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Health Care Law Update

Presented by the CBA Health Care Law Practice Group

Thursday, December 6, 2018

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8:25 a.m.	**Welcome & Opening Remarks**	
8:30 a.m.	**Digital Health and Connected Devices – Managing Privacy and Data Security in the Digital Health Era** Jennifer O. Mitchell, Esq. & Geoffrey L. Oberhaus, Esq., *Dinsmore & Shohl LLP*	**TAB A**
9:30 a.m.	**Pharmacy Benefit Managers, Group Health Plans and Enrollees: Allies in Better Health or Implacable Adversaries?** William M. Freedman, Esq., *Dinsmore & Shohl LLP*	**TAB B**
10:30 a.m.	**Break**	
10:45 a.m.	**Affordable Care Act Developments** Kimberly D. Wilcoxon, Esq., *Thompson Hine LLP*	**TAB C**
11:45 a.m.	**Break**	
12 p.m.	**Group Luncheon Presentation Attorney Conduct: Achieving Your Peak Professional Performance – The Role of Exercise and Nutrition in Mental Health & Work-Life Balance** Cindy Cassell, Ph.D., RD, LD, *Sports Nutritionist, Kettering Sports Medicine Center*	**TAB D**
1 p.m.	**Break**	
1:15 p.m.	**Breakout Sessions:** **Breakout I: Chronic Care Management and Remote Patient Monitoring** Sara M. Cooperrider, Esq. *Taft Stettinius & Hollister LLP*	**TAB E**
	Breakout II: Compliance 101 Lisa A. Taylor, Esq., *VP & Chief Compliance Officer, UC Health*	**TAB F**
2:15 p.m.	**Medical Marijuana** Monica H. McPeek, Esq., *Director of Risk Management at TriHealth, TriHealth* Brian F. Higgins, Esq., *Frost Brown Todd LLC*	**TAB G**
3:15 p.m.	**Adjourn**	

TAB
A

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Jennifer Orr Mitchell

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Jen focuses her practice on complex health care litigation, investigations, regulatory compliance, and cybersecurity. She has significant experience leading the defense of health care entities in False Claims Act (FCA) and other litigation involving claims of health care program fraud and abuse. Her practice involves handling health care litigation in federal and state courts nationwide, including serving as national litigation counsel for a health care provider with locations across the country. She is experienced in ERISA and other benefits and coverage litigation, as well as business practices, fiduciary, class action and mass tort litigation. Jen is chair of Dinsmore's Health Care Industry and Government Relations practice groups.

Within the constantly evolving health care legal landscape, she provides guidance to clients across the health care industry as to how to comply with the Federal and state anti-kickback laws, the Stark law, the HIPAA regulations, Medicare/Medicaid rules and regulations, the Affordable Care Act, MMSEA/MSP requirements, FDA and ADA regulations, and other laws, rules and regulations impacting their businesses.

Drawing upon her health care litigation and compliance background, Jen has an active investigations practice.

SERVICES

Health Care Industry

False Claims Act

Government Relations

Litigation

White Collar Crime

ERISA Litigation & Administrative Proceedings

Cybersecurity & Data Privacy

Pharmaceutical & Medical Devices

Government Investigations

She conducts health care due diligence, compliance audits and investigations for clients nationwide and represents them when they are under investigation by federal and state authorities for health care fraud and abuse, HIPAA breaches, and other regulatory non-compliance.

Jen leads the firm's health care privacy and cybersecurity practice and initiatives. In her cybersecurity practice, she works with clients in all industries to minimize the risk of privacy and data security breaches and assists with all aspects of privacy and security compliance, governance, audits/investigations, enforcement actions, breach analyses, training and strategic planning. She has a thorough understanding of federal and state privacy and data security laws, has served as a health care privacy expert witness, and is a frequent presenter on cybersecurity and privacy topics.

Education

- University of Akron School of Law (J.D., cum laude, 1998)
- Miami University (B.A., 1995)

Bar Admissions

- Ohio
- Kentucky

Court Admissions

- U.S. Supreme Court
- U.S. Court of Appeals for the Sixth Circuit

- U.S. District Court for the Southern District of Ohio
- U.S. District Court for the Northern District of Ohio
- U.S. District Court for the Eastern District of Kentucky
- U.S. District Court for the Eastern District of Wisconsin

Affiliations/Memberships

- Xavier University, Cincinnati, Ohio
  - Adjunct professor of Health Law & Policy
- University of Cincinnati
  - Former adjunct professor in Health Law & Policy in the Graduate Program in Health Services Administration at the College of Allied Health Sciences
- American Bar Association
  - Health Law Section
  - Vice chair, eHealth Privacy & Security
- Association of Defense Trial Attorneys
  - Ohio State chair
  - Membership vice chair
  - Chair of We Prefer to Refer (WPTR) Committee
- Cincinnati Bar Association, Health Law Committee vice chair
- LifeCenter Organ Donor Network, Board of Directors
- American Heart Association, Greater Cincinnati Heart Ball Executive Leadership Team
- YWCA Rising Stars Alumnae Committee
- United Way WINGs and Roebling Society
- American Health Lawyers Association

- Defense Research Institute
- Society of Ohio Healthcare Attorneys
- The University of Akron School of Law, Legal Writing former adjunct professor
- Cincinnati USA Regional Chamber
  - Leadership Cincinnati Class 40 (2016 - 2017)
  - WE Lead Class 9 (2014 - 2015)
- Board of Children, Inc., Board of Directors

Distinctions

- Potter Stewart American Inn of Court, barrister
- Forty Under 40, from the *Cincinnati Business Courier* (2007)
- YWCA Women of Achievement Rising Star (2007)
- YWCA Rising Stars Board Leadership Program (2008)
- *Best Lawyers*© for Health Care Law

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Geof facilitates and protects innovation from the origination of the idea, registration/protection of the innovation, licensing of the innovation, and enforcement of the innovation. This can include patentability opinions, freedom to operate studies, licensing agreements, development agreements, patent applications, trade secret protections, copyright and trademark registrations, distribution agreements, channel-partnering agreements and the like. In addition, Geof provides advice and counseling on exporting the innovation and related technology outside of the United States to maintain compliance with various export regulations such as EAR and ITAR.

He provides advice and creative solutions to help clients accomplish their business goals while minimizing the risk of privacy and data security related issues. This can include privacy audits, business planning/advice to incorporate privacy by design, strategic planning for day-to-day and situational responses and creation/review of appropriate policies and agreements.

Geof's practice focuses on IT licensing, patent

SERVICES

Entertainment Industry

Intellectual Property

Privacy, Data Protection & Internet Technologies

Patent Procurement & Management

International Business

Intellectual Property Licensing

Intellectual Property Litigation

Cybersecurity & Data Privacy

Pharmaceutical & Medical Devices

protection, litigation, trade secrets, copyrights, trademark, software protection, e-commerce, privacy law, licensing, open-source, export compliance (EAR & ITAR). He serves as the vice chair of the Systems Committee and is past chair and member of the firm's Professional Development Committee, as well as a member of the Workplace Harassment Committee.

Health Care Industry

Education

- Rutgers University School of Law, Camden (J.D., 1998)
  - Albert P. Blaustein Memorial Award for the highest standard of legal scholarship published in the Rutgers Law Journal
- University of Detroit (B.S., cum laude, 1992)
  - Chemical Engineering

Bar Admissions

- Ohio
- U.S. Patent & Trademark Office

Court Admissions

- U.S. District Court for the Southern District of Ohio

Affiliations/Memberships

- American Bar Association
- Cincinnati Bar Association

- Cincinnati Intellectual Property Law Association (Cincy IP), CIO
- International Association of Privacy Professionals
- Intellectual Property Owners Association, IP Licensing Committee
- Licensing Executives Society
- United Way of Greater Cincinnati
  - The Tocqueville Society
  - Tocqueville Advisory Council
- United Way Health Impact Council

Distinctions

- New Century Community Service Award from United Way of Greater Cincinnati (2010)
- Ohio *Rising Star*®
- *Who's Who in America*
- *Who's Who in Emerging Leaders*

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Diving into Digital Health and Connected Devices

December 7, 2018

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Overview

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Overview

- **Cybersecurity and Privacy Landscape**
- **Managing Privacy and Data Security in the Digital Health Era**
- **Prosecution Case Studies of Combination Products**
  - AliveCor Kardiaband™ → Apple Watch EKG
  - Abilify MYCITE® → Pill/Sensor/App – Compliance Monitor
- **Understanding IVDs – Connecting Wearables to Electronic Medical Records**
- **Tackling Cybersecurity Challenges**

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Cybersecurity and Privacy Landscape

"You can't list your iPhone as your primary-care physician."

Healthcare Privacy and Security Overview

- → The healthcare industry was the victim of **88%** of all ransomware attacks in U.S. industries in 2016.
- → **89%** of studied healthcare organizations have experienced a data breach, which involved patient data being stolen or lost, over the past two years
- → Ransomware attacks on healthcare organizations will **quadruple** by 2020.

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Healthcare Privacy and Security Overview

- Health data breaches are costing the U.S. healthcare industry an estimated **$6.2 billion**
  - ⇒ Notification Costs
  - ⇒ Organizing the incident response team
  - ⇒ Conducting investigations and forensics to determine the root cause of the data breach
  - ⇒ Determining the victims of the data breach
  - ⇒ Lost Business
  - ⇒ Legal services for defense
  - ⇒ Legal services for compliance
  - ⇒ Investigations & Enforcement fines/penalties

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Healthcare Privacy and Security Overview

→ The healthcare industry is the most targeted sector

- ⇒ Personal medical information remains one of the most valuable types of data
- ⇒ Personal health information is **50** times more valuable on the black market than financial information.
- ⇒ Stolen patient health records can fetch as much as **$60-100** per record or more.
- ⇒ 2014 FBI warning to healthcare providers

  The healthcare the industry "is not as resilient to cyber intrusions compared to the financial and retail sectors, therefore the possibility of increased cyber intrusions is likely."

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Healthcare Privacy and Security Overview

The privacy and security of healthcare data in the U.S. is governed by a patchwork of federal and state regulations and standards.

- → **HIPAA –** Applies to "Protected Health Information"
- → **42 CFR Part 2** – Regulates the confidentiality of substance use records
- → **FTC Act** - Applies to "unfair or deceptive acts or practices," including failure to live up to privacy promises to consumers
- → **State Laws**
  - ⇒ **Ohio's new Data Protection Act**
- → **GDPR**

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HIPAA Overview

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Made up of two rules:

- → **Privacy Rule –** Enacted in April 2003 and protects all "PHI" (Protected Health Information), which includes just about any piece of information that might possibly identify a person, in any form, including oral information.
- → **Security Rule –** Enacted in April 2005 and mandates various safeguards for Electronic PHI (or "ePHI"), training and written security program.

Applies to all "Covered Entities" and their "Business Associates"

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HIPAA Security Rule

Mandates protections and safeguards for electronic PHI ("ePHI")

- → Administrative
- → Physical
- → Technical

The Security Rule provides guidance as to the nature and function of each individual safeguard.

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42 CFR Part 2

Applies to:

- → Part 2 Program: a federally assisted program providing substance use disorder diagnosis, treatment, or referral for treatment

Requires:

- → Formal policies and procedures to protect against unauthorized uses and disclosures of electronic records:
  - ⇒ (i) Creating, receiving, maintaining, and transmitting such records;
  - ⇒ (ii) Destroying such records, including sanitizing the electronic media on which such records are stored, to render the patient identifying information non-retrievable;
  - ⇒ (iii) Using and accessing electronic records or other electronic media containing patient identifying information; and
  - ⇒ (iv) Rendering the patient identifying information non-identifiable in a manner that creates a very low risk of re-identification (e.g., removing direct identifiers).

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The FTC Act

FTC Enforcement Authority

→ Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45

⇒Prohibits "unfair or deceptive acts or practices in or affecting commerce"

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State Laws

State Data Breach Notification Laws

→ Forty-eight states, the District of Columbia, Guam, Puerto Rico and the Virgin Islands have enacted legislation requiring private or government entities to notify individuals of security breaches of information involving personally identifiable information.

⇒Alabama and South Dakota are the only states without a data breach

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State Laws

State Data Breach Notification Laws

- → Provisions are often broader in scope than other privacy laws
  - ⇒ Usually cover "personal information" (e.g., name combined with SSN, drivers license or state ID, account numbers, etc.)
  - ⇒ Usually refer to "breach of the security of a **system**"…but some include paper form of PHI.
- → Time periods for notification may be much shorter than other laws, such as HIPAA
  - ⇒ 45 days in Ohio
  - ⇒ 15 days in California
  - ⇒ New Mexico most recently enacted in June 2017

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State Laws

Ohio's Data Protection Law

- → On August 3, 2018, Ohio Governor John Kasich signed the Ohio Data Protection Act, which will provide a legal safe harbor against data breach claims to businesses that implement specified cybersecurity controls.
- → The Act went into effect on November 2, 2018 and is now codified at O.R.C. §§ 1354.01-1354.05. Ohio is the first state in the country to implement a law that provides a data breach safe harbor for businesses.
- → The DPA provides companies with an affirmative defense from tort claims arising out of a data breach concerning personal information if a written cybersecurity program is in place that "reasonably conforms to an industry recognized cybersecurity framework."

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State Laws

Ohio's Data Protection Law

→ The Act recognizes the following as industry recognized cybersecurity frameworks:

- ⇒ National Institute of Standards and Technology (NIST) "framework for improving critical infrastructure cybersecurity" along with **NIST** special publications 800-171; 800-53; and 800-53a;
- ⇒ The Federal Risk and Authorization Management Program (FedRAMP) security assessment framework;
- ⇒ The **Center for Internet Security Critical Security** controls for effective cyber defense;
- ⇒ For Covered Entities, as defined by **HIPAA** rules, the security requirements of HIPAA set forth in the Code of Federal Regulations 45 CFR Part 164 subpart C and HITECH as set forth in 45 CFR part 162;
- ⇒ Title V of the **Gramm-Leach-Bliley Act** of 1999, as applicable to financial institutions; and
- ⇒ The payment card industry (**PCI**) data security standard, as applicable to companies that accept payment cards.

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State Laws

Ohio's Data Protection Law

→ The written cybersecurity program must: (1) protect the security and confidentiality of information; (2) protect against any anticipated threats or hazards to the security or integrity of information; and (3) protect against unauthorized access to and acquisition of the information that is likely to result in a material risk of identity theft or fraud.

→ For a company to be entitled to the affirmative defense under the Act, the size and scope of the cybersecurity program must be appropriate for the organization based upon five factors: (1) the size and complexity of the organization; (2) the nature and scope of the activities of the covered entity; (3) the sensitivity of the information to be protected; (4) the cost and availability of tools to improve information security and reduce vulnerabilities; and (5) the resources availability to the organization.

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Costs of a Data Breach

Legal frameworks provide for different fines and penalties in the event of a breach

- → Civil Penalties
  - ⇒ HIPAA violations range from $112 to $55,910 per violation, based on level of knowledge; $1.67 million mad/year (adjusted for inflation)
  - ⇒ FTC can impose fines up to $40,654 (adjusted for inflation) per violation
- → Criminal
  - ⇒ HIPAA provides for criminal fines up to $250,000 and imprisonment of up to 10 years.

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Costs of a Data Breach

- → **HIPAA Penalties –**
  - ⇒ Healthcare industry has highest cost per capita in event of a data breach
    - $402 compared to overall mean of $221
  - ⇒ However, for "consumer" wearable industry, costs are more in line with average
    - $218 per record

- → **GDPR Penalties –**
  - ⇒ Breaches resulting from willful misconduct or gross negligence can result in fines of the greater of €20 million or 4% of gross global revenue penalties

Healthcare Cybersecurity Tips

HHS Top 10 tips for Cybersecurity in Healthcare

1. Establish a security culture
2. Protect mobile devices
3. Maintain good computer habits
4. Use a firewall
5. Install and maintain anti-virus software
6. Plan for the unexpected
7. Control access to PHI
8. Use strong passwords and change them regularly
9. Limit network access
10. Control physical access

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Healthcare Cybersecurity Tips

Health Care Industry Cybersecurity Task Force – Six Security Imperatives:

- **Define and streamline leadership, governance, and expectations for health care industry cybersecurity**
  - standardized risk assessments
- **Increase the security and resilience of medical devices and health IT**
  - two factor authentication where a health care provider is accessing EHR outside the clinical setting
- **Develop the health care workforce capacity necessary to prioritize and ensure cybersecurity awareness and technical capabilities**
  - identify a cybersecurity leader in each organization
  - certify higher education programs in cybersecurity
- **Increase health care industry readiness through improved cybersecurity awareness and education**
- **Identify mechanisms to protect research and development efforts and intellectual property**
- **Improve information sharing of industry threats, weaknesses, and mitigations**
  - have a cybersecurity incident response plan which is reviewed and tested annually

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EXAMPLE PHOTO & TEXT

Managing Privacy in the Digital Health Era

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Traditional Modalities of Telehealth

Synchronous, Real-Time

→ Live, two-way interaction between a patient and a health care provider using audiovisual technology

Asynchronous, Store-and-Forward

→ Transmission of a patient's recorded health history through a secure electronic communication system to a health care provider

→ E.g. services that transmit medical data, x-rays, images, lab results

Remote Patient Monitoring

→ Collection of a patient's personal health and medical data via electronic communication technologies. Once collected, the data is transmitted to a provider at another location, with continual tracking by original provider

mHealth

→ Wearable devices/smart phones to track health and wellness

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"We now feel it's cheaper to do surgery via Skype. So, go home and lie down in front of your computer."

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Mobile Health Applications (mHealth)

- **mHealth: "[T]he use of mobile and wireless devices to improve health outcomes, healthcare services, and health research."**
- **By 2020, worldwide mobile health market expected to grow to 49 billion**
- **Purposes:**
  - Track food intake, physical activities, food, weight
  - Communicate with provider
  - Medical monitoring
- **Legal Issues: HIPAA, FDA, FTC, FCC, COPPA, GDPR**
- **FTC Interactive Tool for Developers of Mobile Health Apps (OCR, FDA)**

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Types of PII/PHI

Protected	Highly Protected
• Name (in conjunction with other data elements) • Date of Birth • Full Face Photographic • Account Numbers (General) • Health Plan Beneficiary Numbers • Certificate/License Numbers • Drug Enforcement Administration Number • Vehicle Identifiers and Serial Numbers • Signature	• Health Information • Social Security Number • Passport Information • Financial Data • Sensitive Personal Information • e.g., racial or ethical origin, political opinion, religious belief, trade union membership, health, sexual preference • Drivers License Number • Medical Record Numbers • Biometric Identifiers • Physical Characteristics • Account Numbers (e.g., Credit Card)

* Above is an illustrative list that can be used in data classification, not exhaustive.
** Combination of any of the terms above could be classified as PII.

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Understanding Complex Global Regulatory Environment

Region	Jurisdiction	#	Source
Canada	National	1	Canada National – Personal Information Protection and Electronic Documents Act (PIPEDA) ** Alberta and BC also have provincial data protection acts (PIPA Alberta and PIPA BC respectively), as well as a national act covering personal data in the Private Sectors.*
Europe	European Union	2	European Union – CURRENT Data Protection Directive (Directive 95/46/EC)
		3	European Union – May 25, 2018 General Data Protection Regulation (GDPR)
Japan	National	4	Japan National – Act on Protection of Personal Information (APPI)
Uruguay	National	5	Uruguay National – Data Protection Act Law No 18.3331 (2008); Decree No. 414/009 (2009)
US	Federal		United States – Federal – Health Insurance Portability & Accountability Act (HIPAA) Privacy Rule
			United States – Federal – Health Insurance Portability and Accountability Act (HIPAA) Security Rule
		6	United States – Federal – Controlling the Assault of Non-Solicited Pornography and Marketing (CAN-SPAM) Act
		7	United States – Federal – Fair Credit Reporting Act (FCRA)
		8	United States – Federal – Junk Fax Prevention Act (JFPA)
		9	United States – Federal – Telephone Consumer Protection Act (TCPA)
	California	10	United States – Federal – Children's Online Privacy Protection Act (COPPA)
		11	United States – California –Civil Code 1798.29 and 1798.82-1798.84 (SB 1386) (Breach Notification)
		12	United States – California –Civil Code 1798.85 (SSN Law)
		13	United States – California –Civil Code 1798.91 (Senate Bill No. 1633 - An act to add Title 1.81.25 (commencing with Section 1798.91))
		14	United States – California –Civil Code 56.11
		15	United States – California –Confidentiality of Medical Information Act (CMIA)
	Connecticut	16	United States – Connecticut – General Statutes 42-470
		17	United States – Connecticut – Public Act 08-167
	Massachusetts	18	United States – Massachusetts – 201 CMR 17.00
	New Jersey	19	United States – New Jersey – NJSA 56:8-162
		20	United States – New Jersey – NJSA 56:8-163
		21	United States – New Jersey – NJSA 56:8-164
	Texas	22	United States – Texas – Health and Safety Code CHAPTER 181
		23	United States – Texas – Business and Commerce Code CHAPTER 501
		24	United States – Texas – Business and Commerce Code CHAPTER 521
Corporate Standards		25	Intra-Company Agreements, Binding Corporate Rules (BCRs), Privacy Shield Certifications
Standards		26	AICPA Generally Accepted Privacy Principles (GAPP)

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Digital Health – Mobile Device Delivery Model

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Data Privacy Analysis for Digital Health

DATA PRIVACY ANALYSIS

- What data is being collected?
- Who is collecting?
- Where is it going?
- How is it being used?
- Who has access to it?

REGULATORY CONSIDERATIONS

- Health data → HIPAA regulatory enforcement
- Global data processing → cross-border considerations (e.g. GDPR and notice/consent obligations)
- individual's rights to the data
- private right of action under state, national or territorial national law
- Agency enforcement (FTC activity increasing to ensure privacy/security under state law)

OTHER CONSIDERATIONS

- Vendor Due Diligence
  - Information Security Assessment
  - Privacy Assessment
- Contracts
  - Data Sharing Agreements
  - Data Ownership Agreements
  - Responsible Party for Regulatory Compliance
- Cross-Border Agreements
  - Standard Contract Clauses
  - Data Protection Appendices

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Consider Privacy in the Design

Privacy by design is an approach to projects that promotes privacy & data protection compliance from the start.

ANALYZE & COLLABORATE	• Business – Legal – IT Cross Functional Collaboration • Strategy • Selection • RFP • Contract Negotiations
AGILITY & FLEXIBILITY	• Ongoing analysis of developing legislation, policy or strategies that have privacy implications • Flexibility in contracts (e.g., term/termination, right to amend • Embark on data sharing intiatives • Use data for new purposes
PRIVACY PROCESSES	• Vet new technology for compatibility with system requirements • Build new IT systems for storing or accessing personal data • Map data collection

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Maximize the Value of Data Value through Connectivity

- → **Expected growth in Medical IoT → $117B revenue by 2020 and $536.6B by 2025**
- → **According to McKinsey Data Valuations Legislative and Regulatory Recap**
  - ⇒ "Big Data" Analytics Value → $9B to U.S. Public Health Surveillance
  - ⇒ "Big Data" Analytics Value → $300B to U.S. Healthcare Market
- → **Over 200 companies engaged in digital health technology development since 2010**
- → **Medical IoT devices generate data which can create actionable insights and turn these into revenue**
- → **Opportunity for organizations to improve quality of care and maximize efficiency based on insights gained from data generated from connected devices, software, and applications**
- → **BUT organizations have yet to derive significant value from digital health because, in part, of the uncertain and complex privacy regulatory environment**

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Regulatory Impact:

Data Ownership vs. *HIPAA* and *GDPR Restrictions*

HIPAA Restrictions

- **HIPAA only applies to medical devices (as defined by the FDA) that send data directly to a covered entity:**
  - Patients own their own Health Information
  - State law may assign ownership to records that contain Health Information
- **HIPAA does not apply for most other wearables, personal "medical" devices, and other health related platforms used by consumers:**
  - Consumers generally own this data, but may be modified by the manufacturer's Terms of Use
  - Most emerging technology Terms of Use have broad use rights for the vendor, even if they don't change the ownership. Vendors own derivative works created from the exploitation of the licensed data
  - May include "social media" applications like FitBit, Jawbone, etc.
- **HIPAA restricts covered entity from selling identifiable PHI or using PHI for marketing communications without authorization from the individual**
- **Sale of de-identified PHI is permissible**

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Regulatory Impact:

Data Ownership vs. *HIPAA* and *GDPR Restrictions*

GDPR Restrictions

- **GDPR, unlike HIPAA, covers all personal data defined as any data from which a living individual is identified or identifiable, whether directly or indirectly. GDPR applies to any organization engaged in certain personal data processing activities**
  - EU data subjects have specific rights to their information
  - GDPR, although targeting personal data, creates "sensitive personal data" classification that imposes certain requirements for this data category
  - State law may assign ownership to records that contain Health Information
- **GDPR applies to all wearables, personal "medical" devices, and other health related platforms used by consumers assuming organization engaged in data collection falls within territorial scope.**
  - Consumers own this data and individuals rights may not be modified by manufacturer's Terms of Use
  - Strict notice requirements mandated by GDPR to ensure transparency of data
  - If data processing is done based on consumers' consent, individual may revoke consent at anytime
  - Consumer may exercise right to be forgotten and request deletion of data
  - Consumer may exercise right to move data based of data portability requirement
  - GDPR's data ownership rights create issues for data ownership for digital health participants
- **GDPR does not follow HIPAA de-identified standard, but anonymized personal data is deemed out of scope for GDPR and may be used freely**
- **Sale of personal data to party covered by GDPR means third party must comply with GDPR (via Data Controller's obligations under law)**

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Mobile Medical Applications and FDA

On February 9, 2015, the FDA issued Guidance on mobile medical apps:

- → **"The FDA is issuing this guidance document to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms."**
- → **"The FDA intends to apply its regulatory oversight to only those mobile apps that are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended."**

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Mobile Medical Applications and FDA

When do FDA regulations apply?

- → **"When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device."**

Definition of "Mobile Medical App":

- → **Mobile app that meet statutory definition of "device" and are intended and either are intended:**
  - ⇒ To be used as an accessory to a regulated medical device; or
  - ⇒ To transform a medical platform into a regulated medical device.

Mobile Apps FDA does not intend to enforce requirements:

- → **Mobile apps that help patients self-manage their diseases without providing specific treatment, provide easy access to information related to patients' treatments; automate simple tasks for providers; help patients document, show, or communicate potential medical conditions to health care providers.**

Applicable regulatory requirements that apply: Quality system regulation, labeling, premarket notifications, registration, listing, and others.

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Prosecution Case Studies of Combination Products

AliveCor Kardiaband™ → Apple Watch EKG

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Case Study #1- AliveCor

→ **AliveCor Kardiaband–**

⇒ Personal EKG & HRV meter

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AliveCor Kardiaband- EKG (1)

FDA Cleared 11/30/17 – 1st Medical device accessory for Apple Watch – Identifies possible Atrial Fibrillation (Afib) events

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AliveCor Kardiaband- EKG (2)

Patent Portfolio*

- **16 Patents / 7 Applications / 2 Abandoned**
  - 14 Families
  - 4 trackone Filings (3 patents / 1 application)
    - ~25% of Current Portfolio
  - 1 filing PCT-PPH (Patent Prosecution Highway)
    - Used Korea as Searching Patent Authority (because of their speed)
  - Very few "Alice" 101 Rejections – 2
    - 1 overcome – Now US 9,247,911
    - 1 under Final Action – 15/421,107

- **AliveCor was not an overnight success:**
  - Brains behind company (David Albert) has been working at this for 30+ years
  - Albert started with HRM in 1970's (while in Medical School)
  - Critical mass started in 2007, with release of iPhone, accelerated with release of Apple Watch.

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AliveCor Kardiaband- EKG (3)

Key Prosecution Take-Aways:

→ **Utilize** trackone PRIORITIZED EXAMINATION **for speed if it makes sense.**

- ⇒ https://www.uspto.gov/patent/initiatives/usptos-prioritized-patent-examination-program
- ⇒ Original non-provisional or RCE.
- ⇒ "Final Disposition" (Final or NOA) promised in 12 months.
- ⇒ Max. 4 independent claims, and 30 total claims.
- ⇒ **$4,000 Fee** ($2,000 small entity).
- ⇒ Cannot file EOT when responding, or TrackOne status removed.
  - [nudge-nudge, wink-wink].

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Prosecution Case Studies of Combination Products

Abilify MYCITE® → Pill/Sensor/App – Compliance Monitor

Thanks to Wes Nicolas of Novo Nordisk

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Case Study #2- Abilify

- **Bilify MYCITE®**
  - Patient Compliance tracker
    - Modified pill
    - Sensor patch
    - App

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Case Study #2- Abilify

- **Background:**
  - Abilify® from Otsuka first approved in 2002 to treat schizophrenia, bipolar disorder, and depression.
  - To facilitate patient compliance, Otsuka modified Abilify pill to contain IEM (ingestible event marker) using technology from Proteus, including wearable patch sensor, and app interface, submitted to FDA in 2015.
  - Complete Response letter in April 2016. Resubmitted May 2016.

  - FDA Approved: 11/13/2017

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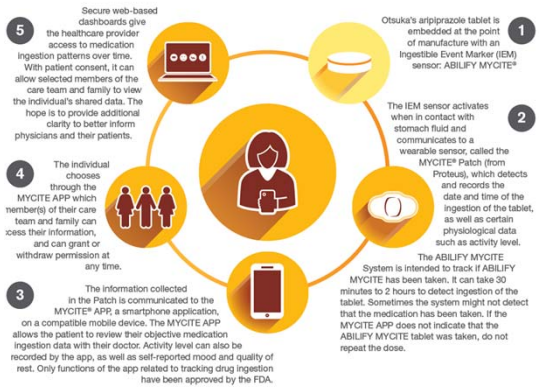
Introducing ABILIFY MYCITE® (aripiprazole tablets with sensor)

How the ABILIFY MYCITE System works:



AbilifyMyCite®
(aripiprazole tablets with sensor)
2, 5, 10, 15, 20, 30 mg

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AbilifyMyCite®

Patent Portfolio*

- **31 Orange Book Listed Patents**
  - 9 Otsuka patents (provided drug)
  - 22 Trackone patents (provided ingestible "device" and "data" thereof)
- **15 Patent Families**

- **"Special" Prosecution:**
  - 3 of 31 filed at USPTO as PCT-PPH (~10% of portfolio)
    - Used Korea as searching Patent Office (because of their speed)
  - 1 Proteus application used old USPTO Pilot program "pump and dump" to speed examination

- **Method of using device claims provided many FDA use codes! (next slide)**

*Based on FDA Orange Book Search on 1/17/2018

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Various Use Codes applicable to the "device":

U-2167

METHOD OF USING A TABLET EMBEDDED WITH A SENSOR THAT COMMUNICATES INFORMATION VIA A SIGNAL THROUGH THE BODY OF A PATIENT TO A RECEIVER

U-2168

METHOD OF USING A LOGIC CIRCUIT TO STABILIZE BATTERY VOLTAGE SUPPLIED TO A SENSOR EMBEDDED WITH A TABLET AND THAT COMMUNICATES INFORMATION VIA A SIGNAL THROUGH THE BODY OF A PATIENT TO A RECEIVER

U-2169

METHOD OF USING A RECEIVER TO IDENTIFY A SIGNAL FROM A TABLET EMBEDDED WITH A SENSOR THAT COMMUNICATES INFORMATION THROUGH THE BODY OF A PATIENT

U-2170

METHOD OF USING A RECEIVER TO RECEIVE A SIGNAL FROM A TABLET EMBEDDED WITH A SENSOR THAT COMMUNICATES INFORMATION THROUGH THE BODY OF A PATIENT

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Use Code Drill Down- A Look at **Patent & Label** Text:

AbilifyMyCite

Closest Patent text - U.S. 9,268,909:

Claim 1.) A method of stabilizing battery voltage of a battery device while optimizing power delivered to a receiver during communication of a broadcast packet, the method comprising:

receiving, by a logic circuit, a broadcast packet having a predetermined number of bits for communication by a controller to a receiver located remotely from the controller;

determining, by the logic circuit, a number of cycles in which a sampled battery voltage is either greater than or less than or equal to a nominal battery voltage over a first subset of the predetermined number of bits of the broadcast packet; and

performing either a tune-up or tune-down procedure based on the number of cycles counted in which the sampled battery voltage is not equal to the nominal battery voltage for more than one half of a total number of cycles counted.

U-2168

METHOD OF USING A LOGIC CIRCUIT TO STABILIZE BATTERY VOLTAGE SUPPLIED TO A SENSOR EMBEDDED WITH A TABLET AND THAT COMMUNICATES INFORMATION VIA A SIGNAL THROUGH THE BODY OF A PATIENT TO A RECEIVER

Closest Label text (p. 27):

11 Description

…

An aripiprazole tablet with an imbedded Ingestible Event Marker (IEM) sensor. The IEM is a 1 mm sized sensor …[u]pon contact with gastric fluid, magnesium and cuprous chloride within the IEM react to activate and power the device. The IEM then communicates to the MYCITE Patch…

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AbilifyMyCite

Key Prosecution Take-Aways:

→ **Patient Prosecution Highway (PPH and PCT-PPH)**

⇒ Utilize allowance(s) in US other jurisdictions to speed up US examination.

⇒ May require "Petition to Expedite under 1.182" to get PPH started.

→ **Strengthen nexus between FDA and device patents by:**

⇒ Claiming method (of using device) to provide FDA use codes for OB listing.

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Understanding IVDs – Connecting Wearables to Electronic Medical Records

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- **Convergence of IVD Devices, Wearables, Monitors and Apps**
  - The wearable medical devices market is expected to reach $14.41 Billion by 2022 up from $5.31 Billion in 2016

- **Common Connected Medical Devices**
  - Physiological Monitors: weight scales, blood pressure monitors, EKG, glucose monitors, heart rate monitors, pulse oximeters, and more
  - IVD Devices: biopsy equipment, blood analysers, virus detection systems and immuno-assays
  - Wearables: activity trackers, sleep apnea detectors, medication compliance monitors, EKG, heartrate monitors
  - Implants: glucose monitors, pacemakers, hearing devices, and more

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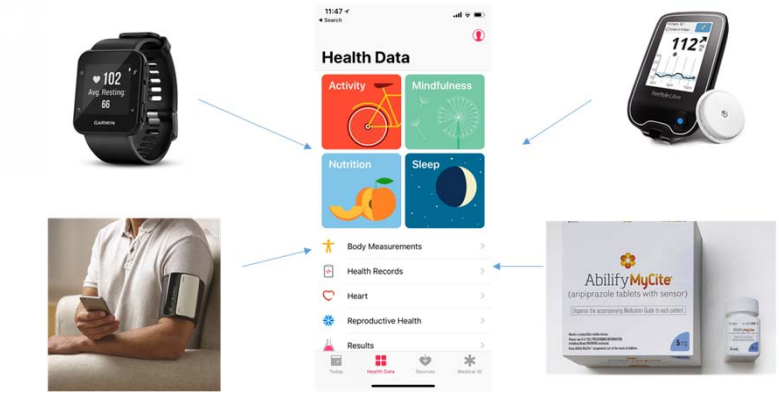

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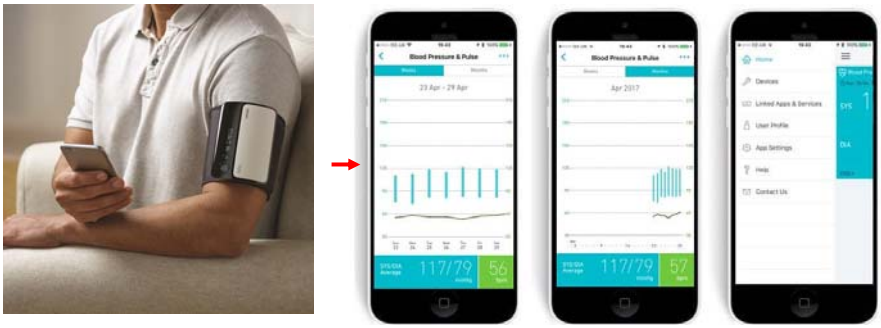
Use Case #1- Blood Pressure Monitor



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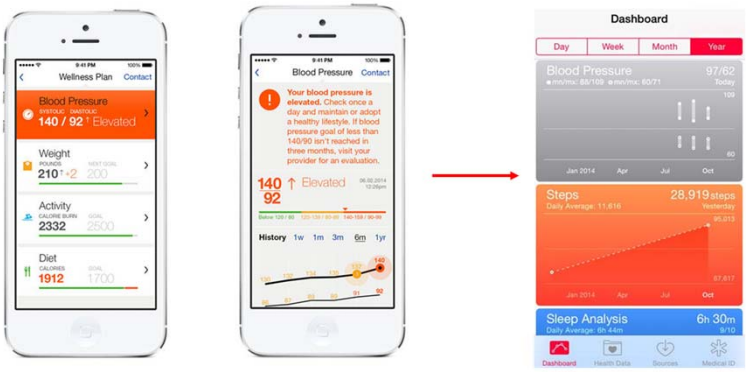
Use Case #1- Blood Pressure Monitor



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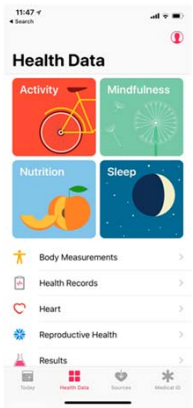
Use Case #2- Fitness App



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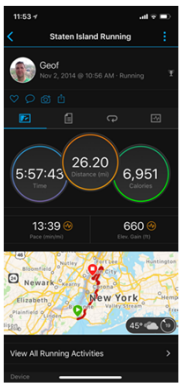
Use Case #2- Fitness App



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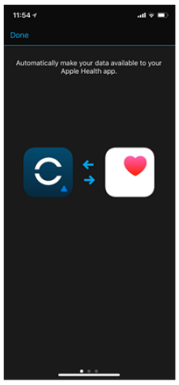
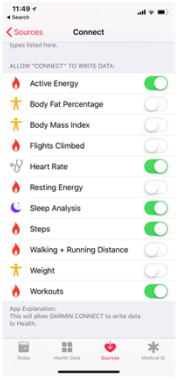
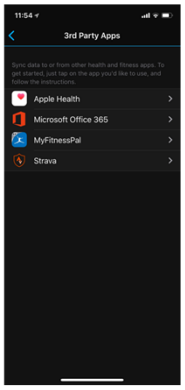
Use Case #2- Fitness App







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Tackling Cybersecurity Challenges

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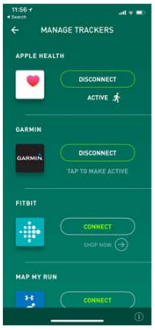
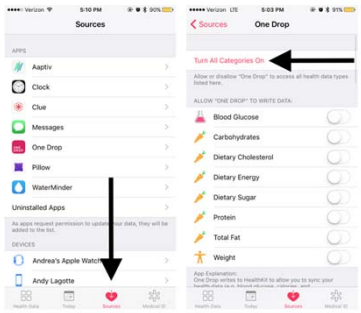
Do you know where your data is?





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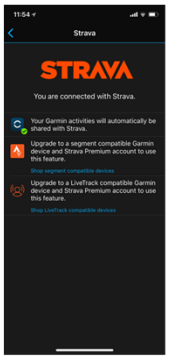

Strava Fitness App Can Reveal Military Sites, Analysts Say – NY Times, Jan. 29, 2018

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Connected Device Security

FDA Issues Final Guidance on Device Security

- → Actively monitor and detect cybersecurity vulnerabilities in their devices;
- → Understand, assess and detect the level of risk a vulnerability poses to patient safety;
- → Establish a process for working with cybersecurity researchers and other stakeholders to receive information about potential vulnerabilities (known as a "coordinated vulnerability disclosure policy")
- → Deploy mitigations (e.g., software patches) to address cybersecurity issues early, before they can be exploited and cause harm.

⇒ https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM482022.pdf

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What could go wrong?

Hacking Threat Prompts FDA to Issue Pacemaker Recall

- → 500,000 RF –enabled pacemakers could be hacked
- → The FDA has reviewed information concerning potential cybersecurity vulnerabilities associated with St. Jude Medical's RF-enabled implantable cardiac pacemakers and has confirmed that these vulnerabilities, if exploited, could allow an unauthorized user (i.e. someone other than the patient's physician) to access a patient's device using commercially available equipment," the agency added. "This access could be used to modify programming commands to the implanted pacemaker, which could result in patient harm from rapid battery depletion or administration of inappropriate pacing."

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What could go wrong?

Developer Warns Doctors, Patients About Hacking Threat

- → Johnson & Johnson warns that digital insulin pumps could be hacked
- → Possibly could deliver fatal does of insulin to a user
- → "The probability of unauthorized access to the OneTouch Ping system is extremely low," the company said in letters sent to doctors and roughly 114,000 patients in the U.S. and Canada. "It would require technical expertise, sophisticated equipment and proximity to the pump, as the OneTouch Ping system is not connected to the internet or to any external network."

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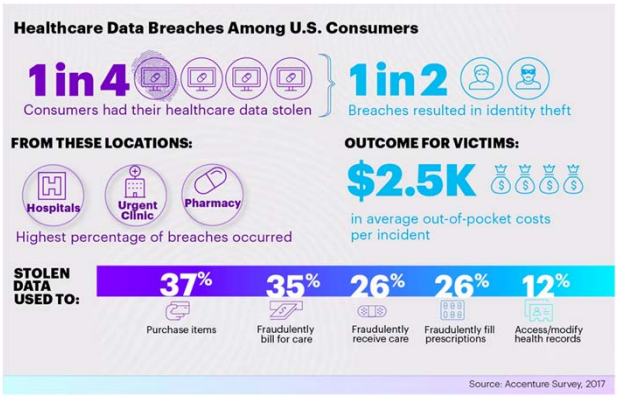
What could go wrong?



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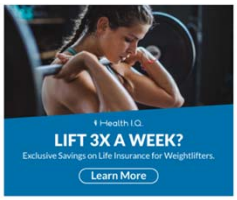
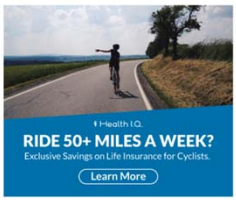
Future Uses of Your Data





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Future Uses of Your Data

Questions?

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Accomplish more.

TAB
B

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Mr. Freedman's health care practice involves the business aspects of health care law, including the structure, design and operation of hospital and health care provider relationships, representation of physician practices, and representation of the numerous types of health care delivery organizations in which health care providers become investors and members. Mr. Freedman represents and has designed managed health care delivery systems including health maintenance organizations, preferred provider organizations, independent physician associations, physician-hospital organizations and a variety of hospital/physician joint ventures. Mr. Freedman's health care practice focuses on the various regulatory compliance steps unique to the health care industry, including anti-kickback and anti-referral statutes and regulations, the privacy requirements in state laws and the federal Health Insurance Portability and Accountability Act, billing practice compliance, and health care incident reporting and disclosure obligations.

Mr. Freedman's employee benefits practice serves a diverse client base with respect to the design, preparation and implementation of pension and welfare benefit plans and their ERISA-related issues, including the effect of laws such as ERISA, the Internal Revenue Code, the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act, "COBRA" health care continuation coverage requirements under both state and federal laws, and the health care coverage rules of the Affordable Care Act.

Mr. Freedman has served as an Adjunct Professor of Health Law & Policy of the Department of Health Services Administration, Xavier University, Cincinnati, Ohio and the College of Allied Health Sciences, University of Cincinnati, Cincinnati, Ohio.

EDUCATION	**BAR ADMISSIONS**
J.D., Harvard Law School (1973) B.A., Carleton College (1968)	**State:** Ohio **Specialty:** The United States Tax Court
PROFESSIONAL AFFILIATIONS **American Bar Association**, Employee Benefits Committee of the Section of Taxation, Health Law Section **Cincinnati Bar Association** **American Health Lawyers Association** **Ohio State Bar Association** **Society of Ohio Hospital Attorneys**	

Cincinnati Bar Association

Health Care Law Update

December 8, 2018

Pharmacy Benefits Managers, Group Health Plans and Enrollees: Allies in Better Health or Implacable Adversaries?

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Table of Contents

I. Drug Prices, Especially Niche Generics and Specialty Drugs, are Increasing--A Lot

A. Henry Waxman, Bill Corr, Kristi Martin, and Sophia Duong, "Getting to the Root of High Prescription Drug Prices: Drivers and Potential Solutions," Commonwealth Fund, July 10, 2017"

1. "Our findings and conclusions are based on interviews with subject matter experts and organizations that are engaged with prescription drug development and utilization, pricing, regulation, and clinical practice …We also reviewed policy documents, proposals, and position statements from a variety of stakeholders and performed an extensive literature review."

2. Ten major problems play a role in high U.S. prescription drug prices. These problems, along with their specific drivers, are creating barriers to health care access that affect patients, providers, and payers.

   a. High launch prices and high annual increases for patented brand-name drugs.

   b. Brand-name drugs, with Orphan Drug Act market exclusivities, are introduced with high launch prices and experience high annual price increases.

   c. Some manufacturers create, or take advantage of, natural monopolies for drugs that enable them to significantly increase prices.

   d. The lack of robust competition among manufacturers of generic drugs results in less price competition and higher prices.

   e. The lack of price competition among biologics and biosimilars results in higher prices.

   f. Anticompetitive behavior by some manufacturers undermines competition, resulting in higher prices.

   g. Some manufacturers use current patent-protection policies for brand-name drugs to extend monopoly pricing.

   h. Patients, providers, and payers lack information about the comparative effectiveness of drugs at the point in time when critical health care decisions are made.

   i. The pharmaceutical distribution system does not make essential pricing information available to patients, providers, and payers at the point of care—information that patients and their providers need when deciding on the best course of treatment.

j. Federal law imposes limitations on state authority to negotiate prices for Medicaid and implement other price-related measures to reduce high drug prices.

B. CMS Office of the Actuary 2016 Survey of National Health Expenditures:

1. Retail prescription drug spending slowed in 2016, increasing 1.3 percent to $328.6 billion. The slower growth in 2016 follows two years of significant growth in 2014 and 2015, 12.4 percent and 8.9 percent, respectively.

2. This significant growth in 2014 and 2015 was largely attributable to increased spending on new medicines and price growth for existing brand-name drugs... Growth slowed in 2016 primarily due to fewer new drug approvals, slower growth in brand-name drug spending as spending for hepatitis C drugs declined, and a decline in spending for generic drugs as price growth slowed.

C. The World of Generic Drug Pricing--The Fewer the Competitors, the Higher the Price

1. Dave et. al., "High Generic Drug Prices and Market Competition: A Retrospective Cohort Study," Annals of Internal Medicine, July 4, 2017

a. Data was collected from MarketScan Commercial Claims and Encounters, an employer and health plan drug database, from January 2008 to June 2013, as well as Red Book, a drug information database. The collected research from 5-and-a-half years was separated into 11 periods of 6 months. For each period, average drug prices were calculated to be compared to the baseline period (the first 6-month period). The market competition was then qualified using the Herfindahl-Hirschman Index (HHI), which quantifies market shares.

b. Results: Generic drug price rises accelerated when market competition declined

c. Of the 1120 generic drugs included in the study period, there was an average price increase of 30%. Drugs in the group categorized as low-competition demonstrated a 63.8% increase in average price; there was a 43.8% increase for those in medium competition, and 9.7% increase among those in high competition.

2. "Association Between Percentage Change in Drug Price and Median Number of Manufacturers Among Formulations of Topical Dermatologic Generic Drugs From 2013 to 2016" (Li et. al., JAMA Dermatology, 11-5-18)

   a. "The present analysis included 116 topical dermatologic generic formulations, representing 70.5% of the total Medicare Part D dermatologist-coded claims from 2015. Drug formulations with **1 to 2 manufacturers** during the study period sustained a median percentage **increase** in price of **12.7%,** whereas those with **more than 6 manufacturers** had a median percentage **decrease** in price of **20.5%.** Formulations with 1 to 2 manufacturers had a 20.6%, 19.5%, and 33.2% higher percentage increase in price than those with 3 to 4 manufacturers, 5 to 6 manufacturers, and more than 6 manufacturers, respectively. **There was a statistically significant inverse association between the percentage change in drug price and median number of manufacturers**."

   b. "Twenty-eight formulations of topical dermatologic generic medications (24.1%) increased in price by more than **100%,** and 9 of these formulations (7.8%) increased in price by more than **500%**. Of the 9 topical formulations in our study with price escalations higher than 500% from 2013 to 2016, 5 (55.6%) were formulations of clobetasol. In addition, econazole nitrate cream, 1%, clobetasol ointment, 0.05%, and hydrocortisone solution, 0.1%, each had price increases higher than **900%** during this period."

   c. "Our findings suggest that the association of the number of manufacturers of dermatologic agents with drug price is consistent with previously reported FDA data, which has shown that the entry of a second generic drug manufacturer reduces the drug price by approximately one-half, with subsequent decreases resulting from the third(44%), fourth (39%), fifth (33%), and sixth (26%) generic drug competitor. For drugs in populated markets (>6 manufacturers), the mean generic drug price is reduced to less than 20% of the brand-name drug price."

   d. The authors suggest two remedies that can surmount the inherent barriers to entry by new manufacturers of these generic drugs:

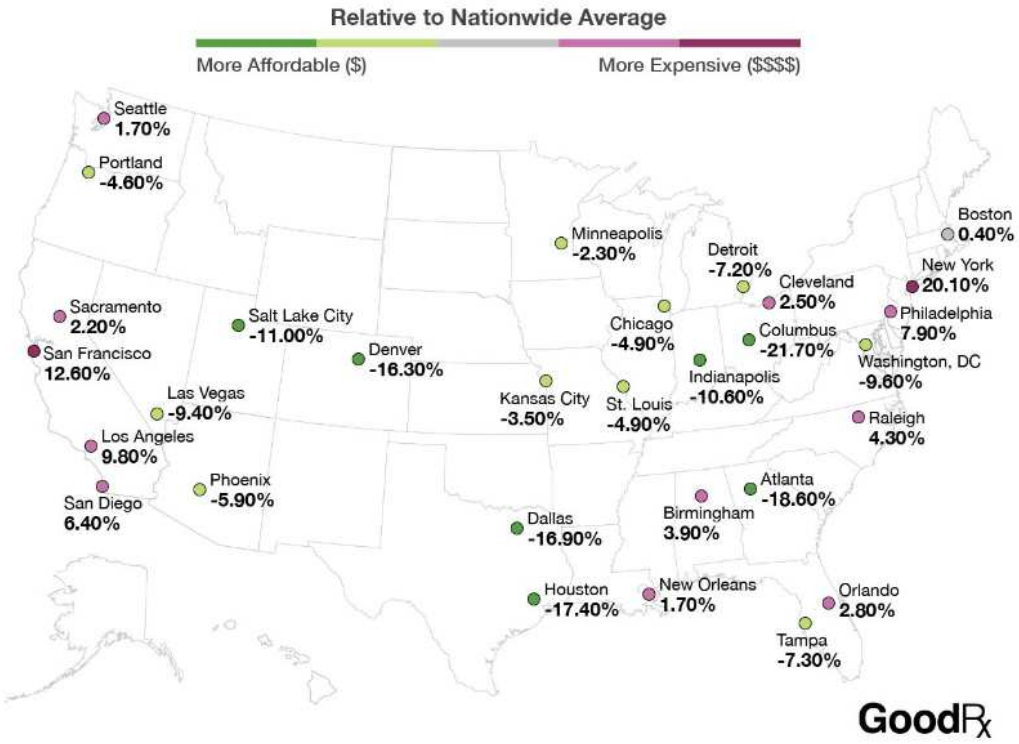
      i. Given the association between drug price and market competition, policy changes aimed at destabilizing existing drug monopolies and duopolies through increasing marketplace competition may reduce drug costs with time. The FDA recently began expediting generic drug applications from manufacturers entering markets with 3 or fewer generic drug competitors, but this step may not be

adequate in the short-term. Although increased drug prices by one manufacturer may encourage other competitors to enter the market, this may not occur in smaller markets that manufacturers do not find financially lucrative to enter. In addition, logistical factors, such as the timely acquisition of raw materials, development of manufacturing infrastructure, and establishment of reliable distribution channels, may further preclude new manufacturers from entering a market despite low levels of competition.

ii. "In consideration of these challenges, policymakers should explore temporizing strategies. **Importation of select, vetted off-patent topical medications from outside the United States** may offset price increases among medications with limited market competition until additional manufacturers can be approved…Workarounds such as **adjusting pharmacy regulations to allow automatic therapeutic exchange of the cheapest same class, same-vehicle agent for a given prescription** (eg, halobetasol cream for clobetasol cream) may enable patients to receive cheaper, effective medication without treatment delays imposed by prior authorization requests for high-cost topical medications. This process would overcome issues of physician inertia in prescribing practices and eliminate a need for physicians to spend their time monitoring drug costs. Ultimately, patients would quickly receive cheaper, effective medication, and reducing prior authorization workload and patient complaints about costs would improve physician wellness. Physicians who want to prescribe specific agents could specify "no substitutions" and receive the exact prescription if desired."

D. Where You Live Plays a Large Role in Determining the Price You Pay for Prescription Drugs--And Price Does Not Correlate to Cost of Living

1. GoodRx July 6, 2018 Study of Most, and Least, Expensive Cities for Prescription Medications (https://www.goodrx.com/blog/most-least-expensive-cities-prescription-medications/)



2. "The data looked at cash prices of the 500 most commonly prescribed medications in 30 of the most populated cities in the US over the last 12 months (ending April 2018). These numbers are based on a representative sample of US prescription fills (not fills using GoodRx) and comes from several sources including pharmacies and insurers."

City	Percent Above National Average
New York, New York	+20.10%
San Francisco, California	+12.60%
Los Angeles, California	+9.80%
Philadelphia, Pennsylvania	+7.90%
San Diego, California	+6.40%
Raleigh, North Carolina	+4.30%
Birmingham, Alabama	+3.90%
Orlando, Florida	+2.80%
Cleveland, Ohio	+2.50%
Sacramento, California	+2.20%

10 of the MOST expensive cities for drugs

City	Percent Above National Average
Columbus, Ohio	-21.70%
Atlanta, Georgia	-18.60%
Houston, Texas	-17.40%
Dallas, Texas	-16.90%
Denver, Colorado	-16.30%
Salt Lake City, Utah	-11.00%
Indianapolis, Indiana	-10.60%
Washington, DC	-10.60%
Las Vegas, California	-9.40%
Tampa, Florida	-7.30%

10 of the LEAST expensive cities for drugs

3. "This data highlights the nonsensical and variable nature of drug pricing. Take Cleveland and Columbus for instance. These two cities in Ohio are a mere 150 miles apart, but their prices for prescription drugs differ significantly. In Cleveland, drug prices as a whole are 2.50% higher than the national average, while in Columbus, they are 21.70% lower than the national average. How is it that cities in the same state could have such wildly different pricing for prescription drugs?

4. “Differences in cost of living might account for some of the large price variations. Cities with a higher cost of living, like SF and NY, have higher costs for prescription drugs. But this doesn’t explain the full story.

5. “For instance, prices for drugs in Washington DC — where the cost of living is relatively high — are 9.60% lower than the national average. Alternatively, Raleigh, which has a lower cost of living, has higher prescription drug costs, around 4.30% higher than the national average.

6. “Another factor that could be at play here is a phenomenon that we refer to as the “big box effect”. Many larger big box stores offer popular brand and generic drugs for cheap, often $4 for a 30-day supply and $9 for a 90-day supply. Some states have more of these big box stores, giving residents more opportunities to save on medications.

7. “There is also the matter of the retail markup that a pharmacy puts on a prescription. Some pharmacies will claim a higher margin to support their business, and those pharmacies may be distributed unevenly across states.”

E. "Managing the High and Rising Cost of Prescription Drug Coverage--Segal's Research Finds Wide Variance in Pharmacy Benefit Managers' Prior Authorization Denial Rates for Specialty Drugs" (Segal, Practical Research for Multiemployer Plans, Fall 2017)

1. “Specialty drug spending continues to grow through the introduction of new, innovative medications, increased utilization and price inflation for existing specialty medications. One of the most frequently prescribed specialty medications, Humira® Pen, which is used to treat certain types of arthritis and Crohn’s disease, has an average retail price of $5,249 per month for the most common dosage. Humira has increased in price fore than 68 percent between 2013 and 2016.” Spinraza™, a new treatment for spinal muscular atrophy, costs an astounding $750,000 for the first year of treatment. These are just a couple of examples of drugs that are expected to drive total annual spending on specialty medications to $402 billion by 2020, accounting for 47 percent of overall prescription drug spending. Specialty drugs…accounted for more than one-third of total spending in 2016. With specialty drug trend continuing to increase by double-digits annually, that share is expected to increase dramatically over the next few years…” [Citations omitted.]

F. The Express Scripts 2017 Drug Trend Report: Did the Rate of Prescription Drug Cost Increase Moderate?

1. According to Express Scripts, its survey of group health plans for which it serves as the PBM revealed that, for 2017, drug costs for its employer, union, and other commercial plans rose just 1.5 percent last year, on a per-person basis, the smallest increase in the more than two decades the company has been measuring it

2. That's the good news.

3. Express Scripts reported that it has developed programs that make drug makers negotiate separate discounts depending on what disease a drug is treating -- which should create more price competition for drugs that are approved for multiple uses. In addition, Express Scripts has entered into inflation-protection contracts that force drug makers to give back money if the drug manufacturer's price increase exceeds a predetermined benchmark. **Even with these discounts, inflammatory-drug spending rose 15.3 percent**.

G. Prescription Drugs Could Make Up Close To 15% Of Total Health Care Spending, Rather Than The 10% That's Often Attributed To Them

1. "Spending On Prescription Drugs In The US: Where Does All The Money Go" (Yu et. al., Health Affairs, 7-31-2018)

2. "We used a mix of financial disclosures and third-party market data to quantify the overall market size based on the revenues that accrued not only to drug manufacturers but also to each of the intermediaries involved with the distribution, administration, or reimbursement of medicines in 2016. To avoid double counting where the same drug changes hands at different prices throughout the supply chain, we netted out the cost of the product to isolate the gross profit (for all but the manufacturers). Combining this with the manufacturers' net sales of the products, we provide a view of how spending is allocated throughout the entire system."

3. "We estimate that in 2016, total US expenditures on pharmaceutical drugs, including the gross profits of all the intermediaries, were $480 billion. Two-thirds of this total ($323 billion) was captured by drug manufacturers in the form of net revenues. The remaining third ($157 billion) was retained as gross profits in the supply chain. Of this share, nearly half was captured by retail and specialty pharmacies ($73 billion), and about 20 percent ($35 billion) by providers, such as hospitals and doctors' offices. PBMs and wholesalers together captured approximately 25 percent ($23 billion and $18 billion, respectively)."

4. "Our analysis also explains why the oft-cited claim that 10 percent of US health care spending is directed toward drugs could be misleading. That number refers to the net receipts of manufacturers of around $325 billion, which is essentially 10 percent of total health care spending based on a CMS estimate of $3.3 trillion in national health expenditures for 2016. But the inclusion of both the non-retail drug markets along with gross profits of the other parties involved in drug distribution, payment, and reimbursement brings pharmaceutical sector spending closer to 15 percent of total health care spending."

H. Plan Design Changes are Shifting Prescription Drug Costs From the Employer-Sponsor to the Participant

1. Source: "Improving The Affordability Of Specialty Drugs By Addressing Patients' Out-Of-Pocket Spending" (Dusetzina et. al., Health Affairs Policy Options Paper, 3-15-2018, https://www.healthaffairs.org/do/10.1377/hpb20180116.800715/full/)

2. Definition of "specialty drug" (which happen to be the drugs with the largest costs):

   a. "The Centers for Medicare and Medicaid Services (CMS) defines a product as "specialty-tier eligible" when the sponsor-negotiated price is $670 per month or more.[4] However, most specialty drug spending is concentrated on products used for rare, complex, and life-threatening conditions. These products include medications for HIV (average monthly price per fill: $1,556), inflammatory conditions ($3,588), multiple sclerosis ($5,056), oncology ($7,891), and hepatitis C ($15,708).[2] Among drugs offered through outpatient pharmacy benefits, specialty drugs currently make up only 1–2 percent of use but 40–50 percent of drug spending,[2,5] making them an important target for payers and policy makers alike.

[2] Express Scripts Lab. 2015 drug trend report. St. Louis (MO); Express Scripts, 2016 April. [The Express Scripts Lab. 2017 drug trend report: Spending on specialty drugs, which accounted for 40.8% of total spending, was up 11.3% in 2017, driven by higher utilization (8.1%) and unit costs (3.2%) (available at http://lab.express-scripts.com/lab/drug-trend-report/2017-dtr).]

[5] Pew Charitable Trusts. Specialty drugs and health care costs [Internet]. Philadelphia (PA): Pew Charitable Trusts; 2016 Dec [cited 2018 Jan 22]. Available from: http://www.pewtrusts.org/~/media/assets/2016/12/specialty_drugs_and_health_care_costs.pdf

   b. "[B]oth commercial and Medicare Part D plans have shifted away from copayments (where the patient pays a flat dollar amount per prescription) and toward greater reliance on deductibles (where the patient pays 100 percent of the drug's negotiated price until the deductible is met) and coinsurance (where the patient pays a predetermined percentage of the drug price)."

   c. "Patients in employer-sponsored plans are now paying more of their out-of-pocket expenses for retail prescriptions in the form of deductibles and coinsurance, as opposed to copays. For example, deductibles grew from 4 percent of cost-sharing payments in 2004 to 24 percent in 2014; coinsurance increased from 3 percent to 20 percent over that same period.[37] In 2014 an estimated 10-15 percent of people with drug coverage through employer-sponsored coverage who are treated for one of several high-cost conditions (cancer,

mental illness, digestive disease, or endocrine, circulatory or blood disorders) spent over $5,000 annually out of pocket on retail and nonretail drugs.[38]

[37] Cox C. What are recent trends and characteristics of workers with high drug spending? Peterson-Kaiser Health System Tracker [serial on the Internet]. [Updated 2016 Oct 27; cited 2017 Jul 31]. Available from: http://www.healthsystemtracker.org/chartcollection/recent-trendscharacteristics-workershigh-drug-spending/?_sf_s=recent#item-start

[38] Henry J. Kaiser Family Foundation. The Medicare Part D prescription drug benefit [Internet]. Menlo Park (CA): KFF; 2017 Oct 2 [cited 2018 Jan 25]. Available from: https://www.kff.org/medicare/fact-sheet/the-medicareprescription-drug-benefit-fact-sheet/

d. "Furthermore, most plans use drugs' point-of-sale prices—instead of net prices that are achieved as a result of plan negotiated rebates—as the basis for calculating patient cost sharing."

I. Inter-Brand and Brand/Generic Competition Has Not Lowered Prescription Drug Prices

1. Source: "Promoting Competition To Address Pharmaceutical Prices" (Darrow and Kesselheim, Health Affairs Policy Options Paper, 3-15-2018, https://www.healthaffairs.org/do/10.1377/hpb20180116.967310/full/HPP_2018_CMWF_02_W.pdf)

2. Inter-brand competition:

"Inter-brand competition among drugs can sometimes lead to lower prices. The 2013 launch price of sofosbuvir (Sovaldi), a direct-acting antiviral for hepatitis C, was $84,000, while competitor glecaprevir/ pibrentasvir (Mavyret) was launched in 2017 at $26,400 amidst growing competition. In many cases, however, inter-brand competition does not lower prices. The tyrosine kinase inhibitor imatinib (Gleevec) was introduced to treat chronic myelogenous leukemia in 2001 at a price of $26,400 per year. Over the next decade, multiple other tyrosine kinase inhibitors were approved for the same indication, but imatinib's list price continued to rise to over $120,000 per year.

Several factors that mitigate the potential price-lowering effects of inter-brand competition include the perception of price as a signal of efficacy, imperfect information, and legal mandates on purchasers." [Internal citations omitted.]

a. Imperfect Information: "In many cases, the absence of comparative effectiveness information can frustrate price competition. Many new drugs obtain Food and Drug Administration (FDA) approval based on single-arm or placebo-controlled trials, producing no

direct comparative data to facilitate evidence-based prescribing or use."

b. Legal Mandates on Purchasers: "Inter-brand competition is also weakened if payers cannot leverage the threat of formulary exclusion during price negotiations. US laws limit formulary exclusion in major sections of the market."

i. Fully insured plans: Many states have laws that prevent private payers from excluding cancer drugs from their formularies. See Hansen K, Bondurant E. Cancer insurance mandates and exceptions [Internet]. Denver (CO): National Conference of State Legislatures; 2009 Aug [cited 2017 Dec 15]. Available from: http://www.ncsl.org/portals/1/documents/health/CancerMandatesExcept09.pdf

ii. To the extent not prohibited by the Affordable Care Act, self-insured plans may design formularies free from state law limits and may use cost-sharing to suppress demand. "However, manufacturers have partially neutralized these efforts by offering copay "coupons" to help defray patient out-of-pocket expenses or by supporting nonprofit patient assistance programs that fulfill a similar role."

II. The Pharmacy Benefit Manager's Revenue Sources: The Overview

A. A Quick Overview

1. Pharmacy benefit managers generate these distinct revenue streams:

a. In their administrative services agreements with group health plans, PBMs may charge a per participant per month administrative charge.

b. In their administrative services agreements with group health plans, PBMs offer to supply prescription drugs to enrollees who fill their prescriptions at a specified price. However, that price may be different than -- and higher than -- the price the PBM contractually agrees to pay to its in-network dispensing pharmacies (and may also exceed the cost the PBM incurs for drugs its captive prescription pharmacy must pay).

c. In its agreements with drug manufacturers, the PBM may receive rebates on drugs the PBM chooses to include in the drug formulary that the PBM in turn contracted with group health plans to design and administer. The excess of the gross rebates over the portion the PBM forwards to the group health plan constitutes an additional revenue stream. PBMs use algorithms to determine whether a drug

is brand or generic; this may enable PBMs to characterize a generic as a brand name drug in the drug formulary; since the rebates manufacturers pay on brand name drugs is much higher than the rebates a generic manufacturer will pay, the discount the PBM offers to the plan is much smaller.

d. Clawbacks represent another revenue stream. A clawback is the amount by which an enrollee's out of pocket obligation for a prescription drug exceeds the amount the in-network pharmacy is entitled to be paid under the terms of its provider agreement with the PBM. PBMs routinely require the in-network pharmacy to return that excess to the PBM. That obligation is called a "clawback.

III. The Pharmacy Benefit Manager's Revenue Sources: Rebates

A. Rebates Cloud the Assessment of Actual Sale Prices for Drugs--and Rebates are Growing

1. "Frequently Asked Questions About Prescription Drug Pricing and Policy" (Congressional Research Service, 4-24-2018)

a. "Drug companies price discriminate, meaning they sell the same drug to different buyers (wholesalers, health plans, pharmacies, hospitals, government purchasers, and other providers) at different prices. The final price of a drug may include rebates and discounts to health plans and pharmacy benefit managers that are not publicly disclosed. Market participants, such as wholesalers, add their own markups and fees. Complicating the picture even more, pharmaceutical manufacturers offer direct consumer discounts, such as prescription drug coupons that can be redeemed when filling a prescription at a pharmacy."

b. The most commonly published drug prices do not include these discounts and rebates, which appear to be growing in size and importance. According to IQVIA [(formerly IMS Health), a private firm that provides consulting, technology, and other services for the health care industry], the gap between the wholesale invoice prices and the final discounted price for brand-name drugs has increased significantly in the past several years. Prescription drug spending from 2006 to 2016 rose 67% on an invoice basis but 42% on a net basis. More than two-thirds of the spending growth occurred from 2013 to 2016."

B. The Gross to Net Rebate Bubble

i. *New Data Show the Gross-to-Net Rebate Bubble Growing Even Bigger,* Adam J. Fein, Ph.D., President of Pembroke

Consulting, Inc. and CEO of Drug Channels Institute, June 14, 2017 (http://www.drugchannels.net/2017/06/new-data-show-gross-to-net-rebate.html_

(a) Despite a slowdown in brand-name drug list prices, the gross-to-net bubble is alive and well. The bubble reflects the growing spread between a manufacturer's list price for a drug and the net price to a third-party payer after rebates.

(b) According to the most recent QuintilesIMS report, the total value of pharmaceutical manufacturers' off-invoice discounts, rebates, and other price concessions has more than doubled over the past five years, from $59 billion 2012 to an astonishing $127 billion in 2016.

(c) Those payments offset more than half of the increase in list-price based spending. And though the gap between invoice and net prices shrank in 2016, the value of manufacturers' discounts and rebates payments still grew last year, by $11 billion.

C. Are PBMs Disgorging the Rebates? How Much of the Rebates Flow to Employer-Sponsors of Group Health Plans? To Plan Participants Who Purchase the Drugs That Generate the Rebates?

1. The data is not a model of clarity.

2. There is some evidence that, for the portion of manufacturer-to-PBM payments that the manufacturer and the PBM agree to characterize as "rebates," PBMs are passing on that amount to group health plans and/or the participants who purchase the rebate-generating drugs.

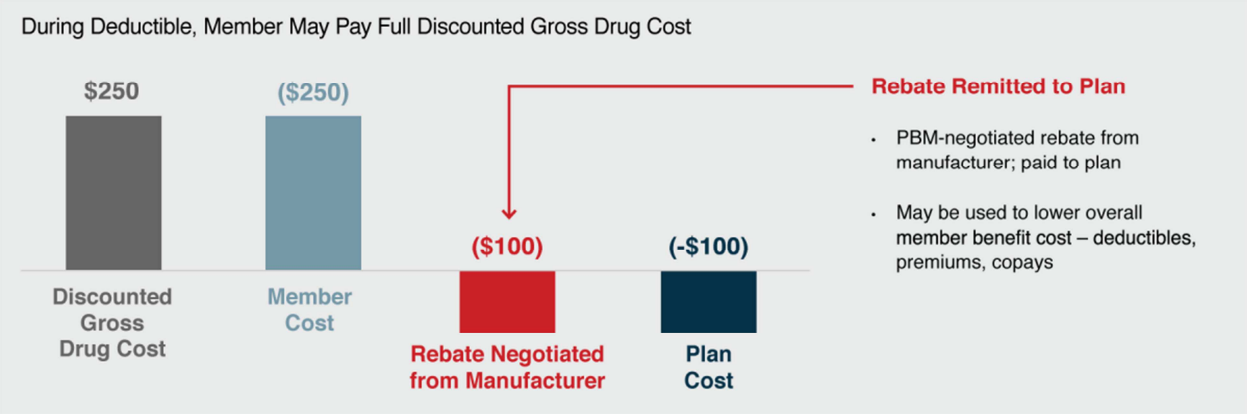
   a. Source: "The Impact of Prescription Drug Rebates on Health Plans and Consumers" (Charles Roehrig, PhD, Altarum, April 2018).

   b. "There were 187 million persons with prescription drug coverage under private health plans in 2016. **They spent $194 billion** on prescription drugs at the point of purchase, with $167 billion paid by the insurer and $27 billion paid by the consumer. **Private health plans received manufacturer rebates of $23 billion**, which is 12% of point-of-purchase spending. In general, these rebates reduce the net cost of the health benefit and should be reflected in lower health care premiums. Those with private coverage made use of $9 billion in manufacturer coupons, reducing their net out-of-pocket costs to $18 billion, a reduction of 33% (we estimated $1 billion in coupons were used by those with no coverage)." (Page 7.)

c. Result: of the amount of the rebates paid by PBMs to employer-sponsored health plans or their participants, the vast majority went to the plan, not to the participant who purchased the drug that generated the rebate.

3. *Will CVS Health's Point-of-Sale Rebates Deflate the Gross-to-Net Bubble—and Disrupt the PBM Business?* Adam J. Fein, Ph.D., President of Pembroke Consulting, Inc. and CEO of Drug Channels Institute, June 15, 2017 (http://www.drugchannels.net/2017/06/will-cvs-healths-point-of-sale-rebates.html)

> "What happened to those rebates? Some portion was shared directly with patients in the form of lower out-of-pocket costs for prescriptions. *But I suspect a majority flowed back to plan sponsors, which used the funds to reduce premiums and offset other healthcare costs. A sponsor could theoretically use those rebate payments to offset costs in any area, including hospital and physician payments. PBMs also retained a portion of those rebates as their profits.* Unfortunately, consumers with deductibles and coinsurance did not benefit directly from these rebates. The problem is especially acute for patients taking specialty drugs. Those patients can face economically debilitating coinsurance—in some cases with no limit on out-of-pocket expenses. Since manufacturer rebates do not get passed through to the point of sale, the coinsurance is based on the drug's list price"
>
> "WHOSE MONEY IS IT?
>
> "Last week, CVS Health addressed this question in Consumer Transparency: Helping Members with High-Cost Drugs at the Point of Sale, https://payorsolutions.cvshealth.com/insights/consumer-transparency. The white paper describes a benefit design in which rebates reduced patients' out of pocket costs when the prescription is filled.
>
> "CVS Health builds its argument around high deductible health plans (HDHPs). It provides the following useful example in which the patient pays the full prescription price of $250 while the plan gets a rebate and "makes" $100.



"In theory, the $100 rebate could be shared with the patient when the prescription is filled. In that case, the patient's cost would be $150 and the plan's cost would be $0. Sounds simple, right?

"*Alas, the plan now loses the $100 that it had been using to offset premiums and other spending. Therefore, plan sponsors would pay higher premiums to maintain the same overall cost-share structure in the plan. The white paper provides an example in which a 180,000-member plan would have to raise premiums by 3% to offset the rebates that would go the member instead of the plan.*

"FYI, Express Scripts offers a POS benefit design called SmartShareRx. The company tells me that few clients have chosen to share rebates directly with patients. That said, it doesn't appear that Express Scripts is actively marketing this solution. My Google search for "SmartShareRx" turned up zero results."

"CVS Health's white paper implies that a switch to POS rebates will require only a few actuarial math tweaks. But the reality is more complex.

"A major barrier is health plans and employers, both of which have baked ever-growing rebate dollars into their healthcare economics. I suspect that rebate dollars are now concentrated with a relatively small number of products and therapeutic categories. Fixing the out-of-pocket cost problem for a few patients will raise costs for everyone else—or for the plan.

D. Do Medicare Part D Plans Do A Better Job Extracting Rebates From Manufacturers? Yes. Why?

1. Total rebates reported by Medicare Part D plans amounted to 22% of point-of-service spending in 2016. For private insurers, this figure was 12%. Virtually all of these reported rebates are for branded drugs. For Medicare Part D, about 70% of point-of-service spending was for branded drugs, while this figure was 75% for private insurers. Thus, the rebate share of branded drugs is roughly 31% for Medicare Part D and 16% for private insurers. (Page 10.)

2. "This differential in rebate percentages between Medicare Part D and private insurers has been attributed to various factors, most notably a "wider use of utilization management and multi-tiered and exclusionary formularies" under Medicare plans.

3. "Medicare Part D plans have more leeway in negotiating with manufacturers and, therefore, achieve greater rebates. This more aggressive negotiating stance is likely due to differences in the market places for Part D plans and private plans.

    a. "Private plans are predominately employer-sponsored insurance plans in which benefit packages are designed to attract and retain talent. Prescription drugs are a relatively small component of what is covered and employees are largely insulated from premiums. Under these conditions, restrictive drug formularies are more likely to be a source of complaint from employees who may be unaware of any impact on premiums. This leads to less restrictive formularies (for example, fewer drugs excluded) and a weaker bargaining position with manufacturers."

E. For Fully Insured Plans, PBMs Are Inaugurating Arrangements Under Which All Rebates are Passed to Patients at the Point of Purchase. Self-Insured Plans Have Not Pursued (and May Not Be Aware of) This Option

1. UnitedHealthcare March 6, 2018 Announcement: it and its pharmacy benefit manager will pass on all drug rebates and discounts they receive to enrollees in UnitedHealth fully insured plans

    a. However: "Employers who self-insure already have the option of passing the savings onto customers of UnitedHealthcare, Mr. Schumacher [Dan Schumacher, the president of UnitedHealthcare]said. CVS Health, a large pharmacy benefit manager, also allows employers to share the discount with their workers and has offered rebates to its own employees since 2013. OptumRx also offers the option of sharing the discount directly with consumers. **But while some employers seem interested, it has not taken off, Mr.**

Schumacher said. "We have some customer interest," he said. "It's in the early innings." "UnitedHealthcare Says It Will Pass On Rebates From Drug Companies to Consumers," New York Times, March 6, 2018, https://www.nytimes.com/2018/03/06/health/unitedhealth-drug-prices.html).

2. On March 27, 2018, Aetna announced that, starting in 2018, Aetna will pass all rebates at the point of sale to enrollees who participate in fully insured plans sponsored by Aetna.

F. Using the PBM's Proprietary Algorithm to Characterize a Generic as a Brand Name Drug and Keep the Higher Rebate

1. From, "The Algorithm Black Box," Bob Herman, Axios, April 2, 2018, https://www.axios.com/algorithm-black-box-express-scripts-18f3d873-77ce-40eb-9a0c-578b608d1b6e.html

2. "How it works:

   a. "Imagine a generic drug has an average sticker price of $100, and its cost (including money for the drug maker, wholesaler and pharmacy) is $15.

   b. "The PBM says it will apply an 80% discount on generic drugs, meaning an employer should only pay $20 for the drug. The PBM pockets $5 on normal spread pricing (after subtracting the $15 cost).

   c. "However, using the algorithm, the PBM could define the generic drug as a brand, which only commands a 17% discount.

   d. "Under that scenario, an employer would pay $83, or more than four times what it should for the generic, and the PBM pockets $68 after subtracting the drug's cost.

3. From the Express Scripts template:

   "Brand/Generic Algorithm" or "BGA" means ESI's standard and proprietary brand/generic algorithm, a copy of which may be made available for review by Sponsor or its Auditor upon request. The purposes of the algorithm are to utilize a comprehensive and logical algorithm to determine the brand or generic status of products in the ESI master drug file using a combination of industry standard attributes, to stabilize products "flipping" between brand and generic status as may be the case when a single indicator is used from industry pricing sources, and to reduce Sponsor, Member and provider confusion due to fluctuations in brand/generic status. Sponsor or its Auditor may audit ESI's application of

its BGA to confirm that ESI is making brand and generic drug determinations consistence with such algorithm."

G. But We Have Only Looked at Amounts that the PBM and the Manufacturer Agree to Characterize as "Rebates." Do Manufacturers Pay Amounts to the PBM With Other Labels?

1. "The Drug Pricing Contract Express Scripts Doesn't Want You To See" (Bob Herman, Axios, April 2, 2018)

2. Axios obtained a document that helps answer those questions — a copy of the template that Express Scripts uses for its contracts. We reported on its contents [see the next article], and posted the document itself to DocumentCloud so readers could evaluate it for themselves.

3. After Express Scripts forced DocumentCloud to remove the contract template, claiming copyright infringement, Axios and Bob Herman prepared an analysis of the agreement based on portions of the Express Scripts template as well as new reporting and pharmacy benefits documents.

4. The Express Scripts contract explicitly says "rebates do not include things" like "administration fees" from drug manufacturers, "inflation payments" and numerous types of "other pharma revenue."

   a. "There are so many carve-outs of what they consider a rebate that it's very murky of what's being kept and what's being passed through (to clients)," an industry source said.

   b. The contract also says Express Scripts negotiates rebates "on its own behalf and for its own benefit, and not on behalf of sponsor."

5. "Inflation payments": according to the Express Scripts template, "inflation payments" are not considered rebates. PBMs receive inflation payments from drug companies to cover year-over-year hikes to a drug's list price.

   a. "If employers don't ask about inflation payments, PBMs keep them by default.

   b. "The state of Delaware, however, modified its contract with Express Scripts in 2015 to ensure those inflation payments are routed back to Delaware's state employees, according to a copy of the contract that is publicly available."

6. From the Express Scripts template:

   "Rebates" mean retrospective formulary rebates that are paid to ESI pursuant to the terms of a formulary rebate contract negotiated

independently by ESI and directly attributable to the utilization of certain Covered Drugs by Members. For sake of clarity, Rebates do not include, for example, Manufacturer Administrative Fees; inflation payments; product discounts or fees related to the procurement of prescription drug inventories by ESI Specialty Pharmacy or the Mail Service Pharmacy; fees received by ESI from pharmaceutical manufacturers for care management or other services provided in connection with the dispensing of products; or other fee-for-service arrangements whereby pharmaceutical manufacturers generally report the fees paid to ESI or its wholly-owned subsidies for services rendered as "bona fide service fees" pursuant to federal laws and regulations (collectively, "Other Pharma Revenue"). Such laws and regulations, as well as ESI's contracts with pharmaceutical manufacturers, generally prohibit ESI from sharing any such "bona fide service fees" earned by ESI, whether wholly or in part, with any ESI client."

H. The Smaller the Client, the More Likely the PBM Will Tell the Client It is Keeping the Rebates But Offering the Client a Larger Discount on Administrative Fees and/or Drug Prices. Who Wins?

1. According to Axios, the PBM always wins.

2. "Alex Schmelzer [http://www.mesa-rxinnovations.com/about-us.html], a consultant who works with employers on drug benefits, said PBMs have occasionally offered employers discounts on administrative fees — in exchange for giving up all rebates.

    a. "Small companies with cash-strapped HR departments don't have a lot of resources to analyze whether it's a good trade for them, and may view a quick discount as attractive. But those rebates, especially on expensive drugs like insulin and autoimmune medications, are huge cash flows for PBMs.

    b. "Employers are giving up a lot of money," Schmelzer said of those kinds of offers. "It almost never works in favor of the employer."

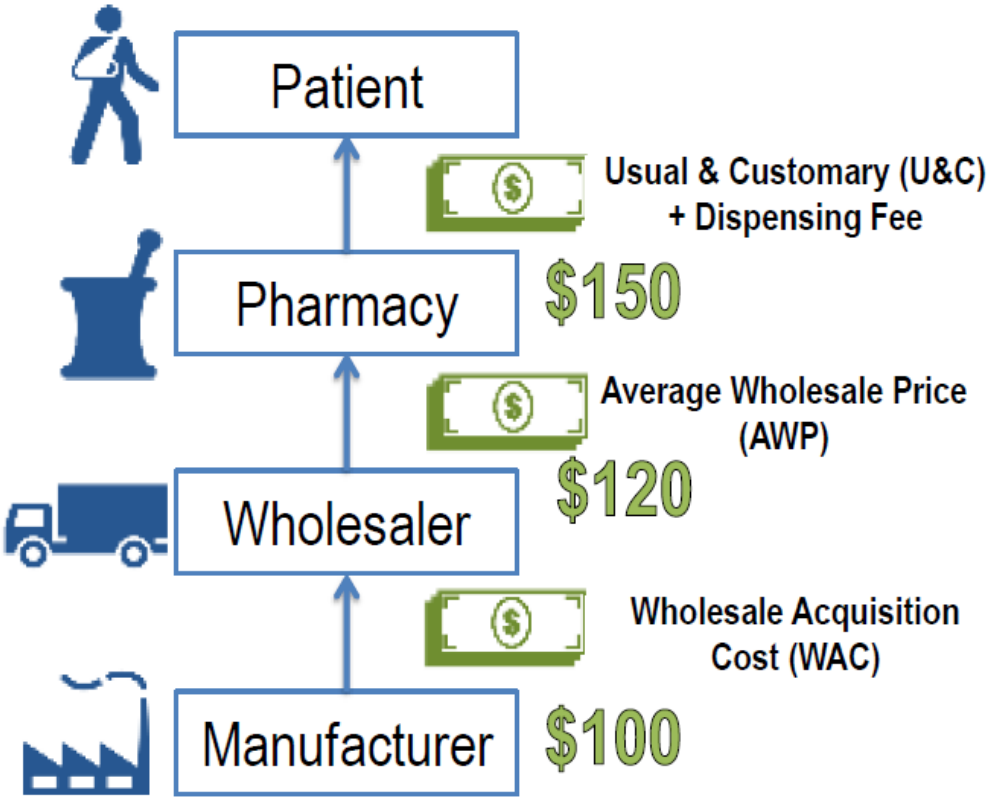
    c. "Why it matters: Rebates are the holy grail of the drug supply chain and are the financial hook for many parties at a negotiation table. Schmelzer worked at a Wall Street hedge fund for 18 years analyzing health care but left after seeing the problems in the pharmaceutical system.

    d. His tipping point: When Horizon Pharma started charging a high price for its drug Duexis. Even though Duexis is essentially a combination of Advil and Pepcid, PBMs were putting it on their approved drug lists because Horizon was offering steep rebates. The drug company won sales, and the PBM won bigger rebates.

e. "Employers were left holding the bag paying hundreds of dollars for something that should cost pennies," Schmelzer said. "It was another example of rebates and coupons inflating the price of a drug."

IV. The Pharmacy Benefit Manager's Revenue Sources: The Price Spread Between the Price the PBM Charges the Employer-Sponsored Plan and its Participants, on the One Hand, and the Amount the PBM Pays the Pharmacy

A. A Quick Tour of Popularly Used Defined Terms



"Is there a Generally Accepted Alternative Price Benchmark to the WAC Price?" (University of Maryland School of Pharmacy, ISPOR.org,)

B. A Table of Commonly Used Terms

Table 1. Common Terms and Acronyms Used in Drug Pricing

Term	Definition
Federal upper limit (FUL)	A price ceiling used by the Centers for Medicare and Medicaid Services (CMS) to control prices for certain medications paid to pharmacies
Maximum allowable cost (MAC)	A price ceiling, similar to the FUL, established at the state level
Usual and customary price (U&C)	The average cash price paid at a retail pharmacy
Average wholesale price (AWP)	An estimate of the price retail pharmacies pay for drugs from their wholesale distributor. This price is calculated and published by companies such as Medi-Span and First Databank
Wholesale acquisition cost (WAC)	An estimate of the manufacturer's list price for a drug to wholesalers or other direct purchasers, not including discounts or rebates. This price is defined by federal law
Average manufacturer price (AMP)	The price a manufacturer charges wholesalers or pharmacies that purchase directly from the manufacturer after discounts. This price is defined by federal law
Average sales price (ASP)	A calculation of the weighted average of manufacturer's sales price for a drug for all purchasers, net of price adjustments. This price is defined by federal law
Estimated acquisition cost (EAC)	An estimate of the price generally paid by providers for a drug. Formula specific for each state as defined by the state Medicaid agency
Average Actual cost (AAC)	An estimate of retail pharmacy acquisition costs for drugs through a review of actual pharmacy invoices
Dispensing fee	The amount reimbursed to the pharmacy to cover the charge for professional services and overhead costs
National Drug Code (NDC)	An 11-digit code used by Medicaid to identify a drug based on its manufacturer, strength, and package size

Source: References 3-5, 7, 14.

"Understanding Drug Pricing," Joey Mattingly, PharmD, MBA, US Pharm. 2012;37(6)(Generic Drug Review suppl):40-45, accessed on May 22, 2018 at https://www.uspharmacist.com/article/understanding-drug-pricing

C. "Wholesale Acquisition Cost"

1. Manufacturer supplied list price of the wholesalers purchase from the manufacturer, published by First Databank ("FDB").

2. "…as published by First Databank (FDB), WAC represents the manufacturer's published catalog or list price for a drug product to wholesalers as reported by the manufacturer.

3. "WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price.

4. "FDB does not perform […] analysis of actual transaction prices for purposes of reporting WAC."

5. "FDB relies on manufacturers report for the WAC data field."

D. "Average Wholesale Price"

1. Source: "Average Wholesale Price (AWP) as a Pricing Benchmark," Medically reviewed on Nov 29, 2017 by L. Anderson, PharmD., available at https://www.drugs.com/article/average-wholesale-price-awp.html (accessed May 22, 2018).

2. "AWP is a benchmark that has been used for over 40 years for pricing and reimbursement of prescription drugs for both government and private payers. Initially, the AWP was intended to represent the average price that wholesalers used to sell medications to providers, such as physicians, pharmacies, and other customers. However, the AWP is not a true representation of actual market prices for either generic or brand drug products. AWP has often been compared to the "list price" or "sticker price", meaning it is an elevated drug price that is rarely what is actually paid. AWP is not a government-regulated figure, does not include buyer volume discounts or rebates often involved in prescription drug sales, and is subject to fraudulent manipulation by manufacturers or even wholesalers. As such, the AWP, while used throughout the industry, is a controversial pricing benchmark."

3. "The AWP may be determined by several different methods. The drug manufacturer may report the AWP to the individual publisher of drug pricing data, such as Medi-Span. The AWP may also be calculated by the publisher based upon a mark-up specified by the manufacturer that is applied to the wholesale acquisition cost (WAC) or direct price (DIRP). The WAC is the manufacturer's list price of the drug when sold to the wholesaler, while the DIRP is the manufacturer's list price when sold to non-wholesalers. Typically a 20% mark-up is applied to the manufacturer-supplied WAC or DIRP, which results in the AWP figure.

4. Publishers sell the published AWPs to government, private insurance, and other buyers of prescription drugs, who use these data tables to determine reimbursement and retail prices.

5. "Reimbursements are based on AWPs. However, pharmacies purchase drugs based on the WAC. The difference between the WAC (what the pharmacy actually paid for the drug) and the reimbursement from insurance (based on AWP) is known as the spread, and equates to the profit that the pharmacy receives."

6. "Market pricing on brand drugs tend to be about 16.6 percent less than the AWP. However, the relation of AWP to generic pricing is not clear. Older generics tend to have a large spread between the AWP and WAC, which in turn gives a large spread, and higher profit margins for the pharmacy or other provider of the drug. Many payers, such as PBMs or HMOs, will

determine a maximum allowable cost (MAC) pricing on generics to avoid being overcharged."

E. Price Spreads Are Built Into the Agreement Between the PBM and the Plan, and Are Not Disclosed

1. Here is an excerpt from an administrative services agreement between a PBM and an employer-sponsor of a typical -- less than 10,000 enrollees -- self-insured group health benefit plan."

a. From the "Definitions" section":

"Maximum Allowable Cost" or "MAC" means the cost basis for reimbursement established by the PBM, as modified from time to time, for the same dose and form of Generic Drugs which are included on The PBM's applicable MAC List.

"MAC List(s)" means the lists of MAC payment schedules for Prescription Drugs, devices and supplies identified as readily available as a Generic Drug or generally equivalent to a Brand Drug (in which case the Brand Drug may also be on the MAC List) and developed and maintained or selected by The PBM and that, in each case, are deemed to require or are otherwise capable of pricing management due to the number of drug manufacturers, utilization and/or pricing volatility.

"Usual and Customary Retail Price" or "U&C Price" means the cash price less all applicable Customer discounts which Participating Pharmacy usually charges customers for providing pharmaceutical services.

b. The agreement defines the pricing as:

Brand discount: "AWP - x%"

Generic discount: "AWP - y%" (y% is much larger than x%)

c. The agreement then states:

"The pricing and services set forth herein are subject to the following Terms & Conditions:

"The pricing and services contained herein are limited to prescription drugs dispensed by a Participating Pharmacy to Plan Participants.

"Prescriptions dispensed by a Participating Retail Pharmacy shall be processed at the lower of the pharmacy's submitted Usual & Customary Retail Price, MAC (where applicable) plus a Dispensing Fee, or discounted AWP cost plus a Dispensing Fee.

The Customer [the Plan] acknowledges that the PBM contracts with Participating Retail Pharmacies directly or through a pharmacy benefit management ("PBM") subcontract to provide the Customer and Plan Participants with access to Covered Services. The prices negotiated and paid by the PBM to Participating Retail Pharmacies vary among Participating Retail Pharmacies in the PBM's network, and can vary from one pharmacy product, plan or network to another. *Under this Schedule and Service and Fee Schedule, the Customer and the PBM have negotiated and agreed upon a uniform or "lock-in" price to be paid by the Customer for all claims for Covered Services dispensed by Participating Retail Pharmacies. This uniform price may exceed or be less than the actual price negotiated and paid by the PBM to the Participating Retail Pharmacy for dispensing Covered Services. Where the uniform price exceeds the actual price negotiated and paid by the PBM to the Participating Retail Pharmacy for dispensing Covered Services, The PBM realizes a positive margin. In cases where the uniform price is lower than the actual price negotiated and paid by the PBM to the Participating Retail Pharmacy or PBM for dispensing Covered Services, the PBM realizes a negative margin.* **Overall, lock-in pricing arrangements result in a positive margin for the PBM. Such margin is retained by the PBM in addition to any other fees, charges or other amounts agreed upon by the PBM and the Customer**, as compensation for the pharmacy benefit management services the PBM provides to the Customer. *Also, when the PBM receives payment from the Customer before payment to a Participating Pharmacy, the PBM retains the benefit of the use of the funds between these payments.*

V. The Pharmacy Benefit Manager's Revenue Sources: Clawbacks

A. Overview

1. Clawbacks occur when commercially insured patients' copayments exceed the total cost of the drug to their insurer or pharmacy benefit manager.

2. Network service agreements between the PBM and the dispensing pharmacy obligate the pharmacy to rebate the excess to the PBM. The PBM may share some portion of the clawback with the employer-sponsor (or may not).

B. Prevalence and Significance of Clawbacks

1. Source: "Overpaying For Prescription Drugs: The Copay Clawback Phenomenon" (Van Nuys et. al., University of Southern California Schaeffer Center for Health Policy and Economics, March 2018).

2. This study used reimbursement data "from a survey by the Centers for Medicare & Medicaid Services which was published for six months

beginning in January 2013, the National Average Retail Price. The survey was authorized in the Deficit Reduction Act of 2005, which sought to reduce spending on mandatory programs such as Medicaid. The Act provided for a monthly national survey of retail prices for Medicaid-covered outpatient drugs; these benchmarks could then be used by state Medicaid pharmacy programs to evaluate their reimbursement methods. NARP data are based on 50 million retail pharmacy transactions from independent and chain pharmacies nationwide. They measure per-unit mean reimbursement to retail pharmacies for commercially insured patients for over 4,000 common outpatient drugs, listed by 11-digit national drug code (NDC), and represent the total cost to the PBM, including dispensing fees and pharmacy markup."

3. "Our copayment data come from a 25 percent random sample of Optum Clinformatics™ Data Mart pharmacy claims from commercially insured patients in the first half of 2013. These data represent 9.5 million prescriptions filled by 1.6 million subscribers during that period. Each claim contains the name of the drug and its NDC, the quantity filled and the copayment paid by the beneficiary. Data from First Databank is used to characterize whether each NDC corresponds to a brand or generic drug.

4. Results:

Table 1: Frequency and Average Size of Overpayments, 2013

	Number of Claims	Number of Claims with Overpayment	Percentage of Claims Involving Overpayment (95% CI)	Mean Overpayment (SD)
All Drugs	9,539,846	2,188,578	22.94% (22.91, 22.97)	$7.69 (8.59)
Generic	7,295,525	2,055,024	28.17% (28.14, 28.20)	$7.32 (7.43)
Brand	2,244,321	133,554	5.95% (5.92, 5.98)	$13.46 (18.01)

Source: Optum Clinformatics™ Data Mart pharmacy claims, January-June 2013, and CMS NARP reimbursements from the same period. Confidence intervals are binomial.

"In 2013, **almost one quarter of filled pharmacy prescriptions** (23%) involved a patient copayment that exceeded the average reimbursement paid by the insurer by more than $2.00. Among these overpayment claims, **the average overpayment is $7.69**. Overpayments are more likely on claims for generic versus brand drugs (28% vs. 6%), but the average size of the overpayment on generic claims is smaller ($7.32 vs. $13.46). **In 2013, total overpayments amounted to $135 million in our sample, or $10.51 per covered life.** With over 200 million Americans commercially insured in 2013, these findings suggest the practice of overpayments may account for a non-negligible share of overall drug spending and patient out-of-pocket costs.

C. Gag Clauses

1. Agreements between PBMs and in-network pharmacies typically included "gag" clauses: provisions that forbade pharmacies from disclosing to patients when they could save money by paying cash instead of using the plan's pharmacy benefit.

2. This practice has generated many lawsuits against insurers and pharmacies (see the article for an extensive list of citations and see below for an analysis of a recent clawback case).

3. Maryland, Arkansas, Louisiana, North Dakota, Georgia, Connecticut, Maine and Texas have passed statutes forbidding the practice; legislation is pending in North Carolina and New York. Some of these legislative efforts only affect fully insured plans; others regulate pharmacy benefit managers and therefore indirectly affect self-insured plans as well.

4. Ohio:

   a. Ohio Revised Code Chapter 3959 regulates and licenses third party administrators, including pharmacy benefit managers, for both fully-insured and self-insured plans. ORC §3959.12(A)(5): an administrator's license may be suspended upon a finding that the entity has used fraudulent, coercive, or dishonest practices.

   b. Ohio Department of Insurance Bulletin 2018-02, "Pharmacy Benefits-Prohibited Practices," effective April 3, 2018: "[T]he Department defines the following practices as a violation of the statutes cited above [license suspension statute and §§3923.02 and 3923.021, prohibiting fully insured policies from containing ambiguous, misleading or deceptive provisions and which obligate policies to provide benefits that are reasonable in relation to the premium charged] and prohibits any entity from the following:

      1) Prohibiting any person, directly or indirectly, from informing, by any means, an individual about less expensive ways to purchase prescription drugs that may also be available under any insurance policy or benefit plan.

      2) Requiring cost-sharing in an amount, or directing a pharmacy to collect cost-sharing in an amount, greater than the amount an individual would pay for the prescription drug if the drug were purchased without coverage under a health benefit plan."

5. "Know the Lowest Price Act of 2018," Public Law No. 115-262 (10/10/2018): This bill prohibits a prescription drug plan under Medicare or Medicare Advantage from restricting a pharmacy from informing an enrollee of any difference between the price, copayment, or coinsurance of

a drug under the plan and a lower price of the drug without health-insurance coverage.

6. "Patient Right to Know Drug Prices Act," Public Law No. 115-263 (10/10/2018)

a. This Act affects all employer-sponsored group health plans and all insured health benefit plans. Section 2 of the Act adds Section 2729 to the Public Health Service Act, which is incorporated by reference into ERISA.

b. Text: "SEC. 2729. Information on prescription drugs.

"(a) In general.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall—

"(1) not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the plan or coverage from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and

"(2) ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, with respect to such plan or coverage, restrict, directly or indirectly, a pharmacy that dispenses a prescription drug from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.

"(b) Definition.—For purposes of this section, the term 'out-of-pocket cost', with respect to acquisition of a drug, means the amount to be paid by the enrollee under the plan or coverage, including any cost-sharing (including any deductible, copayment, or coinsurance) and, as determined by the Secretary, any other expenditure."

VI. Employers and Pharmacy Benefit Managers Occasionally Cooperate--For Their Own Benefit

A. Co-Pay Accumulator Programs

1. Background

a. In order to induce prescribers and enrollees to use branded prescription drugs, manufacturers distribute direct-to-consumer coupons that enrollees use to offset their out of pocket costs.

b. Another strategy used by drug manufacturers: direct-to-consumer copay assistance programs, in which the manufacturer reimburses all or a portion of the enrollee's copayment obligation (or out-of-pocket obligation for plans for which the drug coverage is included in the overall deductible and annual out of pocket maximum payment obligation).

c. This undermines the employer's health plan design that seeks to encourage enrollees to use lower-cost (usually generic) drugs in the plan's Tiers 1 and 2 price bands, rather than Tier 3 (which usually contains the more expensive branded drugs and therefore are tagged with a higher deductible or out of pocket cost).

d. Note: the pharmacy benefit manager may not object to this practice: it maximizes rebate income.

e. How about plan sponsors? It depends upon the amount of the rebates that the pharmacy benefit manager shares with the plan sponsor.

f. Couponing is a major dollar item: in 2016, participants in employer-sponsored health plans redeemed $9 billion in manufacturer coupons, reducing their net out-of-pocket costs to $18 billion, a reduction of 33%. "The Impact of Prescription Drug Rebates on Health Plans and Consumers" (Charles Roehrig, PhD, Altarum, April 2018; III.C.2.b.

2. Employers Have Begun to Respond: Co-Pay Accumulator Programs

a. Employers, health insurers and pharmacy benefit managers have adopted "copay accumulator" programs that exclude the value of drug copayment coupons toward a person's out-of-pocket costs. "Pharmacy Sticker Shock Is Here" (Axios Vitals, Monday, July 9, 2018

b. Excerpt from PepsiCo Health and Insurance Benefit Programs January 2018 Summary of Material Modifications:

Prescription Drugs

Co-Pay Assistance Programs

If you are a participant in the Core Plus, Healthy Advantage, and BlueCare HMO of Florida medical options you may be eligible for Co-Pay Assistance Programs ("Co-Pay Assist Program"). Co-Pay Assist Programs are third-party programs that may help you pay for certain high cost medications. These medications are normally specialty medications issued through Accredo, Express Scripts' specialty pharmacy. If applicable, Co-Pay Assist Programs pay all or a substantial portion of your cost for a prescribed medication. Individuals should contact Express Scripts at 888-737-7479 with questions regarding whether a Co-Pay Assist Program applies to a specific prescribed medication.

The amount paid by a Co-Pay Assist Program is not an amount that is paid by you and you are not required to repay that amount. For this reason, such amounts are not credited to your deductible or out of pocket maximum. However, the actual amount that you do pay for the medication (if any) after the Co-Pay Assist Program payment has been applied to your cost, is credited to your deductible and out of maximum, because like any other co-pay, this amount is actually paid by you. Please note that the 2018 Healthy Advantage plan design changes introducing per prescription maximums are intended to reduce the impact of high cost medications on your out of pocket cost. The per prescription cost maximums, per IRS guidelines, can only apply after you have met your deductible.

c. Excerpt From Walmart Associates' Health and Welfare Plan 2018 Summary Plan Description:

Expenses that don't count toward the annual deductible. The following expenses are not applied toward either the network or out-of-network annual deductible:

- Pharmacy copayments/coinsurance (including copay assistance from a third party)
- Non-network providers' charges that are above the maximum allowable charge
- Charges for services provided at any Walmart Care Clinic that is not a network provider under your plan (however, any eligible tests performed outside the clinic will count toward your deductible)

- Charges excluded by the Plan
- Charges paid 100% by the Plan such as network preventive services and certain Centers of Excellence services, and
- Charges for out-of-network preventive services.

B. Large Employers Possess the Bargaining Power to Move From Spread Pricing to Pass-Through Pricing Models in Their Agreements With Pharmacy Benefit Managers

1. Background: Spread Pricing Produces Significant Revenue and Profit for Pharmacy Benefit Managers and a Significant Gamble for Health Plans and Enrollees

    a. See IV.E: Pharmacy Benefit managers typically offer discounts from a (fictional) list price, which bears no relation to the actual amount the pharmacy benefit manager has agreed to pay the dispensing pharmacy (that price may bear little resemblance to the price the pharmacy paid to acquire the drug).

    b. The terms to fear: “Average Wholesale Price” and “Maximum Allowable Cost.” Both are fictitious.

2. “PBMs use three contract ploys — the MAC definition, MAC pricing formulas, and so-called MAC guarantees — to deprive health plans of most savings on generics”

    a. Typical definition: “MAC or "maximum allowable cost" means the unit price established by the PBM for a multi-source drug included on PBM’ s MAC drug lists developed for PBM’ s clients, which may be amended from time to time by PBM, in its sole discretion.

3. What can a pharmacy benefit manager do with this definition? “Don't Get Caught By PBMs' MAC Mousetraps--References To Maximum Allowable Prices In Contracts Between Plans And PBMs Need To Be Scrutinized, Since Things Are Not Always What They Seem” (Linda Cahn, Managed Care, September 2008 -- and still regarded as an accurate picture. Accessed at http://pharmacybenefitconsultants.nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/11/dont-get-caught-in-pbm-mac-mouse-traps.pdf)

    a. “A PBM can create different MAC lists for different clients.

    b. “A PBM can include on — or exclude from — its MAC lists any drugs the PBM wants to include or exclude, For example, a PBM is free to include 500 drugs — or 2,000 drugs—and equally free to leave thousands of drugs off its MAC lists,

c. "A PBM can change the drugs it includes — or excludes — whenever it wants to do so,

d. "A PBM can select any prices it wants as the MAC prices for the drugs on its MAC Lists. For example, for a generic drug that actually costs $4, a PBM can create a MAC price of $40, or a MAC price of $100 (or any other price it wants).

e. "A PBM can change its MAC prices for any drug on its MAC lists whenever it wants to do so.

f. "If a PBM does not include a drug on its MAC list, the drug's price will default to whatever other pricing exists in the contract.

4. The PBM appears to be offering a huge discount from MAC or AWP -- 50-60%. Sound good? It's not.

a. Source: *"Inside AWP: The Arbitrary Pricing Benchmark Used To Pay For Prescription Drugs"* (46Brooklyn, November 8, 2018, https://www.46brooklyn.com/research/2018/11/7/visualizing-how-aint-whats-paid-awp-really-is).

b. 46Brooklyn selected 50 commonly dispensed generic drugs, and "pulled three pricing benchmarks (NADAC, AWP, and Wholesale Acquisition Cost - WAC) for every National Drug Code (NDC), which is a fancy way of saying the unique product identifier for each drug (some drugs may have several NDCs associated with it). We then took all those NDCs and rolled them up into each of the 50 drug groupings. This gave us 50 "buckets" of drugs, each containing their own unique assortment of respective NDCs."

c. "AWP and WAC [wholesale acquisition cost, used in the MAC definition] have very little relation to actual NADAC [what Medicaid programs report they actually paid for drugs--which may itself be inflated because those programs used PBMs with spread pricing arrangements, too] drug prices. But **we were surprised how egregiously disconnected pricing on some drugs are. The most striking example is Amlodipine Besylate 10 MG Tab, which carries an AWP that is an eye-popping 123x its NADAC**.

d. 46Brooklyn reports that typical discounts off AWP offered by PBMs are in the high-70s to the low-80s, depending on the size of the payer. That is not a good deal: **You will see that most of these 50 generic drugs are well above an 80% discount to AWP."**

e. Smaller payers don't get discounts in the 70--80% range: they are lucky to get discounts in the 40-50% range.

5. Large employers have awakened: abandon spread pricing and insist on pass-through pricing plus a per-prescription administrative fee

    a. Ohio Medicaid requires all of its Medicaid managed care plan vendors to terminate agreements with pharmacy benefit managers that contain spread-pricing models: see *August 14, 2018 Letter from Ohio Medicaid Director to Medicaid Managed Care Plans Instructing Plans to Terminate Spread-Pricing Agreements with Pharmacy Benefit Managers and Adopt a Pass-Through Pricing Model, Effective January 1, 2019*, cited in *Ohio Firing Pharmacy Middlemen That Cost Taxpayers Millions* (Columbus Dispatch, August 14, 2018, http://gatehousenews.com/sideeffects/ohio-firing-pharmacy-middlemen-cost-taxpayers-millions/site/dispatch.com/).

    b. Not all initiatives have met with success: Pharmaceutical Care Management Association v. Rutledge, (8th Cir. 6-8-2018)-- ERISA and Medicare Part D preempt an Arkansas statute that obligated pharmacy benefit managers to reimburse pharmacies for generic drugs at a price equal to or higher than the pharmacies' cost for the drug.

        i. That statute was designed to help independent and chain pharmacies--it could help employers and enrollees only to the extent it encouraged pharmacy benefit managers to abandon spread-pricing agreements with plan sponsors.

C. Changes to the Pricing Model for Provider-Administered Specialty Drugs

1. CMS Advance Notice of Proposed Rulemaking, October 30, 2018 (83 FR54546): change the current system of reimbursing institutional providers that administer specialty drugs covered under Medicare Part B (these drugs are not covered under the Medicare Part D drug insurance program) by--

    a. substituting private-sector pharmaceutical vendors for the current Part B "buy and bill" practice;

    b. changing the Part B Average Sales Price plus 6 percent reimbursement system to a flat fee; and

    c. implementing international reference pricing.

2. The proposal would take the form of a randomized controlled trial, exposing half of the Part B fee-for-service program to the new pricing regimen beginning in 2020 and phasing it in until 2025.

3. Current Practice: “Buy and Bill”

   a. Physicians administering specialty pharmaceuticals in their offices purchase medications directly from manufacturers or through wholesale distributors and billed the patient’s insurers for the cost of the medications incident to their administration. Buy and bill is the required acquisition method for Medicare fee-for-service providers, and it also is the most popular payment methodology in use in private sector group and individual health benefit plans, especially for oncolytics--cancer treatment therapies.

   b. Medicare current formula for payment: Average Sales Price plus 6% (currently 4.3% due to budget sequestration).

      i. Average Sales Price (ASP): adopted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and defined at 42 CFR §§414.804 and 414.904, ASP is the volume-weighted average price based on the manufacturer’s quarterly sales reports for specialty pharmaceuticals. Manufacturers must take into account nearly all drug discounts when calculating quarterlyASPs, including rebates, chargebacks, and discounts given for volume purchasing and cash payments.

      ii. Key for success from the perspective of the providers: can we acquire the drugs for less than the ASP? Answer: the larger we are, the more likely it is that we can do so.

      iii. NB: the incentive is to purchase and dispense the most expensive treatment alternative, since 6% of a larger number is more than 6% of a smaller number (and the ability to negotiate larger than average discounts on more expensive drugs in a treatment class is easier than for less expensive drugs in the same treatment class).

4. The Changes in the Advance Notice of Proposed Rulemaking

   a. Switch from buy and bill to white-bagging:

      i. Private sector vendors, rather than physicians or institutional providers that employ physicians, would purchase the drugs and supply them to physicians as requested by physicians (transferring storage and risk of loss costs from the institutional provider to the vendor), and the vendors would compete for physician business based on a number of different factors. The vendors would then bill Medicare for the administered drugs at a rate based on international prices.

ii. "[V]endors would have the flexibility to offer a variety of delivery options, including beneficiary-specific prescriptions, pre-ordering approaches such as onsite inventory management solutions, and other arrangements that would not require physicians and hospitals to purchase the drugs or face greater buying costs. Physicians and hospitals would select the vendors that offer delivery mechanisms that best meet their patient care needs, practice size and location(s), and support needs." 83 F.R. at 54550.

iii. The total amount that will be paid to practitioners will be approximately equal to the historic aggregate 6% add-on amounts that have been paid on an annual basis. But, the amount actually paid to a particular practitioner will be "a set payment amount per encounter or per month (based on beneficiary panel size) for an administered drug, which would not vary based on the model payment for the drug itself. We are considering whether to set a unique payment amount for each class of drugs, physician specialty, or physician practice (or hospital). That is, there would be a set payment amount per administered drug that would be based on—(1) which class of drugs the administered drug belongs to; (2) the physician's specialty; or (3) the physician's practice." 83 FR at 54553.

b. The International Price Index model to pay the vendors. "The amount Medicare will reimburse the private sector vendors would be tied to an international reference price, referred to as the 'International Pricing Index'(the "IPI"). IPI is based on a basket of sixteen other countries. Indexing would be phased in over time, from 2020 to 2025.

5. Implementation challenges: "Administration Outlines Plan To Lower Pharmaceutical Prices In Medicare Part B" (Rachel Sachs, Health Affairs Blog, October 26, 2018)[1]

a. [W]hat if pharmaceutical companies won't sell their products to the vendors at the new reference price? What happens if they insist on their current, higher price? One possible answer: nothing. Medicare is still required to cover the product, nothing in the proposal explicitly uses CMMI's authority to waive this requirement, and perhaps companies would use balance billing or other creative arrangements to recoup the relevant expenditures. If that were the case, though, the program would simply fail to lower drug prices,

[1] https://www.healthaffairs.org/do/10.1377/hblog20181026.360332/full/

and the administration has told us that the proposal will have real impacts in that area.

b. "Another possible answer is that vendors would simply cease providing certain drugs to physicians, if the pharmaceutical company is unwilling to make sufficient concessions to render the benchmarked Medicare reimbursement worthwhile for the vendor. If that were the case, though, patients would lose access to some, or even many, Part B products – and the administration has told us that the proposal will operate 'without any restrictions on patient access' (something the pharmaceutical industry disagrees with). So far, the administration has not explained how exactly this proposal would avoid each of these pitfalls.

c. "I would note here an additional argument from Professor Fiona Scott-Morton, who argues[2] that the proposal could fail to have any effect for a different reason. As she notes, the pharmaceutical company and the relevant foreign countries could work together 'to set a US-level invoice price and offset it' with a number of other possible factors, meaning that although the international reference price would quickly rise to meet the US level, other countries would be no worse off. The pharmaceutical industry is endlessly creative, and it will attempt to come up with a solution to any proposal that threatens its bottom line. The administration's request for comments about data sources in this area indicates a desire to plan for this possibility, but they may not be able to fully prevent it."

d. "The administration frames this proposal as 'cutting down on foreign freeloading,'[3] arguing that other countries do not pay their fair share of pharmaceutical investment. Yet the proposal will not clearly *raise* prices abroad and end the 'freeloading.' It simply aims to *lower* them here. And crucially, the United States and the United States alone is responsible for the high prices we pay for prescription drugs. Other countries have made hard choices to cover or not cover certain drugs, based on factors including their price and their effectiveness. Not only have we not made such choices, but we have also legally required our public payers to reimburse most and in many cases all drugs approved by the Food and Drug Administration, a combination which places the leverage over drug pricing squarely in the hands of the pharmaceutical industry. We could have changed our own policies at any time. The failure to do so is our own. Arguably, with this proposal *we* are "freeloading" on the efforts by other countries to engage in serious cost control.

[2] https://twitter.com/ProfFionasm/status/1055572895664140290
[3] https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html

e. Note: nothing in the Food, Drug and Cosmetic Act grants the FDA the power to evaluate and possibly reject a drug application on the ground that its cost exceeds its value:

"FDA doesn't have a direct role in drug pricing. Indeed, of the core provisions of the Federal Food, Drug and Cosmetic Act (FDCA) where such direct pricing authority might logically reside, such authority is starkly absent. For example, section 505(b)(1) of the Act requires that a New Drug Application contain, among other things, full clinical data on the safety and efficacy of the drug, detailed information on its composition and manufacturing processes, and the drug's proposed labeling, but nowhere does this section require an applicant to provide FDA with the proposed pricing of the drug.

"After reviewing an NDA, FDA may refuse to approve it pursuant to section 505(d) if, among other things, the sponsor failed to submit adequate clinical study data, the submitted data showed the drug to be unsafe or ineffective, the labeling is false or misleading, or the manufacturing facilities or processes are inadequate to assure its safety. Nowhere in this section, however, is there any authority for FDA to refuse to approve a new drug based on a conclusion that the pricing of the drug is or would be unreasonable."

"For FDA, Addressing Drug Pricing Is a Matter of Doing Its Job Better" (James N. Czaban, DLA Piper, Food and Drug Law Institute, https://www.fdli.org/2018/08/update-for-fda-addressing-drug-pricing-is-a-matter-of-doing-its-job-better/).

VII. How Do Pharmacy Benefit Manager Prescription Drug Utilization Management Programs Perform? Do They Save Money? For Whom?

A. Types of Prescription Drug Utilization Management Programs

1. Prior Authorization.

a. Instead of filling a flagged drug at the point of sale, the PBM's staff conducts a coverage review: contact the prescribing physician to confirm diagnosis and review other drug treatment options.

b. Purpose: increase likelihood that the appropriate drug has been selected; avoid use of drugs that are either not indicated or for which an off-label use has not been validated.

2. Step Therapy

a. Require the use of lower cost therapeutically equivalent drugs first before stepping up to more expensive drugs.

b. Same methodology as used in prior authorization.

3. Quantity Duration

a. PBM's clinical staff establishes the quantity of a specified drug that will be dispensed within a specified time period.

b. PBMs typically rely upon prescribing guidelines approved by FDA and Centers for Disease Control and Prevention.

B. Does Prior Authorization Result in Predictable Denial Rates Across Pharmacy Benefit Managers?

1. "Managing the High and Rising Cost of Prescription Drug Coverage--Segal's Research Finds Wide Variance in Pharmacy Benefit Managers' Prior Authorization Denial Rates for Specialty Drugs" (Segal, Practical Research for Multiemployer Plans, Fall 2017): No, there is no uniform pattern among PBMs.

2. This study used data from six PBMs about their prior authorization denial rates for non-Medicare eligible prescriptions within ten key therapeutic drug classes for the 2015 calendar year.

3. Results:

a. No apparent industry standards: denial rates varied wildly from PBM to PBM for the same therapeutic drug class and in their overall rate of denials (one PBM had very low denial rates in all but one therapeutic class; one had a high denial rate for every one of the ten therapeutic classes).

b. "The huge variance in denial rates we found among PBMs and the potential impact on a plan's cost and participant satisfaction strongly suggests plan sponsors should consider evaluating prior authorization approval or denial rates in their future requests for proposals from PBMs."

c. "Some PBMs offer prior authorizations that range from $25 to $60 per review. Other PBMs offer a per-claim fee or a PMPM pricing fee for bundled packages, which include prior authorization, step therapy and quantity limits, or PMPM fees for a la carte programs. Consequently, when considering any drug UM program, plan sponsors should take into account total net savings. These savings should include both projected savings and costs of program (and rebates, if any), as well as the impact on participants."

C. How Well Do Pharmacy Benefit Managers Construct and Administer Step Therapy Protocols? Recent Study: Not Well at All

1. Source: "Variation in the Use of Step Therapy Protocols Across US Health Plans (Chambers, Panzer and Neumann, Health Affairs Blog, 9-14-18)[4]

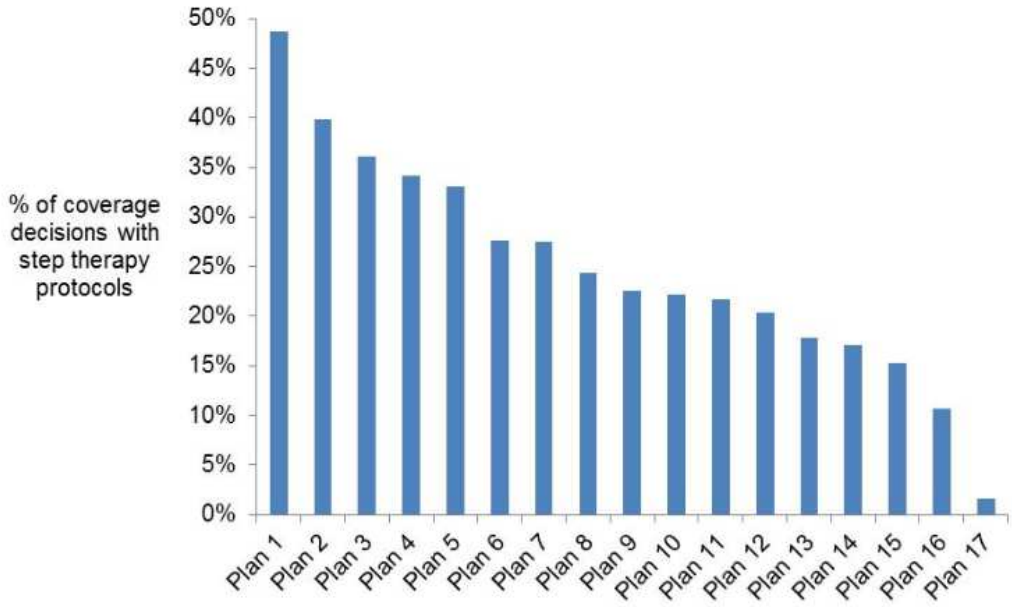
2. CMS has authorized Medicare Advantage Plans to use step therapy protocols for Part B drugs. August 7, 2018 Letter from CMS Administrator to Medicare Advantage Orgaizations, "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage," https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf The policy, which will be implemented on January 2019, is intended to help address rising drug spending by allowing Medicare Advantage plans more flexibility and leverage when negotiating with product manufacturers.

3. "We used the Specialty Drug Evidence and Coverage (SPEC) Database.[5] a database developed by researchers at Tufts Medical Center, to examine trends in US commercial health plan specialty drug coverage. Information in SPEC is extracted from publicly available coverage decisions issued by 17 of the 20 largest commercial health plans relevant to their commercial lines of business. SPEC includes information on how plans cover specialty products and the evidence that plans cite in their coverage decisions. Roughly one in four coverage decisions in SPEC includes a step therapy protocol (1,208 of 4,809 decisions). (Decisions are current as of August 2017)."

4. "We found wide variation in the frequency with which health plans apply step therapy protocols in their specialty drug coverage decisions, ranging from 2 percent to 49 percent across the included plans (Exhibit 1).

[4] https://www.healthaffairs.org/do/10.1377/hblog20180912.391231/full/
[5] https://cevr.tuftsmedicalcenter.org/databases/spec-database

Exhibit 1: Frequency That Health Plans Apply Step Therapy Protocols In Their Specialty Drug Coverage Decisions



5. "*Some Step Therapy Protocols Are More Burdensome Than Others.* Some step therapy protocols are more onerous than others. For example, of the 1,208 coverage decisions that include a step therapy protocol, 761 (63 percent) require patients to step through a single therapy, while 447 (**37 percent) require stepping through multiple therapies**. Moreover, 181 **(15 percent) of protocols include three or more steps, and some require patients to fail up to five treatments before patients can gain access to a particular therapy**."

6. Even when plans require the same number of steps, some protocols are more involved than others.

7. *Use Of Step Therapy Protocols Varies Across Diseases*. Health plans use step therapy protocols differently for drugs indicated for different diseases.

8. *Conclusion:* "Because plans independently judge the strength of a product's evidence and value, and tailor drug coverage decisions to their own enrollees and situations, some variation in plan behavior is expected. Moreover, how aggressively plans manage specialty drugs is presumably influenced by negotiated prices, available financial resources, the degree of competition within a plan's operating region, and local practice patterns. Nonetheless, the extent of the variation seems notable and, at the very least, raises questions about whether they are grounded in sound clinical evidence."

VIII. Recent Litigation Involving Pharmacy Benefit Managers

A. Sheet Metal Workers Local Welfare & Benefit Fund v. CVS Pharmacy, Inc. (D.C. RI 3-31-2018)--Plaintiffs Permitted to Amend Complaint to Allege a RICO Conspiracy Among CVS and Pharmacy Benefit Managers to Withhold from Health Benefit Plans Lower Drug Prices CVS Offered to Cash Customers Under its Health Saving Pass Program

1. Original complaint: the Plan alleged that CVS overcharged the Plan and its enrollees by collecting more for generic drugs than it was allowed under the National Council for Prescription Drug Program.

    a. The NCPDP obligated CVS to charge the Plan no more than the "Usual and Customary" price for drugs.

    b. CVS, seeking to compete with big-box retailers that had reduced prices on generic drugs, introduced the Health Savings Pass Program ("HSP") in November 2008. The program allowed individual cash-paying CVS customers to access discounted prices by paying an annual membership fee.

    c. Why the membership fee? Although it was nominal, CVS, the original complaint alleged, took the position that, since the HSP price was not available to cash customers, but only to HSP members, CVS was not required to offer that price to the Fund and its enrollees, but could instead report the higher price paid by non-HSP-member cash customers as the U&C price.

    d. The original complaint asserted this resulted in negligent misrepresentation, unjust enrichment, and violations of state-consumer-protection acts.

2. The amended complaint: A RICO charge is added: Plaintiffs allege that four of the country's largest PBMs--Caremark, Express Scripts, Inc., OptumRx, Inc., and MedImpact Healthcare Systems, Inc.--participated in the scheme, too.

    a. The court noted an anomaly in the relationship between a Plan, the PBM, and the pharmacies that are paid to dispense drugs: “PBMs contract with health plans like Plaintiffs to reimburse pharmacies like CVS when a plan's members fill their prescriptions. PBMs ostensibly work on behalf of their health-plan clients to, among other things, negotiate low pharmacy drug prices. The interests of PBMs and health plans are not perfectly aligned, however. Health plans want cheap drugs; PBMs want the difference between what they pay pharmacies for drugs and what they charge health plans for those drugs to be as large as possible. In other words, the difference

between what PBMs pay and what they charge is their gain, but the health plans' loss."

b. "The PBMs allegedly increased this spread by deliberately hiding from health plans the fact that CVS was not reporting its HSP price as its U&C price. Each PBM developed an internal policy interpreting definitions of U&C price in their respective contracts with CVS as excluding HSP prices. Plaintiffs allege that this was no coincidence - that CVS prompted the PBMs to keep the ruse a secret, and that each PBM knew the others had agreed to do so. This assurance was paramount to the scheme, for if any one PBM had confessed, the health plans would have put a stop to it, insisting they pay no more than CVS's cash customers in accordance with their contracts with the PBMs."

3. Primary defense: lack of diligence on the part of the plaintiffs, which the defendant alleged, should result in a denial of the attempt to amend the complaint to add the RICO charges. Court: sufficient diligence shown to move to amend the complaint after large document production revealed the basis for the amended complaint.

4. Second defense: lack of a RICO conspiracy. Court: enough has been shown at this pleading stage to go forward: "But for now, at the motion-to-dismiss stage, the Court finds it at least plausible, assuming the allegations in the [amended complaint] are true, that each PBM, at the behest of CVS, acted against its individual interest by choosing to adopt an internal policy interpreting U&C price to exclude CVS's HSP price, with the expectation (and in at least one instance, a confirmation) that competitors would do the same. In short, Plaintiffs have adequately pleaded a rim around a spoked hub."

5. NB: Note absence of ERISA claims or attempt on the part of the PBM to argue that ERISA does apply and that (i) the PBM was not a fiduciary and/or (ii) even if it was, no plan assets were involved.

B. United States ex rel. Rahimi v. Rite Aid (E.D. Mich. 4-11-18)--District Court Refuses to Dismiss False Claims Act Complaint that Rite Aid Falsely Billed Medicare Part D and Medicaid Programs When it Submitted Claims at a Cost Higher Than That Offered to Cash Customers in the Rite Aid Discount Savings Program

1. Pharmacist Azam Rahimi alleges Rite Aid charged Medicare Part D and Medicaid prices that were significantly higher than the prices charged to its customers who belong to the company's "Rx Savings" discount program.

2. Rahimi alleged that Rahimi discovered the scheme by talking to a friend who was a pharmacist at a Rite Aid in New York, then investigating

himself by calling Rite Aid pharmacies across the country and asking for its Medicaid price on two medications.

3. Court: although the accusations were plausible, Rahimi and the government did not prove that higher prices were ever actually submitted to Medicare or state programs. Government instructed to provide specific evidence that Rite Aid submitted false claims to government programs and examples of the pharmacy submitting those claims.

C. In re: UnitedHealth Group PBM Litigation, No. 16-cv-3352, 2017 WL 6512222 (D.Minn. December 19, 2017): Court Dismisses Class Action Complaint Alleging Entitlement to Clawbacks-Copayments Exceed Price Pharmacy Agreed as Payment from PBM and Which is Returned to the PBM

1. Plan members filed a complaint against UnitedHealth Group, Inc. and some of its wholly-owned subsidiaries under ERISA, the Racketeer Influenced and Corrupt Organizations Act ("RICO"), and various state laws relating to breach of contract, fraud, and deceptive trade practices arising out of the PBM's conduct in administrating pharmacy benefits that allegedly caused Plaintiffs to overpay for prescription drugs purchased at retail network pharmacies.

    a. This is a "clawbacks" case: the PBM paid the dispensing pharmacy an amount less than the plan members' out of pocket obligation (or less than the cash price the pharmacy would accept from a cash-paying customer). The pharmacy collected the full out of pocket payment and remitted the excess to the PBM.

    b. "Under each of Plaintiffs' plans, the plan documents provide that plan members must pay copayments or coinsurance when filling prescriptions at retail pharmacies. Plaintiffs allege, however, that they were entitled to pay less than they were charged as copayments or coinsurance under the terms of their plans because their plans entitled Plaintiffs to receive the benefit of the discounted rate, in the form of lower copayments or coinsurance amounts. Plaintiffs allege that they purchased certain drugs on numerous occasions and were overcharged due to OptumRx's contribution calculations, resulting in spreads and clawbacks."

    c. The plaintiffs' lawsuit asserts a variety of ERISA and other violations

2. The ERISA §502(a)(1)(B) claim.

    a. The claim: the PBM required pharmacies to collect and remit to the PBM the excess of plan members' out of pocket obligation over the amount to which each pharmacy was entitled under the terms of its

agreement with the PBM. That violated the terms of the plan documents.

b. The disposition of the motion to dismiss turned upon the language that appeared in the plan documents.

c. Example:

i. Plan document (the "Outpatient Prescription Drug Rider"): the enrollee is responsible for paying the lower of (1) "the applicable Out-of-Pocket Expense," or (2) "the Network Pharmacy's Usual and Customary Charge."

ii. Summary of Benefits lists different flat copayment amounts for different tiers of drugs.

iii. The Outpatient Prescription Drug Rider defines "Usual and Customary Charge" as "the usual fee that a pharmacy charges individuals for a Prescription Drug Product without reference to reimbursement to the pharmacy by third parties."

iv. A separate "UCR Rider" defines Usual, Customary and Reasonable (UCR) Charge" as the lesser of several things, including "the amount the provider agrees to accept as reimbursement for the particular covered services, supplies and/or drugs."

v. "However, as Defendants point out, that term is not equivalent to "Usual and Customary Charge," which is used in the Outpatient Prescription Drug Rider. Under the plain and unambiguous terms of Ackerman's [the affected individual named plaintiff covered under this] plan, he was not entitled to pay the discounted rate if it was less than the copayment amount."

d. Failure to exhaust administrative remedies: the Court sided with the defendants: time for filing administrative claims had not expired; no evidence that pursuing those claims would be futile.

3. The ERISA §404 Breach of Fiduciary Duty Claim

a. The claim:

i. "Defendants breached their fiduciary duties with respect to the ERISA Plaintiffs and the ERISA Subclass when they, generally, (1) required pharmacies to charge a spread for prescription drugs (a benefit calculation), (2) required pharmacies to remit the spread, (3) set their own compensation by requiring the clawbacks, (4)

misrepresented and failed to disclose the manner in which they charged for prescription drugs, (5) prohibited pharmacies from disclosing to patients the discounted rates or to sell at those rates, and (6) negotiated the discounted rates."

ii. The spread between the plan enrollees' out of pocket obligation and the actual reimbursement to which the pharmacy was entitled constitute plan assets; the PBM exercised discretionary control over those assets and used them "as "leverage" in negotiating discounted rates, spreads, and clawbacks with pharmacies."

b. The PBM's defense: it is not a plan fiduciary--it processed claims in accordance with the terms of the plan, and did not exercise any discretionary authority or control; the clawbacks were not plan assets.

c. Court:

i. Actions "(1)" and "(3)": "Defendants did not act as fiduciaries because they did not exercise discretionary authority over the plan or its assets when calculating and relaying copayment and coinsurance obligations to pharmacies…. Plaintiffs do not allege facts showing that Defendants' actions constituted anything more than ministerial claims processing.

ii. Actions "(2)," "(3)" (in part), "(5)," and "(6)": The Defendants also did not act as fiduciaries when engaging in [these actions] because all of these activities involved the performance of contractual terms negotiated with plans or pharmacies. The terms of payment between the plan sponsor and the PBM are settlor functions and do not implicate fiduciary conduct; "negotiating prices with providers is also not a fiduciary function, but rather the administration of a network administrator's business."

iii. Action "(4)": Although it is a breach of the duty of loyalty to affirmatively mislead a participant or beneficiary, "there are no allegations showing that Defendants misrepresented or failed to disclose the terms of the ERISA Plaintiffs' member contribution responsibilities under the plans."

iv. Misuse of plan assets: the court concluded that the spread/clawbacks were not plan assets

(a) The spreads came from plan members, not the plan.

(b) "That Defendants were able to leverage the size of their member base, garnered as a result of doing business with multiple plans and administrators, to negotiate lower rates with pharmacies does not constitute exercise of or control over administration agreements or insurance policies."

4. The ERISA §§406(a)(1)(C)-(D) and 406(b) Prohibited Transaction Claim

a. The claim: the clawbacks siphoned plan assets to the PBM.

b. The response of the defendants, accepted by the courts: ERISA §§ 406(a)(1)(C)-(D) and 406(b) prohibit certain transactions between a plan and a fiduciary and, in the case of ERISA §406(b), plan assets. Since the PBM is not a fiduciary, and since the clawbacks did not constitute plan assets, no prohibited transactions occurred.

5. The ERISA §702 Claim

a. Text of ERISA §702(b) (29 U.S.C. §1182(b):

(b) In premium contributions

(1) In general. A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

(2) Construction Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer may be charged for coverage under a group health plan except as provided in paragraph (3)[no group-based discrimination on basis of genetic information]; or

(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence

to programs of health promotion and disease prevention.

b. The claim: plan enrollees who purchased prescription medications did so subject to the spread, whereas plan members who did not need the specific drugs that lead to spreads did not pay a spread, so Defendants discriminated against the plan participants with respect to these participants' contributions as a condition of continued enrollment.

c. The defendants and the court: "Generally speaking, discrimination does not occur if plan terms apply uniformly to similarly situated plan members. See 29 C.F.R. § 2590.702; see Zurich Am. Ins. Co. v. O'Hara, 604 F.3d 1232, 1238–39 (11th Cir. 2010). Because Plaintiffs do not allege facts showing that any of the relevant plans' terms did not apply uniformly to plan members, Count V [this claim] is dismissed."

6. A RICO claim was also made, alleging a conspiracy between the PBM and the network pharmacies. Unlike the Sheet Metal Workers case, above, this court rejected the RICO claim at the pleading stage:

"Generally speaking, a "hub-and-spokes" enterprise, in which the hub serves as a contact point for other members who otherwise do not interact, is not sufficiently coherent unless the members spokes are connected by a unifying rim. 'This is because without a 'rim,' there are no allegations of concerted actions among the spokes, only allegations of parallel conduct. And an association-in-fact enterprise requires more than parallel conduct; it requires relationships among those associated with the enterprise, and it requires those associated with the enterprise to 'function as a unit, that they be "put together to form a whole.' Id. (quoting In re Ins. Brokerage Antitrust Litig., 618 F.3d at 374).

"Plaintiffs failed to allege a RICO enterprise. Optum Rx serves as the hub for pharmacies in the network. The pharmacies are the spokes. But the CAC [the amended class action complaint] contains no allegations demonstrating any concerted actions among the spokes. It only alleges parallel collection of spreads through adherence to pharmacy-by-pharmacy network contracts and general network policies. The pleaded structure lacks "relationships among those associated with the enterprise" showing that they "associated together for a common purpose." Boyle, 556 U.S. at 944, 946 (emphasis added). This is demonstrated by the inferential notion that, absent OptumRx's efforts to develop its network of pharmacies, there would be no basis upon which to conclude that the pharmacies now in the network are part of an enterprise; there are no allegations showing that the pharmacies have relationships between

themselves in addition to their individual contractual relationships with OptumRx." [Most citations omitted.]

D. Negron v. Cigna Health & Life Ins. (D. Conn. Mar. 12, 2018): Court Refuses to Dismiss Lawsuit Alleging Cigna Engaged in Clawback Scheme to Retain Excess of Copayment Amount Over Cash Retail Price of Prescription Drugs

1. Complaint describes a clawback scenario identical to that described in asserts the same claims as those advanced by the plaintiffs in In re: UnitedHealth Group PBM Litigation.

2. The complaint illustrates the operation of the PBM-to-plan pricing mechanism and the very different PBM-to-pharmacy payment amount:

> "In their complaint, plaintiffs have included an example of the asserted Clawback scheme applied to a prescription Vitamin D that a pharmacy purchased from the manufacturer or wholesaler for $0.60. Pursuant to the Pharmacy Benefit Manager Pharmacy Agreement (PBM Pharmacy Agreement), defendants' pharmacy benefit manager paid the pharmacy 0.96 for the Vitamin D, a fulfillment fee of $1.40, and $0.21 in tax. Thus, in accordance with the PBM Pharmacy Agreement, the contracted charge made by the pharmacy was $2.57. The PBM Pharmacy Agreement required the pharmacy to charge the patient a $7.68 "copayment" for the prescription Vitamin D, which represents almost 300% of an overcharge. The PBM-Pharmacy Agreement then required the pharmacy to pay the PBM or insurer the "Spread" between the contracted fee and the "copayment" amount collected from the patient. Thus, plaintiffs allege that defendants received a $5.11 Clawback. The PBM Pharmacy Agreement prohibited the pharmacy from disclosing to the patient the amount paid to the pharmacy or the Clawback.

3. This court reached conclusions on the various ERISA claims that are the reverse of those reached by the court in In re: UnitedHealth Group PBM Litigation.

4. The ERISA §502(a)(1)(B) claim.

   a. Need to exhaust administrative appeals: the PBMs failed to demonstrate that they maintained standard reasonable claim procedures that complied with the DOL claims procedure regulation: the PBM offered a "customer service" telephone function which did not include any of the elements of the claims procedure regulation requirements (notice of adverse benefit determination, for example). Result: the PBMs are not entitled to the protections of the exhaustion requirement and the deferential standard of review by the court, and the court refused to dismiss this claim at the pleading stage.

5. The ERISA breach of fiduciary duty claims.

a. Court: the court accepted the complaint's allegation that the clawbacks were not permitted under the terms of the plan, and therefore concluded that the PBM did more than engage in ministerial acts:

> "Plaintiffs have asserted that Cigna was granted by contract discretionary authority regarding "the computation of any and all benefit payments" including prescription drug benefits; that Cigna delegated to OptumRx exercise of its fiduciary duties concerning prescription drug benefits; and that defendants' discretion to compute "any and all benefit payments" allows them to determine the insureds' cost-sharing payments. Plaintiffs argue that defendants Cigna and OptumRx, as its agent or delegate, exercised discretionary control over the management of the plans by determining the amount pharmacies charged patients for prescription drugs, and by requiring pharmacies to charge more than required under the plan; and that defendants' deviation from the plan terms constituted an exercise of fiduciary discretion related to benefits.
>
> "In UnitedHealth Group, the Court found that the defendants did not act as fiduciaries where the complaint "alleged 'instantaneous' calculations, based on plan terms, and relay of those calculation to pharmacies...." 2017 U.S. Dist. LEXIS 208328 , 2017 WL 6512222 , at *9. UnitedHealth Group went on to explain: "Plaintiffs do not allege facts demonstrating that Defendants had discretion over the instantaneous calculations they were performing, except to the extent that Plaintiffs allege Defendants did not apply the correct calculations. But if calculations may be construed as an exercise of discretion solely on the basis that the calculations were incorrect under the terms of the plan, any mistake could transform ministerial conduct into fiduciary act." Id. **In the instant case, plaintiffs do not allege that defendants made incorrect or mistaken calculations. Instead, they have alleged that defendants' exercise of discretion violated the plan terms by instituting the charging of cost-sharing payments greater than the amount paid to the pharmacy.**
>
> "For purposes of ruling on this motion to dismiss, the Court finds that plaintiffs have asserted a plausible claim of fiduciary status based on defendants' exercise of discretion as to computation of benefits that violated the plan terms."

b. Unlike the courts in In re: UnitedHealth Group PBM Litigation and in UnitedHealth, this court concluded that the PBM's ability to

determine how much it would pay the pharmacies effectively allowed the PBM to determine its compensation -- the amount of the clawback spread. That raises the PBM's role to that of a fiduciary.

c. Are the clawback spreads plan assets. The courts in In re: UnitedHealth Group PBM Litigation and UnitedHealth said, no. This court concluded that, at the pleading stage, the plaintiffs, by alleging a violation of plan terms, could avoid a motion to dismiss:

> "Plaintiffs assert that defendants have a beneficial interest in the participants' cost-sharing payments, which pay for a portion of the plans' prescription drug benefits. However, plaintiffs have not alleged that the plan has the right to the recoupment of the copayments or Clawbacks. In fact, the Spread is alleged to be unauthorized under the plan terms. The Court finds that the cost-sharing payments do not constitute assets under ordinary notions of property rights. However,…fiduciary status can be imposed on an entity that fails to abide by plan terms."

6. The "settlor function" defense.

a. The court: "Plaintiffs allege that defendants have inflated cost-sharing payments in contravention of the plan terms, **which provide that patients should not pay more than the pharmacy is paid for a drug**. [Emphasis added.] Consistent with the foregoing discussion regarding defendants' conduct that was not authorized by the plan terms, the Court finds that plaintiffs have alleged plausible breach of fiduciary duty claims that do not concern plan design. The Court will leave plaintiffs to their proof that defendants have breached their fiduciary duties with respect to the alleged inflated cost-sharing payments."

E. Forth v. Walgreen Co. (D.C. N.D. IL 3-9-2018)--Plaintiffs Stated a Viable Claim That Walgreen's Discount Generic-Drug Program Sold Generic Drugs for Cash at a Price Below That Charged to Insured Patients, Resulting in Fraudulent Overstatement of "Usual and Customary" Price Used to Establish Insured Patient Price

1. Same facts as in Sheet Metal Workers Local Welfare & Benefit Fund v. CVS Pharmacy, Inc.: Walgreens operated a discount generic-drug program, the "Prescription Savings Club," which offered cash paying customers discounts on generic drugs in exchange for a yearly membership fee of $20 per individual or $30 per family. Although the plan covering the plaintiffs provided that the participants' obligation would not exceed the "usual and customary" price, Walgreens excluded the Prescription Savings Club price when reporting its "usual and customary" price.

a. Result: the price charged to plan participants exceeded the Prescription Savings Club price, inflating the participants' out of pocket obligation (and, presumably, the plan's share of the cost as well).

2. The complaint does not allege ERISA violations: it alleges a variety of state law claims: fraud, negligent misrepresentation, unjust enrichment, violation of state unfair business practices acts.

3. The court's decision notes that the plaintiffs are (i) individuals who purchased generic drugs at Walgreens either through private insurance plans or through federal health insurance plans, and (ii) the IBEW collectively bargained multiemployer benefit plan.

4. Walgreens did not make any ERISA preemption arguments. Instead, it sought to demonstrate that the plaintiffs failed to make a false statement of fact (in response to the fraud and unjust enrichment claims) or failed to satisfy the statutory requirements contained in the various state deceptive practices acts.

5. The court disagreed and refused to dismiss all but two of the claims (the court dismissed the negligent misrepresentation claim and the claim involving the Missouri Merchandising Practices Act).

6. The use of the membership fee to avoid inclusion in "usual and customary" warrants particular attention:

> "First, Walgreens contends that Plaintiffs fail to plead any "factual allegations to support [their] bald legal conclusion that the definitions of the term 'U&C pricing' set out in those contracts required Walgreens to report the prices offered to PSC members as its U&C prices." But this is not the basis of Plaintiffs' claim. Rather, Plaintiffs' allegations (which must be taken as true for the purposes of this motion) claim that U&C prices are known throughout the pharmaceutical industry as "the price the pharmacy charges the direct-pay public," Am. Compl. ¶ 5, and they provide examples of industry sources defining U&C prices as such..[7]
>
> "Walgreens' next argument is that, because cash-paying customers need to opt in to the PSC and pay a yearly membership fee to access PSC prices, such prices cannot qualify as U&C prices. Although Walgreens does not develop this argument further, Walgreens appears to imply that prices that can only be accessed with an annual membership fee cannot qualify as prices "charged to the cash-paying public." But the Seventh Circuit recently rejected a substantially similar argument, where a large retailer argued that pharmacy prices offered through a membership program with an annual fee of $10 did not qualify as "usual and customary" prices for the purposes of reporting prices to Medicare. United States ex rel. Garbe

v. Kmart Corp., 824 F.3d 632, 643–44 (7th Cir. 2016). The Seventh Circuit explained that because "Kmart offered the terms of its 'discount programs' to the general public and made them the lowest prices for which its drugs were widely and consistently available, the Kmart 'discount' prices at issue represented the 'usual and customary' charges for the drugs."

"Here, Plaintiffs have plausibly alleged that the PSC prices qualified as U&C prices and that Walgreens made false statements of fact every time it reported higher-than-PSC prices as U&C prices to insurance providers. PSC membership was offered to the general public at a nominal fee of $20 per year. Plaintiffs have also pleaded that the majority of Walgreens' cash-paying customers pay no more than the PSC prices, that Walgreens' reported U&C prices are "up to 5 times its own PSC prices," and that while Walgreens' PSC prices accord with the U&C prices charged by competitors, Walgreens' reported U&C prices are "up to 11 times the U&C prices reported by some of its most significant competitors.". Other than attempting to distinguish Garbe as occurring in the Medicaid regulatory context,. Walgreens does not respond to Plaintiffs' line of argument." [Internal citations omitted.]

7. The pesky footnote 7: "Of course, to the extent that a particular third-party payer's agreement with Walgreens defined U&C prices in a particularized way and Walgreens' prices for that particular payer were consistent with that definition, this would undercut Plaintiffs' claim. But such factual issues cannot be resolved without further discovery."

8. Result: for courts that adopt the reasoning in Forth, the key will be, how did the plan document or agreement with the PBM define the price for prescriptions? A "U&C" ceiling frequently appears in PBM agreements, even for agreements for plans with relatively small numbers of enrollees (for this purpose, "small means less than 10,000).

TAB
C

Kim Wilcoxon, Esq.
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Kim is a partner in the Employee Benefits & Executive Compensation practice group of Thompson Hine, where she has been practicing for seventeen years. She has significant experience advising employers and other benefit plan professionals on legal and practical compliance issues relating to welfare benefit plans. Kim has been closely following the Affordable Care Act since its infancy and writes a monthly column on the ACA for the Cincinnati Bar Association Report. Kim is a frequent speaker and loves to help people understand and apply the law. When not working, Kim likes to spend time trying new craft beers with her husband or rock climbing with her two sons.

Affordable Care Act Developments

Cincinnati Bar Association
Healthcare Law CLE
December 6, 2018
Kim Wilcoxon, Thompson Hine

SmartPaTH

THOMPSON HINE

Today's Presentation

- Federal and state responses to elimination of the individual mandate penalty
- Lawsuits relating to the constitutionality of the Affordable Care Act
- Administrative actions to "support and empower"
- IRS enforcement of the employer mandate penalty

Individual Mandate

- All non-exempt individuals must be enrolled in minimum essential coverage or pay the shared responsibility payment
- Applies to
  - All U.S. citizens living in the United States
  - All permanent residents
  - All foreign nationals who qualify as resident aliens for tax purposes
- Certain exemptions apply

Individual Mandate Penalty Amount

Tax Cuts and Jobs Act

- Individual mandate penalty amount is the greater of:
  - The following amount per person (for 2017)
    - $695 per adult
    - $347.50 per child under 18
    - Maximum: $2,085 per household
  - 2.5% of yearly household income
    - Maximum: Total yearly premium for the national average price of a Bronze plan sold through the Marketplace
      - $3,264 for a single individual in 2017
      - $13,056 for a family of 4 in 2017

$0

0%

Scenario 1

- 1,000 individuals each pay $100 in premiums to Insurance Company (total $100,000)
- 1 paying individual incurs $25,000 in claims
- Net gain of $75,000

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5

Scenario 2

- 1,000 individuals each pay $100 in premiums to Insurance Company (total $100,000)
- 1,000 paying individuals each incur $25,000 in claims (total $25,000,000)
- Net loss of $24,900,000

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6

Before the ACA

- Insurance companies could evaluate an individual's medical condition and choose
  - To charge more based on health status
  - To exclude coverage for certain pre-existing conditions
  - To refuse to issue a policy to the individual due to their health status
- HIPAA prohibited or limited employer-provided group health plans from taking these actions

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7

Past Attempts at Health Care Reform

- Common elements
  - Guaranteed issue
    - Health insurers cannot deny coverage to a person based on a health condition
  - Community rating
    - Health insurers cannot vary premiums within a geographic area based on age, gender, health status or certain other factors

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8

Impact of Common Reform Elements

- "Death spiral"
  - Individuals waited until they got sick to buy insurance
  - Insurance companies increased premiums because more of the paying individuals were sick
  - More healthy people chose not to buy insurance until they got sick
  - Insurance companies further increased premiums
  - Even fewer healthy people bought insurance
- Insurance companies left the market

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9

Past Attempts at Health Care Reform

- State of Washington
  - Adopted guaranteed issue and community rating requirements in 1993
  - Over the next 3 years
    - Premiums increased by 78%
    - The number of enrolled decreased by 25%
  - By 1999, 17 of the state's 19 private insurers had left the market, and the remaining two had announced their intention to do so

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10

Affordable Care Act

Tax Cuts and Jobs Act

- Guaranteed issue
- Community rating
- Mechanisms to encourage healthy people to purchase insurance
  - Tax penalty for failure to maintain coverage
  - Tax credit to help pay for coverage
    - Credit amount based on income
    - Unavailable to individuals with income over 400% of the federal poverty level
- Coverage mandates for insurance policies and employer-provided health plans

Example 1

- Adam is a single, healthy 27-year-old taxpayer with an annual income of $40,000
  - National average cost of a Bronze plan sold through the Marketplace: $3,264
  - Penalty for failure to obtain health coverage: $740

2017 figures obtained from the Individual Shared Responsibility Provision Payment Estimator at https://taxpayeradvocate.irs.gov/estimator/isrp/

Example 2

- Beth is a married taxpayer with a spouse and three young children; her annual household income is $200,000
  - National average cost of a Bronze plan sold through the Marketplace: $13,056
  - Penalty for failure to obtain health coverage: $4,480

2017 figures obtained from the Individual Shared Responsibility Provision Payment Estimator at https://taxpayeradvocate.irs.gov/estimator/isrp/

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Example 3

- Cindy is a married taxpayer with a spouse and grown children over the age of 26; her annual household income is $500,000
  - National average cost of a Bronze plan sold through the Marketplace: $6,528
  - Penalty for failure to obtain health coverage: $6,528

2017 figures obtained from the Individual Shared Responsibility Provision Payment Estimator at https://taxpayeradvocate.irs.gov/estimator/isrp/

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State-Imposed Individual Mandates

- Multiple states require/will require residents to pay a penalty if they do not obtain health coverage
  - Massachusetts
    Currently effective
  - New Jersey
    Effective January 1, 2019
  - Vermont
    Effective January 1, 2020
- Employer reporting is required

Massachusetts Reporting

- Form 1099-HC
  - Used by individuals to demonstrate satisfaction of the individual mandate
  - Must be provided to Massachusetts residents receiving creditable coverage under a health plan
  - Provided by the insurance company if
    - Health plan is fully insured and
    - Insurance company is subject to Massachusetts state insurance law
  - Plan sponsor is otherwise responsible
    - May contract with another entity
  - Forms are due January 31 of each year

Massachusetts Reporting

- Health Insurance Responsibility Disclosure (HIRD) form
  - New requirement
    - Prior requirement used same name
  - Used to help MassHealth identify persons who qualify for the premium assistance program
  - Online filing due by November 30 of each year
  - Applies to an employer that reported six or more employees in any Massachusetts Department of Unemployment Assistance wage report during the previous 12 months

State-Imposed Employer Mandate

- Massachusetts Employer Medical Assistance Contribution Supplement
- Effective January 1, 2018 – December 31, 2019
- Contribution required if all of the following apply:
  - Employer has at least 6 employees in Massachusetts
  - Employee is not disabled and earns a minimum of $500 in a quarter
  - Employee enrolls in any of the following coverages for more than 56 days during a quarter
    - Subsidized Massachusetts ConnectorCare coverage
    - MassHealth coverage

Section 1332 Waivers

- State innovation waivers/state relief and empowerment waivers
  - A state may apply to the Secretary for the waiver of all or any of the following requirements for plan years beginning on or after January 1, 2017
    - Part I of subtitle D (qualified health plans)
    - Part II of subtitle D (Exchanges)
    - Section 1402 (reduced cost-sharing)
    - Sections 36B, 4980H and 5000A of the Internal Revenue Code of 1986
  - Coverage must remain as accessible, comprehensive and affordable as before the waiver
  - Changes may not add to the federal deficit

Essentially, we are getting rid of Obamacare.
Some people would say, essentially, we have gotten rid of it.

President Trump, April 28, 2018

Texas v. United States

Challenging States	Intervening States
Alabama	California
Arizona	Connecticut
Arkansas	D.C.
Florida	Delaware
Georgia	Hawaii
Indiana	Illinois
Kansas	Kentucky
Louisiana	Massachusetts
Maine	Minnesota
Mississippi	New Jersey
Missouri	New York
Nebraska	North Carolina
North Dakota	Oregon
South Carolina	Rhode Island
South Dakota	Vermont
Tennessee	Virginia
Texas	Washington
Utah	
West Virginia	
Wisconsin	

NFIB v. Sebelius

- 2012 U.S. Supreme Court decision
- The individual mandate is not a valid exercise of Congress's power under the Commerce Clause and the Necessary and Proper Clause
- The individual mandate may be upheld as a valid exercise of Congress's power to tax
- Because the individual mandate was not found to be unconstitutional, the Court did not need to determine whether it could be severed from the rest of the ACA

Texas v. United States

- Plaintiffs argue
  - The Tax Cuts and Jobs Act eliminated the tax penalty of the ACA without eliminating the mandate
  - Without a tax penalty, the individual mandate is not a valid exercise of the taxing power
  - The individual mandate is not severable from the rest of the ACA, so the entire ACA is unconstitutional

Changes for 2019

Tax Cuts and Jobs Act

- Individual mandate penalty amount is the greater of:
  - The following amount per person (for 2017)
    - $695 per adult
    - $347.50 per child under 18
    - Maximum: $2,085 per household
  - 2.5% of yearly household income
    - Maximum: Total yearly premium for the national average price of a Bronze plan sold through the Marketplace
      - $3,264 for a single individual in 2017
      - $13,056 for a family of 4 in 2017

$0

0%

Texas v. United States

- Plaintiffs argue: Trump administration
  - The Tax Cuts and Jobs Act eliminated the tax penalty of the ACA without eliminating the mandate
  - Without a tax penalty, the individual mandate is not a valid exercise of the taxing power
  - The individual mandate is not severable from the rest of the ACA, so the entire ACA is unconstitutional
    - Guaranteed issue is unconstitutional
    - Community rating is unconstitutional
    - The remainder of the ACA can stand

Pre-Existing Conditions

Maryland v. U.S.

- Seeking declaration that the individual mandate will not become unconstitutional when the tax penalty is reduced to zero
- Sets up potential for a circuit split

City of Columbus v. Trump

- Cities of Chicago, Columbus, Cincinnati, Baltimore
- Argue that Trump and his administration have taken actions that
  - Undermine the ACA, and
  - Violate the constitutional duty to "take care that the laws be faithfully executed"

Support and Empower

- Example: Brian Not his real name
  - December 2009
    - Employer ceased contributing to health coverage
    - Saved money by purchasing an individual policy without maternity coverage
    - Individual policies did not require coverage of essential health benefits

Essential Health Benefits

- Individual and small group policies must cover all EHBs
- Self-insured plans and large group policies are not required to cover all EHBs
  - Annual and lifetime dollar limits may not apply to any EHBs that are covered
- EHBs vary by state, but all must cover at least 10 categories of benefits

Ambulatory care	Emergency services	Hospitalization
Laboratory services	Maternity care	Mental health/substance use disorder
Pediatric services including oral and vision care	Prescription drugs	Preventive care
Rehabilitative and habilitative services		

Executive Order

- Executive Order Promoting Healthcare Choice and Competition Across the United States
  - Addresses three topics
    - Association health plans
    - Short-term limited duration insurance
    - Health reimbursement arrangements
  - Instructs agencies to "consider proposing regulations or revising guidance"
    - By December 11, 2017 for AHPs and STLDI
    - By February 9, 2018 for HRAs

Association Health Plans

- Health plans that cover employees of unrelated employers
- Final regulations issued June 21, 2018
  - Creates a new category of AHPs
  - Does not require changes to current AHPs
- Effective dates
  - September 1, 2018 for fully insured AHPs
  - January 1, 2019 for existing self-insured AHPs
  - April 1, 2019 for new self-insured AHPs

Final AHP Regulations

- Allow employers to be treated as a single employer if
  - The members of the association are in the same trade, industry, line of business or profession OR have their principal places of business in the same state or metropolitan area
  - The unrelated employers are members of an association that has a formal organizational structure with a governing body and bylaws or similar indications of formality
    - The activities of that association must be controlled by the employer members, either directly or indirectly through regular election of representatives
    - In addition, the association may not be a health insurance issuer or be owned by one
  - The association does not
    - Deny membership to an employer due to the health status of any eligible person
    - Charge any one employer member a higher premium based on the health status of its population
  - Coverage is not to be offered to anyone other than the members' employees, former employees (who were formerly eligible), and beneficiaries of the employees or former employees

Final AHP Regulations

- Allow a self-employed individual to join an AHP if the individual
  - Works at least 20 hours per week (or at least 80 hours per month), or
  - Receives a specified level of earned income from his or her business

Impact of AHP Status

- Single-employer status applies solely to determine whether a policy is issued to a small or large employer
  - Allows working self-employed individuals and smaller groups to band together to purchase policies in the large group market
    - No requirement to cover all essential health benefits
  - AHPs would still be MEWAs
- AHPs are still subject to certain state laws
  - 11 states have sued over the final regulations
  - Several states have issued or are planning to issue restrictive guidance

Short-Term Limited Duration Insurance

- STLDI existed before the ACA
  - Defined as a policy with an expiration date less than 12 months after the original effective date
  - Excluded from the definition of individual insurance coverage
- The ACA defined "individual insurance" to exclude STLDI but did not define STLDI
  - Regulations limited STLDI to less than 3 months
- Final regulations issued August 3, 2017
  - Expanded STLDI to less than 12 months
  - Allows renewal of up to 36 months
- The administration has been sued over the final regulations (Association for Community Affiliated Plans et al. v. U.S. Department of the Treasury et al.)

Short-Term Limited Duration Insurance

- STLDI is not "individual insurance"
  - Need not cover all essential health benefits
  - Need not comply with other ACA mandates for individual insurance, such as
    - Pre-existing condition exclusions
    - Annual and lifetime dollar limits
- Group STLDI must still comply with group health plan rules
- STLDI still subject to state regulation

  At least 4 states have banned STLDI

Short-Term Limited Duration Insurance

- Limited impact on employer-provided plans
  - Individuals who lose coverage due to moving out of an HMO service area in the individual market have a special enrollment right into a group health plan
  - A group health plan that wraps around individual health insurance coverage is an excepted benefit if certain conditions are satisfied

Health Reimbursement Arrangements

- Allow for employer reimbursement of qualifying medical care expenses, including certain premiums
- Treated as a group health plan
- Currently do not allow employers to reimburse current employees for individual insurance premiums
  - Group health plans may not impose annual or lifetime dollar limits on essential health benefits
  - Non-grandfathered group health plans must cover all recommended preventive care services
  - Retiree-only plans are exempt from these requirements
- May be integrated with group health plan coverage or Medicare if certain requirements are met

GHP Integrated HRA	Retiree-Only HRA	QSEHRA
Any employer may offer	Any employer may offer	Offered only by non-ALEs
Employer must offer a traditional group health plan	No requirement to offer other coverage	Employer may not offer other health coverage
No requirements regarding eligibility (nondiscrimination rules apply)	May not cover more than 1 current employee	Must be offered to all employees (with limited exclusions) and no former employees
Dollar limit set by plan sponsor	Dollar limit set by plan sponsor	$5,050/$10,250 (adjusted)
May not reimburse individual insurance premiums	May reimburse individual insurance premiums	May reimburse individual insurance premiums

39

GHP Integrated HRA	Retiree-Only HRA	QSEHRA	IHC Integrated HRA
Any employer may offer	Any employer may offer	Offered only by non-ALEs	Any employer may offer
Employer must offer a traditional group health plan	No requirement to offer other coverage	Employer may not offer other health coverage	Employer may not offer a traditional group health plan to employees in the eligible class
No requirements regarding eligibility (nondiscrimination rules apply)	May not cover more than 1 current employee	Must be offered to all employees (with limited exclusions) and no former employees	Must offer to all members of the eligible class
Dollar limit set by plan sponsor	Dollar limit set by plan sponsor	$5,050/$10,250 (adjusted)	Dollar limit set by plan sponsor
May not reimburse individual insurance premiums	May reimburse individual insurance premiums	May reimburse individual insurance premiums	May reimburse individual insurance premiums

40

Proposed HRA Regulations

- Integration with individual health insurance coverage
  - Status of integrated HRA under the employer mandate rules
  - Impact of integrated HRA on eligibility for premium tax credit
  - Creation of individual market special enrollment right
- Treatment of account-based plans as excepted benefits
- Application of ERISA to individual insurance purchased through an account-based plan

Proposed Effective Dates

- Rules on integrated HRAs and excepted benefit HRAs
  - Plan years beginning on or after January 1, 2020
- Rules on eligibility for the premium tax credit
  - Taxable years beginning on and after January 1, 2020
- Individual special enrollment rules
  - January 1, 2020

Taxpayers may <u>not</u> rely on these proposed rules

Integration with Individual Insurance (*proposed*)

- HRA must require participants and any dependents covered by the HRA to be enrolled in individual health insurance that complies with the ACA rules on lifetime/annual dollar limits and coverage of preventive services
- The HRA must implement reasonable procedures to substantiate the required coverage
- Employer may not offer the same class of employees a choice between the employer's traditional group health plan and the HRA

- The HRA must be offered on the same terms to all employees within the same class
- Participants must receive a notice explaining how the HRA impacts eligibility for the premium tax credit
- Participants must be allowed to opt out of the HRA and waive future reimbursements at least annually and at termination of employment

Integration with Individual Insurance *(proposed)*

- Permitted classes:
  - Full-time employees*
  - Part-time employees*
  - Seasonal employees*
  - Employees covered by a collective bargaining agreement
  - Employees who have not satisfied a waiting period
  - Employees who are under age 25 as of the first day of the plan year
  - Non-resident aliens with no U.S.-based income
  - Employees whose primary site of employment is in the same rating area
- Retirees are considered to be in the class they were in immediately before separation from service

**As defined by Code Section 105(h) or 4980H – employer must choose and include definition in plan document*

Integration with Individual Insurance *(proposed)*

- Examples:
  - Traditional health plan offered to full-time employees and HRA offered to part-time employees
  - No traditional health plan offered, and HRA offers:
    - $5,000 maximum reimbursement to non-union employees
    - $3,500 maximum reimbursement to union full-time employees covered by CBA #1
    - $2,500 maximum reimbursement to union part-time employees covered by CBA #1
    - $4,000 maximum reimbursement to union employees covered by CBA #2
  - No traditional health plan offered, HRA available only to full-time employees, and HRA offers:
    - $5,000 maximum reimbursement to employees with no dependents
    - $7,500 maximum reimbursement to employees with one or more dependents

Impact on Employer Mandate *(proposed)*

- An employer that offers an HRA integrated with individual health insurance coverage will have made an offer of coverage under 4980H(a)
- Treasury/IRS plan to issue guidance to describe a safe harbor for determining whether an HRA integrated with individual health insurance coverage is affordable minimum value coverage
  - It is anticipated that the current safe harbors would also be available

Impact on Premium Tax Credit Eligibility (*proposed*)

- Individual who is covered by an HRA integrated with individual health insurance is ineligible for the premium tax credit
- Individual who is eligible for, but opts out of, an HRA integrated with individual health insurance is ineligible for the premium tax credit for any month in which the HRA is affordable and provides minimum value coverage

Individual Market Special Enrollment *(proposed)*

- An individual will have a special enrollment right to enroll in individual health insurance coverage (through or outside the Marketplace) if
  - The employer newly begins to offer an integrated HRA or QSEHRA after the start of the calendar year
    - Applies when employer first begins to offer the plan
    - Applies when employee first becomes eligible
- Individuals may request enrollment up to 60 days in advance of the special enrollment event
- Individual health insurance coverage must become effective as of the later of
  - The first day of the first month following the individual's plan selection
  - The first day of the first month coincident with or next following the date of the special enrollment event

Excepted Benefits

- Excepted benefits are not subject to the ACA coverage requirements
  - Need not cover essential health benefits
  - Need not cover preventive care
- An excepted benefit HRA would not need to be integrated with other coverage

Excepted Benefit Reimbursement Arrangements *(proposed)*

- Applies to all account-based plans other than health flexible spending accounts (HRAs)
- HRA must not be an integral part of the plan
  - Other group health plan coverage (other than excepted benefits or another HRA) must be made available by the same plan sponsor to participants offered the HRA
    - The participant need not enroll in the other group health coverage
- HRA must provide benefits that are limited in amount
  - Amounts made newly available for reimbursement for a plan year may not exceed $1,800 (to be adjusted for years beginning after 2020 using C-CPI-U)
    - Aggregate maximums in all HRAs offered by the plan sponsor to the participant for the same period
    - Funds carried over are disregarded

Excepted Benefit Reimbursement Arrangements *(proposed)*

- HRA cannot provide reimbursement for premiums for certain health insurance coverage
  - Cannot provide reimbursement for
    - Individual health insurance (except as noted below)
    - Group health plans (except as noted below)
    - Medicare Parts B or D
  - May provide reimbursement for
    - Individual health insurance or group health plan coverage that consists solely of excepted benefits
    - Short-term limited duration insurance
    - COBRA or other group continuation coverage
    - Other coverage not explicitly excluded

Excepted Benefit Reimbursement Arrangements *(proposed)*

- HRA must be made available under the same terms to all similarly situated individuals, regardless of any health factor
  - "Similarly situated individuals" has the same meaning given under the HIPAA nondiscrimination rules
  - Benign discrimination not permitted
    - Example: Employer may not make greater amounts available under an HRA to persons with cancer
    - Example: Employer may not offer the HRA only to employees who fail a physical examination

GHP Integrated HRA	Retiree-Only HRA	QSEHRA
Any employer may offer	Any employer may offer	Offered only by non-ALEs
Employer must offer a traditional group health plan	No requirement to offer other coverage	Employer may not offer other health coverage
No requirements regarding eligibility (nondiscrimination rules apply)	May not cover more than 1 current employee	Must be offered to all employees (with limited exclusions) and no former employees
Dollar limit set by plan sponsor	Dollar limit set by plan sponsor	$5,050/$10,250 (adjusted)
May not reimburse individual insurance premiums	May reimburse individual insurance premiums	May reimburse individual insurance premiums

53

GHP Integrated HRA	Retiree-Only HRA	QSEHRA	Excepted Benefit
Any employer may offer	Any employer may offer	Offered only by non-ALEs	Any employer may offer
~~Employer must offer a~~ traditional group health plan	No requirement to offer other coverage	Employer may not offer other health coverage	~~Employer must offer a~~ traditional group health plan
No requirements regarding eligibility (nondiscrimination rules apply)	May not cover more than 1 current employee	Must be offered to all employees (with limited exclusions) and no former employees	Must offer to all similarly situated individuals
Dollar limit set by plan sponsor	Dollar limit set by plan sponsor	$5,050/$10,250 (adjusted)	$1,800 (adjusted)
May not reimburse individual insurance premiums	May reimburse individual insurance premiums	May reimburse individual insurance premiums	May not reimburse individual insurance premiums other than STLDI or excepted benefits

54

Application of ERISA to Individual Insurance *(proposed)*

- Rule applies to
  - HRAs integrated with individual health insurance
  - QSEHRAs
  - Retiree-only HRAs
  - Other HRAs that are offered to fewer than two current employees on the first day of the plan year
  - Cafeteria plans that allow employees to pay for the portion of individual insurance premiums not covered by the integrated HRA or QSEHRA

Application of ERISA to Individual Insurance *(proposed)*

- Individual insurance purchased through an applicable plan will not be subject to ERISA or treated as group health insurance if
  - The purchase of individual insurance is completely voluntary
  - The employer does not select or endorse any particular issuer or individual health insurance coverage
    - Employer may provide general contact information for insurance available in a state and may provide general health insurance educational information
  - Reimbursement is limited to individual health insurance coverage
  - Employer does not receive consideration in connection with the employee's selection or renewal of individual insurance coverage
    - This requirement is not intended to affect the plan's ability to reimburse the employer for certain administrative expenses
  - Each plan participant receives an annual notice that the individual insurance coverage is not subject to ERISA

Objections to Coverage of Contraceptives

- Nongrandfathered health plans must cover all recommended preventive services
  - Includes female contraceptives
  - Limited exceptions and accommodations currently apply for churches and certain religious objectors
- Final regulations allow religious and moral objectors to be exempt from this requirement

Objections to Coverage of Contraceptives

- Applies to plans sponsored by
  - Churches with religious objections
  - Nonprofit organizations with religious or moral objections
  - For-profit entities that are not publicly traded, with religious or moral objections
  - For-profit entities that are publicly traded, with religious objections
  - Other non-governmental employers with religious objections
  - Non-governmental institutions of higher education with religious or moral objections

Objections to Coverage of Contraceptives

- A group health plan will not violate the ACA preventive care rules if
  - The plan does not cover some or all required contraceptives, or
  - A separate option is offered to objecting individuals
- No self-certification is required, but plan documents must describe extent of coverage

To the maximum extent permitted by law, the Secretary of Health and Human Services and the heads of all other executive departments and agencies with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.

Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal

Employer Mandate Enforcement for 2015

- Testimony of IRS Acting Commissioner David Kautter
- As of April 17, 2018:
  - IRS identified approximately 330,000 employers subject to the mandate
  - Approximately 10,000 employer mandate penalty letters had been issued
    - Approximately 3,000 had been settled
      - 82% - Forms filled out incorrectly, no penalty owed
      - 12% - Penalty owed
  - Approximately 22,000 additional ALEs are subject to penalties

House of Representatives' Committee on Oversight and Government Reform

April 17, 2018 Hearing

Were these employers notified prior to receiving a penalty letter? I mean, after all, we're talking *years* of no enforcement and then all of a sudden, this is a pretty big change coming down the pipe. These employers are accustomed to this employer mandate not being enforced. Were they notified beforehand?

No, the letter is the first they heard from the IRS on this.

Q. Will employers be liable for the employer shared responsibility payment for 2015 if a full-time employee receives a premium tax credit for coverage received through a Marketplace in that year?
Yes. The IRS will independently determine any liability for the employer shared responsibility payment without regard to whether the Marketplace issued a notice or the employer engaged in any appeals process. More information on the IRS process can be found at www.irs.gov.

63

House of Representatives' Committee on Oversight and Government Reform
April 17, 2018 Hearing

The question is, this thing needs to cease until the problems are resolved and this Committee gets the documents that have been requested and until, I mean, these employers don't even know that it's been re-instituted, or instituted for them.

We've been trying to work with everyone who we've sent a letter out to, Congressman, and our challenge is, it's the law. And I don't think anybody on this Committee wants the IRS determining which laws it's going to enforce and which ones it's going to ignore.

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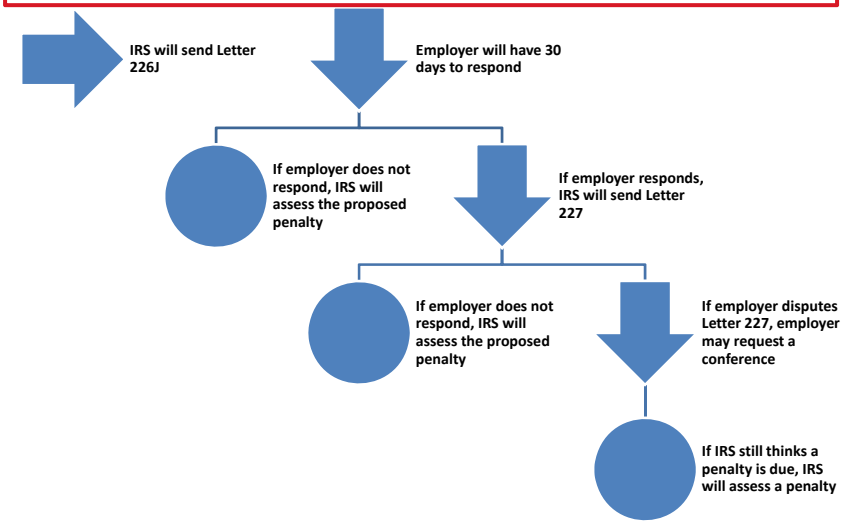
64

Employer Mandate Penalty Process



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65

Employer Mandate Penalty

- Successful arguments
  - Reporting mistake
  - IRS data error
- Unsuccessful arguments
  - Employee should not have qualified for the premium tax credit based on household income
  - Assessment is not authorized by statute

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66

Case Study 1 – Reporting Error

	Information Reported to IRS						
Month	a. Form 1094-C, Part III, Col (a) Minimum essential coverage offer indicator offered to at least 70%	b. Form 1094-C, Part III, Col (b) Full-time employee count for ALE member	c. Allocated reduction of full-time employee count for IRC Section 4980H(a)	d. Count of assessable full-time employees with a PTC for IRC Section 4980H(a)	e. Count of assessable full-time employees with a PTC for IRC Section 4980H(b)	f. Applicable IRC Section 4980H provision	g. Monthly ESRP amount
Jan	No	144	80	2	-	4980H(a)	$ 11,093.33
Feb	No	148	80	4	-	4980H(a)	$ 11,786.66
March	No	149	80	5	-	4980H(a)	$ 11,960.00
Apr	No	159	80	5	-	4980H(a)	$ 13,693.33
May	No	159	80	4	-	4980H(a)	$ 13,693.33
June	No	163	80	4	-	4980H(a)	$ 14,386.66
July	No	159	80	3	-	4980H(a)	$ 13,693.33
Aug	No	154	80	4	-	4980H(a)	$ 12,826.66
Sep	No	157	80	3	-	4980H(a)	$ 13,346.66
Oct	No	167	80	3	-	4980H(a)	$ 15,080.00
Nov	No	177	80	3	-	4980H(a)	$ 16,183.33
Dec	No	193	80	2	-	4980H(a)	$ 19,585.66
						Total Proposed ESRP	$ 167,959.95

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67

Case Study 2 – IRS Error

	Information Reported to IRS						
Month	a. Form 1094-C, Part III, Col (a) Minimum essential coverage offer indicator offered to at least 70%	b. Form 1094-C, Part III, Col (b) Full-time employee count for ALE member	c. Allocated reduction of full-time employee count for IRC Section 4980H(a)	d. Count of assessable full-time employees with a PTC for IRC Section 4980H(a)	e. Count of assessable full-time employees with a PTC for IRC Section 4980H(b)	f. Applicable IRC Section 4980H provision	g. Monthly ESRP amount
Jan	No	3,116	6	1	-	4980H(a)	$ 539,066.66
Feb	No	3,116	6	1	-	4980H(a)	$ 539,066.66
March	No	3,116	6	1	-	4980H(a)	$ 539,066.66
Apr	No	3,116	6	1	-	4980H(a)	$ 539,066.66
May	No	3,116	6	1	-	4980H(a)	$ 539,066.66
June	No	3,116	6	1	-	4980H(a)	$ 539,066.66
July	No	3,116	6	-	-		$ -
Aug	No	3,116	6	-	-		$ -
Sep	No	3,116	6	-	-		$ -
Oct	No	3,116	6	-	-		$ -
Nov	No	3,116	6	-	-		$ -
Dec	No	3,116	6	-	-		$ -
						Total Proposed ESRP	$ 3,234,399.96

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68

Case Study 2 – IRS Error

Form **14765** (April 2017)

Department of the Treasury - Internal Revenue Service

Employee Premium Tax Credit (PTC) Listing

Any month not highlighted is a month that the employee received a PTC and no safe harbor or other relief from the ESRP was applicable. The employee is an assessable full-time employee for that month.

Employer name	Employer ID number	Tax year
		2015

Employee Name (last, first)	SSN (last 4 digits)	All 12 months Indicator Codes (Form 1095-C, lines 14 and 16 combined)	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Additional Information Attached
		First row - as filed Second row - for corrections	0/2A	0/2A	0/2A	0/2D	0/2D	0/2D	NoPTC	NoPTC	NoPTC	NoPTC	NoPTC	NoPTC	

	All 12 Months	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
14 Offer of Coverage (enter required code)	1H												
15 Employee Share of Lowest Cost Monthly Premium, for Self-Only Minimum Value Coverage	$ 153.07	$	$	$	$	$	$	$	$	$	$	$	$
16 Applicable Section 4980H Safe Harbor (enter code, if applicable)		2A	2A	2A	2D	2D	2D	2A	2A	2A	2A	2A	2A

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69

Employer Mandate Penalty

"SEC. 4980H. SHARED RESPONSIBILITY FOR EMPLOYERS REGARDING HEALTH COVERAGE.

"(a) LARGE EMPLOYERS NOT OFFERING HEALTH COVERAGE.—If—

"(1) any applicable large employer fails to offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) for any month, and

"(2) at least one full-time employee of the applicable large employer has been certified to the employer under section 1411 of the Patient Protection and Affordable Care Act as having enrolled for such month in a qualified health plan with respect to which an applicable premium tax credit or cost-sharing reduction is allowed or paid with respect to the employee,

then there is hereby imposed on the employer an assessable payment equal to the product of the applicable payment amount and the number of individuals employed by the employer as full-time employees during such month.

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70

Section 1411 Certifications

CMS FAQs

1

Federally facilitated Exchanges will begin sending Section 1411 certifications in 2016

2

Employers will receive Section 1411 certifications if:

- An employee received the tax credit for at least one month in 2016
- The employee provided a complete address for the employer

3

The IRS will issue penalties as appropriate regardless of whether the Exchange issued a Section 1411 certification

Affordable Care Act Developments

Kim Wilcoxon, Partner
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TAB
D

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Statement of Qualifications

Cindy completed her undergraduate degree in Exercise Science at Purdue University and completed a Masters in Health Promotion and an Interdisciplinary Doctorate from the University of Cincinnati. She completed her RD Internship at Northern Colorado University and then completed her rotations at Mercy Hospitals in the Greater Cincinnati, Ohio area.

Cindy is passionate about health, disease prevention and agriculture. She worked at Children's Hospital Medical Center in the Cardiovascular Exercise Lab for 8 years. In 2001, Cindy created Nutrition Access, a private practice and corporate healthcare consultant.

List of clients include:

- Kettering Sports Medicine Center
- Advanced Bariatric Services
- Pediatric Practices/ Family Practices
- Corporate Wellness/Insurance Agencies
- Many small and large businesses onsite worksite wellness
- Oncologists
- UC Health executive physical program

Cindy has also been very active in the American Dietetic Association. She served as newsletter editor for the Sport, Cardiovascular and Wellness Nutrition practice group, a 5,000 member specialty group of the American Dietetic Association. She has served as president of the local Greater Cincinnati Dietetic Association and is also active in the Ohio Dietetic Association.

An excellent presenter, Cindy is a National speaker for Sports Nutrition conferences and a NCAA authorized speaker. She has also done "Health Talk" radio show for 13 weeks on local Cincinnati airwaves WLW 1520.

Cindy's personal commitment to fitness is exemplified by her accomplishments: NCAA All-American while at Purdue, competitive runner, completed several marathons and triathlons, and serving as a track and cross country coach for Seven Hills School. Since 1998 to present her family business, Vista Grand Ranch Buffalo farm-distribute and markets buffalo meat. The most interesting part of this agriculture experience is as a 4 H advisor for a Clermont County club.

Peak Personal Performance: Updates on Nutrition Research and Exercise

Cindy Cassell PhD, RD, LD
Clinical Sports Dietitian
Integrative Nutritionists
Nutrition Access LLC
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513.310.7963
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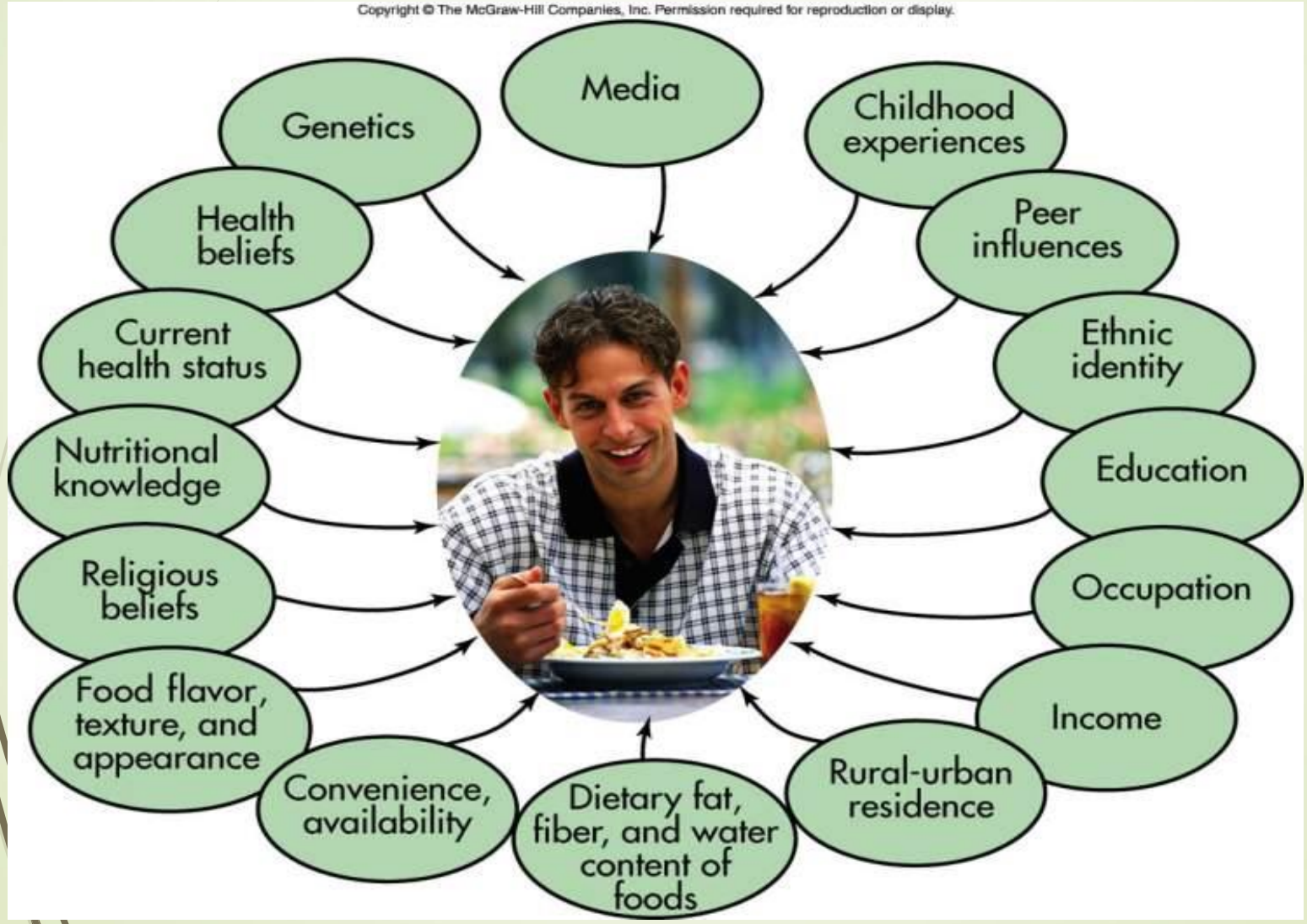
The Reality of our Food Decisions: Knowledge does not equal behavior



Is this what your meals are like?

- Average family sits down for dinner at home 2.5 times a week
- Average family stops for take-out 2 times a week
- Most children and adults think carbohydrates are bread and potatoes
- Trends in grocery shopping to meet our needs for healthy quick food
  - Salad bar
  - Whole foods
  - More Asian food
  - More fast food restaurants with dark green lettuce

Key Recommendations of Dietary Guidelines

- Consume a healthy eating pattern that accounts for all foods and beverages within an appropriate calorie level.
- A healthy eating pattern includes:
  - A variety of vegetables from all of the subgroups—dark green, red and orange, legumes (beans and peas), starchy, and other
  - Fruits, especially whole fruits
  - Grains, at least half of which are whole grains
  - Fat-free or low-fat dairy, including milk, yogurt, cheese, and/or fortified soy beverages
  - A variety of protein foods, including seafood, lean meats and poultry, eggs, legumes (beans and peas), and nuts, seeds, and soy products
    - Oils

Healthy Eating Pattern Limits:

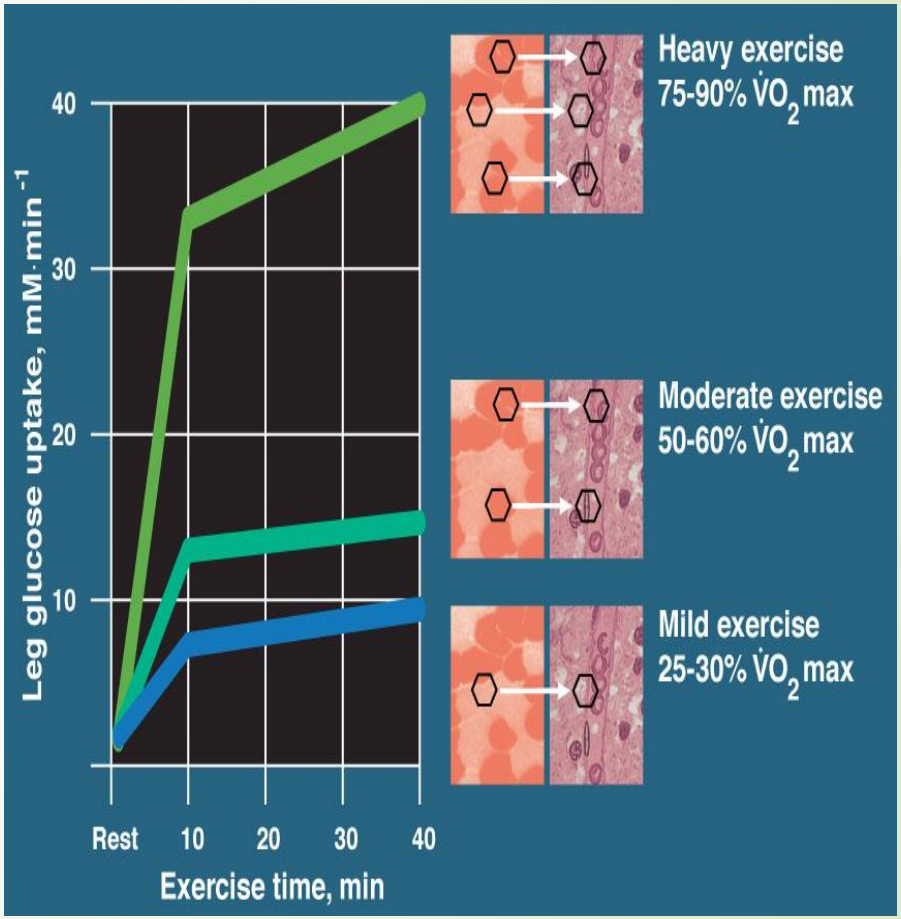
- Saturated fats and *trans* fats, added sugars, and sodium
- Key Recommendations that are quantitative are provided for several components of the diet that should be limited. These components are of particular public health concern in the United States, and the specified limits can help individuals achieve healthy eating patterns within calorie limits:
- Consume less than 10 percent of calories per day from added sugars
- Consume less than 10 percent of calories per day from saturated fats
- Consume less than 2,300 milligrams (mg) per day of sodium
- If alcohol is consumed, it should be consumed in moderation—up to one drink per day for women and up to two drinks per day for men—and only by adults of legal drinking age.[

Obesity Epidemic

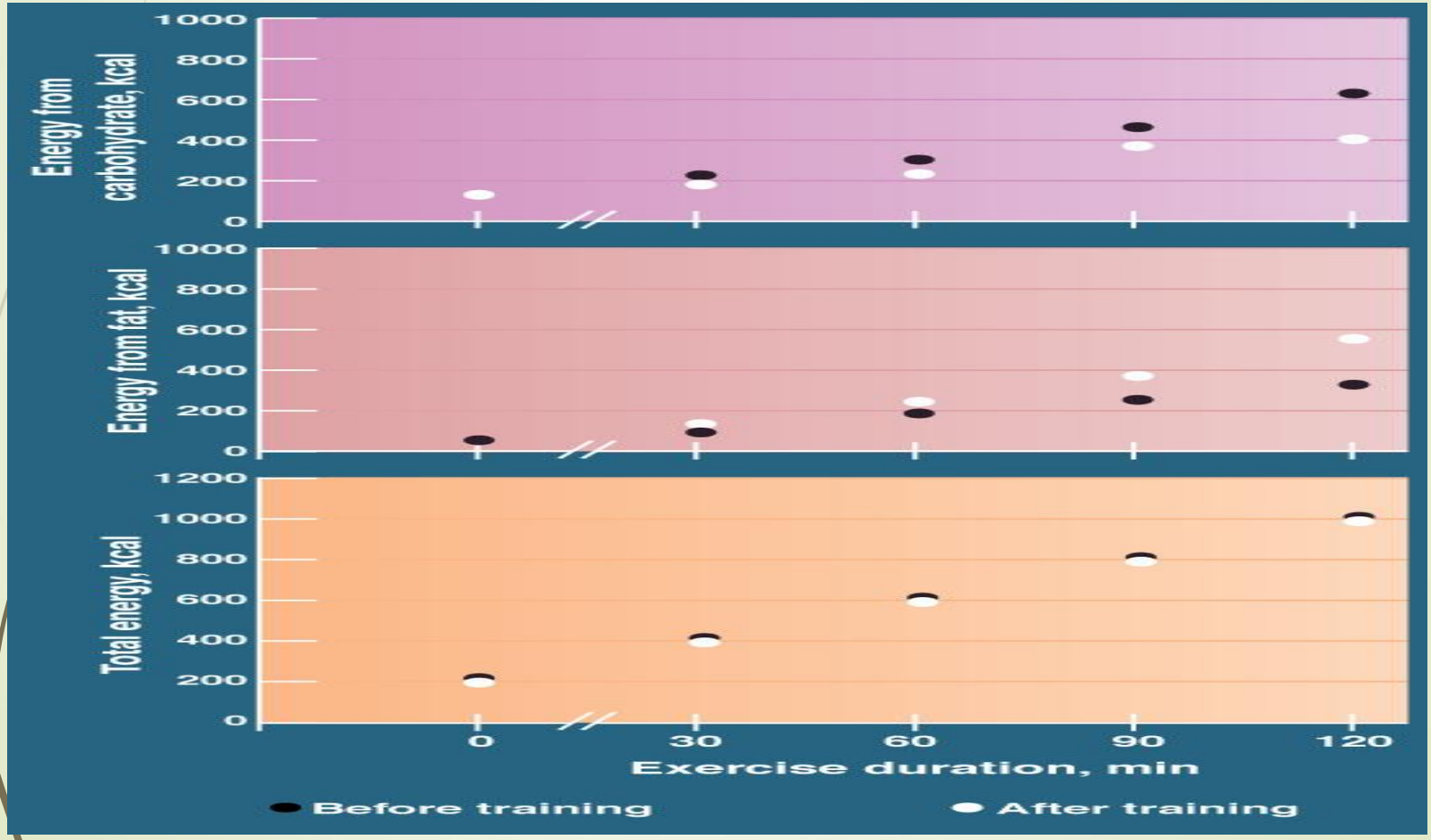
- To address the obesity epidemic, the AHA urges to maintain a waistline of:
  - Men – 40 inches or less.
  - Women – 35 inches or less.
- Devote at least an hour daily to moderate activity (brisk walking, swimming, or cycling) to maintain a normal body weight.

Energy Usage for Exercise

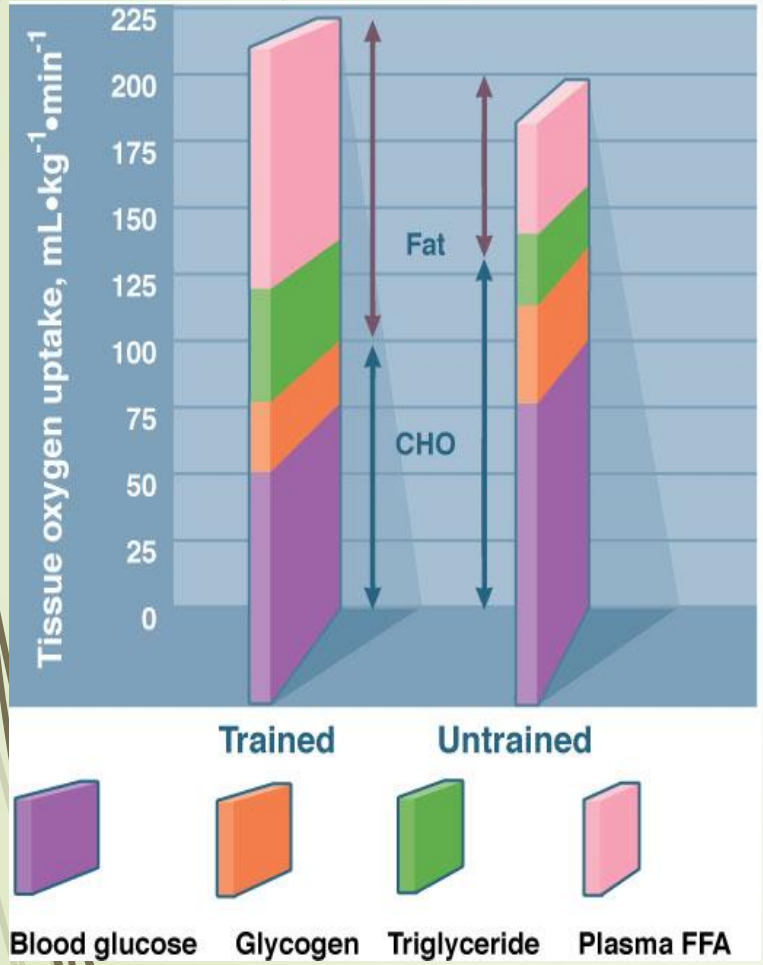
- When exercise progresses beyond several minutes, the aerobic system predominates with oxygen uptake capacity becoming the important factor.



Why we use more fat for energy as we become more fit



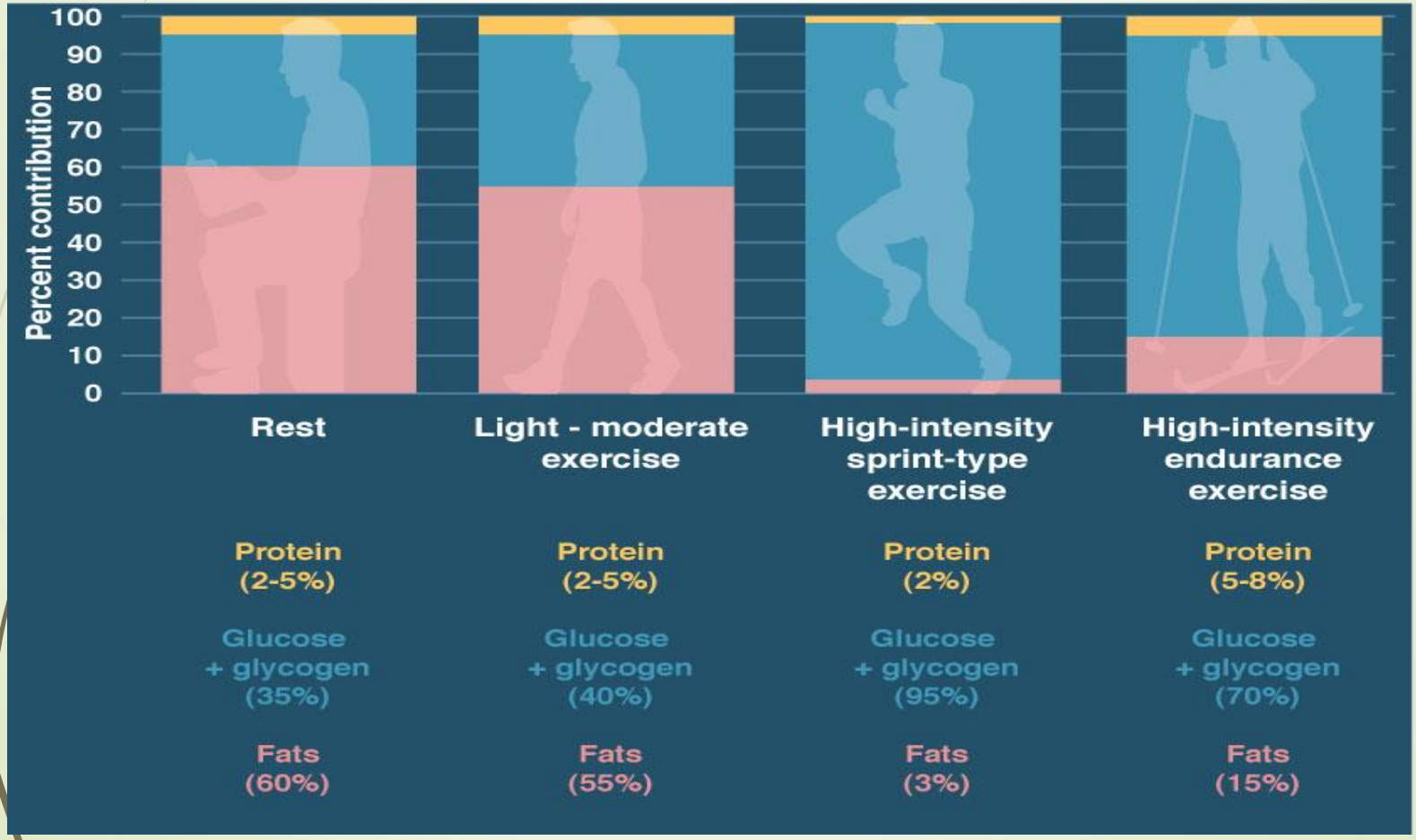
Carbohydrate Use During Exercise



- Trained muscle has an augmented capacity to use carbohydrates aerobically for energy

- Due to an increased oxidative capacity of the mitochondria and increased glycogen storage

Energy Utilization Based on intensity



So what about the fats in our diets?

- Are these the same? What types of oil?
- Currently hydrogenated oils are not seen as positive sources of fats while monosaturated oils are better.

Types of Fats

Dietary Fat: Increased percentage of purple fat is best

Dietary fat	Cholesterol (mg/tbsp)	Breakdown of fatty-acid content (normalized to 100%)
Canola oil	0	6% 22% 10% 62%
Safflower oil	0	10% 77% Trace – 13%
Sunflower oil	0	11% 69% 20%
Corn oil	0	13% 61% 25%
Olive oil	0	14% 8% – 1% 77%
Soybean oil	0	15% 54% 7% 24%
Margarine	0	17% 32% – 2% 49%
Peanut oil	0	18% 33% 49%
Vegetable shortening	0	28% 26% – 2% 44%
Palm oil	0	45% 12% – 1% 37%
Palm kernel oil	0	52% 10% – 1% 11%
Coconut oil	0	92% 2% 6%
Lard	12	41% 11% – 1% 47%
Beef fat	14	52% 3% – 1% 44%
Butter fat	33	66% 2% – 2% 30%

Polyunsaturated fat

Fats to Decrease Inflammation

- Omega 3 Fatty acids help reduce inflammation in the body by supporting biologic processes that fight stressors.
  - Increase intake if salmon, cold water fish
  - Fish oil supplements if necessary
  - Olive oil
  - Flax seed/walnuts/pecans

The carbohydrates: sugars, starches, and fibers

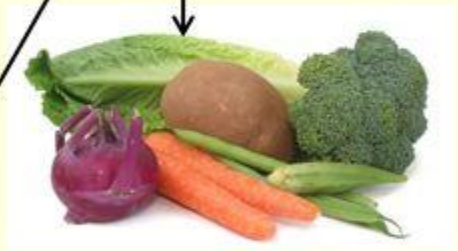
- Simple carbohydrates:
  - Monosaccharides – single sugars
  - Disaccharides – sugars composed of pairs of monosaccharides

- Complex carbohydrates:
  - Polysaccharides – large molecules composed of chains of monosaccharides

Carbohydrates

- Carbohydrates are nutrients that supply your body with energy.
- There are three kinds:

sugar cellulose starch



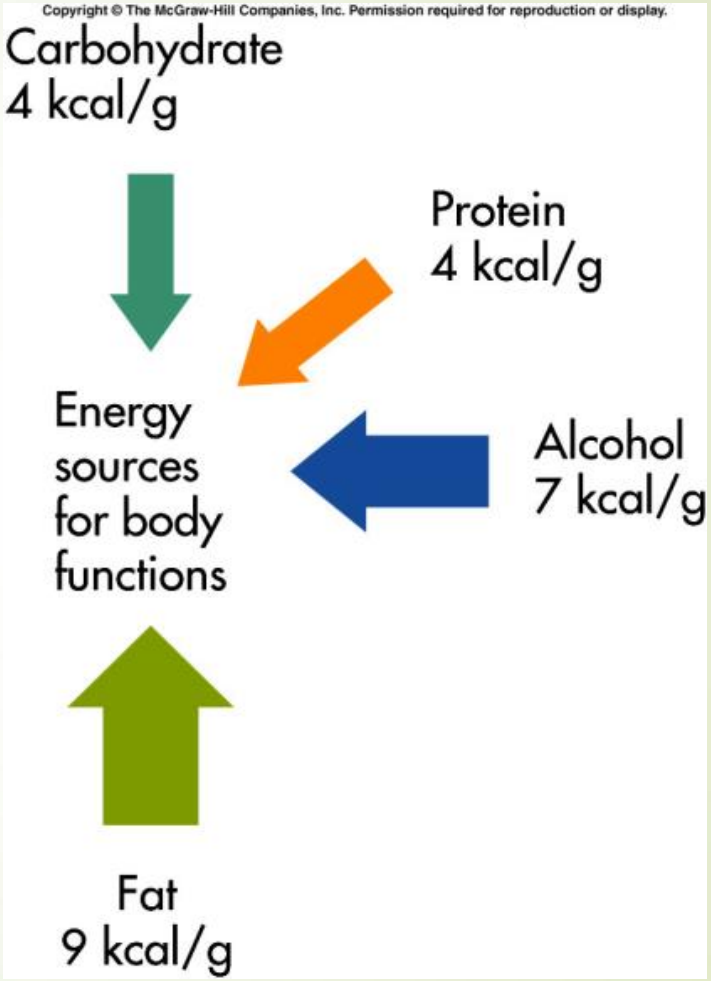
The Energy Balance Equation

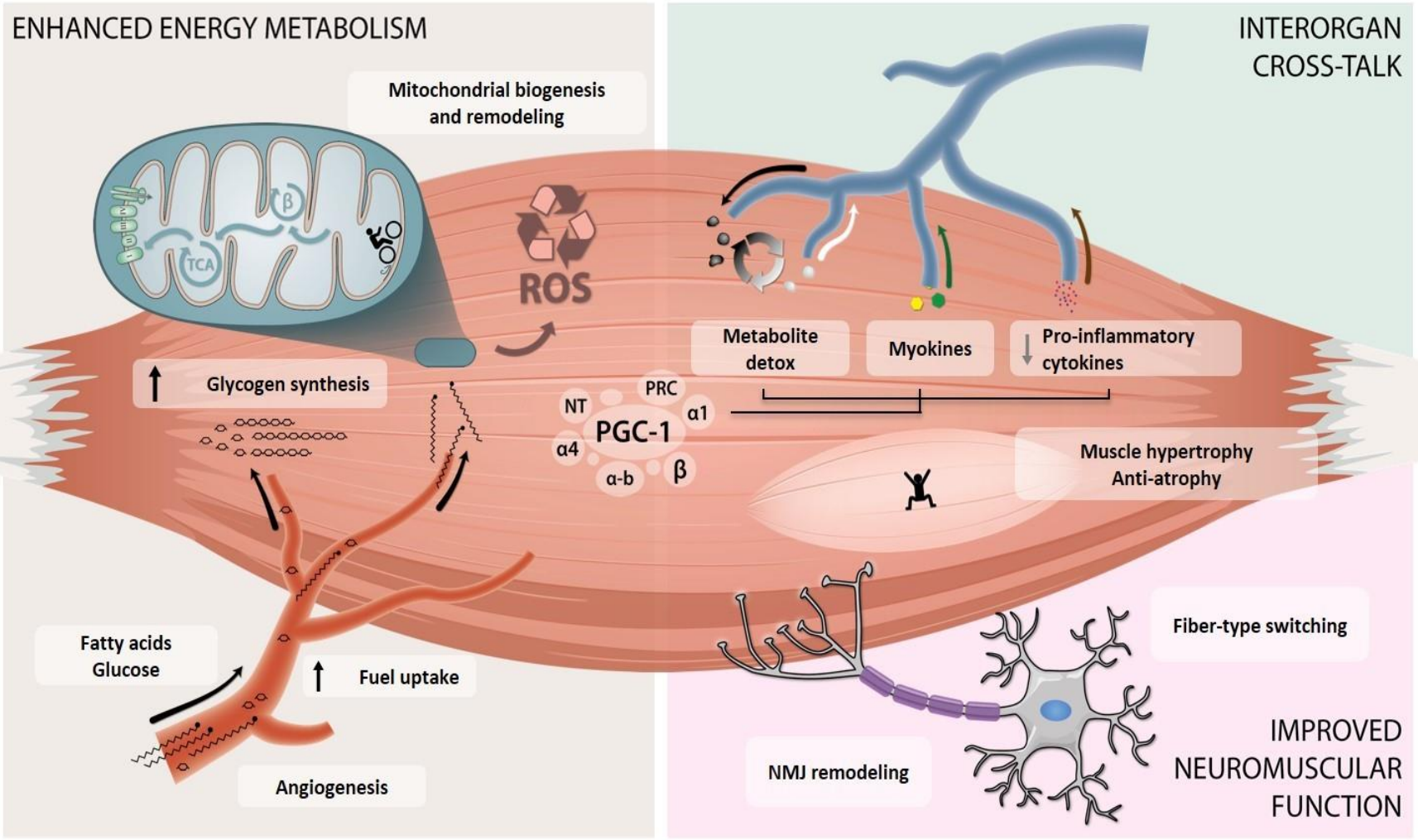
- Physically active people maintain a lighter, leaner body and a more healthful disease risk profile, despite increased intake of the typical American diet.

The Reality of Metabolism and How our Bodies Really Work

- The fuel mixture that powers exercise generally depends on the intensity and duration of effort, and the exerciser's fitness and nutritional status.

- It takes energy to move throughout the day. Energy comes from calories. The type of calories we eat versus the work we do usually determines how our body uses calories.

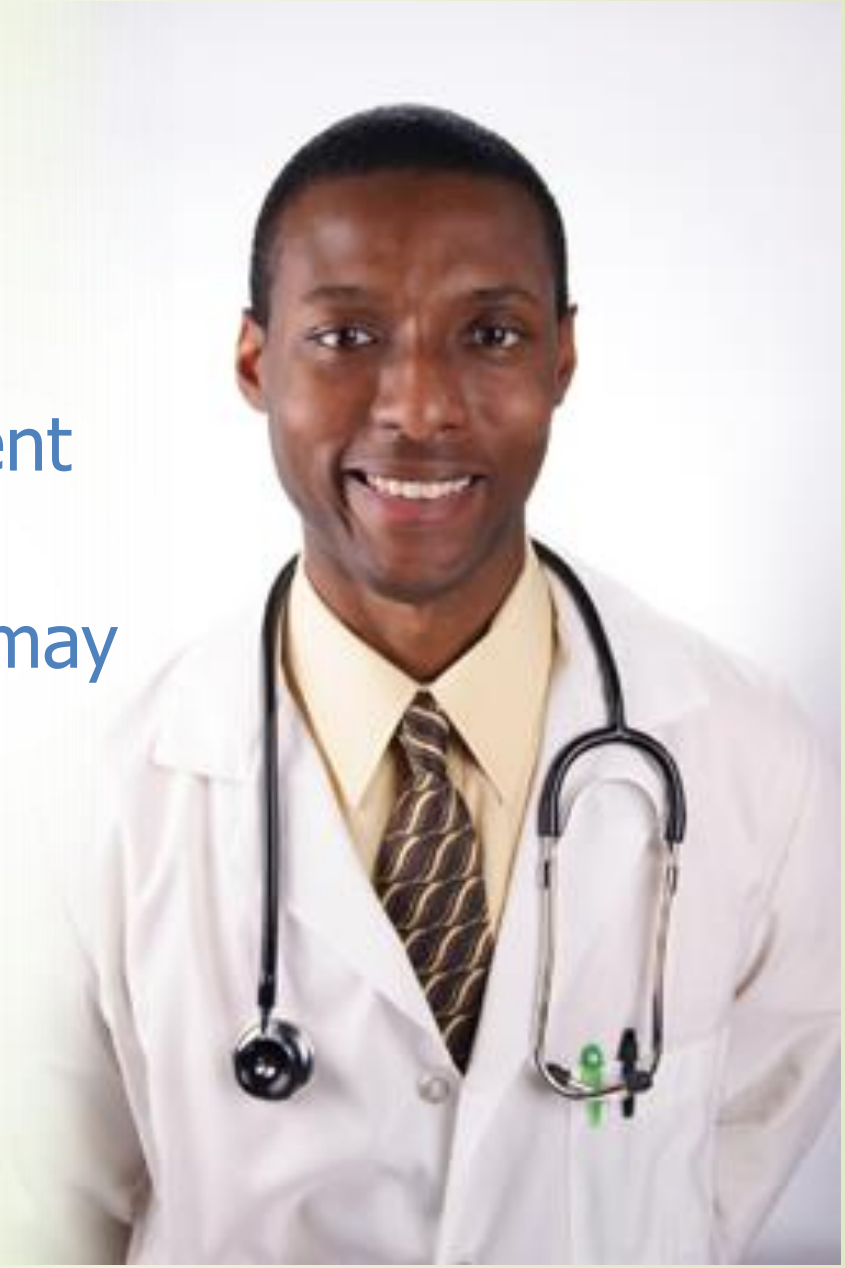




Correia J et al., *Trends Endocrinol Metab* 2015

Disease

- Eating "Functional foods" may help prevent disease
- Eating "functional" may decrease risk of:
  - Heart disease
  - Cancer
  - Diabetes



Stay Younger Longer

- Functional foods may keep you feeling younger longer
- They may help reduce signs of aging
  - Skin damage
  - Loss of vision
  - Joint flexibility

What are Functional Foods?

It contains a large amount of nutrients which are linked with a reduced risk for disease.

Super foods are rich in:

- Vitamins
- Minerals
- Phytochemicals

Phytochemicals

- "Phyto" from the Greek word meaning "plant"
- They give foods taste, aroma, color, and other characteristics
- They are believed to promote good health

Oxidation and Free Radicals

- Oxidation: a reaction involving oxygen
- Free radical: an unstable by-product of oxidation
- Free radicals can damage:
  - Cell walls
  - Cell structures
  - DNA within the cells

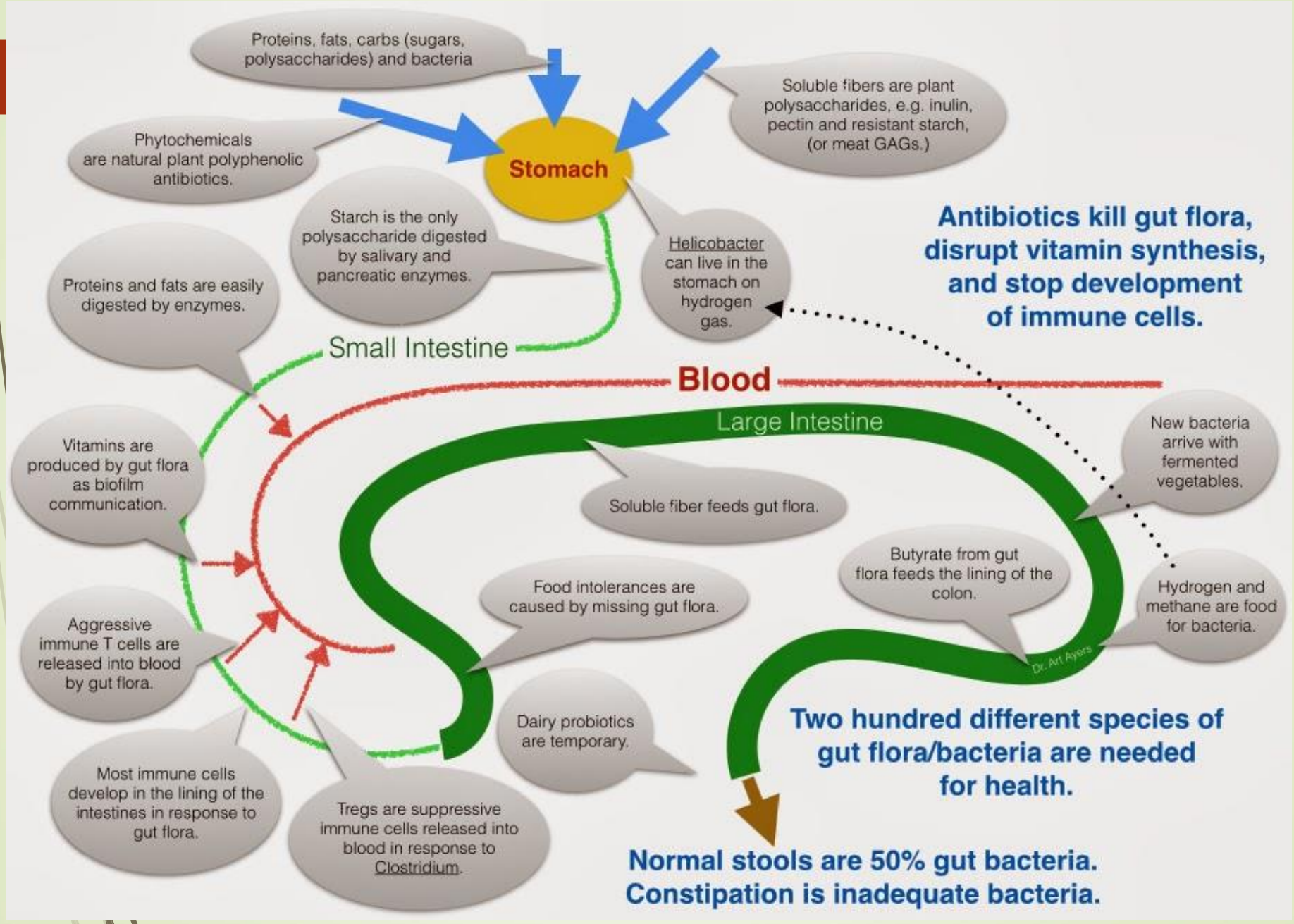
Antioxidants

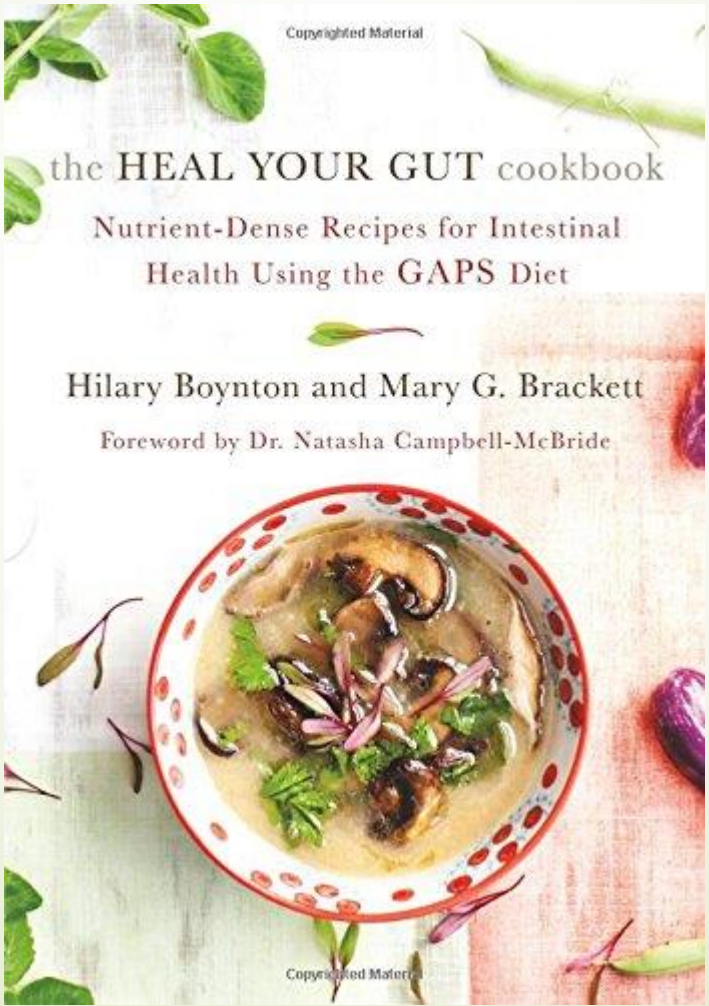
- Are present in foods as:
  - Vitamins
  - Minerals
  - Phytochemicals
- Stabilize free radicals which could otherwise stress or damage cells

Super Foods

- Dark Green Vegetables
- Berries
- Legumes
- Orange Fruits and Vegetables
- Whole Grains
- Cold Water Fish
- Tomatoes
- Cultured Dairy Products

The Importance of Your Gut Microbiome for Optimal Health


Proteins, fats, carbs (sugars, polysaccharides) and bacteria
Soluble fibers are plant polysaccharides, e.g. inulin, pectin and resistant starch, (or meat GAGs.)
Phytochemicals are natural plant polyphenolic antibiotics.
Stomach
Starch is the only polysaccharide digested by salivary and pancreatic enzymes.
Helicobacter can live in the stomach on hydrogen gas.
Antibiotics kill gut flora, disrupt vitamin synthesis, and stop development of immune cells.
Proteins and fats are easily digested by enzymes.
Small Intestine
Blood
Large Intestine
Vitamins are produced by gut flora as biofilm communication.
New bacteria arrive with fermented vegetables.
Soluble fiber feeds gut flora.
Butyrate from gut flora feeds the lining of the colon.
Hydrogen and methane are food for bacteria.
Food intolerances are caused by missing gut flora.
Aggressive immune T cells are released into blood by gut flora.
Dr. Art Ayers
Dairy probiotics are temporary.
Two hundred different species of gut flora/bacteria are needed for health.
Most immune cells develop in the lining of the intestines in response to gut flora.
Tregs are suppressive immune cells released into blood in response to Clostridium.
Normal stools are 50% gut bacteria.
Constipation is inadequate bacteria.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the HEAL YOUR GUT cookbook
Nutrient-Dense Recipes for Intestinal Health Using the GAPS Diet
Hilary Boynton and Mary G. Brackett
Foreword by Dr. Natasha Campbell-McBride
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Dark Green Vegetables

- Rich in many vitamins, minerals, and phytochemicals
- Try these:
  - Spinach
  - Broccoli
  - Bibb lettuce
  - Collard greens
  - Romaine lettuce
  - Bok choy
  - Kale
  - Swiss chard
  - Mustard and turnip greens

Berries

- Rich in vitamin C, fiber, and phytochemicals
- Try these:
  - Blueberries
  - Raspberries
  - Cranberries
  - Strawberries
  - Blackberries

Legumes

- Low-fat plant protein
- Rich in fiber, B vitamins, minerals and phytochemicals
- Try these:
  - Black beans
  - Pinto beans
  - Garbanzo beans
  - Lentils
  - Kidney beans
  - Lima beans
  - Adzuki beans
  - Cannellini beans
  - Black-eyed peas
  - Soy beans

Orange Fruits and Vegetables

- Contain a high level of beta-carotene and other nutrients
- Try these:
  - Sweet potatoes
  - Carrots
  - Pumpkin
  - Cantaloupe
  - Mangoes
  - Winter squash
  - Orange bell pepper

Cultured Dairy Products

- Excellent source of calcium
- Contain "probiotics" – bacteria that promote healthy digestion and immune stimulating activities
- Try these:
  - Yogurt labeled "live active culture"
  - Kefir
  - Buttermilk

Tomatoes

- Rich in vitamin C and carotenes including lycopene and betacarotene
- May support prostate health (in men) and a healthy immune system
- Cooked tomatoes = better absorption of carotenes

Functional Food Claims

- Yucca root supplements
  - Grow in arid regions of North America
  - Medicinal folklore, yucca contains cpds that suppress intestinal microorganisms-which play a role in joint inflammation
- Mangosteen Juice
  - Has some significant anti-inflammatory effects
  - No human studies
  - Tropical fruit in southeast Asia
  - Usually packaged with other juices so not much mangosteen juice
  - Rich in antioxidants-specifically xanthones

Reducing Arthritis Pain with Functional Foods

- What does this mean?
  - Yucca plants, Mangosteen juice, antioxidants
- Evidence based research claims?
- Clinical trials versus antidotal product claims
- Peer reviewed journals versus marketing articles
- Some of the reasons:
  - Often test of one group or one person
  - Many are animal studies that are not convertible to human subjects

Omega 3 Fatty Acids Results

- Meta analyses of three randomized controlled trials for RA patients found that fish oil supplementation significantly decreased the number of painful/or tender joints on physical examination.
- The most recent of these meta-analyses also associated omega-3 PUFA supplementation with improvements in pain intensity and duration of morning stiffness
- Clinical benefits were observed at a minimum dose of 2.7 g/day of EPA and DHA and were not apparent until at least 12 weeks of supplementation
- Six of the seven studies demonstrated a reduced need for anti-inflammatory medications

Omega 3 Fatty Acids

- Some Food Sources of Alpha-linolenic Acid (18:3n-3) (216)
  - Food Serving Alpha-Linolenic acid (g)
- Flaxseed oil 1 tablespoon 7.3 g
- Walnuts, English 1 oz 2.6 g
- Flaxseeds, ground 1 tablespoon 1.6 g
- Walnut oil 1 tablespoon 1.4 g
- Canola oil 1 tablespoon 1.3 g
- Soybean oil 1 tablespoon 0.9 g
- Mustard oil 1 tablespoon 0.8 g
- Tofu, firm ½ cup 0.7g
- Walnuts, black 1 oz 0.6 g

EPA and DHA

- **Some Food Sources of EPA (20:5n-3) and DHA (22:6n-3)** (3)

Food Serving	EPA (g)	DHA (g)	Amount providing 1 g of EPA + DHA
Herring, Pacific 3 oz*	1.06	0.75	1.5 oz
Salmon, chinook 3 oz	0.86	0.62	2 oz
Sardines, Pacific 3 oz	0.45	0.74	2.5 oz
Salmon, Atlantic 3 oz	0.28	0.95	2.5 oz
Salmon, sockeye 3 oz	0.45	0.60	3 oz
Trout, rainbow 3 oz	0.40	0.44	3.5 oz
Tuna, white 3 oz	0.20	0.54	4 oz
Crab, Dungeness 3 oz	0.24	0.10	9 oz
Tuna, canned 3 oz	0.04	0.19	12 oz

- *A 3-oz serving of fish is about the size of a deck of cards.

Influence of Diet on Exercise

- When carbohydrates are low, exercise intensity decreases to a level determined by how well the body mobilizes and oxidizes fat.
- Carbohydrate depletion during prolonged exercise coincides with a reduced exercise capacity.

Weight Management Techniques

- Increasing high fiber foods with more fruits and vegetables
- Increasing energy out with water aerobics and core strength
- Not skipping meals
- Think before you Drink: Dairy and then new yogurts and drinkable products

Portion Sizes are Important

 =	2 tbsp. measure	2 tbsp. salad dressing, peanut butter, margarine, etc.
 =	Medium/small fruit	½ – ¾ cup measure
 =	1 standard bagel	Bagel or English muffin
 =	⅓ to ¾ cup	Baked potato; ground or chopped foods; ½ cup = 2 oz.
 =	Large fruit (or 1 cup volume)	Apple or orange
 =	1 cup	Ready-to-eat breakfast cereal

TAB
E

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Sara focuses her practice on corporate governance, transactions and regulatory compliance for health care providers, including health systems, hospitals, academic medical centers, pharmacies, and licensed independent practitioners, including but not limited to physicians, dentists, and advanced practice providers. She also counsels companies working in the health care industry, including medical device and pharmaceutical companies, medical staffing companies, and pharmacy benefit managers--and likewise, self-insured employers engaging in contracts with pharmacy benefit managers.

Prior to joining Taft, Sara served as Corporate Counsel at The Kroger Co., where she was lead in-house counsel for The Little Clinic and Kroger Prescription Plans, the Kroger retail health clinics and pharmacy benefit manager. Sara was also formerly Assistant and Associate General Counsel at UC Health, Greater Cincinnati's academic health system.

Sara completed her juris doctor and master of public health at George Washington University. While in law school, Sara was the president of the Health Law Student Association and worked as a law student extern at the Department of Health and Human Services, Centers for Medicare and Medicaid Services Office of General Counsel and also at the Milken Institute's Center for Health Policy Research in Washington DC.

Industries

Health Care and Life Sciences
Audits, Investigations and Healthcare Litigation
Hospitals and Health Systems
Medical and Dental Groups

Education

George Washington University Law School (2009)
George Washington University School of Medicine and Health Sciences, M.P.H. (2009)
Miami University, B.A. (2006)

Admissions

State - Ohio

Speeches and Publications

- Speaker, Health Care Law: New Developments and Trends in Telehealth and Telemedicine; National Telehealth Conference, University of Cincinnati College of Nursing, Cincinnati, Ohio; March 25, 2016
- Speaker, A Brave New World: Value Based Payment & Population Health; Cincinnati Bar Association Continuing Legal Education Health Care Seminar; December 10, 2015
- Speaker, Insights on Legal Requirements of Nonprofits, Cincinnati Academy of Leadership for Lawyers,

Cincinnati Bar Association; September 29, 2015

- Speaker, Telehealth Legal & Policy Challenges; National Telehealth Conference, University of Cincinnati College of Nursing, Cincinnati, Ohio; March 21, 2014

Awards

- Ohio State Bar Foundation 2016-2017 Community Service Award for Attorneys 40 & Under, District 1

Professional Affiliations

- Cincinnati Bar Association
  Board of Trustees (2016-present), Secretary (2018-2019)
- American Health Lawyers Association
  Member

Community Involvement

- Beech Acres
  Board Member (2015-present), Treasurer (2017-present)
- Junior League of Cincinnati
  Board Member (2012-present)
- March of Dimes
  Greater Cincinnati/Northern Kentucky Board of Directors (2014-2017)

Reimbursement & Innovation:
Chronic Care Management and Remote Patient Monitoring

Sara M. Cooperrider
Partner, Taft Stettinius & Hollister LLP

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1

Agenda

- During this presentation we will discuss innovative value-based reimbursement programs, Medicare reimbursement in chronic care management ("CCM") and remote patient monitoring ("RPM"), and practical implementation issues faced by health care organizations and practitioners as they adapt to an ever-changing landscape
- The "regulatory sprint to coordinate care" is on…

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2

Background: MACRA and ACA

- The Affordable Care Act (2010) ("ACA") and the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") underpin the innovative payment initiatives in Medicare and Medicaid
  - ACA § 3021 – Establishment of Center for Medicare and Medicaid Innovation (CMMI) within CMS
  - ACA § 3022 – Medicare shared savings program
  - MACRA § 101(b)-(c) – Creation of Merit-based Incentive payment System (MIPS) and consolidation of Medicare quality incentive programs into MIPS
  - MACRA § 101(e)(1) – Creation of Physician-Focused Payment Model Technical Advisory Committee (PTAC)
  - MACRA § 101(e)(2) – APM Incentive Payments

3

Value-Based Programs

- The major value-based payment initiatives underway at CMS:
  - the Medicare Shared Savings Program, established under section 3022 of the ACA;
  - the Next Generation ACO model, another "accountable care" model being tested by CMMI under its authority under section 3021 of the ACA (Section 1115A of the Social Security Act)

4

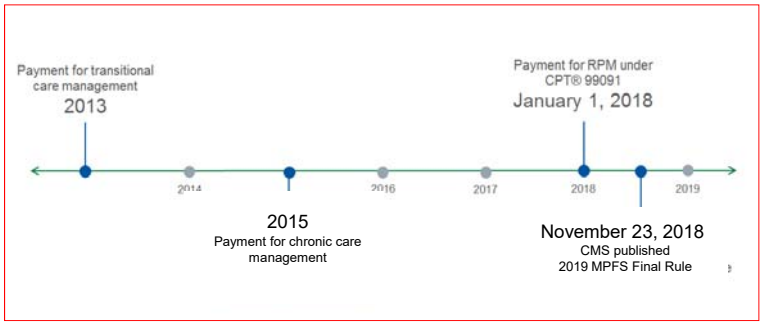
Value-Based Programs

- Oncology Care Model, payment and service delivery model being tested by CMMI, underway since 2016;
  - payment arrangements that include accountability for episodes of care for chemotherapy administration to cancer patients.
- Bundled Payment for Care Improvement (BPCI) and "BPCI Advanced", CMMI model recently launched in a second phase.
  - Four broadly defined models of care, which link payments for the multiple services beneficiaries receive during an episode of care.
  - Organizations enter into payment arrangements that include financial and performance accountability for episodes of care.

Value-Based Programs - Primary Care

- CMMI's MAPCP Demonstration (2011-2016), CPC initiative (launched 2012) and CPC+ model (2017-2021)
  - Medicare primary care initiatives supporting enhanced care management including care management fee
  - Disallow separate billing for CCM services beyond what Medicare provides for patients participating in the initiatives
- During the past eight years, CMS has made a strong commitment to support primary care and has increasingly recognized care management as an important component that contributes to improved patient health and reduced expenditure growth--through CMMI and MPFS

Medicare Physician Fee Schedule (PFS)



Chronic Care Management (CCM)

Monthly payment to:

- Practitioners (*e.g.*, physicians, nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwives)
  - their practice entities per reassignment
- FQHCs, RHCs
- Coordinating care for Medicare beneficiaries with multiple chronic conditions
- Services provided by clinical staff incident to the service of a practitioner can be furnished under general supervision of a physician or other practitioner and the clinical staff need not be a direct employee of the practitioner or practitioner's practice.

CCM Required Elements

- Certified EHR
  - Structured recording of demographics, problems, medications and medication allergies
  - Summary care record
- Care management and planning
  - Plan of care (electronic)
- Enhanced access to care and 24/7 communication
  - Telephone/asynchronous (e.g., secure messaging, email)

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9

CCM Required Elements (continued)

- Continuity of care with designated care team member
- Manage transitions of care
- Coordination of care
  - home & community-based providers
- Documented beneficiary consent (medical record)
- Initiating visit (AWV, IPPE, TCM or comprehensive E/M) required if beneficiary is new or not seen within 12 months

Taft/ 10

10

CCM CPT Codes

- 29490 (since 2015)
  - 2017- relaxed service elements & billing requirements
  - 20 minutes/month
- Complex CCM (2017)
  - 29487 – 60 minutes/month
  - 29489 – add-on – 30 minutes/month (after 1st 60)
- CCM Initiating visit – G0506 (2017)
  - Add-on – face-to-face assessment and care planning during CCM initiating visit, AWV or IPPE

11

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CCM Mathematica Report

CMS' evaluation contractor, Mathematica, analyzed CCM's impact

- Provider experience
- Beneficiary experience
- Total cost of care

- Higher rate of advanced care planning
- Evidence that CCM was more effective at r

reducing Medicare expenditures among beneficiaries who died during the follow-up period suggesting better management of end-of-life care

12

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Provider Experience

- Qualitative interviews with CCM providers
  - Enables practice to devote resources necessary to properly manage complex patients
  - "Patients who consented to CCM have overwhelmingly positive views of CCM services"
  - Improved patient satisfaction and compliance
  - Decrease in ER visits and hospitalizations

13

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13

13

Beneficiary Experience

- Qualitative telephone interviews
  - Improved coordination among providers
  - Improved access to primary care provider
- Data suggests reduction in potentially preventable admissions - diabetes, COPD, CHF, UTI, dehydration, pneumonia

14

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14

14

Table III.13. Estimated differences between CCM and comparison beneficiaries: 12-month quality of care outcomes

	Non-CCM	CCM	Difference (CCM minus non-CCM)
Likelihood of hospitalization with a primary diagnosis of diabetes (%)			
Pre-CCM	0.7	0.7	0
Post-CCM	0.7	0.6	-0.1*
Difference (CCM minus non-CCM)	0.0	-0.1***	-0.1***
Likelihood of hospitalization with a primary diagnosis of COPD (%)			
Pre-CCM	1.3	1.4	0.1***
Post-CCM	1.3	1.4	0.1*
Difference (CCM minus non-CCM)	0.0	0	0
Likelihood of hospitalization with a primary diagnosis of CHF (%)			
Pre-CCM	1.7	1.9	0.2***
Post-CCM	2.0	1.9	-0.1**
Difference (CCM minus non-CCM)	0.4***	0.0	-0.3***
Likelihood of hospitalization with a primary diagnosis of UTI (%)			
Pre-CCM	1.2	1.3	0.1***
Post-CCM	1.4	1.4	0
Difference (CCM minus non-CCM)	0.2***	0.1***	-0.1***
Likelihood of hospitalization with a primary diagnosis of dehydration (%)			
Pre-CCM	0.8	0.9	0.1**
Post-CCM	1.1	1.1	0
Difference (CCM minus non-CCM)	0.3***	0.2***	-0.1
Likelihood of hospitalization with a primary diagnosis of pneumonia (%)			
Pre-CCM	1.2	1.4	0.2***
Post-CCM	1.5	1.5	0
Difference (CCM minus non-CCM)	0.2***	0.1**	-0.2**

Source: Medicare 2014–2016 enrollment and FFS claims data.
Note: Number of CCM beneficiaries = 273,225; number of comparison beneficiaries = 202,679.

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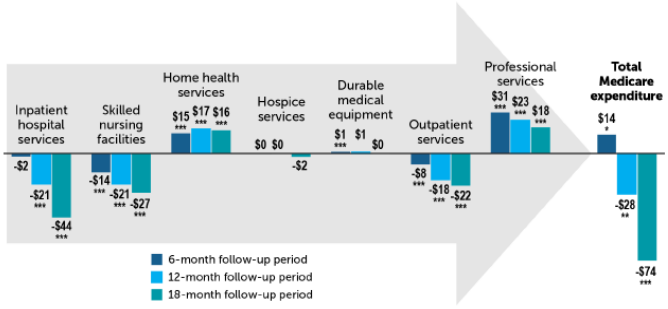
15

15

Impact on Total Cost of Care

Figure III.7. Estimated PBPM impact of CCM on total expenditures and by expenditure category: 6-, 12-, and 18-month follow-up periods



Source: Medicare 2014–2016 enrollment and FFS claims data.

16

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16

16

Impact on Utilization

Table III.12. Estimated differences between CCM and comparison beneficiaries: 12-month follow-up utilization outcomes

	Non-CCM	CCM	Difference (CCM minus non-CCM)
Average number of primary care visits			
Pre-CCM	10.4	10.5	0.2*
Post-CCM	10.2	11.5	1.3***
Difference (CCM minus non-CCM)	-0.2**	1***	1.1***
Average number of specialty visits			
Pre-CCM	11.9	12.1	0.1
Post-CCM	12.8	12.9	0.1
Difference (CCM minus non-CCM)	0.8***	0.8***	0.0
Emergency department visits, including observation stays (per 1,000 beneficiaries)			
Pre-CCM	608	604	-5
Post-CCM	671	643	-28**
Difference (CCM minus non-CCM)	62***	39***	-23**
Hospitalizations (per 1,000 beneficiaries)			
Pre-CCM	470	482	12***
Post-CCM	621	586	-35***
Difference (CCM minus non-CCM)	152***	104***	-47***
Likelihood of hospice utilization (%)			
Pre-CCM	0.8	1.1	0.3***
Post-CCM	4.9	5.8	0.9***
Difference (CCM minus non-CCM)	4.1***	4.7***	0.6**

Source: Medicare 2014–2016 enrollment and FFS claims data.

17

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17

Shared Staffing

- CMS acknowledges providers may not have internal capacity to provide CCM
- Arrangements with 3rd parties permitted
  - Sufficient integration (e.g., use of EHR)
  - Responsibility for key components allocated between parties; billing provider ultimately responsible
  - Fee should be consistent with level of work performed

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18

18

Shared Staffing (Example)

Billing Provider

- Secure patient consent
- Provide Staffing Company with remote access to patient's EHR
- Validate care managers' qualifications and competencies
- Supervise clinical staff
- Respond to care managers' inquiries
- Review/approve patient care plan and any revisions
- Address transitions of care
- Provide coordination of care
- Bill and collect; pay negotiated rate to Staffing Company

Staffing Company

- Provide information sufficient for billing provider to validate qualifications and competencies
- Connect to provider's EHR
- Develop draft electronic care plan in provider's EHR
- Deliver ongoing care management services; document in provider's EHR

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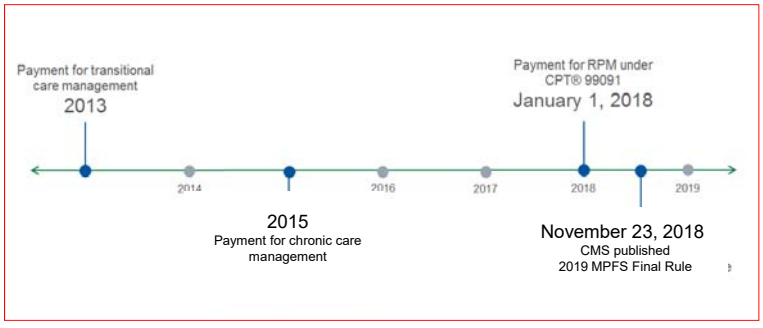
Medicare Physician Fee Schedule (PFS)



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Remote Patient Monitoring

RPM Defined

Use of digital technologies to collect health data from an individual in one location and electronically transmit that information securely to healthcare providers in a different location for assessment and recommendation

21

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21

21

RPM Billing Rules

CPT® 99091

Accessing, reviewing, interpreting, and acting on various physiological data

- 30 minutes over 30-day period
- Not a Medicare Telehealth service (limits on locations)
- Document beneficiary consent
- Initial face-to-face visit required
- No limits on eligible recipients
- Performed by a practitioner or meet all requirements for "incident to" billing

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22

Medicare Billing Rules

- Personally performed by individual under whose NPI the service is billed
- Performed by clinical staff in compliance with "incident to" billing rules

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23

RPM Incident to Billing

Ten requirements – all must be satisfied

1. CMS has not stated that service cannot be billed "incident to"
2. Service is not one for which payment is made under a separate benefit category (e.g., diagnostic tests)
3. Individual qualifies as auxiliary personnel (billing physician bears expense of providing the service)
4. Individual has not been excluded from any federal health program

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24

RPM Incident to Billing (continued)

Ten requirements - all must be satisfied

5. Billing physician determines individual is qualified and has appropriate training
   - Qualified under state law (if service requires licensure)
   - Appropriate training and experience
6. Service provided for established patient (last 3 years) and relates to existing medical condition treated by the billing physician's practice
7. Service furnished under billing physician's **direct** supervision, *i.e.*, present in same suite of offices, immediately available to assist

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25

RPM Incident to Billing (continued)

Ten requirements - all must be satisfied

8. Service is not performed in an institutional setting
   - Hospital inpatient, HOPD, SNR
   - Provider-based physician clinic OK
9. All elements of service are performed by individual, another individual who meets above requirements, or billing practitioner
   - Each could count to 30 minutes (unless performing same task at same time)
10. Medical record note must be signed by ancillary staff member and (depending on the MAC) supervising physician.

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26

"30 Minutes"

What counts?

"Accessing the data, reviewing or interpreting the data, and any necessary modifications to the care plan that result, including communication with the patient and/or her caregiver and any associated documentation."

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27

Time-Based Codes

Documentation is key

- Gold standard: record start and stop times
- Include provider's name and specific description of the work performed
- Appropriate use of documentation tool
  - Written policy and staff education

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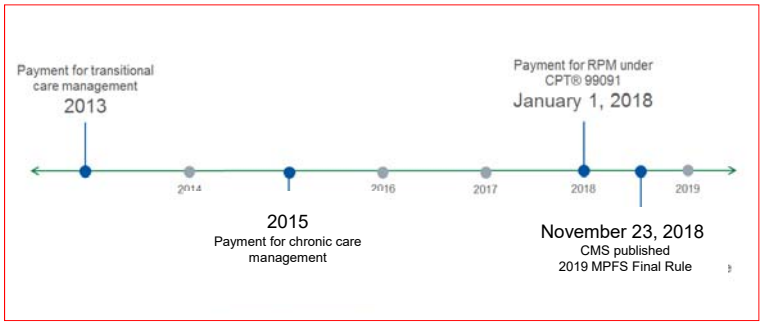
Medicare Physician Fee Schedule (PFS)



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2019 Medicare Physician Fee Schedule

Non-Face-to-Face Services

- Medicare Telehealth Services
- Remote Patient Monitoring (RPM)
- Virtual Check-In
- Interprofessional Internet Consultation
- Chronic Care Management
- Bundled Episode of Care for Management and Counseling
- Treatment for Substance Abuse Disorders

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2019 MPFS RPM Codes

CPT® 99453

- Set-up and patient education on use of equipment
- No physician work required to bill

CPT® 99454

- Device supply with daily recordings or programmed alerts transmission, each 30 days
- No physician work require to bill

CPT® 99457

- Remote physiologic monitoring treatment management services
- May be performed by clinical staff (general supervision)

31

CMS Proposed Rule for Medicare Advantage

- Telehealth would have equal footing to in-person visits under Medicare Advantage (MA) in the 2020 plan year under the proposed rule announced November 1, 2018
- All MA plans would pay for the telehealth version of all "covered Part B in-person services"
- MA plan enrollees would be eligible for telehealth services whether they live in urban, suburban or rural areas, and they could receive them from home, as compared to restrictions under FFS Medicare
  - Proposed §422.135(c) MA plans would advise enrollees in the evidence of coverage document they may receive the services through electronic exchange
  - Proposed §422.135(c)(3) MA plans would identify providers offering services for telehealth benefits in provider directories

32

Common Issues and Concerns

- Common legal issues that arise in structuring participation in care coordination initiatives:
  - Requirements for the legal structure and governance of the parties delivering services
  - Innovative payments and enhanced benefits:
    - Payment waivers
    - Shared savings
    - Performance-based payments
    - Care coordination payments
    - Enhanced benefits

33

Common Issues and Concerns (continued)

- Health care fraud and abuse laws:
  - Financial sharing arrangements
  - Patient engagement incentives
  - Donation or provision of CEHRT
  - Stark exceptions
  - Anti-kickback safe harbors
  - IRS guidance

34

Common Issues and Concerns (continued)

- Safeguards against stinting on medically necessary care, cherry-picking or otherwise steering patients
- False Claims Act and accuracy in quality reporting, coding, risk adjustment, and documentation
- State law considerations such as:
  - Prohibition against the corporate practice of medicine
  - Patient notice/consent requirements

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35

Questions?

Sara M. Cooperrider - scooperrider@taftlaw.com - 513.357.8710

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36

36

TAB
F

Lisa Ann Taylor

Lisa Taylor currently works as the Vice President and Chief Compliance Officer for UC Health in Cincinnati, Ohio. Lisa has worked for over 18 years in the areas of audit, risk assessment, leadership reporting, and development of overall Compliance and Ethics Programs in both health care and manufacturing. Prior to her current role, Lisa served as an Assistant Manager in Corporate Compliance for Toyota Motor Engineering and Manufacturing North America (TEMA) and as the Corporate Compliance Officer for Children's Medical Center Dallas (CMCD) where she was responsible for the overall Compliance and Ethics Program. Lisa began her compliance career with Cincinnati Children's Hospital Medical Center assisting with the overall development of the program and HIPAA compliance.

Lisa received her BS (1996) from the College of Mount St. Joseph in Cincinnati, Ohio, and her JD (2000) from Salmon P. Chase College of Law at Northern Kentucky University in Highland Heights, Kentucky. She is a member of the bar in Ohio and Indiana. She is also a Certified Compliance and Ethics Professional (CCEP) through the Society of Corporate Compliance and Ethics (SCCE).

Lisa is active in her community through programs affiliated with her church. Lisa has been published and is a noted speaker on topics related to compliance and ethics.

Lisa resides in Lawrenceburg, Indiana, with her husband John and their son Nathan.

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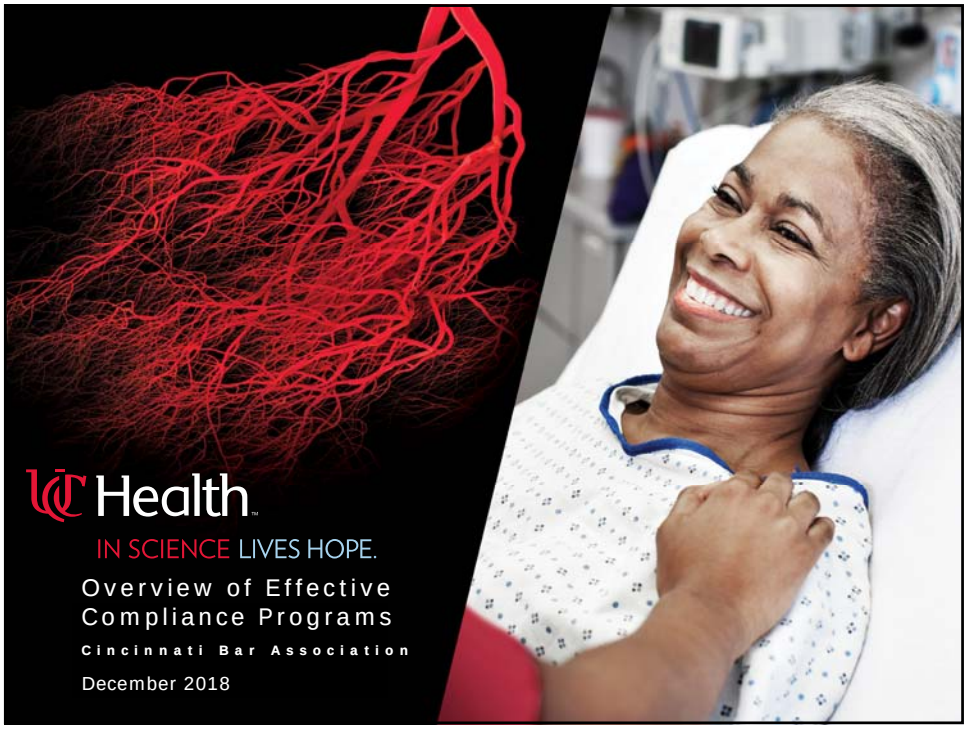
lisa.taylor@uchealth.com



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WHAT IS COMPLIANCE?

The goal of compliance is to ensure that your company is conducting business in a legal and ethical manner.

To do this, you need a compliance program designed to:

1) prevent, detect, and resolve potential violations of federal, state, and local laws and regulations, and
2) promote an organizational culture that encourages ethical conduct.

3

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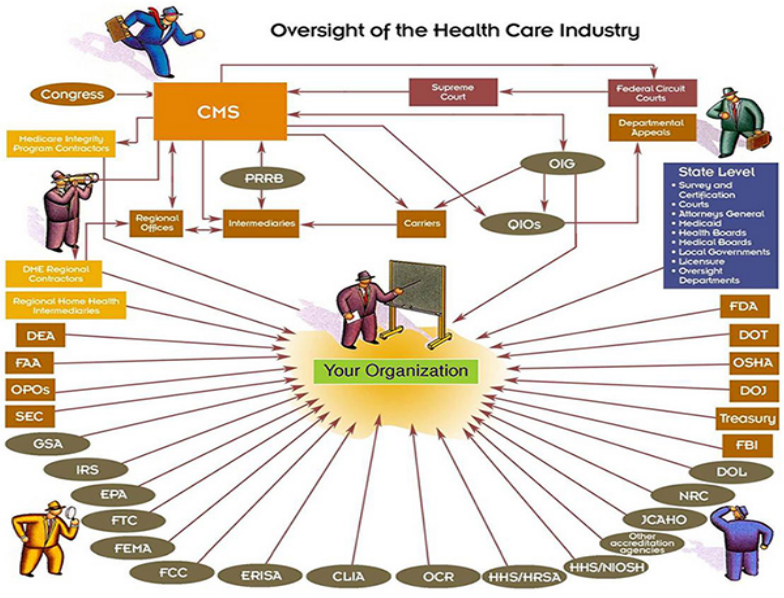

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THE GOVERNMENT WEIGHS IN…

- United States Sentencing Commission Guidelines – Effe Compliance Programs
- Office of Inspector General Compliance Program Guidance
- Corporate Integrity Agreements

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Reference Sites:

- **United States Sentencing Commission Guidelines Chapter 8 - https://www.ussc.gov/guidelines/2015-guidelines-manual/2015-chapter-8**
- **Holder Memorandum (2013)- https://www.documentcloud.org/documents/1094233-attorney-general-eric-holders-memorandum-on.html**
- **OIG Compliance Program Guidance for Hospitals – https://www.oig.hhs.gov/authorities/docs/cpghosp.pdf**
- **OIG Compliance Program Guidance for Hospitals Supplement - https://www.oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf**
- **OIG Compliance Program Guidance for Individual and Small Group Physician Practices - https://www.oig.hhs.gov/authorities/docs/physician.pdf**

6

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THE GOVERNMENT HAS RESOURCES…..

CMS.gov
Centers for Medicare & Medicaid Services

7

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IT'S LESS EXPENSIVE….

- To avoid fines and penalties….
- $10,781.40-$21,562.80 Per Claim
- Treble Damages
- Qui Tam – 15-25%

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ESTABLISH THE CULTURE

Wisdom

is knowing the right path to take …

Integrity

is taking it

9

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10

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7 ELEMENTS OF A COMPLIANCE PROGRAM

1. Written Standards of Conduct, Policies and Procedures
2. Oversight and Organization of the Compliance Program
3. Education and Training
4. Open Lines of Communication
5. Auditing and Monitoring
6. Promptly Responding to Compliance Violations
7. Enforce the Compliance Program Through Disciplinary and Incentive Guidelines

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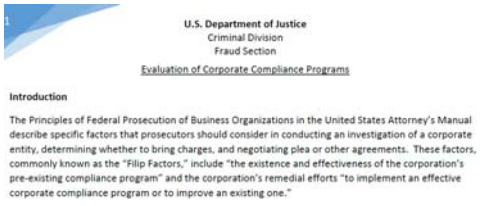
Resources:

- **Measuring Compliance Program Guidance – A Resource Guide: https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf**
- **Evaluation of Corporate Compliance Programs – DOJ: https://www.justice.gov/criminal-fraud/page/file/937501/download**



12

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Written Standards of Conduct, Policies and Procedures

13

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CODE OF CONDUCT

- Why it's important
- What can you say
- Train, communicate and train again

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POLICY EXAMPLES

- Reporting Issues/HELPLINE
- Investigations
- False Claims/Repayment
- STARK/Kickback
- Gifts
- EMTALA

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Oversight and Organization of a Compliance Program

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REQUIREMENTS

- Knowledgeable governing body
- High – Level personnel
- Chief Compliance Officer
  - Day-to-day Responsibility

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THREE SECTIONS IN UC HEALTH'S COMPLIANCE DEPARTMENT

- **Billing Compliance:** Monitor documentation of billing of health care items and services; Provide guidance on billing questions or concerns
- **Compliance Program and Consultation**: Provide guidance regarding the UC Health Code of Conduct, policies, and various federal, state, and local laws and regulations; Manage the 24-hour Compliance HelpLine
- **Privacy Compliance**: Provide training and respond to privacy complaints and investigations; Manage the HIPAA Hotline and MIDAS reports

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Compliance Responsibilities

- Implement the 7 Elements of the Compliance Program
- Provide Consultation to Business Units

19

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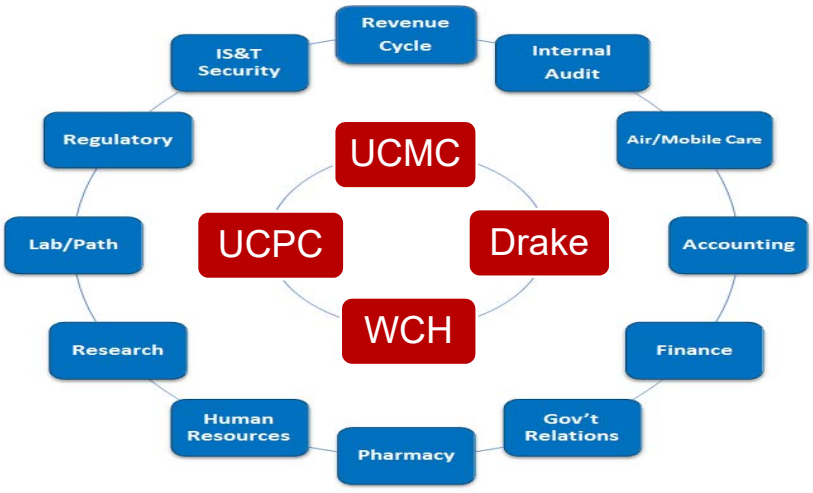
Compliance Steering Committee



20

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COMPLIANCE STRUCTURE

- Overall Plan
- Regulated Area Plans
- Reporting

21

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Education & Training

22

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EDUCATION AND TRAINING

- Annual
- Specified
- As Needed
- Track
- Government's 1st request

23

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Open Lines of Communication

24

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COMMUNICATION

- HELPLINE
- Ways to Report
- Investigations

25

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COMMUNICATION

26

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Auditing and Monitoring

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AUDITING AND MONITORING

- Risk assess yearly
- Develop audit plan
- Monitor certain risks
- Engage partners

28

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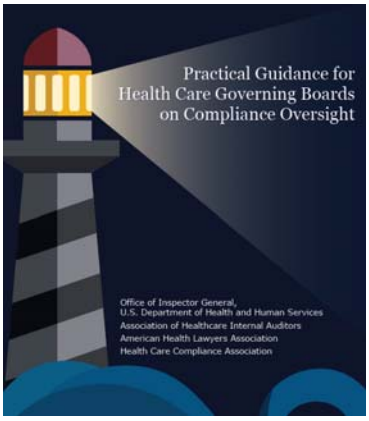
OIG/HCCA Guidance

https://www.oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf



29

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REPORTING

CONFIDENTIAL Prepared by the Compliance Department

Compliance Matters
June 13, 2018

Compliance & Business Ethics Department Overview

A. Written Standards of Conduct, Policies, and Procedures
1. New or Revised Laws, Regulations and Guidance
   i. Bipartisan Budget Act of 2018
      a. Increased Anti-Kickback penalties for fraud and abuse from $25,000 to $100,000 per violation and prison terms from 5 to 10 years.
      b. Civil Monetary Penalties (CMPs) amounts doubled. CMPs may be assessed for, among other things, submitting reimbursement claims for medically unnecessary services, employing a practitioner excluded from the federal health care programs, and failing to report and return an identified overpayment within 60 days.
      c. Provided additional leeway under the Stark Law for expired arrangements and contracts not in writing or signed
   ii. CMS Transmittal 3971; Effective January 1, 2018; Implementation Date March 5, 2018; E/M Service Documentation Provided by Students (Manual Update)
   iii. OIG Work Plan Updates; November 2017 – April 2018; 36 Items Added; reviewing 8-9 for risk
   iv. Modifier -25 updated guidance from CGS; Email notification distributed to UCP February 7, 2018. (Modifier -25 is used to identify a significant and separately identifiable E/M service preformed on the same date by the same provider as a procedural service)
2. Revised Policies and Procedures
   i. Code of Conduct
   ii. Code of Conduct Distribution Policy
   iii. Exclusion and Sanction Checking

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Audit & Compliance Committee Dashboard

LEGAL

Claims	Trended Claims History

COMPLIANCE

Projects and Investigations	Time Frame Reported: Feb 2018	Mar 2018	April 2018	May 2018	June 2018	July 2018	Comments
Investigations and HELPLINE - Internal							
Investigations - External							
BC Audits Refunded							
Proactive Reactive							

EXTERNAL AUDIT

	Due Date	Comments	Status

INTERNAL AUDIT

	Area	Comments

30

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Promptly Responding to Compliance Violations

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PROMPTLY RESPOND

- Communicate
- Payback – 60 days
- Document

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Enforce the Compliance Program Through Disciplinary and Incentive Guidelines

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DISCIPLINE

- Policy
- Progressive
- Based on Violations – "Severe" or "Pervasive"

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INCENTIVES

- Trinkets
- Recognition
- Thank Yous
- Compliance and Ethics Week

35

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Thank you
And
Questions

Lisa A. Taylor, JD, CCEP, UC Health
(513)585-8043 or lisa.taylor@uchealth.com

36

TAB
G

Monica H. McPeek, Esq.

Monica is the Director of Risk Management and Associate General Counsel for TriHealth, a multi-hospital and physician practice healthcare system. Monica's practice focuses exclusively on health care law. Monica's nineteen-year career in Health Care Law also includes advising and assisting numerous health care clients in private practice.

Brian F. Higgins

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PRACTICE AREAS

Business Succession Planning

Contract Negotiation, Preparation, and Review

Corporate Governance

Corporate/Business

Health Law

Hospital and Health Care Finance

Mergers and Acquisitions, Joint Ventures and Direct Investment

Regulated Business

CONCENTRATIONS

Health Care

INDUSTRIES

Health Care

BAR MEMBERSHIPS

Ohio, 2016

CLERKSHIPS

New York State Supreme Court, Judge John Curran

EDUCATION

University of Cincinnati, College of Law, J.D., 2015

Brian is an associate in Frost Brown Todd's regulated business group. His focus on the health care industry provides him an opportunity to advise business and health care entities in corporate matters, formation and structuring, contract negotiation, and regulatory compliance. Prior to joining the firm, Brian completed a corporate law fellowship working as corporate counsel to Medpace, Inc., a clinical research organization focused on the development of pharmaceuticals and medical devices. Brian developed an interest in the health care industry after serving as a Legal Intern to The Christ Hospital's legal department.

Brian graduated from the University of Cincinnati's College of Law where he was a member of the Moot Court Honor Board and an Associate Editor on the Immigration and Nationality Law Review. He finished his first year of law school at Northern Kentucky University's Chase College of Law and finished in the top 10% of his class.

Experience

Brian has formed fully-operational international subsidiary companies in countries all over the world. He has assisted biotechnology start-up companies draft their operating agreements while maintaining all of their corporate governance documents and contracts. Brian has regularly negotiated consulting agreements for doctors and medical writers, and confidentiality agreements to protect pharmaceutical assets. Brian has developed knowledge on Ohio's medical marijuana law and provides updates on the regulations potentially impacting physicians and patients. In addition, he produces advisories related to Ohio's industry regulations for medical marijuana cultivators, processors, and dispensaries.

Brian F. Higgins

- Dean's List - Spring 2014, Fall 2014, Spring 2015
- Moot Court Honor Board Member
- Associate Editor of the Immigration and Nationality Law Review

Denison University, B.A., Spanish, 2009

- Dean's List Fall 2006, Spring 2007, Spring 2008
- National Spanish Honor Society Inductee (Sigma Delta Pi)

Memberships & Affiliations

Ohio State Bar Association

Recent Blog Posts

Recommending Physicians Get Ready: Ohio BOP Announces Launch of Patient & Caregiver Registry for Ohio Medical Marijuana Program

Congress Seeks to Strengthen Response to the Opioid Crisis Through the Support for Patients and Communities Act

Ohio Physician's Guide to Cannabis Compliance 2.0: Budding Issues for Ohio's Medical Marijuana Physicians

CMS Removes Gag From Mouths of Pharmacists, as Ohio and Other States Follow Suit.

CMS Pushes Home Health Agencies into the Choice Demonstration

Grandma Wants Special Brownies? Ohio Nursing Facilities Prepare for Medical Marijuana

Ohio Physician Alert: Application Available to Become Certified to Recommend Medical Marijuana

Ohio Hospitals: Are You Ready for Medical Marijuana?

Green Grass in the Bluegrass: Kentucky's Medical Marijuana Law

Dramatic Shift in Federal Enforcement Priorities Related to Legalized Marijuana Use

FBT Publications

November 15, 2018
Foreign National's Marijuana Investment = U.S. Lock Out?

May 4, 2017
The Green Rush is on: Don't be left out!
Legal Update

March 20, 2017
Ohio Cultivates Marijuana Dispensary Rules as White House Sends Smoke Signals of Approval
Legal Update

March 7, 2017

Huge Payday for Insurance Company under the Affordable Care Act's Exchanges
Legal Update

January 31, 2017
Ohio Releases Proposed Rules for Medical Marijuana Processors
Legal Update

January 23, 2017
High Street Releases Proposed Rules for Ohio's Medical Marijuana Cultivators
Legal Update

December 20, 2016
Highlights of Medical Marijuana Proposed Rules for Ohio Dispensaries and Physicians
Legal Update

December 20, 2016
What will Happen to the Affordable Care Act Under a Trump Administration? (Part 1)
Legal Update

October 3, 2016
Ohio's Medical Marijuana Law
Legal Update

News

March 16, 2018
Is home delivery for medical marijuana coming to Kentucky?
WCPO

Volume 4, 1st Quarter, 2018
Ohio Hospitals: Are you ready for medical cannabis?
Canna Healthcare Magazine

March 5, 2018
Will Ohio's medical pot program go up in smoke?
WCPO, Channel 9

December 22, 2016
How HHS Secretary Nominee Price's plan could change ACA forever
Employee Benefit Adviser

FBT Events

November 13, 2018
Ohio's Medical Marijuana Law: How it Will Work and Workplace Implications

February 10, 2017
Affordable Care Act Forum

November 15, 2016
VonLehman Construction Insights 2016

Press Releases

August 26, 2016
Brian Higgins Joins Frost Brown Todd's Health Law Practice in Cincinnati

Non-FBT Publications And Events

Published book review (2013) in the Immigration and Nationality Law Review's national publication about Ediberto Roman's book titled "Those Damned Immigrants: America's Hysteria over Undocumented Immigrants."

Ohio Hospital Association Annual Conference, "Medical Marijuana and The Opioid Crisis: Risk Management for Hospitals" - June 2018

Ohio's Medical Marijuana Law

CBA – Health Law Series

Brian Higgins, Esq.
Monica McPeek, Esq.

December 6, 2018

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1

Presenters

1) Brian Higgins, Esq.
   a. Healthcare/corporate law attorney
   b. Advised health systems, senior living facilities, and physicians on medical marijuana law.
   c. Drafted policies and forms to implement varied approaches to law.

2) Monica McPeek, Esq.
   a. Director of Risk Management and Associate General Counsel for Risk and Insurance Management
   b. Implemented one health system's approach to medical marijuana.

2

2

The most pun presentation.

It was high time Ohio passed a medical marijuana law. By no means a trailblazer, Ohio is still one of the earlier midwestern states to pass this type of legislation. Today, we will get into the weeds on what the law says. Put bluntly, it creates a tightly rolled regulatory scheme where the joint efforts of the program's licensees and the State will define its success. Industry stakeholders have high hopes the law will lead will lead to a pot of gold and plant the seed for recreational use in the future, while opponents hope the budding marijuana industry goes up in smoke. Monica and I will try and clear the legal haze for you this afternoon.

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3

Today's Roadmap

1) Medical marijuana, generally.
2) Overview of Ohio's medical marijuana program.
3) How federal law and government impacts Ohio's medical marijuana program.
4) Implications the program will have on providers.
5) Practical insights from one health system's approach to medical marijuana.

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Medical marijuana, generally

1) Cancer/palliative treatment (nausea, vomiting, increases appetite)

2) Alzheimer's disease (depression, increases appetite)
   - THC helped slow the advancement of beta-amyloids (protein clumps on brain that cause Alzheimer's) Source: https://content.iospress.com/articles/journal-of-alzheimers-disease/jad140093).

3) General pain (joints, like arthritic pain, nerve damage, chronic pain)

4) Anxiety/mental health (OCD, PTSD, panic attacks, moderate depression)

5) Glaucoma

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Medical marijuana, generally (continued)

1) Michigan
   a. Legalized recreational use
   b. > 21 = use and grow up to 12 plants for personal consumption. *Compare* other states.

2) Missouri
   a. Legalized medical marijuana for conditions the *physician* sees fit.

3) Utah
   a. Legalized medical marijuana
   b. Allows qualified patients with physician approval to a purchase two ounces of medical marijuana in any two week period.

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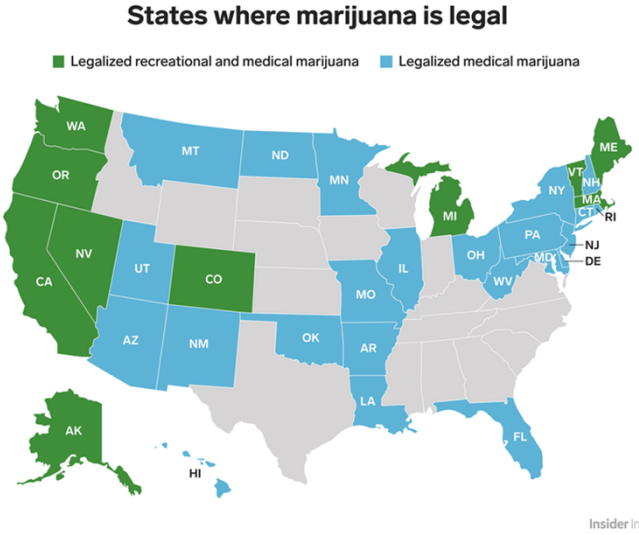

Photo Source: https://www.businessinsider.com/legal-marijuana-states-2018-1 (November 7, 2018)

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An overview of Ohio's medical marijuana program

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1) 29th State plus D.C. to medical marijuana

2) Patient estimates of 200,000+ (*source: Ohio Medical Marijuana Control Program)*

3) O.R.C § 3796 et. seq.

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An overview of Ohio's medical marijuana program (continued)

1) Cultivators/processors/laboratories/ dispensaries all awarded provisional licenses

2) 336 physicians certified to recommend.
   - 200,000 patients / 336 physicians = Roughly 595 patients per physician

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Physician-CTR Map as of 11/3/18

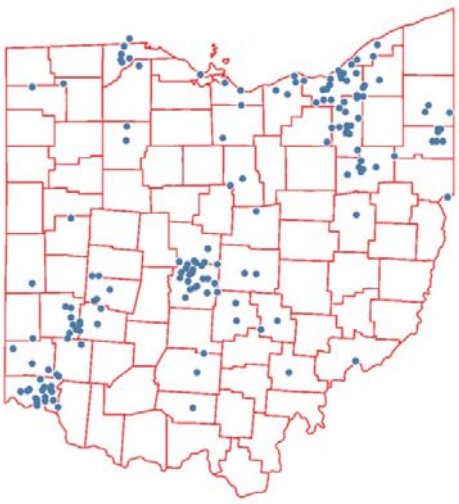

Photo Source: https://www.medicalmarijuana.ohio.gov/Documents/Physicians/Map%20of%20Physicians%20with%20Certificates%20to%20Recommend%20Medical%20Marijuana.pdf

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10

An overview of Ohio's medical marijuana program (continued)

1) Supposed to begin September 2018 → ???

2) "What's the hold up?"
   a. Patient & Caregiver Registry
   b. Testing labs
   c. Product

3) Product availability?
   a. Soon
   b. Limited to plant-material
   c. Slow progression state-wide

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11

An overview of Ohio's medical marijuana program (continued)

1) Authorizes the recommendation, cultivation, processing, sale, and use of marijuana for medical purposes.

2) "Financial institutions" protected from state criminal law liability if serving compliant licensee.

3) Prohibits the disqualification of a patient from medical care or transplant list.

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An overview of Ohio's medical marijuana program (continued)

4) Professional "immunization" from disciplinary action for engaging in professional or occupational activities related to medical marijuana.

5) Patient/caregiver not subject to arrest/criminal prosecution for medical marijuana related conduct.

6) Allows an employer to continue its establishment and enforcement of a drug testing policy, drug-free workplace policy, or zero-tolerance drug policy.

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13

An overview of Ohio's medical marijuana program (continued)

7) Physicians are not required to provide instructions for use (dosages and forms). Look to your "budtender".

8) 21 qualifying medical conditions to get a recommendation.

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14

Qualifying medical conditions:

- AIDs, Alzheimer's disease, Amyotrophic lateral sclerosis; Cancer; Chronic traumatic encephalopathy; Crohn's disease; Epilepsy or another seizure disorder; Fibromyalgia; Glaucoma; Hepatitis C; Inflammatory bowel disease; Multiple sclerosis; Pain that is either of the following: (i) Chronic and severe; (ii) Intractable; Parkinson's disease; positive status for HIV; Post-traumatic stress disorder; Sickle cell anemia; Spinal cord disease or injury; Tourette's syndrome; Traumatic brain injury; and Ulcerative colitis.

O.R.C § 3796.02

15

15

Qualifying medical conditions (continued):

1) What is the number of Ohioans it is estimated have a qualifying medical condition?
   A. 800,000.
   B. 3.5 million.
   C. 5 million.
   D. I am just here for the credit.

2) First petition period just opened (Pennsylvania, NY -- opioids). https://www.wdtn.com/news/local-news/petition-period-open-to-add-more-qualifying-medical-conditions-to-ohio-medical-marijuana-list/1566921956

16

16

The program's components

Applicant difficulties

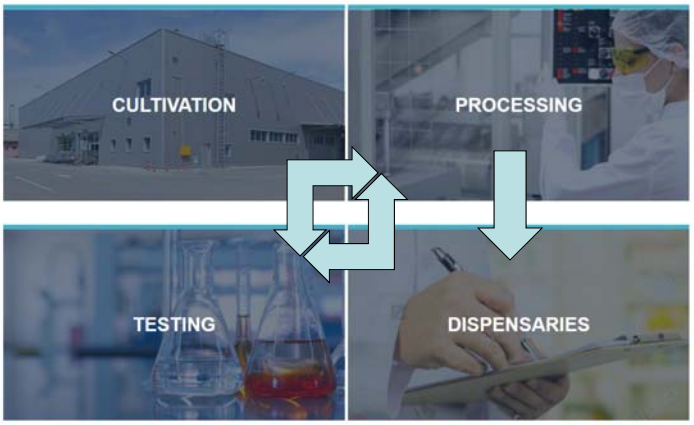

Photo Sources:
https://www.medicalmarijuana.ohio.gov/

17

17

The program's components (continued)

1) Cultivators (24/24)
2) Processors (10/40)
3) Testing Laboratories (5/?)
4) Dispensaries (60/60)

18

18

How will a patient get medical marijuana?

1) Schedule appointment;
2) Be evaluated by physician with certificate to recommend;
3) Be diagnosed with qualifying medical condition;
4) Receive a recommendation and have physician register patient; and
5) Purchase product at dispensary.

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19

The in-person evaluation

1) Physician must:
   a. assess medical history, Rx history;
   b. and SUD history;
   c. review current medications for interactions;
   d. perform physical examination; and
   e. determine whether patient suffers from qualifying medical condition.

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The in-person evaluation (continued)

1) If qualifying medical condition diagnosed (or confirmed), then physician must:
   a. develop treatment;
   b. review OARRS report (review for indicators of possible abuse or diversion);
   c. explain risks and benefits of treatment;
   d. obtain the patient's consent prior to completing a recommendation; and
   e. determine whether patient needs a "caregiver".

21

21

What is a "caregiver"?

1) Authorized to purchase, possess, and administer medical marijuana.
2) Must be 21 years old.
3) Magic number is 2.
4) Future watch: look at Colorado.

22

22

Hospice caregivers

1) Two-patient limitation does not apply if patient's care is being provided in a Hospice program and approval is given from the State Board of Pharmacy. ***O.A.C § 3796:7-2-02.***

2) In other words, this will allow an individual to serve as a caregiver to multiple Hospice program patients.

23

23

Methods of administration

1) No smoking/combustion.

2) Vaporization permitted.

3) Ingestion.

4) Topical.

24

24

Forms of medical marijuana available:

1) Oils;
2) tinctures;
3) plant material;
4) edibles; and
5) patches.

25

25

What about CBD Oil?

1) CBD = Cannabidiol, plant compound found in the cannabis plant

Cannabis plant species

Hemp plants (hemp-derived CBD oil = <.3%THC)

Marijuana plants (MJ-derived CBD oil = .3% THC and more)

2) BOP:
   a. Included in definition of "marijuana."
   b. Restricted sales.
   c. *Compare* Federal Farm-Bill →hemp-derived CBD legal

26

26

What about CBD Oil? (continued)

1) FDA-approvals to be aware of:
   a. Epidolex
      i. Marijuana-derived CBD oral solution
      ii. Seizure treatment for rare forms of epilepsy
      iii. Schedule V (an approved "CBD-drug")

   b. Marinol
      i. Synthetic THC
      ii. Treats nausea/vomiting associated with chemo and weight-loss associated with AIDS.
      iii. Schedule III

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27

Impact of federal law on Ohio's medical marijuana program

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28

The Federal Controlled Substances Act

1) Designates marijuana as Schedule I controlled substance (along with LSD, heroin).
   a. High potential for abuse.
   b. No currently accepted medical use in treatment.
   c. There is a lack of accepted safety for use of the drug under medical supervision.

29

29

What does the Federal Controlled Substances Act prohibit?

1) Pretty much everything that Ohio's medical marijuana law allows.
2) Prohibits possessing, prescribing, distributing, dispensing, and administering marijuana.
3) Prohibits conspiring to violate, and aiding and abetting the violation of, the CSA.
4) Anyone who leases, rents or controls a place where medical marijuana is used can be subject to criminal prosecution, and the forfeiture of assets, such as real property and leasehold interests.

30

30

Legal implications for a violation of the Federal Controlled Substances Act

1) Imprisonment and fines.
2) Loss of federal benefits, contracts, licensure, grants and payments (Medicare/Medicaid enrollment).
3) Loss of federal tax exemption.
4) Loss of industry accreditations.

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Federal enforcement actions against doctors/facilities/patients for violating the Controlled Substances Act

1) 30 jurisdictions with medical marijuana – no examples?
2) Massachusetts doctors crossed line.

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Why has federal law enforcement been so limited?

1) The Rohrabacher Amendment

2) Prescription v. Recommendation

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Restraints on Federal law enforcement - The Rohrabacher Amendment

1) Biggest restraint.

2) Included in federal government's spending bill.

3) Prohibits DOJ from using federal funds to interfere with those strictly complying with a state's medical marijuana law.

4) Must be extended September 30, 2019 (Rohrabacher lost seat).

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Restraints on Federal law enforcement – "Prescription" v. "Recommendation"

1) Ohio physicians will not "prescribe" medical marijuana, they will "recommend" it.

2) Mirrors *Conant v. Walters*, 309 F.3d 629 (9th Cir. 2002) decision.
   a. Federal government cannot prosecute physicians or revoke a DEA license for a recommendation.
   b. First amendment right.
   c. Recommendation may not lead to marijuana usage (legal gymnastics).

35

35

Other important marijuana-related rulings

1) Despite the state legalization of medical marijuana, the federal government has the right to regulate and criminalize the sale and utilization of marijuana. *Gonzalez v. Raich,* 545 U.S. 1 (2005)(holding that Congress did not exceed its authority under the Commerce Clause insofar as the marijuana prohibition applied to personal utilization of marijuana for medical purposes).

2) Inability to deduct business expenses for federal tax purposes. *Olive v. Commissioner of Internal Revenue*, 792 F.3d 1146 (9th Cir. 2015)(dispensary precluded from deductions because business consisted of trafficking controlled substance).

36

36

Important marijuana-related rulings (continued)

3) Inability to seek federal bankruptcy protection. *In re Arenas*, 535 B.R. 845 (B.A.P. 10th Cir. 2015) (while debtors have not engaged in "evil" conduct, they cannot obtain bankruptcy relief because their marijuana business was a federal crime).

4) Forfeiture of assets. *In re Rent-Rite Super Kegs West Ltd.*, 484 B.R. 799 (Bankr. D. Colo. 2012) (debtor and mortgage lender forced to forfeit warehouse property because debtor rented warehouse to marijuana cultivator in violation of CSA which prohibits renting property for manufacturing controlled substance).

37

37

Important marijuana-related rulings (continued)

5) RICO claims successfully brought against cultivators to bring to jury. *Safe Streets Alliance v. Hickenlooper*, 859 F.3d 865, R.I.C.O. Bus. Disp. Guide (CCH) P 12898, 97 Fed. R. Serv. 3d 1641 (10th Cir. 2017) (finding that property owners adequately alleged that the adjacent marijuana growers were engaged in racketeering activity and that their pattern of illegal acts was the direct cause of injuries to their property).

   - November 1, 2018: Jury ruled in favor of grower in RICO suit for noxious odors that allegedly caused property values to decrease.

Source: https://mjbizdaily.com/jury-rules-in-favor-colorado-marijuana-grower-racketeering-lawsuit/?utm_medium=email&utm_source=mjbiz_daily&utm_campaign=MJD_20181101_NEWS_Daily_A_11012018&elqTrackId=227B30918653ECABA6A6D5268D0E2656&elq=016b1d30805e455696d992e9a0d543b8&elqaid=791&elqat=1&elqCampaignId=502

38

38

Status of Attorney General

1) Sessions resigns at request of President Trump on November 7, 2018.
   a. Sessions did not like marijuana (Cole Memorandum).
   b. People who smoke weed are not "good people."
   c. Stocks soared upon resignation (and came back to earth eventually).

39

39

Status of Attorney General (continued)

Photo source: https://www.miaminewtimes.com/news/acting-attorney-general-may-have-fbi-conflict-over-involvement-with-world-patent-patent-marketing-10896679

1) Matthew Whitaker, acting Attorney General
   a. Former Chief of Staff to Sessions
   b. "Acting" – new AG needs to be nominated and confirmed.
   c. Seems anti - praised Iowa's CBD-only medical "marijuana" law and denounced President Obama's limited enforcement of the Controlled Substances Act.

40

40

State and federal law takeaways

1) Even though Ohio law makes medical marijuana legal, federal law reigns supreme and still designates marijuana as illegal.
2) However, the federal government's enforcement of marijuana laws has been limited due to various restraints.
3) This does not mean such enforcement will remain limited, though. "It depends."
4) August 14, 2018 proposed rule – DEA increases amount of "marihuana" grown for federal research by 4,063 pounds. Will expand number of federally licensed marijuana producers.

41

41

Implications for providers: developing an approach to medical marijuana

42

42

Notable health systems involved in medical marijuana

1) Mayo Clinic – Rochester, Minnesota
2) Mount Sinai Hospital – Manhattan, New York
3) University of Pittsburgh Medical Center – Pittsburgh, Pennsylvania
4) Marin General Hospital – Marin, California

43

43

Implications for providers: developing an approach to medical marijuana (continued)

1) Analyze risk tolerance and risk appetite and make organizational decision:
   a. Prohibition?
   b. Permission?
      a. All-out or tailored?
      b. Physicians allowed to get CTR?
2) Develop policies and procedures to effectuate decision.

44

44

Prohibition approach

1) Risk mitigation – federal law compliance (no risk to federal funds).

2) Risk increase:
   a. Can lead to "don't-ask-don't tell."
   b. Utilization outside of POC and without staff knowledge = safety issues
   c. Diversion issues.

3) Optics issues (majority of country in favor).

45

45

Prohibition approach (continued)

1) Zephyrhills Health and Rehab Center

2) Charlotte Simpson – chronic pain patient due to Parkinson's and arthritis.

3) Denied usage

4) Nursing facility cited federal law compliance.

Source: https://merryjane.com/health/florida-nursing-home-denies-medical-marijuana-patient-prescription-access.

46

46

Prohibition approach (continued)

1) Sanford, Maine Hospital
2) Eric Chapman – chronic pain patient due to motorcycle accident.
3) Denied usage
4) Hospital cited federal law compliance.

Source: https://acphospitalist.org/archives/2017/01/marijuana-policies-hospital.htm

47

47

Permission approach

1) Risk increase – federal law compliance issues (risk federal funds)
2) Goal – comply with state law and federal Controlled Substances Act (as best as possible).
3) All-out permission:
   a. Patient self-administration, secured storage, patient access only.
   b. Caregiver-to-patient model.
   c. Physicians with CTR strictly follow law.
4) Tailored permission:
   - Only allow inpatient utilization for certain qualifying medical conditions.

48

48

Permission approach (continued)

1) Hebrew Home at Riverdale

2) Residents are allowed to buy medical marijuana from a dispensary, keep it in locked boxes in their rooms, and take it on their own.

3) The staff is not allowed to buy, store, or administer medical marijuana.

Source: https://www.nytimes.com/2017/02/19/nyregion/retirement-medicinal-marijuana.html.

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49

Implications for providers: developing an approach to medical marijuana (continued)

1) Develop policies and procedures
   - Mitigating factor for federal prosecutors.

2) Develop an informed consent to treat form
   a. The general nature and purpose of treatment.
   b. The expectation of treatment.
   c. The risks and benefits of treatment.
   d. Federal law disclosures.
   e. Work-place consequences.

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50

Implications for providers: developing an approach to medical marijuana (continued)

1) Note:
   a. Patient & Caregiver Registry Access Limited to dispensary employees and CTR-physicians only.
   b. All providers with OARRS access can see patient's full dispensation history.

51

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Implications for providers: developing an approach to medical marijuana (continued)

1) Gather organization to talk about risk tolerance and risk appetite to determine an approach.

2) Make organizational decision before patients show up with medical marijuana or physicians ask about CTR.

3) Implement decision via policies and procedures.

52

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1) Healthlawmattersblog.com
   a. "Ohio Physician's Guide to Cannabis Compliance 2.0: Budding Issues for Ohio's Medical Marijuana Physicians"
   b. "Grandma Wants Special Brownies? Ohio Nursing Facilities Prepare for Medical Marijuana"
   c. "Ohio Physician Alert: Application Available to Become Certified to Recommend Medical Marijuana"
   d. "Ohio Hospitals: Are You Ready for Medical Marijuana?"
   e. "Dramatic Shift in Federal Enforcement Priorities Related to Legalized Marijuana Use"

53

53

Any questions?

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54

54