BUCHANAN HEALTHCARE
INSIDER SYMPOSIUM

TUESDAY, OCTOBER 18, 2022

CYTO | PHL

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

This PowerPoint presentation is for informational purposes only and does not constitute legal advice or a legal opinion on any specific facts or circumstances. The contents are intended as general information only. You are urged to consult your own lawyer concerning your situation and specific legal questions you may have.

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

Keynote Speaker

Don McDaniel

CEO, Canton & Company

All comments are the opinion of the speakers and do not necessarily represent the views of Buchanan Ingersoll & Rooney.

CANTON & COMPANY

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

CANTON & COMPANY

PE: Friend or Foe … and what does it mean to me?

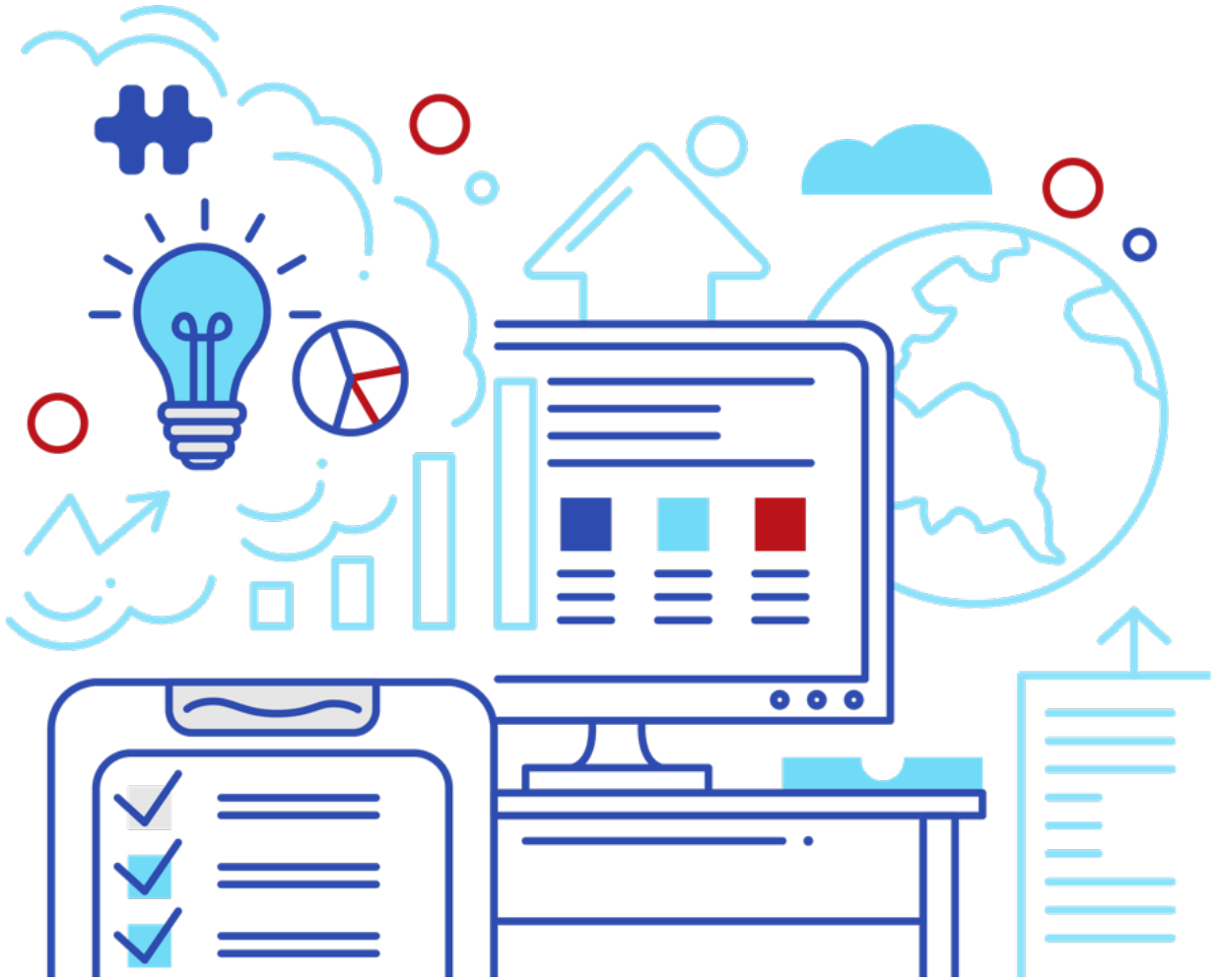
Buchanan's Healthcare Insider Symposium

Don McDaniel

October 18, 2022

Agenda

- Introductions and goals
- A quick quiz
- What a mess!
- Strange bedfellows
- How to be ready



Goals

- Healthcare's private investment climate
- The goals and motivations of private investors
- So what?
- Implications and Opportunities

Take-aways

- Health care is dysfunctional and behind
- Implications
  - Consumers and proxies – retail is not just happening at the pharmacy
  - Triangulating institutional players – Place of service highly correlated with cost
  - Impactful, integrated technology and workflow – not science experiments
  - Lots of capital chasing massively depressed labor productivity
- Remedies
  - Transparency – need more
  - Variation – need less
  - Educated choice – moving to the Unregulated HEDGE
  - Consumer sovereignty
- HELP YOU THINK OUT OF THE BOX ABOUT YOUR BUSINESS

FACTFULNESS

Ten Reasons We're Wrong about the World – and Why Things Are Better Than You Think

Hans Rosling with Ola Rosling and Anna Rosling Rönnlund

Dr. Hans Rosling (1948 – 2017)

- Public health physician and statistician, adviser to WHO and UNICEF, co-founder Gapminder Foundation, wonderful Ted-Talker, sword swallower
- “This book is my last battle in my lifelong mission to fight devastating ignorance” -Hans Rosling
- Tells the story of the “secret, silent miracle of human progress” Melinda Gates

Some Quick Quiz Questions

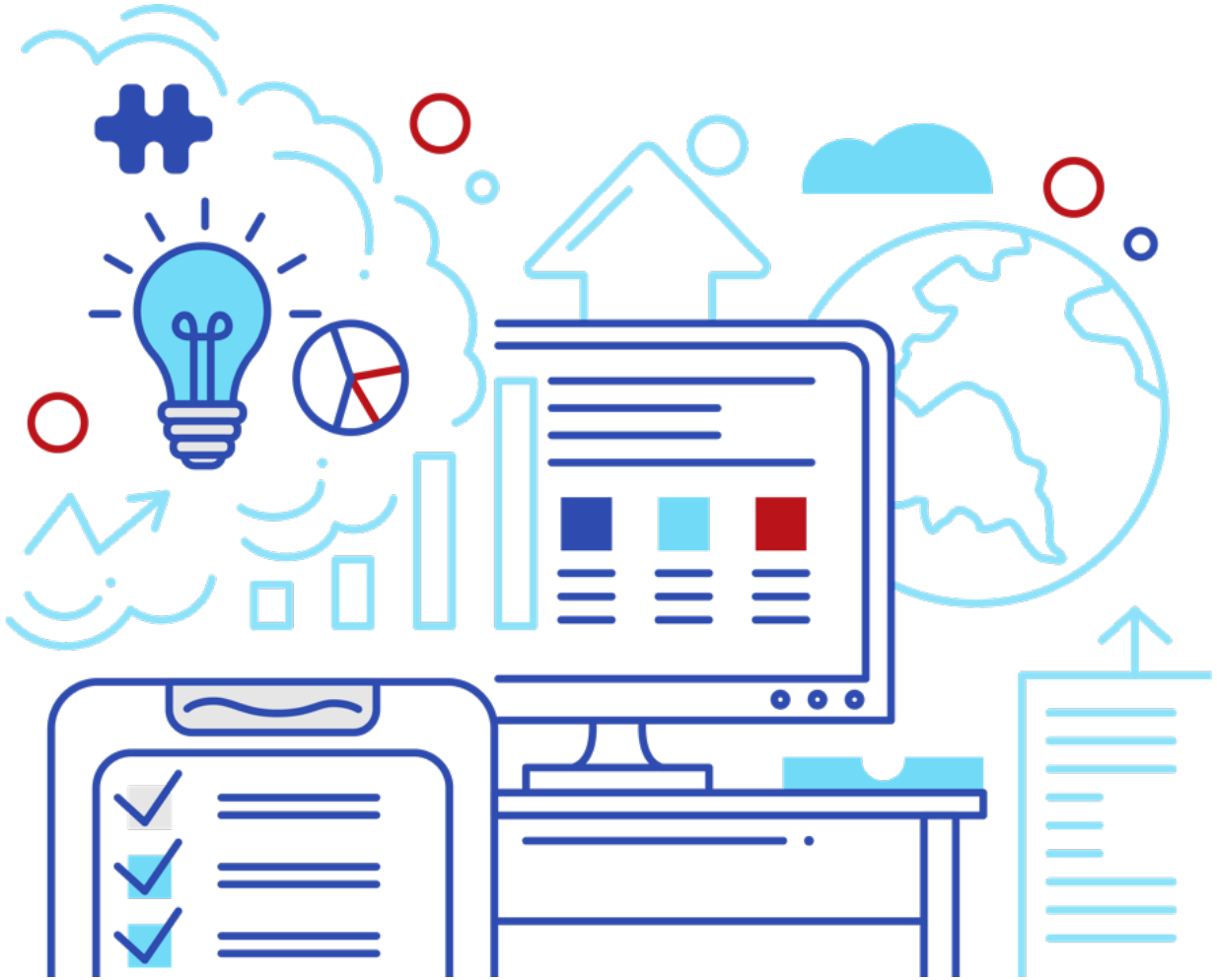
1. In the past 20 years, the proportion of the world population living in extreme poverty has …
   A. Almost doubled
   B. Remained more or less the same
   C. Almost halved
2. How many people in the world have some access to electricity?
   A. 20%
   B. 50%
   C. 80%
3. How did the number of deaths per year from natural disasters change over the last 100 years?
   A. More than doubled
   B. Remained more or less the same
   C. Decreased to less than half

Take-aways

- Things aren't nearly as bad as we think they are – we continue to pierce the ceiling of progress and innovation!
- "The good old days" weren't really that good
- Let's develop a fact-based world view
  - Be aware of how our instincts make it difficult to get facts right
  - Be realistic about the extent of our knowledge
  - Be prepared to change your opinion when presented with facts and data

How is Factfulness relevant to this discussion?

- Our mental model about healthcare was changed forever in 1965 – and hasn't changed much since!
- We are convinced that markets won't work in healthcare – investors are betting otherwise
- We are convinced that "patients" (pejorative) are not smart enough to make their own decisions



The Ugly Truth

“Everything we take for granted
in the other 80% of our (economic) lives
are challenges in healthcare.”

Steve Klasko, MD
former CEO Thomas Jefferson University

How we got here – some sentinel events

- Third Party Insurance and a lack of consumer sovereignty have kept the watchdog at bay
- The "Great Society" created "Great Gaming"
- Payment as the regulator - Fee-for-Service has driven misaligned incentives
- "Fourth Party" - Employers have been complicit -- "Out to Lunch?"
- Government's growing role – provider, purchaser, payer, regulator, educator, trainer, insurer-- has created a feeding frenzy without accountability

Intractable Problems - what a ...

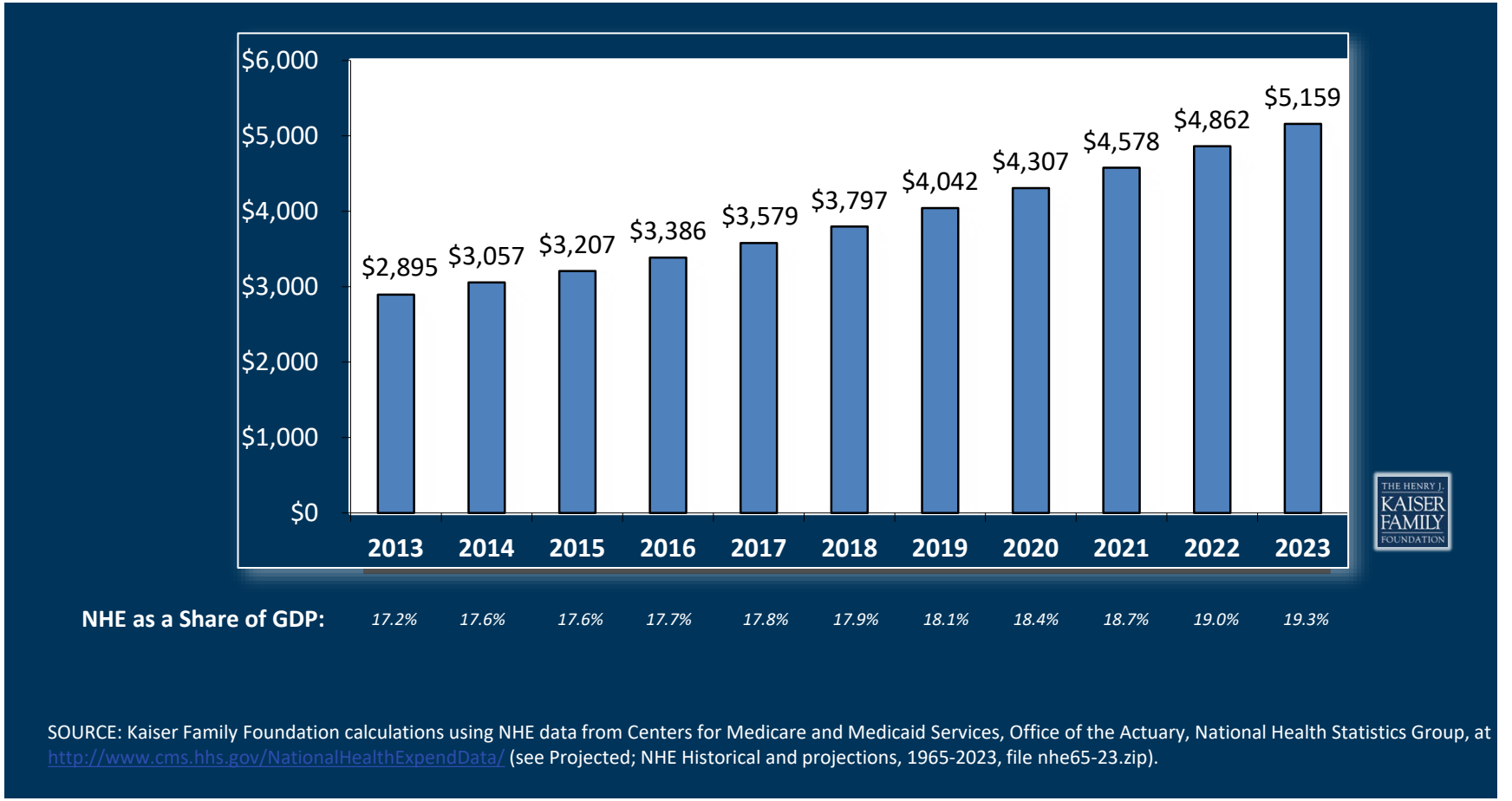
Political

Economic

Socio-cultural

Technological

Spending Growth



SOURCE: Kaiser Family Foundation calculations using NHE data from Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, at http://www.cms.hhs.gov/NationalHealthExpendData/ (see Projected; NHE Historical and projections, 1965-2023, file nhe65-23.zip).

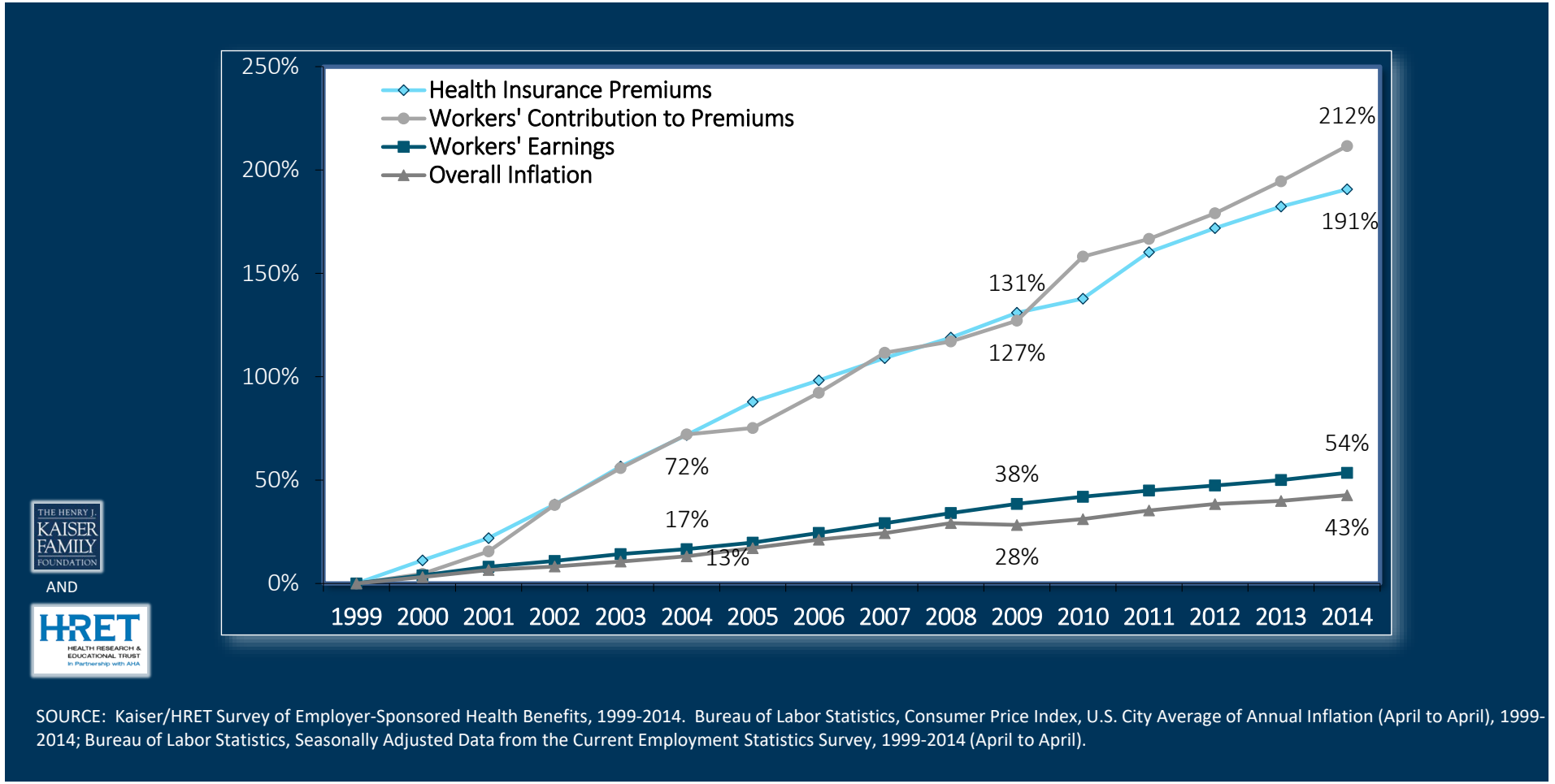
Is the juice worth the squeeze?

TABLE: Seventeen High-Income Countries Ranked by Life Expectancy at Birth, 2007

Males			Females		
Rank	Country	Average Length of Life	Rank	Country	Average Length of Life
1	Switzerland	79.33	1	Japan	85.98
2	Australia	79.27	2	France	84.43
3	Japan	79.20	3	Switzerland	84.09
4	Sweden	78.92	3	Italy	84.09
5	Italy	78.82	5	Spain	84.03
6	Canada	78.35	6	Australia	83.78
7	Norway	78.25	7	Canada	82.95
8	Netherlands	78.01	7	Sweden	82.95
9	Spain	77.62	9	Austria	82.86
10	United Kingdom	77.43	9	Finland	82.86
11	France	77.41	11	Norway	82.68
12	Austria	77.33	12	Germany	82.44
13	Germany	77.11	13	Netherlands	82.31
14	Denmark	76.13	14	Portugal	82.19
15	Portugal	75.87	15	United Kingdom	81.68
16	Finland	75.86	16	United States	80.78
17	United States	75.64	17	Denmark	80.53

SOURCE: Data from the Human Mortality Database, the World Health Organization Mortality Database, and Statistics Canada, as reported in Ho, J. Y. and S.H. Preston (2011). *International Comparisons of U.S. Mortality.* Data analyses prepared for the National Academy of Sciences/Institute of Medicine Panel on Understanding Cross-National Health Differences Among High-Income Countries. Population Studies Center, University of Pennsylvania.

Inflationary and regressive



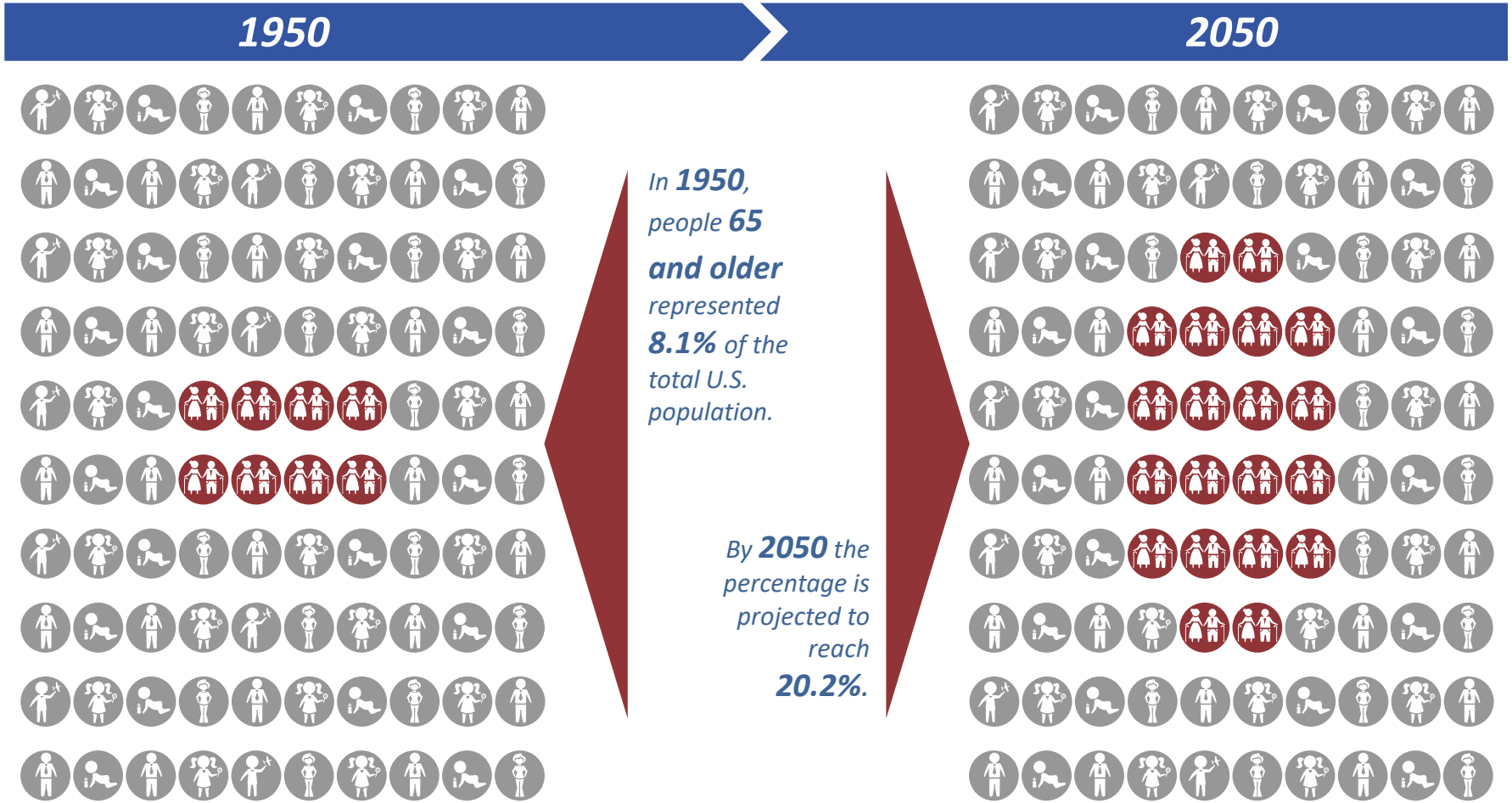
THE HENRY J. KAISER FAMILY FOUNDATION

AND

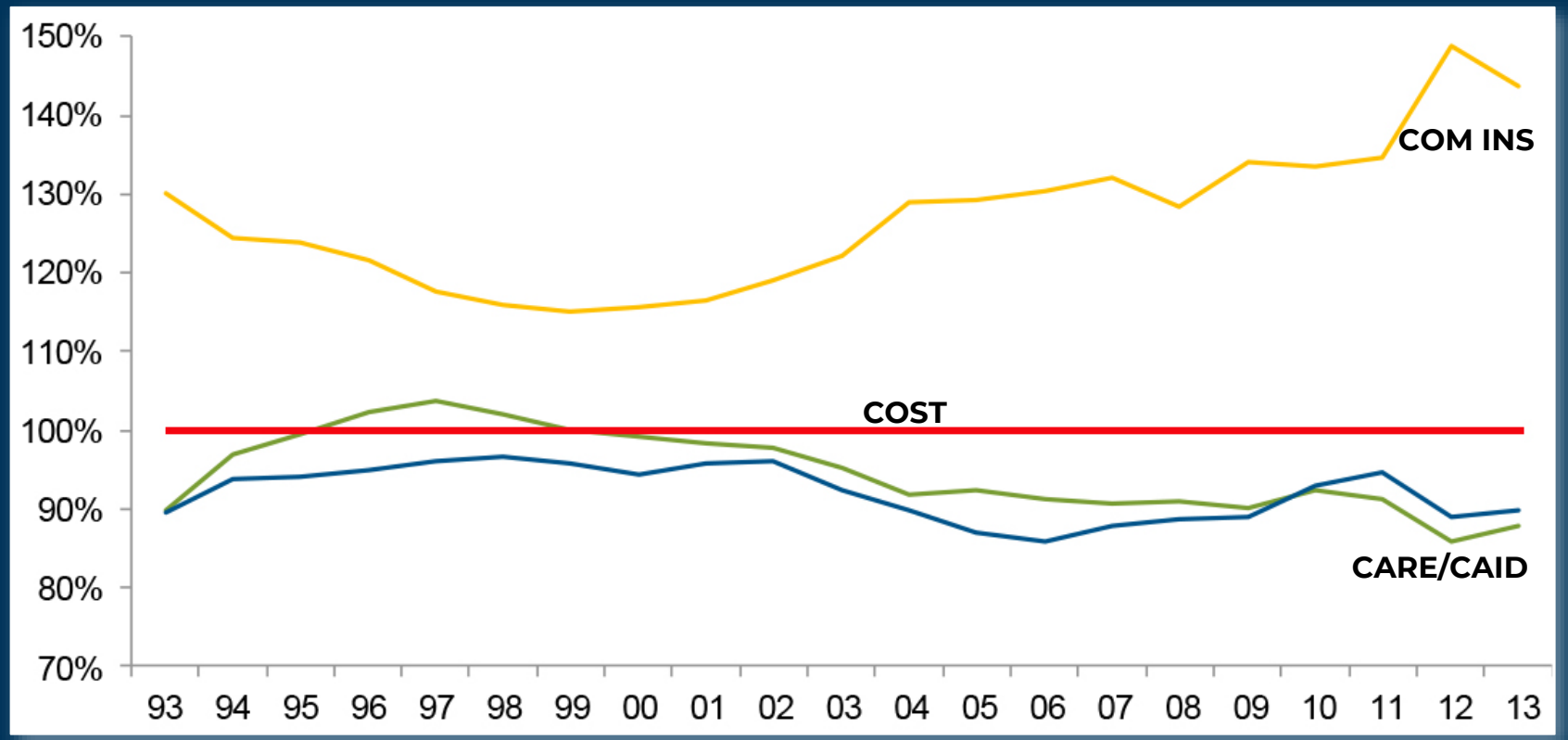
HRET HEALTH RESEARCH & EDUCATIONAL TRUST In Partnership with AHA

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 1999-2014. Bureau of Labor Statistics, Consumer Price Index, U.S. City Average of Annual Inflation (April to April), 1999-2014; Bureau of Labor Statistics, Seasonally Adjusted Data from the Current Employment Statistics Survey, 1999-2014 (April to April).

The Demographic Tsunami



The Entitlements are Under-Water

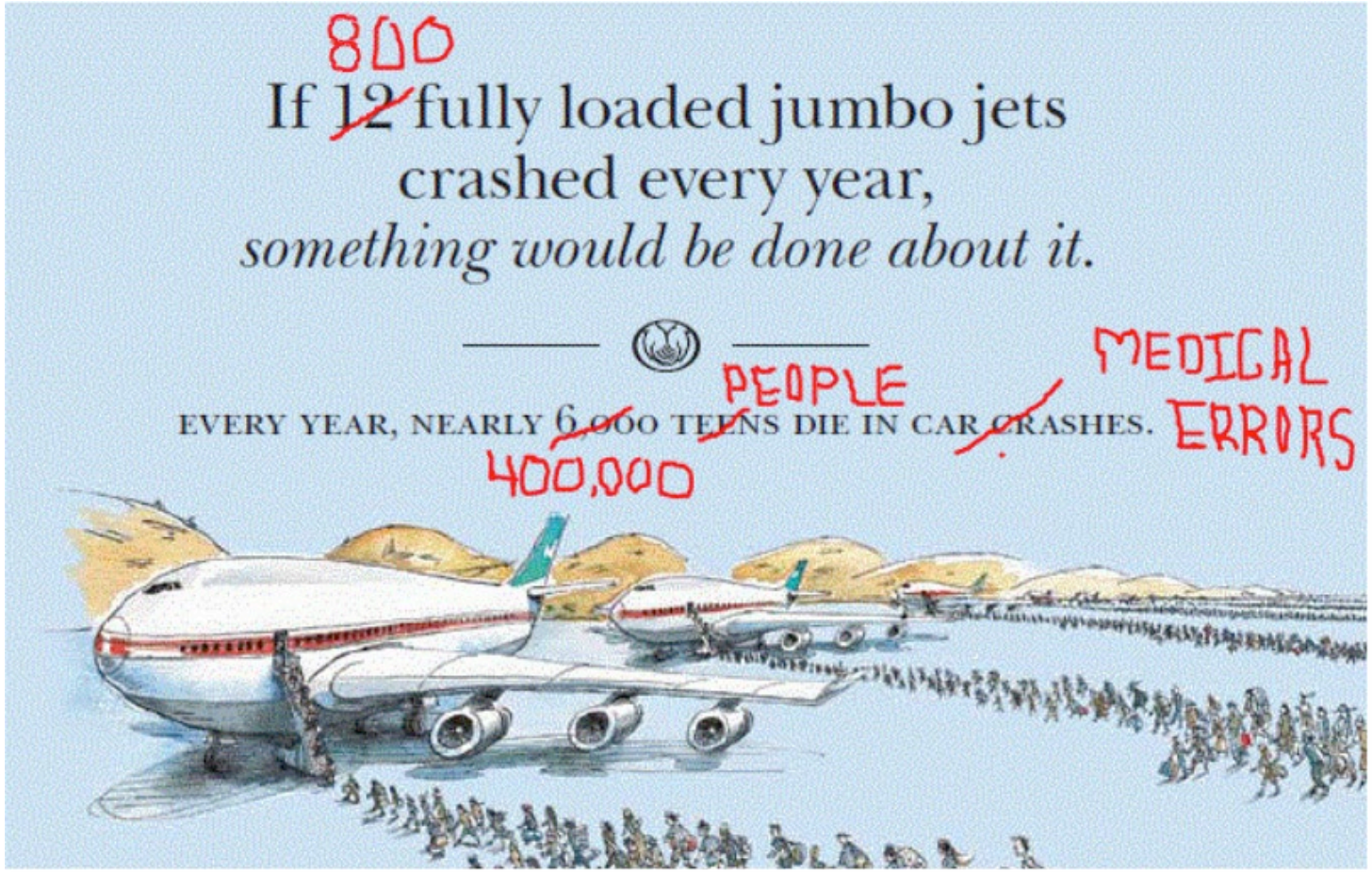


Source: Avalere Health analysis of American Hospital Association Annual Survey data, 2013, for community hospitals.

(1) Includes Medicare Disproportionate Share payments.

(2) Includes Medicaid Disproportionate Share payments.

Healthcare is not safe



Decidedly Unproductive

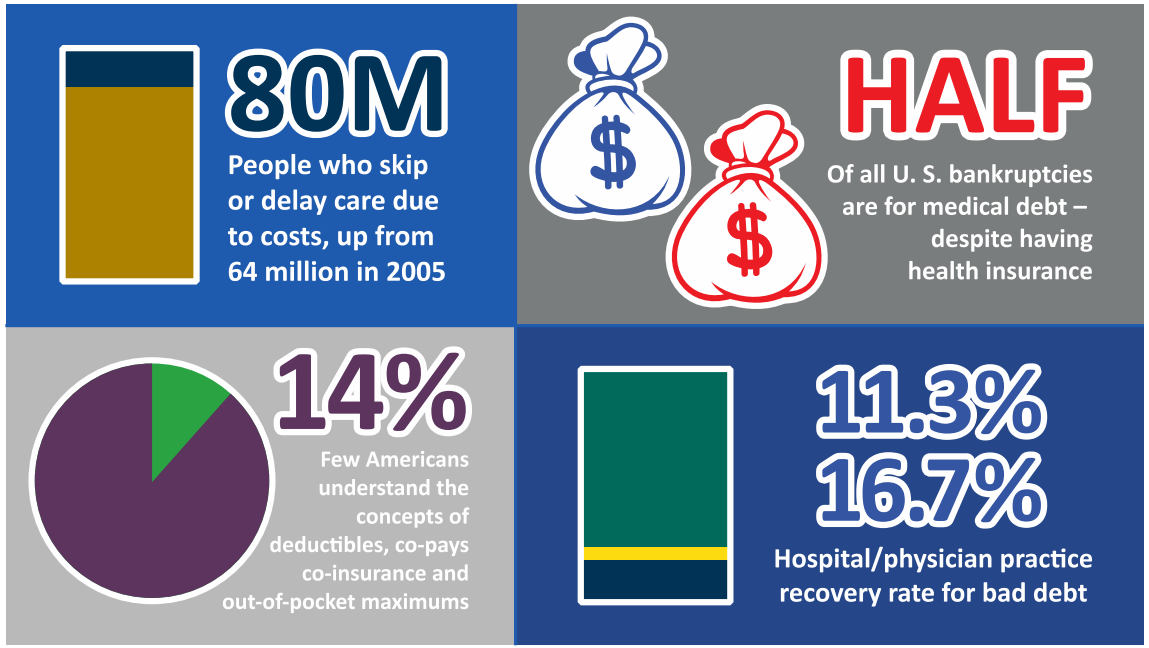
Hospital and Health System Landscape Point of No Return?

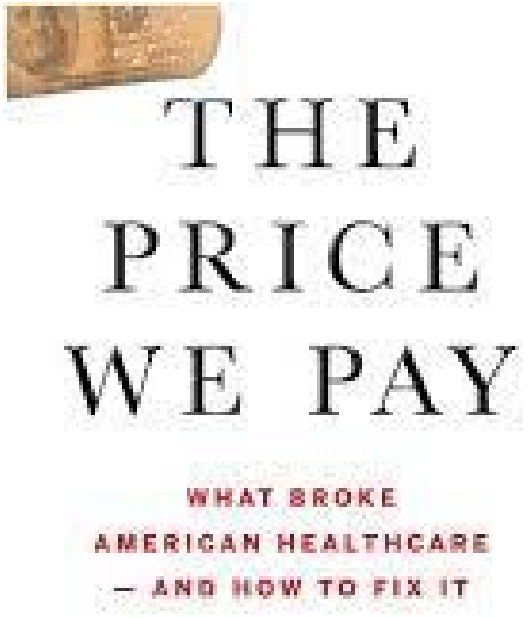
- **$54 billion:** Projected net income losses to hospitals and health systems in 2021.[1]
- **More than a third of hospitals** were expected to end 2021 with negative operating margins.[1]
- Hospitals and health systems are paying **$24 billion** more per year for qualified clinical labor than they did pre-pandemic.[2]
- Travel nurse rates jumped **over 200%**. Hospitals are spending approximately **62.5%** more for travel RNs than they did at the start of 2020.[3]

1"Financial Effects of COVID-19: Hospital Outlook for the Remainder of 2021," Kaufman, Hall & Associates LLC, Sept. 2021.
2Alkire, Michael J. et al. "PINC AI Data Shows Hospitals Paying $24B More for Labor Amid COVID-19 Pandemic," Data & Analytics Blog, Premier, Inc., Oct. 6. 2021.
3"2021 NSI National Health Care Retention & RN Staffing Report," NSI Nursing Solutions Inc., March 2021.

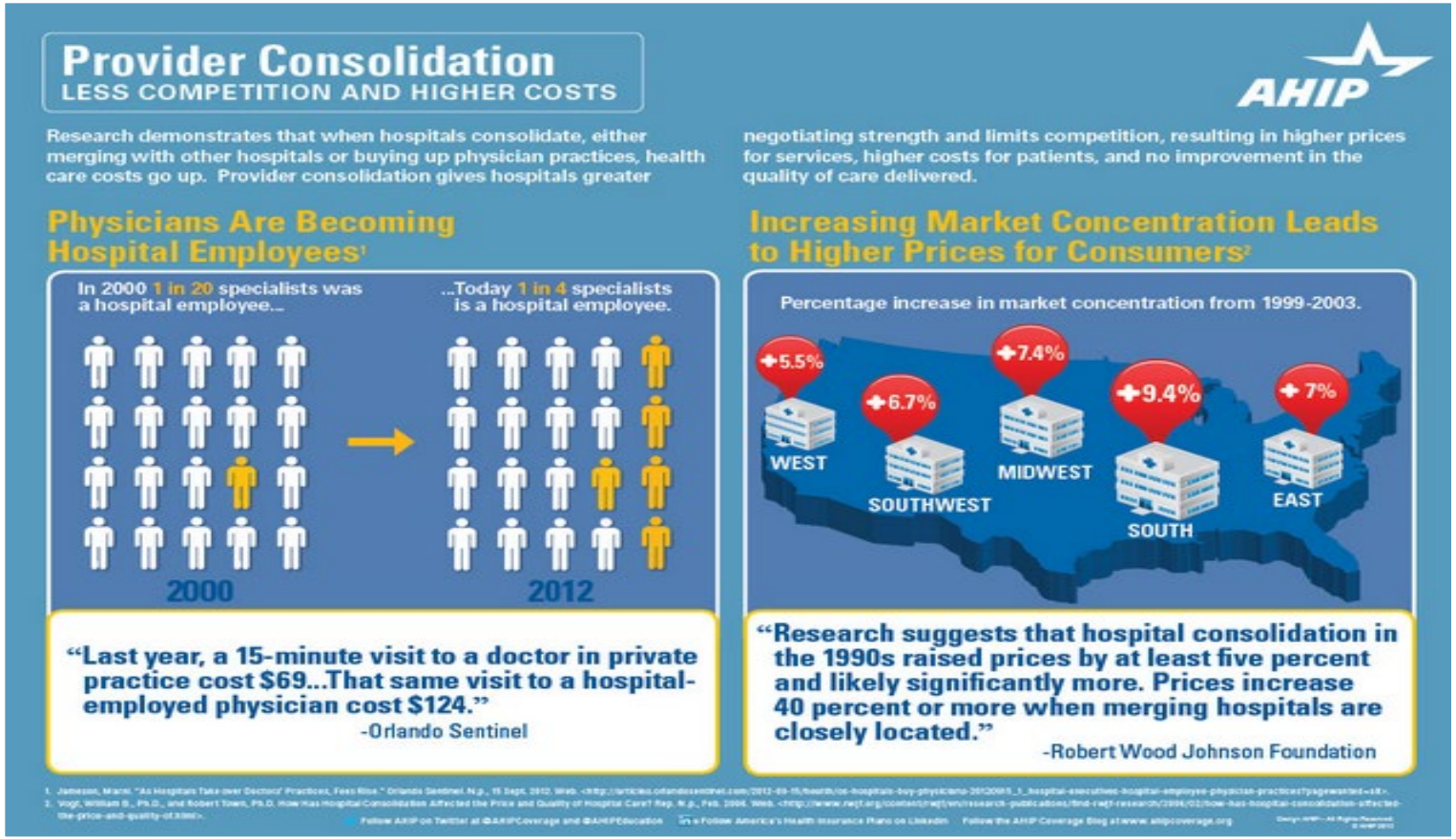
American Hospital Association™
Advancing Health in America

Personal finance at your peril!





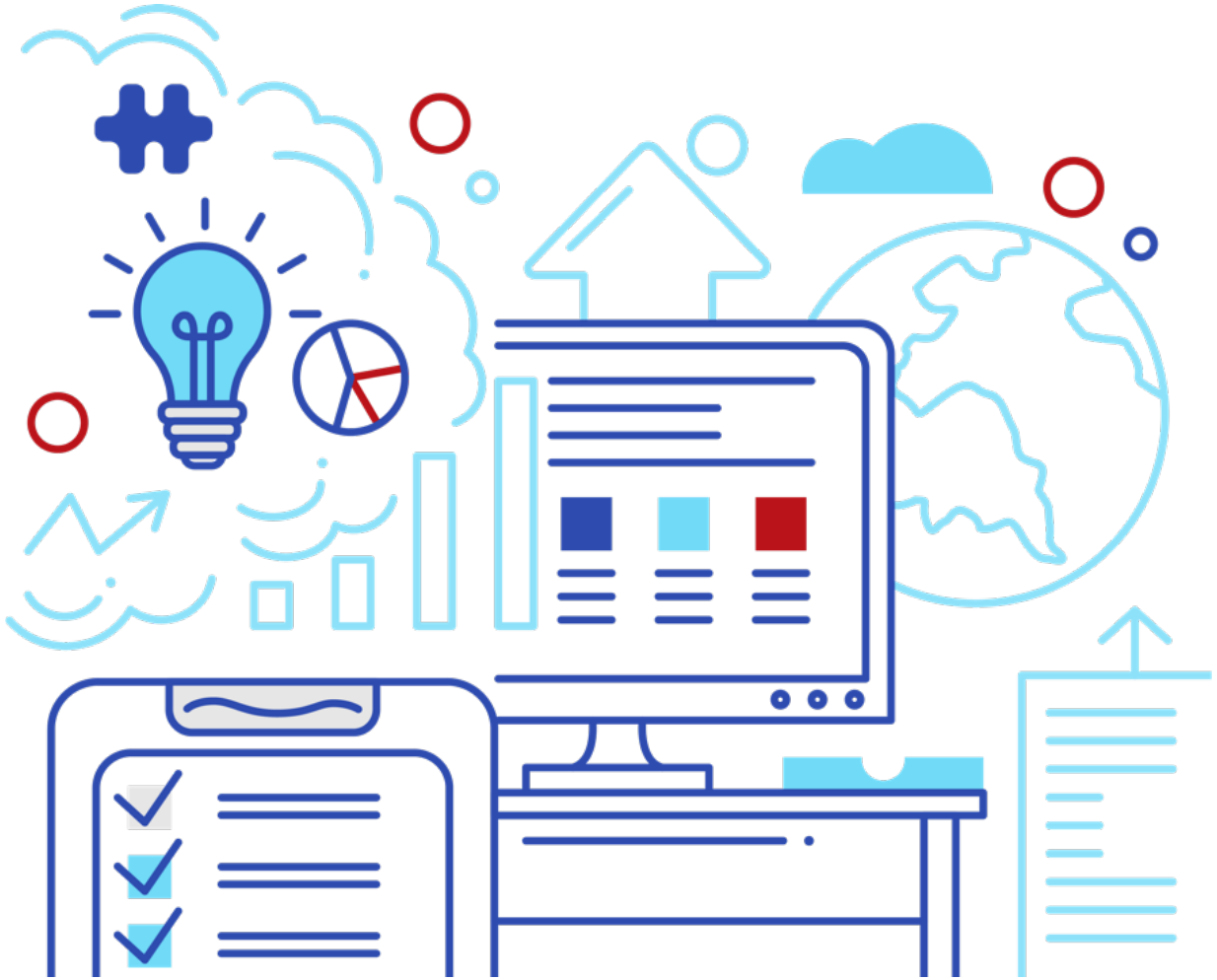
Hospitals won’t disrupt themselves!



Mistreated – “multi-organ system failure”*

- 1/3 of physicians dissatisfied; 1/2 urge their kids NOT to follow into medicine
- Variation in clinical practice and outcomes could easily be 30%
- Sepsis is 2% of all admissions; 17% of all deaths; sepsis is 10x mor deadly than heart attack
- Less than 15% of patients use email to communicate with their provider
- 1/3 of physicians don’t wash their hands regularly despite undisputed evidence that they should
- Hospitals make decisions about who will be allowed to buy them based on the suitor that will keep the most staff
- The entrenched status quo – insurers, hospitals, specialty societies and drug/device manufacturers

*Robert Pearl, MD, Mistreated



The Opportunity

Healthcare megatrends that will change everything

1

Aging

All-time record increase in aging population in the US will continue to grow from 54M to 74M in 2030[1]

2

Consumerism

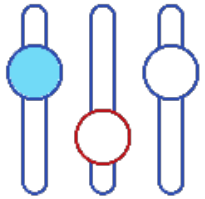
Today, consumers want healthcare to come to them - the same way that Amazon brought the mall to them

3

Economics

Continued, excessive growth in spending driving movement toward a “defined contribution” healthcare

4



Technology

Advancing and evolving technology enables care anywhere

VBC and Patient-Centric Care to drive better health quality outcomes, innovative delivery and financial sustainability

1 https://www.prb.org/resources/fact-sheet-aging-in-the-united-states

The healthcare opportunity

$265 billion Medicare FFS & MA Beneficiary services are predicted to shift to the home by 2025

$4.1+ trillion US Healthcare spending continues to grow at an alarming rate

45% The MA market now makes up 45% of all Medicare enrollment

99k deaths CDC estimates that HAIs account for 1.7M infections and 99,000 deaths each year

Closing good deals is not trivial

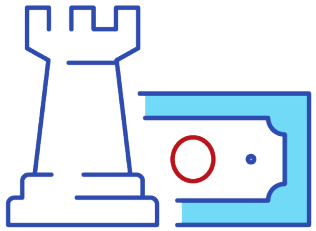
Increased competition with supply/demand imbalance requires speed to acquisition

Investors who win have access to strategic, domain and operating capabilities for scalability

Alignment between the care mission and economic models are critical for success

Sources: Fierce Healthcare, McKinsey, KFF, CDC

Capital Response



Chasing arbitrage

Tons of institutional capital chasing decades of bad results, inefficiency, defensive medicine, fraud and abuse & unnecessary care

Privatizing entitlements

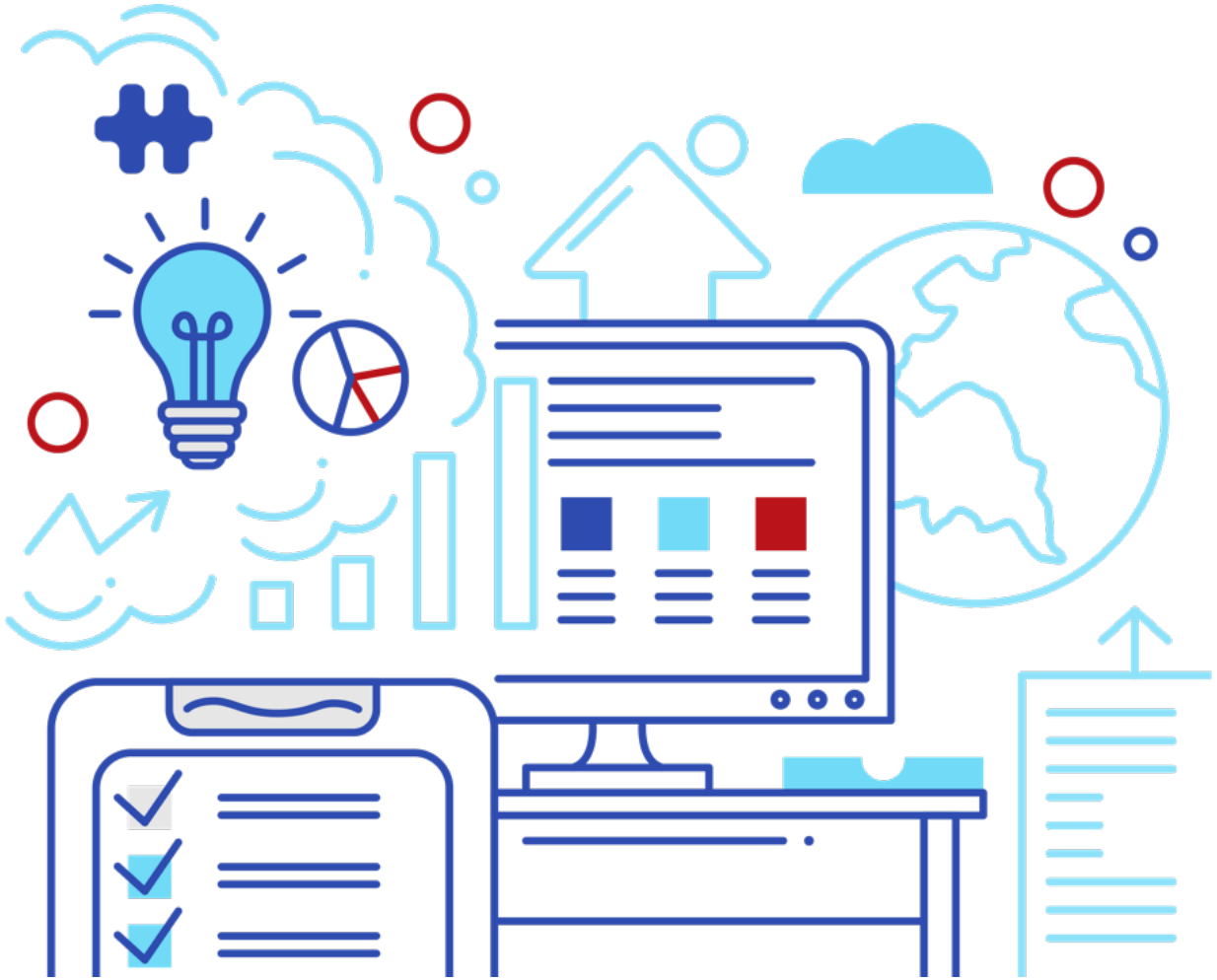
Outsize impact of massive growth in Medicare Advantage and managed Medicaid

Location, location, location

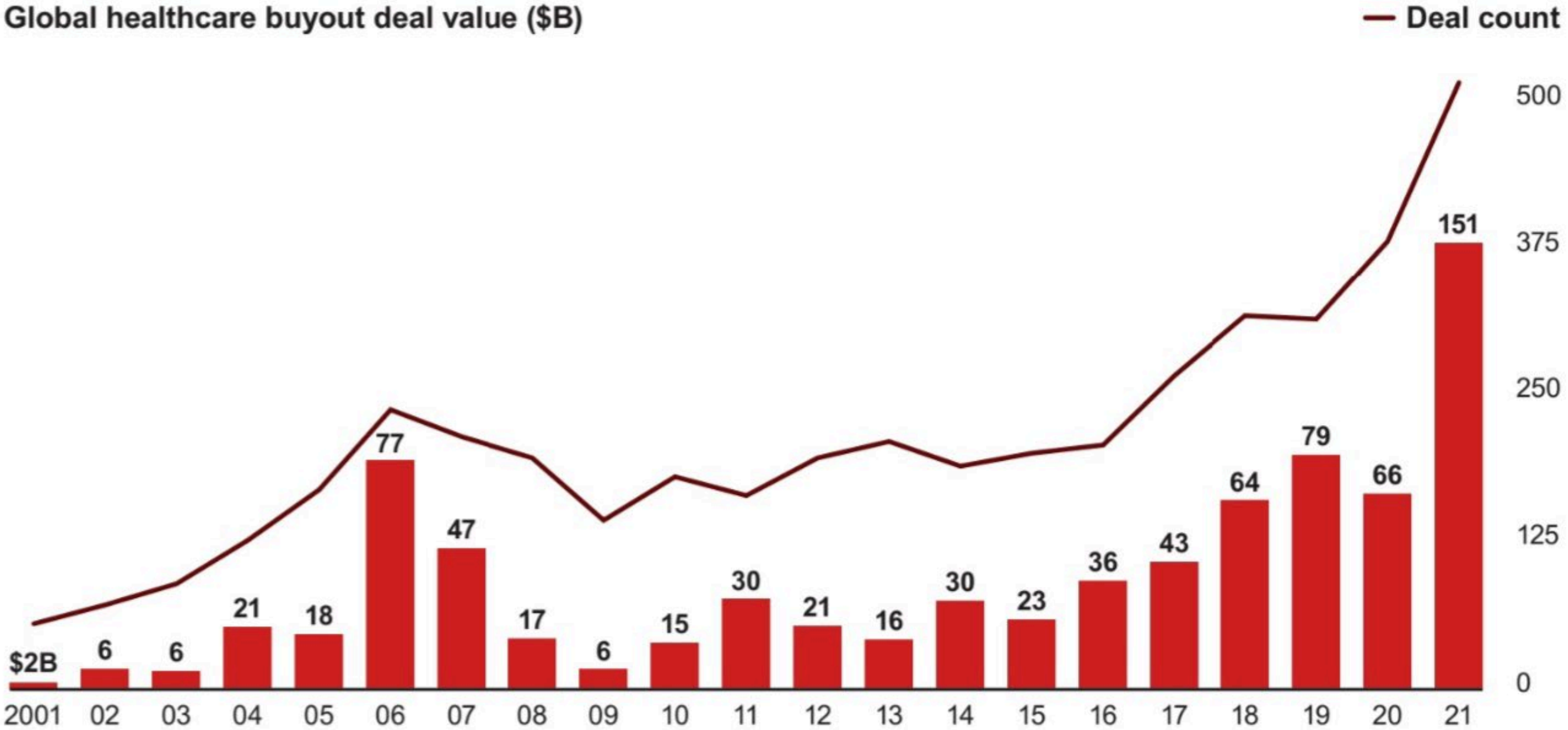
Massive shift of spend from institutional settings to home and community

The insurgents

Engaged consumer pockets desire a new kind of engagement – which top-notch retailers understand

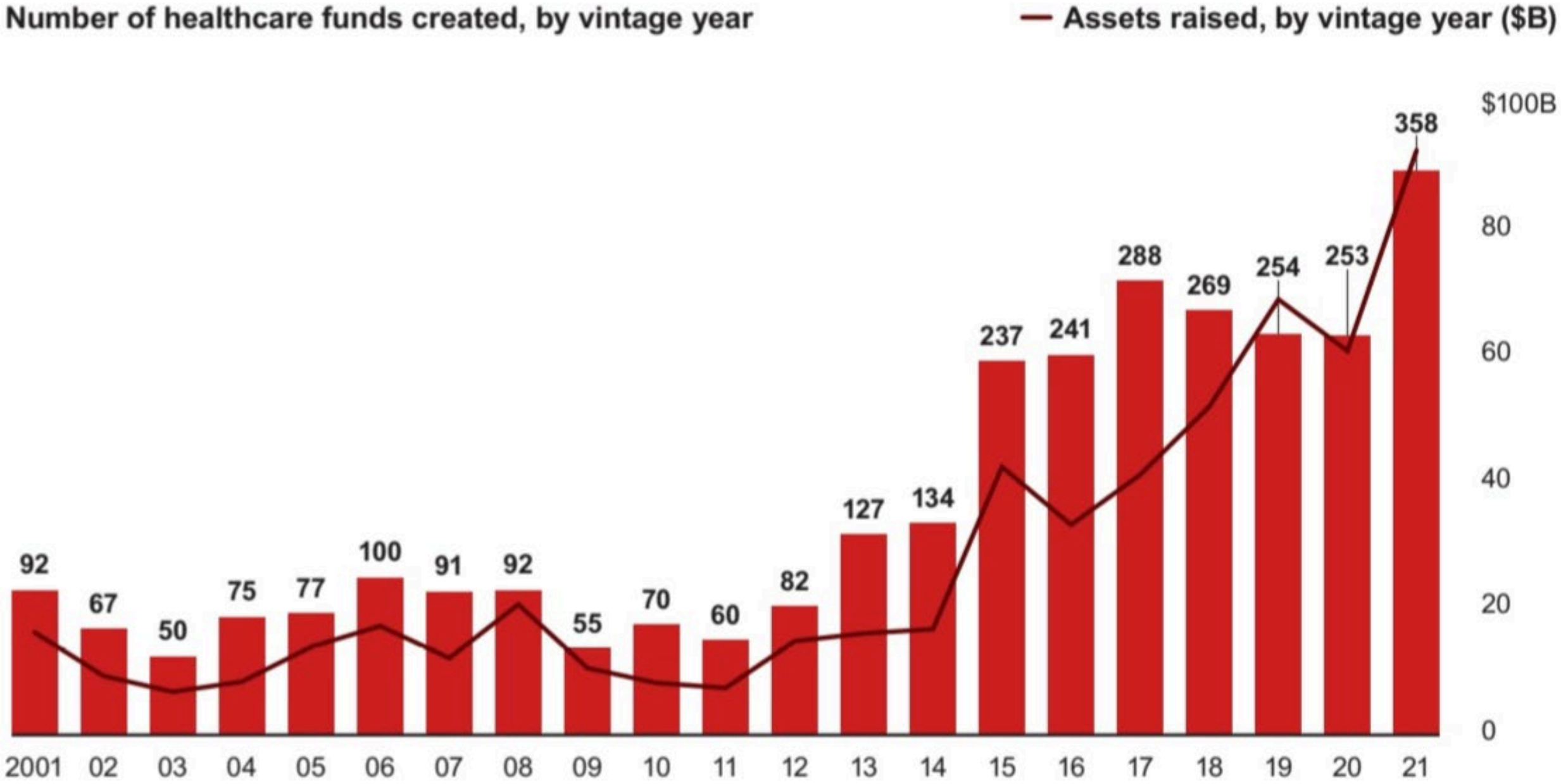


The PE Response



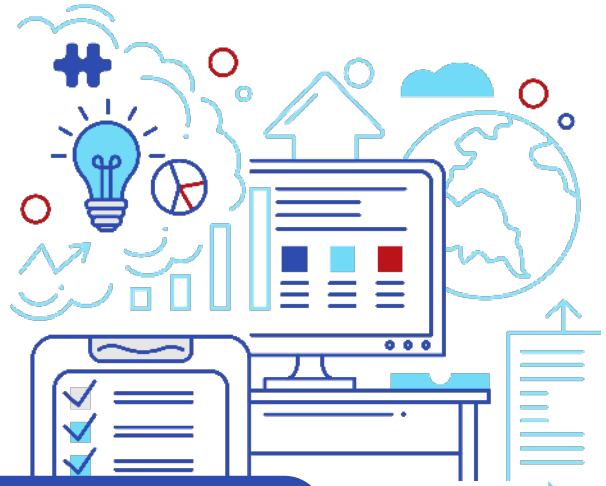
Notes: Dollar numbers are rounded; excludes spin-offs, add-ons, loan-to-own transactions, and acquisitions of bankrupt assets; numbers based on announcement data; includes announced deals that are completed or pending, with data subject to change; deal value doesn't account for deals with undisclosed values; total buyout deal values updated based on Dealogic 2021 sponsor classifications

Sources: Dealogic; AVCJ; Bain analysis



Source: Preqin

Value drivers for Investors



Investment Strategy

Discovery & insights
Evaluate investment thesis and market map. Raise funds. Identify and source investment opportunities.

Transaction Support

Due diligence/validation/ transition planning
Source opportunities, compete, diligence, prepare and close.

Value Acceleration

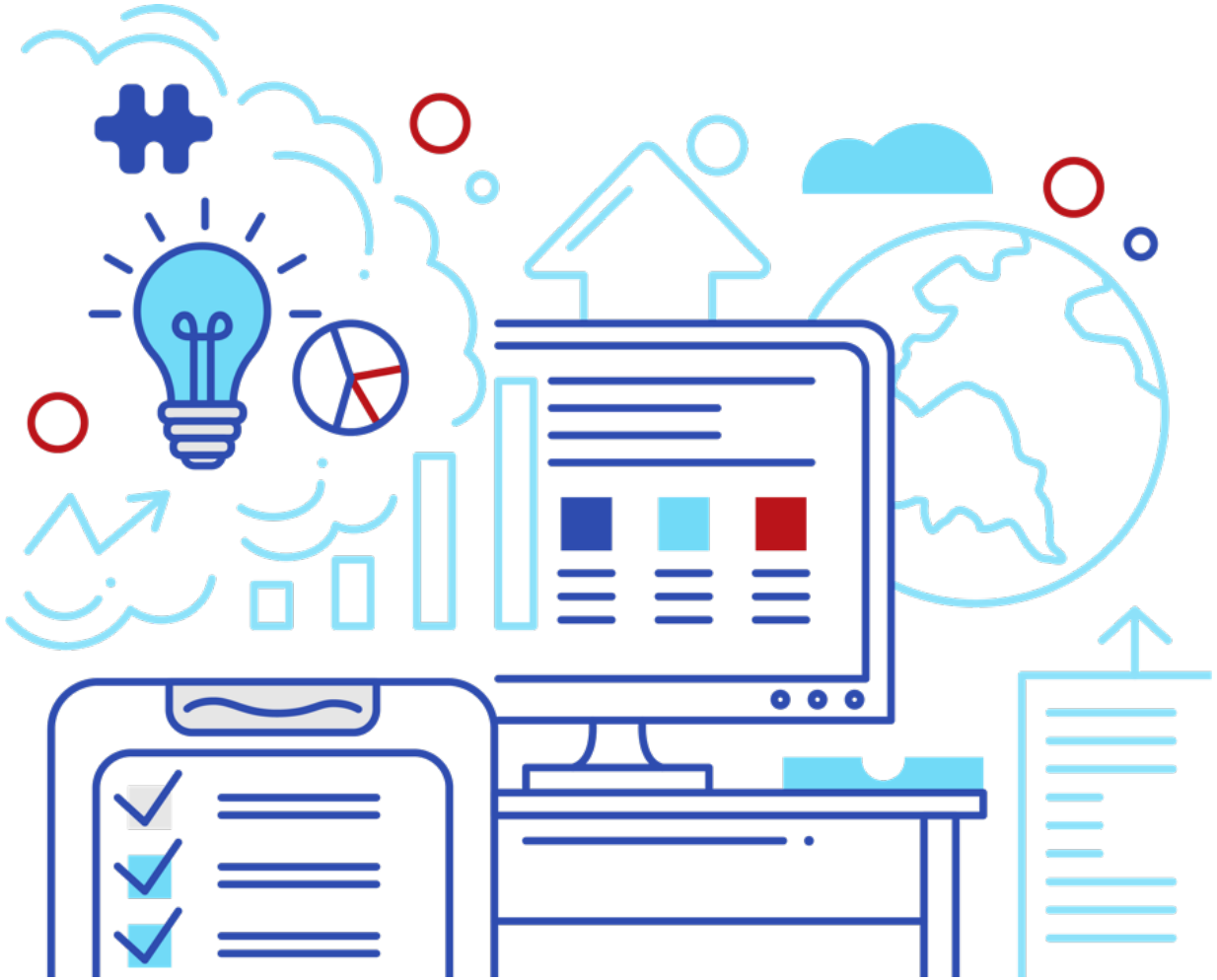
Business building & value acceleration
Align “right people on the bus in the right seats”, unlock channels of growth, perfect operating rhythm, capture value and ensure a successful exit.

Unconventional wisdom

- De novo builds
- Non-traditional assets
- Non-traditional partners
- Hyper-rapid decision cycles – much higher risk
- Ebb-and-flow – cycle swings from growth-bias to operating-affirmation – back and forth

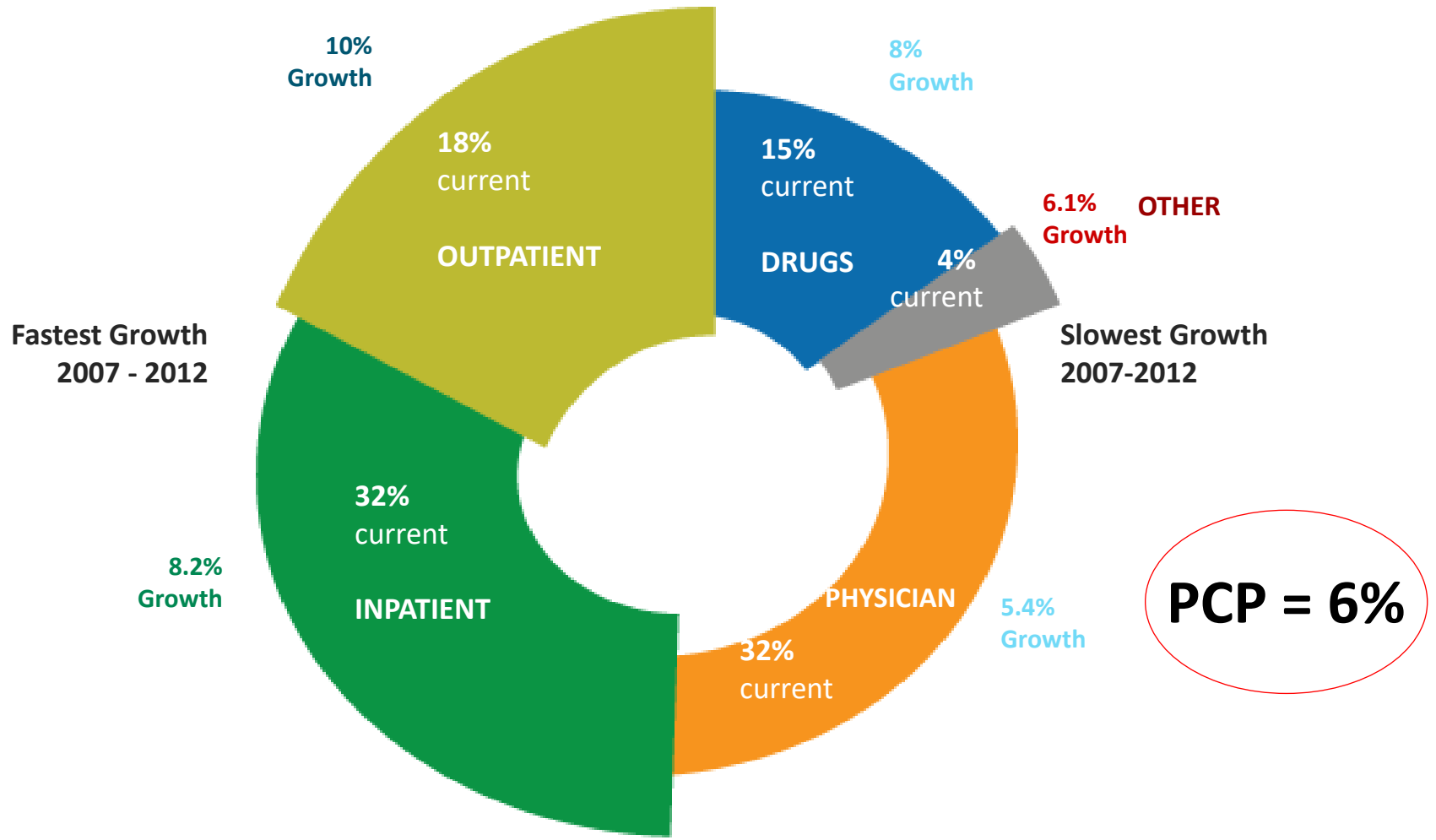
What we're hearing and seeing

- "MA-ize" Medicaid
- CMS moving from "encouragingly supportive" to "strongly suggestive"
  - " goal for CMS … to eliminate risk-free fee-for-service arrangements"
  - Determining how to promote national transformation / alignment beyond Medicare.
  - Mandatory Alternative Payment Models?
- Capital and conveners – but beware – "Notice, we're in a landgrab"



What's the appetite?

The rise of the ALT-ACUTE!



PitchBook Data, Inc.

John Gabbert Founder, CEO

Nizar Tarhuni Senior Director, Institutional Research & Editorial

Paul Condra Head of Emerging Technology Research

Institutional Research Group

Analysis

Rebecca Springer, Ph.D.
Senior Healthcare Analyst
rebecca.springer@pitchbook.com

Publishing

Designed by **Megan Woodard**

Published on September 16, 2022

Contents

EMERGING TECH RESEARCH

Walmart, Amazon, and CVS Make Waves in Healthcare Services

Implications for PE and VC

PitchBook is a Morningstar company providing the most comprehensive, most accurate, and hard-to-find data for professionals doing business in the private markets.

Key takeaways

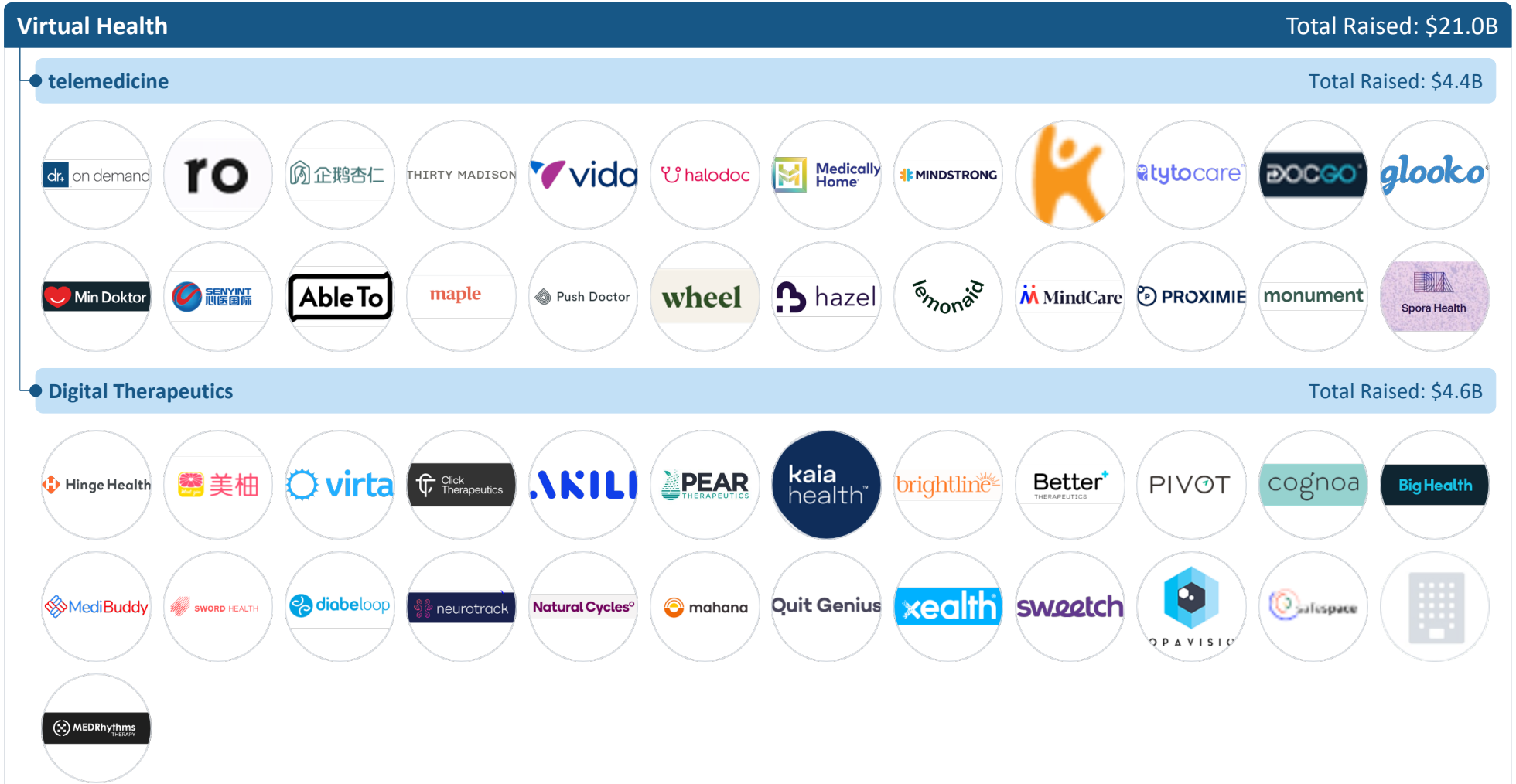
- Walmart, Amazon, and CVS all have established healthcare services plays, but recent M&A and partnership announcements by the retail giants have made it clear that their healthcare forays are accelerating.

- Nontraditional retail players are innovating on the site-of-care theme by offering

Q3 2021: Retail Healthtech Market Map

PitchBook

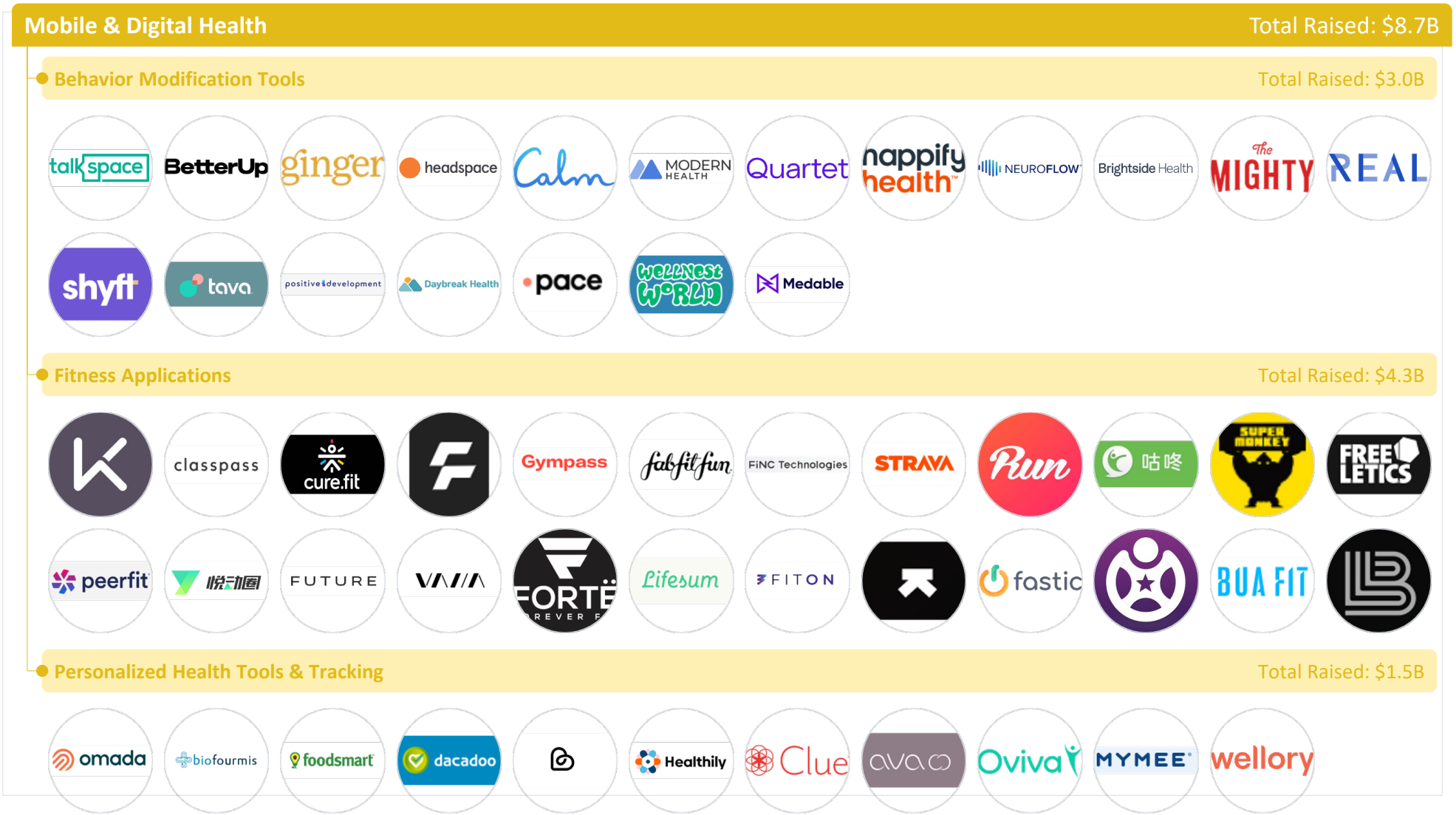
PitchBook Map



Q3 2021: Retail Healthtech Market Map

PitchBook

PitchBook Map



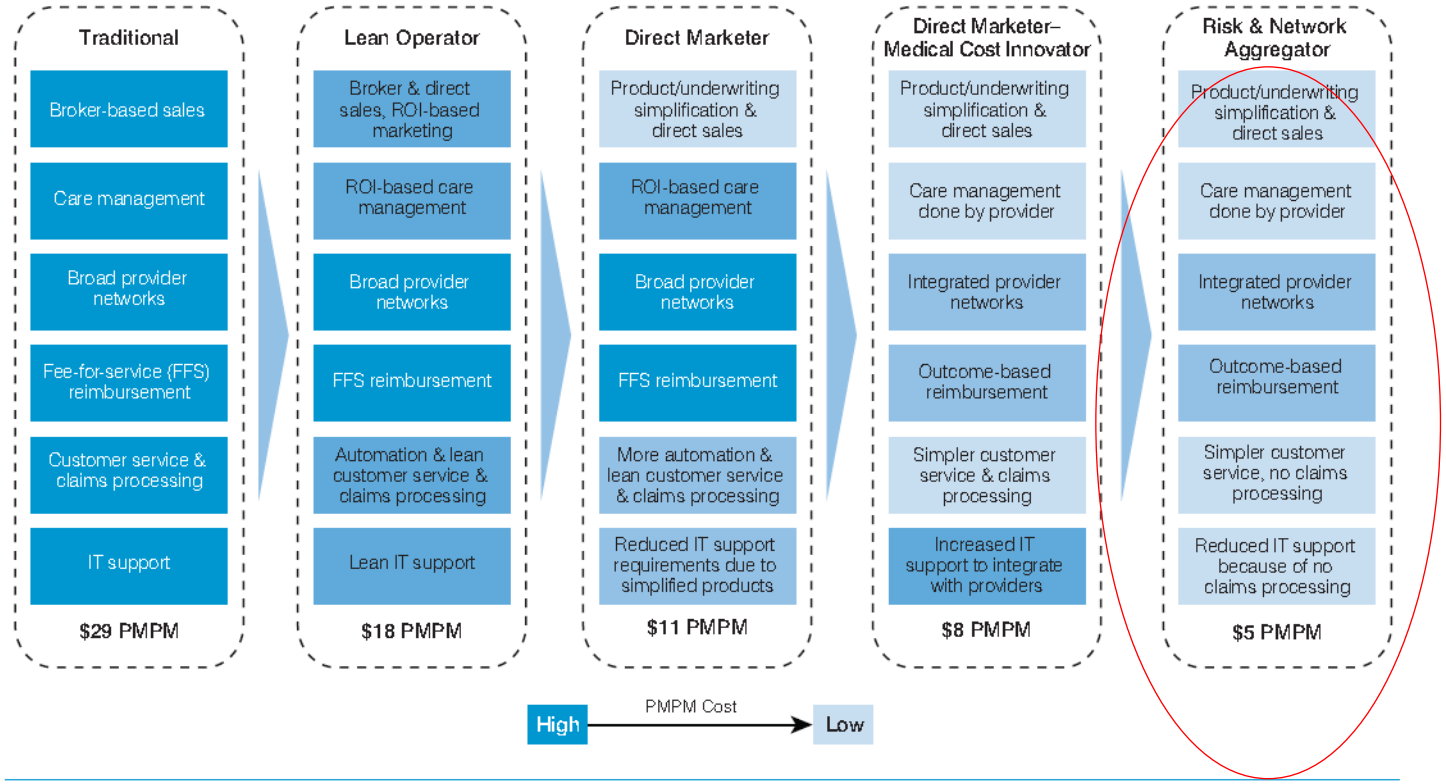
Q3 2021: Retail Healthtech Market Map

PitchBook

PitchBook Map

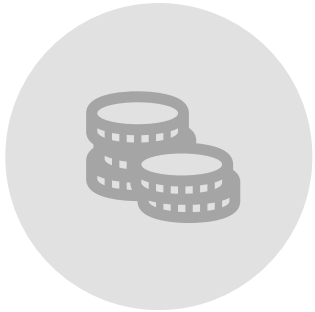
The (really) lean (digital) health plan

Exhibit 2
Fit-for-Purpose Operating Models Can Dramatically Reduce Administrative Costs



Note: PMPM costs are based on an average-performing plan with 2 million members.
Source: Booz & Company

Could be a dark winter



Economic factors

Long-Covid memories

fragile-gig economy

Centers of Excellence

What's it mean to me?

- Depends on your current seat.
- Need to challenge conventional thinking.
- Do you own heavy assets? Why?
- Hospitals – what do you want to be when you grow up?
- Do you understand the value of your assets?
- Is your physician organization underwater?
- What's your senior strategy?
- How well do you speak "consumer"?

THANK YOU

Don McDaniel
dmcdaniel@cantoncompany.com

443.904.2882

Buchanan
Ingersoll·Rooney

DOJ Enforcement Trends in Telehealth & DME

Jason P. Bologna, Shareholder | White Collar Defense, Compliance & Investigations, Buchanan Ingersoll & Rooney
Andria R. Adigwe, Associate | Healthcare, Buchanan Ingersoll & Rooney

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

Agenda

1. Current Standards: Telehealth & DME
2. State and Federal Responses to COVID-19
3. Fraud & Abuse Implications
4. DOJ Trends & Key Takeaways

Current Standards: Telehealth & DME

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

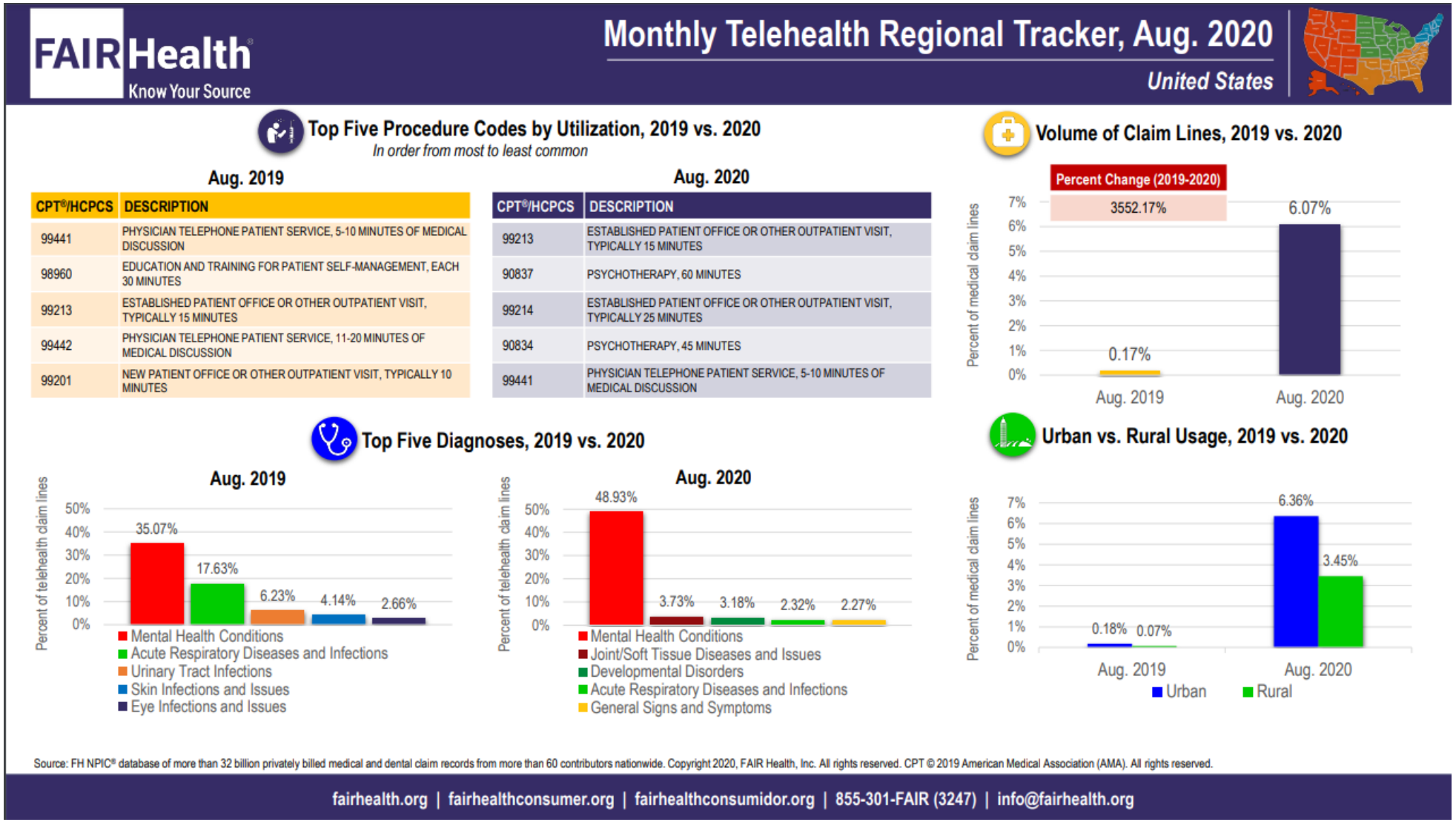
Definitions

- Telehealth / Telemedicine
  - exchange of medical information from one site to another through electronic communication to improve a patient's health.
  - Telecommunication technology
  - Medicaid and Medicare reimbursements

- Durable Medical Equipment
  - 42 U.S.C. 1395k-x
  - Supplies and equipment ordered by providers for everyday or extended use and generally not useful in the absence of illness or injury

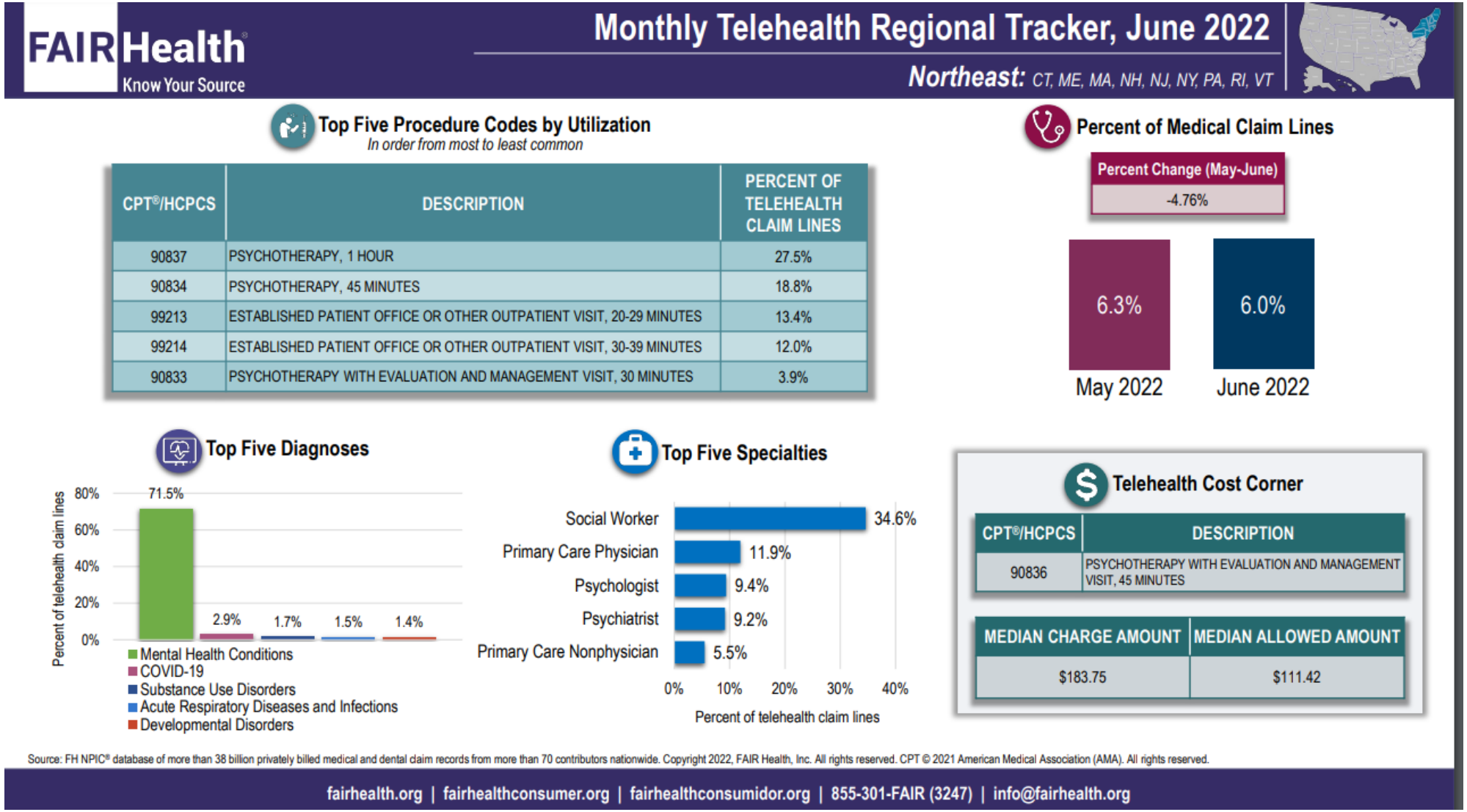
  - Generally Coverage requires
    - Necessity for Equipment
    - Reasonableness of Equipment

Telehealth Use in Northeast 2020



Fair Health available at https://s3.amazonaws.com/media2.fairhealth.org/infographic/telehealth/aug-2020-national-telehealth.pdf

Telehealth Use in Northeast 2022



Fair Health available at https://s3.amazonaws.com/media2.fairhealth.org/infographic/telehealth/june-2022-northeast-telehealth.pdf

Durable Medical Equipment

Patients may:

1. Rent equipment
2. Buy equipment

- Blood sugar meters
- Blood sugar test strips
- Continuous Positive Airway Pressure (CPAP) devices
- Hospital beds
- Home infusion services
- Infusion pumps & supplies
- Nebulizers & nebulizer medications
- Oxygen equipment & accessories
- Pressure-reducing support surfaces
- Suction pumps
- Traction equipment
- Walkers
- Wheelchairs & scooters

Public Health Emergency (COVID)

- Telehealth Waivers
  - Licensing
  - Reimbursement etc.

- DMEPOS Waivers
  - Replacement of Lost DME
  - Relaxation of prior authorization requirement

Fraud & Abuse Implications

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

Statutes

- False Claims Act
  - 31 U.S.C. § § 3729-3733
- Anti-Kickback Statute
  - 42 U.S.C. § 1320a-7b(b)
- Physician Self-Referral Law
  - 42 U.S.C. § 1395nn
- Exclusion Statute
  - 42 U.S.C. § 1320a-7
- Civil Monetary Penalties Law
  - 42 U.S.C. § 1320a-7a

Department of Justice – July 20, 2022 Press Release

Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

- **The Department of Justice today announced criminal charges against 36 defendants in 13 federal districts across the United States for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment (DME) schemes.**
- The nationwide coordinated law enforcement action includes criminal charges against a telemedicine company executive, owners and executives of clinical laboratories, durable medical equipment companies, marketing organizations, and medical professionals. In connection with the enforcement action, the department seized over $8 million in cash, luxury vehicles, and other fraud proceeds.
- Additionally, the Centers for Medicare & Medicaid Services (CMS), Center for Program Integrity (CPI) announced today that it took administrative actions against 52 providers involved in similar schemes.
- **"The Department of Justice is committed to prosecuting people who abuse our health care system and exploit telemedicine technologies in fraud and bribery schemes," said Assistant Attorney General Kenneth A. Polite, Jr. of the Justice Department's Criminal Division. "This enforcement action demonstrates that the department will do everything in its power to protect the health care systems our communities rely on from people looking to defraud them for their own personal gain."**

Department of Justice – Press Release

- **Today's announcement builds on prior telemedicine enforcement actions involving over $8 billion in fraud, including 2019's Operation Brace Yourself, 2019's Operation Double Helix, 2020's Operation Rubber Stamp, and the telemedicine component of the 2021 National Health Care Fraud Enforcement Action.** Specifically, the Operation Brace Yourself Telemedicine and Durable Medical Equipment Takedown alone resulted in an estimated cost avoidance of more than $1.9 billion in the amount paid by Medicare for orthotic braces in the 20 months following that enforcement action.

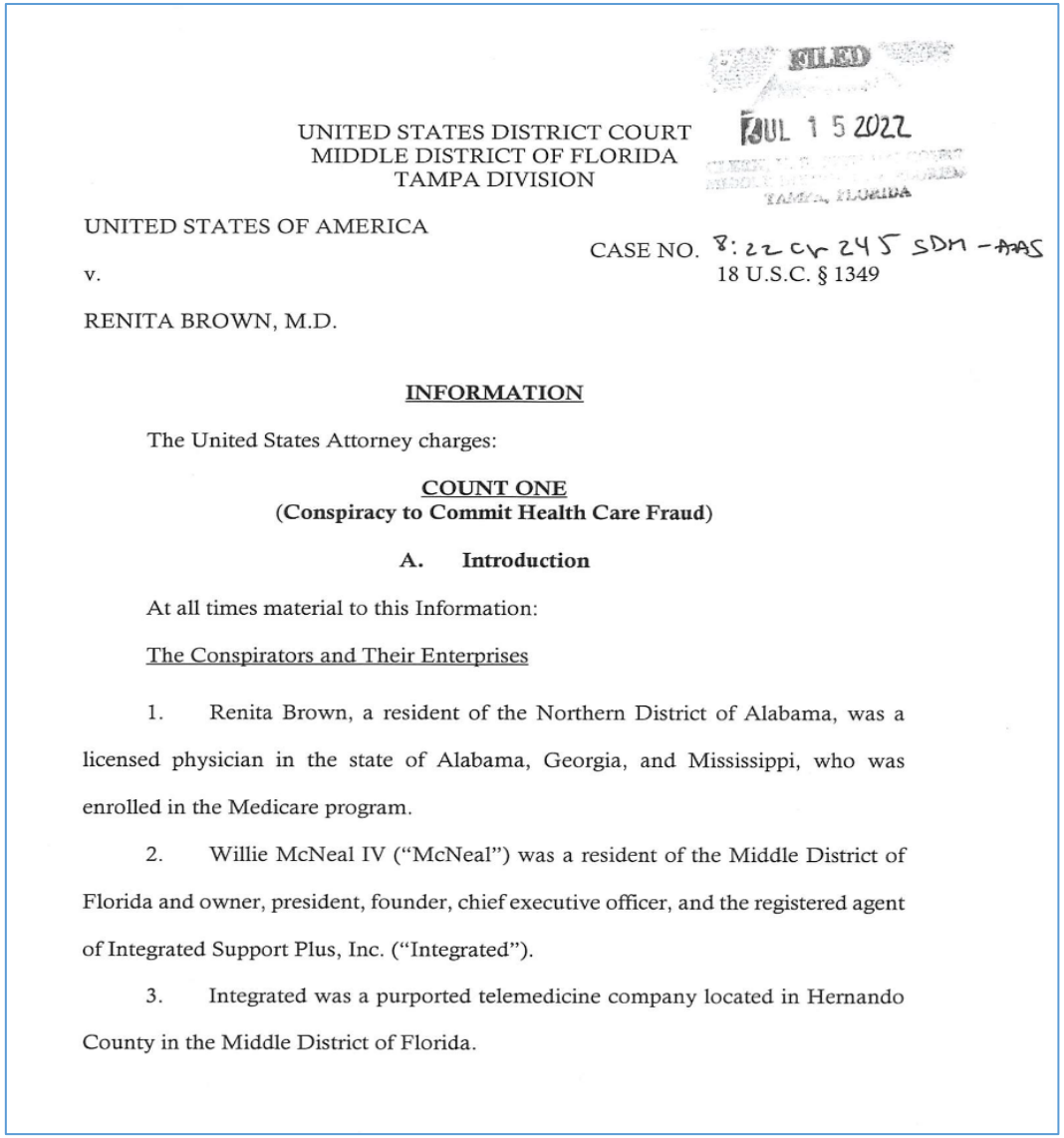
How Does the Government Come up with Task Force Names?

A. Use rejected film titles from 1980s James Bond films.
B. Use 50 yellow post-it notes, write a random word on each note, place the notes on a wall, begin throwing darts.
C. Use a new agent to take three shots of tequila, then close both eyes, open nearest dictionary and point at random word. If necessary, repeat process to select a second word.
D. Use winning answers from 1990s re-runs of Wheel of Fortune.
E. All of the above.

Case Summaries

- **Renita Brown**, 63, of Gadsden, Alabama, was charged by information for referring **over $7.3 million in billings to Medicare for medically unnecessary braces.** Between in or around January 2018 and in or around October 2018, **Brown, a physician, was paid to sign doctors' orders for braces for Medicare beneficiaries she had no preexisting relationship with, never examined, ran no diagnostic testing on, and in some cases, never spoke with.** The braces she prescribed were preselected for her. During that time period, **Brown signed over 7,800 doctor's orders at the request of two purported telemedicine companies.** The case is being prosecuted by Trial Attorney Catherine Wagner of the National Rapid Response Strike Force.

Court Documents – USA v. Renita Brown, M.D.



FILED
JUL 15 2022
TAMPA, FLORIDA

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

RENITA BROWN, M.D.

CASE NO. 8:22 cr 245 SDM-AAS
18 U.S.C. § 1349

INFORMATION

The United States Attorney charges:

COUNT ONE
(Conspiracy to Commit Health Care Fraud)

A. Introduction

At all times material to this Information:

The Conspirators and Their Enterprises

1. Renita Brown, a resident of the Northern District of Alabama, was a licensed physician in the state of Alabama, Georgia, and Mississippi, who was enrolled in the Medicare program.

2. Willie McNeal IV ("McNeal") was a resident of the Middle District of Florida and owner, president, founder, chief executive officer, and the registered agent of Integrated Support Plus, Inc. ("Integrated").

3. Integrated was a purported telemedicine company located in Hernando County in the Middle District of Florida.

USA v. Renita Brown, M.D. – cont'd

16. A Medicare claim for DME reimbursement was required to set forth, among other information, the beneficiary's name and unique Medicare identification number, the equipment provided to the beneficiary, the date the equipment was provided, the cost of the equipment, and the name and unique physician identification number of the physician who prescribed or ordered the equipment.

17. Medicare would pay a claim for the provision of DME only if the equipment was medically necessary, ordered by a licensed provider, and actually provided to the beneficiary. Medicare claims were required to be properly documented in accordance with Medicare rules and regulations. Medicare would not reimburse providers for claims that were procured through the payment of kickbacks and bribes.

20. The manner and means by which the defendant and her conspirators sought to accomplish the purposes of the conspiracy included, among others, the following:

a. It was a part of the conspiracy that Renita Brown would and did falsely certify to Medicare that she would comply with all Medicare rules and regulations, and federal laws, including that she would not knowingly present or cause to be presented a false and fraudulent claim for payment by Medicare and that she would comply with the Anti-Kickback Statute.

USA v. Renita Brown, M.D. – cont'd

b. It was further a part of the conspiracy that Renita Brown would and did work directly, or indirectly through staffing companies, for various purported telemedicine companies, including Integrated and AffordADoc.

c. It was further a part of the conspiracy that McNeal, Harry, Stockett, and others would and did pay, or cause to be paid, Renita Brown in exchange for signing brace orders.

d. It was further a part of the conspiracy that McNeal, Harry, Stockett, and others would and did pay, or cause to be paid, Renita Brown between $20 and $30 for each purported telemedicine consult she completed.

e. It was further a part of the conspiracy that Renita Brown would and did sign medically unnecessary orders for pre-selected braces for Medicare beneficiaries (a) without seeing, speaking to, and/or otherwise communicating with or examining the Medicare beneficiaries', and (b) without determining the Medicare beneficiaries' need for the braces.

f. It was further a part of the conspiracy that Renita Brown would and did electronically sign orders and other Medicare-required documents for medical braces that contained false and fraudulent statements, including that she had spoken with the Medicare beneficiary, that she had established a valid prescriber-patient relationship with the Medicare beneficiary, that she medically assessed the Medicare beneficiary, and/or that she conducted various examinations and diagnostic tests on the Medicare beneficiary.

g. It was further a part of the conspiracy that between in or about June 2018 and in or about October 2018, Renita Brown would and did cause the submission by durable medical equipment companies of false and fraudulent claims to Medicare for approximately $7,318,227.55 that were medically unnecessary and/or ineligible for reimbursement, of which Medicare paid approximately $3,582,795.09.

Case Summaries

- **Brian Tisdale**, 45, of Armory, Mississippi, was charged by information for his role in an **approximately $5.9 million conspiracy to defraud Medicare and pay kickbacks. Tisdale owned two DME companies.** Beginning as early as March 2020, **Tisdale engaged in a scheme to pay kickbacks for Medicare beneficiaries' information and doctors' orders for DME. A substantial portion of the doctors' orders** purchased by Tisdale contained signatures by physicians or other health care providers whose names and professional identifying information **were used without the doctors' authorization and prior knowledge.** The case is being prosecuted by Assistant United States Attorney David O'Neal of the Northern District of Georgia.

Court Documents – USA v. Brian Tisdale

FILED IN OPEN COURT
U.S.D.C. Atlanta

JUL 14 2022

Kevin P. Weimer, Clerk
By: Deputy Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA	Criminal Information
v.	
BRIAN TISDALE	1:22-CR-0234

THE UNITED STATES ATTORNEY CHARGES THAT:

COUNT ONE
Conspiracy to Defraud the United States and Pay Health Care Kickbacks
(18 U.S.C. § 371)

1. Beginning on a date unknown, but at least by on or about March 2020, and continuing until on or about April 2021, within the Northern District of Georgia, and elsewhere, the defendant,

BRIAN TISDALE,

did willfully, that is, with the intent to further the object of the conspiracy, and knowingly, combine, conspire, confederate, and agree with DME Owner 1, Lead Seller 1, Lead Seller 2, Prescription Seller 1, and others known and unknown to the United States Attorney,

a. to defraud the United States by impairing, impeding, obstructing, and defeating through deceitful and dishonest means, the lawful government functions of the United States Department of Health and Human Services in its

2. At all times material to this Information, the defendant, BRIAN TISDALE, engaged in a scheme to buy and use fraudulent prescriptions for durable medical equipment ("DME"). Over the course of the scheme, these prescriptions were used by the defendant, along with other co-conspirators not named herein, to fraudulently bill the Medicare Program ("Medicare") for at least approximately $6,000,000.

USA v. Brian Tisdale – cont'd

26. Defendant TISDALE and his co-conspirators obtained Medicare beneficiary information from international call centers, which called the beneficiaries and up-sold them in order to get them to accept braces that call center employees marketed as free or low-cost. In many instances, the DME ordered for these recruited beneficiaries was medically unnecessary.

30. A substantial portion of the doctors' orders that defendant TISDALE and DME Owner 1 purchased from Prescription Seller 1 contained signatures or purported approvals of physicians or other health care providers whose names and professional identifying information were used without their true authorization and prior knowledge.

31. Defendant TISDALE and his co-conspirators, through Medihealth and Liberty, submitted and caused the submission of false and fraudulent claims to Medicare in the approximate amount of $6,000,475 and received Medicare reimbursements in the approximate amount of $3,877,277, for braces that were (a) procured through the payment of illegal kickbacks and bribes; (b) medically unnecessary; (c) ineligible for Medicare reimbursement; and/or (d) not provided as represented.

Case Summaries

- **Jean Wilson**, 51, of Richmond Hill, Georgia, was charged by superseding indictment with conspiracy to defraud the United States and pay and receive health care kickbacks, conspiracy to commit health care fraud and wire fraud, soliciting and receiving health care kickbacks, conspiracy to commit money laundering, income tax evasion, and filing a false individual tax return. **Wilson, a nurse practitioner and purported telemedicine company owner, is alleged to have committed an over $137 million scheme (including over $81 million in newly alleged loss in the superseding indictment) in which she owned and controlled two telemedicine companies, Advantage Choice Care, LLC and Tele Medcare, LLC, that solicited illegal kickbacks and bribes in exchange for medically unnecessary orders for orthotic braces and prescriptions for pain creams.** Wilson conspired to launder the proceeds of the funds through shell companies and by hiding cashiers' checks. She also engaged in income tax evasion by not filing returns and filing of false returns and by hiding and concealing her income earned in part through the scheme. The case is being prosecuted by Trial Attorneys Darren Halverson and Kelly Lyons of the Newark Strike Force.

Court Documents – USA v. Jean Wilson

2018R00919/DCH

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FILED
JUL 15 2022
AT 8:30
1:50 P M
WILLIAM T. WALSH
CLERK

UNITED STATES OF AMERICA	:	Hon.
	:	
	:	Crim. No.
v.	:	
	:	18 U.S.C. § 2
	:	18 U.S.C. § 371
JEAN WILSON	:	18 U.S.C. § 1349
	:	18 U.S.C. § 1956(h)
	:	26 U.S.C. § 7201
	:	26 U.S.C. § 7206(1)
	:	42 U.S.C. § 1320a-7b(b)(1)(B)

SUPERSEDING INDICTMENT

The Grand Jury in and for the District of New Jersey, sitting at Newark, charges:

COUNT 1
(Conspiracy to Defraud the United States and Pay and Receive Health Care Kickbacks)

1. At all times relevant to this Superseding Indictment:

Individuals and Entities

a. Defendant JEAN WILSON was a United States citizen who resided in Bayonne, New Jersey and Richmond Hill, Georgia.

b. Reinaldo Wilson was a United States citizen who resided in Bayonne, New Jersey and Richmond Hill, Georgia.

4. The manner and means by which the defendant and her co-conspirators sought to accomplish the goal of the conspiracy included, among others, the following:

a. Defendant JEAN WILSON and Reinaldo Wilson falsely certified to Medicare that they would comply with all Medicare rules and regulations, and federal laws, including that they would not knowingly present or cause to be presented a false and fraudulent claim for payment by Medicare and that they would comply with the Federal Anti-Kickback Statute.

b. Defendant JEAN WILSON and Reinaldo Wilson created, owned, and controlled the ACC Network.

c. Defendant JEAN WILSON, Reinaldo Wilson, and others solicited and received illegal kickbacks and bribes from Person A, Person B, Person C, Person D, and others in exchange for arranging for the ordering of Braces and prescription drugs for Medicare beneficiaries.

USA v. Jean Wilson – cont'd

d. Defendant JEAN WILSON, Reinaldo Wilson, and others caused the ACC Network to receive Medicare beneficiary information in order for the ACC Network health care providers to sign Brace orders.

e. Defendant JEAN WILSON, Reinaldo Wilson, and others facilitated the ordering of Braces and prescription drugs by refraining from charging a fee to Medicare beneficiaries or billing Medicare and Medicare sponsors for purported telemedicine consultations conducted by the ACC Network health care providers.

f. Defendant JEAN WILSON, Reinaldo Wilson, and others, through the ACC Network, paid health care providers to order Braces and prescription drugs for Medicare beneficiaries that were procured through the payment of kickbacks and bribes, medically unnecessary, ineligible for Medicare reimbursement, and not provided as represented.

g. Defendant JEAN WILSON, Reinaldo Wilson, and others transferred Brace orders to Brace providers, Person A, Person B, Person C, Person D, recruiters, and others to support false and fraudulent claims to Medicare and Medicare sponsors that were submitted by Brace providers located in the District of New Jersey and elsewhere.

h. Defendant JEAN WILSON, Reinaldo Wilson, and others concealed and disguised the payment and receipt of illegal kickbacks and bribes by causing them to be paid to the ACC Network indirectly through nominee companies and bank accounts opened by Reinaldo Wilson, defendant JEAN WILSON, and others.

i. Defendant JEAN WILSON, Reinaldo Wilson, and others concealed and disguised the scheme by entering into sham contracts and agreements that labeled kickback and bribe payments as "medical" and "consultation" expenditures.

j. Defendant JEAN WILSON, Reinaldo Wilson, and others falsified, fabricated, altered, and caused the falsification, fabrication, and alteration of Brace orders and other records to support claims for Braces and prescription drugs that were procured through the payment of kickbacks and bribes, medically unnecessary, ineligible for Medicare reimbursement, and not provided as represented.

k. Defendant JEAN WILSON, Reinaldo Wilson, and others caused Brace providers to submit and cause the submission of more than $137 million in claims to Medicare, Medicare sponsors, and Part D plans, for Braces and prescription drugs that were procured through the payment of kickbacks and bribes, medically unnecessary, ineligible for Medicare reimbursement, and not provided as represented. Medicare, Medicare sponsors, and Part D plans paid these Brace providers and pharmacies in excess of $66 million for these claims.

Case Summaries

- **Mark Gulow**, 66, of Garden, Michigan, was charged by information with health care fraud related to a nearly $3 million dollar scheme to defraud Medicare. **Gulow, a physician, worked for a purported telemedicine company during the COVID-19 pandemic and approved over 2,000 orders for DME without performing actual patient assessments to determine whether these individuals needed the prescribed equipment.** The case is being prosecuted by Trial Attorney Patrick Suter of the Detroit Strike Force.

Court Documents – USA v. Mark Gulow, D.O.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATESOF AMERICA,

Plaintiff,

v.

MARK GULOW, D.O.

Defendant.
_____/

Case: 2:22-cr-20358
Assigned To : Berg, Terrence G.
Referral Judge: Patti, Anthony P.
Assign. Date : 7/11/2022
INFO USA V GULOW (LH)

VIO: 18 U.S.C. § 1347
18 U.S.C. § 2
18 U.S.C. § 982

INFORMATION

THE UNITED STATES ATTORNEY CHARGES:

GENERAL ALLEGATIONS

At all times relevant to this Information:

The Medicare Program

1. The Medicare program ("Medicare") was a federal health care program providing benefits to persons who were 65 years of age or older or disabled. Medicare was administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency under the United States Department of Health and Human Services ("HHS"). Individuals who received benefits under Medicare were referred to as Medicare "beneficiaries."

2. Medicare was a "health care benefit program," as defined by Title 18,

22. Thereafter, MARK GULOW devised and engaged in a scheme to submit false and fraudulent claims to Medicare for DME that was medically unnecessary and not eligible for reimbursement from Medicare.

23. MARK GULOW agreed with others at Company 1 to sign DME orders for Medicare beneficiaries in exchange for approximately $15 per patient

USA v. Mark Gulow, D.O. – cont'd

consultation.

24. MARK GULOW received pre-filled unsigned prescriptions for DME, from accomplices working on behalf of Company 1, for him to electronically sign.

25. MARK GULOW ordered braces without determining their medical necessity, for patients with whom he lacked a pre-existing doctor-patient relationship, without a physical examination, without communicating with the Medicare beneficiary, and frequently without reviewing the patient information that was provided to him.

26. MARK GULOW and others falsified, fabricated, altered, and caused the falsification, fabrication, and alteration of patient files, brace orders, and other records, all to support claims to Medicare for braces that were ineligible for Medicare reimbursement, and not provided as represented.

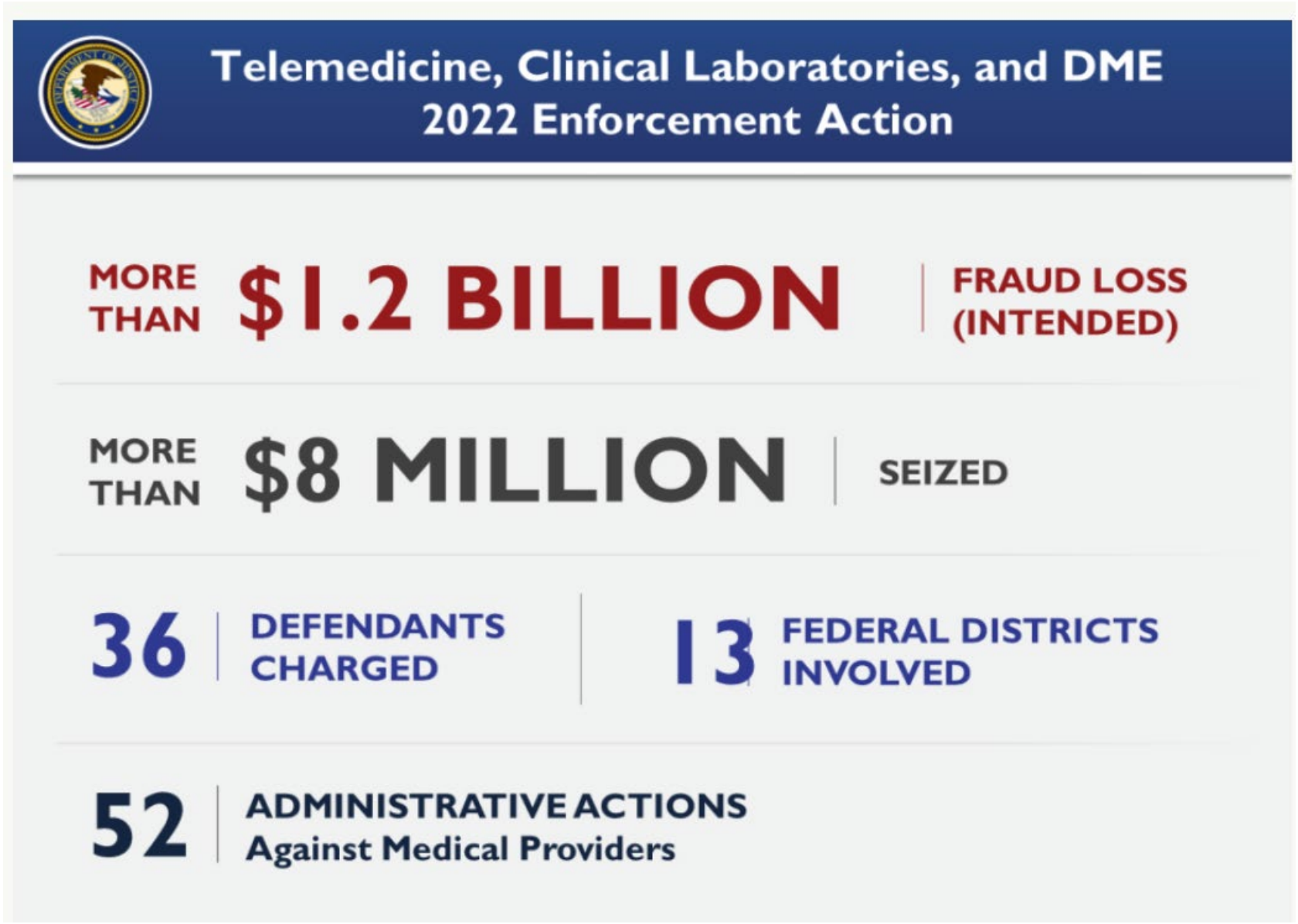
27. Specifically, MARK GULOW (a) falsely stated that he determined, through his assessment of the Medicare beneficiary, that a particular course of treatment, including the prescription of DME, was appropriate and medically necessary; (b) falsely attested that the he was treating the Medicare beneficiary; (c) falsely represented that he had performed certain diagnostic tests prior to ordering braces; and (d) concealed the fact that he never saw the beneficiaries face-to-face, and never had any telephone conversations with the beneficiaries.

28. MARK GULOW submitted orders for DME on behalf of beneficiaries residing in the Eastern District of Michigan, and elsewhere, which caused DME providers to ship DME to beneficiaries, including to beneficiaries residing in the Eastern District of Michigan, and to submit claims to Medicare that were not eligible for reimbursement.

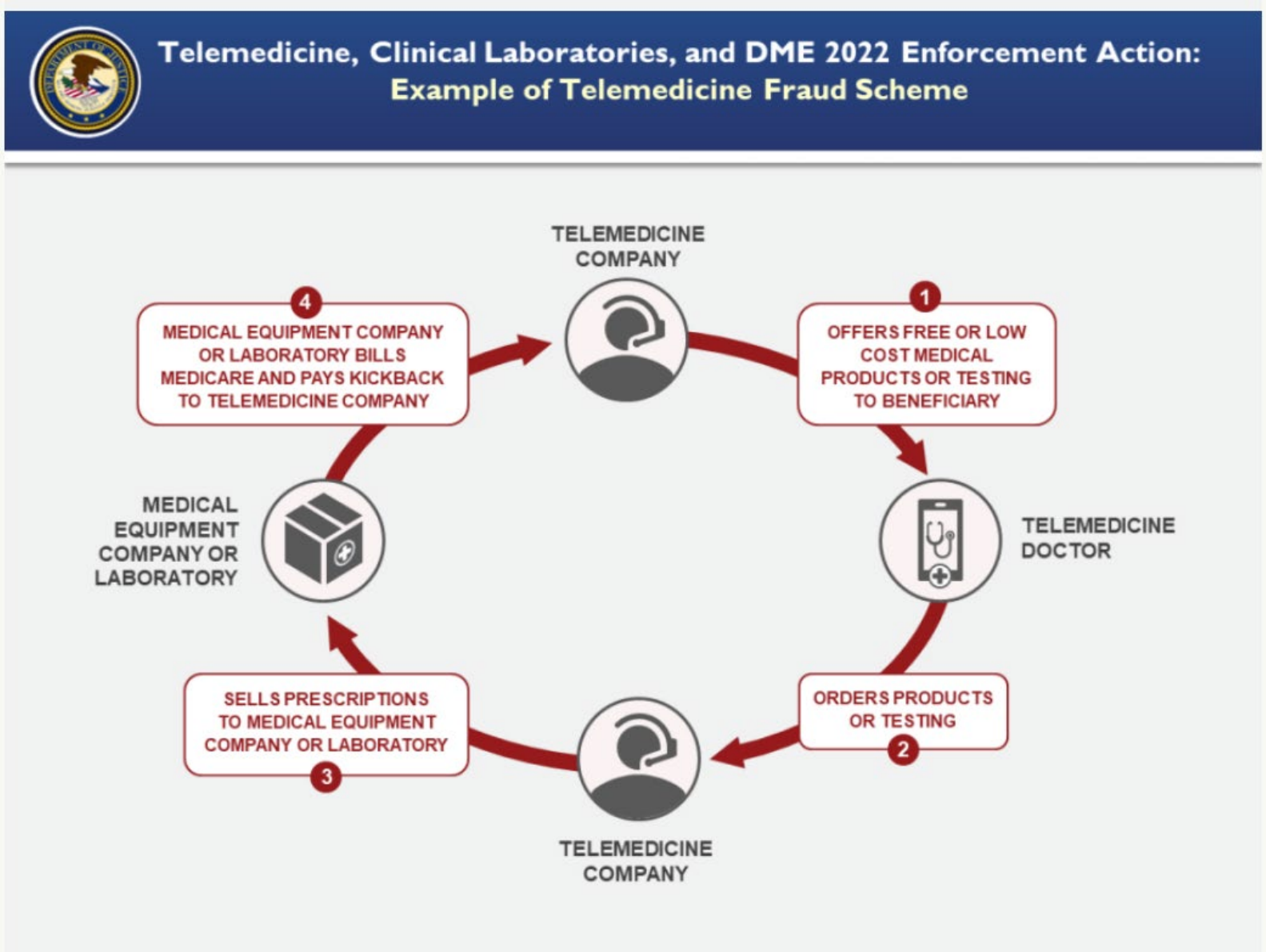
29. From in or around April 2020, through in or around February 2021, MARK GULOW and others submitted and caused the submission of more than $2.9 million in false and fraudulent claims to Medicare for DME that was ineligible for Medicare reimbursement because the DME was not eligible for reimbursement.

DOJ Trends & Key Takeaways

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM



https://www.justice.gov/criminal-fraud/telemedicine-enforcement-action



https://www.justice.gov/criminal-fraud/telemedicine-enforcement-action

Telehealth Legislation

- Various State Law Proposals
- CONNECT for Health Act
- Tele-Mental Health Improvement Act
- Ensuring Telehealth Expansion Act

Trends

- Heightened Scrutiny of Telehealth businesses (prescription and actual consultations)
- Increased state and federal governmental collaboration during investigation and prosecution
- Increased criminal, civil and administrative enforcement

Tips

- Have a written compliance policy
- Enforce your written compliance policy
- Consult with Healthcare attorneys as soon as possible
- Identify Individual vs corporate responsibility as quickly as possible and report to DOJ

Questions?

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

THANK YOU

Jason Bolgona
Buchanan Ingersoll & Rooney
Shareholder
215 665 3928
jason.bologna@bipc.com

Andria Adigwe
Buchanan Ingersoll & Rooney
Associate
212 440 4409
andria.adigwe@bipc.com

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

Buchanan
Ingersoll·Rooney

Setting The Table: Planning for Partnership in an Evolving Landscape

John Washlick, Shareholder, Buchanan Ingersoll & Rooney PC
Kristofer Blohm, Managing Director, Kaufman Hall & Associates
David De Simone, JD, MHL, CPHRM

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

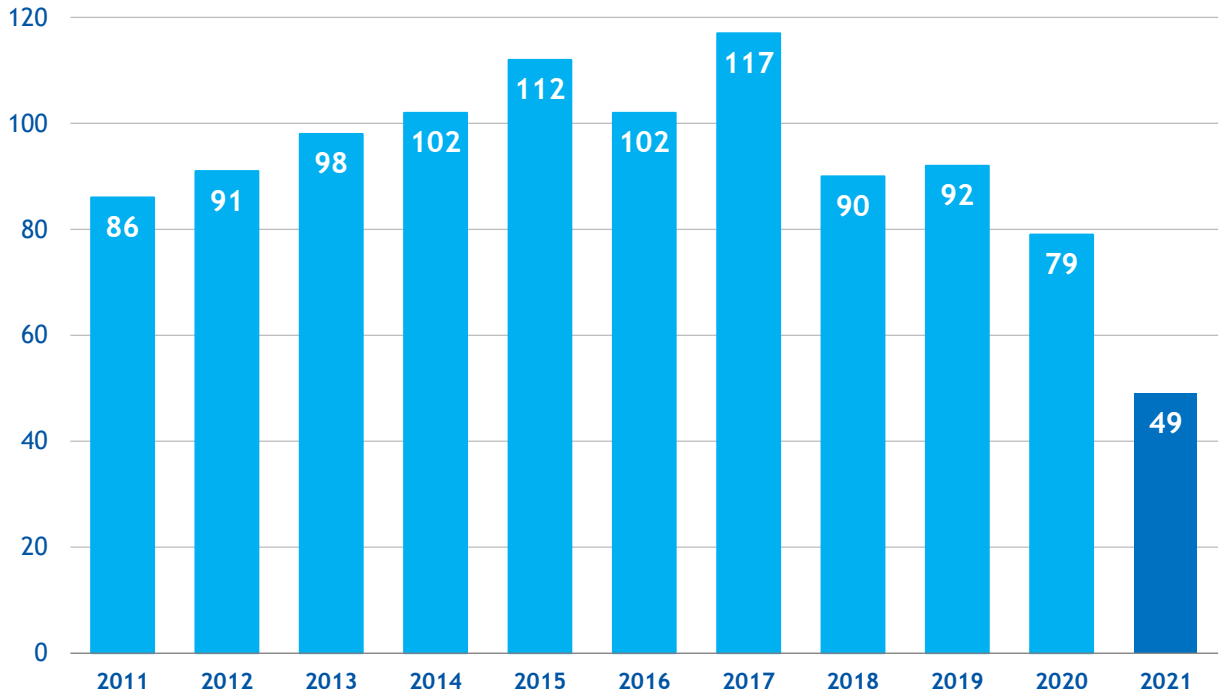
Changes in the Healthcare Services Landscape and Implications to Competitive Strategy

	GROWTH & SATURATION		MATURATION		TRANSFORMATION	
	Prior to 1900	1900-1945	1945-1969	1970-1999	2000-2019	2020 & *Beyond*
Market Focus	Informing and Meeting Demand		Sustaining/Expanding Demand		"Buyer" Preference	
Competitive Advantage	Existence and Presence		Broader Service Offering and Payer Relationships		Scale ➔ Value ➔ Innovation	
Nature of Growth	Rapid & Largely Unchallenged		Service Expansion and Clinical Efficiency		Holistic/Optimized Service Offering and Platform	
Success Factors	Size and Availability of Market		Capital, Sites and Technology		Better, Cheaper and/or Faster	

Transformation Marked by Significant Consolidation

- The ACA's emphasis on integrated care delivery, accountable care organizations, and other risk-based care delivery models spurs another wave of consolidation. Health systems seek scale to increase efficiencies and absorb risk.
- Care accelerates its migration from inpatient to outpatient settings. By 2019, Kaufman Hall data indicates that outpatient services accounted for more than 50% of average health system revenues.
- The lower cost of care in ambulatory and outpatient settings opens the way for new competitors who do not need to carry the high costs of acute inpatient beds.
- By 2019, two-thirds of community hospitals are in a health system.
- Despite a slowing in the number of transactions over the last several years, transaction sizes have risen.

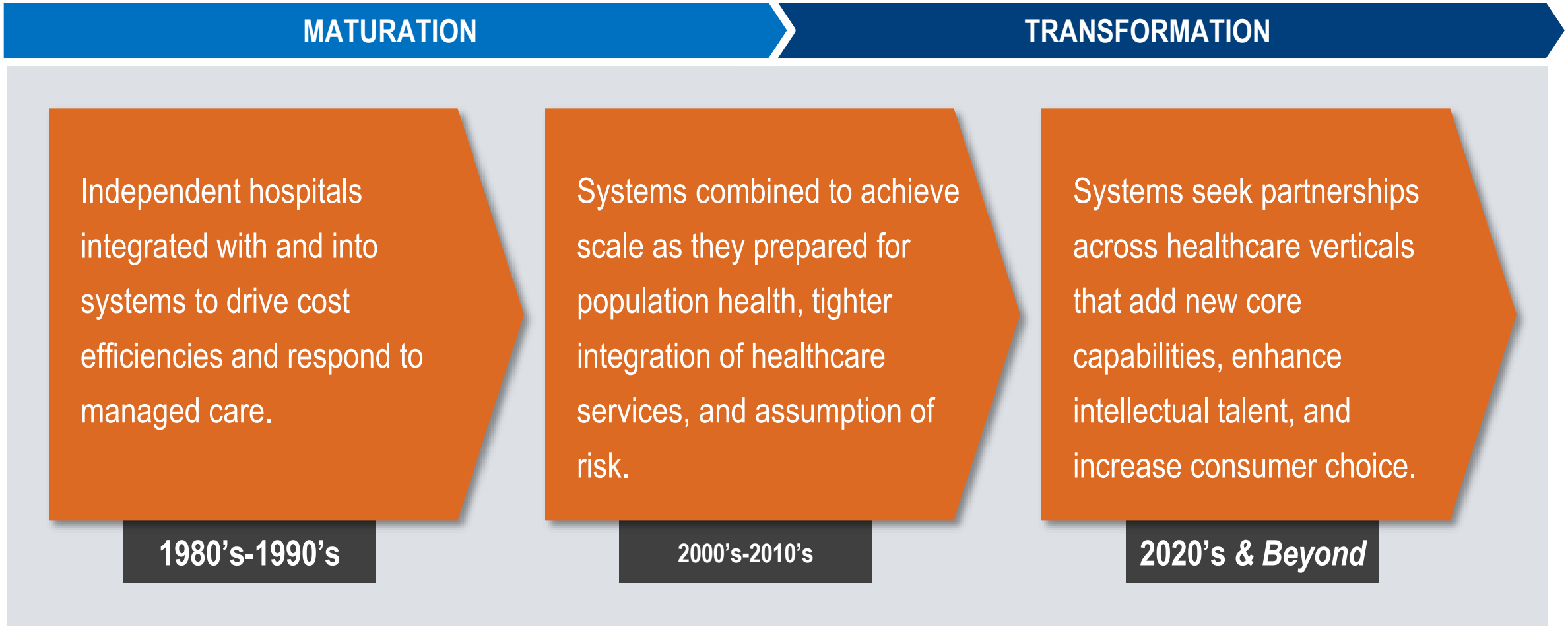
Number of Announced Transactions, 2011–2021



The Evolution of Partnership Strategies

	MATURATION		TRANSFORMATION	
	1945-1969	1970-1999	2000-2019	2020 & *Beyond*
Strategic Rationale	Tactical, Driven by Distress or Need		Aggregate to Achieve Scale ➔ Position and Transform for Value	
Commercial Principles	Combining Forces, Maximizing Operating Leverage, and Pursuing Diversification		Pursuing Capabilities, New Channels, Novel Expertise, and Intellectual Capital	
"Seller"/Smaller System Drivers	Access to Capital, Infrastructure Base, and Market Influence		Value-Based Models, Population Health Initiatives, Clinical & Business Intelligence	
"Buyer"/ Larger System Drivers	Extending Operating Leverage and Economies of Scale		Platform for New Markets and Convener of Best-in-Class Service and Delivery	

Timeline of Prevailing Partnership Strategies



The Distinction Between Forms of Market Consolidation

	AGGREGATION	TRANSFORMATION
Strategic Focus	Leveraging economies of scale for increasing marginal profits	Use of innovation to materially change/overcome industry dynamics
Revenue Strategy	"Buy low, sell high" approach to acquiring revenue	Pursuit of high "quality of revenue" strategic pursuits
Expense Strategy	Intense focus on fixed cost to maximize operating leverage	Total cost evaluation, attacking all sources of waste/excess
Capital Strategy	Driven by capacity, specialization/ distribution, and throughput	Frequently aimed at entirely new channels, markets, or access points
Market Posture	Market share, reliant on sheer size and barriers to entry	Market expansion, driven by alignment and collaboration

Recent Takeaways from Lessons from the Pandemic

- **Realize the imperatives of scale**
  - Larger systems were better able to deploy resources, segregate facilities for infected/non-infected patients, and weather financial impacts that hit different facilities and markets at different times.
- **Focus on core markets and services**
  - Operational disruptions and financial pressures made non-core assets or assets in non-core markets less attractive, prompting divestiture or monetization of these assets.
- **Seek partnerships to add capabilities and meet consumer demand for new or enhanced services**
  - A new trend toward “coopetition” brings together organizations that are both potential competitors and partners to offer access to new services or enhance delivery of existing services that require specialized skillsets. Partnerships allow health systems to focus on their core business and enhance or expand service offerings.

Key Question: How Do We Plan for the Partnerships of the Future?

THANK YOU

John Washlick
Shareholder, Healthcare
Buchanan Ingersoll and Rooney
john.washlick@bipc.com

Kristofer Blohm
Managing Director
Kaufman Hall & Associates
KBlohm@kaufmanhall.com

David De Simone
JD, MHL, CPHRM

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

Buchanan
Ingersoll·Rooney

Attracting and Retaining Talent inThrough Compensation Strategies

Carrie G. Amezcua
Anthony Andrisano
Robert Ramsey, III
Jaime S. Tuite

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

Buchanan Ingersoll & Rooney

Overview

1. State of the Healthcare Sector Labor Market
2. Recruitment Loans vs. Signing Bonuses
3. Incentive Compensation Plans
4. Employment Agreements
5. Developing and Documenting Consistent Enforcement Efforts

1. Healthcare Labor Market

Current State of Healthcare Labor Market

- 32% of registered nurses report considering leaving direct patient care in the next year
- 175,000 openings for RNs are projected each year through 2029
- 1.2 million new RNs will be needed by 2030 to address the current shortage

McKinsey & Company, Surveyed Nurses Consider Leaving Direct Patient Care at Elevated Rates, February 2022
Bureau of Labor Statistics, Employment Projections 2019 – 2020, https://www.bls.gov/ooh/healthcare/registered-nurses.htm.
The Growing Nursing Shortage, https://www.usa.edu/blog/nursing.

Registered Nurse Shortages by State (Projected)

Difference between supply and demand expected by 2030

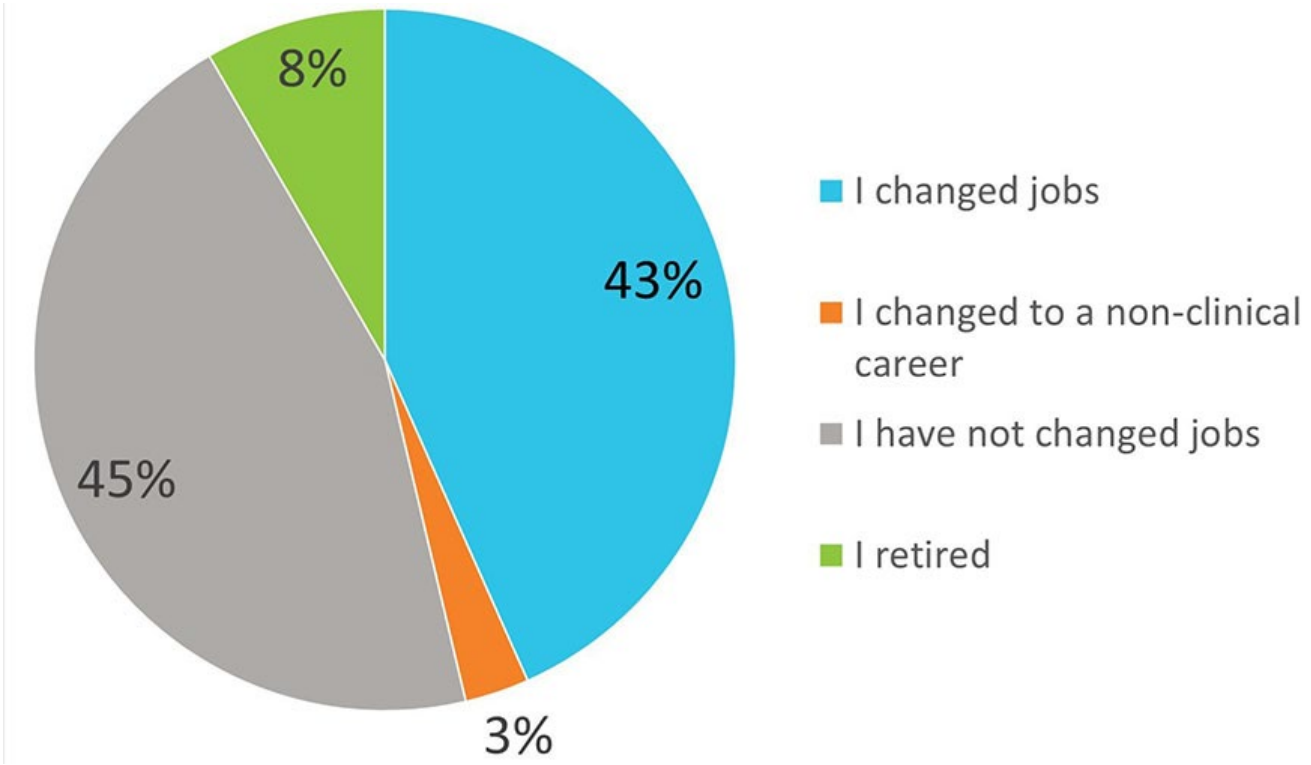
Most Severe Shortages

Rank	State	Supply (2030)	Demand (2030)	Difference
1	California	343,400	387,900	-44,500
2	Texas	253,400	269,300	-15,900
3	New Jersey	90,800	102,200	-11,400
4	South Carolina	52,100	62,500	-10,400
5	Alaska	18,400	23,800	-5,400
6	Georgia	98,800	101,000	-2,200
7	South Dakota	11,700	13,600	-1,900
8	Montana	12,300	12,100	200
9	North Dakota	9,900	9,200	700
10	New Hampshire	21,300	20,200	1,100

Source: U.S. Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis, "Supply and Demand Projections of the Nursing Workforce: 2014-2030," 2017: *https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/nchwa-hrsa-nursing-report.pdf*

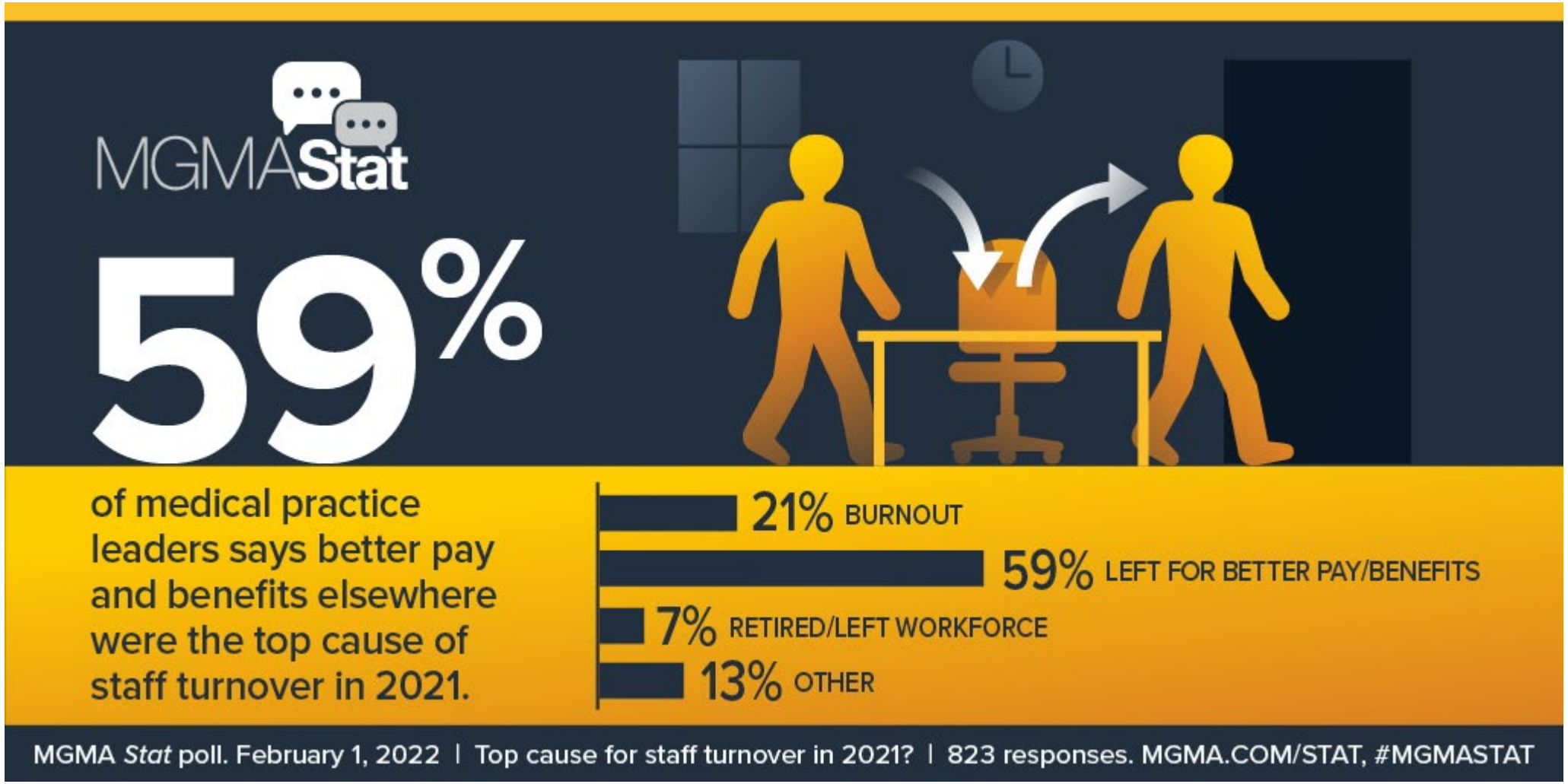
https://www.usa.edu/blog/nursing-shortage

Physician Career Changes 2020-2022



https://chghealthcare.com/blog/physicians-changed-jobs-survey

Reasons for Physician Turnover



https://www.mgma.com/data/data-stories/as-compensation-competition-continues,-medical-gro

Cost of Physician Turnover

- The turnover of a single physician may cost a hospital between **$400,000 - $600,000** in recruitment, onboarding costs, and short-term revenue loss
- A yearlong physician vacancy could cost up to **$1M in lost patient revenue**
- Primary care physician turnover leads to almost **$980M in excess healthcare costs**

https://physiciansthrive.com/contract-review/the-growing-problem-of-physician-turnover/(considering recruiter costs, onboarding, and lost patient revenue) https://www.healthcarefinancenews.com/news/primary-care-physician-turnover-leads-almost-980m-excess-healthcare-costs, citing https://www.sciencedirect.com/science/article/pii/S0025619621007096. Mayo Clinic Proceedings, Vol. 97, Issue 4, April 2022, Pg. 693-702

2. Recruitment and Retention Payments

Recruiting and Retention Payments

- Recruiting Bonuses or Loans
- Forgivable Student Loans
- Signing Bonuses
- Tuition Reimbursement
- Retention Bonus
- Incentive Compensation

Sample Recruitment Bonus with Repayment Schedule

- Employer is providing a moving and recruitment lump-sum payment of [Amount] to Provider. This amount will be paid to provider with their first paycheck on [Date]
- This payment will be included in Provider's gross income as wages and subject to withholding of all applicable taxes
- Provider agrees to reimburse Employer if they voluntarily terminate employment prior to the completion of two (2) years of service according to the following schedule:
  - 100% if employed less than 6 months
  - 75% if employed 6 months but less than 12 months
  - 50% if employed 12 months but less than 18 months
  - 25% if employed 18 months but less than 24 months

Signing Bonus | Sample Provision

Lump Sum with Repayment Obligation

- Employer will pay Provider a signing bonus of [Amount] within ninety (90) days of the Start Date. If you are not in Good Standing (as defined in Employer's Handbook), or your employment is terminated for Cause (as defined in the Employment Agreement), or if you resign, or give notice of an intent to resign, prior to the Signing Bonus Payment Date, you shall not be eligible to receive the Signing Bonus
- If you give notice of an intent to resign or your employment is terminated for Cause on or prior to the first anniversary of the Signing Bonus Payment Date, **you must immediately repay the gross, before–tax amount of the Signing Bonus to Employer, in its entirety**

Retention Bonus | Sample Provision

- I understand that I will receive the following designated one-time payment (less applicable taxes) in my paycheck dated October 1, 2022
- I understand and agree that if I fail to complete my two-year commitment for any reason (including my resignation, the termination of my employment by Employer for any reason, transfer from my Position to another position (including a different location or reduction in hours), I must return the full amount of the bonus received
- I hereby promise, under those circumstances, to pay back the net amount of the $75,000 Retention Bonus I received immediately upon my separation and no later than seven (7) days after my separation from Employer. Unless otherwise prohibited by applicable law, I authorize Employer to deduct the monies toward the amount owed from my final paycheck

Advance vs. Loan

- **Salary Advance:**
  - Paying an employee part of their salary in advance
  - Advance recovered by employee in installments
  - When is the compensation earned?
- **Loan:**
  - At the time funds are transferred, there must be an unconditional repayment obligation and an unconditional intention of the part of the employer to secure repayment
  - Employee's receipt of funds is not treated as an income-realization
  - Amounts become taxable to employee as compensation at the time the employer forgives any portion of the loan

Advance vs. Loan (cont'd)

- **To Evidence a Bona Fide Loan:**
  - Ability of the borrower to repay
  - Existence of a debt instrument
  - Security, interest, a fixed repayment debt, and repayment schedule
  - Treatment of funds as a loan by the parties, including records and documentation
  - Has the borrower made repayments
  - Whether the lender has demanded repayment
  - Likelihood the loan was disguised as compensation for services and
  - Testimony of purported borrower and lender

See Welch v. Commissioner, 204 F.3d 1228, 1230 (9th Cir. 2000), *affirming* T.C. Memo 1998-121; *Frierdich v. Commission,* 925 F.2d 180, 182 (7th Cir. 1991)

Advance vs. Loan (cont'd)

In *Fisher v. Comm'r*, 108 T.C.M. (CCH) 469 (T.C. 2014), the United States Tax Court found that a medical practice's payment to a physician were not "**bona fide loans**" but payments for services and thus gross income

- The physician produced a memorandum referencing the payment as "an installment loan" and set out an interest rate
- Because there was no fixed repayment date or schedule, the court found this could not constitute a debt instrument
- The physician argued that the loan was intended to finance the cost of research for her book
- Based upon this testimony, the court also found that the payments were for services and therefore taxable compensation

Healthcare Regulatory Considerations

- Stark Law
  - Basic Prohibition
  - Exception

- Anti-Kickback Statute
  - Statutory Prohibition
  - Safe Harbor

Stark Law Considerations

- Two Exceptions to Consider
  - Bona Fide Employment Exception
  - Physician Recruitment Exception

- Employment Exception
  - FMV for services furnished and not determined by volume or value of referral

Stark Law Considerations (cont'd)

- Physician recruitment exception (42 C.F.R. § 411.357(e))
- Payment is to induce physicians to relocate to hospital's service area:
  - Meaning of "relocate"
  - Carve outs
- Four basic requirements:
  - Set out in writing and signed by the parties
  - Not conditioned on referrals
  - Amount is not determined by taking into account referrals
  - Staff privileges at other hospitals permitted

4. Employment Agreements

Employment Agreements vs. Other Contractual Obligations

- In *Johnson Reg'l Med. Ctr. v. Halterman,* 2:14-CV-02175 (W.D. Ark. July 24, 2015), a medical center hired a new doctor and the parties executed the following documents:
  - a Promissory Note for a $50,000 loan
  - a Recruitment Agreement setting out conditions for loan forgiveness
  - an Employment Agreement setting out terms and conditions of employment
- Doctor became injured at work after 2 months and resigned because he claimed he was unable to perform his job
- When the employer tried to recoup the loan, he argued that his performance was excused under the Employment Agreement and therefore his performance under the Recruitment Agreement was also excused, thereby relieving him of his repayment obligation

Employment Agreements vs. Other Contractual Obligations (cont'd)

- Doctor argued that where "the parties' contract is contained in more than one document, all of the documents must be considered together"
- The Court examined the following distinctions between the Employment and Recruitment Agreements:
  - Independent merger clauses
  - No cross reference between the documents
  - Each agreement set out differing obligations for each party and differing occurrences that could terminate the agreement
  - Each document included independent substantive provisions, including choice of law, assignment, notices, waiver, etc.
- Based on these factors, the Court found in favor of the medical center on its motion for summary judgment, requiring repayment

Reasonable Notice

- What is the market standard for “reasonable notice,” particularly in a competitive market?
- Reasonable notice provisions are frequently litigated; is the notice truly reasonable?
- Will the notice that the healthcare entity has to provide in without cause situations be the same as the notice required by the employee?
- What happens if the employee refuses to work?
- What happens if the employee continues to work but becomes a “bad actor” or an unproductive employee?

Reasonable Notice | Sample Provision 1

- Physician may terminate this Agreement without cause by giving the Corporation ninety (90) days' written notice. If the Physician terminates this Agreement without cause by giving the Corporation ninety (90) days' written notice, the effective date of termination shall be considered the ninetieth day following the receipt of notice by the Corporation. For purposes of calculation of this ninety (90) day period, day one (1) shall be the day the notice is given to the Corporation. If the Physician terminates this Agreement under this Paragraph without cause by giving the Corporation ninety (90) days written notice, the Physician shall be entitled to receive compensation as outlined in Agreement. The Corporation reserves the right to require the Physician to use any vacation accrued but not taken during the 90-day notice period or to prohibit the Physician from doing so

Reasonable Notice | Sample Provision 1 (cont'd)

- Hospital may terminate this Agreement without cause by giving the Physician ninety (90) days' written notice. No reason need be given in such notice. During the ninety (90) day notice period, unless the Hospital exercises its right, the Physician agrees that he or she shall continue to fully and completely carry out his or her duties as outlined by this Agreement and that failure to do so shall result in termination with cause and forfeiture of any compensation due under this Agreement
- **Lawful? May the compensation be forfeited?**

Liquidated Damages

- A contract clause requiring employee to pay a certain portion of salary or lost patient revenue if the employee does not adhere to requirements for termination of contract
- May require employee to pay amount for working for competitor/violating non-compete (*e.g.*, two times annual salary, lost patient revenue during notice period)
- Supported by rationale that costs associated with termination/violation of non-compete are impractical and difficult to quantify (consider recruitment costs, loss of patient revenue)
- Cannot be a penalty!

Liquidated Damages | Sample Provision

Because of the significant investment Employer has made in the employed Provider, the cost of recruitment of a potential replacement for Provider, and the potential loss of patient service availability revenues, if Provider resigns and terminates this Agreement (other than by reason of death or disability) prior to the expiration of the initial term of this Agreement, both parties agree that the amount of damages sustained by Employer would be impracticable or extremely difficult to calculate. Accordingly, Provider and Employer agree that it is fair and reasonable to provide for liquidated damages in such instance as set forth herein. Specifically, Provider will pay Employer as liquidated damages an amount equal to twenty percent (20%) of the amount of Provider's base compensation as set forth in Section __ for the remainder of the initial term of the Agreement as of the actual date of termination **or the amount of actual damages, if they can be readily calculated**. In addition, Provider shall forfeit [bonus, incentive payments, reimbursements, loan repayments] to the extent Provider fails to meet the required Eligibility Factors.

Liquidated Damages | Sample Provision (cont'd)

Provider shall make any payment due under this Section __ within thirty (30) days of the effective date of Provider's termination of the Agreement, or, alternatively, Employer may deduct any such payment from any compensation due to Provider at the time of or following Provider's termination. The parties agree that the liquidated damages provided for herein are reasonable in amount and not a penalty. In the event that Employer has been adjudicated as having breached this Agreement, and there is no breach of the Agreement by Provider, the liquidated damages provision contained in this Section __ shall be waived.

- Limit to only the initial term of Agreement?

Liquidated Damages | Practical Guidance

- State law frequently does not allow for both injunctive relief and monetary damages, *e.g.*, New Mexico Supreme Court determined that "a party can elect liquidated damages or injunctive relief, but cannot have both." *Bowen v. Carlsbad Ins. & Real Estate*, 104 N.M. 514, 724 P.2d 223, 227 (1986)
- In other words, it may be best to take a layered approach and separate liquidated (monetary) damages and injunctive relief (*e.g.*, for breaches of failure to provide notice of termination versus breach of non-compete)
- Consider how much notice to require and scope of non-compete/non-solicitation provisions that may trigger liquidated damages or injunctive relief

Restrictive Covenants

- Non-compete obligations tied to patient areas vs. specific competitors
- Non-solicit obligations tied to patients and other relationships
- Non-solicit obligations tied to employees
- Confidentiality and Trade Secret Protection
- Protection of Patient Health Information
- Need to be aimed at preventing unfair competition

Stark Law Considerations

- Compensation must fit within an exception
  - **Employment exception** allows for compensation for **"personally performed"** services
- Other requirements also apply
- Recommend that plan is in writing
- Value-based exception?

Anti-Kickback and Stark Law Considerations

- Violations of the Anti-Kickback Statute and the Physician Self-Referral Law (Stark Law) may result in nonpayment of claims, Civil Monetary Penalties, exclusion from all federal health care programs (including Medicare), and criminal and civil liability.

Antitrust Considerations

Competition in labor markets measured by:

- Salaries
- Quality
- Quantity

Harm in labor markets produces the same three "evils" as any other antitrust inquiry anticompetitive prices (i.e., wages), lower quantities (i.e., employees), and/or lower quality (i.e., benefits).

Enforcement

-Federal (FTC/DOJ)

-State (AGs)

-Private Plaintiffs

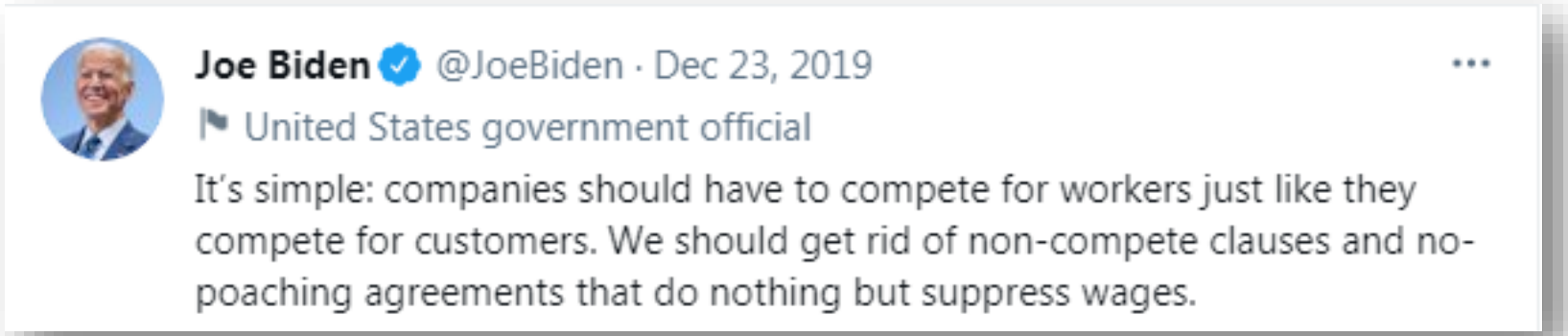
Potential Penalties

- Civil Damages (Treble)
- Criminal Charges

Antitrust Enforcement

In 2016, DOJ & FTC issued an advisory to Human Resource personnel concerning antitrust and employment. Since 2016, antitrust enforcement of violations of antitrust in the labor markets has been steady and shows no sign of slowing.

The bulk of federal enforcement has been focused on no-poach agreements and wage fixing agreements; generally resulting in settlement agreements.



State enforcement has been focused on broad non-compete agreements.

Private plaintiffs often follow on government investigations for no-poach, non-compete, and wage fixing.

Antitrust Enforcement| States

State AGs Actively Enforcing No-Poach and Non-Compete Antitrust Violations

- July 2019 Illinois AG/Check Into Cash Settlement prohibits Check Into Cash from requiring non-competes for store-level employees
- July 2022, New York AG secured $1.25m settlement with title insurance companies for use of no-poach agreements among brokers
- June & Dec. 2016 – New York and Illinois settle with Jimmy Johns to remove non-compete agreements in hiring packages for line workers and delivery drivers

Policy activity shows AG philosophies

- Pennsylvania AG filed amicus brief in the *Beemac* case, arguing against no-hire restrictions
- NAAG Multistate Antitrust Task Force has Labor and Antitrust Committee, led in part by member of PA's Antitrust Division
- Group of 18 Ags submitted comments to FTC on antitrust and labor issues

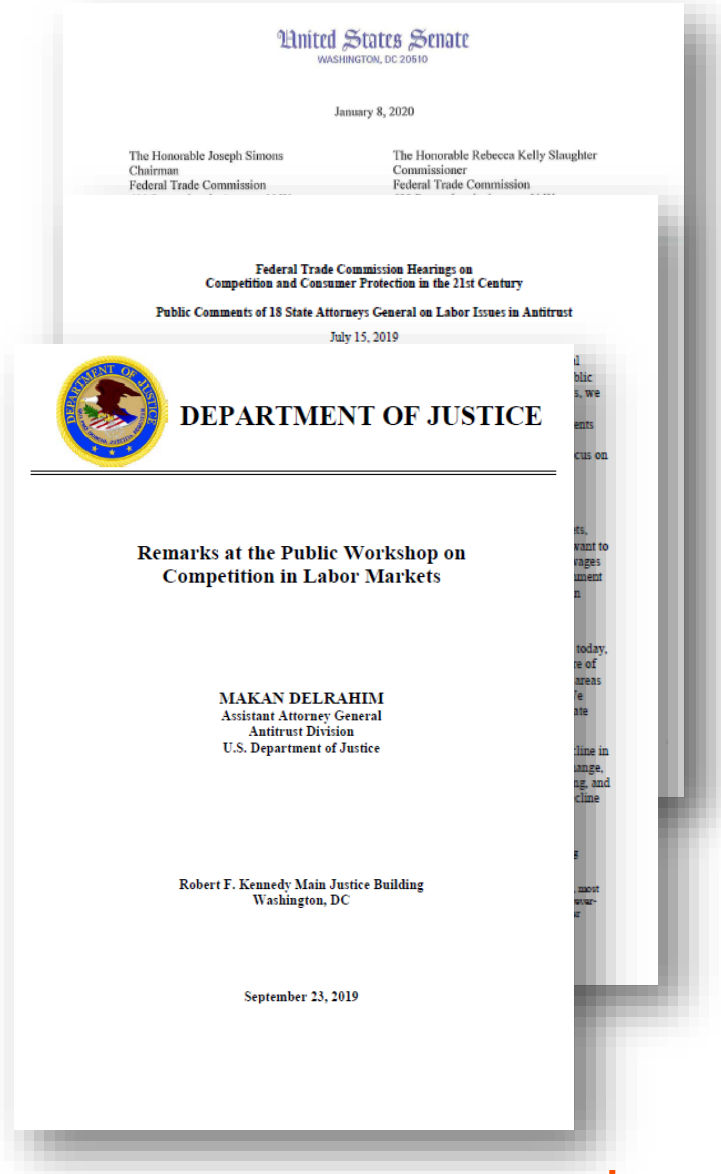
Antitrust Enforcement| Federal

The FTC considering using rulemaking authority for the first time since 1968 to address the overuse of non-competes by employers.

The focus of the Rule would be to address the increased use of non-competes without any legitimate business justification.

FTC and DOJ have cited labor issues in merger challenges and have required parties to eliminate or scale back non-compete provisions in transaction agreements.

FTC signed MOU with the NLRB to share information, including on non-compete and non-disclosure provisions.


United States Senate
WASHINGTON, DC 20510

January 8, 2020

The Honorable Joseph Simons
Chairman
Federal Trade Commission

The Honorable Rebecca Kelly Slaughter
Commissioner
Federal Trade Commission

Federal Trade Commission Hearings on
Competition and Consumer Protection in the 21st Century

Public Comments of 18 State Attorneys General on Labor Issues in Antitrust

July 15, 2019

DEPARTMENT OF JUSTICE

Remarks at the Public Workshop on
Competition in Labor Markets

MAKAN DELRAHIM
Assistant Attorney General
Antitrust Division
U.S. Department of Justice

Robert F. Kennedy Main Justice Building
Washington, DC

September 23, 2019

Antitrust Enforcement| Federal

- *United States v. Jindal et al.* - DOJ alleged that defendant – the owner and clinical director of a therapist staffing company – conspired with other staffing companies to artificially fix the pay rates of therapists.
- *United States v. DaVita; United States v. Thiry; United States v. Surgical Care* – DOJ alleged, DaVita, its CEO, and Surgical Care agreed not to hire each other's employees.
- DOJ lost Jindal, DaVita and Thiry trials; Surgical Care trial scheduled for January.
  - Trial is not cheap!
- DOJ announced it is close to securing a guilty plea from another healthcare staffing company accused of agreeing not to hire a competitor's nurses and fix wages.

Private Plaintiff Litigation| Non-Compete and No Poach

- Nevada Anesthesiologists - As part of their employment agreements, anesthesiologists are subject to a two-year, post-employment non-compete restraint that prohibits them from providing anesthesiology services within 25 miles of major current facility at which they worked or at any other facility where they worked for the two years before termination of their employment

- Duke/UNC – Non-medical faculty and medical faculty class actions against Duke and UNC for agreeing not to compete for each other's faculty; $54.5 million settlement for medical faculty; $19 million settlement for non-medical faculty

- SCA employees – follow on class action from US v. Surgical Care criminal indictment by employees of SCA; survived motion to dismiss

Employment Agreements – Questions to Ask

1. What is the purpose of the contract? (Can't just be to restrict)
2. What is the business justification for including any restrictive covenants, including non-compete, no-hire and non-solicit? (Can't just be to restrict)
3. Is the language drafted in the most narrow way to protect the business interest? (Review the geography, duration, connection to the business interest, and is a non-solicit better than a no-hire, including with exceptions for responding to ads)
4. How transparent are the restrictions and do the third parties know about them (i.e. are the employers aware, how will the restrictions impact customers)?
5. Is it enforceable? Will you seek to enforce it or is it just to deter competition?
6. Who is the contract/agreement restricting – the employee or a competing employer? (the latter carries much higher risk)

5. Enforcement Considerations

Enforcing Repayment Provisions in PA

- Damages under $12k → Magisterial District Court
- Damages over $12k → Common Pleas Court
- Damages under $25k → May require arbitration in Common Pleas Court
- Outstanding Loan Payments → Debt Collection Procedures Apply

Note: These amounts vary by jurisdiction

Recovering Loan Payments

- Fair Debt Collection Practices Act (FDCPA) governs the process for recovering consumer debt
- Attorneys may be "debt collectors" under the FDCPA. *Heintz v. Jenkins*, 514 U.S. 291 (1995)
- Conservative approach is for healthcare entity to seek recovery directly or to follow the FDCPA
- Remember Stark Law considerations . . .

Fair Debt Collection Practices Act (FDCPA)

- Protects consumers from "abusive, deceptive, and unfair debt collection practices" (15 U.S.C. § 1692)
- A debt collector is "***any person*** who uses instrumentality of interstate commerce or mails in any business the principal purpose of which is the collection of any debts, or who regularly collects or attempts to collect directly or indirectly, debts owed or due or asserted to be owed or due another" (15 U.S.C. § 1692a(6))
- Strict liability statute
- The sole defense to a claim for violation of its provisions is a showing by the debt collector, "by a preponderance of the evidence, that the violation was not intentional and resulted from a bona fide error notwithstanding the maintenance of procedures reasonably adapted to avoid any such error" (15 U.S.C. § 1692k(c))

Fair Debt Collection Practices Act (FDCPA) (cont'd)

- **FDCPA regulates certain debt collection activities:**
  - Acquisition of location information from third parties
  - Communications with consumers in collecting debts
  - Communications with third parties
  - Conduct deemed to be harassing, abusive, or unfair
  - Communications that are false or misleading
  - Furnishing deceptive forms
  - Providing notice to the consumer and validation of debts

Fair Debt Collection Practices Act (FDCPA) (cont'd)

- Must provide the consumer at least ***five days*** to dispute the debt from the date the validation notice is received (15 U.S.C. §1692g)
  - If no response received → proceed with demand letter
  - If the consumer disputes in writing any portion of the debt or requests the name and address of the original creditor, the collector must stop all collection efforts until he or she mails the consumer a copy of a judgment or verification of the debt

Fair Debt Collection Practices Act (FDCPA) (cont'd)

- Select Itemization Date
- Determine the amount of the debt as of the Itemization Date
- Determine the Itemized Amounts since the Itemization Date
- Calculate total debt owed

Fair Debt Collection Practices Act (FDCPA) (cont'd)

- Demand for Payment

In the June 11th Letter we informed you that you could dispute the validity of the Debt, or any portion of it, *in writing* postmarked within 30 days after you received that letter. We also informed you that if you did not timely dispute the Debt, or any portion of it, *in writing* we would assume the Debt was valid. The June 11th Letter was not returned undelivered to us and we did not receive from you any written dispute of the Debt. Accordingly, we assume that you received the June 11th Letter and the debt referenced therein is valid.

PLEASE TAKE NOTICE that demand is hereby made on you to pay the amount set forth above by certified check, cashier's check or money order payable to Buchanan Ingersoll & Rooney P.C. Trust Account and sent to me at the post office address listed on the top of this letter. Upon receipt and clearance of full payment, a release will be provided. If the full amount listed above is not paid within ten (10) days of your receipt of this letter, we will have no alternative but to commence the appropriate actions against you to collect funds due and owing.

Fair Debt Collection Practices Act (FDCPA) (cont'd)

- Initiate Civil Complaint

Pa.R.C.P.M.D.J. No. 206 sets forth those costs recoverable by the prevailing party.

To The Defendant: The above named plaintiff(s) asks judgment against you for $ 3,992.24 together with costs upon the following claim (Civil fines must include citation of the statute or ordinance violated):

The Defendant duly executed, acknowledged and delivered the Recruitment Loan Agreement, in the Commonwealth of Pennsylvania, dated March 30, 2018 in favor of [redacted] ("[redacted]"), pursuant to which [redacted] extended to the Defendant a loan in the original principal amount of $5,000 ("Loan"). Under the Agreement, the Defendant was required, among other things, to remain in active employment with [redacted] for a period of time not less than twenty four (24) months to begin at the time of the disbursement of the Loan. In exchange, [redacted] agreed to forgive Defendant's obligation to repay the Loan on a prorated basis during each pay period in which Defendant satisfied the agreed upon employment obligation. Defendant's employment with [redacted] ended on or around November 10, 2018. Defendant has an outstanding balance of $3,992.24 still due and owing to [redacted].

Collecting the Debt

- Locate all jurisdictions where debtor owns property
- File lien against real property
- File Writ of Execution
  - Once entered, writ and interrogatories to the garnishee are delivered to Sheriff's Office
  - Sheriff can then collect debt by:
    - Seizing bank accounts (except for martial property or retirement accounts)
    - Seize and sell personal assets
    - Seize and sell home or real property

Prevailing Party Attorneys' Fee Provision

- **Payment of Attorneys' Fees**. In the event that any of the parties to the Agreement [or Incentive Plan] shall bring any action or proceeding against the other, declaratory or otherwise, arising out of or related to the terms of this Agreement [or Incentive Plan], Provider shall pay the Companies' reasonable attorney's fees, actual court costs, and third-party expenses incurred in prosecuting or defending such action and/or enforcing any judgment, order, ruling, or award granted therein pursuant to applicable state and federal law.

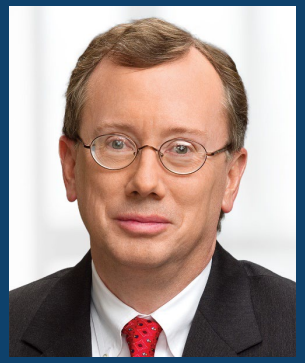
Stark Considerations in Collections & Enforcement

Consistency of Enforcement Actions

- When defining the scope of enforcement action:
  - Establish a consistent policy
  - Monitor for adverse impacts
  - Document enforcement efforts
  - Consider:
    - What is the desired deterrent effect?
    - What are the cost considerations?
    - What volume of recovery is necessary for cost-effective enforcement?

Buchanan Ingersoll · Rooney

Carrie G. Amezcua
Phone: 215-665-3859
Email: carrie.amezcua@bipc.com



Robert Ramsey, III
Phone: 412-562-3890
Email: robert.ramsey@bipc.com

Anthony Andrisano
Phone: 717-237-4968
Email: anthony.andrisano@bipc.com

Jaime S. Tuite
Phone: 412-562-8914
Email: jaime.tuite@bipc.com

Thank you

Buchanan Ingersoll·Rooney

PA Venue Rules are Changing: The Impact to Providers

Matthew T. Corso, Esq. & Michael W. Bootier, Esq.

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

Background – Malpractice Crisis

- From 2000 to 2003, Philadelphia issued 407 of the 1,144 verdicts involving medical malpractice.
  - Of those 407 cases:
    - 58 ended with payouts between $1 million and $5 million
    - 16 had payouts between $5 million and $10 million and
    - 9 had payouts of more than $10 million

Health professionals complained that malpractice insurance costs were so high — particularly in high-risk practices like obstetrics — that doctors could no longer afford to practice in the state

https://www.spotlightpa.org/news/2022/08/pa-medical-malpractice-lawsuits-venue-shopping-supreme-court/
https://www.pacourts.us/news-and-statistics/research-and-statistics/medical-malpractice-statistics

Pennsylvania's Medical Care Availability and Reduction of Error Act ("MCARE") 2002

- Passed in response to the increasing number of medical malpractice filings
- The MCARE Act resulted in the adoption of Pa.R.C.P 1006 (a.1) – an exception to Pennsylvania's rule for claims brought against medical professionals
  - Under Pa.R.C.P. 1006, *a medical professional liability action may be brought against a healthcare provider for a medical professional liability claim only in a county in which the cause of action arose*

GOAL: Eliminate frivolous medical malpractice cases and prevent forum shopping

https://www.bipc.com/pennsylvania-supreme-court-considers-repeal-of-mcare-venue-rule

IMPACT

Before the MCARE Act, approximately **2,700** medical malpractice cases were filed in Pennsylvania every year

Following the passage of MCARE Act and accompanying Rule 1006(a.1), the number of malpractice filings reduced to approximately **1,500** annual filings

https://www.pacourts.us/news-and-statistics/research-and-statistics/medical-malpractice-statistics

Pennsylvania Medical Malpractice Filings

	2000-2002 Average	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	% Change 2000-2002 Average 2020
Luzerne	34	38	79	36	41	46	54	48	37	48	30	49	50	47	53	47	50	46	33	-2.9
Lycoming	18	15	18	9	5	4	5	7	3	9	8	7	6	4	9	7	12	9	12	-33.3
McKean	4	0	3	1	4	1	2	5	3	0	3	2	7	6	0	2	0	0	3	-25.0
Mercer	43	41	31	30	21	20	25	16	19	17	5	14	14	12	10	10	10	9	15	-65.1
Mifflin	3	4	1	1	1	3	2	3	1	3	3	0	0	9	0	2	2	4	2	-33.3
Monroe	11	5	3	7	5	7	5	12	2	20	6	16	9	16	11	8	5	3	8	-27.3
Montgomery	22	14	102	104	95	103	81	102	66	100	95	94	89	116	105	107	99	115	121	450.0
Northampton	73	47	41	12	2	2	3	18	15	23	26	14	13	14	17	20	35	13	14	-80.8
Northumberland	9	4	6	2	2	2	6	6	1	4	1	5	7	7	3	2	3	2	2	-77.8
Philadelphia	1,204	577	559	540	569	586	553	491	381	418	389	382	382	381	378	406	416	406	348	-71.1
Pike	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	
Potter	3	6	1	2	1	1	1	1	2	1	1	3	0	2	3	3	0	0	0	-100.0
Schuylkill	29	13	12	9	11	5	12	11	13	15	14	14	23	10	14	15	11	11	12	-58.6
Snyder/Union	7	6	2	2	1	4	3	6	5	1	1	4	6	2	0	3	4	5	6	-14.3
Somerset	8	8	5	8	3	8	3	6	8	4	6	7	5	3	7	2	11	6	3	-62.5
Sullivan/Wyoming	4	2	3	1	0	2	0	1	0	0	0	0	1	0	0	0	0	1	1	-75.0
Susquehanna	0	0	0	1	0	3	1	0	0	0	6	4	0	1	0	0	1	2	2	
Tioga	3	0	0	1	1	1	0	1	1	0	1	0	0	0	2	2	0	1	1	-66.7
Venango	8	5	3	4	3	2	4	2	3	1	1	0	4	4	2	0	2	2	6	-25.0
Washington	7	4	21	29	26	25	21	21	31	39	21	31	19	30	25	30	24	28	27	285.7
Wayne	3	3	7	7	4	0	5	4	5	6	0	2	3	1	4	5	0	4	5	66.7
Westmoreland	62	49	26	35	27	18	19	12	14	107	52	37	27	29	27	25	22	25	29	-53.2
York	48	33	15	20	15	23	23	39	31	16	16	23	31	22	12	31	29	29	28	-41.7
State Total	2,733	1,712	1,819	1,711	1,702	1,640	1,602	1,532	1,490	1,675	1,510	1,560	1,512	1,530	1,541	1,449	1,583	1,565	1,476	-46.0

Notes:

- A filing refers to the commencement of a civil action by complaint or praecipe for writ of summons. To avoid double-counting, adjustments were made to the filing figures for cases transferred from one judicial district to another pursuant to Pa.R.C.P. 1006(a)(1).
- "Percent Change from 2000-2002 Average" was computed as follows:
  The 2017 Filings were subtracted from the 2000-2002 Average. The difference was then divided by the 2000-2002 Average.
  The resulting proportion was multiplied by 100 to convert it to a percentage.
- Liability actions brought against dental professionals may be included in some county counts.

Order Amending Rules 1006, 2130, 2156, and 2179 of the Pennsylvania Rules of Civil Procedure

On August 25, 2022, the Supreme Court of Pennsylvania adopted amendments to Pennsylvania Rules of Civil Procedure 1006, 2130, 2156, and 2179 governing venue in medical professional liability actions.

Starting January 2023, plaintiffs may sue in any Pennsylvania county in which care occurred, where a defendant could be served, or where any transaction or occurrence giving rise to the suit took place.

https://casetext.com/regulation/pennsylvania-code-rules-and-regulations/title-231-rules-of-civil-procedure/part-i-general/chapter-1000-actions/subchapter-a-civil-action/venue-and-process/rule-1006-effective-112023-venue-change-of-venue

Potential Scenarios

- Patient is treated at a hospital in Philadelphia and a nursing home in Bucks County
- Patient is treated at an urgent care center in Montgomery County and then treats at a hospital in Montgomery County that is part of a health system that also has hospitals in Philadelphia
- Patient treats at a hospital in Montgomery County that is part of a health system that also has hospitals in Philadelphia
- Patient treats at an urgent care center in Bucks County, with no ties to Philadelphia, and is seen by a doctor who lives in Center City

Future Impact and Potential Strategies

- Availability of malpractice insurance? Premiums?
- Impact on availability of care?
- Venue shopping?
- Potential strategies?

Thank you

Michael W. Bootier

215-665-3833

michael.bootier@bipc.com

Buchanan Ingersoll & Rooney

Buchanan Ingersoll·Rooney

The Federal No Surprises Act: An Overview

Sal Rotella and Sydney Bierhoff

October 18, 2022

Agenda

- Health Care Reimbursement Basics
- Introduction to the No Surprises Act – Statute/Rules (Link)
  - NSA Statute: 133 pages
  - Part I Rulemaking re patient protections (July 13, 2021): 114 pages
  - Part 2 Rulemaking re IDR provisions and good faith estimates (October 7, 2021): 163 pages
  - Part 3 Rulemaking re price info transparency (Nov. 23, 2021): 43 pages
  - Part 4 Rulemaking re updated IDR processes (August 18, 2022): 38 pages
- Provider and Facility Requirements (insured/uninsured/self-pay patients)
- Independent Dispute Resolution
- Considerations for Providers

Health Care Reimbursement Basics

Payment for Health Care Services - Parties

- Patient
  - Insured – Patient has (and uses) insurance policy contract with health plan
  - Uninsured – Patient doesn't have health insurance
  - Self-Pay – Patient has health insurance but chooses not to use it
- Health care provider
  - Professional (e.g., physician, nurse practitioner)
  - Facility (e.g., hospital, hospital OP department, ASC, freestanding ED)
- Health plan
  - May or may not have network services contract with health care provider

Trip to the Doctor

- Like any other routine, daily commercial transaction
  - Doctor has a list price for all services – full billed charge on all claims/invoices
  - Patient is responsible for full billed charge
- Unlike a routine transaction
  - Doctor agrees not to seek payment in full at time of service
  - Doctor agrees to accept third party payment and patient assigns doctor right to it
  - Doctor visit may take place at facility that separately charges patient
- Third party payor (i.e., not patient)
  - Agreement between patient and health plan (i.e., insurance policy) that plan will pay for care
  - Even if plan pays doctor and/or facility, patient (a/k/a plan member) typically still may owe **patient cost share** and **balance bill amount**

In Network (INN) Services

- Health plan administrators/insurers (Aetna, Cigna, United) create provider networks
  - Enter into contracts with providers (i.e., participation agreements) that set network rate (less than full billed charge) that provider accepts as payment in full – no balance billing of patients for difference
  - INN providers benefit through increased volume of patients from network plans
- Patient cost share payments – Portion of network rate owed by patient
  - Co-pay: Fixed dollar amount paid at time treatment is provided
  - Deductible: Fixed dollar amount member must pay to providers in a given coverage year before insurance benefits kick in
  - Co-insurance: Percentage of network rate owed by patient, e.g., 20 percent

Out-of-Network (OON) Services

- Providers are unable, or choose not, to join certain networks
  - No contract between provider and plan that sets reimbursement rate
  - But member might have OON benefits – i.e., plan sets an "allowable amount" that it will pay to OON provider for services rendered to member
- OON patient cost share payments – Portion of "allowable amount"
  - Tend to be higher than for INN services, as disincentive for member to go OON
  - Otherwise the same co-pay, deductible, and co-insurance as for INN, except that co-insurance is a percentage of the allowable amount (as opposed to of the network rate)
- Balance bill – Provider can also bill OON patient for difference between allowable amount and (higher) full billed charge

Payment for Sample Doctor Visit – INN/OON

- Patient A – INN (Billed charge of $1,000)
  - Provider's network rate is $600
  - Patient's co-pay is $10, deductible is $100, and co-insurance is 20 percent (of $600)
  - Patient pays $230 in cost share; plan pays $370 – no further billing
- Patient B – OON (Billed charge of $1,000)
  - Patient's OON benefit sets an allowable amount of $800
  - Patient co-pay is $20, deductible is $150, and co-insurance is 30 percent (of $800)
  - Patient pays $410; plan pays $390
  - Provider call also balance bill patient for $200 ($1,000 - $800)

Introduction to the No Surprises Act

Surprise Medical Bills

- A "surprise bill" is an unexpected balance bill (i.e., for the difference between the provider's billed charge and the allowable amount paid by insurance) sent to a patient by an OON provider
- Two primary circumstances leading to surprise bills
  - *Patient not in a position to choose INN provider* - Air ambulance services/emergency services/inpatient hospital services after emergency services (post-stabilization care)
    - Covered emergency medical condition includes mental health/substance use disorder crisis
  - *OON practitioner providing services to patient at an INN facility* – Patient may have selected INN hospital, but then is not aware that one of the professionals providing the care is OON
    - This means that while INN facility and INN physicians cannot balance bill patient, OON physician can
    - Good example is surgery at INN hospital, where surgeon is INN but anesthesiologist is OON

Evolution of the No Surprises Act (NSA)

- NSA
  - Signed into law in December 2020 (amended Public Health Service Act, Internal Revenue Code, and Employee Retirement and Income Security Act)
  - Went into effect January 1, 2022 (though not all provisions being enforced yet)
- Prior to the NSA, the Affordable Care Act offered limited financial protection to patients who received OON emergency services
  - Required commercial plans and insurers generally to cover OON emergency care similarly to INN emergency care, but no prohibition on balance billing
  - Required plans and issuers to pay a reasonable amount for OON emergency care, thereby effectively limiting balance bill that could go to patient
- Prior to the NSA, some states had their own NSAs, but these protected members of fully-insured plans only

NSA Core Provisions - Patient Protections

- For insured patients
  - No balance bills for OON emergency services (in hospital ED or freestanding ED)
  - No (higher) OON patient cost share bills for OON emergency and some OON non-emergency (elective) services
  - No balance bills or (higher) OON patient cost share bills for supplemental care (like anesthesiology and radiology) rendered by OON provider at INN facility (like a hospital or ASC)
  - Provider must give patient a notice explaining that OON care may be more expensive
  - For elective OON care at INN facility and for all OON post-stabilization care, provider can only bill patient for (higher) OON patient cost share amount or for balance bill **if** provider gets signed, advance "notice and consent" form from patient
- For uninsured/self-pay patients (i.e., patients who choose not to use coverage)
  - Must provide patient a good faith estimate of cost of scheduled care
  - Patient may file a dispute if charged at least $400 more than the estimated cost of care

NSA Core Provisions – For Providers and Payors

- Provider to give estimate of cost of scheduled care
  - If patient is insured and using insurance – GFE must go to group health plan, individual or group health insurance, or FEHB
  - Estimate to extend to any reasonably expected item or service, even if to be provided by another provider or facility, and to include billing and diagnostic codes
- Provider/Payor IDR - Upon provider's receipt of payment or denial from OON plan
  - If parties disagree, either side must start 30-day open negotiation period
  - If negotiations are unsuccessful after 30 days, either party may start Independent Dispute Resolution (IDR) process within next 4 business days
  - IDR entity to decide payment amount – selected by parties from list of certified organizations
  - Provider and facility each submit payment offers and supporting information to selected entity
  - IDR entity to choose from submitted offers; payment to be made within 30 days

Patients Protected by the NSA

- Generally applies to items and services furnished to individuals who are enrolled in group health plans, group or individual health insurance coverage, or Federal Employee Health Benefit program plans
- The good faith estimate (GFE) requirement and the requirements related to the patient-provider dispute resolution process (distinct from payor/provider IDR) apply to uninsured/self-pay patients
- Surprise billing protections apply to any group health plan or group/individual insurance that covers emergency care, non-emergency care at INN facility, or air ambulance services, **even** if plan/coverage does not otherwise cover OON items or services
- Requirements do not apply to beneficiaries or enrollees in the federal health care programs that have their own protections against high medical bills:
  - Medicare (including Medicare Advantage)
  - Medicaid (including Medicaid MCOs)
  - Indian Health Services
  - Tricare
  - Veterans Affairs Health Care

State Surprise Billing Laws – Patient Protections

- States must, at a minimum, ensure the protections afforded by the NSA; states can establish additional protections for balance billing
- For example, the New York Surprise Bill Law imposes stricter protections for fully-insured plans and other insurance plans that opt-in to its protections
  - LONGER NOTICE PERIOD - A patient whose insurance ID card says “fully insured coverage” may not waive balance billing protections with less than 72 hours advance notice even for elective items or services
  - NY NSA COVERS MORE HOSPITAL SERVICES - Even with notice and consent, a hospital or physician may not bill more than the INN cost share amount for post-stabilization services provided to an inpatient whose insurance ID card says “fully insured coverage”

In the first two months of 2022, the NSA prevented more than 2,000,000 surprise medical bills across all commercially insured patients. If only a fraction of these claims are ultimately disputed through IDR, it would still far exceed the government's estimate. Should the trend hold, more than 12,000,000 surprise bills will be avoided in 2022 due to the NSA.

AHIP & BCBSA, *More Than 2 Million Surprise Bills Avoided During January-February 2022*, AHIP.ORG (May 2022).

Provider and Facility Requirements

Requirements as of January 1, 2022

- Under the NSA, providers/facilities may not balance bill patients for the following services:
  - OON emergency services, including certain post-stabilization services (PHSA 2799B-1; 45 CFR 149.410)
  - Non-emergency services by nonparticipating providers at certain participating health care facilities, unless notice and consent was given in some circumstances (PHSA 2799B-2; 45 CFR 149.420)
  - Air ambulance services provided by nonparticipating air ambulance providers (PHSA 2799B-5; 45 CFR 149.440)
- Must disclose patient protections against balance billing (PHSA 2799B-3; 45 CFR 149.430)
- Must provide a good faith estimate in advance of scheduled services, or upon request (PHSA 2799B-6; 45 CFR 149.610 (for uninsured or self-pay individuals))
- Must ensure continuity of care when a provider's network status changes (PHSA 2799B-8)
- Must improve provider directories and reimburse enrollees for errors (PHSA 2799B-9)

Continued Care and Provider Directory Requirements

- Providers/facilities must ensure continuity of care when its network status changes
  - Provider/facility must continue to accept cost-sharing amounts and payment from the plan or issuer for up to 90 days after the date that the continuing care patient was notified of the provider's change in network status
  - Must continue to adhere to contract as if it was still in place
- Any provider of facility that has, or has had, a contractual relationship with a plan or issuer to provide items or services under such plan or coverage must submit provider directory information to a plan or issuer in certain circumstances:
  - Beginning or termination of the network agreement;
  - Upon request or as determined appropriate; and
  - When there are material changes to the information

Requirements with Respect to Insured Patients

Required Disclosures

- A provider or facility must disclose to the insured to whom it is providing items and services information regarding federal and state (if applicable) balance billing protections, including methods to report violations
- The provider or facility must post the disclosure in a prominent location within the facility and its public website
- The provider or facility must give a copy of the disclosure to each patient that they provide NSA-covered services to, no later than the date when payment is requested
- To be considered in good faith compliance with the disclosure requirement, providers must use the August 2022 revised model disclosure form

Notice & Consent Documents for Insured Patients

- To balance bill, providers/facilities must provide Notice & Consent documents for:
  - Emergency services provided by out-of-network facilities, providers, and air ambulance services
  - Non-emergency services provided by out-of-network physicians at in-network facilities
- Facilities covered by the Act do not include all health care facilities
- Notice must be provided, and consent must be obtained, pursuant to the following timeframes:
  - If scheduled greater than 72-hours in advance, at least 72-hours in advance of the service
  - If the service is scheduled less than 72-hours in advance, no later than the day the appointment is made
  - At least 3 hours in advance of services scheduled to be provided the same day
- Notice and consent forms must be used verbatim and providers and facilities must use the new notice and consent forms provided in August 2022 by CMS beginning January 1, 2023

Emergency OON Services

Permissible Billing Practices

- OON providers/facilities cannot bill, or hold liable, patients covered by the NSA who (a) receive emergency services, including certain post-stabilization services, and (b) receive such services at a hospital or an independent freestanding emergency department, for a payment amount greater than the in-network cost-sharing requirement for such services
- Cost-sharing is calculated as if the total amount that would have been charged by a participating provider or participating facility were equal to the recognized amount

Exceptions

- Balance billing for post-stabilization services is permitted if each of the following conditions are met:
  - Beneficiary, enrollee or participant is “stabilized”;
  - Beneficiary, enrollee or participant is capable of receiving notice and providing informed consent;
  - The non-participating provider or facility provides written notice and obtains consent; and
  - Any applicable state law requirements are satisfied
- Balance billing is always prohibited for emergency and non-emergency items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished

Non-Emergency Services

Permissible Billing Practices

- Cannot bill or hold liable insureds who received covered non-emergency services at a participating health care facility by an OON provider for an amount greater than the in-network cost-sharing requirement for such services, unless **notice and consent requirements are met**
  - Health care facilities include: hospitals, hospital outpatient departments critical access hospitals, and ambulatory surgical centers
- Cost-sharing amount is calculated as if the total amount that would have been charged by a participating provider or facility were equal to the recognized amount

Exceptions

- Notice and consent requirements do not apply to the following list of ancillary services, and the prohibition against balance billing still applies to:
  - Items and services related to emergency medicine, anesthesiology, pathology, radiology and neonatology;
  - Diagnostic services, including radiology and laboratory services;
  - Items and services provided by a nonparticipating provider if there is no participating provider who can provide such item or service at such facility; and
  - Items and services provided by assistant surgeons, hospitalists, and intensivists

Air Ambulance Services

- Providers of air ambulance services cannot bill insureds who receive covered air ambulance services from a nonparticipating air ambulance provider for an amount greater than the in-network cost-share requirement for such services
- The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount or the billed amount for the services

Requirements with Respect to Uninsured and Self-Pay Patients

Determining whether a patient is self-pay

- A self-pay patient is an insured individual who does not seek to submit claims to their plan
- A health care provider or facility must determine whether an individual scheduling an item or service is covered by a health care plan subject to the NSA and, if so, whether the patient plans to submit claims for such items or services to their plan
- If a physician does not accept assignment but the patient plans to submit a claim to their plan, the patient is not a self-pay patient and the NSA's requirements for insured patients apply

Good Faith Estimates (GFE)

- The provider or facility must provide notice, in clear and understandable language, of the GFE of the expected charges, expected service(s), and diagnostic code(s) of scheduled services.
- Timeframe for provision of GFE
  - If scheduled at least 3 business days in advance, the GFE must be provided no later than 1 business day after the date of scheduling
  - If scheduled at least 10 business days in advance, the GFE must be provided no later than 3 business days after the date of scheduling
  - No later than 3 business days after the date of an uninsured or self-pay patient's request (even if the patient has not yet scheduled the service).

Example of how itemized lists of expected items or services could be displayed in a good faith estimate for uninsured (or self-pay) individuals

Details of Services and Items for [Provider/Facility 1]

Service/Item	Address where service/item will be provided	Diagnosis Code	Service Code	Quantity	Expected Cost
	[Street, City, State, ZIP]	[ICD code]	[Service Code Type: Service Code Number]		
Total Expected Charges from [Provider/Facility 1]					$
Additional Health Care Provider/Facility Notes					

Details of Services and Items for [Provider/Facility 2]

These additional Provider/Facility costs may not be included until 2023

Service/Item	Address where service/item will be provided	Diagnosis Code		Service Code	Quantity	Expected Cost
	[Street, City, State, ZIP]	[ICD code]		[Service Code Type: Service Code Number]		
Total Expected Charges from [Provider/Facility 2]						$
	Additional Health Care Provider/Facility Notes					

Disclaimer (example)

This Good Faith Estimate shows the costs of items and services that are reasonably expected for your health care needs for an item or service. The estimate is based on information known at the time the estimate was created.

The Good Faith Estimate does not include any unknown or unexpected costs that may arise during treatment. You could be charged more if complications or special circumstances occur. If this happens, federal law allows you to dispute (appeal) the bill.

If you are billed for more than this Good Faith Estimate, you have the right to dispute the bill.

You may contact the health care provider or facility listed to let them know the billed charges are higher than the Good Faith Estimate. You can ask them to update the bill to match the Good Faith Estimate, ask to negotiate the bill, or ask if there is financial assistance available.

You may also start a dispute resolution process with the U.S. Department of Health and Human Services (HHS). If you choose to use the dispute resolution process, you must start the dispute process within 120 calendar days (about 4 months) of the date on the original bill.

There is a $25 fee to use the dispute process. If the agency reviewing your dispute agrees with you, you will have to pay the price on this Good Faith Estimate. If the agency disagrees with you and agrees with the health care provider or facility, you will have to pay the higher amount.

To learn more and get a form to start the process, go to https://www.cms.gov/nosurprises/consumers or call 1-800-985-3059.

For questions or more information about your right to a Good Faith Estimate or the dispute process, visit https://www.cms.gov/nosurprises/consumers or call 1-800-985-3059.

Keep a copy of this Good Faith Estimate in a safe place or take pictures of it. You may need it if you are billed a higher amount.

Good Faith Estimates & Co-Providers/Facilities

- Co-providers/co-facilities must submit, and convening providers/facilities must receive, GFE information upon the request of the convening provider/ facility no later than 1 business day after receipt of the request
  - Co-providers/co-facilities must notify and provide new GFE information to a convening provider/facility if they anticipate any changes to the scope of the information previously submitted.
  - If any changes to the co-providers or co-facilities listed in the GFE occur less than 1 business day before the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept the GFE amount for the relevant items or services included in the GFE of the replaced provider or facility
- HHS will exercise its enforcement discretion in situations where a GFE provided to an uninsured or self-pay individual does not include expected charges from co-providers or co-facilities through December 31, 2022

Summary of Requirements as of January 1, 2023

- Providers and facilities must provide GFE information for individuals enrolled in a health plan or coverage who seek to submit claims to their plan
- Convening providers and facilities must provide a GFE to uninsured and self-pay patients, including information from co-providers/co-facilities
- Providers and facilities must furnish GFEs to plans or issuers
- Plans and issuers must provide an advanced explanation of benefits to insured individuals

Independent Dispute Resolution

Dispute Resolution

- If self-pay patient's actual responsibility is $400 (or more) greater than the estimate, patients pursue separate alternative dispute resolution process called "SDR"; patient fee is $25. (45 C.F.R.§ 149.620.)
- The NSA directs the Departments of Health and Human Services (HHS), Labor and Treasury to establish a federal independent dispute resolution (IDR) process for nonparticipating facilities and providers
  - When no state law or the All-Payer Model Agreement (APMA) does not apply, plans and issuers must calculate the OON rate for OON emergency services and services provided by nonparticipating providers at in-network facilities
  - IDR process is applicable when providers/facilities disagree with plans/issuers over reimbursement rates

Application of Federal IDR Process

- Applies to:
  - Self-insured plans sponsored by private employers, private employee organizations, or both in all states, except in cases in which a self-insured plan has opted into a specified state law if permitted, or an All-Payer Model Agreement applies
  - Federal health benefits plans except where an Office of Personnel Management's (OPM) contract with an FEHB Carrier includes terms that adopt the state process.
  - Cases where the plan/issuer and provider/facility are in different states
- Does not apply:
  - To items or services payable by Medicare, Medicaid, CHIP, or TRICARE

State Process*	Federal IDR Process	Bifurcated Process*
Alaska	Alabama	California
Georgia	Arizona	Colorado
Maine	Arkansas	Connecticut
Michigan	District of Columbia	Delaware
	Hawaii	Florida
	Idaho	Illinois
	Indiana	Maryland
	Iowa	Missouri
	Kansas	Nebraska
	Kentucky	Nevada
	Louisiana	New Hampshire
	Massachusetts	New Jersey
	Minnesota	New Mexico
	Mississippi	New York
	Montana	Ohio
	North Carolina	Texas
	North Dakota	Virginia
	Oklahoma	Washington
	Oregon	
	Pennsylvania	
	Rhode Island	
	South Carolina	
	South Dakota	
	Tennessee	
	Utah	
	Vermont	
	West Virginia	
	Wisconsin	
	Wyoming	
	American Samoa	
	Guam	
	Northern Mariana Islands	
	Puerto Rico	
	U. S. Virgin Islands	

Negotiation

- Open Negotiation Period: 30 days to resolve dispute, beginning on the day that the provider receives initial payment or denial
- Continued Negotiation is permitted even after the federal IDR process is initiated
  - Parties may agree on an OON rate for a qualified IDR item or service after providing notice of IDR initiation to the Secretary as long as the decision comes before the certified IDR entity makes its payment determination
  - If the plan owes money to a provider based on the agreed upon rate, the plan must pay the provider/facility no later than 30 business days after the agreement is reached
  - Parties are prohibited from seeking any additional payment from the participant or beneficiary
  - Initiating party must send a notification to the Secretary and to the certified IDR entity no later than 3 business days after the date of the agreement which includes the OON rate and signatures from both parties

Initiation of the Federal IDR Process

- Either party may initiate the Federal IDR process by submitting a Notice of IDR Initiation to the other party and to the Secretary within 4 business days after the close of the open negotiation period
  - Must include the party's preferred choice of certified IDR entity
  - If party knows or reasonably should have known that the provider or facility provided notice and obtained consent, it cannot initiate the Federal IDR process
- Selection of certified IDR entity within 6 business days of the initiation of the IDR process
  - Lack of response from non-initiating party within 3 business days will constitute acceptance of the initiating party's certified IDR entity selection
  - If parties do not agree within 6 business days, HHS will appoint a certified entity
- Within 3 business days of its selection, the certified IDR entity must submit an attestation that it does not have a conflict of interest and that the federal IDR Process is applicable

Offers

- No later than 10 business days after selection of the certified IDR entity, each party must:
  - Pay the certified IDR entity fee; and
  - Submit a payment offer to the certified IDR entity
- Batched items or services may be submitted jointly as part of one payment determination provided that all of the following conditions are met:
  - Items and services are billed by providers or facilities with identical National Provider Identifiers or Tax Identification Numbers
  - Payment will be made by the same plan or issuer
  - Items and services are the same or similar (e.g., comparable codes in different systems)
  - Items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period

Determination of Payment Price and Related Issues

- No later than 30 business days after being selected, the certified IDR entity must designate one of the submitted offers as the OON rate and submit a written statement to HHS and the parties involved specifying the reasoning behind the OON rate, including (1) information proving weight was given to the QPA and (2) information proving the selected OON rate represents the value of the qualified IDR item or service
  - Within 30 business days of the determination, any amount due from one party to the other party must be paid and the certified IDR entity must refund the prevailing party's fee
- *Texas Medical Association, et al. v. HHS et al.,* No. 6:21-cv-425-JDK, 2022 WL 542879 (E.D. Tex. Feb. 23, 2022)
  - Court found that the Rule's rebuttable presumption that the QPA is the correct OON payment amount and the requirement that an IDR entity gives more weight to the QPA over other permissible factors conflict with the "unambiguous terms" of the NSA
- *LifeNet, Inc. v. HHS, et al*., No. 6:22-cv-00162-JDK, slip op. (E.D. Tex. July 26, 2022)
  - Departments continued to apply the identical QPA presumption referenced in other portions of the Rule, specifically as applicable to air ambulance providers
  - Consistent with the Texas Medical Association case, the Court struck down the challenged portions of the Rule instead of remanding to the Departments to establish further justification, reasoning that the Departments "cannot justify the challenged portion of the Rule on remand" and the "remaining portions of the Rule and the [NSA] itself provide sufficient framework' for all interested parties to resolve payment disputes" (quoting Texas Medical Association 2022 WL 542879, at *14)

HHS Guidance Regarding Payment Determination

Factors that must be considered

- The QPA for the applicable year for the same or similar item or service
  - No longer presumed to be the correct OON rate
- Credible information submitted by a party that clearly demonstrates that the QPA is materially different from the appropriate OON rate

Prohibited Factors

- Usual and customary charges
- The amount that would have been billed by the provider or facility had the NSA not applied
- Payment or reimbursement rate for items/services furnished by the provider or facility that are payable by a public payor

Certified IDR entities should select the offer that best represents the value of the item(s) or service(s) under dispute after considering the QPA and all additional permissible information submitted by each party to determine the offer that best reflects the appropriate OON rate.

Summary of August 2022 Final Rule

- Provides guidance for determining the OON rate of items and services and delineates information required to be included in the certified IDR entities' written determination
- Defines "downcode" and requires additional information to be provided by the plan or issuer to the provider/facility if the QPA is based on a downcoded service or modifier
  - "Downcode" means "the alteration by a plan or issuer of the service code to another service code or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower QPA than the service code or modifier billed by the provider, facility, or provider of air ambulance services"
  - If the QPA is based on a downcoded service code or modifier, the plan or issuer must provide to the provider/facility with its initial payment or notice of denial of payment: (1) a statement that the billed service code or modifier was downcoded; (2) an explanation of why the claim was downcoded, including a description of which service codes or modifiers were altered, added, or removed; and (3) the amount that would have been the QPA had the service code or modifier not been downcoded
- AHA and AMA Response
  - Dropped their lawsuit challenging the prior QPA instruction on September 21, 2022.
  - "We have serious concerns that the August 2022 final rule departs from Congressional intent just as the September 2021 interim final rule did. Hospitals and doctors intend to make our voices heard in the courts very soon about these continued problems."

Challenges of the IDR Process

- The certified IDR entity is limited in its ability to determine the appropriate OON rate
- The court ruling in *Medical Association et. al. v. HHS* delayed the initial launch of the HHS' IDR portal and will create delays for parties who already submitted disputes through the portal
  - As HHS works to make regulatory adjustments to comply with the court ruling, the 30-business-day negotiating period has expired for hundreds of cases, which will cause an influx of cases moving to IDR; currently more than 46,000 disputes have been filed since the online portal opened in April 2022

Considerations for Providers

Potential Changes to NSA

- Current gap in protection for certain covered services
  - NSA does not prevent balance billing for services furnished by OON provider referred by an INN physician at a location that does not fall within statute's definition of "facility" (e.g., referral of patient to OON freestanding lab by INN physician during office visit)
- Lawsuits challenging the NSA
  - Federal judge ruled in favor of Texas Medical Association's challenge to Interim Final Rule provision that set QPA (i.e., insurer's median in-network rate for given service in given market) as overriding criterion for determining proper rate for OON payment in provider/plan IDR proceedings
  - CMS' Final Rule in August 2022 removed above provision, but still requires arbitrators to start decision-making process by first considering the QPA and dismissing any additional information already accounted for in the QPA (e.g., patient acuity or complexity of service)
  - On Sept. 22, 2022, TMA filed new lawsuit challenging revised IDR process as leading to same faulty results; AHA and AMA plan to file amicus brief

Ensure Ongoing Compliance

- Ensure notice and consent forms, disclosures, and GFEs account for relevant state and federal laws
  - Consider logistics of providing sufficient advance notice
  - Make requisite public disclosures of policies and procedures
  - Do not frame GFE given to uninsured and self-pay patients as a contract with the patient
- Understand the requirements that the government will start enforcing as of January 1, 2023
  - Provision of GFEs to insurer or plan in case of insured patients
  - Convening provider to incorporate charges by co-providers and co-facilities into GFE (ensure efficient and secure communication channels for transmission of GFE information between convening provider and others)
  - Update NSA forms to comply with revised templates CMS issued in August 2022

Consider business and practical implications

- Appreciate complexity of applying NSA regulatory framework to everyday operations of providers and facilities, especially large physician groups and large hospitals
- If applicable state law includes additional NSA protections, determine whether to apply same to all patients or only members of plans covered by state law
  - Logistical challenges to treating members of fully insured plans and self-funded plans differently
    - Identifying members of fully-insured plans
    - Setting up processes for billing certain claims differently
- Timely submit open negotiation notices under NSA to payors and then submit unresolved claims through federal portal to start IDR process
  - https://nsa-idr.cms.gov/paymentdisputes

Buchanan
Ingersoll · Rooney

Thank You

Salvatore G. Rotella, Jr.
Shareholder
Phone: 215-665-5365
Email: salvatore.rotella@bipc.com

Sydney R. Bierhoff
Associate
Phone: 215-665-5372
Email: sydney.bierhoff@bipc.com

Buchanan Ingersoll·Rooney

State Legislative and Regulatory Developments Impacting the Health Care Industry

Hannah W. Kranz, Senior Advisor
PA State Government Relations

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

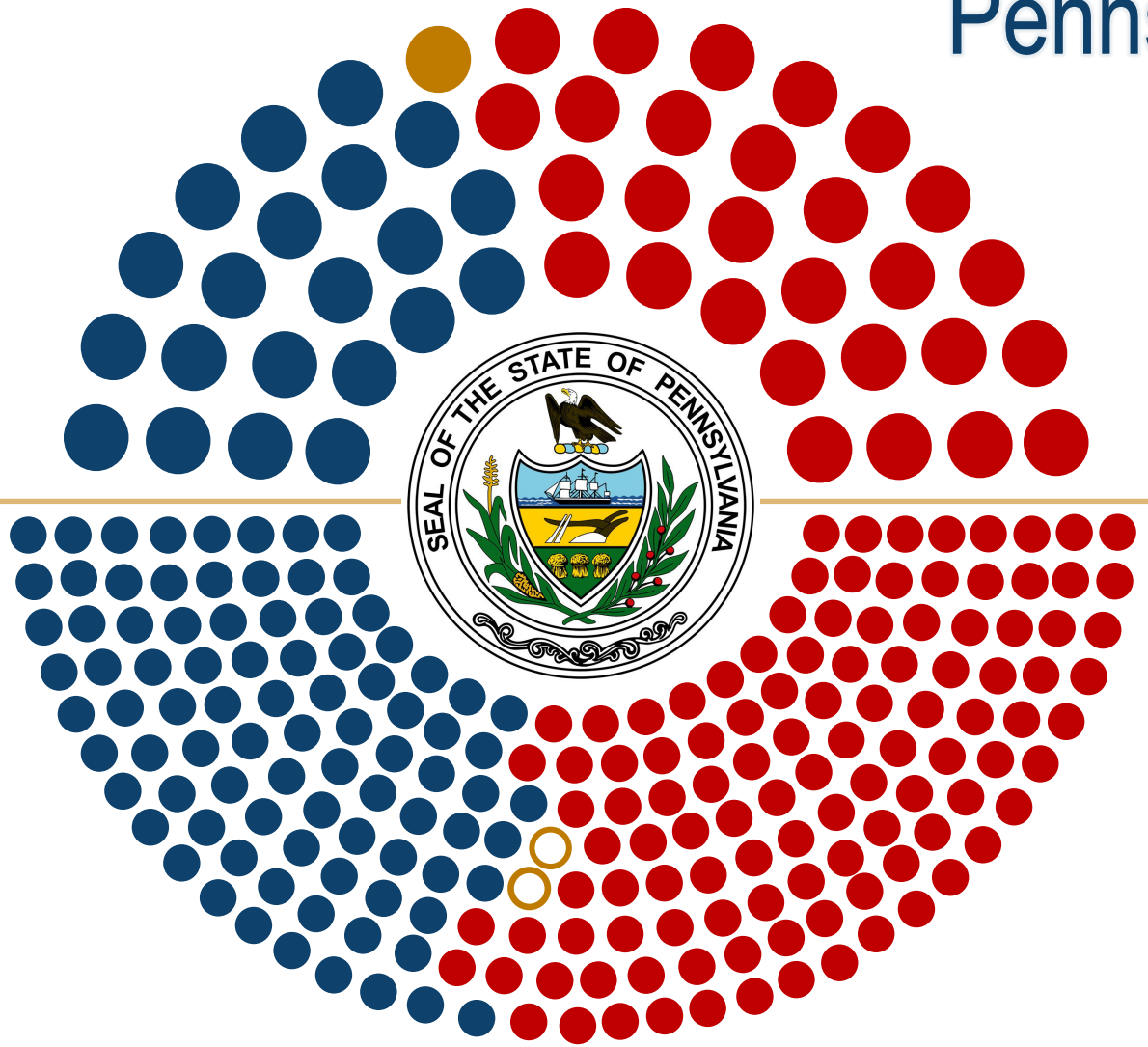
AGENDA

- 2022 Election & Implications
- Session Statistics
- Notable Issues
  - State Budget
  - Health Care Workforce
  - Behavioral Health
  - Prior Authorization Reforms
  - Medical Liability Venue
  - Other
- Agency Initiatives & Activities

NOVEMBER 8, 2022
Who's on the ballot?

- Governor (Gov. Tom Wolf is term limited)
- Lieutenant Governor (Lt. Gov. John Fetterman is term limited)
- U.S. Senate (Sen. Pat Toomey retiring)
- U.S. House (all 17 seats)
- PA House of Representatives (all 203 seats)
  - At minimum, 45 new members of the House in '23
- PA Senate (25 of 50 seats; even-numbered districts)
  - At minimum, 7 new members of the Senate in '23

Pennsylvania General Assembly



Senate

50 Seats

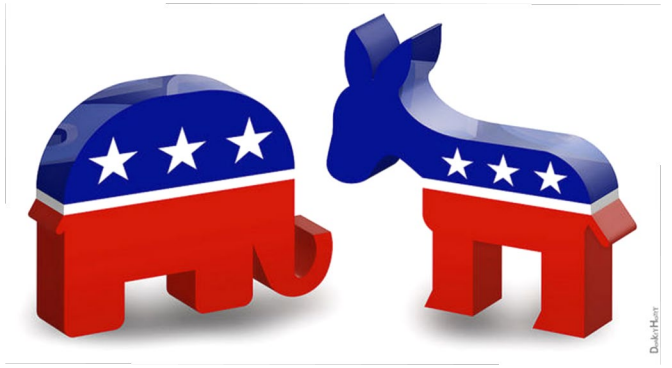
- 28 Republican
- 21 Democrat
- 1 Independent

House of Representatives

203 Seats

- 113 Republican
- 88 Democrat
- 2 Vacant

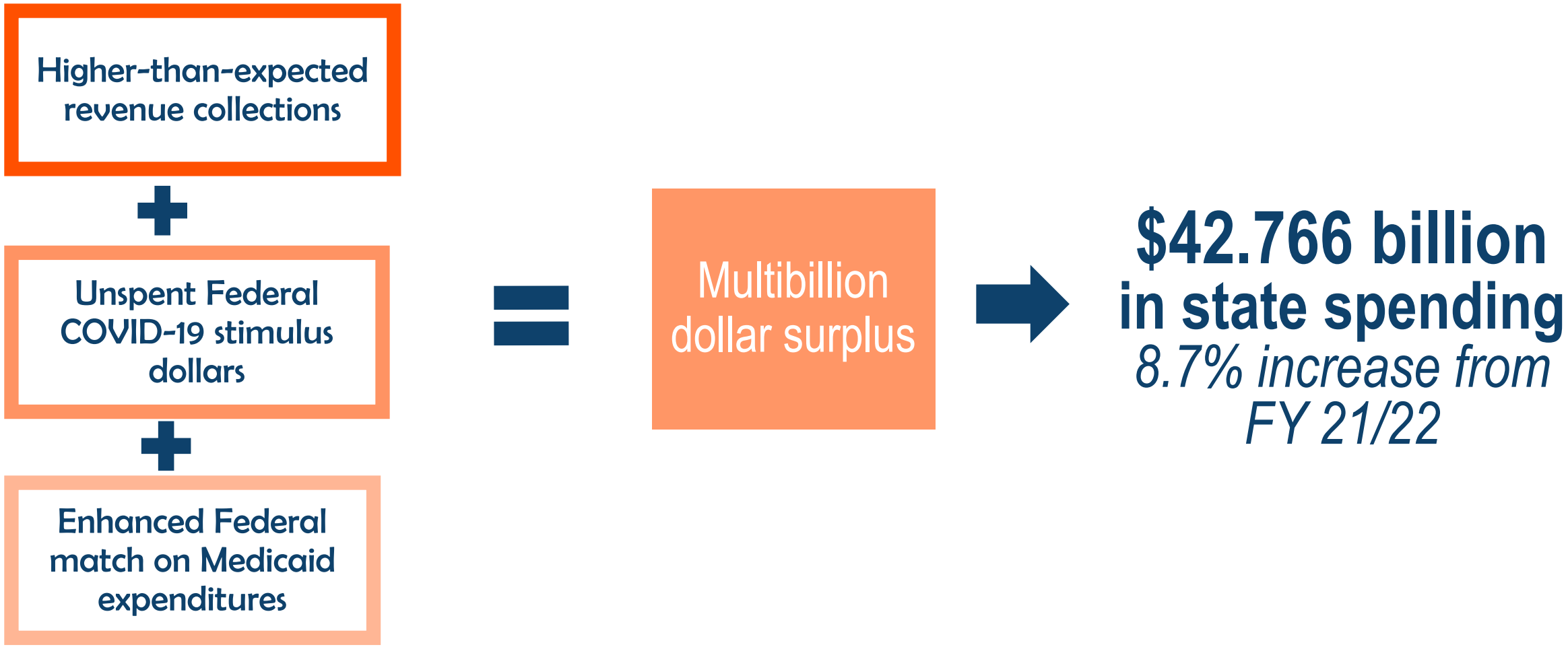
Session Statistics



	Democrat		Republican		Total		
	Introduced	Enacted	Introduced	Enacted	Introduced	Enacted	
House Bills	1307	1	1464	138	2771	139	5%
Senate Bills	492	2	774	81	1277	85	7%
Total	4252	**3**	4773	**219**	9055	**224**	**2%**

*as of 10/11/22

State Budget – Fiscal Year 2022/23



FY22/23 Budget – Health Care Highlights

$1.5 billion	• to correct payment delays to Medicaid managed care organizations
$250 million	• For Long Term Care programs
$294 million	• for MA nursing facility rate increases
$100 million	• for adult behavioral health priorities identified by a new Commission for Adult Mental Health
$100 million	• for mental health services in schools
$90 million	• for retention/recruitment of qualified childcare providers
$35 million	• for the Student Loan Relief for Nurses Program
$16 million	• to expand evidence-based home visiting programs and family support services
$18.8 million	• to serve an additional 832 individuals with intellectual disabilities on emergency waiting lists

FY22/23 Budget – Health Care Highlights *cont…*

$20 million	• to increase supplementary payments to personal care homes
$15 million	• restoration to county mental health services
$25 million	• for new Dependent & Child Care Enhancement Program tax credit
$10.6 million	• increased funding for Bio-Technology Research
$2.5 million	• increase for Primary Health Care Practitioner loan repayment & residency programs
$5 million	• for School-Based Mental Health Internship Program
6% increase	• in funding for disease-related programs
$5.6 million	• increase for county & municipal health departments
$18.8M	• to serve an additional 832 individuals with intellectual disabilities on emergency waiting lists

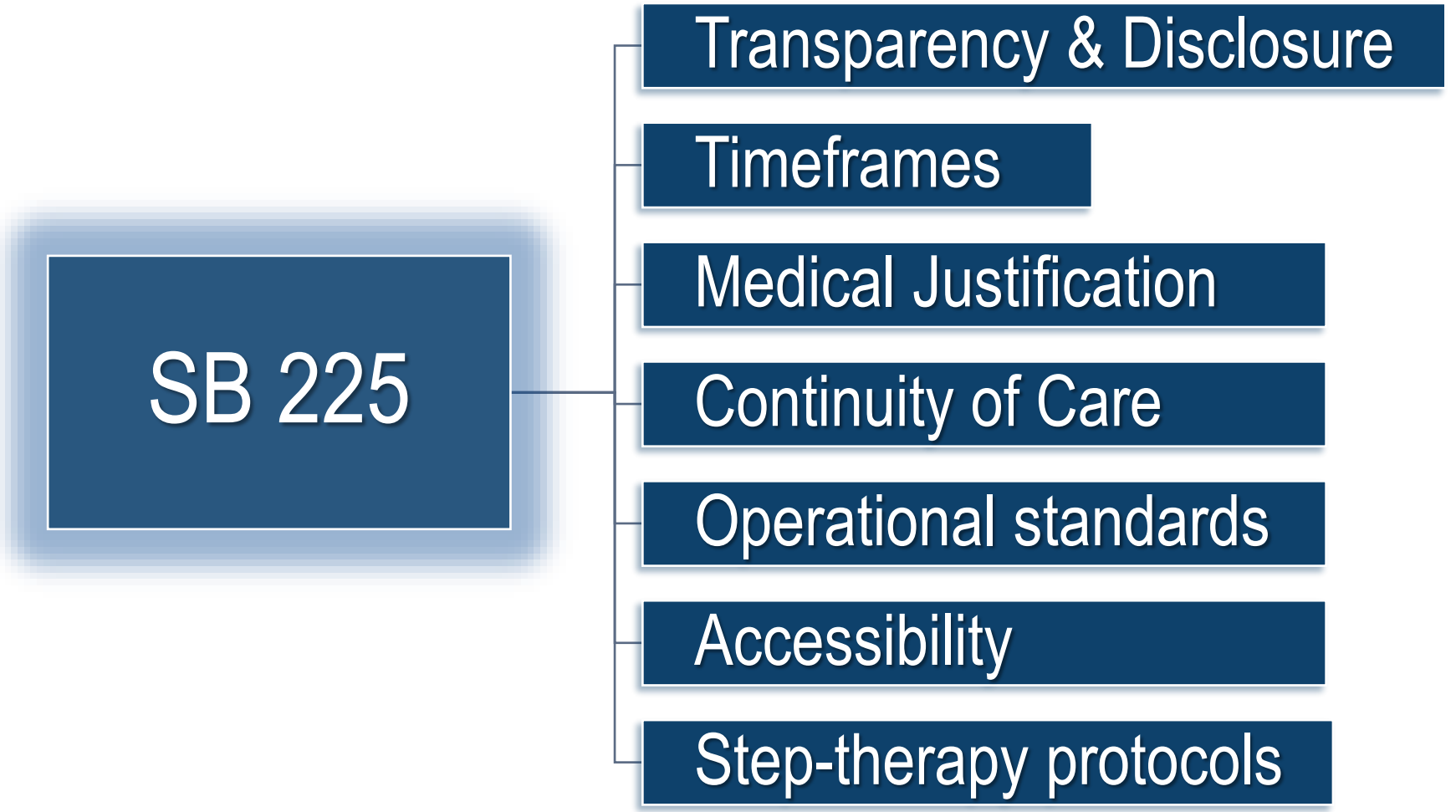
Health Care Workforce

- Extension and codification of numerous COVID-19 regulatory flexibilities
- Direct payments to providers for recruitment & retention
  - Hospitals, Child care providers, HCBS providers
- Provider & service rate increases
  - Personal Assistance Services, Nursing facilities, Ambulance transport fees
- Interstate Health Professional Licensing Compacts
  - Physicians, Nurses, Psychologists, EMS, Occupational Therapists, Counselors, Physical Therapists
- Educational loan relief
  - Student Loan Relief for Nurses Program (PHEAA); Primary Health Care Practitioner Loan Repayment Program; SUD Treatment & Recovery Loan Repayment Program (DDAP)

Behavioral Health

- Confidentiality of Mental Health and SUD Patient Records – Act 32 & 33 of 2022
- Behavioral Health Commission for Adult Mental Health – Act 54 of 2022
- School-Based Mental Health Internship Program – Act 55 of 2022
- Services for Individuals with Complex Behavioral and/or Medical Needs
- Funding for county mental health services
- Launch of 988 National crisis and suicide lifeline
- Integration of behavioral & physical health services (HB 2686, HB 1940)
- System capacity & post-acute treatment pathways (HB 1644)

Prior Authorization/Step Therapy Reforms



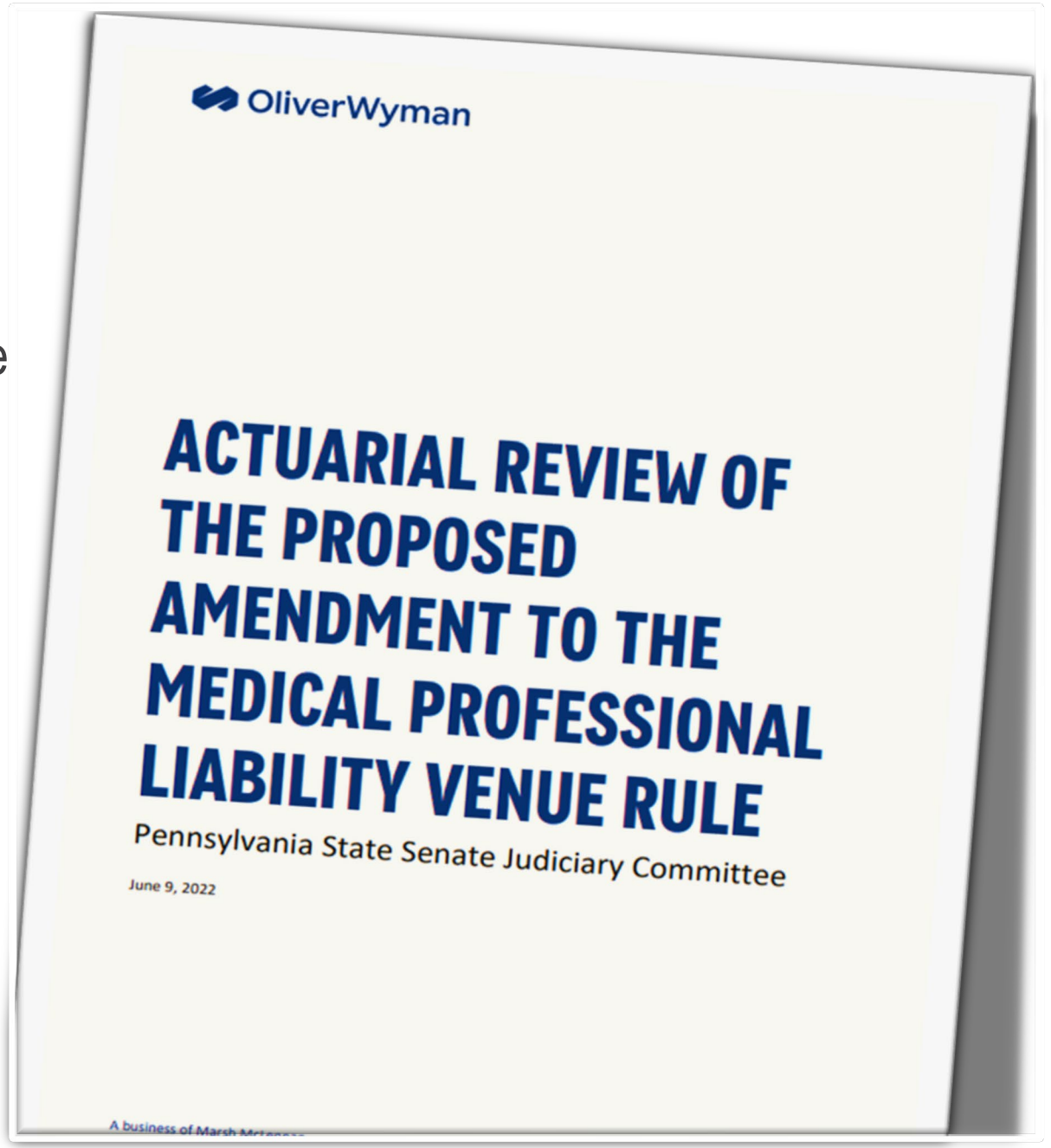
SB 225, PN 1924

- Amends Act 68 of 1998, Article XXI (Quality Health Care Accountability and Protection) of Pennsylvania's Insurance Company Law
  - Incorporates into Act 68 the NAIC Model External Review language, as specified by the Affordable Care Act, to bring oversight of the external review of commercial insurance adverse benefit determinations back to Pennsylvania
  - Updates current Act 68 grievance language to apply it to Medicaid and CHIP external appeals in a manner consistent with federal Medicaid/CHIP requirements
  - Consummates the transfer of insurer/managed care plan oversight responsibilities from the PA Department of Health (DOH) to the PA Insurance Department (PID)
  - Institutes a number of reforms to how health care services are approved by insurers
- Stakeholders involved

Pennsylvania Patient Provider Coalition

Medical Liability Venue

- Senate Resolution 20, adopted in 2019, directed the Legislative Budget and Finance Committee (LBFC) to conduct a study of the impact of venue for medical professional liability actions.
- Actuarial report commissioned by the State Senate Judiciary Committee in 2022
- House Republican Policy Committee – Public Hearing held Sept. 12, 2022
- Advocacy efforts by PA Coalition for Civil Justice Reform
- Potential legislative solutions & outlook…



Medical Liability Venue *cont…*

PA COALITION FOR CIVIL JUSTICE REFORM

Personal jurisdiction

- HB 1540, sponsored by Rep. Donna Oberlander (R-Clarion), House Majority Whip, would allow courts to exercise general personal jurisdiction over a health care provider in a medical professional liability claim in the county of which the cause of action arose.

Constitutional amendment

- HB 2660, sponsored by House Judiciary Chairman Rob Kauffman, proposes an amendment to the Pennsylvania Constitution that would give the General Assembly authority to establish venue for civil litigation by statute.

Subject matter jurisdiction

- Legislation to be introduced by Rep. Torren Ecker (R-Adams) would give the court of common pleas of the county in which a medical liability cause of action arises the exclusive subject matter jurisdiction over that medical liability claim against a health care provider.

Other Prominent Legislative Topics

- Restrictions on non-compete clauses in health care practitioner contracts (HB 681, SB 1358)
- Abortion rights/restrictions (SB 106, SB 956)
- Telemedicine (SB 705)
- Nurse staffing ratios (HB 106)
- Uniform insurer credentialing of providers (HB 2613)
- Opioid epidemic
- Personal Information Privacy (SB 696)
- Childhood Lead Screening (SB 522)
- Lyme Disease Coverage Mandates (HB 1033, SB 100)
- Scope of Practice & Licensure
- Services in Ambulatory Surgery Centers (Act 87 of 2022)
- Government Waste, Fraud & Abuse

Agency Initiatives & Activities

- Innovative Hospital Model Guidance (Outpatient EDs, Microhospitals, Tele-EDs)
- Implementation of Physical Health HealthChoices Reprocurement
- Value Based Payment
- Maternal Health
- Public Health Emergency Unwinding
- Social Determinants of Health
- ARPA HBBS Spending Plan
- Resource & Referral Tool (RISE PA) procurement
- “Agency With Choice” Procurement
- 998 Implementation
- Numerous regulation updates
- Recovery House Licensing
- Opioid Settlement
- Addiction Treatment Locator, Assessment, and Standards (ATLAS) platform

Hannah W. Kranz

Senior Advisor – Government Relations

(717) 237-4819

Buchanan Ingersoll & Rooney

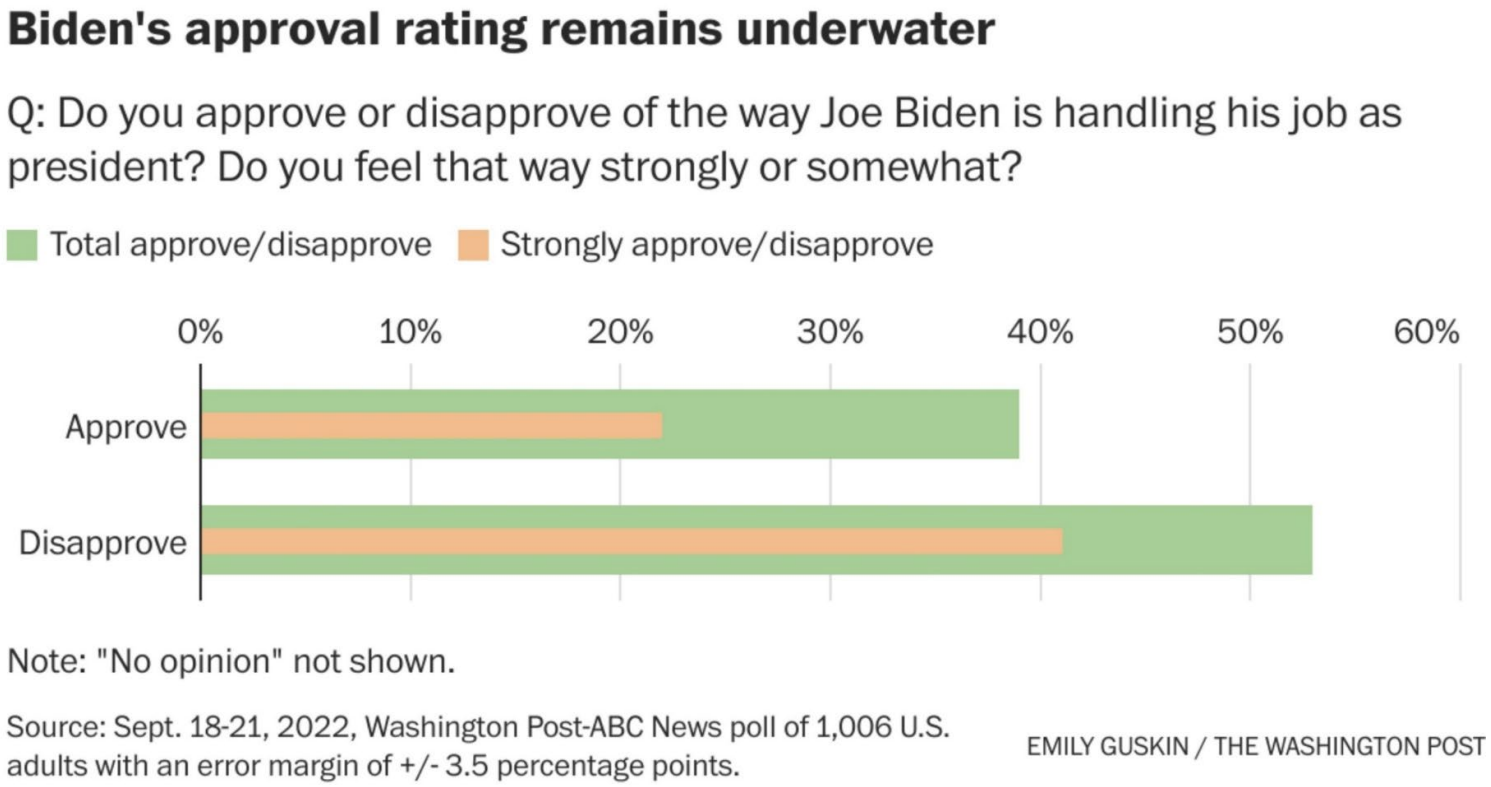
Buchanan
Ingersoll·Rooney

Federal Election Year Presentation: Legislative and Regulatory Developments Impacting the Healthcare Industry

Michael Strazzella
Practice Leader, Federal Government Relations

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM

2022 Mid-Term Elections: Biden's Approval Rating

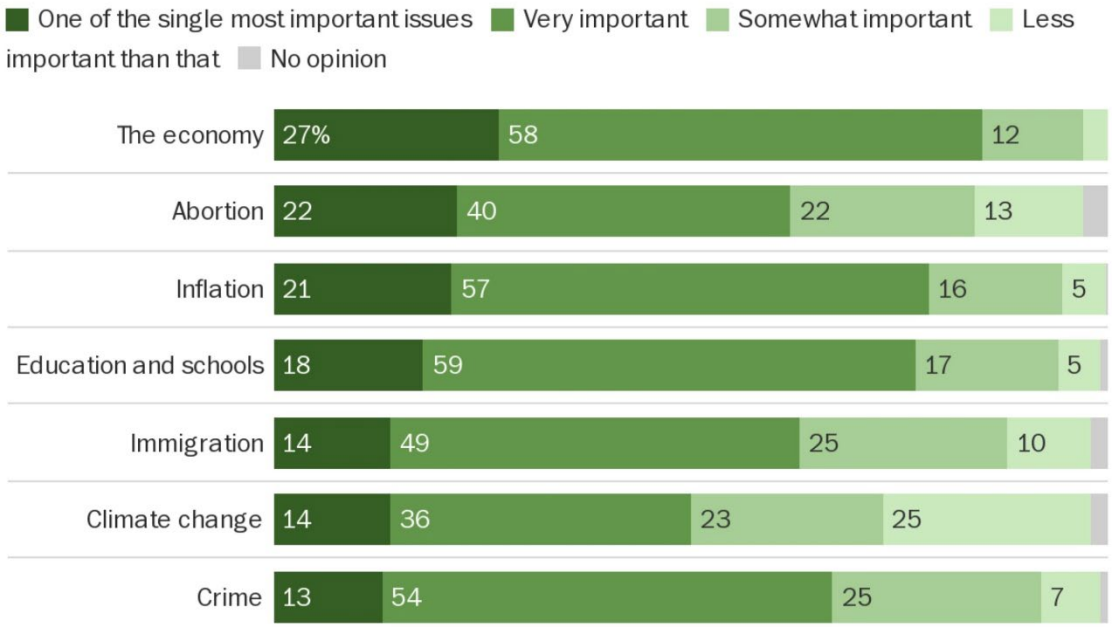


- Based on historical mid-term gains for the President's opposition party, Republicans are confident in winning the House majority in the mid-term elections. In Gallup's polling history, presidents with job approval ratings below 50% have seen their party lose 37 House seats, on average, in midterm elections.

2022 Mid-Term Elections: Top Issues for Voters

Economy, abortion and inflation top issue list for voters this fall

Q: How important will _____ be in your vote for Congress this year?

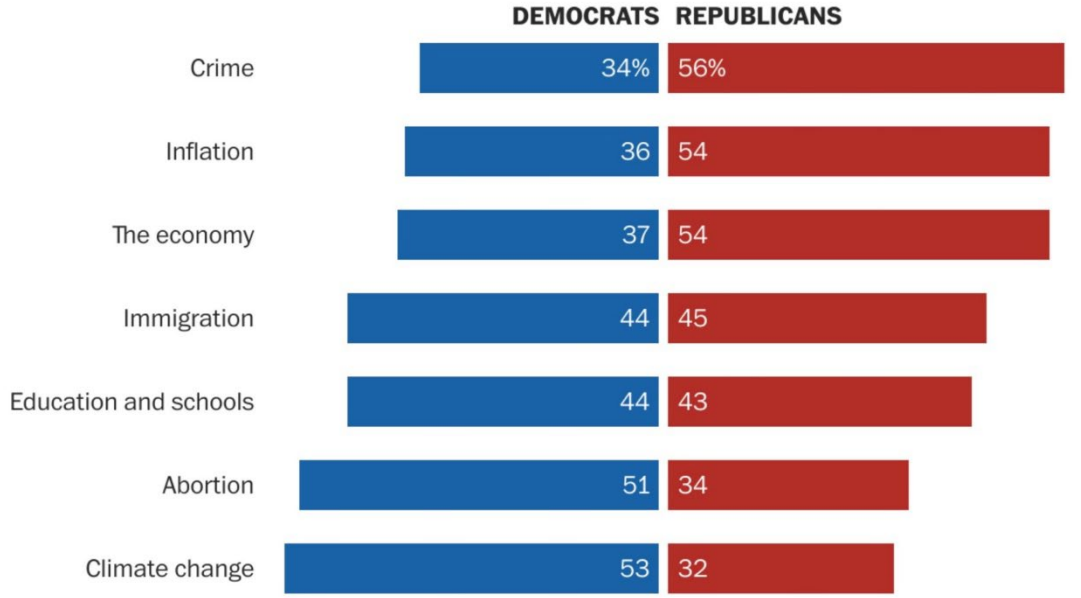


Source: Sept. 18-21, 2022, Washington Post-ABC News poll of 908 registered voters with an error margin of +/- 4 percentage points for the economy, abortion and climate change and 449-459 registered voters with an error margin of 5.5 points for crime, inflation, immigration and education.

EMILY GUSKIN / THE WASHINGTON POST

Which party do voters trust more to handle major issues?

Q: Which political party, the Democrats or the Republicans do you trust to do a better job handling _____?



Note: "Both," "Neither," and "No opinion" not shown.

Source: Sept. 18-21, 2022, Washington Post-ABC News poll of 908 registered voters with an error margin of +/- 4 percentage points for the economy, abortion and climate change and 449-459 registered voters with an error margin of 5.5 points for crime, inflation, immigration and education.

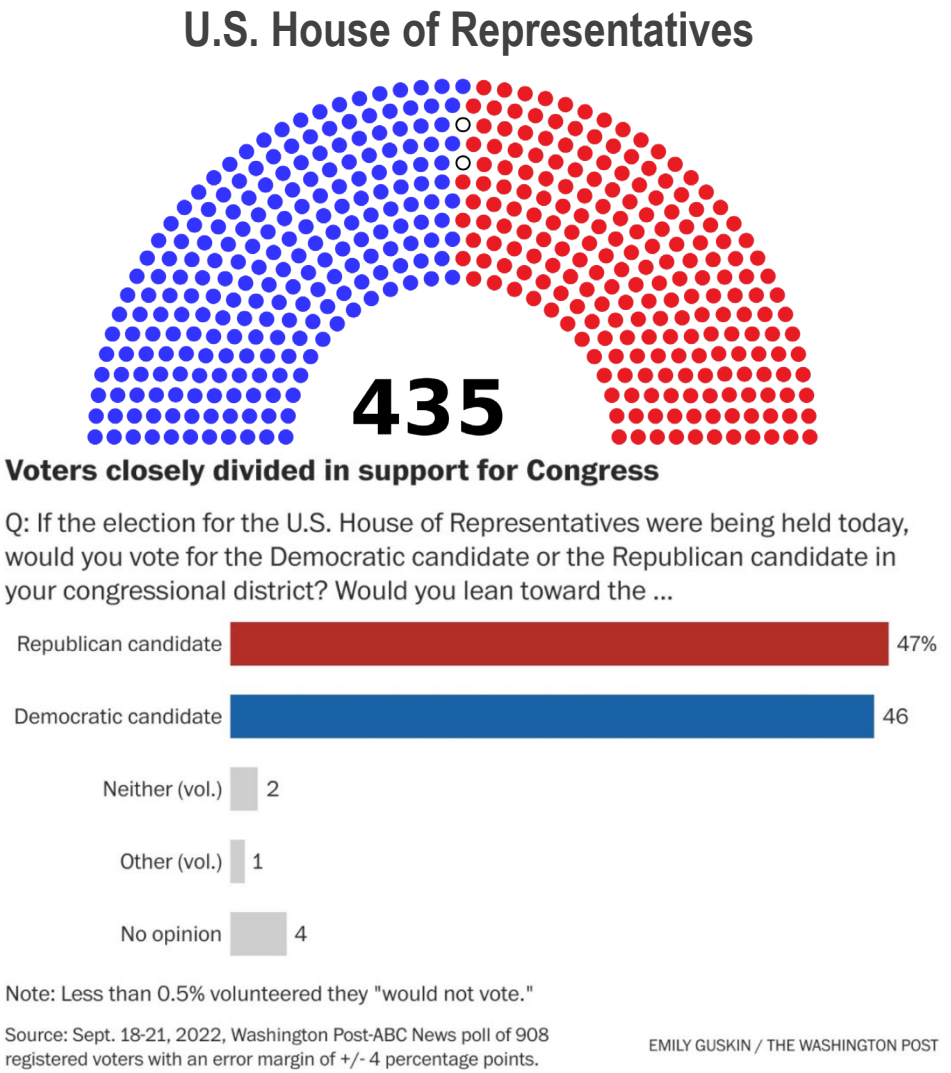
EMILY GUSKIN / THE WASHINGTON POST

2022 House Mid-Term Elections

House Current Party Breakdown :

221 Democrats, 212 Republicans, 2 Vacancies

- Democrats are defending only a five-seat majority in the House
- 30 Democrats are not running for reelection (or are running for other offices); 6 Democrat incumbents were defeated in primaries
- 20 Republicans are not running for reelection; 8 Democrat incumbents were defeated in primaries
- Cook Political Report, to date, lists 32 Democratic seats as “Toss-Up”, “Lean Republican”, or “Likely Republican”; lists only 12 Republican seats as “Toss-Up” or “Lean Democratic”
- Recent generic congressional ballot show a tightening for the battle for control of the House
- So, instead of a “red tsunami” or “red wave” prediction earlier this year of a 20-seat Republican majority, Republicans are now projected to win control with a 10-20 seat majority – or even in the single digits

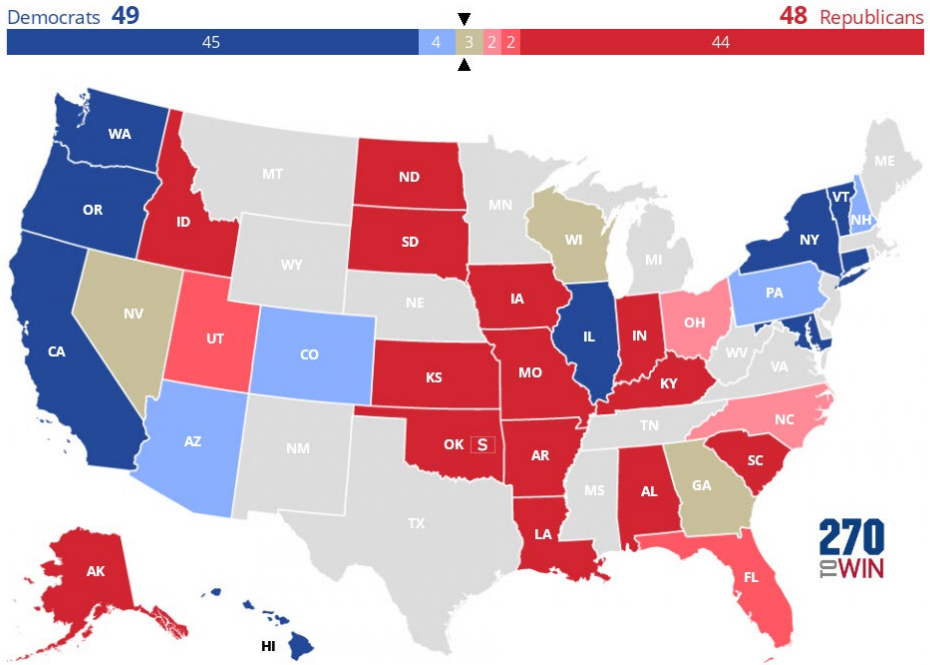


2022 Senate Mid-Term Elections

35 Senate seats are up for election in 2022:

- 21 Republican seats (16 safe; 5 Lean Republican, Toss Up, or Lean Democrat)
- 14 Democratic seats (9 safe; 5 Lean Democratic or Toss Up)

State	Republican	Democrat	Rating
Arizona	Blake Masters	Sen. Mark Kelly	LEAN DEM
Colorado	Joe O'Dea	Sen. Michael Benet	LEAN DEM
Florida	Sen. Marco Rubio	Rep. Val Demings	LEAN REP
Georgia	Herschel Walker	Sen. Raphael Warnock	TOSS-UP
Nevada	Adam Laxalt	Sen. Catherine Cortez Masto	TOSS-UP
N.H.	Don Bolduc	Sen. Maggie Hassan	LEAN DEM
N.C.	Ted Budd (Sen. Burr's seat)	Cheri Lynn Beasley	LEAN REP
Ohio	J.D. Vance (Sen. Portman's seat)	Rep. Tim Ryan	LEAN REP
Pennsylvania	Mehmet Oz (Sen. Toomey's seat)	John Fetterman	LEAN DEM
Wisconsin	Sen. Ron Johnson	Mandela Barnes	TOSS-UP



117th Congress: Relevant Committee Leadership

Senate Committee	Democratic Chair	Republican Ranking Member
Appropriations Committee -Labor, HHS, Education Subcommittee	Sen. Pat Leahy (D-VT) -Sen. Patty Murray (D-WA)	Sen. Richard Shelby (R-AL) – RETIRING -Sen. Roy Blunt (R-MO) – RETIRING
Finance Committee	Sen. Ron Wyden (D-OR)	Sen. Mike Crapo (R-ID)
Health, Education, Labor, and Pensions	Sen. Patty Murray (D-WA)	Sen. Richard Burr (R-NC) – RETIRING

House Committee	Democratic Chair	Republican Ranking Member
Appropriations Committee -Labor, HHS, Education Subcommittee	Rep. Rosa DeLauro (D-CT) -Rep. DeLauro	Rep. Kay Granger (R-TX) -Rep. Tom Cole (R-OK)
Energy & Commerce -Health Subcommittee	Rep. Frank Pallone, Jr. (D-NJ) -Rep. Anna Eshoo (D-CA)	Rep. Cathy McMorris Rodgers (R-WA) -Rep. Bret Guthrie (R-KY)
Ways and Means -Health Subcommittee	Rep. Richard Neal (D-MA) -Rep. Lloyd Doggett (D-TX)	Rep. Kevin Brady (R-TX) – RETIRING -Rep. Vern Buchanan (R-FL)

Senate Appropriations Committee

Patrick Leahy (D-Vt.) is retiring

- He's served as the panel's top Democrat since 2017
- Patty Murray (D-Wash.) is next by seniority; she would need to give up her current top spot on the Health, Education, Labor & Pensions Committee to lead Appropriations in the 118th Congress

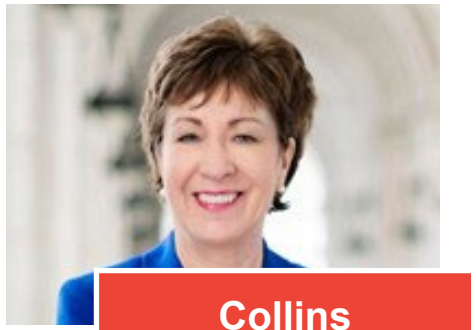
Richard Shelby (R-Ala.) also is retiring

- Susan Collins (R-Maine) is next in seniority and a likely option to succeed Shelby


Leahy


Murray


Shelby


Collins

Senate HELP Committee

Patty Murray (D-Wash.) is likely to relinquish the Health, Education, Labor & Pensions top spot to lead Appropriations

- She's served as panel's top Democrat since 2015
- Bernie Sanders (I-Vt.) would be the most senior Democrat on the panel if Murray goes to Appropriations

Richard Burr's (N.C.) retirement sets up a potential shift for Republicans

- Rand Paul (Ky.) is next in line to serve as the top Republican, but also has seniority on Homeland Security
- Bill Cassidy (La.) is the next most senior Republican on the panel after Paul


Murray


Sanders

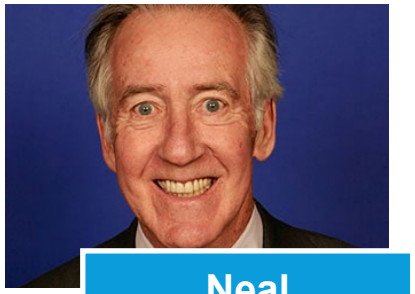

Burr


Paul


Cassidy

House Ways and Means Committee

- Richard Neal (MA) is the top Democrat on the panel
- Kevin Brady (TX) is retiring
  - Brady said GOP committee term limits factored into his retirement decision
  - Vern Buchanan (FL) has the most seniority on the panel
  - Adrian Smith (NE) and Jason Smith (MO) are also running to succeed Brady


Neal


Brady


Buchanan


A. Smith


J. Smith

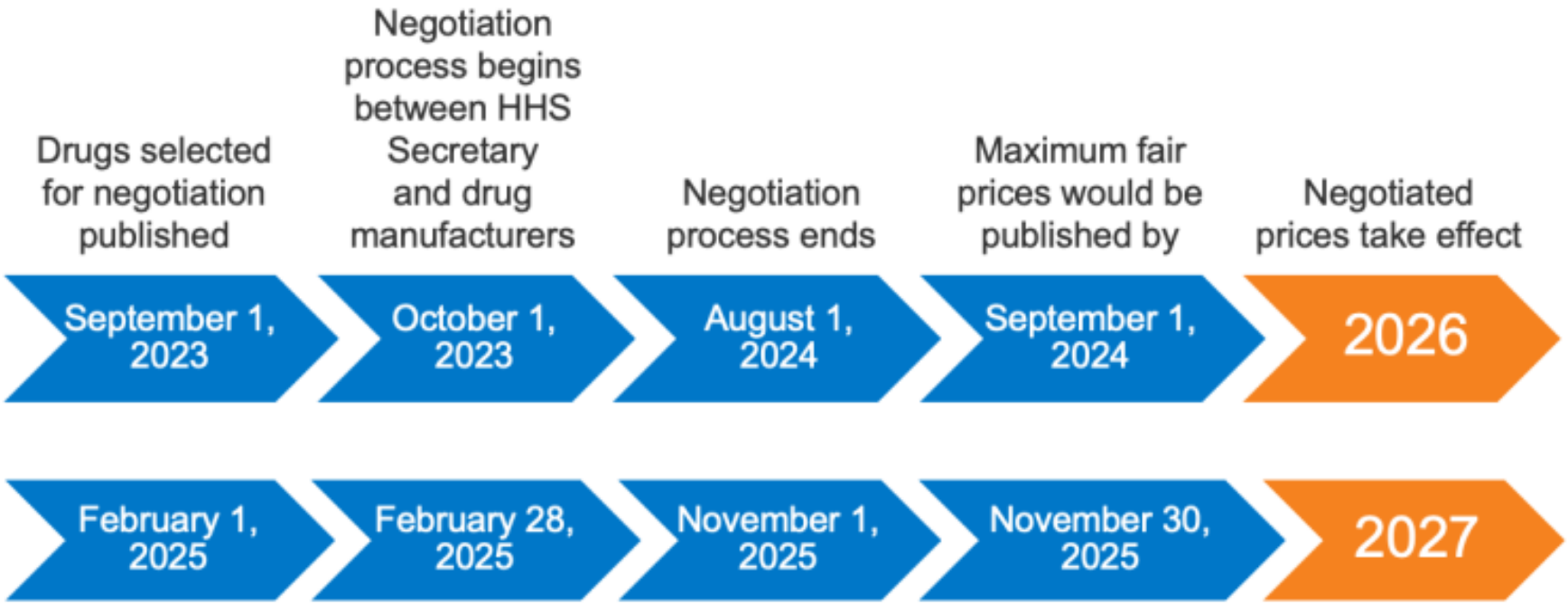
Inflation Reduction Act (PL117-169)

- Requires Medicare to negotiate prices for ‘some’ drugs under Part B & D with highest spending
- Requires Rx companies to pay rebates to Medicare if prices rise faster than inflations for Medicare covered drugs
- Caps beneficiary out-of-pocket spending for Medicare Part D
- $35 insulin cap for Medicare monthly costs
- Expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program
- Eliminate cost sharing for adult vaccines covered under Medicare Part D and improve access to adult vaccines in Medicaid and CHIP
- 3-year extension of ACA subsidies

Inflation Reduction Act | Timeline

Figure 1

Medicare Drug Price Negotiation Timeline for 2026 & 2027



SOURCE: KFF analysis of section 11001 of the Inflation Reduction Act of 2022.

KFF

What's Next?

- Continued expansion of transparency across the delivery system.
- PHE – Medicaid enrollment, Telehealth, staffing
- Medicare Advantage – continued scrutiny
- Rx Reform and PBMs – legislation to regulatory process
- Statutory PAYGO Sequestration: 4% in 2023
- Downstream effect of health inflation
- Mental Health and Substance Abuse (programs, parity, $$s and quality of care)
- SGR

Q&A/Discussion

Michael Strazzella

Practice Leader, Federal Government Relations

Email: michael.Strazzella@bipc.com

Phone: 202.452.7932

Buchanan Ingersoll & Rooney

BUCHANAN HEALTHCARE
INSIDER SYMPOSIUM

TUESDAY, OCTOBER 18, 2022

CYTO | PHL

Buchanan HEALTHCARE INSIDER 2022 SYMPOSIUM