AI HEALTHCARE DISCLOSURE AND PATIENT DECISION

Decision record for the specific encounter below. Complete the actual discussion and signatures; generating this form does not itself establish informed consent or delivery of a required notice.

Patient and Encounter

Provider: Example Clinical Services

Address and human contact: Example clinic. Contact the care coordinator for questions.

Patient or record identifier: Alex Example

Patient/provider locations: Massachusetts provider and patient with neither state connection.

Encounter and intended use: Training example for a single encounter. Review the separately stated first-service and visit facts.

Disclosure and decision date: 2026-10-21

The patient is the identified decision maker, subject to the capacity and authority verification recorded below.

Capacity/authority review status: Complete

Tool, Intended Use and Human Role

Tool/version: Example note assistant

Manufacturer or service provider: Example Systems

Function in this encounter: Synthetic example for the stated patient encounter.

Selected role: Documentation

Actual human review, timing, limits and escalation: The treating professional reviews the use and is available to discuss alternatives.

Verified regulatory pathway: Not Device

Regulatory evidence and intended-use limits: Synthetic example for the stated patient encounter.

FDA clearance, De Novo authorization and PMA approval are distinct pathways. De Novo classification may be Class I or Class II; special controls are not universal. A non-device or exempt determination needs

a basis specific to the function and use. An authorization does not guarantee an outcome, establish this patient's consent, or permit uses outside applicable restrictions. Investigational use can require separate research, device and consent procedures that this form does not supply.

Benefits, Risks and Alternatives

Expected benefits and evidence for this patient: Synthetic example for the stated patient encounter.

Material risks, limitations and uncertainty: Synthetic example for the stated patient encounter.

AI can produce incorrect or incomplete results. Generative output may appear persuasive even when inaccurate; that does not mean every system always hides uncertainty. The relevant errors, population performance limits and consequences depend on the actual tool and patient. The explanation above must address this use, rather than substitute generic warnings for material clinical facts.

Actual alternatives, access/cost limits and consequences of declining: Synthetic example for the stated patient encounter.

This form does not promise an equivalent non-AI service or a referral that the provider has not arranged. Discuss available options and any applicable patient rights without pressure or misleading assurances.

Patient Information and Separate Permissions

HIPAA applicability assessment: Not Applicable

Data, sources, recipients, processing and retention: Synthetic example for the stated patient encounter.

Purpose-specific legal bases and restrictions: Synthetic example for the stated patient encounter.

Business associate agreement assessment: Not Required

Agreement or non-requirement evidence: Synthetic example for the stated patient encounter.

The provider reports no model-training or other secondary purpose within the processing described here. A later change requires a fresh purpose, permission and disclosure review.

Privacy review status: Complete

Privacy, recording and safeguards review record: Synthetic example for the stated patient encounter.

This form is **not a HIPAA authorization** or a general recording, research, marketing, sale or model-training permission. HIPAA permits some uses and disclosures without individual authorization under specified conditions; treatment/payment/operations are not the only bases. Research may, for example, involve a qualifying waiver or a limited data set with a data use agreement. Whether a particular AI activity fits a permitted basis depends on its purpose, parties and information. When authorization is

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required, obtain a valid separate authorization. A BAA alone does not make an otherwise impermissible use lawful, and state or other federal rules can add requirements.

Selected Legal and Delivery Review

The following are selected requirements and implementation records, not a complete survey of every applicable law. A form in a chart does not replace a required spoken disclosure, message disclaimer, notice delivered at the proper time, or actual operational controls.

Other applicable requirements and review: Synthetic example for the stated patient encounter.

California Clinical Decision Support Governance

Independent SB503 scope assessment: Not Applicable

Actual scope and review basis: Synthetic example for the stated patient encounter.

Governance review status: Complete

The recorded assessment places this workflow outside the reviewed SB503 scope. Retain the actual basis and reassess material changes; this choice is not a general California-law exemption.

A completed review can document a future implementation plan before an effective date; it must not describe planned controls as already operating. This patient decision record does not perform vendor diligence, bias testing, monitoring or mitigation. Patient agreement, refusal or a signature cannot waive or substitute for provider/developer duties, and these operational records do not authorize treatment or secondary data use.

Questions, Choice and Next Steps

Questions, responses and unresolved concerns: The patient asked about how the identified tool is used.

Discussion completion status: Complete

Recorded choice: agree. Subject to the completed discussion, identified authority and signatures, the decision maker agrees to the specific clinical AI use described in this form. This choice does not approve unrelated treatment or secondary data use.

Human contact, change/withdrawal, copy and retention process: Synthetic example for the stated patient encounter.

Person explaining the tool: Casey Example MD, Example treating physician

Clinical/legal review and notice-delivery record: Example only. For actual care, document actual provider notification, who received it and the applicable follow-up.

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Limits and Decision Record

Nothing in this form waives or limits malpractice, negligence, product-liability or other nonwaivable rights. It does not allocate liability among the provider, clinician and vendor. Existing clinical and professional duties remain governed by applicable law. No choice of the provider's home state excludes other mandatory law. Material changes in the tool, purpose, risks or data processing require renewed review and any legally required disclosure or consent.

The decision maker confirms the choice recorded above for the described encounter after the documented explanation. The signature is not a blanket certification that every legal requirement has been met.

Patient — Recorded Decision

_____ PRINTED NAME

_____ SIGNATURE

_____ DATE

The person explaining the tool confirms that this record accurately describes the explanation and decision documented for this encounter, within their actual role.

Person Who Explained the Tool

_____ PRINTED NAME

_____ SIGNATURE

_____ DATE

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