

Law & Order-ing: Doubling Down on Life Sciences Arrangements

July 1 – 8:00-9:00 and July 2 – 11:15-12:15

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Agenda

- Key regulatory/compliance considerations and implication in practice
- Best practices regarding development, implementation, and maintenance of common referral source arrangements
 - Key opinion leader engagement
 - Marketing services arrangements
 - Physician-owned distributorships
 - Others
- Critical components to mitigate undue influence
- Perspectives on establishing and operationalizing compliant relationships

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Key Considerations and Implications

- Regulatory overview
- Settlements and current trends
- Areas of focus
 - Pharmaceuticals
 - Medical devices
 - Biotechnology
 - EMRs
 - Other

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Best Practices - Referral Source Arrangements

- Key opinion leader engagement
- Marketing services arrangements
- Physician-owned distributorships
- Others

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Mitigating Undue Influence

- Policies and procedures
- Transparent financial relationships
- Auditing and monitoring
- Other compliance considerations

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Perspectives from the Field

- How do we best establish and operationalize relationships in a compliant manner?
- How do we balance critical need for arrangements with continued regulatory focus?

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Prognostications and Questions

- Mara
- Tynan
- Others?

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