

Weighing Technology  
Against Regulatory  
and Compliance Risk



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Meet Your Faculty



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**Objectives**

At the conclusion of this session, you will be able to:

- Understand and articulate the 2026 CMS regulatory changes affecting Home Health.
- Define the core concepts of artificial intelligence.
- Identify the key risk and compliance considerations associated with AI.
- Explain how AI can support clinical practice.
- Evaluate organizational responsibilities in AI adoption.



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**2026 CMS Changes for Home Health**



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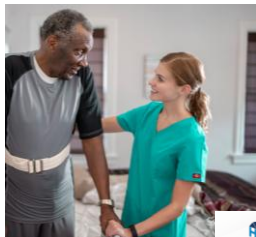
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**2026 Changes of Significance**

- OASIS for all payers
- OASIS E2
- HH VBP Measure Set Changes
- 1.3% Overall payment reduction
- HH CAHPS Updates
- Face-to-Face Encounter Flexibility



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**What is Artificial Intelligence?**

- Software that **enables computers to learn, reason and perform advanced tasks** that once required human intelligence
- It allows machines to **understand language, analyze data and provide helpful suggestions** in real time
- AI systems can **simulate human capacities** like problem-solving, creativity and decision making
- AI combines machine learning, automation and data processing to **support safer, more efficient care delivery**



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**Risks/Concerns with Artificial Intelligence**



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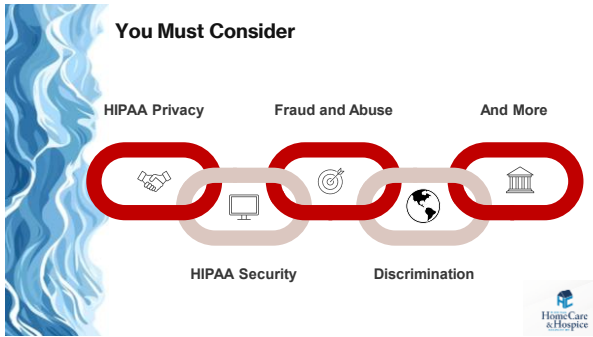
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### Keys To Success

- Clear, well-defined rollout
- Peer-to-peer education to improve adoption and lessen fears
- Reinforces clinical judgement, not replacing it

Hospice Care & Hospice

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### Practical Use Cases

- Documentation support
- Clinical summarization
- Patient communication/education
- Compliant narratives
- Reviewing/condensing MD notes

Hospice Care & Hospice

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**Compliance and AI**

**You will be held responsible for what AI does**

AI should not make decisions. Humans must

AI is not a "deploy it and forget it" tool

Needs to be incorporated into your compliance plan and efforts



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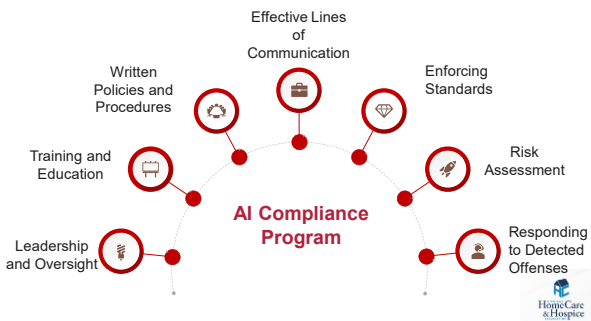
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### NIST Risk Management Framework (RMF)

- National Institute of Standards and Technology (NIST):
  - Identifies risks to systems and data
  - Choose appropriate security controls
  - Implement and test those controls
  - Continuously monitor for threats and weaknesses



It's a **process**, not a checklist!



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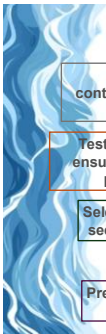
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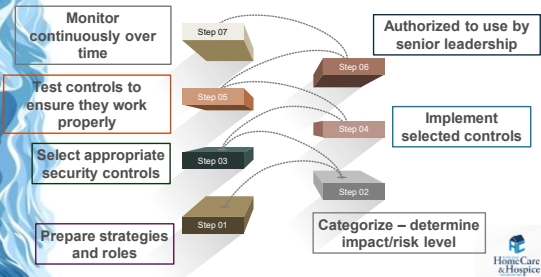
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### 7-steps of the NIST RMF



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### Privacy – HIPAA and PHI

- Will the product ingest your PHI
- How does the vendor safeguard PHI/EPHI
- Will the AI developer or operator be treated as a business associate or covered entity
- Is your PHI used for ongoing development/training of the AI solution



• **Remember: The biggest potential driver for privacy breaches and security incidents is the mistakes individuals make.**



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### Data Security

- Organizations that hold the most data are often targeted by cyber criminals
- How do vendors secure the data in their possession
- Is security a priority or an afterthought
- New technologies introduce new vulnerabilities
- Review the vendor’s security efforts before adoption and regularly thereafter
- Obtain contractual commitments to security. Without such commitment, you may have little recourse



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### Bias/Discrimination



- Biased data can lead to outcomes that have disparate impacts
- Transparency is important to prevent or recognize bias
- Can lead to medical errors, hiring issues or coding errors
- Can result in legal and regulatory liability
- What can the vendor tell you about training the data
- Is it representative of the “universe”



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### Professional Judgement

- Concern that professionals will rely too much on AI
- Can lead to issues, as seen with EMRs and autocomplete
- Double-edged sword
  - Rely too heavily on AI = sued for harm allegedly resulting from overreliance
  - Fail to use AI = sued for harm allegedly resulting from failure to sufficiently utilize AI



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### FDA Regulations

- Software as a Medical Device
- Clinical Decision Support Software
- The traditional FDA review paradigm was not designed for AI, particularly for adaptive AI and machine learning.
- FDA is actively regulating AI and machine learning in medical devices and other healthcare products.



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### Intellectual Property Concerns



- Potential for AI suggestions resulting in Copyright infringement
- Potential for use of training data resulting in IP infringement
- Need to protect intellectual property of AI generated content



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### Risk Management and Insurance

- The various and significant risks require active risk management through a variety of means.
  - Policies and procedures
  - Training
  - Active monitoring and enforcement
  - Contractual protections
  - Insurance



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### THANK YOU

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