Part 2 - EHRs and Audit Trail Discovery Requests

When requesting information from the lawyers, many times, the lawyers will state:

> Objection. The Request as phrased is vague, overly broad, and unreasonably burdensome. Moreover, this Request seeks information that is not relevant or material and is not reasonably calculated to lead to the discovery of relevant or material information that would be admissible at the time of trail.

Here are a few hints to eliminate many of these objections:

Patient Medical Record:

1. Typically, electronic, and scanned documents in reverse chronologic order. The terms medical record, health record, and medical chart are used somewhat interchangeably to describe the systematic documentation of a single patient's medical history and care across time within one particular health care provider's jurisdiction.

2. The medical record includes a variety of types of "notes" entered over time by health care professionals, recording observations and administration of drugs and therapies, orders for the administration of drugs and therapies, test results, x-rays, reports, History and Physical report, physician orders, nursing notes, lab, radiology and other procedure notes, Medication Administrative Report (MAR), daily and hourly Vital signs, operative reports, discharge summary, daily physician notes, etc.

3. The maintenance of complete and accurate medical records is a requirement of health care providers and is generally enforced as a licensing or certification prerequisite.

4. Always request the “revision history” version of the Patient’s Medical Records, not the legal version or the final or complete medical records. The legal or final version is limited to the compete patient record after all of the changes have been made. We need to see everything that was entered, when it was entered, who entered the information and if any of the information was modified or changed. That version is usually known as the Revision history which indicates all information captured or changed/modified.

5. When the administrative staff is producing the patient’s chart there is an option of not including any records or order that have not been signed off on by the provider. If the event were not signed off, there would be no record of the event even though the information was in the chart and may been pending sign-off. Request that all records be provided and include all record even if the document has not been signed off by the provider.

Patient Chart EHR Audit Trail: we need to know:

1. EHR product Company Name, Product Name, and software Version during the time of care by department.

2. I would ask to receive the audit trails in an electronic searchable version (MS-Excel) so that we can search for and re-sort the information. If they will only give you the audit trail in PDF version, then I prefer to have the audit trail in Date and Time order by patient ID or patient name for the entire patient stay to include all views, additions, changes, deletions and if anything was printed.

3. Additionally, some of the EHRs can also provide a “Detailed Audit Report.” The detailed audit report shows the same information as above plus it shows what actual specific “data” was added,

changed, or deleted. This is important if we want to see what actual data was inputted or changed down to the date and second.

End-of-shift Nursing Report - Emergency Room and Nursing Floor:

1. A proper end-of-shift report is a compilation of details recorded by a patient's nurse.
2. Written or printed from the EHR by nurses who are wrapping up their shifts and provided to those nurses beginning the next shift, these details include a patient's current medical status, along with his or her medical history, individual medication needs, allergies, a record of the patient's pain levels and a pain management plan, as well as any discharge instructions.
3. Without these details, a nurse could potentially endanger a patient's life.
4. The different needs of individual patients are best met when the nursing staff understands their current medical situation. An end-of-shift report allows nurses to understand where their patients stand in regard to recovery by providing a picture of a patient's improvement or decline over the last several hours.
5. By knowing what has previously occurred in a patient's treatment plan, nurses can proceed with the right steps to contribute to positive outcomes.
6. Typically, the end of shift report is not stored in the patient's chart because the report typically has multiple patients on the report since the typical nurse has 3-5 patients during their shift.
7. Nursing is required to maintain the Nursing end-of-shift reports, typically on the nursing unit, or stored in Nursing Administration if any notes are charted on the report. Basically, because it includes patient data, and document must be saved if any information is written on the report. Now, if the report comes from the EHR and nothing is noted on the report, the report might not be saved since we can reproduce the report from the EHR at any time.

Every Electronic Health Record (EHR), which was mandated in 2009 by the federal government, is required to have an electronic Audit trail that shows every Add, View, Delete, Print, and Change that was made within the EHR. Hospitals and physicians started installing EHRs in 2000 and 95% were completed by 2015. Prior to 2009, only 17% of healthcare organizations had installed an EHR.

Therefore, between 2009 and 2015, the majority of the healthcare organizations had installed and implemented an EHR and therefore, they should be able to provide an electronic copy of the patient's chart and a through electronic audit trail.

One challenge is that Hospitals were only required to install "modular" EHR software applications. Therefore, you could have a separate EHR software product from different companies, different EHR software products and then you would need to review different audit trails for:

1. Emergency Room
2. Surgery Department
3. Outpatient Clinics
4. Inpatient Setting for Acute Care
5. Inpatient Setting for Behavioral Health
6. Laboratory
7. Pharmacy
8. Radiology
9. Cardiology
10. Other Departments

All of these healthcare organizational departments, in theory, could have different EHR products from different companies. Therefore, when requesting access to a healthcare organization's EHR and audit

trail, we must first determine what software products are uses in what departments. If you just ask for access to the EHR record and audit trail, the defendant's lawyers will state "The Request as phrased is vague, overly broad and unreasonably burdensome."

Which EHR and Audit trail do you want? The request must be related to the Patient's care and departments they cared in. Therefore, we need to know:

- EHR product Company Name, Product Name, and software Version during the time of care by department.

Electronic Audit Trail:

Stage 1 of certification criteria for meaningful use, Section 170.302(r), Audit log, requires healthcare entities to:[1]

1. Record actions related to electronic health information in accordance with the standard specified in §170.210(b)
2. Generate an audit log. Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at §170.210(b)

- The audit trail displays every time a person logged into the EHR, which patient chart they accessed, the date and time and what workstation they were using, and what part of the EHR program they accessed. Each EHR has a standard Audit Trail output format that can be sorted by:

    1. Patient ID or name
    2. Staff person Name
    3. Date and time of activity.
    4. Workstation ID

SAMPLE REQUEST FOR PRODUCTION OF DOCUMENTS

1. **Request for a written list of any and all electronic medical records (EMR), and electronic health records (EHR), and electronically stored information (ESI), in your possession, relating to Plaintiff and Plaintiff's Health Information during the time-period of _____ to _____ and provide a listing of each different EHR product(s) company Name, EHR product(s) software name, and the specific EHR product(s) Version number that was used during the period of care for each clinical documentation software application for each hospital department that captures clinical data on the patient including the Emergency Room, Surgery Department, Outpatient Clinics, Inpatient Setting for Acute Care, Inpatient Setting for Behavioral Health, Laboratory, Pharmacy, Radiology, and Cardiology**

    a. If the hospital uses an EHR during the time-period of care they are required to be able to provide you with a list of EHR module products that are used within the healthcare organization. All this information is maintained within the HIM department and usually includes a schematic of how the module EHR products communicate with each other. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

    b. In your written request, I would first ask for the different EHR software product company name, product name, and software version of all EHR products installed and operational during the time of care (I would enter in the actual date of services) for each clinical

department the patient received care in (so if the patient did not receive care in the Emergency Room or Surgery, then you would delete these departments) to include:

i. Emergency Room
ii. Surgery Department
iii. Outpatient Clinics
iv. Inpatient Setting for Acute Care
v. Inpatient Setting for Behavioral Health
vi. Laboratory
vii. Pharmacy
viii. Radiology
ix. Cardiology
x. Other Departments

c. It is important to know what software they are using in the Emergency Room, Surgery, Pharmacy, and Radiology because many times these departmental applications have error messages when they interface (talk) to the main EHR. Many times, a laboratory clinical order, placed by a physician in the EHR, never gets to or is delayed in getting to the laboratory for processing. Delays in processing Laboratory orders or a medication order could cause clinical and physical harm to the patient.

2. **Request any and all written schematics, documentation, policies, and procedures that will identify any and all modules, applications, services, portals, parts, add-ons, and additional free-standing software which integrates with and transmits data to your primary EHR, EMR, and electronic medical records system that were when in use during the period of _____ to _____ for each of the departmental EHR products listed it request # 1.**

a. Every healthcare organization keeps a one-page visual display of all software utilized in the health systems and how each software product communicates with other software applications.

b. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

3. **Request for any and all Audit Trails and Audit Logs in your possession for each EHR listed in Item 1 for the time period of 07/01/2013 – 07/04/2013 while in the care of _____ Hospital. (indicate the specific time period of the care and indicate the specific hospital name) including all electronically stored information following the federal HIPAA standard, specified in 45 CFR 170.210, sorted in Date and time order for all transactions for the plaintiff and provide the audit trail(s) in .CVS or MS Excel versions so that the audit trails are searchable.**

a. Every hospital must have an audit trail for each EHR and therefore the request is NOT vague, overly broad, and unreasonably burdensome.

b. Once again you need to specify **"which"** EHR audit trails you want over **"what"** time period and in "**what"** format.

c. Start by asking for an audit trail for every EHR product listed in the first question for specific dates where care was provided to your client.

d. Ask them to provide the audit trails (plural because there is usually more than one) following the federal format related to electronic health information in accordance with the standard specified in §170.210(b). The required format includes one-line audit trail for every time someone adds, changes, deletes, prints, and views a specific "page" in the EHR. The electronic audit trail is required to show:

i. Username - ID of the person who accessed the EHR information.

ii. *Event Date/Time - Date and time of entry and a new line item every time a different EHR screen was accessed.*

iii. *Source System - Name of the EHR Product*

iv. *Site ID - Name of the Healthcare Organization (many times there are multiple hospitals part of the same organization)*

v. *Audit Policy - ID of the EHR screen they accessed.*

vi. *Event Action - ID of the action taken when they accessed the EHR (View, Add, Delete, Change, Print)*

vii. *Status – was the specific action rejected, completed,*

viii. *Participant Object Name – This is the name of the patient.*

ix. *Participant Object ID – This is the patient unique ID number assigned during registration.*

x. *Type Code – this is the description of what software name the Participant Object ID was generated from.*

xi. *Location ID - ID of the workstation they used to access the patient's information.*

e. *I would ask to receive the audit trails in an electronic searchable version (MS-Excel) so that we can search for and re-sort the information*. If they will only give you the audit trail in PDF version, then I prefer to have the audit trail in Date and Time order by patient ID or patient name for the entire patient stay to include all views, additions, changes, deletions and if anything was printed.

f. Additionally, some of the EHRs can also provide a "Detailed Audit Report." The detailed audit report shows the same information as above plus it shows what actual specific "data" was added, changed, or deleted. This is important if we want to see what actual data was inputted or changed down to the date and second.

4. **Request for the complete legal medical record of the Plaintiff and Plaintiff's Health Information in its native format, with all manual and electronically stored information and metadata intact for each EHR listed in Item 1 for the time period of _____ to _____while in the care at _____ hospital. (indicate the specific time period of the care and indicate the specific hospital name).**

a. This is traditionally considered the legal medical record for the patient and includes paper forms and electronic EHR data in the format established by the hospital. Every hospital maintains a legal record of care for every patient treated within the hospital based on the format established by Joint Commission.

b. Since we are requesting the legal Medical Record for specific dates and based on the care of the patient, the request is NOT vague, overly broad, and unreasonably burdensome.

c. The information is necessary to determine all information entered within the patient's medical record during the time of care.

5. **Request for the complete detailed Financial billing records of the Plaintiff care for the time period of _____ to _____while in the care at _____. (indicate the specific time period of the care and indicate the specific hospital name).**

a. This is traditionally considered the legal financial detailed billing record for the patient and includes all charges based on clinical care provided. Every hospital maintains a detailed billing record of all transactions performed during the patient's clinical stay and is established by the national HFMA association.

b. Since we are requesting legal billing records for specific dates and based on the care of the patient, the request is NOT vague, overly broad, and unreasonably burdensome.

c. The information is necessary to determine the cost of the care and if the billing records match the clinical care provided during the period of admission.

6. **Request a list of all care providers who care for the patient during the period of _____ and _____ including the care provider's name, credentials, years of experience within the organization, and department they work in.**

a. Every hospital is required to maintain a list of all care providers that interact with the patient during their clinical stay.

b. Normally, we can get that information from the EHR audit trails, but in certain areas, the hospital staff may not be using the same EHRs.

c. For example, the physical therapists may be using a paper-based system for charting their care, and thus, they would not be listed under any electronic EHR audit report.

d. Given that the care might have been provided years ago, the request might be considered overly broad and unreasonably burdensome, but a quick review of the patient's legal medical record would provide a source of the staff's name.

7. **Request for any and all written policy and procedure documents relating to ***Administrative Safeguards*** as required under federal HIPAA guidelines as defined under 45 CFR 164.308 for each EHR listed in Item 1 for the time period of _____ to _____while in the care at _____. (indicate the specific time period of the care and indicate the specific hospital name).**

a. Every healthcare organization is required to have written policies and procedures for each EHR product related to their specific Administrative Safeguards following the Federal requirements under 45 CFR 164.308

b. Traditionally this would be a MS Word file or PDF file format and therefore is NOT vague, overly broad, and unreasonably burdensome.

c. The Administrative Safeguard Policies and Procedures must be maintained and updated during the Hospital's annual Security Risk Assessment as mandated by the Federal Meaningful Use requirements.

8. **Request for any and all written policy and procedure documents relating to ***Physical Safeguards*** as require under federal HIPAA guidelines as defined under section 45 CFR 164.310 for each EHR listed in Item 1 for the time period of _____ to _____ while in the care of St. Joseph Hospital. (indicate the specific time- period of the care and indicate the specific hospital name).**

a. Every healthcare organization is required to have written policies and procedures for each EHR product related to their specific Physical Safeguards as required under federal HIPAA guidelines as defined under 45 CFR 164.310.

b. Traditionally this would be a MS Word file or PDF file format and therefore the request is NOT vague, overly broad, and unreasonably burdensome.

c. The Physical Safeguard Policies and Procedures must be maintained and updated during the Hospital's annual Security Risk Assessment as mandated by the Federal Meaningful Use requirements.

9. **Request for any and all written policy and procedure documents relating to ***Technical Safeguards*** as required under federal HIPAA guidelines as defined under section 45 CFR 164.312 for each EHR listed in Item 1 for the time period of _____ to _____ while in the care at _____ Hospital. (indicate the specific time- period of the care and indicate the specific hospital name).**

   a. Every healthcare organization is required to have written policies and procedures for each EHR product related to their specific Technical Safeguards as required under federal HIPAA guidelines as defined under 45 CFR 164.312.

   b. Traditionally this would be a MS Word file or PDF file format and therefore the request is NOT vague, overly broad, and unreasonably burdensome.

   c. The Technical Safeguard Policies and Procedures must be maintained and updated during the Hospital's annual Security Risk Assessment as mandated by the Federal Meaningful Use requirements.

10. **Request for any and all written communications regarding system errors, computer unscheduled downtimes, identified and documented problems, or complaints relating to your EHR, EMR, and electronic medical record systems listed in Item 1 during the time period of _____ to _____.**

    a. Every EHR product and HIM department maintains either a written log or electronic log of all issues, errors, and downtime for each EHR product by date and time. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

    b. The information is necessary to show if there were any issues with the EHR products during the period of Care.

    c. For example, the EHR was "down" (not working) during a period of time. When this occurs, hospital staff revert to paper records and then they enter the data back into the EHR once the EHR is operational again. This would indicate why there might have been delays in recording in the EHR.

    d. A second example is when the interface between two products is not working. A lab order placed at 2:00 PM should be received within the Laboratory product within a few minutes. However, if the interface is not working an error log would be generated showing why the lab order was delayed. Additionally, when the interfaces are not operational, orders can be lost and never processed, potentially causing physical harm to the patient.

11. **Request for any and all written operating manuals, user manuals, training manuals, cheat sheets, quick access sheets or guides, quick start guides, quick unit guides, reference sheets, policies and procedures, or other training materials relating to inputting, accessing, editing, maintaining, authenticating, and creating information, data content, data, and metadata in the EHR, EMR, and electronic medical record during the time period of _____ to _____ or materials near the time period or the oldest materials available after the time period, for each of the EHR products indicated in Item 1.**

    a. Every EHR product and HIM department maintains user manuals and training materials for each EHR product so that they can train new staff.

    b. One issue might be the timing of the care. The health system may not retain old user manuals and training manuals. Usually, they maintain current user manuals and training guides, but it is always good to ask for information based on the actual time period of care.

c. If they cannot provide the actual materials during the time-period we would accept the oldest user manuals and training documents for each separate EHR software product that they would have available.

d. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

e. The information is necessary to determine the actual processes for entering data into the EHR, changing data in the EHR, and for Printing Data from each of the EHRs during the time period of care for the Plaintiff.

12. Request for any and all written documents relating to the policies and procedures for the medical record department regarding procedures for the protection of medical record information against the loss, tampering, alteration, destruction, or unauthorized use for each EHR listed in Item #1 for the time-period of _____ to _____ or materials near the time period, or the oldest materials available after the time period.

a. Every EHR product and HIM department maintains written policies and procedures on how they handle the protection of medical record information for each EHR maintained and used within the healthcare system. The policies and procures are required to be updated annually based on Federal Joint Commission Mandates.

b. One issue might be the timing of the care. The health system may not retain old policies and procedures. Usually, they maintain current written policies and procedures, but it is always good to ask for information based on the actual time period of care.

c. If they cannot provide the actual materials during the time period, we would accept the oldest written policies and procedures for each separate EHR software product that they would have available.

d. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

e. The information is necessary to determine the actual processes for entering data into the EHR, changing data in the EHR, and for Printing Data from each of the EHRs during the time period of care for the Plaintiff to ensure the protection and validity of the patient's clinical medical record.

13. Request for any and all written documents relating to policies and procedures regarding the requirements for the completeness and timing of the patient history and physical examination and clinical documentation, including a listing of the minimum contents to be included in the medical record for each EHR listed in Item #1 for the time-period of _____ to _____ or written policies and procedures near the time period, or the oldest written materials available after the time period.

a. Once again, every EHR product and HIM department maintains written policies and procedures on how they handle the protection of medical record information for each EHR maintained and used within the healthcare system. The policies and procures are required to be updated annually based on Federal Joint Commission Mandates.

b. One issue might be the timing of the care. The health system may not retain old policies and procedures. Usually, they maintain current written policies and procedures, but it is always good to ask for information based on the actual time period of care.

c. If they cannot provide the actual materials during the time period, we would accept the oldest written policies and procedures for each separate EHR software product that they would have available.

d. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

e. The information is necessary to determine the actual processes for insuring that the patient's medical records are complete and meet minimal document requirements established by the healthcare institution.

14. **Request for any and all documents relating to the written policies and procedures regarding specifications for verbal orders, including who may give verbal orders, who may receive them, and how soon they must be verified or countersigned in writing for each EHR listed in Item #1 for the time-period of _____ to _____ or written policies and procedures near the time period, or the oldest written materials available after the time period.**

    a. Once again, every EHR product and HIM department maintains written policies and procedures on how they handle verbal orders for each EHR maintained and used within the healthcare system. The policies and procures are required to be updated annually based on Federal Joint Commission Mandates.

    b. One issue might be the timing of the care. The health system may not retain old policies and procedures. Usually, they maintain current written policies and procedures, but it is always good to ask for information based on the actual time period of care.

    c. If they cannot provide the actual materials during the time period, we would accept the oldest written policies and procedures for each separate EHR software product that they would have available.

    d. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

    e. The information is necessary to determine the actual processes for handling physician "Verbal Orders" and to meet minimal document requirements established by the healthcare institution.

15. **Request for any and all documents relating to the written policies and procedures regarding the scope of practice, supervision, and record keeping requirements of licensed physician assistants (PAs) or Nurse practitioner (NPs), including their role and responsibly during the time-period of _____ to _____ or written policies and procedures near the time period, or the oldest written materials available after the time period.**

    a. Once again, every EHR product and HIM department maintains written policies and procedures on what responsibly and controls the hospital maintains for all PAs and NPs used within the healthcare system. The policies and procures are required to be updated annually based on Federal Joint Commission Mandates.

    b. If they cannot provide the actual materials during the time period, we would accept the oldest written policies and procedures for each separate EHR software product that they would have available.

    c. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

    d. The information is necessary to determine the actual processes and controls over PAs and NPs to meet minimal document requirements established by the healthcare institution.

16. **Request for any and all documents relating to the written policies and procedures regarding Criteria for admission to and discharge and transfer from the unit during the time-period of _____ to _____ or written policies and procedures near the time period, or the oldest written materials available after the time period.**

    a. Once again, every EHR product and HIM department maintains written policies and procedures on what responsibly and controls the hospital maintains for all PAs and NPs used within the healthcare system. The policies and procures are required to be updated annually based on Federal Joint Commission Mandates.

b. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

c. The information is necessary to determine the level of care an NP or PA can provide and what supervision they are under established by the healthcare institution.

17. **Request for any and all documents relating to the written policies and procedures regarding Protocols for transfer and transport of patients within the hospital or from the hospital to another facility during the time-period of _____ to _____ or written policies and procedures near the time period, or the oldest written materials available after the time period.**

    a. Only add this request if the patient was transferred within the hospital or from the hospital to another facility.

    b. Once again, every HIM department maintains written policies and procedures on what protocols are used for transfer and transport of patients within the hospital or from the hospital to another facility. The policies and procures are required to be updated annually based on Federal Joint Commission Mandates.

    c. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

    d. The information is necessary to determine if the right policies and procedures are followed if the patient is transfer and transported within the hospital or from the hospital to another facility established by the healthcare institution.

18. **Request for any and all documents relating to the written policies and procedures regarding Protocols that define the physician, specialist and consulting physician to be called for patient emergencies, including a response time for physicians to respond to patient emergencies during the time-period of _____ to _____ or written policies and procedures near the time period, or the oldest written materials available after the time period.**

    a. Once again, every HIM department maintains written policies and procedures on what protocols are used for transfer and transport of patients within the hospital or from the hospital to another facility. The policies and procures are required to be updated annually based on Federal Joint Commission Mandates.

    b. Therefore, the request is NOT vague, overly broad, and unreasonably burdensome.

    c. The information is necessary to determine if the right policies and procedures are followed if an emergency or life-threating event occurs during the care of the patient as established by the hospital.

19. **Request for a list of all electronic patient monitoring devices connected to the Plaintiff's during the time-period of _____ to _____ and if the patient monitoring devices were electronically connected and automatically transfers the monitoring device clinical data directly to the EHRs listed in Request #1 or if the electronic patient monitoring device clinical data must be manually re-entered by the Hospitals staff.**

    a. Once again, every Hospital maintains a list of electronic patient monitoring devices that are used within every room or care delivery area within the hospital.

    b. Since we are requesting the data for specific dates and based on the care of patient, the request is NOT vague, overly broad, and unreasonably burdensome.

    c. The information is necessary to determine how patient clinical information from electronic patient monitoring devices is placed into the EHR, either manually, or through electronic transfer.

Part 2 - EHRs and Audit Trail Discovery Requests

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Author: Mark R. Anderson has been a healthcare executive over the past 50 years and has worked for or consulted for over 350 hospitals and with over 26,000 physicians on healthcare policy and procedures; Clinical, Operational, and financial concerns; finance, billing, and collections; staffing based on acuity levels; as well as all aspects of technology. Since the late 1990's Mr. Anderson has been involved with Clinical Information Systems and later with Electronic Medical/Health record systems (EHR) and has assisted numerous law firms with their Malpractice cases where they need an expert to evaluate the federal mandated EHR audit logs and compare those audit logs to the actual legally binding EHR patient medical records. Mr. Anderson is a life fellow with HIMSS and is a Certified professional in Healthcare information systems (CPHIMS).