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Digital Health Developments 2019: Expanded Coverage and Interoperability

Thursday, November 7, 2019

5th Annual North Country Telehealth Conference

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Overview

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1. Historical Background: Medicare Coverage of Telehealth
2. Recent Developments in Medicare Fee-for-Service
3. Medicare Advantage and Telehealth
4. Interoperability
5. Other Digital Health Developments
6. Enforcement Activity

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Historical Background: Medicare Coverage of Telehealth Services

In the beginning …

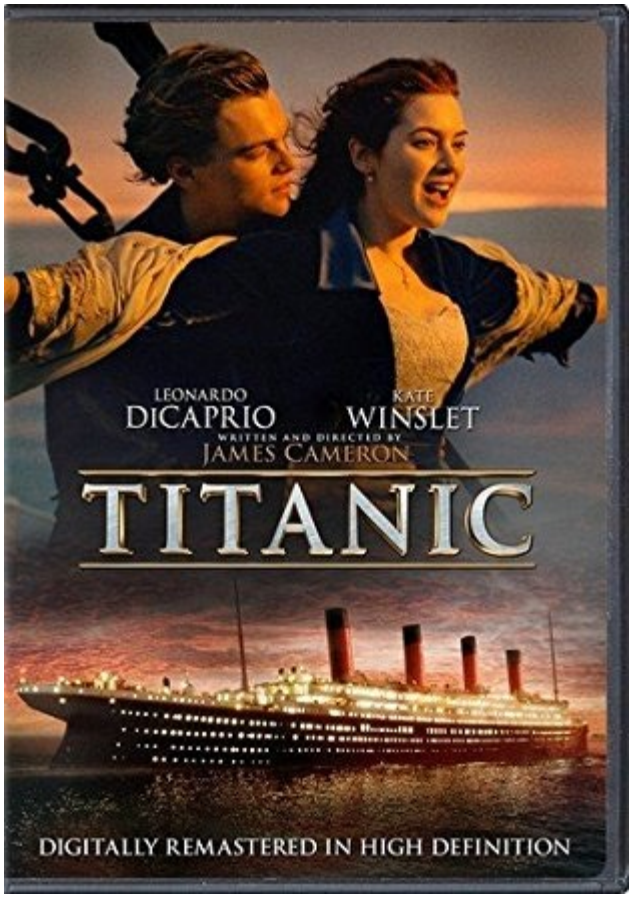
- Balanced Budget Act of 1997 authorized reimbursement for telehealth services.
- Intended to benefit rural beneficiaries, combat access issues.

Ask yourself …

1. How has healthcare technology changed in 20 years?

2. How has the practice of medicine changed in 20 years?

Remembering 1997



Medicare Telehealth Services v. Colloquial Meaning of Telehealth

- Colloquial Meaning of Telehealth (three modalities)
  - Real time, interactive
  - Remote patient monitoring
  - Store-and-forward
- "Telehealth Services" for purposes of Medicare reimbursement: with limited exceptions, must use interactive audio and video telecommunications system that permits real-time communication

Medicare Geographic Restrictions

- Medicare reimbursement of telemedicine is historically very restrictive.
- "Medicare telehealth services" are only paid if the patient is in a health professional shortage area ("HPSA") or a county that is not a metropolitan statistical area ("MSA") (unless an exception applies). 42 C.F.R. 410.78(b)(4).
- Pro Tip: Use CMS "HPSA Find" tool.

Medicare Originating Site Restrictions

- The patient must be located at an approved originating site to be eligible for Medicare reimbursement.
  - Physician or practitioner offices
  - Hospitals/Critical Access Hospitals
  - Hospital-based or CAH-based renal dialysis centers
  - Rural health clinics
  - Federally qualified health centers (FQHCs)
  - Skilled nursing facilities (SNFs)
  - Community mental health centers
  - Renal dialysis facilities (for monthly ESRD treatment) *(newer)*
  - The patient's home – **only** for monthly ESRD treatment, or SUD treatment or a co-occurring mental health disorder *(newer)*
  - Mobile Stroke Units (*newer)*

Medicare Telehealth Services

- CMS publishes a list of services that may be reimbursed via telehealth annually. It is located on the CMS website. Examples include:
  - Office or other outpatient visits
  - ED or initial inpatient consultations
  - ESRD services
  - Individual and group kidney disease education
  - Individual psychotherapy
  - Psychiatric diagnostic interview examination
  - Stroke services
  - Depression Screening
  - Smoking Cessation

If the service isn't on the CMS list, it isn't covered for Medicare FFS beneficiaries, unless an exception applies.

https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.html

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Recent Developments in Medicare Fee-for-Service

2019 PFS

- “For CY 2019, we aimed to increase access for Medicare beneficiaries to physicians’ services that are routinely furnished via communication technology … we do not consider them to be Medicare telehealth services.”

- “Communication Technology Based and Remote Evaluation Services” are born!

CTBRES: Virtual Check-ins: G2012

- Historically, routine non-face-to-face communication before or after a visit was bundled in the payment for the visit itself.
- Reimbursement for virtual check-in used to determine whether office visit or other service is warranted.
  - Established patients only
  - Not related to service provided within previous 7 days or next 24 hours or soonest available appointment
  - Can be completed by audio-video or audio-only
  - Interaction must be with billing practitioner
  - Requires verbal consent, documented in medical record
  - Beneficiary co-payment is not waived (cost-sharing applies)
- *Because CMS has excluded these services from "Medicare Telehealth Services," Medicare's statutory reimbursement restrictions do not apply.*
- *Reimbursement is limited.*

Use of G2012?

- Whose organizations are utilizing G2012?
  - Benefits?
  - Challenges?
  - Lessons learned?

CTBRES: Store-and-Forward Consults: G2010

- Reimbursement when practitioner uses recorded video and/or images captured by a patient in order to evaluate condition.
- Used to determine whether office visit or other service is warranted.
- Includes interpretation and follow up with patient.
  - Established patients only
  - Not related to service provided within previous 7 days or next 24 hours or soonest available appointment
  - Follow-up can be completed by phone, audio-video, secure text messaging, email, or patient portal
  - Must be video and/or image (questionnaire not sufficient)
  - Requires verbal or written consent (could be electronic), documented in medical record
  - Cost-sharing applies

CBTRES: Interprofessional Consults, 99446-99449, 99451-99452

- Reimbursement for consultations when a patient's treating physician or other qualified health care professional requests opinion/advice of a consulting professional with specific specialty expertise.
- Currently, specialist input is often sought through scheduling a separate visit with the patient when a consult between professionals would be sufficient.
- Aligns with shift towards patient-centered "medical home" model, where primary care is involved in care management, team-based approach.
  - Requires verbal or written consent (could be electronic), documented in medical record
  - Cost-sharing applies
  - Requirements for use of each code varies slightly, including time spent

Remote Patient Monitoring

- CMS has introduced new CPT codes for Chronic Care Remote Physiological Monitoring.
  - 99453: Pays for initial equipment set-up and patient education.
  - 99454: Pays for interpretation/monitoring of information from devices that communicate clinical information on a daily basis. Only available for established patients.
  - 99457: Remote physiological treatment management services. To bill using this code, the patient must receive at least 20 minutes of interactive treatment each month.
    - Proposed 2020 PFS – would include add-on code for additional time, and all general as opposed to direct supervision

Other 2019 Developments – Additional Telehealth Services

- CMS has authority to add services to the list of Medicare telehealth services if certain criteria met.
- Added HCPCS Codes G0513, G0514 for prolonged preventive services in the office or outpatient setting requiring direct patient contact beyond the usual service.
- Proposed 2020 PFS would add codes for treatment of opioid use disorder, complementing current policy on treating SUDs via telehealth.

Other 2019 Developments

- **Home Dialysis ESRD beneficiaries** – expanded originating site requirements and removal of geographic restrictions.
  - Monthly ESRD-related clinical assessments via telehealth; if elected must receive a face-to-face visit at least monthly for first 3 months and at least once every 3 consecutive months after.
  - Applies to physician's monthly clinical assessment of a home dialysis ESRD patient (also known as the physician's Monthly Capitation Payment or MCP).
  - Originating site can be a hospital, renal dialysis facility, or home.
- **Acute Stroke Services** – expanded originating site requirements (mobile stroke unit) and removal of geographic restrictions.
- **SUD treatment** – expanded originating site requirements (home) and removes geographic restrictions.

Examples of Exceptions/Waivers

- Next-Gen ACOs, BPCI participants, Comprehensive ESRD Care Model (CEC) and other entities accepting down-side risk may be able to provide telehealth services without standard Medicare limitations.
- MSSP ACOs in two-sided risk models – waiver of geographic restrictions, inclusion of home as originating site beginning performance year 2020.
- CMMI – Emergency Triage, Treat, and Transport (ET3) Model – anticipated start of 2020.
- CMMI – Artificial Intelligence (AI) Health Outcomes Challenge.

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Medicare Advantage and Telehealth

Medicare Advantage and Telehealth

- Effective 1/1/20, BBA 2018 authorized MA plans to provide "*additional* telehealth benefits" and treat as basic benefits:
  - available under Part B
  - clinically appropriate through electronic exchange, i.e. "consistent with professionally-recognized standards of care"
- Can still offer supplemental benefits as telehealth, as well as "traditional" telehealth benefits under Sec. 1834(m).
- CMS expects plans—which are required to coordinate care in MA—to coordinate care provided through telehealth as well.
- CMS defines electronic exchange as "electronic information and telecommunications technology" but declines to cite examples.

Beneficiary Safeguards

- Standard beneficiary protections, e.g. confidentiality, marketing, appeals and grievances, apply.
- Beneficiary must be offered the choice of receiving a Part B service as a telehealth benefit or in-person.

Plan Requirements

- Comply with existing provider selection and credentialing requirements and ensure that providers are complying with any state requirements (e.g. licensing) for the state in which a beneficiary resides.
- Utilize only plan contracted providers if offered as part of basic benefits; if not, then may only be offered as a supplemental benefit.
- In offering “additional telehealth benefits” the cost is added to the plan bid for basic benefits, *excluding capital and infrastructure costs* that are incurred or paid by the plan.
- Plans may not provide enrollees with certain items such as internet service or installing telecommunications systems in the home.

Future Considerations

- While no action at this time, CMS is considering whether and if so how, telehealth could be a factor in MA network adequacy standards.
- Additional, sub-regulatory guidance around bid submission, provider directory information; examples of technology—but not an exhaustive list.

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Interoperability

Overview

On February 22, 2019, the Centers for Medicare & Medicaid Services (“CMS”) and the Office of the National Coordinator for Health Information Technology (“ONC”) issued two proposed rules and related Requests for Information (RFIs) intended to advance interoperability and increase patient access to health information.

As proposed, they will not take effect until early 2020.

Overview

1) Background and context – HHS on interoperability in recent years
2) CMS Proposed Rule

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Background: Understanding HHS and Interoperability

HHS and Interoperability

- Health Information Technology for Economic and Clinical Health (HITECH) Act
- Medicare Access and CHIP Reauthorization Act (MACRA)
- Promoting Interoperability Programs
- Care Coordination and Trusted Exchange Networks

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CMS Proposed Rule on Interoperability and Patient Information

CMS Proposed Rule: What does it require of payers?

- Information Blocking
- Application Program Interfaces (API)
- Health Information Exchanges and Care Coordination Across Payers
- Care Coordination and Trusted Exchange Networks

CMS Proposed Rule: Information Blocking

"Information blocking" is a practice that "is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information." 42 U.S.C. 300jj-52(a).

Examples of information blocking:

- Withholding data
- Intentionally limiting or restricting the compatibility or interoperability of health IT

CMS Proposed Rule: Application Program Interfaces

CMS' (and ONC's) objective:

"Every American should be able, without special effort or advanced technical skills, to see, obtain, and use all electronically available information that is relevant to their health, care, and choices – of plans, providers, and specific treatment options."

CMS Proposed Rule: Application Program Interfaces

If finalized, the Rule will require CMS-regulated payers to adopt and implement an “openly published” API, which will allow third-party software applications to retrieve, with the approval and at the direction of the patient, clinical and payment information.

CMS Proposed Rule: Application Program Interfaces

What does an API actually do? What function does it serve?

APIs create compatible “plugs and sockets” which enable different applications to connect and exchange data. CMS wants patients to be free to use any third-party app to view their health information. The API provides the connection to a payer’s data that makes the information available to the third-party app.

CMS Proposed Rule: API Requirements

The API must be:

1. Standardized – APIs must use modern computing standards.
2. Transparent – payers must make freely and publicly accessible the specific business and technical documentation necessary to interact with an API.
3. Pro-Competitive – practices that support efficient access to, exchange of, and use of electronic health information, supporting a competitive marketplace that enhances consumer value and choice.

CMS Proposed Rule: APIs, Privacy and Security

Many stakeholders have expressed concerns about privacy and security obligations. Covered entities remain subject to the requirements of HIPAA when granting access to a patient's information via an API.

Covered entities implementing APIs must "take reasonable steps to ensure an individual's information is only disclosed as permitted or required by law."

Plans can "deny access to the API if … would present an unacceptable risk to the security of PHI on the organization's system …"

CMS Proposed Rule: OCR FAQ Guidance

FAQ 2039: What is the liability of a covered entity in responding to an individual's access request to send the individual's PHI to a third party?

Covered entities implementing APIs must "take reasonable steps to ensure an individual's information is only disclosed as permitted or required by law."

FAQ 2060: Do individuals have the right to have their PHI transferred as they request, even if the requested transmission is unsecure?

Yes, as long as the PHI is "readily producible" in the manner requested, and the transfer wouldn't present an unacceptable level of risk to the security of the PHI on the covered entity's systems, e.g., risks from connecting an outside system, app or device directly to a covered entity's systems.

CMS Proposed Rule: OCR FAQ Guidance

FAQ 2040: What is a covered entity's obligation under the Breach Notification Rule if it transmits an individual's PHI, and the covered entity learns that the PHI was breached in transit?

If the information is "unsecured PHI," the covered entity must notify the individual and HHS and comply with the HIPAA Breach Notification Rule. ***However,*** *if the individual requested that the PHI be transferred, and the covered entity warned them that it was unsecure and the individual said to transfer the information anyway, the covered entity is not responsible for a breach that occurs during the transmission, including any data breach notification obligations.*

CMS Proposed Rule: APIs and Compliance

CMS has proposed that plans will need to do routine testing and monitoring of APIs to assure that they comply with HIPAA (both the privacy and security rules) and maintain high standards around protected health information ("PHI").

Payers, providers and others utilizing APIs will need to develop robust policies and procedures to ensure that their APIs are regularly monitored, tested, and maintained. They will also need policies and procedures to ensure that members of the organization follow the guidance in the HIPAA FAQs, and document all actions taken.

CMS Proposed Rule: Health Information Exchanges and Coordination of Care Among Plans

The CMS proposed rule requires CMS-regulated payers to maintain a process enabling the electronic exchange of the types of data that must be accessible via APIs. If asked by a beneficiary, plans must:

- Forward their information to a new plan or other entity designated by the beneficiary for up to 5 years after the beneficiary has dis-enrolled from the plan;
- Accept data about a beneficiary from any other payer that has covered the patient in the preceding 5 years;
- Integrate any information they receive from another plan about a beneficiary into the beneficiary's medical record.

CMS Proposed Rule: What about bad actors?

CMS understands that there are circumstances where it would be irresponsible for a plan to allow a third-party app to access a patient's health information, and created a series of information blocking exceptions, which are set forth in the ONC Proposed Rule.

CMS Proposed Rule: Care Coordination and Compliance

Payers will need to ensure that they develop and implement strong policies and procedures concerning care coordination with other payers, and that they are facilitating adequate internal training for staff.

CMS Proposed Rule: Trusted Information Exchanges

21st Century Cures Act Section 4003(b)

"The National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include …"

- A method for authenticating Tax Identification Number (TIN) participants
- A common set of rules for trusted exchange
- Organizational and operational policies to enable the exchange of health information
- A process for filing and adjudicating noncompliance.

CMS Proposed Rule: Trusted Information Exchanges

In other words, healthcare industry stakeholders will need to satisfy the requirements of the Common Agreement.

This includes technology developers, providers, individuals, government agencies, health information networks, and public and private organizations and agencies working to promote the public health.

This, too, will require robust policies and procedures and proactive training of staff.

CMS Proposed Rule: What does it require of providers?

- Information Blocking Attestations
- Admission, Discharge and Transfer (“ADT”) Messages
- Provider Digital Contact Information

CMS Proposed Rule: Information Blocking Attestations for Clinicians, Hospitals and CAHs

Attestation 1: Clinician must confirm that they did not knowingly and willfully **restrict compatibility of interoperability of certified EHR technology** (*i.e.,* they did not engage in information blocking).

Attestation 2: Clinician must confirm that they **implemented technologies, standards and procedures needed** to ensure that certified EHR technology is connected and operating optimally at all times.

Attestation 3: Clinician must confirm that they **responded in good faith and in a timely manner** to requests to retrieve or exchange electronic health information.

CMS Proposed Rule: Revised Conditions of Participation for Hospitals

Hospitals must satisfy Medicare “Conditions of Participation” or “CoPs” to participate in Medicare.

The Proposed Rule introduces a new CoP, requiring certain hospitals to send electronic patient event notifications when a patient is **admitted, discharged, or transferred** to another community provider or facility.

The notifications would include basic demographic and diagnostic information about the patient.

CMS Proposed Rule: Provider Digital Contact Information

CMS previously updated the National Plan and Provider Enumeration System ("NPPES") to capture the digital contact information of providers and facilities.

Because many providers and facilities were not complying, CMS is proposing to publicly report the names and national provider identifiers ("NPIs") of providers who fail to add their digital contact information to the NPPES beginning in the second half of 2020.

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CMS Requests for Information on Advancing Interoperability

CMS RFIs: Advancing Interoperability

With the proposed rules on interoperability, CMS also issued two requests for information ("RFIs") from stakeholders on specific interoperability issues.

1. Strategies for advancing interoperability across care settings, focusing on interoperability and EHR technology challenges in the post-acute care space.
2. Information on how to improve patient matching efforts.

Key Considerations and Next Steps

- There is no specific timeline to finalize the proposed rules. As proposed, would be effective 2020, but noted:
  - "We additionally note that based on public comments received on this proposed rule, we will adjust the effective dates of our policies to allow for adequate implementation timelines, as appropriate."
- Congress has also been monitoring this activity and has been relatively supportive, although flagging the need for appropriate transition time.

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Enforcement Activity and Additional Scrutiny

Overview: Federal Anti-Kickback Statute

Anti-Kickback Statute, 42 USC § 1320a-7b(b)

- Makes it illegal to knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals or generate federal health care program business
- Violation may be found if “one purpose” is to induce referrals, even if there are other legitimate purposes for the payment
- Voluntary safe harbors

Overview: Civil Monetary Penalties – Beneficiary Inducement

Civil Monetary Penalties, 42 USC 1320a-7a(5)

- Prohibits the offer or transfer of remuneration that a person knows or should know is likely to influence a beneficiary's selection of a particular provider for items/services payable under Medicare or Medicaid
- Certain exceptions apply
  - Example: under $15, $75 aggregate
  - Example: promoting access to care, low risk of harm

- OIG Advisory Opinion 19-02 – provision of smart phones to beneficiaries for RPM
- Oct. 17, 2019 OIG Proposed Rule

Overview: Federal Physician Self-Referral Law (Stark)

	THE ANTI-KICKBACK STATUTE (42 USC § 1320a-7b(b))	**THE STARK LAW** (42 USC § 1395nn)
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business	• Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies • Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items/ Services	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	• No intent standard for overpayment (strict liability) • Intent required for civil monetary penalties for *knowing* violations
Penalties	Criminal: • Fines up to $25,000 per violation • Up to a 5 year prison term per violation Civil/Administrative: • False Claims Act liability • Civil monetary penalties and program exclusion • Potential $50,000 CMP per violation • Civil assessment of up to three times amount of kickback	Civil: • Overpayment/refund obligation • False Claims Act liability • Civil monetary penalties and program exclusion for *knowing* violations • Potential $15,000 CMP for each service • Civil assessment of up to three times the amount claimed
Exceptions	*Voluntary* safe harbors	*Mandatory* exceptions
Federal Health Care Programs	All	Medicare/Medicaid

Summary from OIG online compliance materials

Common Misconceptions – Fraud and Abuse Laws Applied to Telehealth

- All the same rules still apply!
  - Common themes: fair market value compensation, set in advance, commercially reasonable
- Misconception #1: “I don’t need to worry about fraud and abuse laws because there aren’t referrals in telehealth…”
- Misconception #2: “I don’t need to worry about fraud and abuse laws because there are no governmental payors…”
- Misconception #3: “I think this arrangement is fine because [insert competitor name] is doing it…”

Federal False Claims Act, 31 USC 3729

- Prohibits “knowingly” submitting or causing to be submitted false or fraudulent claims for payment or false statements or certifications to the government (31 USC 3729)
  - Treble damages and penalties
- Related Criminal Health Care Fraud Statutes
  - 18 USC 287
  - 18 USC 1001
  - 18 USC 1035
  - 18 USC 1347
- Exclusion, CMPs

DOJ Enforcement Activity

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FOR IMMEDIATE RELEASE — Tuesday, April 9, 2019

Federal Indictments & Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Telemedicine and Durable Medical Equipment Marketing Executives Results in Charges Against 24 Individuals Responsible for Over $1.2 Billion in Losses

Hundreds of Thousands of Elderly and/or Disabled Patients Nationwide and Abroad Lured into Criminal Scheme; Center for Program Integrity, Center for Medicare Services, Takes Administrative Action Against 130 DME Companies That Submitted Over $1.7 Billion

DOJ Enforcement Activity

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FOR IMMEDIATE RELEASE Monday, October 15, 2018

Four Men and Seven Companies Indicted for Billion-Dollar Telemedicine Fraud Conspiracy, Telemedicine Company and CEO Plead Guilty in Two Fraud Schemes

On October 12, 2018, the District Court for the Eastern District of Tennessee unsealed a 32-count indictment charging four individuals and seven companies in a $1 billion health care fraud scheme. The court also unsealed an additional two plea agreements and an information charging another individual and his company for their role in the scheme.

Overview: OIG Telehealth Report April 2018

- "CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements"
- Post-payment audit of telehealth claims processed by CMS in 2014 and 2015
- Of the 100-claim sample, OIG determined that 31 of the claims paid by CMS did not satisfy the "Medicare telehealth services" requirements
- Most frequently, the claims failed to satisfy the "originating site" requirement
- Recommendation that CMS continue to engage in post-payment audits of telehealth claims

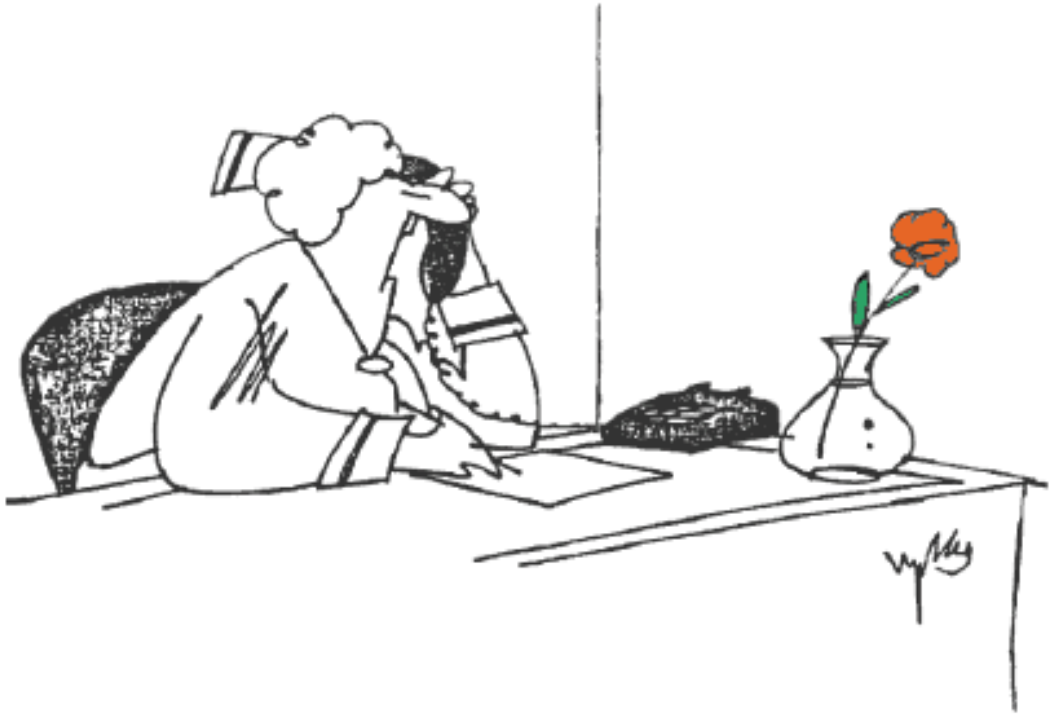
Increased Scrutiny - DTC

- Direct-to-Consumer market, online questionnaires, online prescribing
- Recent State Medical Board actions – implications for licensure
- April 2, 2019 NYT article:


The New York Times

Drug Sites Upend Doctor-Patient Relations: 'It's Restaurant-Menu Medicine'

Establishment of a Physician-Patient Relationship



"The doctor isn't in right now. When you hear the beep, please leave your name, number and a short diagnosis."

Compliance Checklist for Physician Practices – Snapshot of Key Considerations to Mitigate Risk

- ✓ Patient informed consent
- ✓ Verification of patient identity
- ✓ Licensure in the state where the patient is located
- ✓ Sufficient establishment of physician-patient relationship
- ✓ If e-prescribing, consider federal and applicable state requirements
- ✓ Accurate coding, including place of service
- ✓ When appropriate, claims submitted for both originating and distant sites
- ✓ Documentation in medical record to support claim, including medical necessity of any referral/order
- ✓ Use of a secure platform
- ✓ Compliance of arrangements with federal (if applicable) and/or state fraud and abuse laws, including anti-kickback and self-referral laws
- ✓ Review of private payor contracts – is it clear if telehealth services are covered, and the applicable payment?
- ✓ Policies and procedures

Compliance Checklist for Physician Practices – Snapshot of Key Considerations, continued

- ✓ Periodic review of internal practices – compliance efforts are ongoing
- ✓ Auditing – spot check of records, coding reviews
- ✓ Inventory of vendor agreements
  - Corporate structure
  - Fees
  - Data privacy and security – do you need a business associate agreement?
  - Business protection – insurance, indemnification, termination rights
  - If it seems too good to be true…
- ✓ Monitor regulatory developments – telehealth landscape is rapidly changing
- ✓ Work with your legal and compliance teams, or consult with outside resources

Thank You!
Questions?

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