



Research Billing Buzz

A Newsletter from the Office of Clinical Research Billing Compliance

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Research Compliance and Documentation

The purpose of documentation is to reconstruct the trial as it happened, provide an audit trail and serves as substantiation of the participant's progress from consent until completion of the study. After all...

“If it wasn’t documented, it wasn’t done”

In July 2018, the FDA announced its finalized guidance on [“Use of Electronic Health Record Data in Clinical Investigations,”](#) giving directions to sponsors, clinical investigators, contract research organizations (CROs), institutional review boards, and other interested parties on the use of electronic health record data in FDA regulated clinical investigations. Some of the key concepts from the guidance are that:

- EHR data improve patient safety, data accuracy, and clinical trial efficiency;
- Study staff can more easily combine, aggregate, and analyze data from multiple sources (orders, notes, etc.);
- EHR systems provide access to real-time and longitudinal healthcare data, and can facilitate post-trial follow up on patients to assess long-term safety and efficacy.
- From this FDA guidance, use of electronic systems for clinical trial documentation and management is encouraged. The efficiency that electronic documentation allows can significantly save documentation time for sites, while promoting continuity of care. Once again, site documentation programs should cover considerations with electronic systems and their features specific to clinical research. It also is

important that the elements of **ALCOA** should be present whether the documentation is paper or electronic

A ttributable	<i>The record identifies who created or modified the record, when the record changed, and why it changed.</i>
L egible	<i>The record and dates of an entry are clear and can be interpreted and understood.</i>
C ontemporaneous	<i>The data are recorded in real-time, the data are observed, and records are signed (or initialed) and dated accurately.</i>
O riginal	<i>The record is original as it is captured, collected, or is an exact facsimile of the original.</i>
A ccurate	<i>The record is collected and recorded honestly and completely to demonstrate transparency.</i>
C omplete	<i>Up-to-date and with no omissions.</i>

ALCOAC

ALCOAC stands for *Attributable, Legible, Contemporaneous, Original, Accurate and Complete*. The term was first conceived in the 1990's by the FDA and it is used by their auditors and other quality assurance professionals. ACOAC is key to Good Documentation Practice (GDP) and it was adopted by the World Health Organization (WHO).

CMS Medical Records Documentation Requirements

Per Medicare guidance: "The billing provider must include *in the beneficiary's medical record* the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review." ([CMS Claims Manual, Chapter 32, Section 69.3](#))

Medical Necessity

It is a good practice to document all visits in the EHR. This is extremely important if any of the study visits (inpatient or outpatient) are billable to the participant's insurance, The documentation must demonstrate medical necessity, in other words, it must clearly state the rationale for tests and orders. It is also imperative that the notes follow coding and documentation guidelines.

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