DIRECT PRIMARY CARE Summit

AMERICAN ACADEMY OF FAMILY PHYSICIANS

FAMILY MEDICINE EDUCATION CONSORTIUM, INC

acofp American College of Osteopathic Family Physicians

Going on the Legal Offensive (After a Quick Compliance Review)

Phil Eskew, DO, JD, MBA

Activity Disclaimer

The material presented here is being made available by the DPC Summit Co-Organizers for educational purposes only. This material is not intended to represent the only, nor necessarily best, methods or processes appropriate for the practice models discussed. Rather, it is intended to present statements and opinions of the faculty that may be helpful to others in similar situations.

Any performance data from any direct primary care practices cited herein is intended for purposes of illustration only and should not be viewed as a recommendation of how to conduct your practice.

The DPC Summit Co-Organizers disclaim liability for damages or claims that might arise out of the use of the materials presented herein, whether asserted by a physician or any other person. While the DPC Summit Co-Organizers have attempted to ensure the accuracy of the data presented here, these materials may contain information and/or opinions developed by others, and their inclusion here does not necessarily imply endorsement by any of the DPC Summit Co-Organizers.

The DPC Summit Co-Organizers are not making any recommendation of how you should conduct your practice or any guarantee regarding the financial viability of DPC conversion or practice.

Faculty Disclosure

It is the policy of the DPC Summit Co-Organizers that all individuals in a position to control content disclose any relationships with commercial interests upon nomination/invitation of participation. Disclosure documents are reviewed for potential conflict of interest (COI), and if identified, conflicts are resolved prior to confirmation of participation. Only those participants who had no conflict of interest or who agreed to an identified resolution process prior to their participation were involved in this CME activity.

All faculty in a position to control content for this session have indicated they have no relevant financial relationships to disclose.

The content of this material/presentation in this CME activity will not include discussion of unapproved or investigational uses of products or devices.

Learning Objectives

- Evaluate the major legal and regulatory hurdles facing new DPC practices.
- Develop and implement appropriate compliance and mitigation strategies to minimize regulatory risks.
- Evaluate the existing resources and support infrastructure available to support physicians interested in DPC advocacy efforts.
- Choose an appropriate role and level of engagement in DPC-related advocacy based on individual interests.
- Health Savings Accounts and beyond - review common tax questions (for individual patients and employers) and how this might affect your practice design (scope of services and pricing schemes)

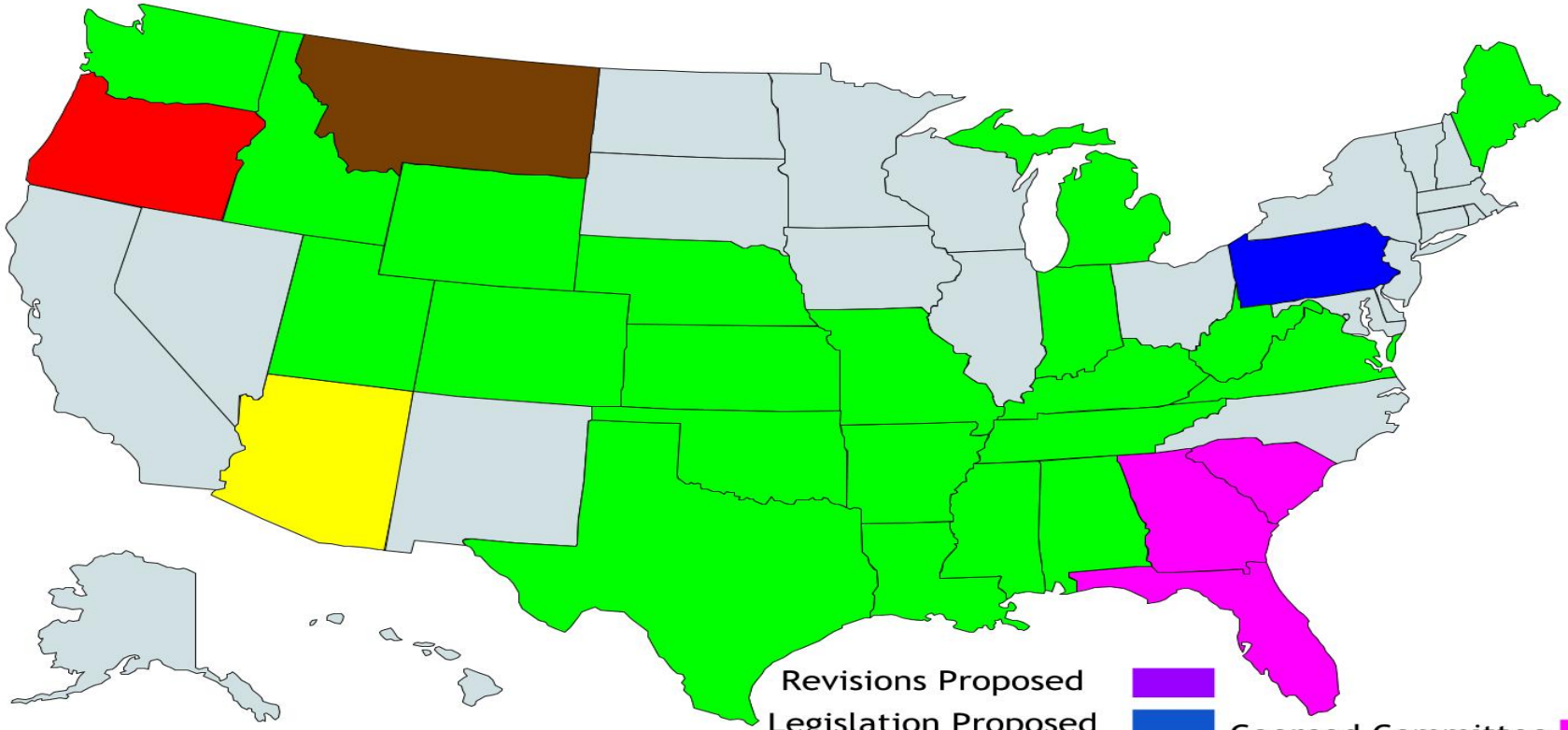
Start with a Mapping Approach

- Pass DPC “not insurance” law or read the insurance code and plan your argument
- Determine if there are any patients you cannot accept (Medicare, Medicaid, HMO, etc)
- Determine your approach to employers, dispensing, labs, pathology, hospitals
- Seek assistance from other DPC practices in your state – many issues are state specific

General Compliance

- HIPAA
- Medicaid
- In Office Dispensing
- Pathology “Direct Billing” laws
- Laboratory “Direct Billing” laws (NY, NJ)
- Patient Abandonment (if practice transition)
- CLIA
- OSHA

States with Direct Primary Care Laws



State DPC Law Comparison

- “Not Insurance” Protections
- Clean DPC Definition (double dipping prohibition)
- Mandatory “Not Insurance” Disclosures
- Written Agreement Requirements
- Policing Authority – Ideally the medical board
- Data reporting obligations (avoid!)
- Separate licensure process (avoid!)

Insurance Commissioner Guidance

- New York
  - OGC Op. No. 09-02-02
- Maryland
  - Report on “Retainer Practices… and the Business of Insurance” Jan 2009
- South Carolina
  - Ins Com Letter 03/28/16
- Massachusetts
  - Ins Com Letter 03/04/16

N.Y. Ins. Law § 1101(a) (McKinney Supp. 2003)

- (1) "Insurance contract" means any agreement or other transaction whereby **one party**, the "insurer", **is obligated to confer benefit** of pecuniary value upon another party, the "insured" or "beneficiary", **dependent upon the happening of a fortuitous event** in which the insured or beneficiary has, or is expected to have at the time of such happening, a material interest which will be adversely affected by the happening of such event.

- (2) "Fortuitous event" means any occurrence or failure to occur which is, or is assumed by the parties to be, to a **substantial extent beyond the control of either party**.

ARTICLE 44 of the NYS Public Health Law § 4401. Definitions (HMO defined)

- 1. "Health maintenance organization" or "organization" means any person, natural or corporate, or any groups of such persons who enter into an arrangement, agreement or plan or any combination of arrangements or plans which propose to provide or offer, or which do provide or offer, a comprehensive health services plan.
- 2. "Comprehensive health services plan" or "plan" means a plan through which each member of an enrolled population is entitled to receive comprehensive health services **in consideration for a basic advance or periodic charge**…

Contracting – Individual Patients (1)

- Consider your state law (DPC/Insurance Code)
- Scope (precisely defined)
- Billing (in arrears)
- Disclosures
  - "Not insurance"
  - Any relevant status (with Medicare, Medicaid, etc)
- Activation
- Termination
- Refundable
  - Enrollment fee (keep), other prepaids refundable

Contracting – Individual Patients (2)

- Ongoing primary care (not insurance)
- Not an emergency (pt should call 911)
- No expectation to file 3rd party claims
- Agreement in isolation does not meet ACA
- I am enrolling voluntarily
- Nontransferable agreement
- For complaints – will first notify the practice
- Do NOT expect controlled substances


States with
DIRECT PRIMARY CARE
LAWS
The Journal of Legal Medicine 2017
Revisions Proposed
Legislation Proposed
Legislation Discussed
Coerced Committee
Governor Veto
Good
Irrelevant
Bad
AMERICAN COLLEGE of LEGAL MEDICINE
THE JOURNAL OF LEGAL MEDICINE
Phil Eskew, D.O., J.D., M.B.A.
Defending Direct Primary Care
Expanding The Direct Primary Care Movement
Lowering Barriers to Entry into DPC for Fellow Physicians

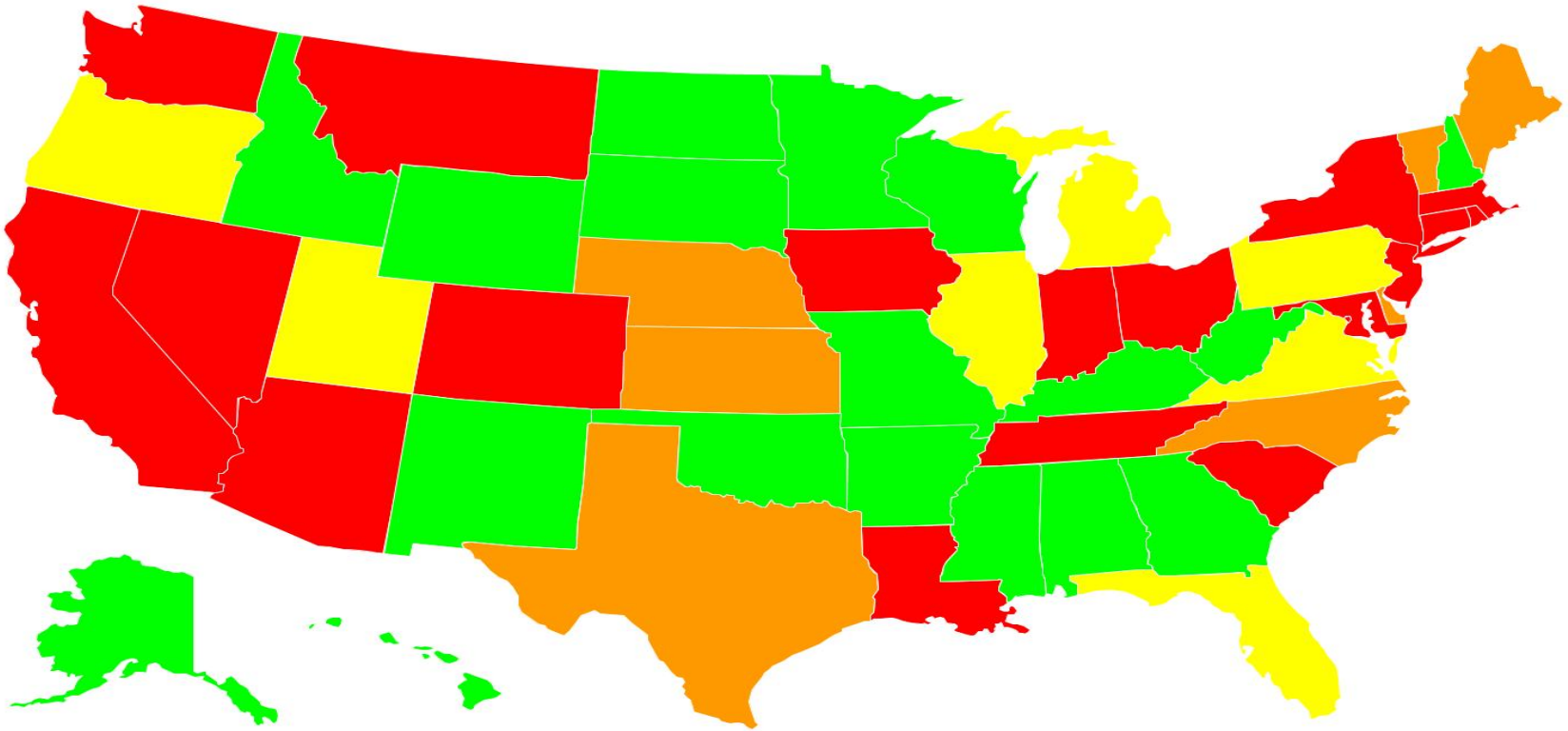
Medicaid Map – Not Yet!

- Too Many Variations
  - "Participate" and still privately contract
  - Not participate to privately contract
  - Ordering only status to privately contract
- Look for Ordering and Referring Status
- Private Contracting Prohibited in KY & CO

Private Contracting Prohibited

- Kentucky - 907 KAR 3:005E
- This emergency administrative regulation is being promulgated to eliminate the option for a Medicaid provider to provide Medicaid cover services to a Medicaid recipient on a “non-Medicaid” (cash-on-the-side) basis.
- Colorado Revised Statutes Title 25.5. Health Care Policy and Financing § 25.5-4-301

Pathology Direct Billing



Direct Billing | Anti-Markup | Disclosure | None

DPC Summit 2017

Kansas House Bill 2027

- Nothing in this subsection shall be construed to prohibit billing for anatomic pathology services by:
- (C) a physician providing services to a patient **pursuant to a medical**
- **retainer agreement** in compliance with K.S.A. 65-4978, and amendments
- thereto, when the bill to the patient for such services:
- (i) **Identifies the laboratory** or physician that performed the services;
- (ii) **discloses in writing to the patient the actual amount charged by**
- **the physician or laboratory** that performed the service; and
- (iii) is consistent with rules and regulations adopted by the board for
- appropriate billing standards applicable to such services when furnished
- under these agreements.

HIPAA Words to Know

- Covered Entity – Do you electronically transmit health information in connection with one or more standard transactions?
- Business Associate - To be a business associate, you need to be providing certain enumerated services to or on behalf of a covered entity.
- Protected Health Information
- Treatment, Payment & Operations

HIPAA – DPC Approach

- Risk Mitigation Focus
- 1st Defense – Not a Covered Entity
- 2nd Defense – Complied with Requirements
  - "Risk Assessment" (updated annually)
  - Compliance Evidence (privacy & security rules)
  - Use Forms (NPP, BAA, etc)
  - Accounting of Disclosures (ability to provide)

HIPAA – Patients' Rights

- a. To receive a Notice of Privacy Practices.
- b. To see or receive a copy of his/her protected health information (PHI).
- c. To request that his/her PHI be corrected.
- d. To ask for PHI to be sent to him/her at a different address or a different way.
- e. To request limits on how his/her PHI is used and disclosed (**especially if privately paid**).
- f. To receive a list of disclosures.

Health Savings Accounts

- “Gap Plan” and “Health Plan” under § 223(c)
- “Qualified Medical Expense” under § 213(d)
- Revisions Favored by Trump and HHS / Price
- Could be litigated – but by the patient (not the physician)

Trump Policy (HHS) Proposal

- "Achieving the President's goals to reform Medicaid will require providing States with more flexibility to improve healthcare delivery to meet the needs of their unique populations. *Direct Primary Care practices, in which physicians offer primary care services to patients at a set price, generally without payer or insurer involvement, are a mechanism to improve physician-patient relationships*. Some State Medicaid programs are already testing this innovative care delivery model. *HHS will explore opportunities for States and providers to further expand Direct Primary Care*, which will support improved health outcomes for Medicaid populations."

Trump Policy (HHS) Proposal

- The "Medicaid Direct Primary Care Initiative" states that "DPC arrangements have the potential to improve Medicaid in the following manner: 1) Increasing Access, 2) Supporting Positive Health Outcomes for Medicaid Patients, and 3) Putting Patients and Doctors in More Control of Healthcare."

Medicare “Opt Out” Considerations

- “Opt Out” = pure practice open to all ages
- Remain in = hybrid, FFNCS, or not open to all
- “Opted Out” Moonlighting is possible
  - Urgent / Emergent Care Exception
  - Workers Compensation
  - Hospice (purely administrative) role
  - Correctional (prison) medicine
  - Part time on-site direct primary care clinic

Medicare “Opt Out” Logistics

- After June 17, 2015 – only need to file one affidavit (MACRA update)
- Quarterly Windows (due 30 days prior)
  - January 1, April 1, July 1,October 1
- Private Contract with the patient
- Do NOT “disenroll” or file form 1490s
- You can still order labs, prescribe, etc

Medicare “Opt Out” Private Contract Terms

- Patient accepts full responsibility for payment
- Agrees not to submit a claim to Medicare
- Agrees that Medicare limits do not apply
- Supplemental plans may elect not to pay
- This is NOT an emergency situation
- Good examples on Medicare Administrative Contractor Websites

We Will Cover

- Restrictive Covenants (Non-competes)
- Leveraging “Out of Network” Status
- Bypassing Pharmacy Benefit Managers
- Obtaining Cash Pricing (using HITECH)

Restrictive Covenants (not to compete)

- Generally courts view as against public policy
- Must protect legitimate business interest
- Reasonableness test
  - Bus Interest vs Employee hardship, injury to public
- Three common requirements
  - Employer must have a valid interest to protect
  - Geographical restriction no overly broad
  - Must have a reasonable time limit

Metcalfe Ins. Invs. V Garrison 191 P.2d 1356 (Alaska) 1996

- A covenant not to compete is unenforceable on grounds of public policy if it
- unreasonably restrains trade, either because: (a) the restraint is greater than is needed to protect the promisee's legitimate interest, or (b) the promisee's need is outweighed by the hardship to the promisor and the **likely injury to the public**.

Metcalfe Ins. Invs. V Garrison 191 P.2d 1356 (Alaska) 1996

- This case, however, presents a rare instance where a party is attempting to enforce a covenant not to compete **against a person employed by a federally funded nonprofit organization that provides free or low-cost healthcare services**. In such a case, **competition will not be presumed and must be proven**.

Metcalfe Ins. Invs. V Garrison 191 P.2d 1356 (Alaska) 1996

- It appears from the record that [defendant] is employed by an organization providing **an important, low-cost service to a population in need of such care**. In a case that implicates such considerations, it is appropriate for a court to closely scrutinize the covenant not to compete to determine whether it is **void for public policy reasons**.

Daniel Boone Clinic, PSC v. Dahhan 734 S.W.2d 488 (Ky. Ct. App. 1987)

- The court reversed and held that defendant was terminated within the meaning of the restrictive covenant when his contract was not renewed upon expiration. The court also held **no inequity would result from enforcing the restrictive covenant. The patients were not third-party beneficiaries to the restrictive covenant**; rather, two distinct contracts existed. The first contract was between the clinic and the patients, which required the clinic to provide medical care meeting the standard of care required of all physicians, but **it did not require the clinic to provide a particular doctor or to give notice of personnel changes**. The second contract was the employment contract, involving professional service to which the patients were only incidental beneficiaries.

Daniel Boone Clinic, PSC v. Dahhan 734 S.W.2d 488 (Ky. Ct. App. 1987)

- Restrictive covenants are valid and not against public policy unless the particular circumstances of the case would cause serious inequities to result.
- Take away: public policy (injury to the public) is likely a losing argument to invalidate a Non-compete in KY

Signing an Employment Contract

- Non-competes: note enforceability
  - Prohibited = CA, MT, ND, SD, DE, MA
  - Restrictive Statute = FL, ID, MI, OR, GA, CO
  - Physician favoritism = VA, TN, TX
- Job description: accuracy & precision
- Schedule: accuracy & precision
- Moonlighting: retain the option
- Research Rights: retain all rights
- Malpractice Tails: avoid them
- Termination: Push for 120 days notice

Network Definitions

- Networks get to define
  - Allowable Fees
  - Medical Services
  - Medically Necessary
  - Prior Authorization
  - HMOs are not bound by CPOM laws

The Network “Shall”

- The networks Physician shall…
  - Refer to other network physicians
  - Prescribe medications from the formulary
  - Provide medically necessary covered services
  - Maintain professional liability insurance
- The Network shall…
  - Have the right to inspect and duplicate all medical and billing records related to medical services rendered to covered members at no cost to the Network
  - Provide medically necessary covered services

Out of Network = Shall NOT!

- Set your fees
- Determine your scope of services
- Determine medical necessity of your services
- Burden you with prior authorizations
  - See talk by Dr. Greg Zydiak
  - Gary Gibson, MD v Medco Health Solutions of Columbus North Ltd.
- Have any right to invade your patient's privacy

Out of Network = Ability to Go Public

- Embarrass the network
- Emphasize their designed delays in care
  - Document & Record plan interactions
  - Note your states rules on recording conversations
- Patient may become plaintiff if plan purchased outside of ERISA (and its immunity provisions)
- If deductible has been met, retaliate with denials or delays by using the ER

Does ERISA affect a DPC Practice?

- Yes – if the employer pays then it applies
- Health benefit plans subject to ERISA's provisions are broadly defined as any fund intended to provide "medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment."
- A health benefit plan is covered by ERISA only if it is "established or maintained by an employer or by an employee organization."

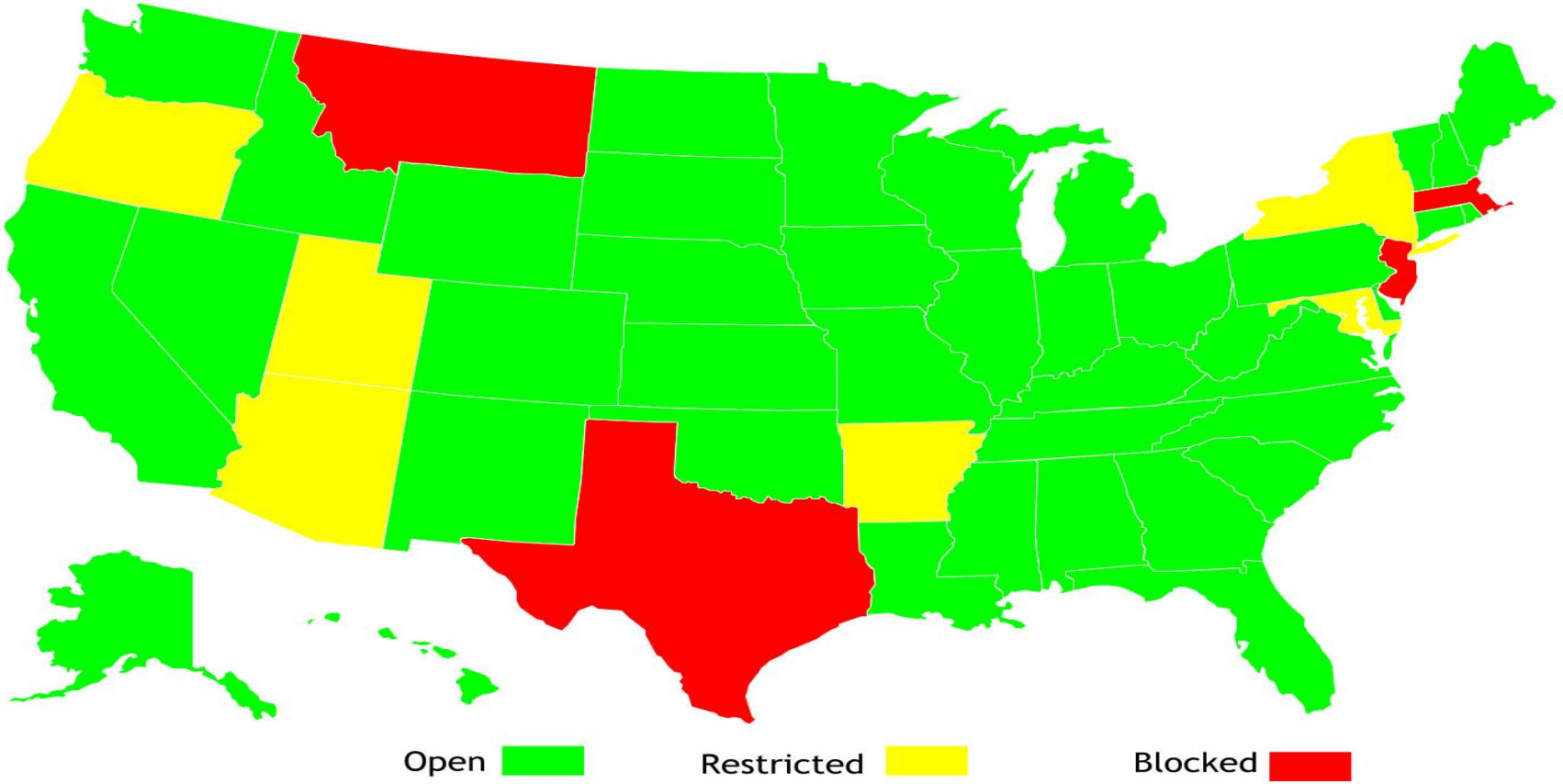
ERISA Immunity Example

- Applies to employer “health benefit plans”
- States may NOT regulate “self-insured” plans
- ERISA gives a right of action to an insuree against an insurer, but generally limits recovery to the value of benefits provided in the plan or a ruling specifying what is actually covered under the plan

Dispensing Can Be

- Wild Wild West (no guidance)
  - If asking, start with Bd of Med, then Bd of Pharm
- Made Easy (KY or GA)
- Made Difficult (MD)
- Permitted with a few exceptions (Utah)
- Prohibited (Texas)

In Office Dispensing



Texas - Dispensing

- Support HB 1482
  - A physician may dispense dangerous drugs to the physician ’s patients and charge the patients for the drugs
  - Before dispensing a dangerous drug to a patient under a physician must disclose to the patient: (1) the cost of the drug to the physician; and (2) the price the patient will be charged for the drug by the physician.
- Become large enough to hire a clinical pharmacist

Utah - Dispensing

- Obtain a “Dispensing Medical Practitioner” license
- If obtained you may dispense only "cosmetic drugs," "injectable weight loss drugs," or a "cancer drug treatment regimen."
- On-site "employer sponsored clinics" receive favorable treatment and are permitted to dispense routine medications that are "prepackaged drugs" that are provided "in a fixed quantity per package by a pharmaceutical wholesaler or distributor."

Utah - Dispensing

- Onsite clinic treating only employees (not open to the general public)
- Be able to dispense the medications without the use of a pill counter by purchasing in the exact quantity you need to avoid any repackaging - a prohibited move
- Avoid controlled substances (since additional rules apply)

New York - Dispensing

- "No prescriber…, may dispense **more than a seventy-two hour supply of drugs, except for**:
  - persons practicing in hospitals as defined in section twenty-eight hundred one of the public health law;
  - the dispensing of drugs at no charge to their patients;
  - persons whose practices are situated ten miles or more from a registered pharmacy;
  - the dispensing of drugs in a clinic, infirmary or health service that is operated by or affiliated with a post-secondary institution;
  - persons licensed pursuant to article one hundred thirty-five of this title;
  - the dispensing of drugs in a medical emergency as defined in subdivision six of section sixty-eight hundred ten of this article;
  - the dispensing of drugs that are diluted, reconstituted or compounded by a prescriber;
  - the dispensing of allergenic extracts; or
  - the dispensing of drugs pursuant to an oncological or AIDS protocol."

North Carolina - Dispensing

- You must annually register with the Board, NCGS 90-85.21(b), with a fee of $75.00
- No mark up to safely avoid self referral law
- Packaging:
  - USP Tight, Light Resistant, NCGS 106-134(7)
  - Child Resistant – 15 USC 1471-1474
  - NCGS 90-85.21(b)
- Labeling: NCGS 106-134.1(b), 90-85.21
- Recordkeeping: NCGS 90-85.21(b), 90-85.26,
- 21 NCAC 46.2300, .2502,
- Patient Counseling: 21NCAC 46.2504(a)
- Prospective DUR : 21NCAC 46.2504(d)

Maryland - Dispensing

- The practice must submit a **detailed application** to the Maryland Board of Physicians and include a **$1,050 fee**
- "Licensed dentists, physicians, and podiatrists are required to obtain a dispensing permit if they dispense prescription drugs to patients under their direct care who have informed the provider that a pharmacy is not conveniently available. The licensee shall **maintain documentation that should include a single form in each patient's chart** for each patient to whom prescription drugs are dispensed. At a minimum, the form shall:
  (1) Indicate the reason, as stated by the patient, that a **pharmacy is not conveniently available** to that patient;
  (2) Include a statement signed by the patient indicating that the patient understands that the determination that a pharmacy is not conveniently available is **made solely by the patient**; and
  (3) Be signed and dated by the patient before dispensing prescription drugs to the patient for the **first time**

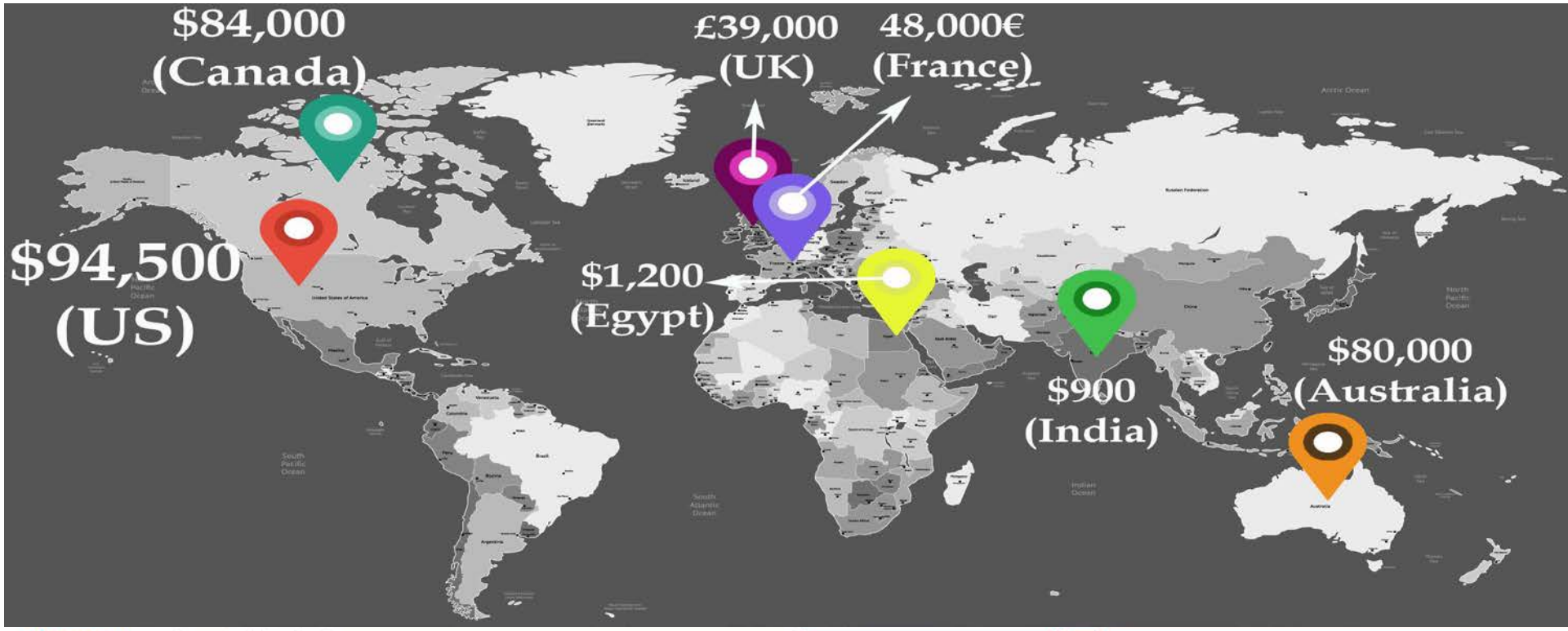
Pharmacy Benefit Managers

- The problem
  - “The Spread Game”
  - “The Packaging & Repricing Game”
  - “Rebate Game”
- The solution
  - Dispense your own medications
  - Pay cash for medications (use GoodRx)
  - Avoid using “plan” at all costs

Bypassing PBMs

- Dispense whenever possible
- GoodRx
- Independent (direct) pharmacy
- Medical tourism
- “Use” plan as last resort

Cost for 12 weeks of Harvoni



HITECH – Cash Pay for Privacy

- Section 13405(a) of the HITECH Act sets forth certain circumstances in which a covered entity now MUST comply with an individual's request for restriction of disclosure of his or her protected health information.
- §45 C.F.R 164.522(a)(1)

HITECH – Cash Pay for Privacy

- Specifically, section 13405(a) of the HITECH Act requires that when an individual requests a restriction on disclosure pursuant to § 164.522, **the covered entity must agree to the requested restriction unless the disclosure is otherwise required by law**, if the request for restriction is on disclosures of protected health information to a health plan for the purpose of carrying out payment or health care operations **and** if the restriction applies to protected health information that pertains solely to a health care item or service **for which the health care provider has been paid out of pocket in full**.

HITECH – HMO / Medicaid Implications

- If a provider is required by State or other law to submit a claim to a health plan for a covered service provided to the individual, **and there is no exception or procedure for individuals wishing to pay out of pocket for the service**, then the disclosure is required by law and is an exception to an individual's right to request a restriction to the health plan pursuant to § 154.522(a)(1)(vi)(A) of the Rule.

HITECH – Medicare Implications

- With respect to Medicare, it is our understanding that when a physician or supplier furnishes a service that is covered by Medicare, then it is subject to the mandatory claim submission provisions of section 1848(g)(4) of the Social Security Act (the Act), which requires that if a physician or supplier charges or attempts to charge a beneficiary any remuneration for a service that is covered by Medicare, then the physician or supplier must submit a claim to Medicare. However, **there is an exception to this rule** where a beneficiary (or the beneficiary's legal representative) refuses, of his/her own free will, to authorize the submission of a bill to Medicare. In such cases, **a Medicare provider is not required to submit a claim to Medicare for the covered service and may accept an out of pocket payment for the service from the beneficiary**. The **limits on what the provider may collect from the beneficiary continue to apply** to charges for the covered service, notwithstanding the absence of a claim to Medicare.

HITECH Privacy Implementation

- Have the patient sign a request that information relative to self-paid services not be disclosed (usually called a Restrictions on Uses and Disclosures Form)
- Flag this information so that it is not shared with the “health plan”
- Inform the patient about the need to make the same request downstream (pharmacies, labs, specialists)

HITECH Privacy Summary

- All covered entities MUST have a process
  - Refusal must be of patient's "own free will"
- Medicare
  - May accept cash payments, but limiting charges apply
- Medicaid
  - May or may not provide an exception (ex KY & CO)
- HMO laws (state based)
  - May or may not provide an exception
- Private Insurance Contracts
  - Federal law trumps terms of private agreements

HITECH Medicare Opt Out Implications

- Continue to be a “participating” physician
- Could attempt to charge all Medicare privately for “covered services” (respecting Medicare limiting charge)
- Might be suspect if all patients need to sign up out of “own free will” but might be easier if you market practice based on heightened privacy
- Theoretically makes a monthly “noncovered services” fee argument stronger

Action Items

- If the data you seek is unavailable, obtain it for the DPC movement
- May Be Able to Obtain Assistance From
  - State Medical Society
  - DPC Coalition
  - Local Attorney
- Be Willing to Author Letters of Inquiry
  - Insurance Commissioner (HMOs, “not insurance”)
  - Medicaid Director (private contracting, HITECH)

Questions?

Contact Info:

Phil Eskew, DO, JD, MBA

phil@dpcfrontier.com

Twitter @philsq

Submit your questions to: aafp.cnf.io