HYPOTHETICALS #3 & #4

HYPOTHETICAL #3 FDA REGULATION OF AI DIAGNOSTIC SOFTWARE

Scenario

A software company develops an AI application that analyzes chest CT scans and predicts the likelihood of lung cancer. Hospitals begin relying on the software when making treatment decisions.

The company markets the product as being more accurate than radiologists but has not obtained FDA clearance or approval.

Questions

1. Which federal law may apply?
2. Why is FDA oversight relevant?
3. What legal risks exist?

Model Answer

The Federal Food, Drug, and Cosmetic Act (FDCA) may apply because software that performs diagnostic functions can qualify as a medical device or Software as a Medical Device (SaMD).

FDA oversight is relevant because the software directly influences clinical decision-making and patient care.

Potential legal risks include:

• Unlawful marketing of an unapproved medical device. • Regulatory enforcement actions. • Product liability exposure. • False advertising claims if performance claims cannot be substantiated.

Organizations considering deployment should verify regulatory status before implementation.

Key Federal Authority: Federal Food, Drug, and Cosmetic Act; 21st Century Cures Act.

HYPOTHETICAL #4 FALSE CLAIMS ACT & AI-ASSISTED BILLING

Scenario

A hospital system deploys an AI coding platform that automatically assigns billing codes for Medicare reimbursement claims.

After implementation, the system begins consistently assigning higher-paying codes than warranted by the medical documentation. Internal compliance personnel raise concerns, but leadership continues submitting claims without investigation.

Questions

1. Which federal law may apply?
2. What conduct creates liability risk?
3. What should compliance personnel recommend?

Model Answer

The False Claims Act may apply because claims submitted to federal healthcare programs must be accurate and supported by documentation.

Liability risk arises when the organization knowingly submits or recklessly disregards the submission of inaccurate reimbursement claims.

The fact that compliance personnel identified concerns strengthens potential government arguments that the organization acted with deliberate ignorance or reckless disregard.

Recommended actions include:

• Immediate coding audit. • Suspension of questionable claims submissions. • Review of AI system performance. • Documentation of corrective measures. • Potential repayment obligations if overpayments occurred.

Key Federal Authority: False Claims Act; Medicare program integrity regulations.