01

Data integrity & documentation

AI-enabled tools, registries and RWE platforms must demonstrate accurate data capture, human oversight and bias mitigation to avoid FCA and FDCA exposure.

02

Device safety, testing & quality

Government is blending FDCA and FCA theories where device safety tests are manipulated, incomplete, or misrepresented during clearance or reimbursement.

03

Pricing, reporting & market communications

Trials and investigations in 2025 show sustained focus on price reporting, spread pricing and misaligned government submissions.

04

Marketing, patient support & remuneration

Speaker programs, patient assistance and digital marketing claims remain high-risk areas, especially where value transfers may influence clinical use.

1

Diagnosis

AI interpreting imaging, labs or genomics.
Risk: Inaccurate/ Biased results driving unnecessary services.

2

Documentation

AI-generated notes and codes.
Risk: Misalignment between actual clinical encounter and documentation.

3

Treatment planning

Genomics/ Personalized medicine and surgical AI.
Risk: Cybersecurity, inaccurate recommendations, unnecessary interventions.

4

Care delivery & monitoring

Telehealth + wearables.
Risk: Phantom monitoring, inadequate clinical oversight, cybersecurity failures.

5

Billing & chart review

AI-driven risk adjustment and retrospective coding.
Risk: Upward-biased tools “cause” false claims.

6

Follow-up & recurring orders

AI-driven test reminders, monitoring, adherence tools.
Risk: Repetitive claims, AKS theories, consent issues.