Fraud and Compliance Considerations for Telemedicine and Digital Health: Navigating the Emerging Landscape

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Introduction

Trends and Key Legal Considerations

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Introduction and Trends

Leveraging Technology to Combat Fraud

Role of Technology in Shifting Toward Value-Based Care

Opportunities and Enforcement Related to COVID-19

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Background on Relevant Laws

Anti-Kickback Statute

- Broad scope – often a consideration in structuring arrangements related to the health care industry

New value-based safe harbors

- Scope and applicability
  - Arrangements with full financial risk
  - Arrangements with substantial downside financial risk
  - In-kind remuneration for care coordination
  - Patient engagement tools and supports
- Excluded participants and limited technology participants

Other key safe harbors

- Investments in small entities
- Personal services
- Warranties and discounts
- GPOs
- Managed care
- Electronic prescribing items and services
- Cybersecurity items and services
- EHR items and services

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Background on Relevant Laws

False Claims Act

- Theories of liability
- Causing submission

Stark Law

- Applies to relationships between physicians and entities that furnish designated health services
- New exceptions for value-based arrangements
- Exceptions for technology donations
- Physician ownership still limited

Civil Monetary Penalties Law

- Restriction on remuneration to Medicare and Medicaid beneficiaries that is likely to influence their choice of provider
- Key exceptions:
  - Incentive to promote delivery of preventive care
  - Remuneration that promotes access to care
  - Items and services connected to medical care of individual in financial need
  - Telehealth tech for in-home dialysis
  - Anything covered by an AKS exception

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Background on Relevant Laws

State Laws

- Anti-kickback, false claims, and self-referrals
- Fee-splitting
- Corporate practice of medicine
- Licensure

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Application in Telemedicine and Digital Health

Key Enforcement Trends and Considerations

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Telehealth and Telemedicine

Impact of COVID-19 and CMS waivers

- Coverage flexibilities and their current status
- Cost-sharing and MA coverage flexibilities

Increasing oversight and enforcement

- OIG work plan and audits
- Operation Rubber Stamp, Operation Brace Yourself

Other OIG guidance on telehealth arrangements

- Advisory Opinion 18-03 – provision of telehealth items and services from FQHC look-alike to clinic
- Advisory Opinion 11-12 – arrangement for tele-neuro consults to community hospitals
- Advisory Opinion 98-18 – sublease of equipment to enable telemedicine consultations

Take-aways

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Technology Donations

Incidental Value

- Laboratory provision of computers
- Advisory Opinion 12-20 – free access to electronic interface

Safe Harbors/Exceptions for Technology Donations

- AKS and Stark
- Electronic prescribing, EHRs, cybersecurity
- Consider:
  - What is being donated?
  - Who is the donor?
  - Who is the recipient?
  - Any conditions on the donation?
  - Documentation
  - Nature of technology – interoperability, restrictions on use
  - Recipient contribution (for EHRs)
  - Cost-shifting

Other donations

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Select Health Care Provider Considerations

- Coding compliance
  - Autonomous AI coding
  - Telehealth coding and billing
  - Remote patient monitoring codes
- Partnerships with technology companies, vendors

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Medical Devices and Manufacturers

Reimbursement

- Eligibility for reimbursement
- Indirect Federal health care program funding

Interactions with Health Care Providers

- Marketing and Promotional Activities
- Financial relationships

Enforcement Examples

- NuVasive, Inc.
- Sanford Health
- Covidien LP

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EHRs and Certified Health IT

Federal Funding

- EHR Incentive Programs
- Certified Health IT
- Program evolution

Enforcement Examples

- CareCloud Health
- Athenahealth
- Practice Fusion
- Greenway Health
- eClinicalWorks

Advisory Opinion No. 14-03

- Prohibited remuneration could occur as part of an arrangement with an EHR vendor under which the laboratory would pay a per-order fee for each test order the vendor transmits to the laboratory.

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Recommendations and Compliance Strategies

Legal Considerations for Compliance

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Structuring Deals and Relationships

Assessing applicability of fraud and abuse laws:

i. Are any items or services related to the arrangement reimbursable, directly or indirectly, under a Federal health care program?

ii. As part of a provider's cost accounting, could any funds from a Federal health care program be applied to items or services that are a part of the arrangement?

iii. Do the items or services related to the arrangement trigger the application of state law or EKRA?

iv. What other types of arrangements exist between the parties?

v. Are any individuals or individual relationships compensated (e.g. compensation to a physician)?

Structuring arrangements with potential fraud and abuse implications:

i. Will there be a written, signed agreement?

ii. Does the agreement cover all services that are a part of the arrangement?

iii. How is compensation structured under the arrangement? Who is getting paid what, and how are fees determined?

iv. Are all associated fees based on fair market value and reflected in the agreement?

v. Will there be any free or discounted items or services as part of the arrangement? Why are these being offered?

vi. Is the compensation methodology structured such that a party or parties make more money when more business is generated under the arrangement?

vii. What are the parties' goals and purposes in structuring the arrangement? Are these permissible? Are any revisions to the structure required to clearly and accurately reflect permissible purposes?

viii. What safeguards can and should the parties adopt to minimize risk of violating applicable laws? Carve-outs (but see OIG commentary)? Limitations on referrals? Oversight/metrics? Others?

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Other Considerations

Joint Arrangements Involving Multiple Parties

Advisory Opinion No-17-07:

- Put numerous safeguards in place
- Assess likelihood to increase costs or utilization
- Ensure little interference with clinical decision-making
- Consider the purpose of arrangement
- Consider whether limitation in number of patients involved and monetary investment makes sense for the arrangement

Marketing

Training for appropriate interactions

Avoid undue influence when using technology

Consider appropriate compensation structure

Consult Code of Ethics by industry organizations (e.g. AdvaMed or PhRMA)

Consider limitations from HIPAA marketing rule when PHI is involved

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Internal Controls

OIG Compliance Guidance

Seven elements of an effective compliance program

- Compliance standards and procedures;
- High-level responsibility;
- Employee screening;
- Educational programs;
- Monitoring and auditing;
- Discipline and enforcement; and
- Response and prevention.

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