

Legal Considerations of EMS Data

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50th Anniversary

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An Imaginary Barrier

How HIPAA Promotes Bidirectional Data Exchange With Emergency Medical Services

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HIPAA BASICS FOR EMS

Am I Covered by HIPAA?
If you work or volunteer for an agency that provides healthcare... including ambulance services and EMS agencies... and that agency bills for healthcare services, you are part of a HIPAA "covered entity."

When Does HIPAA Apply?
If you work or volunteer for a covered entity, HIPAA applies to you both on and off duty.

How Do I Handle the Notice of Privacy Practices?
The Notice of Privacy Practices (NPP) should be provided to patients at the time of service in non-emergency treatment situations.

What Can I Do?
HIPAA applies to your patient information. Ask "How do I handle the notice of privacy practices?"

What Can I Do?
HIPAA applies to your patient information. Ask "How do I handle the notice of privacy practices?"

Follow the 8 commandments:
1. Know your patient information.
2. Know your agency's policy on NPP.
3. Know your agency's policy on NPP.
4. Know your agency's policy on NPP.
5. Know your agency's policy on NPP.
6. Know your agency's policy on NPP.
7. Know your agency's policy on NPP.
8. Know your agency's policy on NPP.

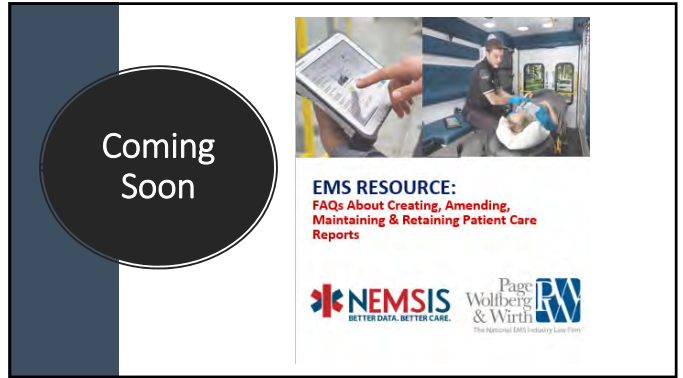
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Our Collaboration With NEMESIS

EMS Body-worn Camera Quickstart Guide:
Legal Considerations for EMS Agencies
Version 1.0

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Coming Soon

EMS RESOURCE:
FAQs About Creating, Amending, Maintaining & Retaining Patient Care Reports

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Let's Do the Lawyer Stuff

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Archeologists Have Uncovered the Fossil Remains of the First Lawyer . . .



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Legal Status of PCR's




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Who "Owns" the PCR Data?



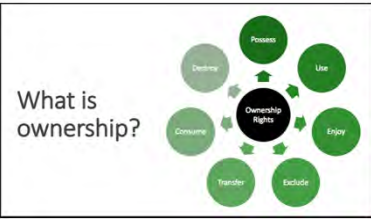
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When we Think of Ownership

What is ownership?



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General Rules

- Medical record ownership matter of state not Federal law
 - Majority of state laws do not directly address ownership
 - Only 20 states say records belong to physician or facility
- Patients always have rights to their records
 - Covered entities under HIPAA must grant right of access, amendment and restriction
 - Providers must grant any rights under State law
- "Ownership" does not confer exclusive right to control PCR information
 - Recipients of ePCR data have rights/duties under law

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Third Parties can Use PCR Data

- State EMS Offices
- Facilities
- Business associates




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Example – State DOH

§ 1021.8. EMS data collection.

- (a) *Reasons for EMS data collection.* The Department . . . may collect EMS data for the purpose of evaluating the effectiveness of the Statewide and regional EMS system plans. . . . and the effectiveness of the Statewide and regional EMS systems in reducing morbidity and mortality
- (b) *Duty to provide EMS data and records.*



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General Duties Legal With PCR Data

EMS agencies must maintain, use and disclose PCR data as outlined in Federal (HIPAA, Part 2, ADA) and state laws

Third parties that receive PCR data must maintain, use and disclose that information as permitted by the law and any agreement

Once properly disclosed to a third party, EMS agencies generally not responsible for subsequent uses or disclosures (except for their BAs)



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More Data Stewards Than Owners



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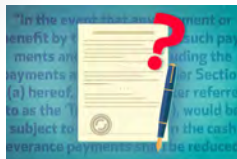
When Does a PCR Become a "Legal" Document?



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There is No Magic Moment



Contract for Deed

CONTRACTOR: [Name and address]

BUYER: [Name and address]

PROPERTY: [Address]

TERMS: [Details of the contract]

ASSIGNMENT: [Details of the assignment]

LEGAL OPINION: [Details of the legal opinion]



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General Rules



PCR data can become "legally" relevant at any time



If documentation exists at time of legal request, may need to be produced




ANY documentation In EMS agency's possession can become "legal records"

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Reasons for "Legal Requests"

- Government audits and investigations
- Criminal investigations and civil discovery
- Criminal and civil cases
- Administrative reviews/proceedings




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About Legal Requests


- Most often, the final PCR is requested and comes into court or evidence
- **Signing** a PCR has legal significance
 - Attesting read PCR and it is complete
 - Attesting to care you provided
- **Billing** a claim has legal significance for the agency and the **practitioner**
 - Attesting you are compliant with all laws including FCA




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What am I held responsible for?



- Actions or omissions attributed to **you**
- Having reviewed the PCR
- Any documentation you wrote, including any addenda




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Best Practices

- All documentation must be truthful and accurate when authored
- Review all PCRs before submission and both providers should sign PCR
- Any incomplete documentation should be amended as soon as identified




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Is there any factor that makes an ePCR an "official" record?

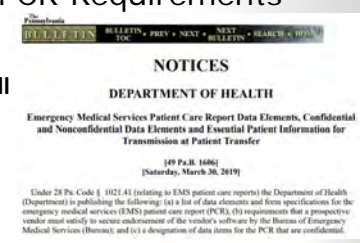



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States Have PCR Requirements

- **Example –**
 - **The Department will publish a list of the data elements**

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Actions that make ePCR "Official"

- ✓ Satisfying any local or state requirements for required data in an ePCR
- 📄 Completion in conformance with agency's policy
- 📄 Signing the PCR
- 🏠 Billing the PCR

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Is There a Specific Definition of a "Closed" ePCR?

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When is a PCR "Closed"

- It's generally when EMS practitioners have completed all mandatory fields and the ePCR is passed on to the **next level**
- For many agencies, point the ePCR is **locked** to provider and must be reopened by administrator/supervisor

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It Really Depends on This

SUBJECT: EMS PATIENT CARE REPORTS

I. POLICY:
EMS Patient Care Reports

II. PURPOSE AND STANDARD:
Documentation of patient contacts and care is a vital aspect of assuring continuity of care, providing a means of quality assurance and historical documentation of the event. It is just as important as the care itself and should be an accurate reflection of the events that transpired. It is imperative that written documentation is left with the patient at the receiving facility.

III. POLICY SCOPE: Departmental

IV. GENERAL INFORMATION:
A. Patient Care Reports
1. All EMS providers must complete a patient care report for each patient contact or request for response (e.g. agency or cancelled or non-incident or a "cancelled call" that must be completed).
2. Identify a patient care report will be completed in its entirety and provided to the receiving hospital's Emergency Department immediately after transferring care to the EMT staff and prior to departing the hospital.

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Practitioners May be Required by Law to Follow Your Policy

- Example- Pennsylvania:
The report shall be made by completing an EMS PCR within the time prescribed by the EMS agency's written policies, no later than 72 hours after the EMS agency concludes patient care, and then submitting it, within 30 days, to the regional EMS council that is assigned responsibilities for the region in which the EMS agency is licensed.


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Legal Best Practices for "Closed" PCR

- If state law speaks PCR requirements that is **the baseline for your policy**
- Require completion of PCR by end of shift
- Lock within 24 hours of end of call for service
 - Some leeway to "reopen"
- Entries after state deadlines should usually be amendments

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Amendments to PCR's



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First, There is a Duty to Amend

- EMS practitioners and EMS agencies have a **legal** and **ethical** duty to ensure PCR is complete and accurate
- PCR's should be amended to:
 - Add information that was incorrectly omitted
 - Correct information that is incorrect
 - Delete information that is erroneous

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And, it Could be **Fraud** if you Amend to:

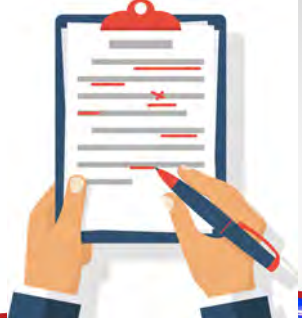
- Falsify information
- Misrepresent the patient's condition
- Cover up mistakes
- Include something that isn't true
- Delete factual information
- Include things the crew clearly does not **remember**

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When, who, and how can an ePCR be amended?



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When?

- Whenever the agency discovers inaccurate or incomplete information on PCR
- **The sooner the better**
 - Later entries are seen as unreliable in court
 - Delayed entries are given less weight by Medicare reviewers
- If a patient requests an amendment and the agency agrees with the amendment

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Who?

- Only the caregiver who wrote the documentation should amend **patient care/clinical** information
- Minor amendments to **demographic** information may be made by others
 - Example: billing office changes "132 Main Street" to "123 Main Street"

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Follow State Rules

- The EMS provider who assumes primary responsibility for the patient shall complete an EMS PCR for the patient and ensure that the EMS PCR is accurate and complete and completed within the time prescribed by the EMS agency
- Whoever must complete the PCR, must do the amendment



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What Medicare Says

- Section 3.3.2.5
 - "All services provided to beneficiaries are expected to be documented in the medical record **at the time they are rendered.** Occasionally, certain entries related to services provided are not properly documented. In this event, the documentation will need to be amended, corrected, or entered after rendering the service."

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Medicare says Amendments Should...

- Clearly and permanently **identify** any amendment, correction or delayed entry as such
- Clearly indicate the **date** and **author** of any amendment, correction or delayed entry, and
- Clearly identify all original content, **without deletion**



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Amendments of ePCRs (Medicare Integrity Manual)

- Distinctly identify any amendment, correction or delayed entry
- Provide a reliable means to clearly identify the original content, the modified content, and the date and authorship of each modification of the record



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Amendments Need to Include...

- Time
- Date
- Author
- Reason

Usually tracked by ePCR software through unique user credentials



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If a crewmember completes, signs, and locks an ePCR, then information is added to the PCR by someone else afterward, is the crewmember responsible for the addition(s)?



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Generally, Not

- Crew is only responsible for information they entered and signed
- ***Unless asked to review and approve the amendment***
- But crewmembers accountable for incomplete/incorrect entries in original PCR



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But, Remember . . .

- The EMS agency is responsible if made by agency
- Others **should not change the original PCR** unless there is a compelling reason
- In some systems, when the crew locks the PCR, it creates a PDF and that should reflect how crew wrote it initially



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Should a billing company/billing department be allowed to alter **clinical information** contained in the ePCR?



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No!

- Billing should only be able to change demographic-type information if clearly incorrect or missing
- The implications
 - False Claims Act
 - Legal issues if PCR is part of an action
- Watch comminutions between billing and ops



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Are there any concerns with a QA/QI committee member altering clinical information contained in an ePCR?



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Yes!


- Errors and omissions found in QA/QI committee should be returned to practitioner who authored the PCR to amend the PCR
- This is also a good teaching tool and fosters accountability



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If a **state agency** is doing quality improvement work and notices that a record from months ago is missing a critical data element, can the state agency instruct the EMS agency to go back and update it?




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Yes, but...

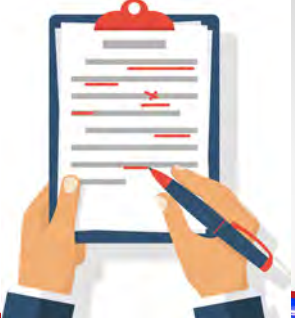
- Should be through an amendment
- Original practitioner should make the amendment whenever possible
- Should include time, date, author and reason for the change



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Should ePCR software providers have the ability to track changes to the ePCR, e.g., an audit trail?




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Yes! Under HIPAA (45 CFR 164.312(b))

- HIPAA Security Rule requires "Audit Controls" (45 C.F.R. § 164.312(b)) - mechanisms that record and examine activity in information systems
- Examples of audit trails:
 - Application audit trails
 - System-level audit trails
 - User audit trails




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And, There Was a **Proposed** Rule. .

- **Access report** to patients with:
 - Date of access
 - Time of access
 - Name of the person or the entity accessing the electronic record
 - A description of what information was accessed
 - A description of the action of the user, if available (such as "create", "modify", "access", or "delete").



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PCR Retention




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Is there a record retention recommendation or requirement from CMS or any other Federal agency?



The diagram shows a central circle labeled "RECORDS RETENTION" with arrows pointing to various icons representing different aspects of record management: a document with a plus sign, a document with a magnifying glass, a document with a trash can, a document with a checkmark, and a document with a lock.

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Federal Rules

- No Federal record retention requirement for PCRs
- HIPAA does not set record retention requirements
- Medicare regulations say to maintain documentation relating to **written orders**, certifications, referrals, prescriptions or requests for payments for Part A or B services, items, or drugs for **7 years**



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State Laws Control for PCRs

- State laws that vary
 - Typically 7-10 years but exceptions for minors
 - Public agencies/hospital based may be different
- State laws usually apply to EMS agencies, not vendors or other third parties
- Third parties should retain:
 - Pursuant to contract and liability considerations



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Examples

Pennsylvania. EMS agencies must retain a copy of the EMS PCR for a minimum of 7 years.

Nevada. Healthcare providers are required to maintain medical records for a minimum of five years, or – in the case of a minor – until the patient has reached twenty-three years of age.

North Carolina. Records relating to minors must be retained until the patient has reached thirty years of age.

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Our Recommendation

- Keep for longer of:
 - 10 years beyond date of service
 - If a minor, for the length of statute of limitations after reaching age of majority
- Exceptions
 - Subject to litigation
 - Excluded under policy
 - Another requirement in place (public agencies)




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When an EMS agency goes out of business, what are the retention, custodial, access duties concerning PCRs?



The diagram shows a central circle labeled "RECORDS RETENTION" with arrows pointing to various icons representing different aspects of record management: a document with a plus sign, a document with a magnifying glass, a document with a trash can, a document with a checkmark, and a document with a lock.

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General Rules

- If agency is purchased or merged, usually records go to purchaser or surviving agency
- If there is no purchase/merger:
 - Look to state law
 - Usually provider must find a way (itself or through a third party) securely store and make records available to patients for required length of retention time



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General Rules Under State Law

- Compliance with state retention length and statute of limitations (minors, etc.)
- Many state health departments and licensing authorities govern closures
- In a few states, a state archive or health department will store health records
- Some states say transfer to another provider



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But, Consider Federal Rules

- False Claims Act goes back as far as 10 years
- Medicare auditors can go back 6 years



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HIPAA Permits Sale of PHI in Mergers and Acquisitions

- The Health Information Technology for Economic and Clinical Health (HITECH) Act prohibited the sale of protected health information w/o authorization
- But exceptions -including activities related to the sale, transfer, merger, or consolidation of all or part of the covered entity



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Best Practices for Closure

- If a merger or sale, patient records may be included in the transaction (permitted by HIPAA)
- Patients should be notified, if possible, and given an opportunity to obtain copies
- Destroy any records beyond retention requirements
- Contact malpractice insurance carrier



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Is the record retention length the same for EMS and state agencies?




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Not Necessarily

- State EMS offices are subject to their own retention laws that apply to government entities
- Typically 10 years, but some require much longer







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Access to PCR Data

Steps to Getting Medical Records

-  Contact or visit your provider's medical records department.
-  Complete a medical records request form in person or online.
-  Select your records.







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Who can request a PCR, and who should be in charge of those requests (agency level, state level, vendor)?

Steps to Getting Medical Records

-  Contact or visit your provider's medical records department.
-  Complete a medical records request form in person or online.
-  Select your records.



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Who Can Request Records?

- Patients and legal representatives
- Health oversight agencies
- Payers
- Law enforcement
- Attorneys
- Other providers
- Anyone with legal right to request record




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Who Should Handle Requests?



- Generally, the **EMS agency** is the central repository of the PCR records
 - Must be under HIPAA
- A vendor can be tasked with handling requests, but agency bears ultimate responsibility
- Other third parties have to fulfill requests
 - .e.g. subpoena, state right to know law



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What about body-cam video, or another type of record outside the PCR?

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Look to State Law & HIPAA

- State law may define what a medical record is
- Under HIPAA a “designated record set” includes and data for treatment or payment
- Ability to request depends upon:
 - Language of subpoena
 - Authority under law

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Additional Questions

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Are there any concerns when an agency or third party transfers a **paper** PCR to an electronic PCR?

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Concerns

- Accuracy, timeliness, completeness
- What becomes part of the record (notes)?
- Need BAA with third party
- Third party should not be “authoring” the PCR
- Can lead to poor documentation if not properly utilized

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Best Practices

- EMS agency must maintain original data that was written
- Scan and maintain in digital format if backed up
 - Loss or theft is of paper is a breach
- Practitioner(s) must still review and sign the PCR and make any corrections

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Best Practices


- Use third party familiar with EMS
- Provide to third party:
 - Dispatch protocols
 - Clinical protocols
 - List of current staff and credentials
 - Securely transmit (encrypt) all data

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Does the third party need to sign the PCR?

- No, but need to track the author of the ePCR and anyone who touched the record
- The practitioners need to sign the final PCR



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If an EMS agency takes patient identifiers from their EMS data system, sends them to an HIE, and gets the HIE to send back outcome data on those patients (outside of our ePCR system), does that data fall under the same protections as the rest of the ePCR?



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PHI IDENTIFIERS

De-Identified for HIPAA means removing...

Names	Photographic Images	Vehicle Identifying Numbers
Addresses	Social Security Numbers	Device Identifying Numbers
Dates	Medical Record Numbers	Web URLs
Phone Numbers	Health Plan Numbers	IP Addresses
Fax Numbers	Account Numbers	Biometric Identifiers
Email Addresses	Certification/License Numbers	Any Other Unique Characteristic




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And, there's this. . .

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graph TD
    A[Safe Harbor § 164.514(b)(2)] --> B[Removal of 18 types of identifiers]
    B --> C[No actual knowledge residual information can identify individual]
    
```



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If You De-Identify Under HIPAA


- **HIPAA** does not apply to uses and disclosures of that information
- But still subject to any state law – look to definition of personally identifiable data (PII)
- May still be “personal data” under GDPR if you're subject to that law



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What About the Outcome Data?

- Subject to HIPAA if it is identifiable
- Subject to state laws (PII) and any other laws
- Must be protected in same manner as ePCR data created by agency
- May have to be produced pursuant to legal process (subpoena)



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