

# WELCOME TO THE FUTURE: A HEALTHCARE BOARD'S PRACTICAL GUIDE TO EMERGING HEALTH COMPLIANCE PROGRAM PRIORITIES

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## Presentation Approach

- Practical, concrete guidance for board oversight of a healthcare compliance program
- Summarize best practices for board processes
- Translate legal and enforcement trends into board oversight recommendations (we will NOT get bogged down in legal theory)
- Highlight emerging compliance priorities

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## Emerging Compliance Priorities

- COVID-19
  - Public health emergency plan implementation
  - Suspension of elective procedures
  - Patient and workforce safety
  - Rapid telehealth implementation
  - Financial stress testing
  - Continued board functionality
  - Fraud and billing issues
- Market Realities
  - VBP initiatives
  - Expansion of non-traditional services (telehealth, health care in the home)
  - Reduction/closure of traditional services and facilities
  - Artificial intelligence, technology innovation and big data
  - Private equity, venture capital and non-traditional partners

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## The Fiduciary Challenge

- Board responsibility to assure effective oversight of organization's compliance with laws
- How should a healthcare board approach this, in light of inherent time constraints and technical complexity?
- Need a disciplined framework for the board and management to address compliance challenges tied to forces of disruption
  - Board resources and information
  - Systematically revisit and adapt
  - Compact between management and governance

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## The Stakes

- Legal
  - Organization vs. individual
  - Civil vs. criminal
  - Fines and penalties
  - False claims act
  - Litigation
- Reputational
  - Philanthropy
  - Media, community, patients, workers, recruits
  - Prospective partners, lenders, investors

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## Best Practices for Board Compliance Oversight

- Refresh the tone at the top--compliance as an essential priority
  - Even in trying times and even under enormous strategic, financial and clinical stress
  - Dedicate board and management time to this
- Key executives provide focused reports on compliance issues associated with pandemic and emerging initiatives
- Special board sessions, or dedicated board time, to address compliance issues associated with pandemic
  - Immediate issues
  - Longer-term implications

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## Best Practices for Board Compliance Oversight

- Evaluate current compliance oversight structure
  - Which committee oversees, and does it have sufficient time, expertise and resources?
  - Should a dedicated compliance committee be convened?
  - Assure compliance is not in a silo; integrate compliance oversight with strategic/financial/IT/quality assurance oversight through committee composition overlap, joint committee meetings
- Re-examine subject matter competencies of the board
  - Consider new board or committee members
  - Direct access to key executives; consider outside advisors on select topics

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## Best Practices for Board Compliance Oversight

- Consider updating compliance tools
  - Examine compliance metrics and incentives in emerging areas such as telehealth and VBP
  - Address whether data analytics is being used to enhance compliance
- Examine with CCO/CLO how updating of compliance priorities occurs, and how new enforcement guidance is implemented
- Assure that HR functions are appropriately aligned with compliance priorities
- Assure alignment of organization's compliance program with those of other organizations, as appropriate

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## Key Enforcement Considerations

- DOJ and OIG remain very active in health care enforcement
- Increased use of data analytics tools—focus on outliers
  - Evaluate root causes of organization outliers in billing, reimbursement, quality, and regulatory compliance; if defensible, document explanation
- Fraud enforcement tends to parallel broader health care trends; need to focus on potential for targeted enforcement attention
  - Addiction treatment, telehealth, home health and hospice, DME/orthotics, compounding pharmacies, AI, PE/VC involvement

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## Key Enforcement Considerations

- Areas of regulatory uncertainty present enforcement agencies and whistleblowers with opportunity
  - New final rules governing Stark and AKS offer new flexibility, especially for VBP, but need to navigate carefully
  - Federal Medicaid waivers in context of COVID-19, and state and local emergency orders/suspensions of health care regulations
  - Shifting federal and state regulation, and shifting government and commercial payer policies, regarding telehealth service delivery
- Board should have a focused understanding of how these are being addressed by management

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## Key Enforcement Considerations

- **New DOJ Guidelines on Evaluation of Corporate Compliance Programs (June 2020)**
  - Importance of periodic updates and revisions to compliance program
  - Emphasis on whether compliance program works in practice, including through use of continuous improvement principles
  - Attention to whether the compliance program is adequately resourced and empowered
  - New guidance on targeted training compliance sessions for board and staff
  - New guidance on merger and acquisition-related compliance issues, including post-acquisition compliance auditing and integration

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## Key Enforcement Considerations

- **A Wild Card: The Change in Federal Administration**
  - Will the new Stark and AKS regulations stand unchanged?
  - Enforcement stance and priorities
  - Balancing of VBP and health care access with fraud enforcement
  - Likely emphasis on racial and ethnic disparities in health care delivery
  - Possible new federal Medicare and Medicaid initiatives

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## COVID-19 Compliance Oversight Priorities

- Continued board functionality
  - Evaluate effectiveness of virtual meetings
  - Frequency of board and committee meetings
  - Address mechanisms for board's focus on COVID-19 issues
  - Evaluate adequacy of public health, clinical, telehealth expertise
  - Sustained interface with key executives, including those from compliance and legal leadership teams, as to COVID-specific compliance issues
  - Consider whether board needs independent guidance, resources in certain key areas

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## COVID-19 Compliance Oversight Priorities

- Board should exercise targeted compliance oversight related to:
  - Public health emergency plan implementation, implementation of federal and state waivers, suspension of federal, state and local regulatory requirements
  - Suspension of elective procedures
  - Rapid implementation of telehealth services
  - Modified patient safety and QA protocols
  - Modified workforce safety protocols, vaccination implementation
  - Government funding compliance
  - Financial stress testing

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## Emerging Compliance Oversight Priorities

- **Telehealth expansion**
  - Focused plan for transition from temporary telehealth expansion to enduring expanded virtual healthcare delivery model
  - Address non-traditional telehealth modalities, such as virtual check-ins, e-visits, remote patient monitoring and telephonic visits
  - System to monitor and implement permanent federal and state statutory and regulatory expansions of telehealth and digital health, along with commercial payer coverage policies
  - Associated compliance considerations: credentialing, informed consent, billing/covered services, QA, privacy and security
  - Special compliance note: contractual or other telehealth affiliations

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## Emerging Compliance Oversight Priorities

- **Care in the Home Innovation**
  - Possible launching of licensed home health services, affiliation with independent home care providers, and/or higher acuity “hospital in the home” models
  - Each has distinct compliance considerations, often different from hospital compliance--separate licensure, new PDGM Medicare reimbursement for home health
  - Acquisition of home health agency requires rigorous due diligence, recognition of 36 month rule
  - DOJ and OIG have been especially active in home health enforcement and auditing: billing/coding, kickbacks, medical necessity, homebound status

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## Emerging Compliance Oversight Priorities

- **Downsizing of Services or Closure of Facilities**
  - CMS/Medicaid agency notification
  - State licensure review
  - Possible CON review
  - Possible legal challenges, litigation; be prepared for negative media, elected official, community attention
  - Board oversight and involvement is imperative
  - If triggered by financial distress, this needs to be addressed from compliance perspective and incorporated into approvals and messaging

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## Emerging Compliance Oversight Priorities

- **AI, Big Data and Technology Innovation**
  - Accelerating at astonishing pace, emergence of big data collaborations across health care spectrum
  - Board may need added technical resources to implement its oversight responsibilities
  - Compliance considerations include technology regulation, privacy and security compliance, research compliance, evolving standards of care
  - Special sensitivity related to AI bias
  - Complex compliance considerations if partnering with third parties
  - Board has responsibility to understand and provide direction, and to determine how the governance structure will address AI and related topics

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## Emerging Compliance Oversight Considerations

- **VBP and Risk Assumption**
  - As indicated, there are complex regulatory and legal considerations
  - Board also needs to assure integrated implementation, under broad board guidance
  - Degree of risk assumption, and impact on financial picture
  - Implementation of social determinants of health, non-traditional partnerships, non-traditional services and patient benefits
  - Relationship between VBP and standard of care, QA efforts
  - Expect increased enforcement and auditing in this area

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## Emerging Compliance Oversight Considerations

- **Private Equity/Venture Capital Arrangements**
  - Board must exercise unflinching due diligence
  - Should encompass regulatory and compliance history
  - What loss of control is required/possible?
  - How does the proposed venture advance the organization's mission?
  - How will regulators, elected officials and community respond?

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## Practical Takeaways

- Board leadership needs to set the tone for compliance oversight
- In the midst of competing pandemic and market challenges, this requires focus and discipline
- Board should partner with executive leadership to develop compliance refresh that targets areas of particular relevance such as telehealth, VBP, pandemic issues, expansion or reduction of services, innovative partnerships
- Assure ongoing attention to regulatory and enforcement activity
- Assure best practices in compliance oversight process, paying attention to board resources and competencies in emerging areas

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## CONCLUSION

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Thank You!

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