
# Digital Health Conference

**Tuesday, September 24, 2019**
**8:30 a.m. – 1:00 p.m. CT**

# AGENDA

## Welcome

### Session I – Payers, Providers and Employers – If You Build It, Will They Come?

(8:30 a.m. – 9:30 a.m.)

You've built an innovative product, service or business model certain to disrupt the world of healthcare. But have you cracked the code for selling your innovation to the right buyers? Learn from industry experts who have vetted hundreds of digital health vendors how different constituents in the industry go about screening and choosing digital health offerings.

**Speakers:**
**Brooks Deibele**, *Regional Market Leader, Holmes Murphy & Associates; former President, Commercial Markets, Blue Cross Blue Shield of Minnesota*
**Kevin O'Leary**, *Head of Innovation, Allina Health*
**Jeff Saunders**, *Of Counsel, Dorsey & Whitney,* ***Moderator***

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### Session II – Present at a Distance: Capturing Value in Remote Patient Monitoring

(9:40 a.m. – 10:40 a.m.)

Remote patient monitoring (RPM) sits in a nebulous space: ever-present with the patient, but not quite as "present" as a virtual visit. The market is exploding with devices, apps, and service companies. How can providers and RPM companies be of best service to the patients and capture value as a company? What types of partnerships should be explored, and what key liability risks should be weighed? Join us as we delve into these and other business and legal considerations.

**Speakers:**
**Greg Anthony**, *Assoc. Administrator, Mayo Clinic Center for Connected Care*
**Harsh Dharwad**, *Chief Technology Officer, Nihon Kohen America*
**Meghan DesLauriers**, *Partner, Dorsey & Whitney*
**Shira Hauschen**, *Managing Principal, Dorsey Health Strategies*, ***Moderator***

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**Session III – Delivering Value in Behavioral Health Through the Use of Data and Technology**
(10:50 a.m. – 11:50 a.m.)

Behavioral health disorders can have a tremendous impact on people's lives, and, in fact, are a leading cause of disability. Behavioral health has been called the greatest unaddressed problem in healthcare today. At the same time, access to behavioral health services, and societal stigma about mental health, can create significant barriers to people getting the help that they need. This session will highlight two companies, AiRCare Health and Sanvello, that have developed tools, using technology and data analytics, to create solutions.

**Speakers:**
**Monika Roots**, *Chief Medical Officer, Sanvello*
**Jaclyn Wainwright**, *Chief Executive Officer, AiRCare Health*
**Ross D'Emanuele**, *Partner, Dorsey & Whitney*
**Alissa Smith**, *Partner, Dorsey & Whitney,* ***Moderator***

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**Session IV – Lunch and Learn: IP Protection for Digital Health Innovation**
(12:00 Noon – 1:00 p.m.)

Digital health technology has many applications from monitoring and analysis to communications and data management – and it employs almost as many types of innovation – from molecular diagnostics to artificial intelligence. Nearly all of it can be protected. But what, exactly, is protectable and how do you go about it? These are the questions we hear often. In this Lunch & Learn, we will review the different types of protection available to the digital health professional. We will also cover some of the recent changes in patent law that affect the industry.

**Brad Hattenbach**, *Of Counsel, Dorsey & Whitney*
**Matt Jonsen**, *Partner, Dorsey & Whitney*

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## SPEAKER BIOS

### Session I – Payers, Providers and Employers – If You Build It, Will They Come?

**Brooks Deibele**
*Regional Market Leader*
*Holmes Murphy & Associates*

Brooks is the Regional Market Leader of Employee Benefits for Holmes Murphy and is based in the Minneapolis, Minnesota office. In his role, Brooks is responsible for leading the EB Practice for the region, where he and his team partner with employers to develop unique employee benefits services and strategies that are tailored to their specific needs. Prior to joining Holmes Murphy, Brooks spent six years at Blue Cross and Blue Shield of Minnesota, where he served as President of Commercial Markets. In this role, Brooks was responsible for BCBS's business in the commercial segment, which included national corporations, large and small employers, public sector groups, labor unions, and ancillary business segments. Additionally, he oversaw the development and management of all commercial products and services, as well as led the commercial segment's distribution and market engagement strategies. Prior to Blue Cross, Brooks spent 10 years at United Healthcare in various national and regional leadership roles in the organization's employer and individual division.

**Charles Montreuil**
*Senior Vice President for Human Resources Rewards*
*Best Buy*

Charles is Senior Vice President of Human Resources at Best Buy. He oversees Compensation, Benefits, HR Communications, HR Operations and HR Technology for the organization, which employs more than 120,000 employees. Since joining Best Buy in 2008, he and his team have managed the executive compensation strategy, raised base pay for hourly employees and have enhanced employee benefits by introducing several innovative programs including paid care giver leave and mental well-being resources. Charles is the executive sponsor of Best Buy's employee wellness group. Prior to joining Best Buy, he held several HR positions at Carlson Companies, which, at the time, included TGI Friday's, Carlson Wagonlit Travel and the Radisson Hotels.

**Kevin O'Leary**
*Head of Innovation*
*Allina Health*

Kevin currently leads innovation for Allina Health, focused on managing Allina's venture capital investments, developing new concepts internally, and integrating external ideas into the organization. Prior to Allina, Kevin led data analytics and population health for Harken Health, a health insurance startup backed by UnitedHealth Group. Kevin also founded a cardiology-focused digital therapeutic startup and started his career working in Piper Jaffray's medical device investment banking group.

**Jeff Saunders**
*Of Counsel*
*Dorsey & Whitney LLP*
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*612.492.6128*

Jeff is a member of Dorsey's Corporate group. His practice includes acting as a trusted advisor to clients in a number of industries, with a primary focus on companies in the healthcare and information technology industries. Jeff has extensive experience across the spectrum of the healthcare supply chain, from medical device and pharmaceutical manufacturers, to healthcare technology and service providers, and helped pioneer the development of consumer-driven and wellness products and services in the healthcare benefits area. He has also held business development and operational roles in the digital health arena and has served on boards of directors of several healthcare services and benefits companies.

## Session II –Present at a Distance: Capturing Value in Remote Patient Monitoring

**Greg Anthony**
*Assoc. Administrator*
*Mayo Clinic Center for Connected Care*

Greg is the Associate Administrator for the Mayo Clinic Center for Connected Care, which is focused on design, development, implementation, and ongoing management of the delivery of digital tools to connect patients and providers at a distance. The Center for Connected Care has comprehensive responsibility for all asynchronous, synchronous and remote patient monitoring solutions across both web and mobile platforms for all Mayo Clinic sites. Mayo Clinic has been an early leader in the Open Notes concept as part of its patient portal development and has designed and developed the Mayo Clinic App, an award winning patient and consumer facing app. Greg has served in leadership roles across a variety of clinical practice specialties through-out his 30 year career at Mayo Clinic as well as partnered closely with colleagues in Research & Education to help facilitate, coordinate, and integrate services to patients, students, and employees.

**Harsh Dharwad**
*Chief Technology Officer*
*Nihon Kohden America*

Harsh is an experienced global technology leader who is passionate about solving healthcare challenges with technological solutions that make a difference in the lives of patients and clinicians. He excels at simplifying complex problems, building high performing cultures and empowering teams to execute the vision of an organization. Harsh is currently the chief technology officer of Nihon Kohden America, where he provides strategic leadership and direction for creating patient data acquisition and management systems that reduce costs, improve quality and increase access to healthcare. Prior to Nihon Kohden, Harsh was director of software development at Pfizer, where he oversaw the development of infusion pump technology and value-added software applications, as well as kick-started an initiative focused on innovation and pipeline development. He worked previously at Hospira as the general manager responsible for leading an R&D site. Harsh has also held technical management positions at companies including Siemens and Philips.

**Meghan DesLauriers**
*Partner*
*Dorsey & Whitney LLP*
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Meghan's practice involves complex business litigation, with a special emphasis on healthcare matters. In addition to representing clients in a broad array of general business lawsuits, Meghan specializes in healthcare litigation – representing health systems, medical clinics, individual providers, insurance companies, telemedicine entities, certification bodies, and professional medical associations. She has successfully assisted corporations and non-profit companies on all sides of legal disputes, and has significant experience addressing international legal issues.

**Shira Hauschen**
*Managing Principal*
*Dorsey Health Strategies LLC*
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Shira has specialized in healthcare and particularly digital health for over 12 years and draws on her experience at Epic Systems Corp., McKinsey & Co., and as Director of Operations for a local telehealth company prior to her tenure at Dorsey. Shira is Managing Principal of Dorsey Health Strategies; together with her team members, she provides business consulting services to health industry clients on a range of healthcare topics, including business strategy, project management, go-to-market strategy, and compliance. She has advised clients on a wide array of digital health topics, including compliance with the patchwork of federal and state laws pertaining to digital health, implications for staffing and scaling up across states, business model development, strategic planning, Big Data, privacy compliance, and launching digital health initiatives. As a licensed attorney and via the integrated approach taken by Dorsey's Healthcare Industry Group, Shira's business consulting advice is attuned to clients' legal landscape.

## Session III – Delivering Value in Behavioral Health Through the Use of Data and Technology

**Monika Roots**
*Chief Medical Officer*
*Sanvello*

Dr. Roots is a child, adolescent and adult psychiatrist, and is the Chief Medical Officer of Sanvello Health, a virtual mental health care company. She is also a Clinical Adjunct Assistant Professor at the University of Wisconsin-Madison. Previously, Dr. Roots was the Chief Medical Officer of CogCubed, a behavioral health analytic company. Teladoc acquired the company in 2016, and most recently, she was the Vice President of Health Services and Behavioral Health for Teladoc Health. Dr. Roots earned her medical doctorate from the University of Sint Eustatius School of Medicine and completed her psychiatry residency and fellowship in child/adolescent psychiatry at the University of Minnesota.

**Jaclyn Wainwright**
*Chief Executive Officer*
*AiRCare Health*

Jaclyn is an international behavioral health expert, and the CEO of AiRCare Health. She is challenging the status quo over how our system is failing to provide effective treatment for mental health disorders. AiRCare's unique approach combines both the heart of clinical care management and the science of AI and machine learning to transform the health of large populations. Over the past five years she has thoughtfully led AiRCare to success in a new marketplace, building and delivering clinical programming that results in dramatically better long-term health outcomes and significantly lower costs for employers and health plans. She has built strategic partnerships with providers, brokers, and data scientists and serves as a behavioral health subject matter expert for Microsoft's Global Industry Leaders Program.

**Ross D'Emanuele**
*Partner*
*Dorsey & Whitney LLP*
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Ross is committed to translating a complex healthcare regulatory environment into practical and concrete advice for his clients. Ross works in the healthcare provider, payor, and drug and medical device segments of the healthcare industry. His areas of expertise include healthcare fraud and abuse, Stark and anti-kickback laws, HIPAA and other privacy and security laws, reimbursement rules and appeals, clinical trial agreements and regulation, FDA regulation, open payments and state "Sunshine Act" laws, accountable care organizations, value-based reimbursement, and telemedicine.

**Alissa Smith**
*Partner*
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Alissa helps healthcare organizations complete strategic transactions and address a wide range of regulatory matters that affect their business. She represents health systems, hospitals, pharmacies, specialty pharmacies, wholesale distributors, pharmacy benefit managers, long-term care providers, vendors in the healthcare industry, home health agencies, medical practices, individual providers, as well as nonprofit and other organizations in the healthcare industry. Alissa's practice involves health law transactional work, federal and state health law regulatory compliance advice, and administrative advocacy before state and federal agencies. She also assists with corporate and health system governance issues and with hospital-provider relations.

## Session IV – Lunch and Learn: IP Protection for Digital Health Innovation

**Brad Hattenbach**
*Of Counsel*
*Dorsey & Whitney LLP*
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Brad helps clients strategically consider their technology, business goals, and markets to craft IP protection strategies that make sense in terms of their stage and budget. These strategies include collaboratively developing and managing U.S. and worldwide portfolios of patent and trademark registrations, providing pre-market product design clearance, analyzing potential acquisition portfolios, and negotiating technology licensing agreements. He also often assists in providing patent expertise and analysis in litigation or administrative actions when clients find themselves accused of infringement or determine it necessary to enforce their patents.

**Matt Jonsen**
*Partner*
*Dorsey & Whitney LLP*
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Matt is a partner in Dorsey's Chem/Bio Practice, where he uses his research experience in genetics, molecular biology, and oncology to help shepherd his client's technologies from the R&D stage through to issued patents. Matt's clients include established and emerging companies and research universities focused on diverse fields, including biopharmaceuticals, stem cell preservation and therapies, medical devices, DNA sequencing, human genetics, cannabis, animal husbandry, and renewable energy. With his deep biotech background, Matt helps develop and manage patent portfolios, and he provides strategic counseling relating to patent and trade secret protection, diligence, transfer, acquisition, and licensing. Matt has experience protecting clients' portfolios in the United States and more than 50 countries world-wide.


## Third Annual Digital Health Conference

# Session I: Payers, Providers and Employers – If You Build It, Will They Come?

**September 24, 2019**

**Brooks Deibele**, *Regional Market Leader, Holmes Murphy & Associates; former President, Commercial Markets, Blue Cross Blue Shield of Minnesota*
**Charles Montreuil**, *Senior Vice President for Human Resources Rewards, Best Buy*
**Kevin O'Leary**, *Head of Innovation, Allina Health*
**Jeff Saunders**, *Of Counsel, Dorsey & Whitney*

## Session Materials:


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Session I
Payers, Providers and Employers –
If You Build It, Will They Come?
Brooks Deibele, Regional Market Leader, Holmes Murphy & Associates; former President, Commercial Markets, Blue Cross Blue Shield of Minnesota
Charles Montreuil, Senior Vice President for Human Resources Rewards, Best Buy
Kevin O'Leary, Head of Innovation, Allina Health
Moderator: Jeff Saunders, Of Counsel, Dorsey & Whitney
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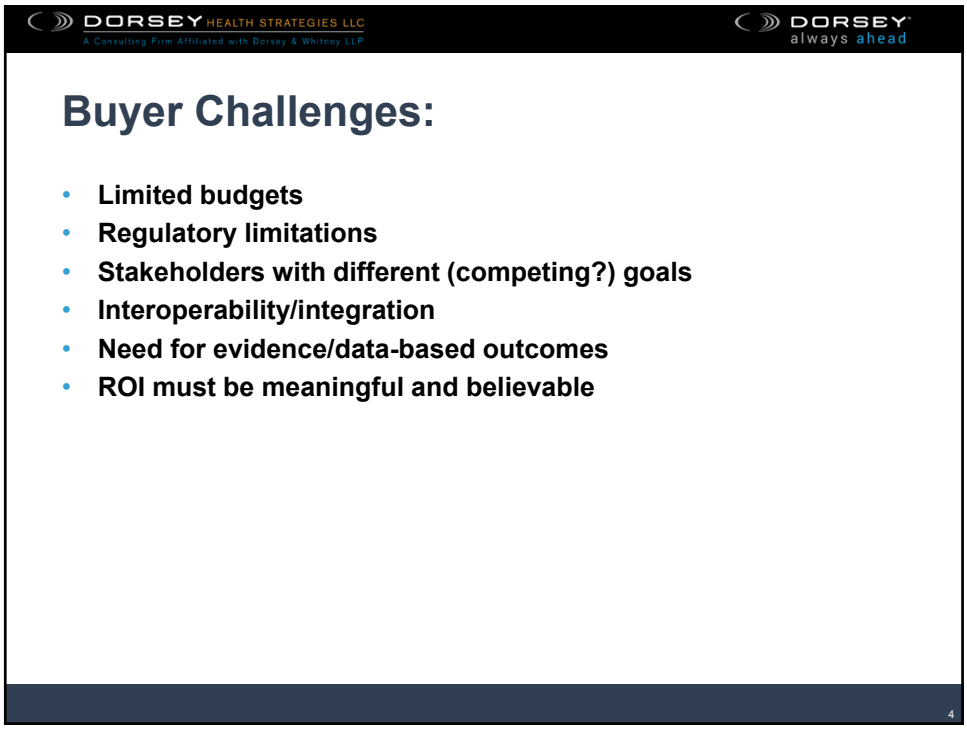
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Buyer Challenges:
Limited budgets
Regulatory limitations
Stakeholders with different (competing?) goals
Interoperability/integration
Need for evidence/data-based outcomes
ROI must be meaningful and believable
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# Top 5 Tips

## 1. Know your decision maker(s) and champions

- There are always several stakeholders
- Understand and speak to their specific motivations
- If your contact can't describe how buy decisions are made, you're talking to the wrong person

- Types of internal buyers
  - Technical (CTO)
  - Financial (CFO)
  - User (benefits; clinicians)
- Which is your champion?
- Which is the decision maker?
- Build a consensus by appealing to the motives and pain points of each

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# Top 5 Tips

## 2. Prepare for a long sales cycle

- Bureaucracies involve multiple stakeholders and move slowly

- Maintain relationships
  - Stay in touch
  - Make each interaction relevant

- Provide champions with selling tools
  - ROI documentation
  - Case studies
  - Implementation Plan

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# Top 5 Tips

## 3. Prove ROI

- Have a trustworthy methodology for measuring ROI
- Provide compelling data on engagement with your product or service
- Have case studies and data showing that your solution actually delivers desired outcomes (e.g., statistical analysis shows that it is your solution that is driving outcomes)

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# Top 5 Tips

## 4. Listen to your early adopters

- Solicit feedback from customers and users
- Their feedback will help inform whether to:
  - Iterate solution
  - Modify business model

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# Top 5 Tips

## 5. Use ≠ Engagement

- An app may have users, but that does not equate to actual, meaningful engagement by the user
- Define exactly what you mean when you talk about engagement with your solution
- At the high level, "engagement" should mean that the user is engaging in a specific set of activities and, therefore, changing behavior

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# Questions?


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**September 16, 2019**

# Breathing Room? California Legislature Passes Two Major Amendments to California Consumer Privacy Act (CCPA)

**Jamie Nafziger and Divya Gupta**

Businesses may receive a bit of breathing room as a result of two amendments to the California Consumer Privacy Act (CCPA) passed on Friday, September 13, 2019, by the California Legislature. The Legislature gave businesses a one-year moratorium on two significant aspects of the law: its application to employees, job applicants, owners, officers, directors, medical staff members, and contractors; and its application to business-to-business transactions. The Governor has until October 13, 2019, to sign or reject the amendments. Although the amendments provide some of the needed clarifications and error corrections and a significant break from needing to respond to certain data subject requests from employees and B2B contacts, businesses will still need to complete their data mapping (even for these categories of consumers) and will still need to be prepared to offer the rights not exempted on January 1, 2020, even if these amendments are signed by the Governor.

For those following the process, five bills passed the Legislature: AB 25, AB 874, AB 1146, AB 1355, and AB 1564. Proposed amendment AB 846 on loyalty programs was shelved. In addition to the two widely applicable amendments about employees and business-to-business transactions discussed in detail below, the Legislature also passed a number of minor or narrowly applicable amendments. The amendments amount to 98 pages of printed material. We will cover only the more significant of them in this article.

The employment-related amendments in AB 25 exempt businesses from many of the CCPA's requirements for one year when applied to employees, job applicants, owners, officers, directors, medical staff members, and contractors "to the extent that the natural person's personal information is collected and used by the business solely within the context of the natural person's role or former role as a job applicant to, an employee of, owner of, director of, officer of, medical staff member of, or a contractor of that business" (emphasis added). The amendment also covers certain use of personal information in the context of emergency contact information and benefits administration.

If AB 25 is signed by the Governor, two CCPA requirements will still apply to these types of individuals when collected and used in this context: (1) the requirements to inform them about the categories of personal information collected and the purposes for which the personal information will be used in 1798.100(b) and (2) the right to sue in a private right of action after a data breach in 1798.150. This would mean the other consumer rights to deletion, access, opt-out of selling, and no price discrimination would not apply in this context for one year (until January 1, 2021). This will be a welcome change to most businesses, to the extent it gives them a break from the experience EU businesses have had responding to data subject requests from employees, ex-employees and job applicants in Europe since the General Data Protection Regulation (GDPR) became effective. Unfortunately, even if this amendment becomes law, businesses will still need to complete their data mapping and draft disclosures in connection with the information of employees, job applicants, owners, officers, directors, medical staff members, and contractors.

The business-to-business (B2B) moratorium in AB 1355 would exempt businesses from many of the CCPA's requirements for one year when applied to "personal information reflecting a written or verbal communication or a transaction between the business and the consumer, where the consumer is a natural person who is acting as an employee, owner, director, officer, or contractor of a company, partnership, sole proprietorship, nonprofit, or

government agency and whose communications or transaction with the business occur solely within the context of the business conducting due diligence regarding, or providing or receiving a product or service to or from such company, partnership, sole proprietorship, nonprofit or government agency" (emphasis added).

The B2B moratorium would not apply to collection or use of personal information outside of the context described in this amendment, to the right to opt-out of "selling" in 1798.120, to the price discrimination provisions of 1798.125, or to the right to sue in a private right of action after a data breach in 1798.150. If this amendment is signed into law, businesses will have a break until January 1, 2021, in the requirements of notice, deletion, access, information about onward disclosures, the opt-out link and the means for exercising consumer rights when it comes to B2B diligence or product/service provision or receipt. This means businesses would still need to complete their data inventories of information received in a B2B context, be prepared to respond to opt-out requests, and apply all other sections of the CCPA to uses of B2B personal information outside of the diligence or transaction itself (such as marketing uses).

Other important amendments include:

- Clarifications regarding authentication of data subject requests in AB 25;
- Changes to language regarding methods for submitting data subject requests in AB 1564;
- Changes to exempt certain vehicle-related information from the right to opt-out from selling in AB 1146;
- Changes to exempt certain warranty and product recall information from the right to deletion in AB 1146;
- Changes to the definition of "personal information" in connection with the reasonability of associating information with a particular consumer or household, with the definition of "publicly available," and with the applicability to deidentified or aggregate consumer information in AB 874;
- Correction of errors in the price discrimination section 1798.120 about "value provided to the consumer" versus "value provided to the business" in AB 1355;
- Clarification regarding impact of encrypting and redacting personal information on civil right of action in AB 1355;
- Changes to the exemption regarding consumer credit and related information in AB 1355; and
- Error corrections in 1798.110(c) regarding privacy notice requirements and in 1798.115(a)(2) regarding right to know in AB 1355.

If these amendments are signed by Governor Newsom by October 13, 2019, they will provide a one-year extension in connection with some provisions of the CCPA. However, the majority of the provisions related to consumer privacy will still be in effect. No fundamental rights have been removed from the CCPA. Businesses will need to continue their compliance efforts with focused intensity over the next several months. We will provide updates regarding the Governor's actions and the California Attorney General's regulatory guidance as they become available.

The completed legislative session gives businesses a clearer understanding of the CCPA's obligations (subject of course to signature by Governor Newsom). For those companies not previously required to comply with the European Union's GDPR, this may pose significant operational and technical challenges. Dorsey has developed fixed fee packages to help clients on their CCPA compliance journey, a simple screening tool (**https://www.dorsey.com/services/ccpa**) which is publicly available to help companies understand whether the CCPA affects them, and a more comprehensive online self-assessment tool for our clients, which can be requested by emailing Dorsey at **CCPA.Assessment@dorsey.com**.

**September 12, 2019**

# CCPA Requires "Reasonable Security": But You Can't have Reasonable Security Without Proper Vulnerability Management

**Divya Gupta and Cody Wamsley, CISSP**

With the California Consumer Privacy Act ("CCPA") set to take effect on January 1, 2020, and the resulting looming specter of statutory damages and data breach class action litigation for failure to implement "reasonable security" on the near horizon, reducing or mitigating the harms that result from such cyber-attacks is more important than ever. Since 2015, more than three in five Californians have been a victim of a data breach, making implementation of reasonable security controls now a critical and necessary component of CCPA compliance.[1] While the retail industry has had record breaking breaches from malware and hacking, especially with card data, no industry is risk free when it comes to adequate data security.

Managing or mitigating risk, however, requires implementing "reasonable security," which derives from the Center for Internet Security's Top 20 Critical Security Controls (CSC 20) per then California Attorney General in 2016, Kamala Harris. In California's 2016 Data Breach Report, Harris stated that "[The CSC 20] are the priority actions that should be taken as the starting point of a comprehensive program to provide reasonable security."[2] Recommendation 1 of the same report is more explicit:

> The 20 controls in the Center for Internet Security's Critical Security Controls identify a minimum level of information security that all organizations that collect or maintain personal information should meet. **The failure to implement all the Controls that apply to an organization's environment constitutes a lack of reasonable security.** (emphasis added).

Based on these statements, the CSC 20 likely comprise a defensive list to detect, prevent, respond to, and mitigate security incidents, and are designed to address various domains of information security to provide organizations with a roadmap to achieve resiliency. Whether the CSC 20 will become the explicit standard for "reasonable security" is still an open question, but given the California AG's previous statements, these controls should be top-of-mind for any organization that seeks to avoid significant liability under the CCPA.

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1 See California's 2016 Data Breach Report, available at https://oag.ca.gov/sites/all/files/agweb/pdfs/dbr/2016-data-breach-report.pdf.

2 https://oag.ca.gov/sites/all/files/agweb/pdfs/dbr/2016-data-breach-report.pdf.

The CSC 20 is broken down into three main categories of controls: Basic, Foundational, and Organizational. The total scope of the CSC 20 is beyond the scope of this article, but suffice it to say that an organization may be hard-pressed to assert that it has "reasonable security" in place if it does not at least adhere to the Basic controls. The Basic controls consist of the following six items:

1. Inventory and Control of Hardware Assets
2. Inventory and Control of Software Assets
3. Continuous Vulnerability Management
4. Controlled Use of Administrative Privileges
5. Secure Configuration for Hardware and Software on Mobile Devices, Laptops, Workstations and Servers
6. Maintenance, Monitoring and Analysis of Audit Logs

Of these six Basic controls, #3, Continuous Vulnerability Management, stands out as one of the most important for an organization to focus on to prevent data breaches. According to a recent study, nearly 60% of recent data breaches were the result of unpatched vulnerabilities.[3] Indeed, the California AG stated that "patching newly discovered security vulnerabilities is critical" while citing the related CSC 20 control. In the last few years, the importance of vulnerability management has become more apparent and this control has risen to become the #3 control in the CSC 20.

Vulnerability management's main purpose is to identify and remedy software vulnerabilities as quickly as possible. It often doesn't take any significant skill on an attacker's part to exploit published vulnerabilities and so once a software vendor releases a patch, knowledge of its associated vulnerability quickly becomes widespread and the race is on between organizations deploying patches and attackers attempting to exploit the vulnerability. Organizations that do not scan for and proactively address vulnerabilities are at great risk for a breach.

Patching software security is a no-brainer, or so you'd think. Well, the challenge lies in the scale of the organization, the effect a patch could have on other organization systems, and the attacker's ability to quickly weaponize ahead of scheduled patch rollouts, among other things. To properly implement vulnerability management may not be as easy as we'd like, but it is critical and low-hanging fruit on the CSC 20 tree.

The European Union deems privacy a fundamental human right, and is taking enforcement seriously -- think Marriott and British Airways GDPR fines. We expect to see similar, if not greater, liability for organizations that violate the upcoming CCPA. Organizations that haven't yet automated the process to monitor for and remediate vulnerabilities on networks and systems should do so now and should institute vulnerability and patch management policies. While all of the CSC 20 controls are important, perhaps the most effective solution to prevent a major data breach for any organization lies in assessing and managing known vulnerabilities. Modernizing

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3 https://www.darkreading.com/vulnerabilities---threats/unpatched-vulnerabilities-the-source-of-most-data-breaches/d/d-id/1331465.

vulnerability management programs should be a focus in the short term run up to January 1, 2020 effective date.

Dorsey's Cybersecurity and Privacy Team has developed a catalog of security practices and procedures to help achieve operational resilience and defend companies from the forthcoming wave of data breach litigation. Notably, Dorsey has partnered with leading technical security industry organizations to offer full service advice.[4]

**Additional references:**

https://www.us-cert.gov/sites/default/files/c3vp/crr_resources_guides/CRR_Resource_Guide-VM.pdf

https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-40r3.pdf

https://www.sans.org/reading-room/whitepapers/threats/implementing-vulnerability-management-process-34180

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4 https://www.dorsey.com/services/cybersecurity-privacy-social-media.

**April 22, 2019**

# CMS's New "Primary Cares Initiative" Places Primary Care at the Center of the Shift to Value-Based Care

**Kristen Barlow and Alissa Smith**

**On April 22, 2019, the Centers for Medicare and Medicaid Services (CMS) announced two sweeping new payment innovation models under the Primary Cares Initiatives. The models will seek to incentivize primary care and other providers to take on greater responsibility and risk for the lives of covered beneficiaries. Both new models are scheduled to be effective for a first performance year of 2020. Read on for key details of the models, projected impact on the Medicare patient population, and our key takeaways for providers.**

**Primary Care First Model provides simplified payments with performance-based adjustments**

**The first model is Primary Care First (PCF), and include two options:**

- **PCF – General. Participating practices will assume financial risk for aligned beneficiaries and, in exchange, the practices will have reduced administrative burdens and will be eligible for performance-based payments or downside risk.**

- **PCF – High Needs Populations. Participating practices will assume financial responsibility for high-need, seriously ill beneficiaries who lack a primary care provider or effective care coordination, and, in exchange, the practices will have higher payment amounts as well as eligibility for performance-based payments or downside risk.**

**PCF – General will provide payment to practices through a simplified payment structure that will provide a population-based payment along with a flat primary care visit fee and a performance-based adjustment providing an upside of up to 50% of revenue as well as a small downside (10% of revenue) incentive to reduce costs and improve quality. The performance-based adjustment will be assessed and paid on a quarterly basis. PCF – High Needs Population will set higher payment amounts to reflect the high-need, high-risk nature of the population as well as a yet-to-be-specified increase or decrease in payment based on quality measures.**

**PCF is open to a range of eligible applicants, including primary care practitioners certified in internal medicine, general medicine, geriatric medicine, family medicine, and hospice and palliative care medicine.**

**Applications for both PCF options will open soon- in Spring 2019, and the model will launch in 26 regions in the U.S. beginning in 2020 and will continue for five years.**

**Direct Contracting Model permits providers to take on greater shared savings/shared losses up to full risk**

**The second model is Direct Contracting (DC), and includes three options:**

- **DC – Professional. Providers will bear risk for 50% of shared savings/shared losses on the total cost of care (all Part A and B services) for aligned beneficiaries. Participants will receive Primary Care Capitation, a capitated, risk-adjusted monthly payment for enhanced primary care services equal to seven percent of the total cost of care for enhanced primary care services.**

- **DC – Global. Participating entities will bear risk for 100% of shared savings/shared losses on the total cost of care (all Part A and B services) for aligned beneficiaries. Participants may receive Primary Care Capitation as described above or may choose to receive Total Care Capitation, a capitated, risk-adjusted monthly payment for all services provided by participants and preferred providers with whom the participant has an agreement.**

- **DC – Geographic. Participating entities will bear risk for 100% of shared savings/shared losses on the total cost of care (all Part A and B services) for aligned beneficiaries in a target region. Participants will be selected as part of a competitive application process and commit to providing CMS a specified discount amount off of the total cost of care for the defined target region. This option will offer a Total Care Capitation payment as well, where CMS will continue to pay claims for services furnished by providers outside of the participants, including outside the target regions. Alternatively, participants can assume full financial risk while having CMS continue to make fee-for-service claims payments to all providers in the target region.**

**The DC model is open to a broad range of entities, including health plans, health care technology companies, ACOs, and others operating under a common governance structure.**

**The DC model will start in January 2020 with an initial alignment year for organizations that want to align beneficiaries to meet the minimum beneficiary requirements. Performance periods will begin in 2021 and continue for five years.**

**CMS has issued a request for information (RFI seeking public comment on the DC-Geographic model, but nonetheless plans to launch the model in 2021.**

**CMS anticipates shifting a quarter of beneficiaries out of fee-for-service (FFS) under the new models**

**CMS anticipates that together, PCF and DC will:**

- **Shift over 25% of all Medicare FFS beneficiaries out of FFS and into value-based care arrangements;**

- **Offer new participation and payment options and opportunities for 25% of primary care practitioners and other providers; and**

- **Create new coordinated care opportunities for a large portion of the 11-12 million dual eligible beneficiaries in the U.S., specifically those in Medicaid managed care and Medicare FFS.**

**Key Takeaways**

**As we wait for additional details from CMS about the structure and payment mechanisms under both PCF and DC models, the following are a few key takeaways to keep in mind:**

- **CMS is committed to voluntary risk-based payment models. After experimenting with mandatory risk-based payment under the Comprehensive Care for Joint Replacement (CJR) bundled payment model and the proposed, but ultimately cancelled, Episode Payment Models (EPMs) for cardiac and orthopedic bundles, CMS has moved away (for now) from mandatory risk for providers. However, it appears that voluntary risk-based programs are here to stay. As these voluntary payment models are introduced, participants have opportunities to receive substantial gains (the full risk models of DC – Global and DC-Geographic, for example) if they have the appetite to bear the concurrent substantial downside risk.**

- **CMS's pace indicates more reform likely to come. The Primary Cares Initiative announcement comes on the heels of the Pathways to Success model, an overhaul of the ACO program which was finalized in December 2018, and the BPCI Advanced bundled payment program, which launched in October 2018. In short, CMS is evaluating its existing models, creating new models, and the pace of change is faster than it has been since the slate of mandatory bundled payment programs were announced in 2016 through 2017. Going forward, the industry should expect this pace of new and revised payment models to continue, not lessen. In fact, Adam Boehler, the director of Centers for Medicare and Medicaid Innovation (CMMI), the part of Medicare that develops and administers payment reform programs, gave a speech in early April 2019 that raised the prospect of a new bundled payment program focused on post-acute care providers, which would be a first of its kind and one that those in the post-acute industry are anxiously awaiting.**

- **Physicians are increasingly the "owners" of the transition to value. For many, there's long been a debate about who should "own" the transition away from fee-for-service toward value-based care. While CMS certainly has targeted acute-care providers for this ownership under ACOs and bundled payment models, physicians have of course been a crucial participant in those programs. Notably, the Primary Care Initiatives place the physician front and center of owning responsibility for the cost and quality of their patients' care – an acknowledgement from CMS that primary care providers and close patient interaction are linchpins for sustained success in transitioning toward better outcomes for the health of a population.**

- **The focus on chronic and serious illness highlights a persistent problem for Medicare in controlling spending. As the population ages, success in controlling spending overall**

**may ultimately come down to targeted efforts to better support and manage the chronically and seriously ill patient populations. While just 17% of Medicare patients live with six or more chronic conditions, they account for half of all spending on Medicare beneficiaries with chronic disease. Moreover, a full quarter of all Medicare spending is spent on Medicare beneficiaries in their last year of life. Including hospice and palliative care physicians in the PCF model, and having an entire model option dedicated to the seriously ill patient population, are clear signs from Medicare that they want to focus on programs and models that may move the dial on this patient population whose health care is notoriously difficult to manage.**

**To learn more about this model, or to discuss how it may impact your organization, please contact smith.alissa@dorsey.com or your regular attorney at Dorsey &Whitney.**

**January 11, 2019**

# FDA Testing New Approaches for Review of Digital Health Device Applications

**Alex Stoflet & Claire H. Topp**

**On January 7, 2019, FDA Commissioner Scott Gottlieb announced significant updates to the FDA's pilot Software Pre-Certification Program, sometimes referred to more broadly as a Digital Health Pre-Certification Program ("Pre-Cert").**

**Pre-Cert was originally announced in 2017 as part of the FDA's Digital Health Innovation Action Plan. The FDA envisions the program as a streamlined process for bringing digital health technologies to market. More specifically, the FDA hopes to develop Pre-Cert into a program by which certain digital health developers can become precertified as part of an "Excellence Appraisal." Excellence-appraised developers could then take advantage of streamlined premarket submission processes for their digital devices. To date, the FDA has been working with a variety of stakeholders, including nine companies "represent[ing] a wide range of companies and technology in the digital health sector," in developing the program.**

**In connection with the announcement earlier this week, the FDA issued "three documents that, together, launch us into the next phase of the agency's vision of Pre-Cert."**

**The first of the three documents is a Regulatory Framework for Conducting the Pilot Program within Current Authorities (the "Framework"). This document builds out the regulatory framework within which the FDA will implement Pre-Cert. Here are some highlights:**

- **At least to start, Pre-Cert is limited to software as a medical device ("SaMD"), defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. The FDA hopes eventually to expand the program to review all medical device software products, including software in a medical device ("SiMD") and other software that could be considered accessories to hardware medical devices.**

- **The FDA intends to utilize the De Novo classification process (section 513(f)(2) of the FD&C Act), an existing pathway for certain new types of low to moderate risk devices to obtain marketing authorization as a Class I or Class II device as opposed to automatic Class III designation, for the next phase of Pre-Cert. Here is an overview of the proposed process:**

- **Participants with a SaMD product may participate in an Excellence Appraisal, as well as an optional Review Determination Pre-Submission. When submitting a product for De Novo Review, an excellence-appraised developer would submit a streamlined "Pre-Cert De Novo Request," in which it would not need to re-submit information reviewed during the Excellence Appraisal or the optional Pre-Submission. Assuming premarket requirements are met, the FDA would classify the device by written order and, if the device is Class II, establish special controls, which may include Excellence Appraisal elements and postmarket data collection elements.**

- **Following a De Novo order, an excellence-appraised developer would also be able to take advantage of a streamlined "Pre-Cert 510(k)" process, in which the developer can again leverage submission requirements already documented during the Excellence Appraisal and optional Pre-Submission process. The FDA expects review of a Pre-Cert 510(k) to be more efficient than the review of a traditional 510(k). The Pre-Cert 510(k) can also be used for modifications to devices, assuming a 510(k) is required for the modification.**

**The second document is a 2019 Test Plan (the "Test Plan"). The Test Plan lays out the scope and approach of the Pre-Cert pilot in 2019. The primary purpose of the Test Plan "is to assess whether the Excellence Appraisal and Streamlined Review components together produce an equivalent basis for determining reasonable assurance of safety and effectiveness for a SaMD product… as compared to the traditional paradigm." Here are some highlights:**

- **Consistent with the Framework, the scope of the Test Plan is limited to: (i) selected SaMD with De Novo Requests, and (ii) selected 510(k) submissions, which would be tested as if they were follow-on 510(k)s for devices classified through a Pre-Cert De Novo Request.**

- **The FDA plans to prioritize selection of submissions that will enable evaluation and testing of all four components (Excellence Appraisal, Review Pathway Determination, Streamlined Review, and Real-World Performance plan) outlined in the Working Model (discussed below), and to focus on cases representing a broad spectrum of software developers (e.g., small and large firms, low- and high-risk products, companies not traditionally considered medical device manufacturers).**

- **During the Test Plan, the FDA will apply both the proposed Pre-Cert pathway and the traditional review process to each test case, enabling it to refine Pre-Cert and confirm the validity of the overall program. Developers participating in the Pre-Cert pilot, after an Excellence Appraisal and optional Pre-Submission, will still need to submit full traditional marketing submissions. Internally, the FDA will then create a "mock Streamlined Review package" and review the submission on parallel paths, traditional and "mock Streamlined." Similarly, the FDA will also be internally conducting retrospective tests of SaMD regulatory submissions previously reviewed.**

**Finally, the third document released is an updated Working Model (currently v1.0). The Working Model, which has been updated over time with continuous public input, describes in greater detail the goal, vision, scope, and process for Pre-Cert. It also includes summaries of public comments that have been received and FDA responses to them. Pre-Cert, if implemented and successful in accomplishing FDA's stated goals, could have a significant impact on the healthcare industry beyond the software developers it promises to impact directly. Digital health is increasingly becoming an important tool for healthcare businesses. Streamlining processes for bringing digital**

**health technology to market and modifying existing technology will in turn increase the rate at which providers are able to utilize updated digital health technologies in practice. As this technology continues to garner the focus and support of regulatory bodies, it will be important not only for developers to understand the FDA's streamlined approval process, but also for providers to prepare for the potential transformative effect digital health tools can have on the care they provide.**


**Third Annual Digital Health Conference**

# Session II: Present at a Distance: Capturing Value in Remote Patient Monitoring

**September 24, 2019**

**Greg Anthony,** *Assoc. Administrator, Mayo Clinic Center for Connected Care*
**Harsh Dharwad,** *Chief Technology Officer, Nihon Kohden America*
**Meghan DesLauriers,** *Partner, Dorsey & Whitney*
**Shira Hauschen,** *Managing Principal, Dorsey Health Strategies*

## Session Materials:

**September 20, 2019**

# Reimbursement for Remote Patient Monitoring Services in 2019

**Randall Hanson and Ross D'Emanuele**

**Medicare reimbursement for remote patient monitoring has taken a number of steps forward throughout this year. New and proposed rules from the Centers for Medicare and Medicaid Services both expand the billing options available to health care providers and also build in additional flexibility in the provision of remote patient monitoring in order to further the health industry's push to value-based care.**

**Remote patient monitoring ("RPM") is a form of digital health in which medical data from individual patients is collected in one location and electronically transmitted to health care providers in a different location for assessment and recommendations. RPM differs from other digital health services in that there is no live interaction between the patient and their health care provider. Instead, RPM is used by health care providers to monitor various aspects of their patient's vital signs, including: weight, blood pressure, blood sugar, heart rate, and oxygen levels. RPM is not only a useful tool for health care providers to use during a patient's hospitalization, but it is also useful in reducing the number of hospitalizations altogether. For example, RPM can be used to allow older or disabled individuals to live at home longer and avoid having to move into skilled nursing facilities, since their vitals can be monitored without having to see a health care provider in person.**

**Until this year, Medicare reimbursement for RPM services was difficult to come by. While Medicare previously offered reimbursement for RPM services billed under CPT code 99091, the code did not take current technology and staffing models into account (likely because the language from the code dates back roughly 16 years). In order to address this issue and further incentivize health care providers to use RPM, the Centers for Medicare and Medicaid Services ("CMS") finalized three new RPM billing codes that were effective January 1, 2019 ("Final Rule"). The new codes are titled, "Chronic Care Remote Physiologic Monitoring" and included the following descriptions:**

- **CPT code 99453: "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment."**

- **CPT code 99454: "Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days."**

- **CPT code 99457: "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month."**

**Finalization of these new codes did not come without fair criticism and disparate interpretations of the level of required supervision. In creating the codes, CMS stated that RPM could not be delivered "incident to" a practitioner's professional services. Therefore, RPM services could not be reimbursed if the services were furnished by auxiliary personnel (individuals acting under the supervision of a physician). Following backlash of this conclusion, CMS issued a technical correction to the Final Rule on March 14, 2019, that allows "incident to" billing of RPM services by auxiliary personnel if they are under *direct* supervision. This was overall a win for RPM reimbursement; however, through separate codes (CPT 99487, 99489, and 99490), CMS allows reimbursement for Chronic Care Management under *general* supervision. The difference being that *general* supervision does not require a physician to be in the same building at the same time as the auxiliary personnel delivering the services. This contradictory treatment resulted in commentators arguing that CMS's approach hinders, rather than increases, a patient's access to digital health services by limiting where a physician may be located during the supervision of such services.**

**CMS seems to be addressing this concern in the proposed 2020 Physician Fee Schedule that was published August 14, 2019 ("Proposed Rule"). The Proposed Rule would allow "incident to" RPM services to be reimbursed under *general* supervision rather than limiting reimbursement to *direct* supervision. By way of example, this means RPM could be reimbursed when the auxiliary personnel use RPM with patients who are in a hospital while the auxiliary personnel are supervised via other telemedicine modalities by a physician at their home. This change would greatly improve a patient's access to RPM by enabling physicians to bill for such services delivered in a more flexible manner.**

**In addition to this change, the Proposed Rule revises CPT code 99457 and adds yet another code to allow for additional reimbursement for each 20-minute interval that RPM services are provided. This is in contrast to the Final Rule's version of CPT code 99457, which allowed only one reimbursement for RPM services delivered for 20 minutes or more.**

**CMS is accepting comments on the Proposed Rule until September 27, 2019. If you would like to submit comments or have any questions, one of the authors or your regular Dorsey attorney would be happy to assist you.**

# The Future of Remote Monitoring

May 28, 2019
By Harsh Dharwad

**With 330 million citizens – the third largest population of any country in the world – and 60 percent of adults suffering from at least one chronic disease, the demands on the U.S. healthcare system continue to grow and costs are increasing.**

But hospitals throughout the country have continued to focus on lowering costs while improving the quality of care, and significant strides are being made in this regard. Just consider for a moment that in 1975 the average hospital stay was 11.4 days. It took 15 years for the average number of days to drop 20 percent to 9.1 days, and another 10 years to drop an additional 25 percent to 6.8.

Despite this hard-fought success, the average hospital stay has only dropped an additional 10 percent since 2000, lingering at 6.1 days for several years in a row.

Remote patient monitoring holds the key to further improving those numbers.

Where appropriate, hospitals have shifted more care to primary care physicians and to home environments. Patients who require only low-level care are discharged quickly and efficiently, while those who are critical are provided round-the-clock care. But a large percentage of patients in hospitals do not fit into either of these extremes. They aren't critical, but they still require a level of ongoing, real-time monitoring to ensure health issues are quickly identified. To date, limitations in technology have required this type of monitoring to take place in hospitals.

Technological advancements have already given patients who are being actively monitored greater freedom of movement within the hospital setting. Initially monitored via radio, hospitals have increasingly switched to Wi-Fi over the past 10 years because it offers more flexibility and range.

Now companies are starting to explore the use of LTE to further increase the range of wireless monitoring. This is initially being studied as a way to allow patients access to areas on hospital campuses that would otherwise be Wi-Fi dead zones, such as walking gardens or corridors between hospital buildings. GPS capabilities embedded into the devices can help healthcare providers quickly locate roaming patients who may be having a health crisis.

While it may seem like a small step in terms of patient monitoring, the shift from Wi-Fi to LTE could have far-reaching implications. With LTE-enabled devices, clinicians can monitor a patient and how they are responding to treatment in real-time, even if that patient is in a remote clinic or relaxing in the comfort of his own home. This could break down the barriers to continuous, uninterrupted care by making monitoring location-agnostic.

In addition, once a patient is connected to LTE-enabled monitoring, all of the data can be automatically fed into the patient's electronic medical record without any additional charting steps. This information will then be available to any of the patient's providers to ensure continuity of care.

LTE-enabled devices could even allow a physician to start monitoring a patient before he or she reaches the hospital door. Paramedics could hook a patient up to the device in an ambulance and the same device could follow the patient through the emergency department, into surgery and to recovery before going home with them. The possibilities of this advancement are endless.

While the technology is still in its formative stages, it could lead to a rapid shift in patient monitoring over the next few years. As a result, we could see another significant drop in the average number of days Americans spend in hospitals when they need to be admitted.

*About the author: Harsh Dharwad is chief technology officer for Nihon Kohden America*

# DORSEY HEALTH STRATEGIES/DORSEY & WHITNEY LLP
# DIGITAL HEALTH CONFERENCE
# SEPTEMBER 24, 2019

## SESSION II: Present at a Distance: Capturing Value in Remote Patient Monitoring

**Links to further reading** about remote patient monitoring**
**** Note: these are primarily clinical, and some may require login access**

***Remote monitoring of patients with heart failure: systematic review (2017)***
*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5291866/*

***Remote monitoring after recent hospital discharge in patients with heart failure: a systematic review and network meta-analysis (2013)***
*https://www.ncbi.nlm.nih.gov/pubmed/23680885*

***Structured telephone support or non-invasive telemonitoring for patients with heart failure (2015)***
*https://www.ncbi.nlm.nih.gov/pubmed/26517969*

***Remote monitoring programs for heart failure patients: case studies (2015)***
*https://www.advisory.com/research/population-health-advisor/white-papers/2015/remote-monitoring-programs-for-heart-failure-patients?WT.ac=Inline_PHA_WP_Telehealth___CTC_2015DEC17_*

***Reduced cost and mortality using home telehealth to promote self-management of complex chronic conditions: a retrospective matched cohort study of 4,999 Veteran patients (2015)***
*https://www.ncbi.nlm.nih.gov/pubmed/24841071*

***Telehealth: scaling remote patient monitoring programs (2014)***
*https://www.advisory.com/research/market-innovation-center/studies/2014/telehealth-scaling-remote-patient-monitoring-programs*

***Effectiveness of remote patient monitoring after discharge of hospitalized patients with heart failure: the better effectiveness after transition – heart failure (BEAT-HF) randomized clinical trial (2016)***
*https://www.ncbi.nlm.nih.gov/pubmed/26857383*

***Does telemonitoring reduce HF readmissions? (2016)***
*https://www.acc.org/latest-in-cardiology/articles/2016/02/08/15/09/does-telemonitoring-reduce-hf-readmissions*


**Third Annual Digital Health Conference**

# Session III: Delivering Value in Behavorial Health Through the Use of Data and Technology

**September 24, 2019**

**Monika Roots,** *Chief Medical Officer, Sanvello*
**Jaclyn Wainwright,** *Chief Executive Officer, AiRCare Health*
**Ross D'Emanuele,** *Partner, Dorsey & Whitney*
**Alissa Smith,** *Partner, Dorsey & Whitney*

## Session Materials:

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## Session III
## Delivering Value in Behavioral Health Through the Use of Data and Technology

**Monika Roots, CMO, Sanvello**
**Jaclyn Wainwright, CEO, AiRCare Health**
**Ross D'Emanuele, Partner, Dorsey & Whitney LLP**

**Moderator: Alissa Smith, Partner, Dorsey & Whitney LLP**

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## The Problem: By the Numbers

- **8 in 10 Americans report that they experience significant stress.**
- **40% of Americans experience some form of mental illness. This is 60M people.**
  - 1 in 5 (or about 19%) of U.S. adults experience mental illness each year. This is 47.6M people.
  - 1 in 25 (or about 5%) of U.S. adults experience serious mental illness each year. This is 11.4M people.
  - 1 in 6 (or about 17%) of U.S. youth aged 6-17 experience a mental health disorder each year. This is 7.7M people.
  - 41% of Veteran's Health Administration patients have a diagnosed mental illness or substance use disorder.
  - 3.7% of US adults experienced a co-occuring substance use disorder and mental illness in 2018. This is 9.2M people.

https://www.nami.org/learn-more/mental-health-by-the-numbers (last visited 9/15/19)
https://news.gallup.com/poll/224336/eight-americans-afflicted-stress.aspx (last visited 9/16/19)

# The Impact

- Physical Health Implications
- Increased Cost of Care for Chronic Conditions
- Emergency Department Care and Hospitalization
- Caregivers
- Homelessness
- Incarceration
- Unemployment
- Graduation Rates
- Lost Earnings
- Disability
- Suicide

https://www.nami.org/learn-more/mental-health-by-the-numbers (last visited 9/15/19)
https://www.integration.samhsa.gov/workforce/mental_disorders_and_medical_comorbidity.pdf (last visited 9/16/19)

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# AiRCare Health and Sanvello

**Two companies using technology and data in behavioral healthcare**

## Laws span the gamut of healthcare and technology; A patchwork that is evolving but lagging behind the market

- Privacy concerns
  - HIPAA, 42 CFR Part 2, GDPR, COPPA, TCPA, state-specific regulations
- Licensure
  - State-specific, clinician-specific, and care-setting specific
  - Some telehealth-specific requirements
  - Specific requirements if first-time seeing the patient
  - Don't forget scope of practice
- Reimbursement
  - CMS requirements, Parity laws, coding, requisite documentation, AMA CPT Codes
- Credentialing & privileging
- Corporate Practice of Medicine (CPOM)
- Fraud and abuse: False Claims Act, AKS, and Stark
- Prescribing
  - Ryan Haight Act
  - DEA registration – note call for telemedicine registration in new opioid legislation
- FDA (Is the software making clinical decisions?)
- Contractual issues
- State-specific documentation- and other patient interaction-related requirements
- State-specific website- and app-related requirements

These are in addition to typical requirements for provision of healthcare (e.g., considerations relating to medical malpractice, informed consent, etc.), as well as requirements of a technology-focused venture (e.g., IP as a critical asset)

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## Questions?

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**Third Annual Digital Health Conference**

# Session IV: IP Protection for Digital Health Innovation

**September 24, 2019**

**Brad Hattenbach,** *Of Counsel, Dorsey & Whitney*
**Matt Jonsen,** *Partner, Dorsey & Whitney*

## Session Materials:


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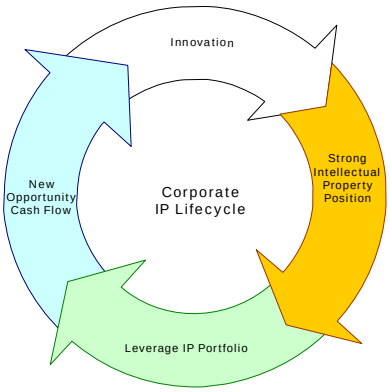
## Digital Health Technology

- What is protectable?
  - Drug candidate screening
  - Gene variant analysis
  - In silico testing
  - Diagnostics
  - Monitoring
  - Predictive analytics
  - Electronic medical records
  - Data management
  - Big data analysis
- How do you protect it?

# Intellectual Property Strategy

**IP Portfolio Management Goals**

- **Provide competitive advantage**
- **Protect current and future product developments**
- **Claim areas of likely value to industry as a whole**
- **Maintain competitively-sized portfolio with attention to cost**
- **Provide basis for corporate valuation**
- **Provide basis for ancillary revenue stream**

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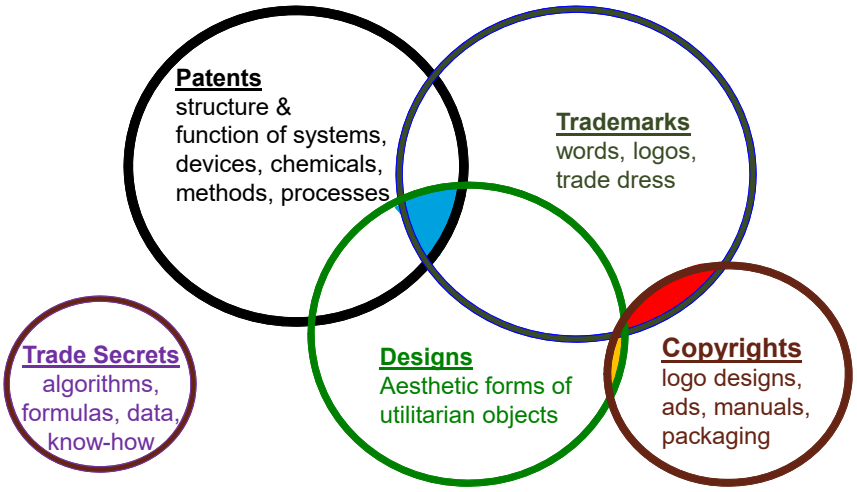
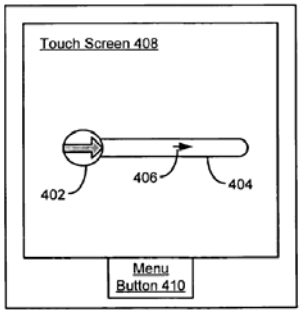
# Intellectual Property Realms



# Utility & Design Patents Can Cover the Same Product

**Apple iPhone - Slide to Unlock**

**U.S. Utility Patent No. 7,657,849**




**U.S. Design Patent No. D675,639**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# Designs, Copyrights, and Trademarks Can Cover the Same Product

(12) **United States Design Patent** (10) **Patent No.:** **US D599,372 S**
**Pelczarski et al.** (45) **Date of Patent:** ** **Sep. 1, 2009**

## U.S. Constitution

- **Article I | Section 8 | Clause 8 –**

**[The Congress shall have power] "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."**

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## Patentability Requirements

- **Useful**
- **Patentable subject matter**
- **Novelty**
- **Non-obviousness**

## *Section 101 – Subject Matter Eligibility*

- **Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**
- **2019 Revised Patent Subject Matter Eligibility Guidance https://www.govinfo.gov/content/pkg/FR-2019-01-07/pdf/2018-28282.pdf**
- **What is NOT patentable?**
  - **Abstract ideas, laws of nature, mathematical concepts, some types of organizing human activity, and purely mental processes**
- **What if a claim mentions a judicial exception?**
  - **examiner is directed to determine whether the judicial exception is "integrated" into a practical application.**
- **What about diagnostic methods based on biomarkers (DNA, metabolites, etc.)?**

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## Diagnostic methods

- **How to tip the balance toward patentability?**
  - **Tie the method to a treatment**
    - ***Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals,* 887 F.3d 1117 (Fed. Cir. 2018), *see also* USPTO *Vanda Memo*, https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF**
  - **Tie the method to a novel isolation method or diagnostic device**
    - **Are there steps that are NOT well-understood, routine or conventional? in *Berkheimer v. HP Inc.*, (Fed. Cir. Feb. 8, 2018) – *see also* USPTO *Berkheimer Memo*, https://www.uspto.gov/sites/default/files/documents/memo-berkheimer-20180419.PDF**
- **General Examples from USPTO – Life Science https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf**

# USPTO Provided Example

- **Example 29 - Diagnosing and Treating Julitis**
  - ***Illustrating the "significantly more" analysis in terms of diagnostic and treatment claims.***
    - ***Claims 1 and 7 are eligible, because they are not directed to any judicial exception***

1. **A method of detecting JUL-1 in a patient, said method comprising:**
   **a. obtaining a plasma sample from a human patient; and**
   **b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.**

7. **A method of treating a patient with julitis, the method comprising administering an effective amount of anti-TNF antibodies to a patient suffering from julitis.**

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- **Example 29 - Diagnosing and Treating Julitis cont.**
  - ***Illustrating the "significantly more" analysis in terms of diagnostic and treatment claims.***
    - ***Claim 2 is ineligible, because it is directed to a law of nature/abstract idea, without "significantly more"***

2. **A method of diagnosing julitis in a patient, said method comprising:**
   **a. obtaining a plasma sample from a human patient;**
   **b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and**
   **c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.**

- **Example 29 - Diagnosing and Treating Julitis cont.**
  - ***Illustrating the "significantly more" analysis in terms of diagnostic and treatment claims.***
    - ***Claims 3-6 are eligible, because, while directed to the same exception, they recite specific and unconventional reagents and/or treatments – i.e. they recite "significantly more."***

3. **A method of diagnosing julitis in a patient, said method comprising: a. obtaining a plasma sample from a human patient; b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting binding between JUL-1 and the porcine antibody; and c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.**
4. **… b. contacting the plasma sample with antibody mAb-D33 and detecting binding between JUL-1 and antibody mAb-D33…**
5. **A method of diagnosing and treating … d. administering an effective amount of topical vitamin D to the diagnosed patient.**
6. **A method of diagnosing and treating … d. administering an effective amount of anti-tumor necrosis factor (TNF) antibodies to the diagnosed patient.**

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# Help is on the way – or is it?

- **Proposed language - "the provisions of section 101 shall be construed in favor of eligibility."**
  - **No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated**

**https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26**

## Data as Trade Secret (and Revenue Source)

- Big data uses
  - Risk factors
  - Diagnosis
  - Determination of outcomes
  - Clinical trials
- Can data technology improve reimbursement revenue?
  - Artificial intelligence mining huge data sets
  - Correlate diagnoses, treatments, general health, lifestyles, etc. to better outcomes
- Data use as an alternative revenue source (Primary?)
- Need to avoid violation of HIPPA rules
  - Aggregation without personally identifiable information

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## Effect of use of AI on Inventorship

- 35 U.S.C. § 101 - "Whoever invents or discovers… may obtain a patent therefor…."
- 35 U.S.C. § 100, "the term "inventor" means the *individual* or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention."
- What level of human involvement in the process of invention is necessary for "inventorship" to arise?

Ben Hattenbach & Joshua Glucoft, Patents in an Era of Infinite Monkeys and Artificial Intelligence, 19 Stan. Tech. L. Rev. 32, 45-49 (2015) available at https://law.stanford.edu/wp-content/uploads/2017/10/PATENTS-IN-AN-ERA-OF-INFINITE-MONKEYS-AND-ARTIFICIAL-INTELLIGENCE.pdf

# Invention by machine or human?

- How is trial and error testing (which is an acceptable method of research for leading to an invention) different from letting a computer model the trials to more quickly suggest a desirable drug candidate?
- Does it matter whether humans seed the AI machine with particular information directed to identify a therapy for a particular disorder or dysfunction?
- Would particular configuration of the AI machine in a unique way be required for inventorship?
- If so, what is the invention? The resulting formulation? The special purpose machine created by the configuration?

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# Impact of AI on Obviousness Analysis[1]

- "*A person of ordinary skill is also a person of ordinary creativity, not an automaton.*" – Justice Kennedy, KSR v. Teleflex
  - Automated AI design systems or programs are becoming known useful tools life sciences fields (e.g., small molecule drug discovery, vector identification for gene therapies, etc.).
  - A person having ordinary skill in the art (PHOSITA) will be expected to use such AI design systems as one of their skills.
  - Does the use of the AI tool render any and all outputs of the tool obvious regardless of novelty of the end result?

1 William Samore, *Artificial Intelligence and the Patent System: Can a New Tool Render a Once Patentable Idea Obvious?*, Syracuse J. of Sci. & Tech. L., v. 29, art. 3, p. 113 (Fall 2013) available at http://jost.syr.edu/wp-content/uploads/Samore-Final.pdf

# Example

- Computer-aided retrosynthesis of precursor molecules to target compounds.
- A number of deep neural networks were prepared and trained on 12 million reactions, which represent essentially *all reactions* ever published in organic chemistry.
- The system solved almost twice as many molecules and did so 30 times faster than traditional search methods.
- "Chemists can no longer distinguish between routes generated by a computer system and real routes taken from the scientific literature."
- Next step is development of machine learning for natural product synthesis.
- Is that "next step," when target drug products are ultimately proposed by machine output, an obvious result?

- Marwin H.S. Segler, Mike Preuss, Mark P. Waller, Learning to Plan Chemical Synthesis, arXiv.org, arXiv:1708.04202v1 (14 August 2017) available at https://arxiv.org/abs/1708.04202

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# Things in IP to ponder

- ***"We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts."*** **– Justice Kennedy, KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (slip at 17) (2007)**

# Thank you!

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## DORSEY'S DIGITAL HEALTH GROUP

Technology is quickly changing the way healthcare is delivered, charted, and paid for. Large employers in all industries are adding telemedicine/virtual care visits to their wellness plans; payors and PBMs are partnering with data analytics companies; providers who have implemented EHRs are now adding additional digital services; and technology companies in non-health industries are looking to pivot into offering healthcare technology services – and digital health specifically. As the digital health industry picks up speed, Dorsey's Health Industry Group is keeping true to its promise to stay "Well Ahead" of industry changes.

With leading industry attorneys around the globe, and with our distinctive additional offering of business consulting advice through our consultancy, Dorsey Health Strategies, Dorsey is uniquely positioned to assist in all aspects of the legal, regulatory, and business issues that arise from the use of technology to deliver and improve healthcare and wellness. Our Digital Health experts work closely with our Privacy, FDA, Intellectual Property, Benefits, Licensing, Corporate, Private Equity, and Litigation attorneys to deliver practical solutions.

## What We Do

Dorsey offers comprehensive guidance on the unique business, legal, and regulatory issues impacting the Digital Health industry, including:

### LEGAL SERVICES

- State Telehealth Regulation
- Corporate Practice of Medicine
- Medical Software Regulation
- DEA Regulation / Ryan-Haight Act
- HIPAA / Privacy and Security
- GDPR and global regulatory issues
- Health Care Fraud and Abuse
- Assessing Exposure and Minimizing Liability Risks
- Digital Health Litigation
- Intellectual Property Strategy
- Formation, Financing, and Governance
- Digital Health Transactional Assistance, including Collaborations
- Reimbursement
- Digital Health Payor Advice
- Digital Health Tax Advice

### BUSINESS CONSULTING SERVICES

- Business Planning to Launch and Scale Digital Health Initiatives
- Assessment of State Requirements, Compliance, and Staffing to Scale Up
- Financial Projections
- Business Model Assessment
- Compliance Analysis, Review, and Program Creation
- Executive Dashboards and Digital Health Compliance Assurance
- EHR/EMR Integration and Optimization with Digital Health Initiative
- Assessing State Regulation Applicability and Staffing Implications
- Project Management Assistance
- Competitive Landscape Assessment
- Digital Health Data Privacy Audit

## Who We Work With

- Medical device manufacturers
- Health care payors (including employers)
- Health care service providers
- Internet commerce companies
- Health wellness vendors
- Pharmaceutical companies
- Technology platform providers
- Telehealth companies
- Venture capital and private equity firms

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