

## **The Road Ahead**

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## **What We Will Cover**

- **Being an Effective Compliance Officer**
- **Top Compliance Priorities for the Coming Year**
- **How to Mitigate Expanding Risks**
- **Practical Approaches and Strategies**



## The Big Priorities

- \*Dealing with Common Compliance Challenges
- \*Compliance Program Assessments
- Physician Relationships
- Statistical Modeling
- \*240-day Report and Return
- \*Better Positions re: FCA

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## Compliance Officers Might Ask. . . .

- What is my role?
- How do I navigate in my culture?
- How do we deal with legacy issues?
- How do we deal with those who push back and other bad habits?
- What is the legal obligation?
- What is the “right” answer and what is the obligation?
- How do we avoid making things worse?



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## Dealing With Stakeholders

- Who is:
  - A stakeholder?
  - On the team?
  - Conflicted in some way?
  - Kept informed?
  - Not kept informed?
  - Able to influence the investigation?
  - Conveying information and how?
  - The ultimate decision maker?



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## Potential Strategies

- Build relationships in non-crisis situations
- Celebrate small successes
- Get public support from board and leaders
- Be flexible and ask for flexibility
- Call in external prophets as needed

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## Delivering Unfortunate News



- Setting the stage appropriately and timely
- Conditioning for flexibility
- Locking in commitments to “do the right thing” early

Expectations are the Seeds of Resentment. . . .

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## \*Compliance Investigation Orientation

- Comprehensive memo
  - Privilege and work product protection
  - Process
  - Communication
  - Potential outcomes
  - Preventive and remedial steps that may be required
- Right people in the room, wrong people not in the room
- Gain buy-in for the process and potential outcomes, *not* specific results



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## \*Compliance Program Assessments

- Should be a positive endeavor
- Compliance Professionals should seek them
- Great way to engage key stakeholders
- What to ensure:
  - Privilege and work product protection
  - Who is doing the review
  - Understand deliverables in advance
  - Collaborative, forward-looking approach
  - Follow-up processes

ASSESSMENT



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## Developing Personal Limits

- Set in advance, on the ground
- Based on self-awareness
- Anticipate challenges to limits
- Never violated
- No apologies



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## Challenges to Limits

- Underestimating the circumstances
- Denial, rationalization, unjustified optimism
- Get There-itis
- Anti-authority
- Impulsivity
- Resignation



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## Elements of a Personal Code. I Will:

- Be impeccable with my word
- Not take things personally
- Not assume
- Always do my best
- Be consistent
- Follow through
- Not compromise my values



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## Enacting a Personal Code

- Be bold
- Be firm
- Be patient
- Break the chain
- Be aware
- Ask for help



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## Physician Relationships



- Physicians, competitors
- Stark and AKS as FCA Overlay
- Repayment to MAC doesn't make sense, no release
- Disclosure to DOJ → CMS
- CMS Voluntary Disclosure Unavailing
- What to do re: Medicaid?
- \*Legislation to adjust Stark SRDP for technical violations
- \*There are agency and legislative efforts to "modernize" Stark (e.g. value-based payments, alternative payment mechanisms (APMS))

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## Physician Relationships – What We See

- Valuation firms tightening up
- Cookie cutter approaches
- Data disconnects
- Wrong data
- Invalid assumptions
- Lack of communication
- No review of draft reports
- Side deals different from contract
- Practices become different from original assumptions
- Physician expectations set in advance of analysis
- No separation of duties

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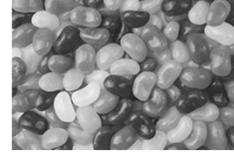
## Physician Relationships – What Not to Do

- Trust existing processes
- Trust what people are telling you
- Rely on old advice
- Fail to question businesspeople, physicians, evaluators
- Fail to document rationales
- Proceed without role definition
- Allow unfortunate email chains to propagate
- Involve too many stakeholders when there is an issue
- Go it alone – need safety valves



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## Statistical Modeling



- Payors and contractors use it
- Providers use it
- Government uses and accepts it
- Courts generally uphold it to calculate FCA damages
- Most courts also require additional, non-statistical evidence of liability (overpayments do not always mean fraud)
- Some courts have refused to allow sampling when the claims require highly unique determinations of medical necessity

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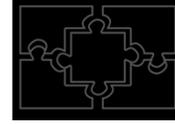
## What is the General Statistical Modeling Process?

- Question to be answered
- Universe of claims to be examined
- Sampling protocol
- Statistical tolerances
- Review tool
- Probe sample
- Comprehensive sample
- Financial estimation (“Extrapolation”)



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## Designing Solid Statistical Modeling

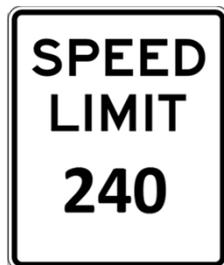


- Key initial decisions impact future viability
- Develop an entire plan before commencing
- Use specialized statistician, reviewer, counsel
- Generate an appropriate review tool
- Timeline and accountability
- Make sure every step is documented, mainstream, and replicable
- Connect the dots: legal arguments and statistical findings

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## 240-day Report and Return

- \*180 days to investigate
- 60 days to report and return
- But: Act with “deliberate speed”



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## \*Better Positions re: FCA

- *Escobar* and its progeny continue to help us
- *Escobar* stringent materiality standard validated
- Medical necessity cases not basis for objective falsehood
- Labs can rely on physician's order
- Statistical sampling can't be used as proof of FCA violation
- Physician upcoding cases on the rise
- DOJ can veto settlements
- DOJ can dismiss cases



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## \*DOJ Has Helped Us

- Sessions Memo, November 17, 2017
  - No more guidance without rulemaking
  - Adjust existing guidance
  - DOJ guidance not binding
  - Cannot be basis for DOJ civil action
- AAG Brand Memo, January 25, 2018
  - Federal agency guidance does not have the effect of law or regulation
  - Adjust existing guidance
  - Guidance not binding
  - Cannot be used to impose different standards than law or regulations
  - Non-compliance with guidance cannot be used as sole basis for civil action
  - HHS-OIG, CMS, FDA

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