Benefits & Compensation

Fourth Annual Forum on Employee Health & Welfare Benefits

June 6, 2019

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Thursday, June 6, 2019

Contents

Dorsey Blogs

Dorsey Health Law Blog available at: https://dorseyhealthlaw.com/

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Fourth Annual Forum on Employee Health and Welfare Benefits

Thursday, June 6, 2019

Agenda

Overview

Dorsey's Benefits & Compensation Group will conduct its fourth annual forum on issues affecting employer sponsored health and welfare benefits. Sessions will focus on practical advice and guidance.

8:15 am – 8:55 am CT **Registration and Breakfast**

8:55 am – 9:00 am CT **Welcome** *(**Liz Deckman**, Dorsey & Whitney LLP)*

9:00 am – 10:00 am CT **Health Plan Litigation: More Risks and Employer Response**

***Tim Goodman**, **Andrew Holly** and **Caitlin Hull**, Dorsey & Whitney LLP*

Group health plan litigation continues to expand. This session will review current health plan litigation and trends. It will also review plan language and how that affects litigation including anti-assignment, right of recovery, subrogation, and venue.

10:05 am – 11:05 am CT **Health Plan Trends & Developments, Including Telemedicine, Wellness, Association Health Plans, and the ACA**

***Liz Deckman**, **Holly Fistler** and **Shira Hauschen**, Dorsey & Whitney LLP*

Employers continue to face rising health care costs and are seeking new options to provide health care while limiting costs. This session will look at developments in telemedicine, wellness programs, association health plans, the ACA and more.

11:10 am – 12:10 pm CT **Working with Insurers and TPAs**

***Nadia Martyn**, Delta Dental of Minnesota; **Deb Shoemaker**, PreferredOne and **Melinda Maher**, Dorsey & Whitney LLP*

Group health plans are complex and subject to numerous federal and state laws. The insurer or third party administrator (TPA) takes care of many aspects of the plan's operation. This session is designed to give you a better understanding of the work done by insurers and TPAS and to help employers work with them. The session is not to address specific questions or concerns, but rather to help employers understand the work done by insurers and TPAs – their role in the health care system and how employers can work most effectively with them.

Fourth Annual Forum on Employer Health and Welfare Benefits
Speaker Biographies

Liz Deckman
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Liz is a Partner in Dorsey's Benefits & Compensation Group. She has designed and implemented all types of tax-qualified retirement plans and trusts, including Section 401(k), profit sharing, money purchase, employee stock ownership (ESOP), cash balance, and defined benefit plans. Liz also drafts and implements health and welfare plans and advises employers on related issues, such as COBRA, health care reform, and fiduciary issues. She also works with deferred compensation plans and IRC Section 409A. Liz's work covers issues such as: the effect of new laws on plans, nondiscriminatory coverage and contribution requirements, limitations on benefits, IRS determination-letter applications and plan defect-correction programs, plan terminations, and early-retirement window benefits. She also assists clients in the employee benefits aspects of mergers and acquisitions.

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Holly is a Senior Attorney in Dorsey's Benefits & Compensation Group. She helps clients achieve their business goals through designing and maintaining employee benefit plans. Holly advises clients on ERISA, tax and related issues affecting qualified retirement plans, non-qualified retirement plans, and health and welfare plans. Holly regularly assists clients with plan documents and administration, as well as with navigating compliance issues with the Affordable Care Act, HIPAA and other changing laws in this field. She devotes a substantial portion of her practice to advising public and private companies on their employee benefits issues.

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Tim is a Partner in Dorsey's Benefits & Compensation Group. Tim works with employers on medical plans, retirement plans, executive compensation, and a wide range of benefits. Tim works with a broad array of employers, with a special focus on assisting cooperatives, agribusiness companies, hospitals and health care entities, and financial institutions. Employers have Tim provide advice on health care reform (the ACA), wellness plans, and other welfare plan matters (ranging from cafeteria and health FSAs to severance and tuition plans). With respect to health care reform, Tim advises employers on the new fees (from the employer shared responsibility fee to the Cadillac tax), assists them in preparing for reporting on Form 1095-C, and explains the new requirements ranging from notice requirements to plan mandates. Tim recognizes the complex nature of the rules governing retirement plans and works with employers to review operations, address errors, and help employers maintain the tax-qualified status of their plans. Tim advises employers on qualified and nonqualified retirement plans (including defined benefit, 401(k), 403(b), 457(b), and 457(f) plans, and section 409A).

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Shira is Managing Principal of Dorsey Health Strategies, Dorsey's healthcare consulting group. Shira has advised clients across a wide array of industry segments on topics including digital health (including telemedicine, mHealth, and remote patient monitoring); compliance with federal and state healthcare-related laws; healthcare IT; Big Data; Lean transformations (process improvement); vendor management, data privacy audits; and comprehensive compliance reviews comparing business practices to legal requirements. As a licensed attorney and via the integrated approach taken by Dorsey's Health Care Industry Group, Shira's consulting advice is attuned to and aligned with clients' legal landscape. Shira also leads our Digital Health team at Dorsey, which brings together a wide range of expertise across our firm. Leveraging her prior professional experience in telehealth and software development, she provides clients with practical solutions to business and regulatory questions. Prior to joining Dorsey Health Strategies, Shira worked at McKinsey & Co. as a consultant specializing in healthcare and healthcare IT. Her prior professional background is also in healthcare and healthcare IT, including working at Epic with large healthcare providers to implement EHRs, and as Director of Operations at a telemedicine company.

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Andrew is a Partner in Dorsey's Trial Group. He has extensive experience as lead counsel defending fiduciaries, sponsors, and insurers in ERISA fiduciary class actions, including cases involving company stock, 401(k) plan fees, defined benefit plans, pension age discrimination claims, Taft-Hartley pension plans, prohibited transaction claims, claims for plan benefits, executive compensation claims, and other fiduciary and plan investment matters. Andrew also handles various other complex civil matters, including tax disputes, and various complex civil matters. Andrew has handled dozens of jury and court trials, arbitrations, regulatory matters, and other evidentiary hearings. In addition to his primary work as defense counsel, he has also litigated various multi-million dollar plaintiffs' actions to successful trial judgment or settlement. A prolific speaker and writer, he has twice been named a "rising star" by *Minnesota Law and Politics* Magazine.

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Caitlin is an associate in Dorsey's Trial Group, Caitlin utilizes strategic, creative thinking to represent clients in corporate investigations, fraud and securities litigation, intellectual property litigation, and other complex commercial disputes. She believes that understanding each client's business objectives is crucial to devising the ideal investigation or litigation strategy, and enjoys helping clients pursue their best possible outcomes. In addition, Caitlin enjoys advising clients on anti-corruption and Foreign Corrupt Practices Act ("FCPA") compliance, including developing effective and practical policies and conducting employee trainings. Caitlin is also committed to an active pro bono practice, including representing criminal defendants and appellants in both federal and state court. While in law school, Caitlin briefed and argued a civil appeal before the United States Ninth Circuit Court of Appeals and tried a case before the United States Bankruptcy Court for the District of Minnesota.

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Melinda is a Partner in Dorsey's Benefits & Compensation Group. Her experience includes working with entities involved with health care on compliance with ERISA, COBRA, HIPAA, Medicare Secondary Payer rules, Federal and State health care mandates, and the Patient Protection and Affordable Care Act (Health Care Reform). Melinda's practice focuses on employee health and welfare plans.

Nadia Martyn
Senior Legal Counsel and Privacy Officer
Delta Dental of Minnesota
Minneapolis, Minnesota

Nadia Martyn joined Delta Dental of Minnesota in 2015. Previously, she worked as a health care associate in the Minneapolis office of Dorsey & Whitney, LLP. As Senior Legal Counsel & Privacy Officer, Ms. Martyn is responsible for providing legal support for all aspects of the insurance business of Delta Dental of Minnesota. In addition, Ms. Martyn serves as the enterprise Privacy Officer, overseeing the enterprise-wide privacy program and privacy law compliance, including HIPAA. She is also a Certified Information Privacy Professional with the International Association of Privacy Professionals, with an emphasis on US privacy law. Nadia holds a B.A. in History from Boston College and a juris doctorate from the University of Minnesota Law School.

Deb Shoemaker
Senior Vice President, Chief Legal Officer and General Counsel
PreferredOne
Golden Valley, Minnesota

Ms. Shoemaker joined PreferredOne in 2000. She has served as PreferredOne's Vice President and General Counsel since 2008 and was promoted to Chief Legal Officer in 2015. Ms. Shoemaker serves as the Secretary of all PreferredOne companies. Prior to 2008, she held the position of PreferredOne's Senior Assistant General Counsel and Senior ERISA Counsel. She was in the Office of the General Counsel at UnitedHealth Group from 1991 to 2000; and before that was in private practice at a large Twin Cities law firm, and was a tax and benefits consultant at a national accounting firm. Ms. Shoemaker has diligently led PreferredOne's ongoing compliance effort with respect to federal and state health care reforms including the Affordable Care Act. Ms. Shoemaker leads PreferredOne's legislative affairs, regulatory affairs and corporate compliance activities and oversees its customer contracting and employee benefits compliance. She has more than 30 years of experience in advising health insurers, administrators and employers on the full range of federal laws that affect employer provided health, dental, cafeteria plan, disability and fringe benefits, and qualified and nonqualified retirement plans, including ERISA, HIPAA, COBRA, the ADA, and federal tax law; as well as Minnesota's and other states' health insurance, third party administrator, and health care provider laws. Ms. Shoemaker holds a Juris Doctor degree from Hamline School of Law and a BA degree from Hamline University.

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Health Plan Litigation: More Risks and Employer Response Planning Ahead for an Effective Defense

June 6, 2019

Andrew Holly
Caitlin L.D. Hull
Tim Goodman

Dorsey & Whitney LLP

Background

- **Health plan litigation continues to expand in all areas**
- **Litigation fights, like all conflicts, are often won before they are even fought**
- **Preparing your plan document(s) (and other related documents) for potential litigation could save significant time and energy should litigation arise**

Litigation Overview

- Examples of different types of litigation
  - Out of network provider litigation
  - Surprise billing
  - Service provider litigation
  - ERISA fiduciary litigation
  - ERISA interference litigation
  - Mental health parity litigation

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Out-of-Network Litigation

- Involve claims raised by out-of-network providers against health plans and their TPA's
  - Often involve ERISA and state law claims
- Example: *California Spine and Neurosurgery Institute v. Boston Scientific Corp.*, Case No. 18-CV-07610 (N.D. Cal. May 3, 2019)
  - Out-of-network health care provider brought state law claims in state court against an ERISA plan insurer based on breach of oral contract and promissory estoppel

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Surprise Billing

- Surprise billing is unanticipated charges from out-of-network clinicians
  - May occur when health care facility or primary physician is in-network
  - Patient left with "balance bill" when facility or physician charges difference between their charges and what health plan covers
- Legislation
  - President Trump has directed cabinet officials to address
  - Congress has multiple proposed bills to address
  - Several states have enacted surprise billing legislation
    - State legislation, however, generally does not reach self-insured employer health plans

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Service Provider Litigation

- *In re: Cigna-American Specialty Health Administrative Fee Litigation*, Case No. 2:16-cv-03967-NIQA, (E.D. Penn.)
  - Plaintiffs brought class action litigation against CIGNA alleging collusion with American Specialty Health (ASH) to misappropriate millions of dollars each year and falsification of Explanation of Benefits (EOB) forms to disguise charges from ASH (a similar case filed in California)
    - Primary legal claim is ERISA breach of fiduciary duty
  - CIGNA uses ASH to build a network of providers and administer claims
    - Allegation is ASH and CIGNA administrative expense billed to members as medical claims costs
      - Resulting in overcharges to participants
      - Resulting in false Minimum Loss Ration (MLR) calculation
- PBM class actions

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ERISA Fiduciary Litigation

- *Frye v. Metropolitan Life Ins. Co.*, 2018 WL 1569485 (E.D. Ark. 2018)
  - Employer and insurer failed to notify employee that her son had aged out of dependent life and AD&D coverage and continued to take premiums
  - Court found that it was breach of fiduciary duty to use flawed administrative procedures that failed to confirm eligibility at enrollment, thereby allowing employees to enroll dependents who either were ineligible or became ineligible
  - Court held that appropriate remedy was surcharge against employer and insurer equal to amount employee would have received if coverage had been in force when her son died

ERISA Interference Claims

- *Stein v. Atlas Indus., Inc.*, 2018 WL 1719097 (6th Cir. 2018)
  - Sixth Circuit has ruled that terminated employee may pursue retaliation and interference claims against his former employer under ERISA § 510, reversing the district court's summary dismissal of the case
  - Employee was fired after he failed to report for work (or call in) during three days after his doctor released him for light-duty work following knee surgery
  - Employee argued that his firing was motivated, at least in part, by employer's desire to avoid liability under its self-insured health plan for large medical bills incurred by the employee's son

Mental Health Parity Litigation

- *Munnelly v. Fordham Univ. Faculty and Admin. HMO Ins. Plan*, 2018 WL 1628839 (S.D.N.Y. 2018)
- Two 2018 cases out of Southern District of New York found in favor of plaintiff and against group health plans in MHPA actions:
  - In *Munnelly*, group health plan's exclusion of residential mental health treatment services was improper even before final mental health parity regulations specifically required them to be covered to same degree as skilled nursing facility services
  - In another case, court refused to dismiss claim from individual with anorexia nervosa who alleged MHPA violation arising from failure to cover nutritional counseling for plaintiff, but covering it for non-mental-health conditions such as diabetes

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Preparing for Litigation: General Principles

- Make sure to keep your documents in order—things change over time
- Keep updated on the law and current litigation developments
- Do what you say, say what you do
- Communicate with and understand what is going on with service providers

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Control and Define Your Plan Documents

- What is your plan document?
  - Is the health plan a stand alone plan?
    - Or is it part of comprehensive welfare benefit plan (wrap plan)?
  - Are the plan's terms set forth in a single plan document (a plan-summary plan description (SPD))?
    - Or are there multiple documents that contain plan's terms?
  - What document is provided to employees?
    - SPD-plan document?
    - SPD?
    - Certificate of coverage?

- Are your delegations in order?
- Is all of this apparent on the face of your documents?
- Properly communicating critical litigation terms
- Out with the old….

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Deferential Review

- *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101 (1989) allows benefit plans to allocate discretionary authority to fiduciaries
- Should not be limited to claims for benefits
- Make sure appointments, delegations are always in order
- Applies to factual determinations as well as plan interpretation

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Exhaustion of Plan Remedies

- A judicially-created doctrine, courts generally require that ERISA's administrative claims process be exhausted prior to litigation
- Courts are increasingly making this a matter of contract, rather than statute, so make sure it is explicit
- Make sure that it does not suggest exhaustion is not required—as DOL language might
- And broad—more than just claims for benefits
- Make sure your ancillary documents and claims procedures reflect proper processes and protocol

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Anti-Assignment Clauses

- Courts recognize these clauses as valid and enforceable
- Cannot preclude authorized representatives
- Make sure is broader than simply claims for benefits
- Be careful with respect to clauses that merely "direct payment" to physicians

- *American Orthopedic & Sports Medicine v. Independence Blue Cross Blue Shield; Horizon Blue Cross Blue Shield of New Jersey*, 890 F.3d 445 (3rd Cir. 2018)
  - Anti-assignment clauses enforceable and not waived by routine processing of a claim form, issuing payment at an out-of-network rate, or summarily denying informal appeals
- *Eden Surgical Ctr. v. Cognizant Tech. Solutions Corp.*, 2018 WL 1958811, 720 F.Appx 862 (9th Cir. 2018)
  - Provider has affirmative duty to inquire as to existence of anti-assignment clauses

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Overpayment Recovery

- Complex area of law – ERISA § 502(a)(3) on the one hand, ERISA preemption on the other
- Make sure plan authorizes recovery of assets and institution of constructive trust/equitable lien on overpayment
- And third-party recoveries
- Offsetting other benefits
- Attorneys' fees

Subrogation

- This is the legal right for the Plan to be reimbursed for any amount an injured participant receives from a third party for injuries also covered by the Plan
- Should broadly cover all possible types of recovery and claims—including claims that are not pursued
- Require first dollar reimbursement from any recovery
- Make clear that the "make whole" doctrine and "common fund" doctrines do not apply
- Attorneys' fees and offsets

Venue and Statute of Limitations

- **Venue Clause**
  - **Choose your district (Federal Court)**
  - **Apply to all claims**

- **Statute of Limitations**
  - **Limitations period on filing claims in the first instance**
  - **Post-exhaustion limitations on claims**

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Arbitration Clauses

- **A complex area of law, with upsides and down sides**
- **If you want to do this, make sure to include waivers of class action rights**
- **Can potentially incorporate a general employment waiver**

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DORSEY HEALTH STRATEGIES LLC
A Consulting Firm Affiliated with Dorsey & Whitney LLP

Health Plan Trends & Developments

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Holly Fistler, Senior Attorney
Shira Hauschen, Managing Principal – Dorsey Health Strategies

Dorsey & Whitney LLP

Telemedicine: Topics We'll Discuss

- Telemedicine & digital health, generally – context setting
- Opportunities and challenges
- On the horizon – digital health trends

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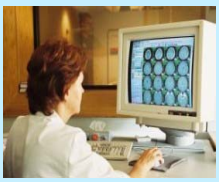
At its simplest, "digital health" is delivering healthcare via technology

- Definitions vary widely, but generally digital health is the broadest category encompassing combinations of healthcare + technology
- Who's speaking? Legal vs. business usage

Virtual care visits / Telemedicine/ Telehealth



Store-and-forward (asynchronous): Remote consults, etc.

Remote patient monitoring (RPM): Often in conjunction with wearables

Use of data in driving care delivery: EHRs; analytics; personalized medicine; IT focus to support healthcare outcomes

What medium? Web-based, mobile (mHealth), app, etc.

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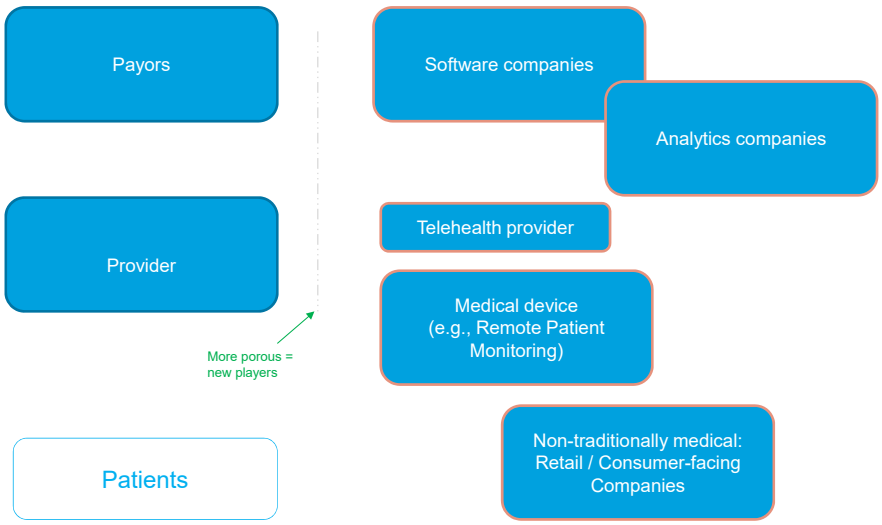
Digital health landscape is diffuse: many different types of companies participate, including those new to the health industry



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Digital health regulations span the gamut of healthcare- and technology-related concerns and are patchwork, evolving, and lag behind the market

- Privacy concerns
  - HIPAA, GDPR, COPPA, TCPA, state-specific regulations
- Licensure
  - State-specific, clinician-specific, and care-setting specific
  - Some telehealth-specific requirements
  - Specific requirements if first-time seeing the patient
  - Don't forget scope of practice
- Reimbursement
  - CMS requirements, Parity laws, coding, requisite documentation
- Credentialing & privileging
- Corporate Practice of Medicine (CPOM)
- Fraud and abuse: False Claims Act, AKS, and Stark
- Prescribing
  - Ryan Haight Act
  - DEA registration
  - 21st Century Cures Act
- FDA
- Contractual issues
- State-specific documentation- and other patient interaction-related requirements
- State-specific website- and app-related requirements

Note: these are concerns primarily for the vendor; however, a savvy purchaser or partner will be aware of and vet the vendor's attendance to these regulations to avoid later issues

These are *in addition* to typical requirements for provision of healthcare

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On the horizon…

<u>Trends in Digital Health (aka, where we will see demand and growth):</u>

- Personalized medicine and genomics
- As regulations and especially reimbursement catch up to the market, expect to see far more clinical offerings (new specialties) offered via telehealth
  - Telepsychiatry and behavioral health, in particular
- Wellness-related offerings will continue to blend into traditional healthcare spaces, and may be regulated as such
- "Big Data" analytics will find firm footing – no longer a question of "if" but "where and what will be done" and via which partner
- Increased reimbursement
  - On pace with increased offerings from gov't? Note VA's offerings.

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Telemedicine

- **Offering telemedicine has potential to decrease total benefit costs, increase convenience for participants**
- **When offering telemedicine, plan sponsors need to be mindful of compliance obligations that may arise:**
  - **ERISA, COBRA and HIPAA rules generally apply, as telemedicine generally provides medical care to participants and dependents**
  - **Coordination with HDHP/HSA coverage to ensure telemedicine benefits do not provide disqualifying coverage**
    - **If services extend beyond categories of permitted coverage (*e.g.*, dental, vision, preventive care, etc.), may cause individual to lose HSA eligibility**
    - **Currently no direct IRS guidance regarding telemedicine**
    - **Conservative approach → ensure HSA-eligible individuals charged FMV of care**
  - **Coordinating telemedicine cost sharing with major medical plan (such as co-pays, expenses towards deductibles, OOPs)**

Telemedicine

- **When offering telemedicine, plan sponsors need to be mindful of compliance obligations that may arise:**
  - **HIPAA privacy and security obligations, both for provider and health plan, to ensure protected health information (PHI) exchanged over electronic medium is secure**
  - **Nondiscrimination considerations, including under Code §105(h) testing for self-insured plans and accessibility for individuals with disabilities**
  - **State licensing requirements may apply if provider is located in another state**

Wellness Programs

- Over past decade, wellness programs growing in popularity and types of offerings
  - Global workplace wellness represents $48 billion industry
    - *Global Wellness Institute, Global Wellness Economy Monitory, October 2018*
  - Offerings continue to diversity and develop in response to employees' needs
    - Physical health and nutrition
    - Mental health and emotional wellbeing
      - Recent trends include employee assistance programs, self-care, resiliency, preventing burn out
    - Financial wellness
    - Onsite clinics, telemedicine
- Industry continues to assess return on investment (ROI)
  - Health care cost reductions may not be as high in short term, yet…
  - Perceived value of wellness initiatives may result value on investment (VOI), such as attracting and retaining employees

Wellness Programs

- Wellness programs – specifically, those focusing on general health and health condition management – are governed by a number of federal laws, including ERISA, HIPAA, Internal Revenue Code, ADA and GINA
- Internal Revenue Code specifies tax treatment of rewards (Code §§ 105, 106)
  - Cash, cash equivalents, other tangible gifts and rewards are generally taxable compensation to the employee
  - Reductions of cost-sharing premiums or additional contributions to HRAs, FSAs or HSAs are generally not taxable
    - These are recognized as employer contributions towards medical insurance coverage
    - Note: Reductions and contributions are subject to the nondiscrimination testing under Code §§ 105 and 125 (if provided in connection with cafeteria plan)

Wellness Programs

- **Regulations under HIPAA and the ADA provide the main framework for wellness programs:**
  - **Regulatory goal: ensure that wellness programs do not use health factors to discriminate among similarly situation individuals with respect to eligibility, premiums or contributions**
  - **HIPAA wellness program regulations issued 2013, effective for plan years on or after January 1, 2014**
  - **EEOC wellness program regulations issued 2016, effective for plan years on or after January 1, 2017**
    - ***AARP v. EEOC* – held EEOC did not sufficiently explain how 30% cost threshold was voluntary, vacated the limitations on incentives section of regulations effective January 1, 2019**
    - **Proposed to have new regulations in effect by 2021**
    - **Update: Chair of EEOC confirmed on May 8, 2019, sworn in on May 15, 2019**
    - **Possibility of Notice of Proposed Rulemaking addressing incentive portion (?)**

Wellness Programs

- **HIPAA and EEOC outline similar, yet distinct, design rules:**

Requirement	HIPAA regulations	EEOC regulations
Reasonable design: • Must promote health or prevent disease • Cannot be overly burdensome, a subterfuge for discrimination or highly suspect in design	Applies to health-contingent programs only; not to participatory programs*	Applies to all wellness programs, regardless of design
Program must be voluntary	N/A	Program cannot: • Require participation • Deny or limit group health plan coverage for nonparticipation • Take adverse employment action for nonparticipation

*** HIPAA regulations distinguish between three types of wellness programs: participatory (e.g., rewards for completing an HRA, attending education seminars, fitness center reimbursements), health-contingent activity-only (e.g., walking, diet or exercise programs), and health-contingent outcome-based (e.g., smoking cessation or attainment of certain biometric results).**

Wellness Programs

- **HIPAA and EEOC outline similar, yet distinct, design rules:**

Requirement	HIPAA regulations	EEOC regulations
Limitations on incentives	No incentive limits for participatory programs. Health-contingent incentives cannot exceed: • 30% of coverage option in which employee participates • 50% of coverage option in connection with programs to prevent, reduce tobacco use Employees must have opportunity to qualify for incentive at least annually	Rules vacated effective 1/1/2019
Must be available on uniform basis	Generally, programs and full incentives must be available to all similarly situated individuals	N/A

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Wellness Programs

- **HIPAA and EEOC outline similar, yet distinct, design rules:**

Requirement	HIPAA regulations	EEOC regulations
Reasonable alternatives	• Health-contingent activity-only programs must offer RAS to individual if unreasonably difficult due to medical condition to participate or satisfy the standard • Health-contingent outcome-based programs must offer RAS to any individual who does not meet the initial standard based on the screening	Reasonable accommodations must be provided to ensure individuals with disabilities have equal access to
Notice to participants	Health-contingent programs must provide notice of terms of program, availability of reasonable alternative standard and contact information	Must provide notice of type of information that is collected as part of the program, how it is used and disclosed, and methods for protecting the information

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Wellness Programs

- **Regulations under GINA provide additional requirements, including:**
  - **Health risk assessments cannot ask for an individual's genetic information, including family health history**
  - **2016 GINA regulations clarified that employee's spouse may be offered limited incentives for providing information about manifested health conditions**
    - **Still may not ask for any other genetic information, including family health history**
    - **Prohibited from providing incentives for children's health information**
  - **Note: Incentive limits from the 2016 GINA regulations were also vacated in the 2017 *AARP v. EEOC* decision**
- **If the wellness program offers medical care, wellness program will also be subject to ERISA requirements**
  - **May be combined with major medical or other plan for ERISA compliance**
- **HIPAA privacy and security rules apply if collects health information**

Association Health Plans

- **On June 21, 2018, Department of Labor (DOL) published final rules expanding availability of AHPs**
  - **Purpose of AHP is to allow small employers to band together and obtain coverage in large group insurance market, which generally imposes fewer coverage requirements**
  - **According to DOL, AHPs will "expand employer and employee access to more affordable, high-quality coverage"**
- **However, AHPs are MEWAs and therefore are subject to regulation under state laws, and they are still subject to certain other federal mandates**

Association Health Plans

- New final regulations expand existing test to determine whether association is employer plan sponsor of group coverage by allowing any size employer, including working owner, to join AHP if:
  - Employers are in same trade, industry, line of business, or profession; OR
  - Each employer has principal place of business in same region that does not exceed boundaries of single state or metropolitan area (even if metropolitan area includes more than one state)
- This permits even those employers from disparate industries to form an AHP, so long as geographic region requirement is met
- Still difficult to be a self insured MEWA (and still prohibited in most states)

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Association Health Plans

- On March 28, 2019, a district court, in a case brought by eleven states and the District of Columbia, ruled that the DOL exceeded its statutory authority when it issued a final rule expanding the type of entities that could sponsor a large group health plan under the auspices of an association health plan
- The court held that the final rule "scraps" the most fundamental distinction between ERISA covered plans which must have an employer-employee nexus and commercial transactions between insurance companies and unrelated insureds
- Remanded the final rule to the DOL to review the impact of its decision under the final rule's severability provision
- DOL filed a notice of appeal on April 26, 2019 and issued FAQs

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Selecting Top Physicians, Centers of Excellence

- **Either the centers of excellence are required (*e.g.,* in-network coverage limited to the selected physicians) or are incentivized**
  - **More generous cost sharing (co-pays waived, 100% co-insurance, etc.)**
  - **Travel costs may be reimbursed as well, though may or may not be excluded from income as a medical expense under Code § 213(d)**
- **Practical considerations:**
  - **Identifying, selecting centers of excellence necessitates coordination with claims administrator, stop loss carrier**
  - **Certain medical fields, procedures easier to quantitatively compare than others**
  - **Travel considerations for employees and family members**
  - **Monitoring results, adjusting plan design**

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Selecting Top Physicians, Centers of Excellence

- **Health plans incentivizing or requiring participants to obtain health care services from selected top performing providers and hospitals**
- **Top performing providers (*e.g.,* Centers of Excellence) identified as offering:**
  - **Concentration of expertise in a particular medical field**
  - **Higher quality procedures and demonstrated outcomes**
  - **Cost-effective pricing**

Cost savings to the health plan + Best outcomes for employees

- **Most often involves medical fields with high levels of specialization, such as:**
  - **Cancer treatment**
  - **Orthopedic surgeries**
  - **Spine surgeries**
  - **Cardiac care**

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On-Demand Health Insurance

- New trend for self-insured plans allowing participants to tailor health coverage to individual needs
  - Overall goal → simplified process, transparent pricing, flexible coverage
- Concept features core benefits and buy-up coverage
  - Employer-sponsored plan provides employees with a basic level of coverage
    - For example, may include preventive care, hospital and urgent care, cancer treatments, maternity care, prescription drug coverage
    - Cost sharing structure may be generous (for example, lower deductibles, small or no co-pays, etc.)
  - Employees may purchase additional coverage for health care needs that arise
- Since on-demand is relatively new, vendors and plan sponsors working together to develop established practices:
  - Creating plan rules for eligibility, changing elections under cafeteria plans, general plan administration
  - Addressing potential nondiscrimination issues related to buy-up coverage

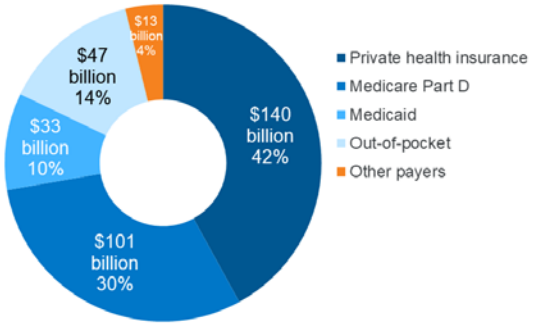
Prescription Drug Spending

- The Trump Administration, as well as Democrats and Republicans, have decided that RX spending is an easy target
- On May 8, 2019, HHS announced a final rule from CMS that will require drug makers to disclose the list price of prescription drugs in TV ads

Prescription Drug Spending

Figure 1

Total U.S. Retail Prescription Drug Spending, 2017



Total U.S. Retail Prescription Drug Spending in 2017: $333 billion

NOTE: Total prescription drug spending accounts for rebates.
SOURCE: KFF analysis of 2017 data from the National Health Expenditure Accounts.

KFF

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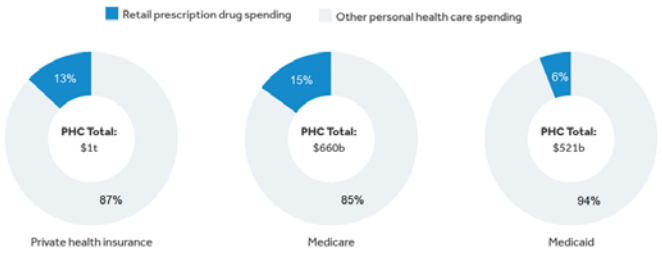
Prescription Drug Spending

Figure 2

Percent of Total Personal Health Care (PHC) Spending Accounted for by Retail Prescription Drug Spending, 2017



NOTE: Total prescription drug spending accounts for rebates.
SOURCE: KFF analysis of 2017 data from the National Health Expenditure Accounts.

KFF

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Prescription Drug Spending

- **Improvements to Medicare Advantage and Medicare Part D Final Rule – May 16, 2019**
  - Part D plans must have a tool that provides clinicians with information to discuss out of pocket costs for prescription drugs at the time a prescription is written
  - Explanation of Benefits required for Part D enrollees to include information on drug prices increases and lower cost therapeutic alternatives
  - Beneficiaries can select a Medicare Advantage plan that negotiates prices for physician administered medicines when beneficiaries are first starting on medicines.
  - Agency considered a policy to ensure that beneficiaries pay the lowest cost for prescription drugs that they pick up at a pharmacy
    - Not implemented for 2020
    - CMS received over 4,000 comments were received

Prescription Drug Spending

- **Federal anti kickback statute makes it a crime to pay or receive remuneration to induce or reward the referral of items or services reimbursable by federal health care programs but some safe harbors**
- **Proposed rule by HHS: Prohibits Part D plan sponsors, Medicaid Managed Care Organizations and PBMs acting with them from offering group or individual coverage (including PBM that provides service to plan or issuer) from receiving a reduction in price or other remuneration with respect to any prescription drug received by an enrollee UNLESS**
  - Reduction in price is reflected at the point-of-sale to the enrollee; and
  - Any other remuneration is a flat fee-based service fee that a drug manufacturer pays to a PBM for services provided to the manufacturer, if certain conditions established by the Secretary are met, including disclosure of fees to plans and issuers

Prescription Drug Spending

- **2018 Employee Benefits Survey – What are employers doing to alleviate drug spending?**
- **Tiered cost-sharing plans are common, offered by 92% of responding organizations**
  - **Three-tiered systems, offered by one-half (50%) of responding organizations, typically have one cost-sharing level for generic drugs, a higher level for preferred brand-name drugs and an even higher level for nonpreferred brand-name drugs. It's common for survey respondents to have four (35.3%) or even five (6.7%) tiers for prescription drug cost sharing**

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Prescription Drug Spending

- **Coverage limits by drug type**
  - **70.9% use a drug formulary**
  - **50% use step therapy, which requires a beneficiary to use the most cost-effective treatment before proceeding to those that are more expensive or are riskier to use**
  - **To reduce plan costs, 39.4% promote the use of generic drugs via financial incentives**
  - **36.3% take this concept a step further and mandate the use of generic options**
  - **20.9% place specific limits on specialty and biotech drugs**
  - **20.5% limit or do not cover lifestyle drugs, which are not considered medically necessary and target conditions such as obesity, infertility or cosmetic issues**

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Prescription Drug Spending

- **Coverage limits by drug type (continued)**
  - **17.5% responding organizations utilize preferential pricing agreements, which are negotiated directly with pharmacies or manufacturers**
  - **13.4% cover select over-the-counter (OTC) drugs**
  - **6.5% utilize reference-based pricing so that the price or reimbursement level of a specific drug is set by drug group or class**

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Prescription Drug Spending

- **Drug Access Controls**
  - **85.3% offer a mail-order drug service (85.3%) to reduce prescription drug costs, focusing particularly on long-term drug therapies**
  - **47.8% use prior authorization or utilization management and 38.7% use preferred provider networks**
  - **23.5% have a drug card program**
  - **14.4% have access to an on-site or near-site pharmacy**
  - **7.4% offer split- or partial-fill strategies, in which prescriptions are filled on a split or partial basis to avoid waste and reduce costs**

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Prescription Drug Spending

- **Purchasing/Administration Initiatives**
  - **65.2% contract with a pharmacy benefit manager (PBM)**
  - **9.6% is part of a collective purchasing group**

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Mirror, Mirror on the Wall…?

- **Future of the ACA?**
  - **Texas v. Azar - individual mandate un-constitutional following tax reform**
    - **Critical component of the ACA**
    - **Inseverable**
  - **ACA declared unconstitutional but remains enforceable**
  - **Appealed to Fifth Circuit**
  - **Trump has weighed in for complete repeal (and a replace after 2020?)**
- **Save American Workers Act**
  - **Full time workers at 40 hours per week, not 30**

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Working with Insurers and TPAs

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Working with Insurers and TPAs

- **Introductions**
- **Ground Rules**
- **Agenda**
- **Questions**

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Working with Insurers and TPAs

- **Insurer vs Third Party Administrator (TPA)**
  - **Structure**
  - **Licensure**
  - **Regulatory oversight**

- **Self-insured vs. insured health or dental plan financial risk**
  - **Insured: employer/employee pays premium but risk beyond that is on the carrier**
  - **Self insured:**
    - **Employer is responsible for claims payment beyond the cost sharing imposed on covered individuals**
    - **Employer may cede some risk to a reinsurer (aka stop loss carrier) whereby claims over a certain threshold are covered by reinsurer**

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Working with Insurers and TPAs

- **Considerations to be self-insured:**
  - **Size and location of employee work force**
  - **Risk profile**
  - **Financial status**
  - **Controlled Group: if affiliates or other entities are outside the controlled group, then you may have a MEWA**
  - **Control of benefits and eligibility**
  - **Other?**
- **Compliance issues**
  - **State law applies for insured plans**
  - **ERISA preempts state law for self insured plans**
  - **HIPAA Privacy obligations are on the employer for self funded plans, and on the insurer for insured plans (generally)**

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- **Eligibility and Benefits**
  - **Insured plan: eligibility and benefits are dictated by state and federal law, cost and, perhaps, the market**
  - **Self insured plan: eligibility and benefits are dictated by federal law, cost, employer's desire for competitive benefits, tax issues (e.g. coverage for non-tax dependents is taxable to employees; may not discriminate in favor of HCEs)**
- **Employer's role in designing eligibility and benefits under insured plan? Self insured plan?**

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- **Contracts**
  - **For insured plans:**
    - **Filed with and approved by the state**
    - **Premium rates filed with and approved by the state**
    - **Contract is really effectively a "policy"**
    - **Require counter signature?**
    - **Issued each year?**
  - **For self funded plans:**
    - **Administrative Services Agreement (ASA)**
    - **Not filed with or approved by the state**
    - **Typically evergreen for some period?**
  - **Typical problem: contracts not signed or signed long after services are being provided**

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Working with Insurers and TPAs

- **Plan documents**
  - **What is the process of the TPA to produce SPDs?**
  - **What is the process of the Insurer to produce SPDs?**
  - **SPD vs Plan Document vs Certificate of Coverage (or other term for insurance)**
  - **Summary of Benefits and Coverage (SBC)**
  - **Other employee communications**
  - **How can employers work most effectively with the TPA or insurer?**

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Working with Insurers and TPAs

- **Understanding networks and how they work**
  - **In Network/Out of Network**
  - **Different levels of in network?**
  - **Are networks consistent for both insured and self funded books of business?**
  - **How does payment work?**
  - **Balance billing**

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- **Claims process**
  - **Who is the claims fiduciary?**
  - **Employer (plan sponsor) involvement? Or delegate to the TPA?**
  - **What is employer's involvement, if any, in insured plan appeals?**
- **What can go wrong in the claims process?**

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- **Compliance:**
  - **Affordable Care Act**
    - **What is the employer's responsibility?**
    - **What is TPA's responsibility?**
    - **What is insurer's responsibility?**
  - **HIPAA Privacy and Security**
    - **What is the employer's responsibility?**
    - **What is TPA's responsibility?**
    - **What is insurer's responsibility?**
  - **COBRA**
    - **What is the employer's responsibility?**
    - **What is TPA's responsibility?**
    - **What is insurer's responsibility?**
  - **Reporting**
    - **Form 5500 filings**
    - **Summary annual report**

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- **New and innovative ways to approach plans:**
  - **Wellness programs**
  - **Disease management**
  - **"Buying up" to health insurance**

- **Common problems for insurers and TPAs:**
  - **Mergers and Acquisitions of clients, which implicates requirements in other states**
  - **Retirees crossing state lines**
  - **Licensing**

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Working with Insurers and TPAs

Questions

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