capella EHR

Version: V6.1

Documentation on Risk Management

This document describes the Risk management details for §170.315(b)(11) Decision support interventions

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Contents

Use of an Artificial Intelligence Language Model in Capella

The use of an Artificial Intelligence (AI) language model for integration into Capella involves several critical components:

- *Purpose and Objectives:* The primary goal of the integrated AI language model is to assist healthcare clinicians by drafting clinical notes for the clinician to review, using historical and real-time patient data (conversation transcripts) from the EHR.
- *Integration with EHR:* the AI language model analyses structured (e.g., lab results, vital signs, medication history) and unstructured data (e.g., physician notes, clinical text, conversation transcripts). The model is integrated into the EHR interface, ensuring seamless workflow integration, and providing a drafted clinical note to clinicians directly within their existing work environment.
- *Data Management:* Patient data is processed and fed into the AI language model. The system ensures that data privacy and security standards (e.g., HIPAA compliance) are maintained, and that the outputs are based on up-to-date, high-quality data.
- *User Interface (UI) Design:* The DSI presents clinical notes clearly and concisely, with explanations to clinicians regarding the factors influencing the draft process.

Development and Training of the AI Language Model

Capella has integrated with an already existing AI language model. Capella does not develop or train the AI language model.

Evaluation of the Draft Clinical Note

Evaluating the effectiveness of the draft clinical note is essential to ensure its value in clinical practice:

- *Clinical Validation:* The model's draft notes are reviewed by clinicians to validate quality of output.
- *Impact on Patient Outcomes:* The goal of the draft clinical note is to produce an output that predicts what the clinician will document based on the visit to help save the clinician time and allow the physician to focus on the patient's care.
- *Clinician Feedback and Adoption:* Clinician acceptance and satisfaction are essential to the success of the system. User feedback is gathered to evaluate how well clinicians are able to incorporate drafted clinical notes into their daily workflow, as well as their confidence in the system's outputs.

Application of Intervention Risk Management Practices

Given the potential risks of predictive errors in clinical decision-making, intervention risk management practices are essential to ensure patient safety and system reliability:

- *Risk Identification:* Potential risks include inaccurate transcriptions or false information included in the drafted clinical note. Inaccurate information could also result in clinician mistrust or overreliance on the system.
- *Risk Assessment:* The likelihood and severity of different risks are assessed by analysing the performance metrics of the AI language model, including its error rates. High-risk scenarios, such as failure to capture key medical information, are given priority in the risk management strategy.
- *Mitigation Strategies:* To minimize risks, Capella uses several strategies:
    - Model Transparency: Outputs from the AI language model are generated as drafts for clinician review and allow clinicians to validate and revise.

- Human Oversight: The model's drafted clinical notes serve as a guide, not as a substitute for clinical judgment. Clinicians are encouraged to consider the model's draft alongside other clinical data and personal experience before making decisions.
- Regular Auditing and Feedback Loops: Continuous monitoring of system performance and clinician feedback ensures that any emerging risks or failures are addressed quickly. Periodic model audits and updates help to maintain accuracy.
- Fail-Safe Mechanisms: The system includes fail-safes, such as requiring clinician verification before the drafted clinical note is posted to the patient's medical record.