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2019 Primary Care Conference
Physician Law: An Evolving Trend

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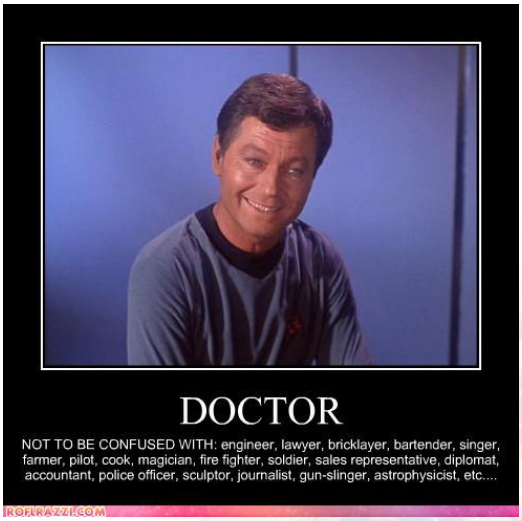
PHYSICAN LAWS: TRENDS & UPDATES



TRENDS & UPDATES

- PRESENTATION TOPICS
- **ACO UPDATES**
- **PHYSICIAN – HOSPITAL INTEGRATION**
- **PHYSICIAN CONTRACTRUAL DANGER ZONES**
- **THE BUSINESS OF MEDICINE**
- **FRAUD & ABUSE**
- **TELEMEDICINE**
- **MEDICAL MARIJUANA**

ACO's: A Difficult Goal

1. According to the **Centers for Medicare and Medicaid Services**, an ACO is "an organization of health care practitioners that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it".
2. Refined and statutorily approved in 2010 PPACA.
3. General Goal(s) of the ACO –
   - Given that **effective** and **coordinated** care (and thus realizing cost savings) are difficult to achieve without integration among the providers that deliver patient care, ACO's are incented (in the form of shared savings) to manage care in a manner that results in cost savings, and
   - Holds providers accountable for clinical outcomes with reporting and other performance measures.

ACO's: A Difficult Goal

4. The final regulations required ACOs to

- Become accountable for the quality, cost, and overall care of its Medicare FFS beneficiaries
- Enter into an agreement with the Secretary to participate in the program 3 or more years
- Establish a formal legal structure allowing the organization to receive and distribute shared savings payments to participating providers
- Include sufficient primary care ACO professionals for its Medicare FFS beneficiaries
- Accept at least 5,000 beneficiaries
- Define processes to promote evidence-based medicine and patient engagement; report on quality and cost measures; coordinate care, such as through the use of telehealth and remote patient monitoring
- 33 Quality Measures

ACO's: A Difficult Goal

5. Initially, 2 models for ACO's approved:

- Under the one-sided model, providers had the opportunity to engage in ACOs and any savings above 2% without any financial risk throughout the three years.
- Under the two-sided model, providers will assume some financial risk but will be able to share in any savings that occur (no 2% benchmark before provider savings accrue)

6. CMS established five domains to evaluate ACO performance:

Patient/caregiver experience Care coordination

Patient safety Preventative health

At-risk population/frail elderly health

ACO's: A Difficult Goal(CONT.)

7. Revisions from 2015 Final Rule – ACO may elect 1 of 3 tracks:

- Track 1 (one-sided model) – may share in savings, but not at risk for any losses during three-year term – savings rate is 50%
- Track 2 (two-sided model) – share in any losses of ACO in exchange for a greater share of any savings – rate is 60%
- Track 3 (alternative two-sided risk model) – higher shared savings rate (75%) along with comparatively higher share of risk

8. Savings Estimates:

- Figures vary, but from 2013-2016 Medicare Shared Savings Program ACOs saved (gross) between $1.5 and $2.6 billion
- After incentive payments, between $383 million loss to $665 million in net savings.

ACO's: A Difficult Goal

9. CMS October 14, 2016 Rule and **MACRA** (Medicare Access and CHIP Reauthorization Act of 2015) created ACOs based on MIPS (Merit Based Incentive Payment System) and Advanced Alternative Payment Models.

- Note, MIPS are budget neutral – winners and losers.
- Now have 4 ACOs

10. CMS December 2018 Final Rule:

- Eliminates (over three years) Track 1 and Track 2
- Offers ACO's two participation options – Basic and Enhanced
- ACO agreements are expanded 3 to 5 years
- Basic (with multiple levels) is to facilitate one-sided ACOs transitiioning over to take on more loss risk
- Enhanced maximum saving rate of 75%

ACO's: A Difficult Goal

11. UPDATE, as of 2018-2019:

- 561 ACOs delivering care to over 10.5 million people
- 81% were not based on risk%
- 76% of the ACO's renewed

12. TREND:

- Physician Incentives, payments incentives and MACRA will induce/force providers toward the riskier paths – CMS will try to smooth this transition
- Ten Year Savings, per the Federal Register (2019-2028), estimated at $2.9 Billion after incentives.
- Obstacles: Perverse payment model, Right-Sizing the ACO staff, Technical Platform Incompatibility and Leadership and Management Structures.

ACO's: A Difficult Goal

- ACOs are gaining in popularity and – despite legislative intent - may have the power to use their large size and market power to eventually raise prices and resist future changes.
- Time will Tell if they achieve their triple aim of (1) better quality and satisfaction for patients, (2) improved health of populations and (3) greater affordability….

Physician-Hospital Integration

1. Historically, Physicians have viewed hospital employment as a danger to their independent clinical decision making as well as their autonomy to advocate on their patients' behalfs.
2. With shift in focus to quality-based compensation and incentivization for physicians to practice in a team-based manner (ACOs, CINs, etc..) there is a persistant trend toward physician alignment with hospitals and health systems through employment or contract.
3. While this alignment appears invitable, Federal laws and regulations govern all/most aspects of physician recruitment and employment.

Physician-Hospital Integration

4. It is unclear how a change to hospital ownership affects the quality of patient care. Given that hospitals generally have greater resources than physician practices, increased hospital ownership of practices may improve quality of care.
5. On the other hand, there may be negative effects on quality, such as less autonomy for physicians and staff or less personalized care. Hospital ownership may also be associated with increased market share by hospitals, and increased costs.

Physician-Hospital Integration

1. Trends in Physician Employment (ie, Hospital-employed physicians)

- 47.1% of physicians are employed by hospitals and healthcare systems,
- 66% of physicians 45 years old or younger identify as employed, compared with only 26% of those age 46 and older
- As of mid-2015, one in four medical practices was hospital owned
- Hospitals acquired 31,000 physician practices, a 50% increase, from 2012 to 2015
- In 2016, the top requested position was Primary Care, followed by internists, hospitalists, and psychiatrists
- The Physicians Foundation survey found that employed physicians see 1.7 fewer patients per day on average than independent physicians – this can add up and exacerbate the physician shortage problems…

Physician-Hospital Integration

2. However, Integration – physician recruitment and employment by a hospital – remains a regulatory minefield.
3. **Stark or Physician Self-Referral Law** (civil statute)

- **Recruitment** – In Writing and Signed; Not Conditioned on Referrals; Remuneraton cannot take into account volume or value or actual or anticipated referrerals; Permitted to establish staff privileges at any other hospital and/or refer business to other entities.
  - Relocation Requirement – (a) a minimum of 25 miles into hospital's geographic area or (b) relocate to hospital's geographic area w/ at least 75% revenue from new patients.
  - To Existing Practice – Records of Actual Costs must be maintained for at least 6 years plus other restrictions…

Physician-Hospital Integration

4. Recruitment and the Anti-Kickback Statute (a criminal statute)

- Remuneration permitted if
  - Practitioner has been practicing current specialty for less than 1 year or Health Professional Shortage Area or Arrangement is
  - In writing (specifies benefits, terms, and obligations)
  - 75% of revenues from new patients (if leaving estab. Practice)
  - If benefits provided less than 3 years, cannot renegotiate in any substantial aspect
  - No referrals requirement – no volume adjustment for M&M
  - No Restriction on staff privileges or referrals to any service

Physician-Hospital Integration

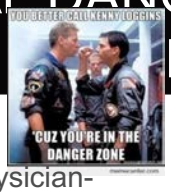
5. **Employment Agreements and the Stark Law**: Exempt if:

- Employment is for identifiable services
- Remuneration is consistent with FMV and not determined by volume or value of referrals (documentation required by HHS)
- Agreement is otherwise commercially reasonable – even if no referrals were made to the employer
- Productivity bonuses are still permitted

6. **Employment Agreements and AKS:** Remuneration does not include any amount paid to employee with a bona fide employment relationship in the furnishing of any item or service for which payment is made in whole or in part under M, M, or other federal healthcare program.

7. Staffing Agreements/Models: Similar statutory requirements.

PHYSICIAN CONTRACTRUAL DANGER ZONES



Contractual Issues & the Contractual Process

1. **Standard Provisions** – While there are a variety of physician-hospital employment relationships, some terms appear in most contracts – compensation, paid time off, professional liability insurance, billing practices, termination.
   - Carefully consider even these standard terms w/ your attorney as definitions vary and some of these provisions may be negotiable.
2. **The Process** – When in doubt, always ask for clarification or perhaps possible modifications.
   - Regardless of an employer's oral explanation or oral promise to change a contractual provision, remember that the written contract is, in most cases, the final word.

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PHYSICIAN CONTRACTRUAL DANGER ZONES

3. Current & Trending Contractual Issues

•Due Diligence/Confidentiality Clauses

•General Due Diligence terms grant recruiter/employer to access otherwise confidential information to deeper evaluation.

•Confidentiality Terms – Both parties must determine what is confidential and whether the other party can access. Both parties may opt to contractually agree to keep discussions confidential including all information shared in the meetings and the due dliligence process.

•No shop clauses – During the due diligence process, the physician or group may not negotiate with other parties.

•Representations and Warranties – Provide assurance that physician or group is eligible for employment w/ no restrictions.

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PHYSICIAN CONTRACTRUAL DANGER ZONES

- **Non-Compete & Non-Solictation Clauses** limit the ability of the physician to (1) To Leave an existing employer (or practice group) and join another within the same geographic market (without a definitive wait-period), and (2) Hire existing staff in their future employment.
- While jurisdictions can vary on the specifics, the general rule of thumb is that a noncompetition or non-solicitation clause is more likely to be upheld if the limits are reasonable in georgraphic scope and duration.
- Again, the physician should be wary of any verbal promises of future leniency with these provisions.
- At court, expect the employer/hospital to put forth an analysis showing how the allowing the departing physician to reestablish a practice immediately in the same area will unduly compromise the hospital's human and financial investment(s).

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PHYSICIAN CONTRACTRUAL DANGER ZONES

- **Standards of Care clauses** can often be attached to the level of performance the that employer requires for work duties (hospital visits, surgeries, surgical assists, taking call hours). Be wary of contracts that require physician to provide care "of the highest quality." The standard is higher than that required in most state's practice laws.
- For instance, in NY, the Court of Appeals adopted the locality rule and the court wrote that a physician or surgeon must use a "reasonable degree of learning and skill that is ordinarily possessed by physicians and surgeons in the locality where he practices." PA is quite similar…
- A more favorable standard is competence…

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PHYSICIAN CONTRACTRUAL DANGER ZONES

- **Malpractice "Tail" Policies** are needed after the physician-hospital relationship is terminated (assuming they were covered under Claims-Made policy).
- Malpractice insurance is usually discussed during the initial job offer/contract negotiations, and then becomes a dormant topic until it's time to leave the employer. Often, the full cost of the necessary tail coverage falls to the departing physician.
- The general rule of thumb is 200% of expiring premium. So if your employer is paying $10,000 per year for your policy, you should anticipate paying $20,000 for tail at the time of your departure (depending on jurisdiction).

THE BUSINESS OF MEDICINE

1. **The Business of Medicine and Business Relationships** subject the physician to five most important fraud and abuse federal laws (not to mention the possible state laws):
- Anti-Kickback Statute
- Physician Self-Referral Law (Stark Law)
- False Claims Act (FCA)
- Civil Monetary Penalties Law
- Exclusion Statute

2. **Fraud and Abuse Enforcement** (along with new provisions in the Medicare Access Act of 2015): Federal health fraud recoveries for FY 2017 totaled $2.6 billion and for FY 2018 totaled $3.5 billion. 9th Consecutive Year that recoveries totalled more than $2 billion.
   - For FY 2017 DOJ and OIG opened 967 new criminal health care fraud investigations and opened 948 new civil health care fraud cases.

THE BUSINESS OF MEDICINE

3. **ANOTHER BIG TAKEDOWN!** In June of 2018, HHS and OIJ, along with state and federal law enforcement partners, participated in another unprecedented nationwide health care fraud takedown representing the largest **multi-agency enforcement operation in history**, both in terms of the number of defendants charged and loss amount.
   - 601 Denfendants Charged including:
     - 165 Medical Professionals
     - $2 Billion in Losses
     - 587 Exclusions Issued
     - 58 Federal Districts
     - 30 Medicaid Fraud Control Units
     - 350 OIG Agents
   - For Every $1 spent on health care related fraud and abuse investigations, more than $4 is recovered.

THE BUSINESS OF MEDICINE

4. **OIG and AKS Enforcement Trends:**

- December 2016 OIG statement revised monetary values of gifts considered nominal value as having a retail value of no more than $15 per item or $75 in aggregate per patient annually. If at or below thresholds, then the gift need not fit into statutory exception to the remuneration prohibition.
- Starting in 2015-2016, OIG continues to focus on compensation arrangements with physicians such as medical directorships. Physicians will be held liable under AKS for compensation payments that do not ensure fair market value for bona fide services physicians actually provided.
- OIG concerned with clinical labs paying compensation to physicians and practices for: (1) blood specimen collection, processing, and packaging, and (2) submitting patient data to a registry or database

THE BUSINESS OF MEDICINE

4. **OIG and AKS Enforcement Trends:**
   - OIG noted that the probability that the payment is for an illegitimate purpose is increased if the payment exceeds the fmv of ther services provided by the physician or group.
5. **False Claims Act Enforcement Trends:**

- Whistleblower (private plaintiff) lawsuits under the qui tam privisions continue to grow at a steady pace – $2.9 billion out of $4.7 billion in recoveries of FY 2016 was related to lawsuits filed under this provision.
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THE BUSINESS OF MEDICINE

5. **False Claims Act Enforcement Trends (con't):**

- Per ACA, CMS released final regulations interpreting the **60-Day Overpayment Rule** for Medicare Parts A and B on February 12, 2016. It is a Reverse False Claims violation if a person fails to report a return of an overpayment to the Medicare or Medicaid program - Upon credible evidence of receipt of potential overpayment, the physician may have up to 8 months to return overpayment (six months plus additional 60 days to report).
  - CMS also finalized the 6 year look back period.

THE BUSINESS OF MEDICINE

6. **The Stark Law Trends:**

- November 2016, CMS adopted new requirement for Physician-owned hospitals – must disclose physician ownership on any hospital website and in any public advertising. Must also submit a an annual report indicating ownership and investment baselines to satisfy one of the safe harbors.

7. **The Civil Monetary Penalties Law:** Concierge Medicine Risks

- Physicians w/ a concierge practice may violate the Medicare Assignment rules if he/she is Medicare enrolled provider and accepts assignment of Medicare benefits – OIG Fraud Alert –
- If accepted assignment, separately billing a Medicare patient for covered services creates a violation of the CMPL.
- $15k per violation, 3X amount charged, potential exclusion.

THE BUSINESS OF MEDICINE

8. **Exclusion Statute Trends:** January 2017, per ACA's expansion of their enforcement authority, implemented final rule to include exclusions for:

- Obstruction of a government audit
- Failure to provide certain payment info when requested by federal healthcare audit
- Failure to provide certain payment info when requested by federal healthcare programs, and
- Making false statements, omissions, or misrepresentations in federal healthcare program enrollment applications.
- Remember, there Mandatory Exclusions for crimes related to healthcare and felonies (min of 5 years) and Permissive Exclusions for civil fraud, kickback, etc. (min of 3 years).

THE BUSINESS OF MEDICINE

8. Exclusion Statute Trends: (SIDE BAR)

- 2018 Study published in *JAMA Network OPEN*. ***4 Characteristics of Physicians Most Likely Excluded from Public Reimbursement.***
- Cross-sectional study of all excluded physicians between 2007-2017. Exclusions occurred due to fraud, health crimes, and substance abuse. .3% of Physicians excluded.
- **Results** – Four characteristics of physicians most likely to be excluded:
  1. Male
  2. Osteopathic Training
  3. Older
  4. Being a Specialist

  - D.O. explanation was not directly explained. Additional spending (and focus) on enforcement was one possibility. Also, higher odds of exclusion were observed in family medicine physicians.

Jamanetwork.com

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TELEMEDICINE

- **Telemedicine.**

1. Has both federal and state definitions and regulations
   - Medicaid: "…telemedicine seeks to improve a patient's health by permitting two-way, real time intertactive communication between the patient and the physician at the distant site…that includes, at a minimum, audio and video equipment." https://www.medicaid.gov/medicaid/benefits/telemed/index
   - NY: "Telemedicine means the delivery of clinical health care services by means of real time twoway, electronic audiovisual communications which facilitate the assessment, diagnosis, consultation, treatment, education, care management and selfmanagement of a patient's healthcare, while such patient is at the originating site and the health care provider is at a distant site."
   - PA no formal adopted standard, just guidelines.

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TELEMEDICINE

- PA no formal adopted standard, just guidelines. Pennsylvania is one of the few states that does not have a dedicated Telemedicine Act and Pennsylvania is attempting to address the two major issues in telemedicine in one Act, i.e. payment parity and professional regulation. Senate Bill 780 of 2017 has been unanimously passed by the Senate and referred to the House Professional Licensure Committee on June 19, 2018.

2. **Adoption/Usage**: Estimated that there are currently about 200 telemedicine networks, with 3,500 service sites in the U.S. Over half of all U.S. hospitals now use some form of telemedicine.
3. **Issues:**
   - Standard of Care: Typically no less than in person treatment;
   - Licensure: What Profession; What Level of License: State?

TELEMEDICINE

2. **Issues:**
   - Prescribing (e.g. limit on controlled substances) – Note NY program for prescribing Marijuana via Telemedicine
   - Informed Consent (e.g. NY – only Psychiatric Treatment)
   - Records (become part of the permanent med record);
   - Level and conditions for reimbursement (efficiency and quality standards in play for Medicaid eligibility of asynchronous review may be in question)
   - Most states are also seeing private insurance and State Medicaid programs a wide variety of reimbursement policies from full to complete denial
3. **Ethical Considerations (e.g. AMA Opinion E)**
   - Inform patient of limits of telemed

TELEMEDICINE

3. **Ethical Considerations (e.g. AMA Opinion E)**
   - Coordinate Care with in-person primary care providers
   - Train to proficiency with use of telemed equipment
   - Recognize limits of technology
   - Always properly and sufficiently document clinical evaluaions and prescriptions;
   - Ensure continuity of care, coordination of care and ultimate responsibility
   - Ensure that malpractice insurance covers the telemedicine act in question
   - Are processes in place to ensure proper creation and termination of the physician-patient relationship?

MEDICAL MARIJUANA

- "Medical Marijuana":
  1. Definition: refers to using the whole, unprocessed jarijuana plant or its basic extracts to treat symptonms of illness and other conditions.
  2. The U.S. Food and Drug Administration (FDA) has not recognized or approved the marijuana plant as medicine. The DEA classifies marijuana as a Schedule 1 (illegal) drug and this has been confirmed by the U.S. Supreme Court: Gonzales vs Raich.
  3. Active ingredients include delta-9-tetrahydrocannabinol (THC), marijuana's main mind-altering ingredient that makes people "high" and Cannabidiol (CBD), a cannabinoid, that does not.
  4. Approximately 30 states now allow marijuana to be used for medical purposes in some fashion

http://www.drugabuse.gov/publications/drugfacts/marijuana-medicine

MEDICAL MARIJUANA

- "Medical Marijuana":

5. Physician do not write scripts for it, howerver. They certify patients for an "approved" use.
6. Possible beneficial uses (3000 year history) include:
   - Chronic Pain and/or Pain
   - Epilepsy
   - Opioid/alcohol addiction
   - Depression/PTSD
   - An antemetic for cancer patients
   - MS; and
   - Glaucoma (P.A. has 21 approved serious health conditions)

http://www.medicalnewstoday.com/articles/320984.php

MEDICAL MARIJUANA

- "Medical Marijuana":

7. Risks:
   - Side effects, e.g. vomiting with children
   - Dosing
   - Contra indicative for patients with certain mental health issues
   - Respiratory issues; and/or
   - Addiction
8. Note that certain marijuana related drugs have been approved: See, e.g. Marinol (III) and Syndros (II) for anusea and weight loss in cancer and HIV patients, and Epidiolex (pending) for epilopsy.

http://www.fda.gov/newsevents/testimony/ucm5u057.htm

MEDICAL MARIJUANA

- "Medical Marijuana":

9. Trending Legal Risks for Physicians
   - Know the limits and requirements of your involvment with medical marijuana under state law (e.g., NY, PA, FL)
   - Secure all required training
   - Watch for required civil liability – what is the standard for certification for your patients
   - Never forget basic standards of care: must have basis for any recommendation/certification of patient eligibility and must follow up.
   - Don't forget the second of the Lopez laws from Scarface.

http://www.medscape.com/viewarticle/845686

MEDICAL MARIJUANA

- "Medical Marijuana":

10. Trending Patient Usage (e.g., usage in Pennsylvania)
   - First Anniversary of Marijuana Law in PA (February 2019)
   - More than 116,000 Pennsylvanians have registered as patients. About 83,000 of those have been issued state medical marijuana cards which allow them to buy cannabis products from several dozen dispensaries operating across the state.
   - Nearly 1,000 physicians have been approved to certify patients to participate in the program, according to the Department of Health.
   - Initially, PA only allowed dispensaries to sell processed cannabis oils, tinctures, and pills. By August, the DOH granted permission to vend the more traditionally smokable marijuana "flower."

MEDICAL MARIJUANA

- "Medical Marijuana":

10. Trending Patient Usage (e.g., usage in Pennsylvania)
    - In PA, there are already a dozen operational growers with 13 more cultivators expected to be producing and processing cannabis by late 2019. PA has approved 45 dispensary locations with the possibility of about 100 more to open this year.
    - The clinical research component (studying longterm effects of usage and related efficacy of the drug and dispensed forms) of PA's Marijuana Legislation has be held up following lawsuits alleging unfair competition.
    - Finally, the race is on to see which state – PA, NY, or NJ – will be the first in the region to legalize all forms of marijuana for adult recreational use.