- Designated record sets that are subject to access by individuals; and
- The title of persons responsible for receiving and processing requests for access to protected health information.

Providing Access

The Pharmacy will allow an individual to access, inspect, and/or obtain a copy of their protected health information that is maintained in a designated record set in a timely and professional manner. A request for access must be in writing. A Request for Access Form may be used by the individual to request access, inspect, and/or obtain a copy of their protected health information. Upon receipt of a request for access PHI, the Privacy Officer or his/her designee shall be responsible for responding to the request. The Response to Request for Access Form shall be used to respond to any requests. Action on a request for access must be taken no later than 30 days after the request is made. If the Pharmacy cannot take action on a request for access to protected health information within the time periods above; the Pharmacy may extend the time required by 30 days with notice to the individual within the original timeframe. In instances where the protected health information is in more than one record set, or at more than one location, the Pharmacy will only produce the protected health information once in response to a request for access.

If the Pharmacy does not maintain the protected health information, but the Pharmacy is aware of where the requested information is maintained, the Pharmacy will inform the individual where to direct the request for access.

The Pharmacy will provide the individual with access to the protected health information in the form or format requested by the individual, if it is readily producible in such form or format. If the requested format is not readily producible, then the Pharmacy will provide the individual with access to the protected health information in an electronic form or, at the option of the individual, a readable hard copy form or such other form as agreed to by the Pharmacy and the individual.

If requested by the individual, the Pharmacy will arrange with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing of protected health information, within the specified time period.

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A summary of the requested protected health information will be provided in lieu of access to the information only when the individual agrees in advance to a summary, and to any related fees imposed.

An explanation of the requested protected health information to which access has been provided will accompany the access only when the individual agrees in advance to a summary, and to any related fees imposed.

Any fees imposed on the individual for a copy of the protected health information or a summary or explanation of such information will:

- Be collected by the Pharmacy prior to providing access to protected health information;
- Be reasonable and cost-based;
- Will be only for the cost of the following:
 - o Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;
 - o Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and
 - o Preparing an explanation or summary of the protected health information.

Denying Access

A denial of access will be issued and will not be subject to review in the following circumstances:

The protected health information is:

- Not maintained in the Pharmacy;
- Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; or
- Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 USC §263a, to the extent the provision of access to the individual would be prohibited by law; or exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR §493.3(a)(2).
- The protected health information is contained in records that are subject to the Privacy Act, 5 USC §552a, and the denial of access under the Privacy Act would meet the requirements of that law;
- The protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

A denial of access will be issued and will be subject to review, upon request by the individual, only in the following circumstances:

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- A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;
- The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or
- The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

In denying access in whole or in part, to the extent possible, the Pharmacy will give the individual access to any other protected health information requested, after excluding the protected health information that was denied. When denying an individual access to protected health information, the denial will be on the Response to Request for Access Form Review of Access Denial.

The Pharmacy will provide for review of a denial of access to protected health information when requested by the individual, if review of the denial is authorized by this Policy and Procedure (see above).

All denial reviews will be conducted by a licensed health care professional who is designated by the Privacy Officer on a case-by-case basis and who did not participate in the original decision to deny access. The designated reviewing official will determine, within a reasonable period of time, whether or not to deny the access requested based on the applicable standards set forth in this Policy and Procedure (see above). The Privacy Officer will promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required to carry out the designated reviewing official's determination.

Breach Notification Policy

POLICY:

It is the policy of the Pharmacy to identify and respond to incidents involving the unauthorized acquisition, access, use or disclosure of protected health information (“PHI”) in violation of the HIPAA Privacy Rule. Any incident that compromises the security or privacy of PHI is a breach subject to this Policy. An incident compromises the security or privacy of PHI if it poses significant risk for financial, reputational, or other harm to the individual (harm threshold). Business associates that access, maintain, modify, record, store, destroy, or otherwise hold, use or disclose protected health information (“PHI”) are required to notify Pharmacy of any incident that may be a breach.