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FAST BREAK: 2023: WHAT'S IN STORE FOR HEALTHCARE

Jake Harper and
Tesch Leigh West
January 26, 2022

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TODAY'S PRESENTERS

Jacob J. Harper

Tesch Leigh West

Agenda

- Telehealth and digital health
- Value-based care
- Managed care updates
- Other healthcare trends

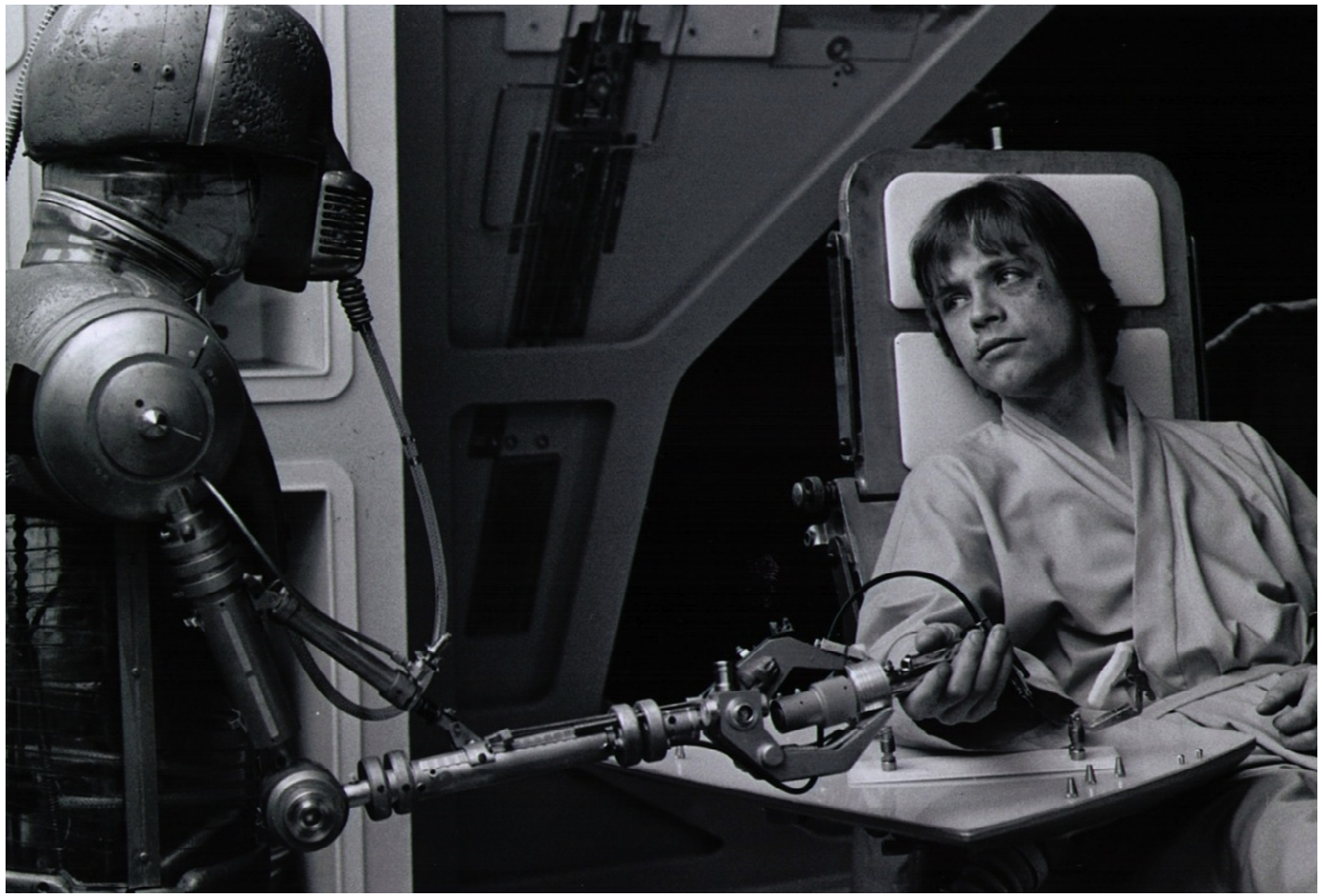
TELEHEALTH AND DIGITAL HEALTH IN 2023

End of the PHE?

- Telehealth has enjoyed an expansion since the announcement of the Public Health Emergency (PHE) for COVID-19 in March 2020.
- Federal flexibilities and waivers were tied to the end of the PHE, with some extended for a period of 151 days after the PHE expiration
- In the Consolidated Appropriations Act of 2023 (passed on December 29, 2022), Congress extended these telehealth flexibilities until December 31, 2024
- But some flexibilities will still expire at the end of the PHE
  - Most importantly, the waiver of the Ryan Haight Act

Digital Health Evolution

Digital Health Evolution



Digital Health Evolution

- FDA and other regulatory agencies are thinking about Artificial Intelligence, Virtual Intelligence, and Machine Learning technologies in the healthcare space

  – FDA has been examining ways to approve and regulate medical devices and clinical decision support software, particularly as they autonomously "evolve" through programmed learning

  – CMS is interested in AI-based technologies and recently published a rule outlining its thinking on this:

> *"Rapid advances in innovative technology are having a profound effect on every facet of health care delivery. Novel and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve outcomes, and reduce overall costs to the program. In some cases, these innovative technologies are substituting for more invasive care and/or augmenting the practice of medicine."*

87 Fed. Reg. 72027 (Nov. 23, 2022).

AMA AI Taxonomy Framework

Service Components	AI Category: Assistive	AI Category: Augmentative	AI Category: Autonomous
Primary objective	Detects clinically relevant data	Analyzes and/or quantifies data in a clinically meaningful way	Interprets data and independently generates clinically ~~relevant~~ meaningful conclusions
Provides independent diagnosis and/or management decision	No	No	Yes
Analyzes data	No	Yes	Yes
Requires physician or other QHP interpretation and report	Yes	Yes	No
Examples in CPT code set	Computer-aided detection (CAD) imaging (77048, 77049, 77065-77067, 0042T, 0174T, 0175T)	Continuous glucose monitoring (CGM) (95251), external processing of imaging data sets	Retinal imaging (92229)

3 overall categories of AI devices based on the "work performed by the machine" in delivering an overall service

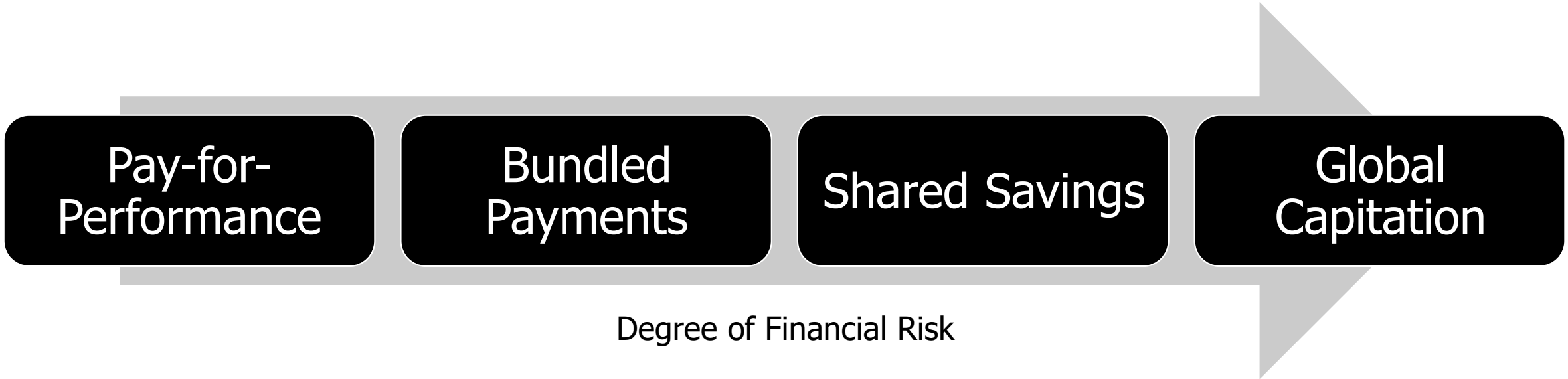
Within the 3rd category ("Autonomous"), there are 3 sub levels describing the level of professional involvement associated with the machine

- **Level I** – AI offers diagnosis/treatment but physician must implement
- **Level II** - AI initiates diagnosis/treatment with override option and may need physician implementation
- **Level III** – AI initiates diagnosis/treatment and physician must contest

VALUE-BASED CARE IN 2023

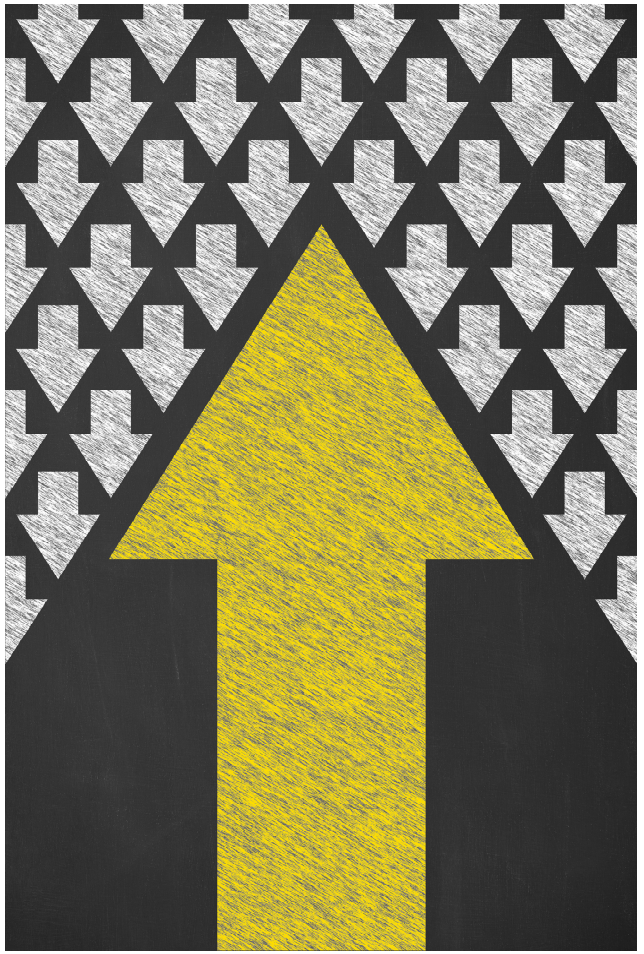
What is Value Based Care?

- Value based care means different things in different contexts but generally refers to the practice of shifting reimbursement models from a focus on volume to value with the objective of lowering costs and improving quality outcomes.
- 15% of physicians participate in value-based payment models, according to Medscape's *Physician Compensation Report 2022*



Risk Sharing Agreements

- Risk sharing agreements may take on a variety of forms and parties may tailor the arrangements to assume more or less risk and to create safeguards such as stop loss insurance.
- **Downside risk** means payment may be less than the expense.
- **Upside risk** means reduced-cost of care and high-quality care may allow increased revenue.
- **Stop-loss clause** is intended to limit the loss a provider would experience for outlier cases with a high-dollar charge.



Oversight of Risk Bearing Organizations

- The legal treatment of risk-bearing organizations varies widely from state to state.
  - Some states treat risk-bearing organizations as performing a traditional or quasi-insurance function.
  - Some states establish licensure and/or reporting requirements.

- Upside only arrangements or pay-for-performance contracts will generally not constitute a risk-bearing organization.

Federal Programs

- In 2021, CMS published a white paper detailing strategic objectives for value-based care.
  - All Medicare beneficiaries with Parts A and B will be in a care relationship with accountability for quality and total cost of care by 2030.
  - The vast majority of Medicaid beneficiaries will be in a care relationship with accountability for quality and total cost of care by 2030.

- 2023 model types that drive transformation – proposed rule

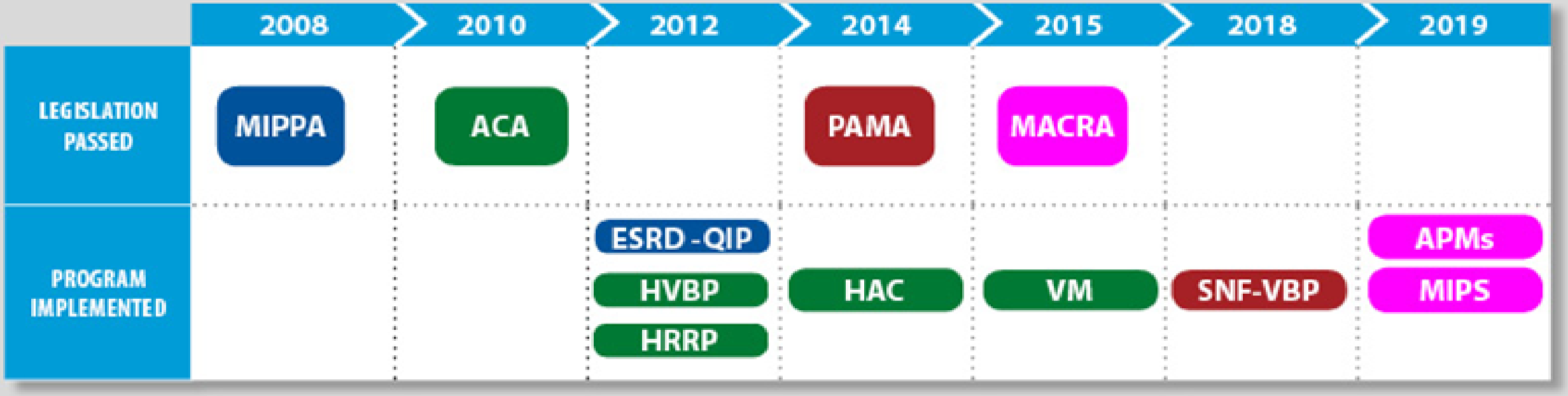
Figure 1. CMS Innovation Center Vision and 5 **Strategic Objectives** for Advancing System Transformation.

Federal Programs (cont'd)

- In November, CMS published an update on the Innovation Center's progress in the implementation of the new strategy.
- Focus on new accountable care models
  - CMS proposed changes to the Medicare Shared Savings Program to support health equity and improve access and quality of care for underserved populations.
  - Reexamines the benchmarking approaches.

- Submit report in response to the Executive Order on Lowering Prescription Drug Costs for Americans that requires the Innovation Center to identify model tests that would lower drug costs and promote access to innovative drug therapies for Medicare and Medicaid beneficiaries
  - Insulin cost sharing

VALUE-BASED PROGRAMS



LEGISLATION

ACA: Affordable Care Act
MACRA: the Medicare Access & CHIP Reauthorization Act of 2015
MIPPA: Medicare Improvements for Patients & Providers Act
PAMA: Protecting Access to Medicare Act

PROGRAM

APMs: Alternative Payment Models
ESRD-QIP: End-Stage Renal Disease Quality Incentive Program
HACRP: Hospital-Acquired Condition Reduction Program
HRRP: Hospital Readmissions Reduction Program
HVBP: Hospital Value-Based Purchasing Program
MIPS: Merit-Based Incentive Payment System
VM: Value Modifier or Physician Value-Based Modifier (PVBM)
SNFVBP: Skilled Nursing Facility Value-Based Purchasing Program

Value-Based Safe Harbors

- **Care Coordination**
  - Allows for arrangements through which value-based enterprise (VBE) parties exchange in-kind remuneration. To ensure the integrity of these arrangements, parties must use in-kind remuneration predominantly to engage in value-based activities that are directly connected to their coordination and management of care for the target patient population.
- **Substantial (or Meaningful) Downside Risk**
  - Allows for exchange of monetary and in-kind remuneration between parties if 1) for the AKS safe harbor, the VBE directly, or through a VBE Participant, assumes substantial downside risk from a payor, or (2) for the Stark exception, the physician accepts meaningful downside risk for failure to achieve the value-based purpose(s) of the VBE.
- **Full Financial Risk**
  - The safe harbor and exception allow for exchange of monetary and in-kind remuneration from a VBE to its VBE Participants if the enterprise assumes full financial responsibility for the cost of all items and services covered by a payor for each patient in the target population.

MANAGED CARE UPDATES IN 2023

Public Health Emergency

- As of January 11, the PHE is set to expire on April 11, 2023.
  - The Families First Coronavirus Response Act established a Continuous Enrollment Condition.
  - States received an additional 6.2% in the Federal Medical Assistance Percentage (FMAP) conditioned upon states refraining form terminating enrollment for most individuals.
  - No disenrollment since March 18, 2020.

- Just before renewing the PHE, HHS laid out a timetable to resume eligibility checks for Medicaid enrollees.
  - Expiration of the continuous enrollment condition and receipt of the temporary FMAP increase will no longer be linked to the end of the PHE.

Key Dates for Unwinding

- Continuous Enrollment Condition ends on March 31, 2023.
- 6.2% FMAP increase will be gradually reduced and phased down beginning April 1, 2023, and will end on December 31, 2023.
- Beginning April 1, 2023, states will be able to terminate Medicaid enrollment for individuals no longer eligible.
  - KFF estimates that between 5.3 million and 14.2 million people will lose Medicaid coverage once the continuous enrollment provision end.
  - HHS estimates that as many as 15 million people will be disenrolled, including 6.8 million who will likely still be eligible.
  - ACA expansion adults, children, people who have moved since the start of the pandemic, those with limited English proficiency (LEP) and people with disabilities.

Medicare Advantage

- In 2022, nearly half of eligible Medicare beneficiaries were enrolled in Medicare Advantage plans.
  - 2022 also demonstrated a rise in Part D enrollment and the share of MA plans that charge no additional premium for the prescription drug benefit.

- Continued scrutiny of upcoding, retrospective chart review, in-home assessments, RAF scores by OIG and DOJ.

- CMS's final rule on the use of extrapolation and the application of a fee-for-service adjuster (FFS Adjuster) in risk adjustment data validation (RADV) audits on February 1, 2023.

OTHER 2023 TRENDS IN HEALTHCARE

Overpayments, FCA, and Non-Competes – Oh My!

- In late December, CMS proposed a small but significant change to the 60-Day Overpayment Rule, which, if finalized, would do away with the "quantification" and "reasonable diligence" standards
  - Varying degrees of concern about the impact of the rule

- The Supreme Court is expected to hear two cases this term on the "knowledge" element of the FCA and if there is an affirmative defense for ambiguous statutes
  - Previously, the Court also heard argument on procedural requirements related to the government's decision to dismiss an FCA *qui tam* after declining to intervene

- The Federal Trade Commission, on January 5, 2023, proposed to ban non-compete provisions from employment contracts
  - Substantial impact in the healthcare, pharma, and medical device space that rely on highly-skilled workers with specialized knowledge; if enacted, this rule would require substantial modifications to most healthcare contracts

Join us next month!

Please join us for next month's webinar:

Fast Break: Personalized Medicine

Featuring

Jackie Berman and Alex Gapihan

February 23rd at 3pm

Morgan Lewis

QUESTIONS?

Thanks and Be Well!

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Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

Thanks and Be Well!

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With a dual focus on litigation and regulatory compliance, Tesch Leigh West represents providers in federal and state government investigations and litigation matters relating to criminal, civil, and administrative allegations, including violations of federal healthcare program fraud and abuse laws. Tesch also represents states, hospitals, clinics, nursing homes, physician groups, health plans and associations, with a focus on Medicare reimbursement, Medicaid supplemental payments and financing options, and analysis related to 1115 Demonstration Waivers.

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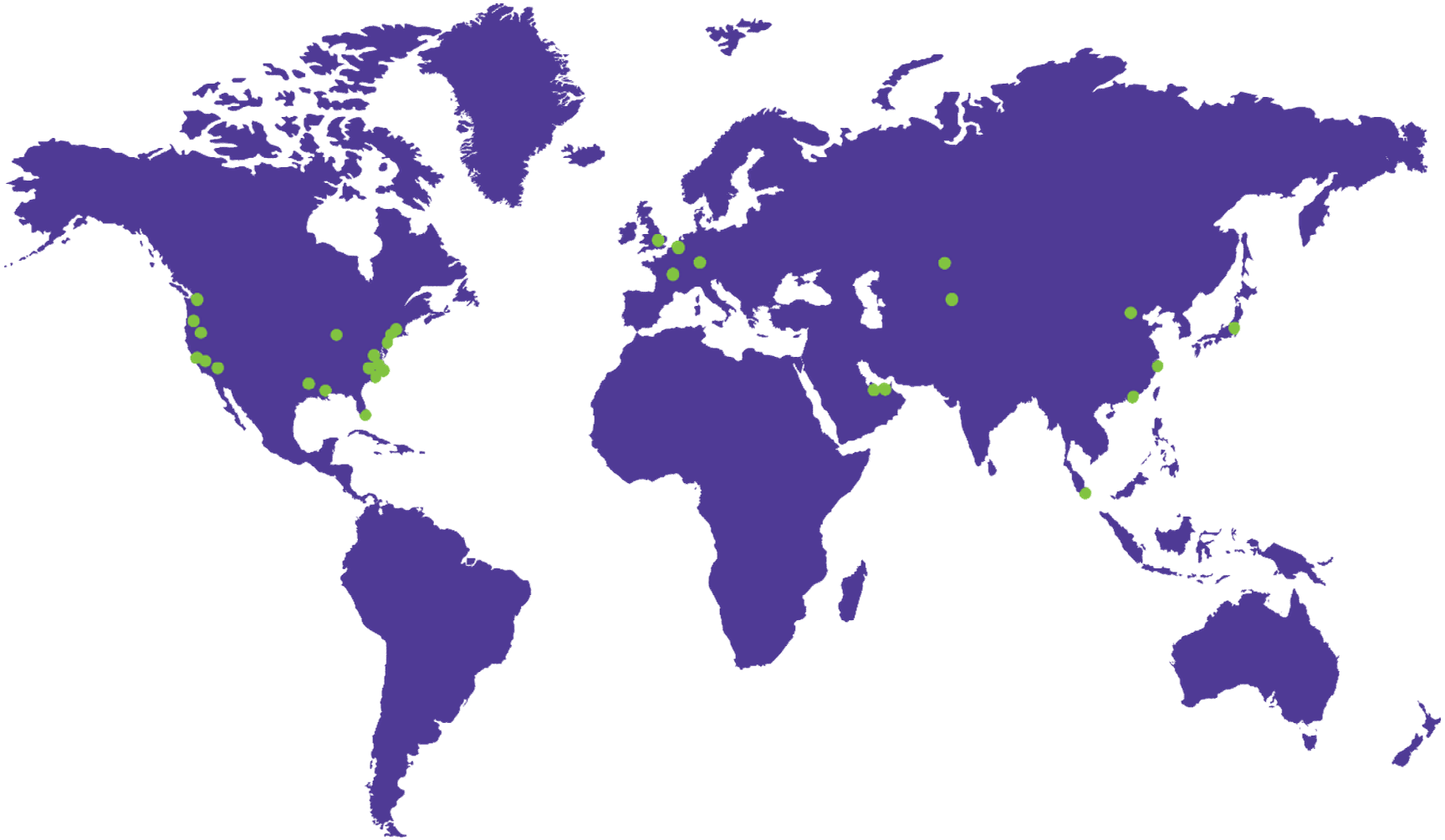

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