

Telehealth and Compliance Challenges

HCCA Boston Regional Conference

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FOLEY
FOLEY & LARDNER LLP

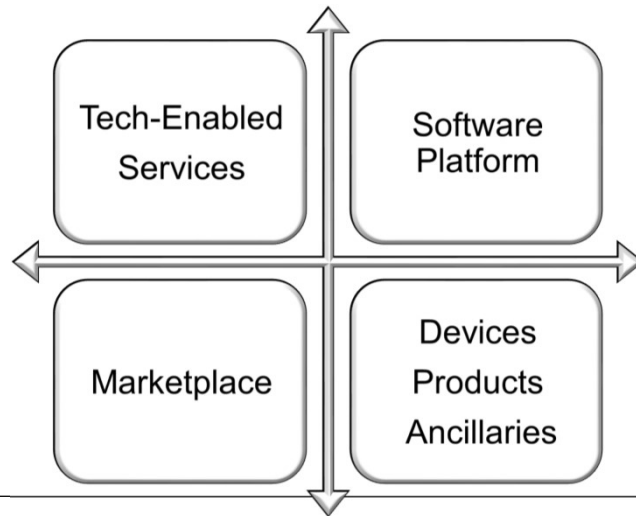
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Agenda

- State Licensure requirements and exceptions
- Telehealth practice standards and establishing a valid practitioner-patient relationship
- Accepted modalities for delivery of telehealth services
- Coverage and Reimbursement
- Direct-to-consumer telehealth, e-commerce, and fraud & abuse issues

2

What Services Do You Offer?



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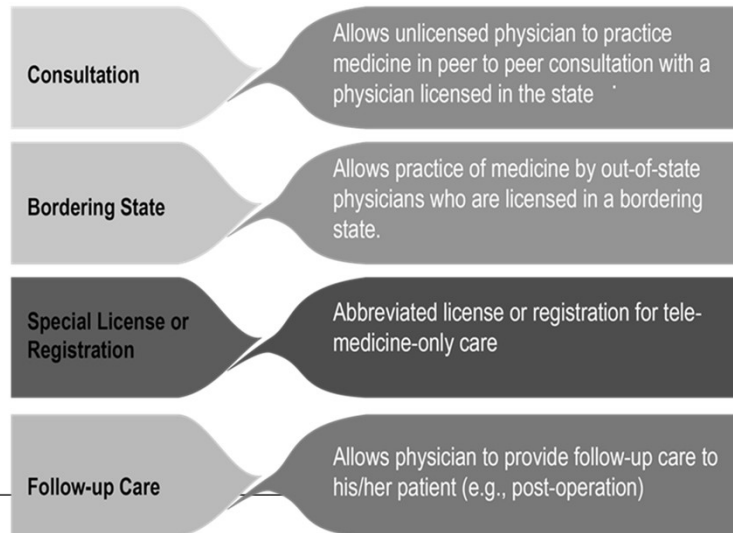
Telemedicine and Licensing

- A physician offering care via telemedicine is subject to licensure rules of the state in which the patient is physically located at the time of the consult.
- State law expressly or implicitly requires licensure if the patient is located in the state at the time of the consult.
- Special rules for VA (pub. May 11, 2018 and eff. June 11, 2018).
- Special rules for military and qualified military contractors when patient is located on base.

4

4

Telemedicine and Licensing



5

Florida Consultation Exception

- **Florida licensure not required for a doctor located and licensed in another state or foreign country who is in actual consultation with a Florida-licensed doctor.**
 - “Any physician lawfully licensed in another state or territory or foreign country, when meeting duly licensed physicians of this state in consultation.” See Fla. Stat. Ann. § 458.303(1)(b).
 - The term “consultation” encompasses the actions of a physician lawfully licensed in another state, territory or foreign country. Such physician is permitted to examine the patient, take a history and physical, review laboratory tests and x-rays, and make recommendations to a physician duly licensed in this state with regard to diagnosis and treatment of the patient. However the term “consultation” does not include such physician’s performance of any medical procedure on or the rendering of treatment to the patient. See Fla. Admin. Code Ann. r. 64B8-2.001(5); Fla. Admin. Code Ann. r. 64B8-9.0141(9)(a),(d).

6

Peer to Peer Consultation Exception

	Must be free	Express Frequency limitations	No established connections or contract/arrangement	No primary diagnosis	No Pathology	No Radiology	Informal/No Written Opinion	No in-state office or meeting place	Other Restrictions
DE		X							
DC									
KY		X		X	X				
MD									
NJ		X			X			X	X
NC		X				X			X
PA									
VA									
WV		X							

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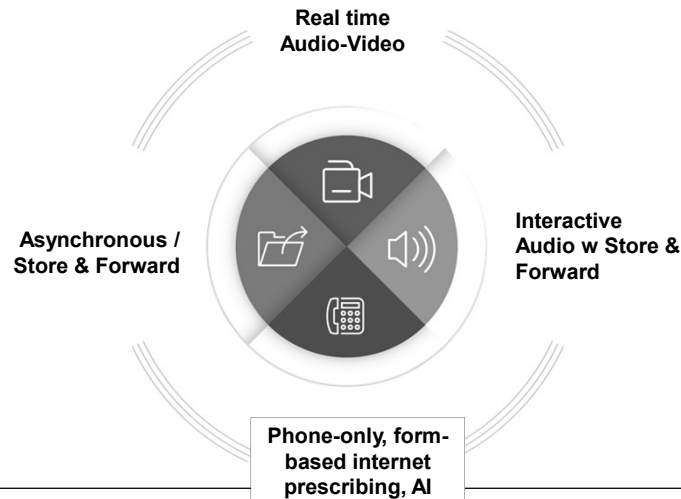
Telemedicine Practice Standards

1	New Patient vs. Established	5	Modality of Communication Technology		Patient Choice of Provider
2	In-Person Exam	6	Remote Prescribing (incl. Controlled Substances)	10	Disclosures
3	Originating Site Restrictions	7	Record-Keeping and Record-Sharing	11	Malpractice & Professional Insurance Considerations
4	Patient-Site Telepresenter	8	Informed Consent	12	Credentialing

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8

Telemedicine and Evolving Modalities



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Characteristics of Asynchronous Telemedicine

- Dynamic, intelligent questionnaires using clinical decision trees based on best practices and evidence-based medicine
- Safeguards and exclusionary criteria
- Established patients with pre-existing doctor-patient relationship
- Incorporates clinically-relevant extrinsic medical information (e.g., photos, videos, diagnostic tests, labs, Bluetooth-enabled devices, prior medical records)
- Identifies the physician, creates a bona fide consult report and medical record, and allows for follow-up questions
- Medically-appropriate uses and emphasis on clinical protocols

10

10

Doctor-Patient Relationship

- Establishing a valid doctor-patient relationship is important because a valid relationship is required prior to a physician issuing an Rx.
- What constitutes a valid doctor-patient relationship varies from state to state.
- Many states do not require an in-person examination to establish a physician-patient relationship.

11

Doctor-Patient Relationship

Some states explicitly allow a physician-patient relationship to be established via telemedicine, e.g., Kansas. HB 2028, § 3(b).

- The next question is what modality is required to establish the relationship via telemedicine.
- Kansas, for example, requires that telemedicine be provided by means of real-time, two-way interactive audio, visual, or audio-visual communications, including the application of secure video conferencing or store-and-forward technology. HB 2028, § 2(a)(5).

12

Doctor-Patient Relationship

Iowa: physicians may establish a valid physician-patient relationship “through telemedicine, if the standard of care does not require an in-person encounter, and in accordance with evidence-based standards of practice and telemedicine practice guidelines that address the clinical and technological aspects of telemedicine.” Iowa Admin. Code r. 653-13.11(7)(b).

- Iowa’s laws and rules do not address what modality is required to establish the physician-patient relationship.

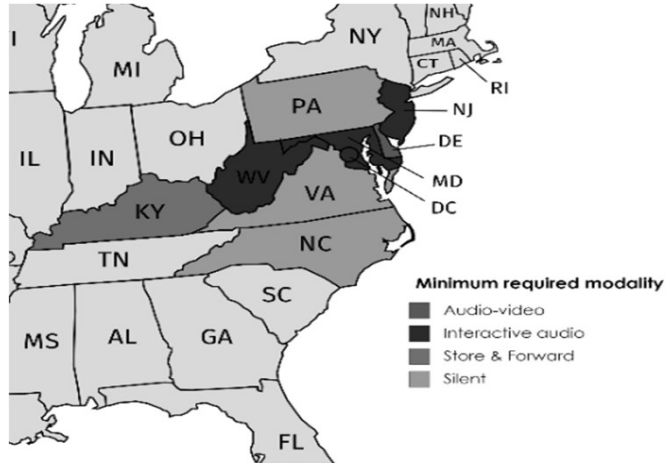
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Doctor-Patient Relationship

- A number of states’ laws and rules do not address whether telemedicine may be used to establish a physician-patient relationship, e.g., Michigan.
- Similarly, Michigan’s laws and rules are silent as to required modality.

14

Minimum Required Modality to Create Doctor-Patient Relationship

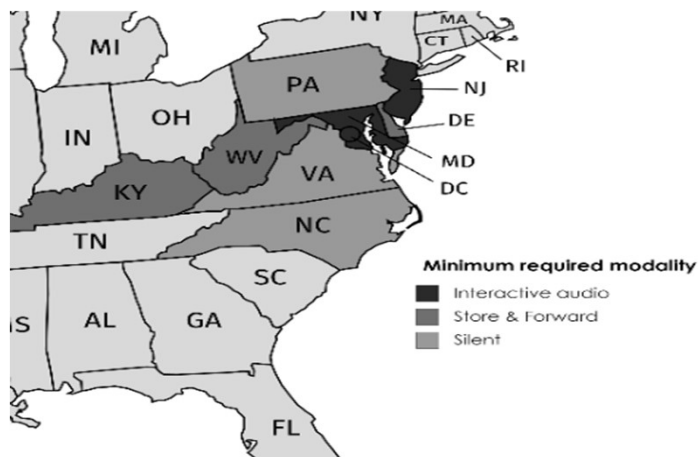


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15

15

Minimum Required Modality *After* Creating Doctor-Patient Relationship



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16

16

Analyzing Telemedicine Modalities and State Law

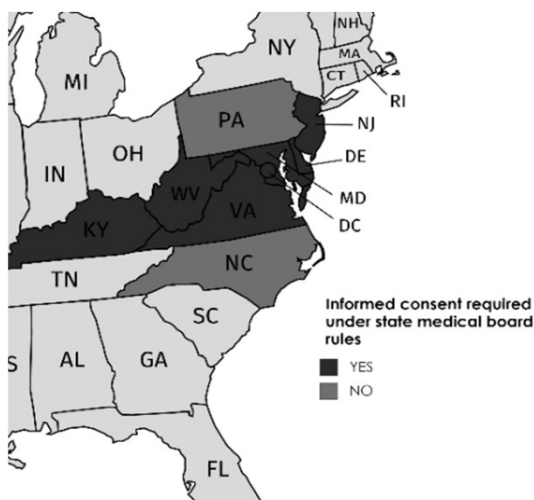
State	Modality used to establish valid doctor-patient relationship	Modality used after creating valid doctor-patient relationship	Modality used to prescribe non-controlled substances	Modality used to prescribe controlled substances	Internet prescribing rule prohibiting internet-based questionnaire?
Arizona	AV: Yes IA: No S&F: No	AV: Yes IA: Yes S&F: No	AV: Yes IA: No S&F: No	AV: Yes IA: No S&F: No	Yes
New Jersey	AV: Yes IA: Yes S&F: No (but may be used with AV and IA)	AV: Yes IA: Yes S&F: No (but may be used with AV and IA)	AV: Yes IA: Yes S&F: No*	AV: Yes (but restrictions for Schedule II) IA: Yes (but restrictions for Schedule II) S&F: Silent	Yes (questionnaire only prohibited before a doctor-patient relationship is established)

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17

17

Telemedicine Patient Informed Consent Requirements

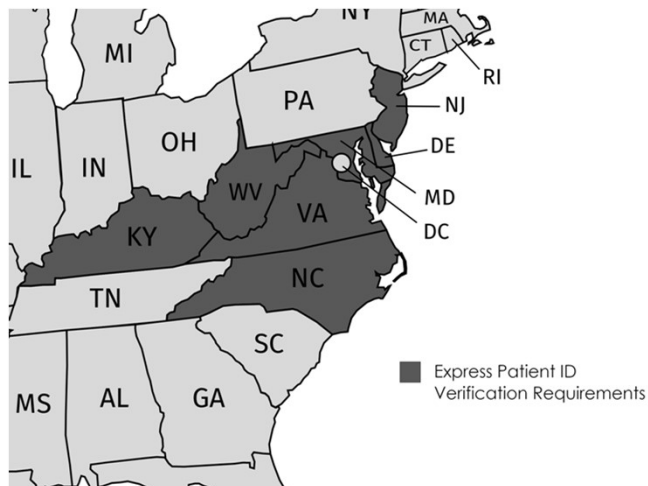


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18

18

Telemedicine Patient ID Verification Requirements

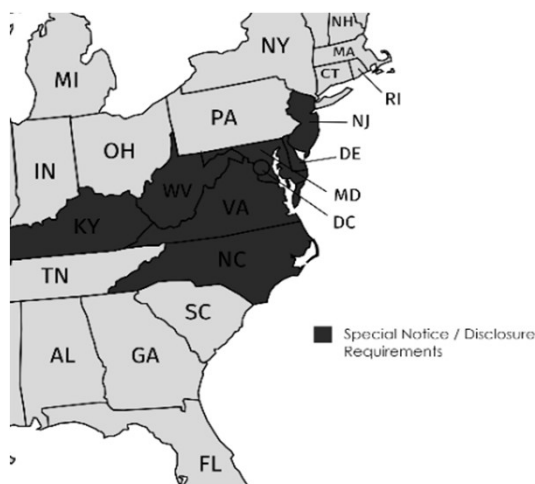


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19

Telemedicine Special Notice/Disclosure Requirements

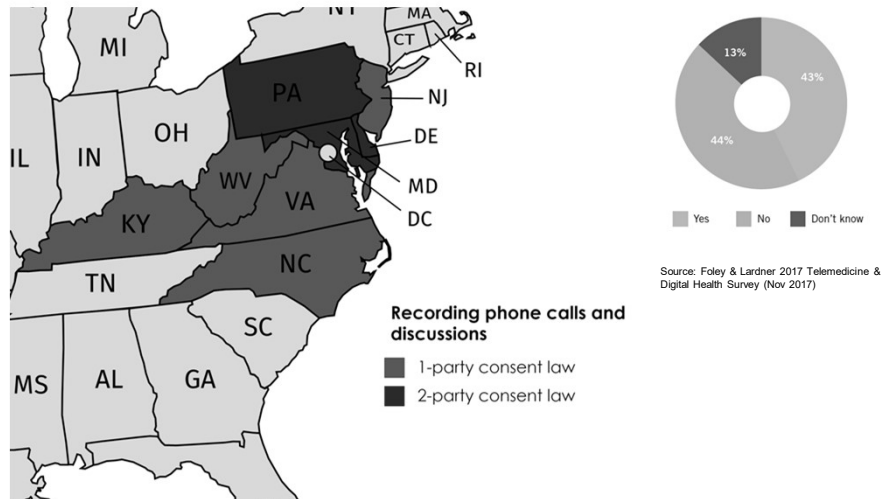


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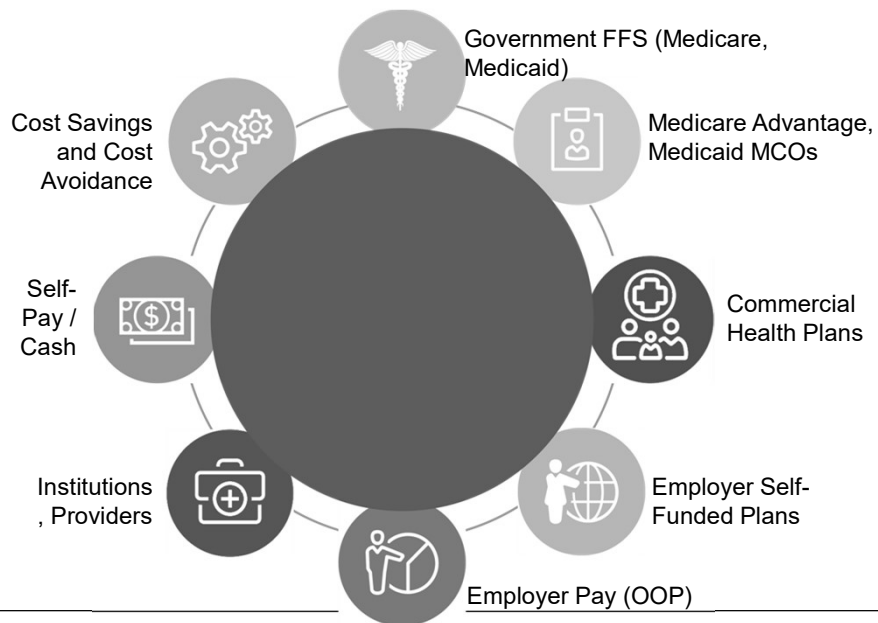
Recording Telemedicine Consults



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What Are the Sources of Payment?

Medicaid FFS

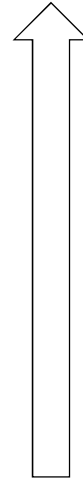
Medicare FFS

Medicaid Managed Care

Medicare Advantage

Commercial Insurance (incl. employer-pay)

Self-Payment (retail medicine)



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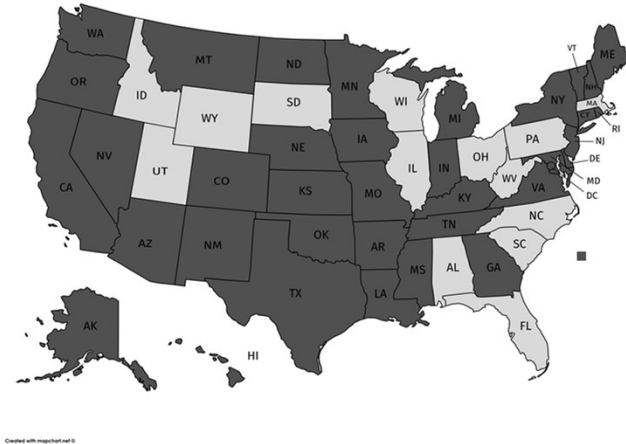
Telehealth Services and Medicare

1. Patient in a qualifying rural area
2. Patient at one of eight qualifying facilities (“originating site”)
3. Service provided by one of ten eligible professionals (“distant site practitioner”)
4. Technology is real-time audio-video (interactive audio and video telecommunications system that permits real-time communication between the beneficiary and the distant site provider)
5. The service is among the list of CPT/HCPCS codes covered by Medicare

24

24

Telehealth Commercial Insurance Laws



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25

25

DTC Telehealth eCommerce Considerations

- Account creation
- Terms of Use
- Online Privacy Policy
- Notice of Privacy Practices
- E-Sign vs. Clickwrap
- FTC guidance for health technology apps
- ADA accessibility and disclosures
- State-specific requirements (disclosures, records management, other practice standards)
- Telephone Consumer Protection Act
- Payment processing and storing CC for recurring payments
- FDA/PhRMA and advertisements

26

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Fraud & Abuse Considerations

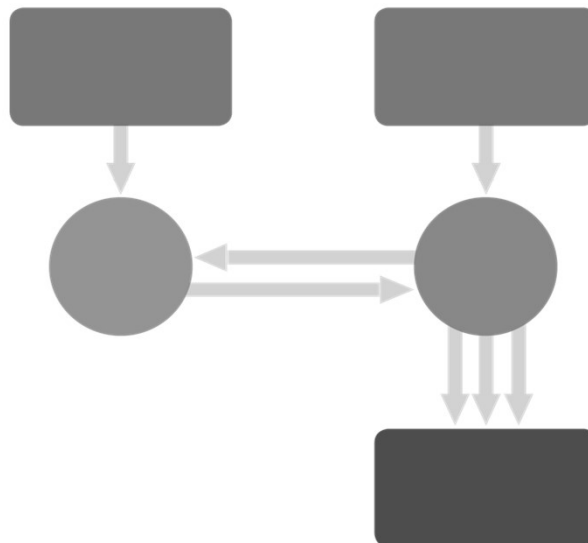
Federal Laws

- Anti-Kickback Statute
- Physician Self-Referral
- Civil Monetary Penalties Law

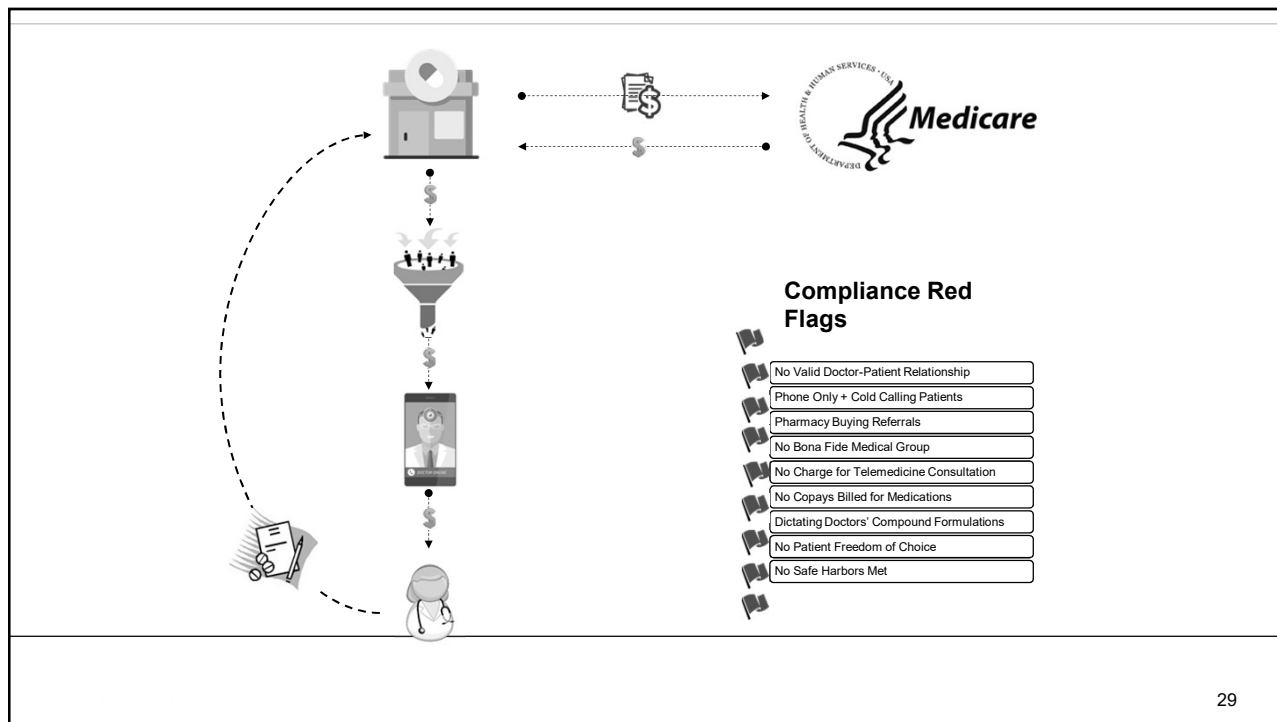
State Laws

- Patient Brokering Acts
- Self-Referral Laws
- Fee-Splitting Laws
- Corporate Practice of Medicine

27



28



29

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30