Employee Health Vaccination Documentation

COVID-19 Vaccine Response
Pediatric Immunization Improvement Project (PIIP)

September 23, 2021
Presented by ...

Heather McClane, MBA, Privacy Officer

- Division of Regulatory and Policy Coordination (DRPC)
- Headquarters Indian Health Service
Purpose

• The purpose of this training is to provide information on the Indian Health Service (IHS) Employee Medical Folder (EMF)

• The EMF is not to be confused with the IHS Patient Health Record (RPMS-EHR)
Considerations

• The HIPAA Regulation at 45 CFR 160.103:
  • Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

• Health plan includes the following, singly or in combination:
  • (xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.
The Department is sensitive to the concerns of commenters that a covered entity not abuse its access to an employee's individually identifiable health information which it has created or maintains in its health care, not its employer, capacity.

To address these concerns, the Department clarifies that a covered entity must remain cognizant of its dual roles as an employer and as a health care provider [or] health plan. Individually identifiable health information created, received, or maintained by a covered entity in its health care capacity is protected health information. It does not matter if the individual is a member of the covered entity's workforce or not. Thus, the medical record of a hospital employee who is receiving treatment at the hospital is protected health information and is covered by the [HIPAA Privacy] Rule, just as the medical record of any other patient of that hospital is protected health information and covered by the Rule. The hospital may use that information only as permitted by the Privacy Rule, and in most cases will need the employee's authorization to access or use the medical information for employment purposes. When the individual gives his or her medical information to the covered entity as the employer, such as when submitting a doctor's statement to document sick leave, or when the covered entity as employer obtains the employee's written authorization for disclosure of protected health information, such as an authorization to disclose the results of a fitness for duty examination, that medical information becomes part of the employment record, and, as such, is no longer protected health information. The covered entity as employer, however, may be subject to other laws and regulations applicable to the use or disclosure of information in an employee's employment record. (67 FR 53192).
An entity that maintains an on-site clinic to provide health care to one or more employees may be a HIPAA covered provider to the extent the clinic performs one or more covered transactions electronically, such as billing a health plan for the services provided. If covered, the entity need not become a hybrid entity so as to avoid applying the Privacy Rule to health information the entity holds in its role as employer, such as sick leave requests of its employees. Such information is already excluded from the definition of “protected health information” as employment records and thus, the Privacy Rule does not apply to this information. However, the identifiable health information the entity holds as a covered health care provider (e.g., the information the clinic holds about employees who have received treatment) is protected health information and generally may not be shared with the employer for employment purposes without the individual’s authorization.
Remember Other Laws

The prior two slides only address relevant HIPAA concerns. The use or disclosure of health information for employment-related decisions may implicate other laws, including but not limited to the Americans with Disabilities Act ("ADA"), Family and Medical Leave Act ("FMLA"), Genetic Information Nondiscrimination Act ("GINA"), and other state and federal laws. For example, once the healthcare employer receives employee health information in its capacity as an employer, it must retain that information in a confidential, secure employee medical file, apart from other personnel records, to comply with the ADA and FMLA.
Employee Health Information Protection

• The IHS Employee Medical Folder is not covered, nor is it protected by the HIPAA Privacy Rule except to the extent the clinic performs one or more covered transactions electronically, such as billing a health plan for the services provided.

• The EMF is protected by the Privacy Act of 1974.
OPM Record

• The EMF is a Personnel Record that belongs to the Office of Personnel Management (OPM).

• The IHS does not own the EMF, nor does the IHS have authority to make storage, disposition or disclosure decisions regarding these records.

• IHS is required to comply with:
  • The System of Records Notice OPM-GOV1-10
  • The regulations at 5 U.S.C. § 552a(b) and 45 C.F.R. § 5b.9(b)(1)
  • The regulations at CFR-2012-title5-vol1-part293.pdf (govinfo.gov)
  • The regulations at 29 CFR 1910.1020
Employee Medical Folder (EMF) means:

- A separate file folder (SF 66–D) is established to contain all of the occupational medical records (both long-term and short-term records) designated for retention, which will be maintained by the employing agency during the employee’s Federal service.

- Records from the EMF are transferred to long-term occupational medical records when an employee separates from the agency.
  - Occupational medical records are records that contain employment-related information about an employee’s health status, including personal and occupational health histories and the opinions and written evaluations generated in the course of diagnosis and/or employment-related treatment/examinations by medical health care professionals and technicians.
Occupational Medical Record (OMR)

• OMR means that an occupation-related, chronological, cumulative record, regardless of the form or process by which it is maintained (e.g., paper document, microfiche, microfilm, or automatic data processing media), of information about health status developed on an employee, including personal and occupational health histories and the opinions and written evaluations generated in the course of diagnosis and/or employment-related treatment/examination by medical health care professionals and technicians.

• This definition includes the definition of medical records at 29 CFR 1910.1020(c)(6); when the term “Occupational Medical Record” is used in these regulations, it includes “Employee Exposure Records” (as that term is defined in this section) and occupational illness, accident, and injury records.
Non-Occupational/Patient Record

• A record of treatment or examination, created and maintained by a health care facility, when the person is admitted to or voluntarily seeks treatment at the health care facility for non-job-related reasons.

• Records maintained by an agency dispensary are patient records for the purposes of these regulations except when such records result as a condition of employment or relate to an on-the-job occurrence. In these cases, the records are “Occupational Medical Records” as defined herein.
Employee Health Vaccination Documentation - Scenarios
Presented by

CAPT Katie Johnson, Pharm D, MHIIM

- EHR Integrated Care Coordinator
- Northwest Portland Area Indian Health Board
EMF vs EHR – Separate Systems of Record

Employee Medical File (EMF) is for **Employee Health**

Electronic Health Record is for **Patient Care**
Disclosures – Specific Written Consent

"Specific written consent" means a written authorization containing the following:

1. The name and signature of the employee authorizing the release of medical information
2. The date of the written authorization
3. The name of the individual or organization that is authorized to release the medical information
4. The name of the designated representative (individual or organization) that is authorized to receive the released information
5. A general description of the medical information that is authorized to be released
6. A general description of the purpose for the release of the medical information
7. A date or condition upon which the written authorization will expire (if less than one year)

A written authorization does not operate to authorize the release of medical information not in existence on the date of written authorization, unless the release of future information is expressly authorized, and does not operate for more than one year from the date of written authorization.

A written authorization may be revoked in writing prospectively at any time.

(29 CFR 1910.1020(c)(12)(i) - 1910.1020(c)(12)(iii)

The IHS-810 meets these requirements
Employee Medical File Paper Form Options

- For COVID-19 vaccines:  

- For other vaccines, consider: https://immunize.org/catg.d/p2023.pdf
Employee Health Vaccines Scenarios

1. Employee presents to employee health nurse for vaccination and does not want the vaccination documented in their patient record

2. Employee presents to the employee health nurse for vaccination and does want the vaccination documented in their patient record as well

3. Employee can be seen as a patient at the same clinic/hospital where they work. They present as a patient to the clinic/hospital and want to also let their Employee Health Program know they received a vaccine today

4. Employee can be seen as a patient at the same clinic/hospital where they work. They present as a patient to the clinic/hospital but does not need to share the vaccination today with the Employee Health Program
Employee Scenario 1

• Employee presents to employee health nurse for vaccination and does not want the vaccination documented in their patient record

Steps:
• Vaccine is given
• Vaccine documentation is placed in EMF
  • *If and only if* it is a COVID-19 Vaccine:
    • Enter COVID-19 vaccination into VAMS
    • Give CDC vaccine card
    • Note: these actions are both disclosures and must be documented on IHS 505 form (two disclosures = two lines)
  • Completed IHS-505 placed in EMF
Employee Scenario 2

• Employee presents to the employee health nurse for vaccination and does want the vaccination documented in their patient record as well

Steps:
• Vaccine is given
• Vaccine documentation is placed in EMF
  • If and only if it is a COVID-19 Vaccine:
    • Enter COVID-19 vaccination into VAMS
    • Give CDC vaccine card
    • Note: these actions are both disclosures and must be documented on IHS 505

• Employee completes an IHS-810 to disclose vaccine to patient health record
• Vaccine entered into RPMS EHR as a historical entry
  • Note: this is a disclosure, you must account for it on IHS 505
• Completed IHS-810 and IHS-505 placed in EMF
IHS 505 Form – Accounting of Disclosures

• Note that each disclosure is documented on a separate line
• In this example, there are 3 disclosures – thus 3 lines on the 505:
  • A COVID vaccine was given to the employee and documented in VAMS
  • The employee received the CDC COVID-19 vaccine card
  • The information was disclosed to the person’s patient file in RPMS EHR
Employee Scenario 3

• Employee can be seen as a patient at the same clinic/hospital where they work. They present as a patient to the clinic/hospital and want to also let their Employee Health Program know they received a vaccine today.

**Steps:**

• Vaccine is given

• Vaccine documented in RPMS EHR

• Patient given documentation of vaccination
  • If it is a COVID-19 Vaccine, this would be the CDC card
  • If it is another vaccine, it could be a printout or visit summary or other documentation

• Disclosures entered into RPMS Release of Information package

• Patient personally takes documentation to Employee Health Program
Employee Scenario 3 - Alternative

• If patient does not obtain documentation of vaccination at the time of the visit, they can go to HIM department (or equivalent) at any time and fill out an IHS 810
  • HIM department (or equivalent) may then either disclose information directly to employee health program
  • HIM department (or equivalent) may give patient summary of visit or other documentation of vaccination and patient can personally deliver it to the employee health program
• HIM department (or equivalent) documents disclosures in RPMS Release of Information package
Employee Scenario 4

- Employee can be seen as a patient at the same clinic/hospital where they work. They present as a patient to the clinic/hospital but does not need to share the vaccination today with the Employee Health Program.

Steps:
- Vaccine is given
- Vaccine documented in RPMS EHR as usual for patients
## COVID-19 Vaccine vs Other Vaccine Documentation

<table>
<thead>
<tr>
<th><strong>COVID-19 Vaccine</strong></th>
<th><strong>Other Vaccines (Ex: Influenza)</strong></th>
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<tr>
<td>• May be required to be documented in VAMS</td>
<td>• Never documented in VAMS</td>
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<td>• Has its own CDC card for recipients</td>
<td>• Typically, does not have a specific card for recipients</td>
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<td>• EUA or VIS, depending on scenario</td>
<td>• VIS</td>
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*ALL* must follow Employee Medical File rules for documentation and disclosures
VAMS – Vaccine Administration Management System

- VAMS is ONLY for COVID-19 Vaccine reporting
- It is NOT a full medical record
- It is a reporting mechanism specific to the COVID-19 vaccine
- A Release of Information is NOT required to enter the information into VAMS. There is an IHS-CDC Agreement in place to allow for disclosure under 5b.9(b)(1) of the Privacy Act
- However, we must account for the disclosure of Personally Identifiable Information (PII) to the Centers for Disease Control and Prevention (CDC)
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Questions & Discussion
Thank You