Hooper, Lundy & Bookman Presents The National Symposium on Health Law and Policy

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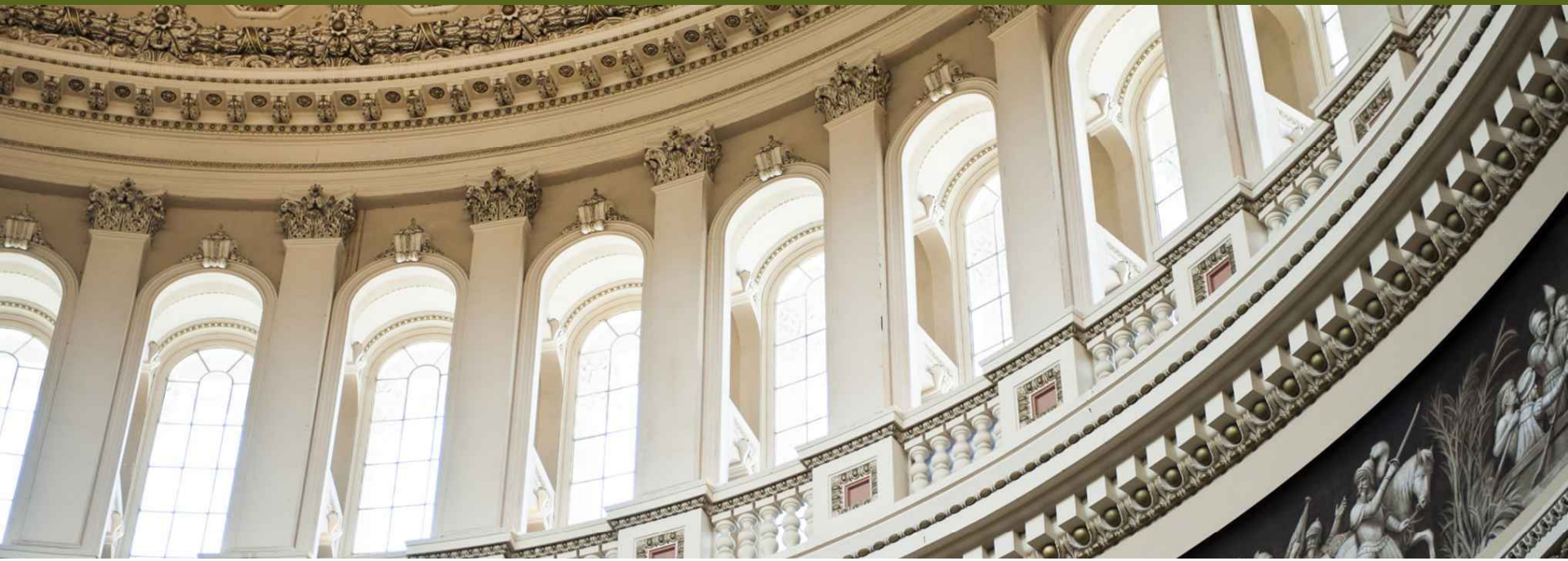


The State of Post-Acute and Long-Term Care: Current Challenges and Future Opportunities

Mark Parkinson – President & CEO, AHCA and NCAL

Mark Reagan – Managing Shareholder, Hooper, Lundy & Bookman, P.C.

Evolution of Skilled Nursing

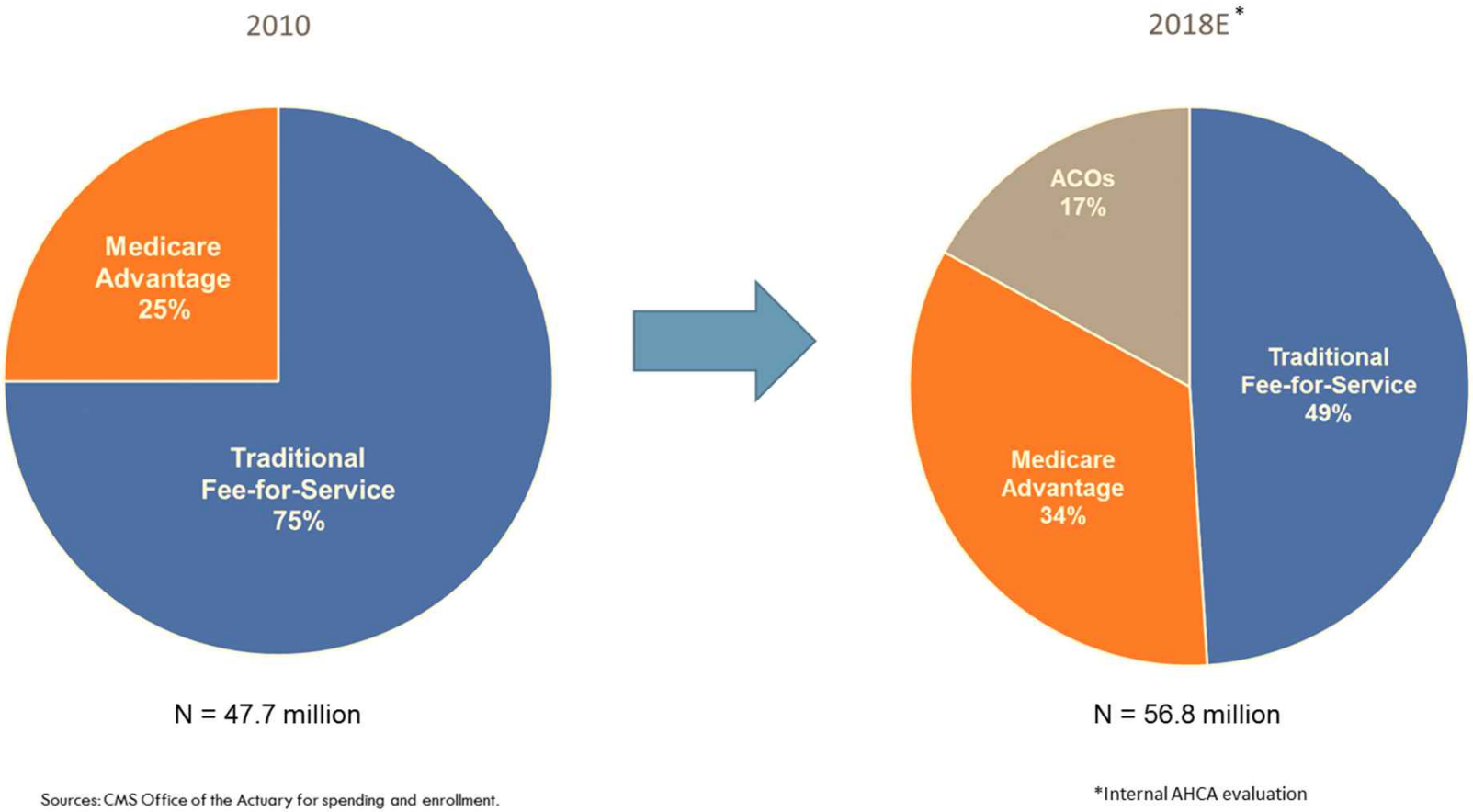
Shift to PPS in late 1990s Made a Huge Difference

- Away from cost-based system to pay based on care
- 20% of companies went bankrupt
- Efficiencies suddenly mattered
- Crushing blow to rural facilities

Post-Acute Saved the Day

- $550/day rate
- Much cheaper than hospital
- SNFs in the driver seat

Then The World Changed Again

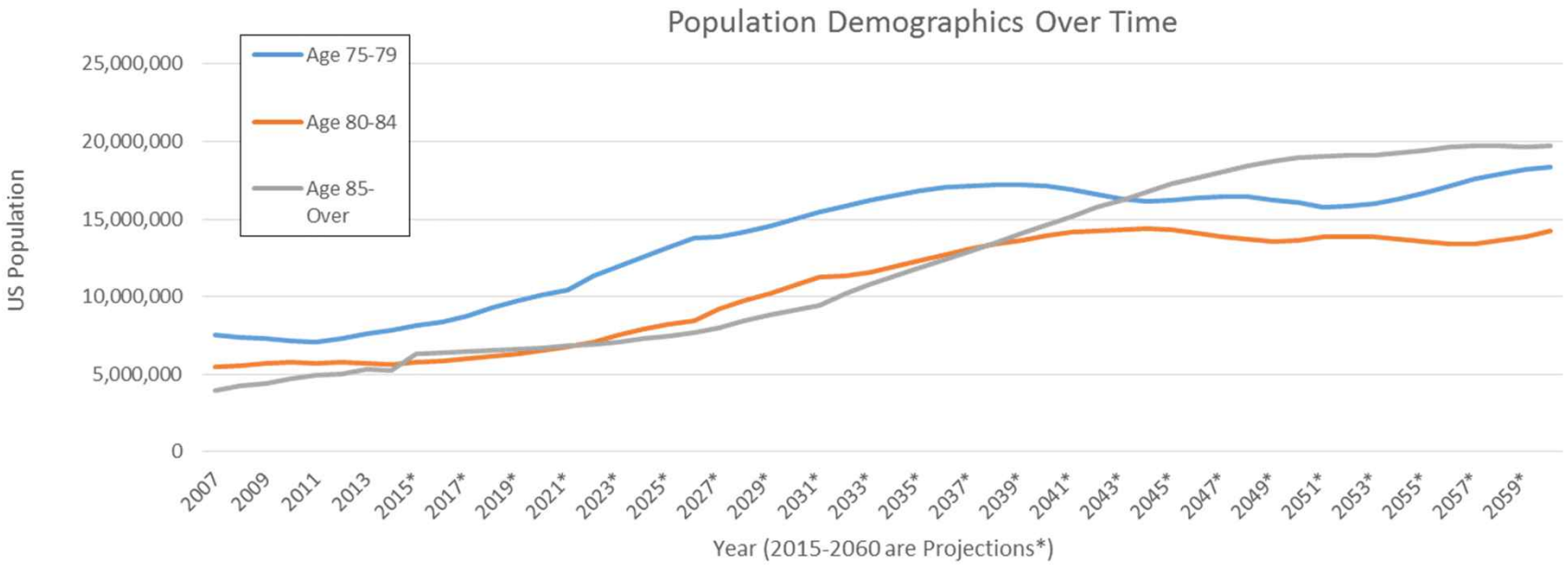


Sources: CMS Office of the Actuary for spending and enrollment.
Avalere analysis for alternative payment model projections.

*Internal AHCA evaluation

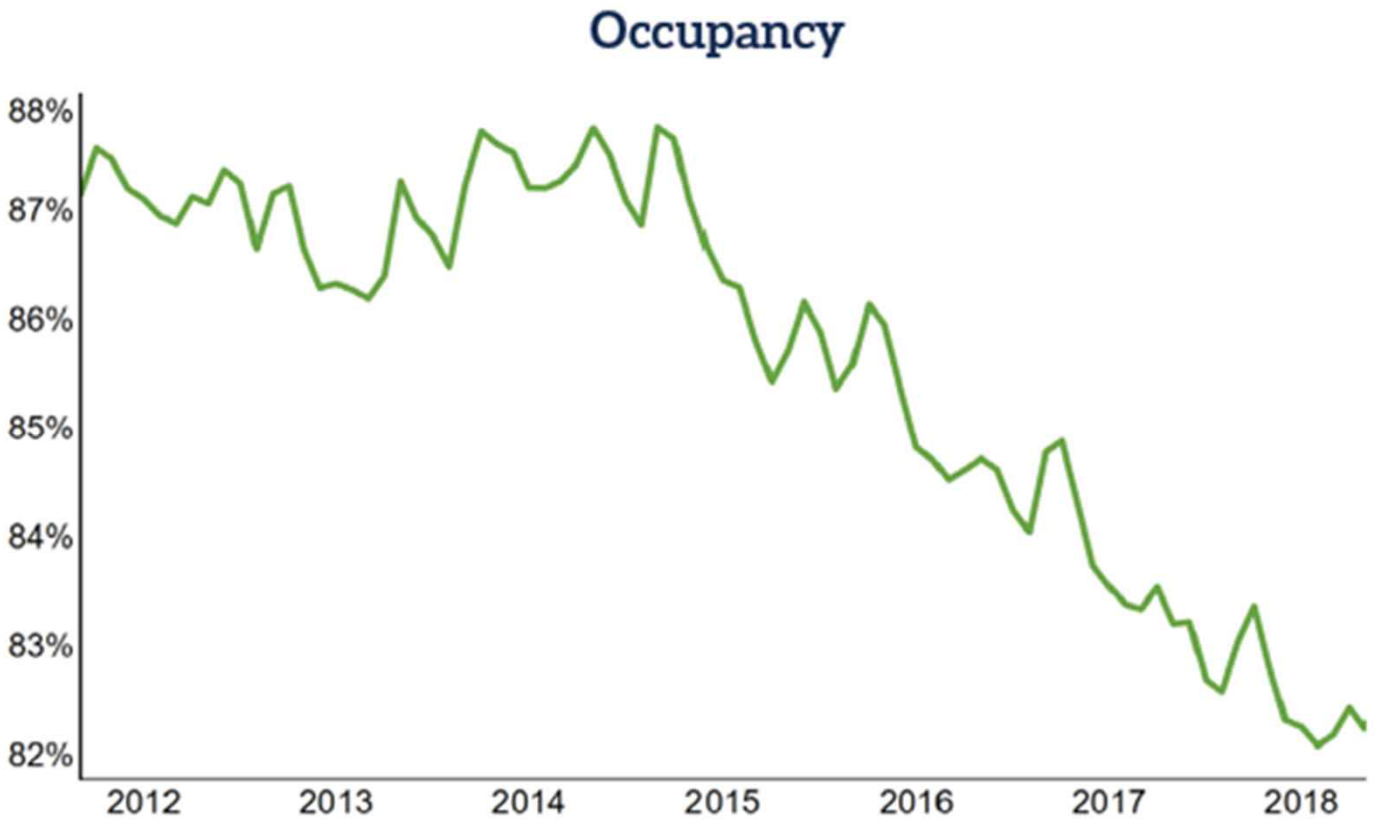
Length of Stay is Declining

Population Growth Isn't Keeping Up



Source: U.S. Census Bureau

Occupancy is Down



Source: NIC, Skilled Nursing Data Report, Through September 2018

SKILLED NURSING news

NEWS ADVERT

Skilled Nursing Pressures Forcing Non-Profits to Sell or Close

The Seattle Times

Nation & World

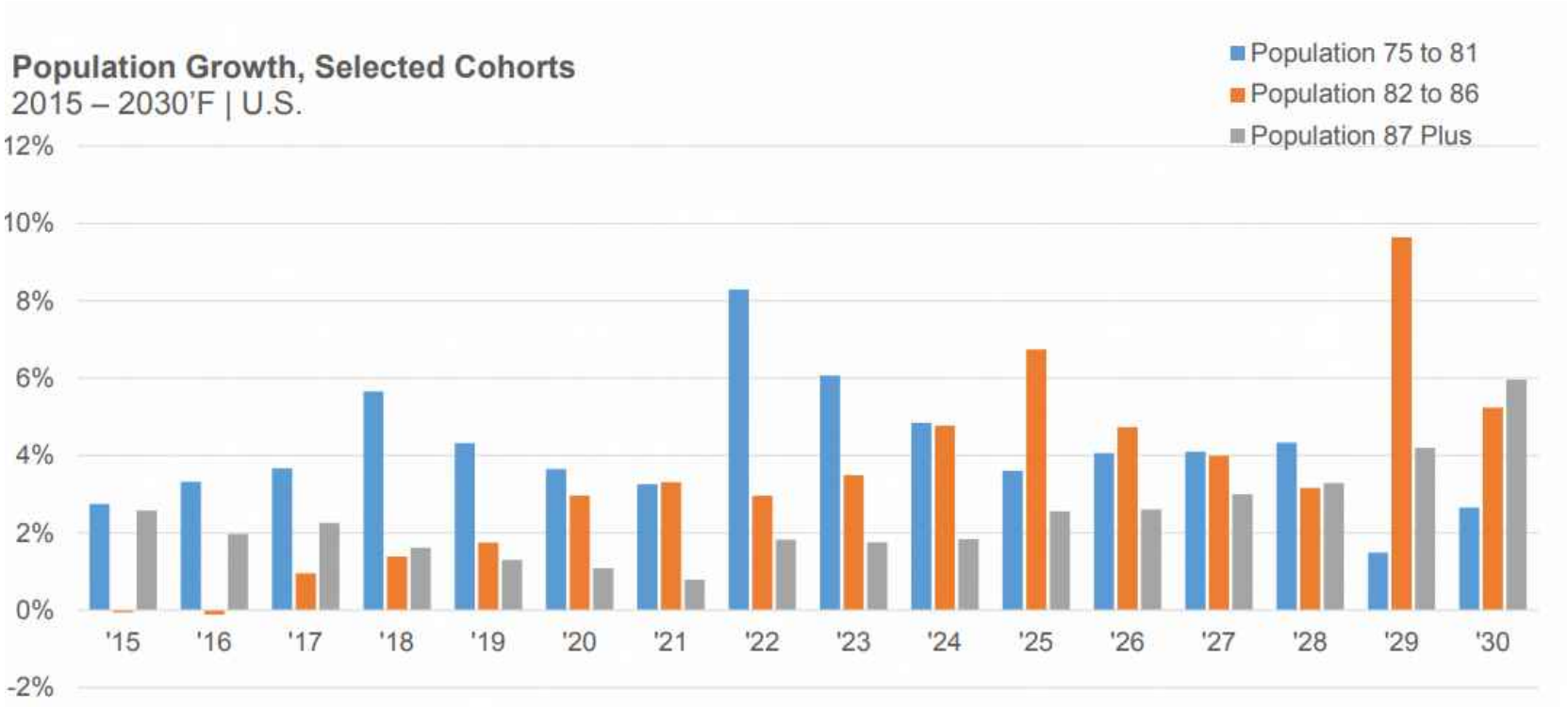
More Wisconsin nursing homes close as costs rise

BOSTON BUSINESS JOURNAL

Health Care

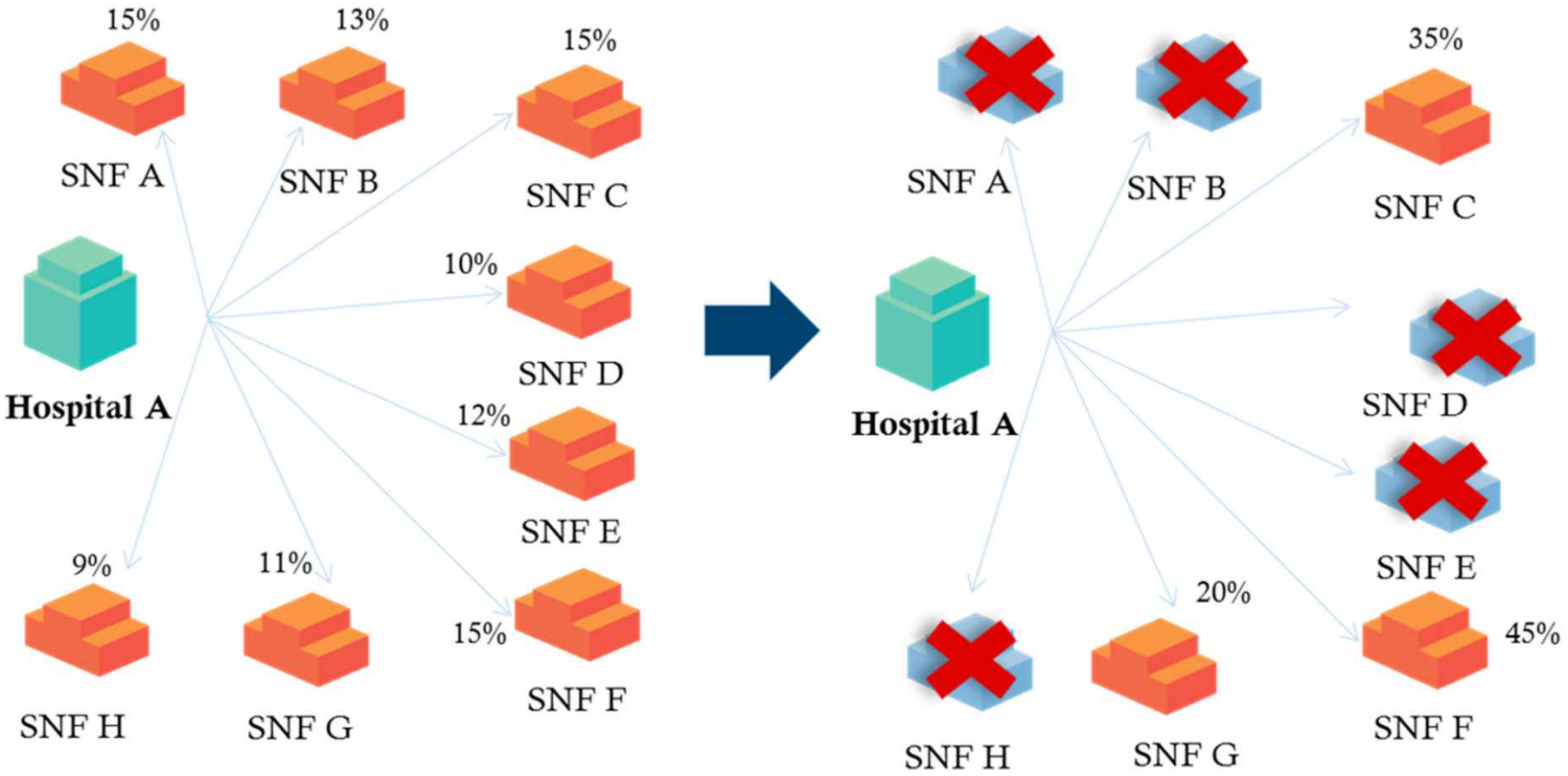
More than 600 workers will be cut as Kindred facilities close in Mass.

Demographics Starting to Help



Source: U.S. Census Bureau

Become a Preferred Provider



PDPM is Providing Hope

- **Providers must prepare for Patient-Driven Payment Model (PDPM)**
  - Payment based on patient characteristics – not therapy minutes
  - Shifts payment from therapy to non-therapy
- **Major cost reductions**
  - Fewer assessments
  - More freedom in how therapy is provided

Population Health Management

- 58 products
- 19% of ISNP covered lives are enrolled in LTC provider owned plans

Evaluating the Cost of Care

- **Average Daily Cost (Medicare)***
  - LTACH = $1,400
  - SNF = $450
- **IRFs cost an average of:****
  - $5,000 more per beneficiary than SNFs for stroke patients
  - $4,000 more for patients recovering from a major joint replacement
- **Average payment*****
  - SNF: $10,808 per stay
  - IRF: $17,085 per discharge
  - LTACH: $38,582 per discharge

*Source: https://homehealthcarenews.com/2018/09/__trashed-13/
**Source: https://www.americanbar.org/groups/health_law/publications/aba_health_esource/2015-2016/december/siteneutral/
***Centers for Medicare & Medicaid Services, Office of Information Products and Data Analysis (OIPDA), Medicare and Medicaid Statistical Supplement, 2011 edition, table 6.2, "Covered Admissions, Covered Days of Care, Covered Charges, and Program Payments for Skilled Nursing Facility Services Used by Medicare Beneficiaries by Demographic Characteristics, Type of Entitlement, and Discharge Status: Calendar Year 2010." available at www.CMS.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/2011.htm. Medicare Payment Advisory Commission (MedPAC), A Data Book: Health Care Spending and the Medicare Program. June 2012, p. 129 (IRF), p. 133 (LTCH), available at www.medpac.gov/documents/Jun12DataBookEntireReport.pdf.

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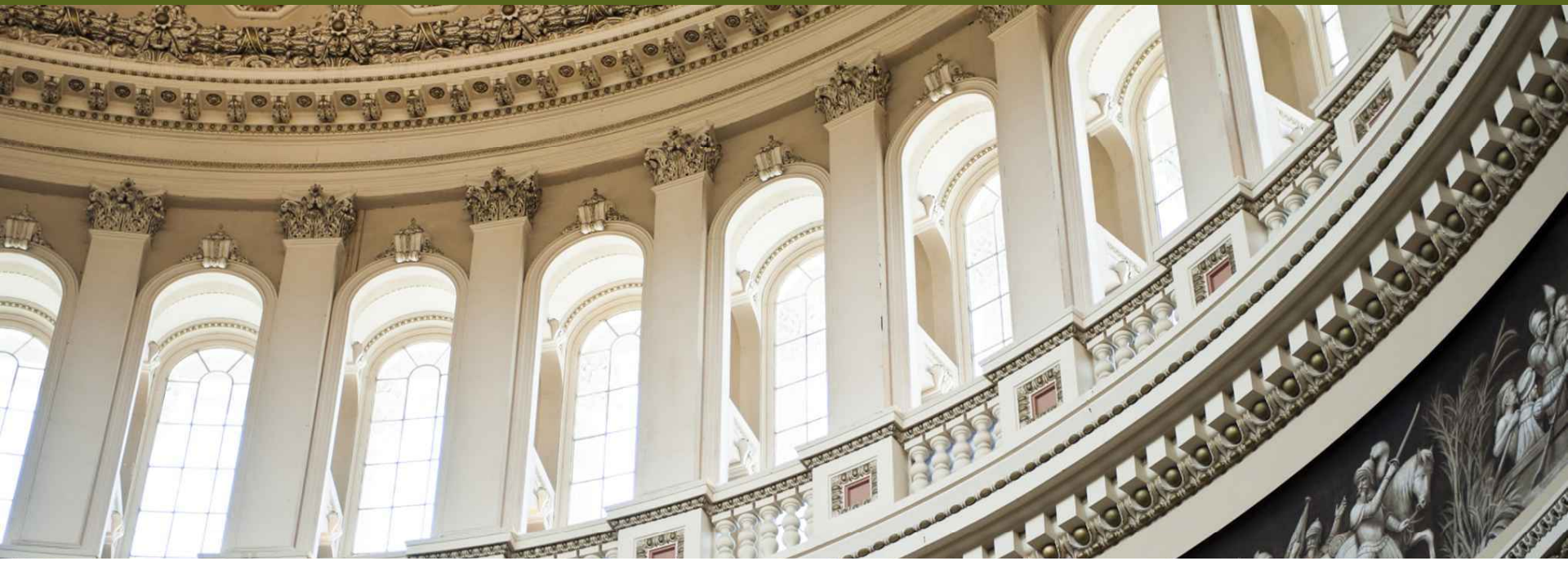

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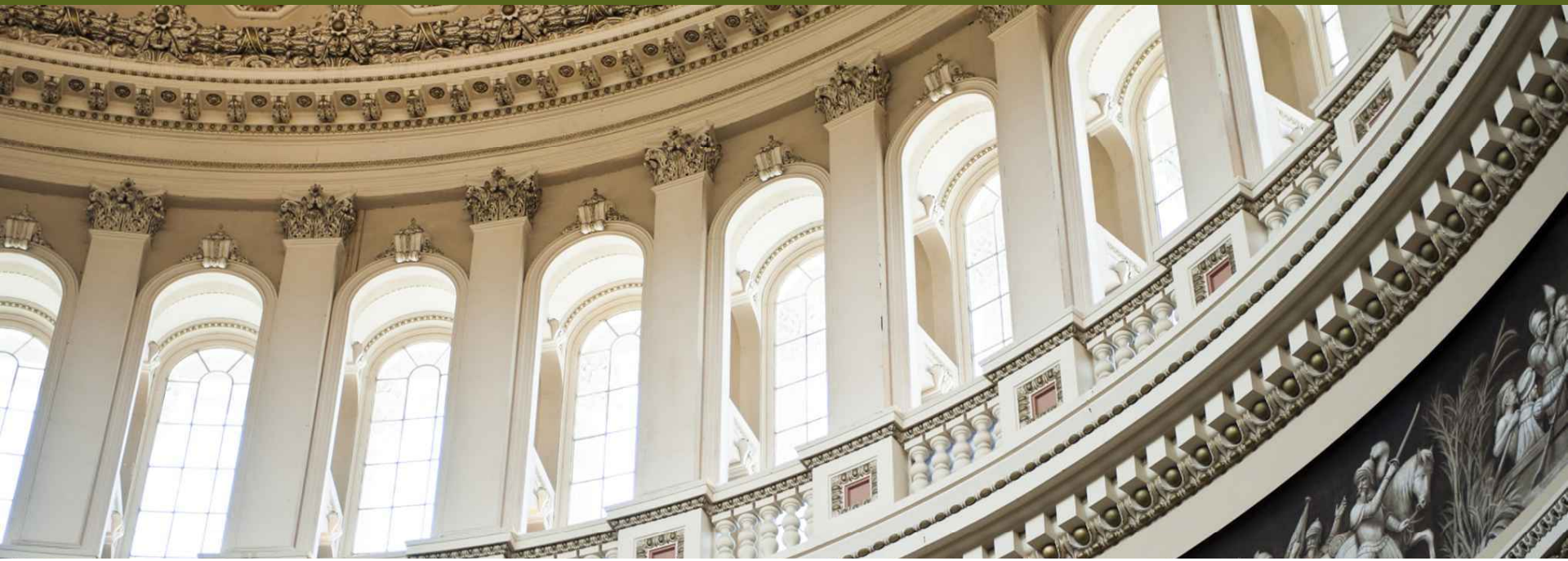


Pricing Transparency and Emerging Trends in Outpatient Reimbursement

Katrina A. Pagonis & Martin Corry – Hooper, Lundy & Bookman, P.C.

Hospital Price Transparency

Publication of Chargemaster and What is Next

42 U.S.C. § 300gg-18(e): Standard Hospital Charges

- "Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1395ww(d)(4) of this title."
- Prior Guidelines
  - Published in FY 2015 IPPS
  - Requires that "hospitals either make a public list of their standard charges, or their policies for allowing the public to view a list of those charges in response to an inquiry."

January 1, 2019 Requirement

- 2019 IPPS Final Rule requires hospitals to -
  - Make public a list of their current standard charges
  - Via the internet in a machine-readable format and
  - Update this information at least annually
- September 2018 FAQ
  - Current standard charges are those “reflected in its chargemaster”
  - The requirement applies “to all items and services provided by the hospital”
  - Compliance with state price transparency rules does not exempt the hospital from federal requirements
- December 2018 FAQ
  - Requirement applies to drugs and biologicals
  - Subsection (d) hospitals must also include “a list of their standard charges for each” DRG (may use Inpatient Utilization and Payment Public Use File (PUF) format)
  - “Specific additional future enforcement or other actions that we may take with the guidelines will be addressed in future rulemaking.”

Considerations

- Patient Relations Risks
  - Charge data is not meaningful to patients
  - Patients do not understand the relationship (or lack thereof) between charges and cost-sharing obligation
- Litigation Risks
  - Inaccurate charge data could give rise to consumer suits
- Public Relations Risks
  - Stories re: “high charges”
  - Stories re: non-compliance
- Regulatory Risks

Outlook

- Price Transparency is a top priority for the administration
- In a May 7 speech, CMS Administrator Verma said that CMS is “just getting started and have asked the public for ideas about what additional information patients need to make more informed decisions about their care.”
- 2019 IPPS Proposed Rule solicited comments on a range of price transparency issues

Questions in 2019 IPPS Proposed Rule Re: Enforcement Mechanism

- Should CMS require hospitals to attest to meeting requirements in the provider agreement or elsewhere?
- How should CMS assess hospital compliance?
- Should CMS publicize complaints regarding access to price information or review hospital compliance and post results? What is the most effective way for CMS to publicize information regarding hospitals that fail to comply?
- Should CMS impose civil money penalties on hospitals that fail to make standard charges publically available as required by section 2718(e) of the Public Health Service Act?
- Should CMS use a framework similar to the Federal civil penalties under 45 CFR 158.601, *et seq*. that apply to issuers that fail to report information and pay rebates related to medical loss ratios, as required by sections 2718(a) and (b) of the Public Health Service Act, or would a different framework be more appropriate?

Price Transparency Questions in 2019 Proposed Rules (IPPS, OPPS, ASC, HH PPS, ESRD, DMEPOS)

- How should we define "standard charges" in provider and supplier settings? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters?
- Should "standard charges" be defined to mean:
  - Average or median rates for the items on a chargemaster or other price list or charge list;
  - Average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or
  - The average discount off the chargemaster, price list, or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together?
- Should "standard charges" be defined and reported for both some measure of the average contracted rate and the chargemaster, price list, or charge list? Or is the best measure of a provider's or supplier's standard charges its chargemaster, price list, or charge list?

Price Transparency Questions in 2019 Proposed Rules (IPPS, OPPS, ASC, HH PPS, ESRD, DMEPOS)

- What types of information would be most beneficial to patients?
- How can health care providers and suppliers best enable patients to use charge and cost information in their decision-making?
- How can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?
- Should providers and suppliers be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service?
- Should providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?
- Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular services performed by that provider or supplier. If so, what changes would need to be made by providers and suppliers. What burden would be added as a result of such a requirement?

Site-Neutral Payment

Section 603 and Services at Non-Excepted (New) Off-Campus Provider-Based Departments

Overview of Section 603

- Beginning 1/1/2017, no OPPS reimbursement for items and services furnished “by an off-campus outpatient department of a provider”
- Exceptions
  - Dedicated EDs
  - Existing (grandfathered) PBDs billing prior to November 2, 2015, and that has not been impermissibly relocated or changed ownership
  - PBD qualifies for mid-build exception
  - On campus or within 250 yards of a remote location of the hospital
- Non-excepted items and services are billed with “PN” modifier, paid at lower rate (40% OPPS in 2018 & 2019)

Dedicated ED Exemption

- Section 603 excludes “items and services furnished by a dedicated emergency department (as defined in [EMTALA regulations])”
- Exclusion is based on site of service, permitting OPPS reimbursement for non-emergency services furnished in an ED
- MedPAC concerns that this exclusion is a loophole
- CMS finalized requirement of “ER” modifier for CY 2019

Relocations of Excepted, Off-Campus PBDs

- CMS concerns that relocations would undermine intent of section 603
- Adopted Extraordinary Circumstances Relocation Exception
  - For temporary or permanent relocations
  - Evaluated on a case-by-case basis by CMS RO
  - Expected to be “limited and rare”
  - Based on extraordinary circumstances beyond the hospital’s control
    - Natural disasters
    - Significant seismic building code requirements
    - Significant public health and safety issues

Change of Ownership of Excepted Off-Campus PBD

- Grandfathering may remain after a CHOW if:
  - Sold with the whole hospital
  - New owner accepts the old provider agreement
- Grandfathering expires if the exempt PBD is acquired not as part of the whole hospital
- Grandfathering expires if the parties allow the existing provider agreement to terminate

Mid-Build Exception: 21st Century Cures Act § 16001

- CY 2017: Mid-Build PBDs for which a provider-based attestation was received prior to 12/2/2015 are deemed excepted (PO modifier in CY 2017)
- CY 2018 and After: Alternative exception for PBDs if they were Mid-Build as of 11/2/2015 if:
  - Provider-based attestation received before 2/13/2017
  - PBD is added to hospital enrollment (855B/PECOS)
  - Certification from the CEO/COO that the department meets the mid-build requirements submitted by 2/13/2017
- MAC should have confirmed receipt of certification/attestation packages
- PBDs that qualify for the mid-build exception bill with the PO modifier in CY 2018 and after

Mid-Build Audits

- Timing: Statute requires completion by 12/31/2018
- Areas of Audit:
  - Provider Based Attestation
  - Enrollment
  - Mid-Build Certification
- Contractor:
  - Cahaba Safeguard Administrators, LLC (“CSA”) is performing the audits
  - midbuildaudits@csallc.com

Service Line Expansions

- Proposals
  - CY 2017: Service Type
  - CY 2018: Comments re: Volume Cap
  - CY 2019: Service Type
- Legality
  - Intent
  - Definition of a department
- Operational Issues

"No, Thursday's out. How about never—is never good for you?"

Reimbursement for Non-Excepted Items and Services

- Services at non-excepted PBDs are statutorily not eligible for OPPS payment
- Non-excepted, off-campus PBD items and services are:
  - Billed on UB-04
  - Billed with the “PN” modifier
  - Paid at 40% OPPS*

*40% is the PFS Relativity Adjuster, calculated to approximate the payment difference between OPPS and the PFS

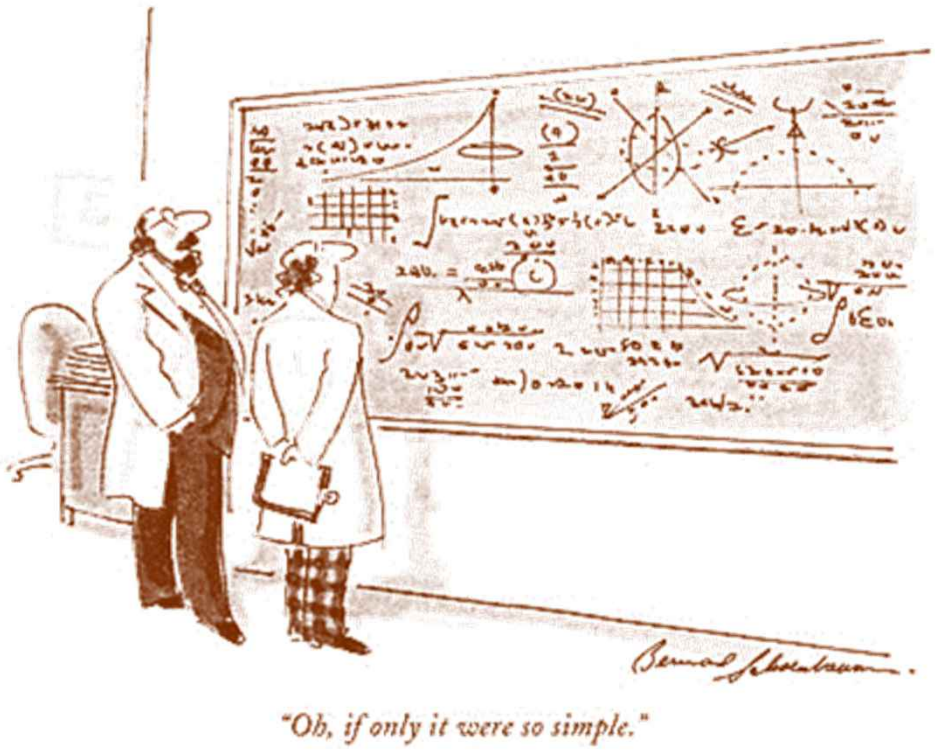
Volume-Control Method

Payment Reduction for Clinic Visits at
Off-Campus Provider-Based Departments

Volume-Control Method: 42 U.S.C. § 1395*l*(t)(2)(F)

- ***Authority:*** "the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services"
- ***Final Rule***: Payment cut on off-campus clinic visits to "control unnecessary increases" in OPD volume
  - Data predates section 603 implementation
  - No evidence of continuing acquisition of physician practices
  - No evidence that payment cut will "control unnecessary" volume increases
  - No metric for distinguishing necessary and unnecessary increases
- ***Jurisdiction***: No review of "methods described in paragraph (2)(F)" (§ 1395l(t)(12))

Volume-Control Method: 42 U.S.C. § 1395/(t)(2)(F)



"Oh, if only it were so simple."

- (t)(9)(A)—requires annual review and revision of "the wage and other adjustments discussed in paragraph (2)"
- (t)(9)(B)—required budget neutrality for "adjustments under subparagraph (A)"
- (t)(9)(C)—permits adjustments to the conversion factor "in a subsequent year" if the volume of OPD services increases "beyond amount established" under "methodologies described in paragraph (2)(F)"

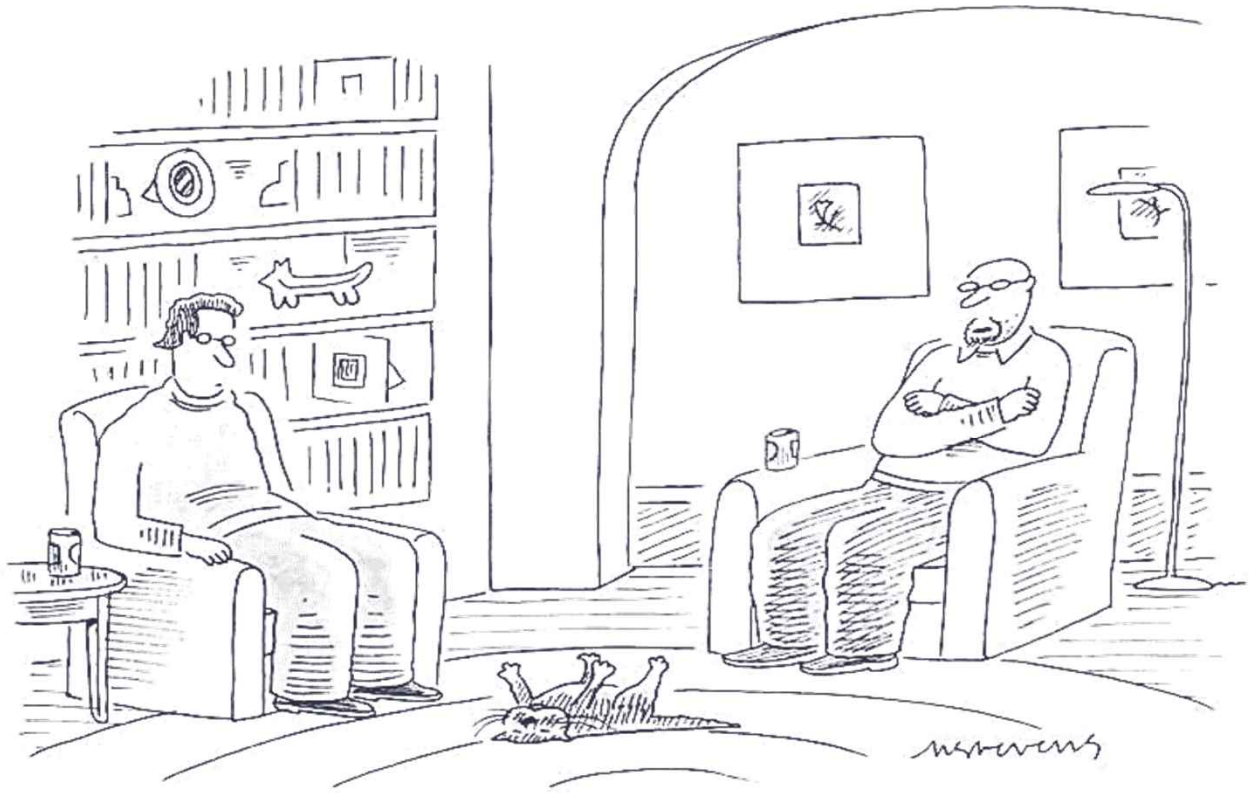
Potential Legal Challenges

- Hospitals with Off-Campus PBDs:
  - May challenge whether this constitutes a lawful exercise of CMS' authority to implement a method for controlling unnecessary increases in volume
  - May challenge implementation of the volume-control method on a non-budget neutral basis
- Hospitals without Off-Campus PBDs
  - May challenge implementation of the volume-control method on a non-budget neutral basis

The Slippery Slope

- Proposed rule solicited comment on the following:
  - Expansion to additional items and services, perhaps adjusting the method to consider enrollment, severity of illness, and patient demographics
  - Prior authorization and utilization management approaches
  - For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?
  - Considerations in provider shortage areas and in rural areas
  - Beneficiary impact
  - Exceptions for additional proposals

Keep Managed Care Agreements in Mind with OPPS Changes



"Cloning is an imperfect science."

Recap and Outlook

No slowdown on the push on Transparency

- Bi-partisan support—albeit with different “roots” –more than just “pro-consumer”—note bipartisan concern over “surprise billing”
- Building a more user friendly market that can support broader payment reforms (e.g., “premium support”) and patient engagement
- Only a matter of time before posting of chargemasters is succeeded by more meaningful price disclosure
- Watch CMMI initiatives that test beneficiary choices and decision-making

Close Scrutiny by CMS on Changes Made to Date

- Section 603 Relocations—”Extraordinary Circumstances” means just that
- While CMS RO’s are the point of contact, Baltimore is coordinating what passes muster for consistent national application
- Even when relocations are for extraordinary circumstances, CMS is watching for any expansion “hitching a ride”
- Word to the wise—if a relocation, e.g. for seismic compliance, is in the works—talk with CMS early to avoid delays—or worse

“Watch this Space”

- ED Departments Section 603 safe harbor – With the new ER claims modifier, CMS is now collecting data on whether this exemption is a loophole as MedPAC has suggested. Congress would need to act—a possible “pay for”
- Mid–Build Audits—wrap up was slated for end of 2018—depending on findings could effect 2020 rule-making—if not certainly 2021
- Service line expansion—twice proposed but not finalized in CY 2017 and 2019 Proposed rules—not finalized, but not going away
- Payment for non-excepted services in PBD’s currently via “relativity factor” (40% of OPPS)—much criticized
- CMS has signaled its interest in “refining” payment e.g. closer look at TC/PE

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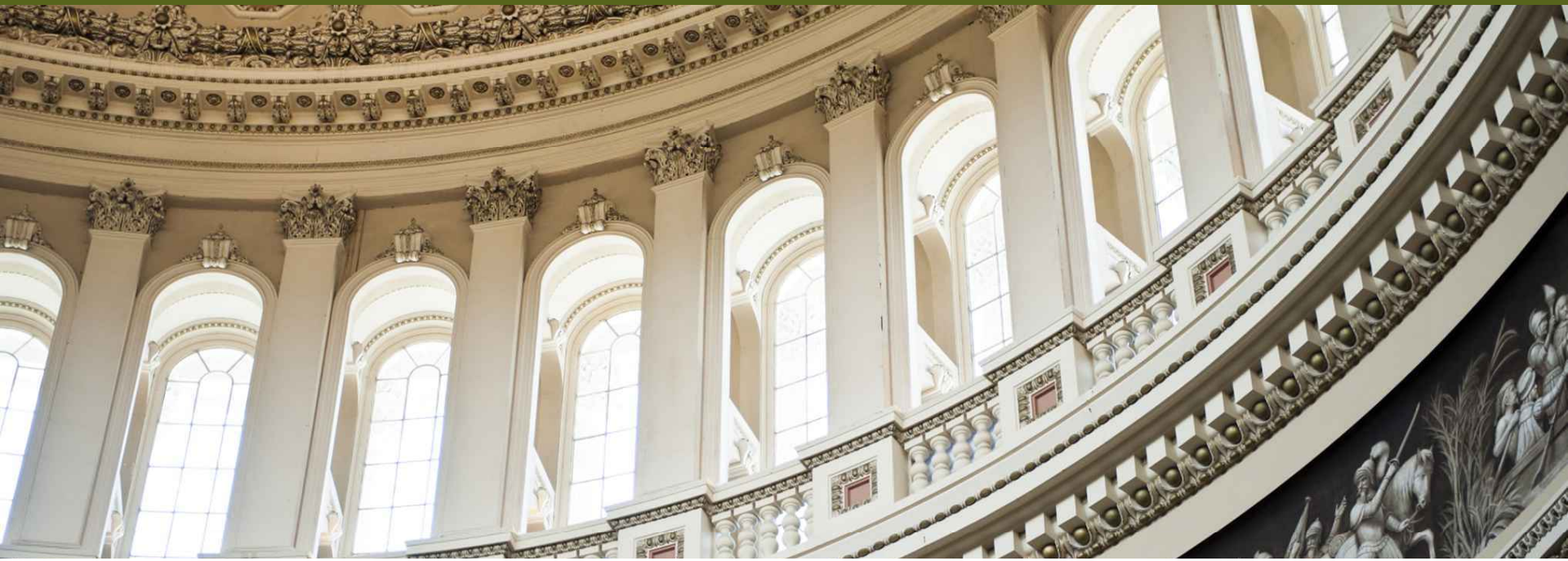

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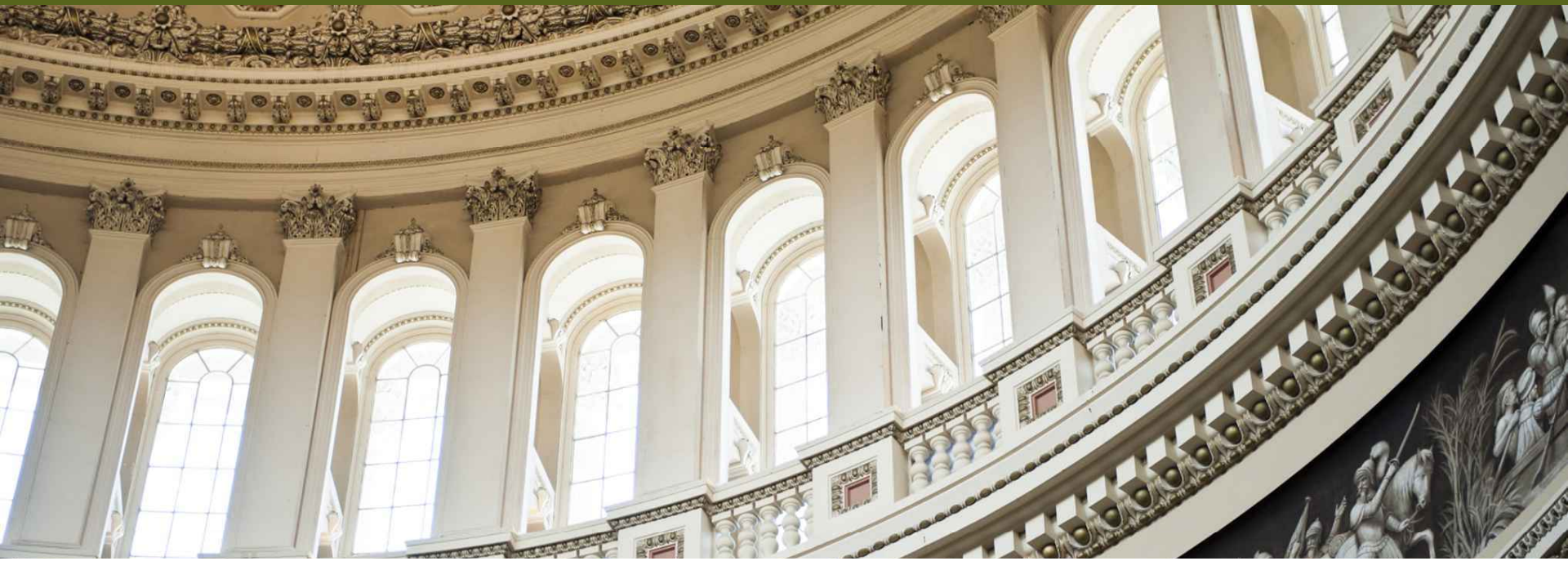


Telehealth and Artificial Intelligence – A Look Into An Accelerating Future

Steve Phillips and Jeremy Sherer – Hooper, Lundy & Bookman

Introduction

Telehealth and Artificial Intelligence (AI): two of the most impactful technologies in health care

Scope and Goals for the Presentation

Telehealth

Regulation, Reimbursement and Regulatory Enforcement

Telehealth Terminology

- **Modalities**
  - **Synchronous Audio-Video**
  - **Store and Forward**
  - **Remote Patient Monitoring**
- **Telehealth vs. telemedicine – what's the difference?**
  - Telehealth refers to the infrastructure utilized to facilitate remote healthcare services and the services themselves. Telemedicine refers only to the clinical services.
  - *Very few people deliberately distinguish between these terms.*

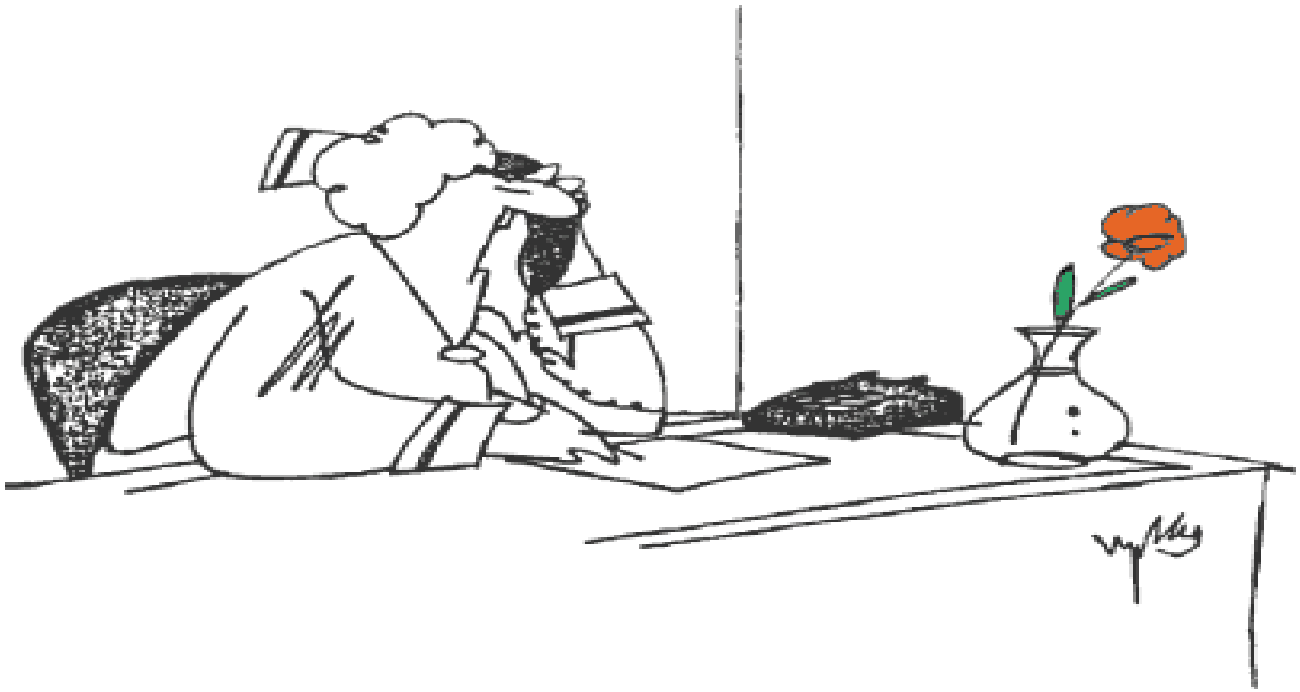
Scope of Practice Issues

Issues to consider on a state by state basis

- What modalities does the state allow?
- What services can be provided via telehealth?
- Who can provide services via telehealth?
- Where can patients receive treatment via telehealth?
- How can a practitioner-patient relationship be established?

Non-Video Modalities

Anything short of synchronous audio-video, *e.g.,* email, fax, telephone, instant message or text, requires caution.



"The doctor isn't in right now. When you hear the beep, please leave your name, number and a short diagnosis."

State-Level Regulatory Considerations

Licensure, Documentation, Informed Consent, Patient Identification

- **Licensure**
  - Where the practitioner and the patient are located, with exceptions (e.g., Maine, Minnesota)
  - What about the Interstate Medical Licensure Compact?
- **Documentation**
  - Telemedicine is still medicine. State-level documentation (and data security) standards still apply.
- **Informed Consent and Patient Identification**
  - Certain states – including California – require informed consent.
  - Some also require patient identification.

State-Level Regulatory Considerations

E-Prescribing

- Clinicians can only prescribe medication pursuant to a valid practitioner-patient relationship.
- Non-Controlled Substances: look to state law.
- Controlled Substances: look to federal and state law. For certain controlled substances, the Ryan Haight Act and the SUPPORT for Patients and Communities Act also apply.

State-Level Regulatory Considerations

Malpractice Insurance

- Does each clinician's malpractice insurance cover services delivered via telehealth?
- Does each clinician's malpractice insurance cover services rendered in every state where one of the clinician's patients is located?

Proxy Credentialing

- Does state law permit proxy credentialing?
- Do each facility's bylaws permit proxy credentialing?

State-Level Regulatory Considerations

Parity Laws

- There are two types of parity laws: coverage parity laws and payment parity laws.
  - Coverage parity laws require payers to cover services delivered via telehealth when the service at issue would be covered if provided in person.
  - Payment parity laws require payers to pay for services delivered via telehealth at the same level as when the service is delivered in-person.
    - Careful! Some payment parity laws contain language stating that they exist “subject to the terms of coverage documents.”

State-Level Regulatory Considerations

Corporate Practice of Medicine Doctrine

- Certain states prohibit non-clinicians from employing or contracting with clinicians.
- Every state that recognizes the corporate practice of medicine prohibition is different.
- When entering a “corporate practice state,” ensure you understand the parameters of that state’s corporate practice prohibition.

CPOM Issues

Through what entities can a clinician practice?

- E.g., PC, LLC, Corporation

Is there an employment vs independent contractor distinction?

What constitutes the practice of medicine?

State-Level Regulatory Considerations

State Fraud and Abuse Authorities

- State self-referral prohibitions, *i.e.,* “mini-Stark laws”
- State anti-kickback laws
- State fee-splitting laws
- State anti-markup laws

Medicare Reimbursement 101

Geographic Restrictions

- "Medicare telehealth services" are only paid if the patient is in a health professional shortage area ("HPSA") or a county that is not a metropolitan statistical area ("MSA") (unless an exception applies).

Originating Site Restrictions

- Hospitals
- Community Access Hospitals
- Hospital-based or CAH-based renal dialysis centers
- Skilled Nursing Facilities (SNFs)
- Community Mental Health Centers
- Physician or practitioner offices
- Rural health clinics
- Federally qualified health centers (FQHCs)
- *New originating sites added starting in July 1, 2019…*

Medicare Reimbursement 101: Telemedicine Exceptions

- Patient is treated at a DEA-registered facility
- Patient is in the presence of a DEA-registered practitioner
- Practitioner is working for the Indian Health Service
- Public health emergency
- Practitioner has special telemedicine registration (which doesn't exist)
- Department of Veterans Affairs emergency
- Other circumstances specified by regulation

→ *Issue is that services aren't available to patients in the home.*

Medicare Reimbursement: Bipartisan Budget Act of 2018, SUPPORT Act of 2018

Bipartisan Budget Act of 2018

Medicare Advantage plans can offer telehealth services can be offered as “basic benefits” beginning in 2020.

Removes geographic restrictions for certain services, and expands originating sites to include:

- Homes and renal dialysis facilities for monthly clinical assessments for home dialysis ESRD patients
- Mobile stroke units for acute stroke services
- Homes for beneficiaries aligned with ACOs that operate under a two-sided model

SUPPORT Act

Removes geographic restrictions and includes the home as an originating site effective July 2019 for treatment of substance use disorders.

Intended to update standards set forth in Ryan Haight Act, which was enacted because of online pill mills, and impact on SUD treatment was not envisioned.

Should establish special registration for telemedicine services.

Medicare Reimbursement: 2019 PFS Final Rule

Virtual Check-ins, Store-and-Forward, Interprofessional Consults

- Synchronous audio or audio-video communication only (except store and forward).
- Is a follow-up necessary? Cannot be related to service provided within previous 7 days, next 24 hours, or soonest available appointment.
- Patient consent is required.
- For existing patients only.

Remote Patient Monitoring

- 99453: Pays for initial equipment set-up and patient education.
- 99454: Pays for interpretation/monitoring of information from devices that communicate clinical information on a daily basis.
- 99457: Remote physiological treatment management services. To bill using this code, the patient must receive at least 20 minutes of interactive treatment each month.
- **These are not "Medicare telehealth services." Therefore, originating site and geographic restrictions don't apply, and patients can obtain these services from the home.**

Medicare Reimbursement: Attitudes are Shifting, But Obstacles Remain

2018 Report to Congress

In conclusion, telehealth offers the promise of a technology and approach to care for a broad range of populations, including those enrolled in Medicare. Emerging evidence indicates that telehealth can be a tool for empowering health care providers and patients to offer the best approaches to care, including consideration of the patient's age, race/ethnicity, geographic location, and diagnoses, and provide high quality care without increasing costs.

Source: Information on Medicare Telehealth, Centers for Medicare & Medicaid Services, November 2018.

2018 Progress Limited

We have come to believe that section 1834(m) of the Act does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. Instead, we believe that section 1834(m) of the Act applies to a discrete set of physicians' services .... For CY 2019, we are aiming to increase access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology by clearly recognizing a discrete set of services that are defined by and inherently involve the use of communication technology.

– 2019 PFS Proposed Rule

Regulatory Enforcement: Is it coming?

Enforcement actions have been limited, but are trending upward

2018 OIG Report on Medicare Telehealth Services

Fall 2018 DOJ Indictments involving Telehealth

State Medical Board Enforcement Actions

Regulatory Enforcement: Is it coming?

2018 OIG Report on Medicare Telehealth Services

- 31% of claims CMS paid failed to meet requirements for “Medicare telehealth services,” most commonly because of originating site issues, costing taxpayers $3.7 million in 2015.
- Medicare spending on telehealth is limited but increasing, and with investment comes scrutiny.
- Will state Medicaid Fraud Control Units (“MFCUs”) follow OIG’s lead?

Regulatory Enforcement: Is it coming?

October 2018, Tennessee

DOJ indicts 4 individuals and 7 companies in telehealth fraud scheme through which they allegedly defraud payors of $1 billion in healthcare claims for services not rendered.

November 2018, New Jersey

DOJ indicts physician charged with prescribing $20 million worth of compounded medications to patients who did not need them via telehealth.

Regulatory Enforcement: Is it coming?

State Medical Board Enforcement

- Issues that attract scrutiny include telehealth modalities, e-prescribing, practitioner licensure, documentation, informed consent, patient identification.
- Hottest area is the combination of telehealth modalities, establishing a physician-patient relationship, and performing an adequate examination.
- Remember that there are exceptions to physician-patient relationship establishment standards, particularly in rural states – e.g., Maine.

Artificial Intelligence

Applications, Benefits, and Risks

Artificial Intelligence (AI)

- AI uses algorithms and software to approximate human thinking in the analysis of data.
- Algorithms are sets of instructions within computer programs that determine how these programs read, collect, process, and analyze data.
- AI enables computer algorithms to approximate conclusions without direct human input.
- AI is an outgrowth of expert systems, Bayesian networks, artificial neural networks and fuzzy set theory developments that begin in the 1960s.
- Growth in computing power and data repositories combined with these algorithms and software have accelerated the development of AI applications.

Current AI Technologies

- Robotic Process Automation (RPA) (aka expert systems) - uses workflow logic and decision trees to automate common tasks
- Computer Vision - algorithms identify text and images and transcribe the information into appropriate repositories
- Voice Recognition - algorithms listen, comprehend and respond to human speech
- Machine Learning - algorithms recognize patterns in data and create their own logic
- Deep Machine Learning - algorithms use neural networks - algorithms that mimic the biological structure and function of the brain with its many interconnecting neurons

Healthcare Applications

- Clinical Decision Support (CDS)
- Predictive Medicine
- Claims Processing
- Marketing/Fundraising
- Customer Service
- Research
- Supply Chain Management
- Financial Management
- Legal Compliance
- Public Health
- Patient Education and Self-Care
- Drug development

Potential Benefits

- Radical cost reductions – clinical and administrative
- Radical patient care improvement – 24/7/365 symptom monitoring, effective predictive and effective personalized medicine, enhanced QA/UI, automation of repetitive, error-prone processes
- Improved patient and provider satisfaction

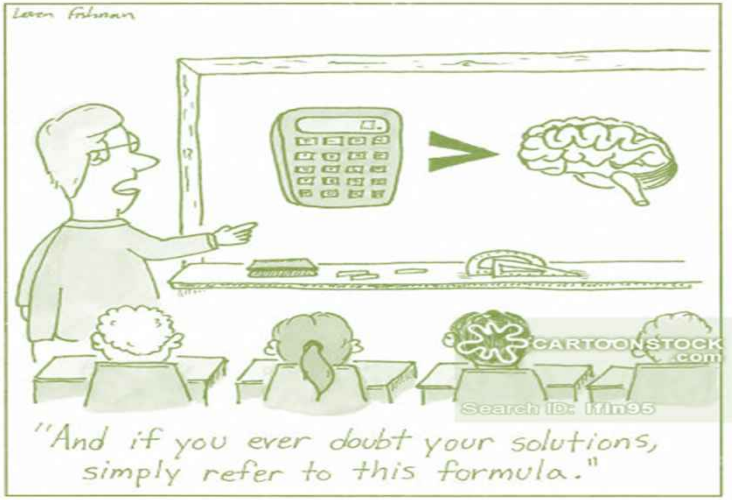
"The doctor has a full schedule, but the computer is available at 11:15 and 3:30 today..."

Potential Risks

- The quality or efficiency of care may not improve
- Algorithmic bias may impair AI applications
- Unlawful uses and disclosures of patient health information may increase
- Malpractice exposure may increase
- Employee and other human relations may suffer
- Providers may have less leverage vis-à-vis technology vendors
- AI may reduce human performance

Algorithmic Bias

- Algorithms can reflect the bias of human designers or reinforce stereotypes and preferences as they process and display data for human users.
- Bias can be introduced during the assemblage of a database, when data must be collected, digitized, adapted, and entered according to human-designed cataloging criteria. When programmers assign priorities for how a program assesses and sorts that data, bias can affect how data is categorized, and which data is included or discarded.



Algorithmic Bias (con’t)

- Algorithms may offer more confident assessments when larger data sets are available and skew algorithmic processes toward results that more closely correspond with larger samples, which may disregard data from underrepresented populations.
- The decisions of algorithmic programs can be seen as more authoritative than human, a process called "algorithmic authority.”
- Detecting and mitigating algorithmic bias can be difficult given the proprietary nature of algorithms, which are typically trade secrets. Even when transparent, the functioning of complex algorithms can be difficult to discern and may change or respond to input or output in ways that cannot be anticipated or easily reproduced for analysis. Even within a single website or application, there may be no single "algorithm" to examine, but a network of many interrelated programs and data inputs.

Legal Issues

- Risk allocation
- Data rights, including patient consent
- Risk mitigation, including security safeguards
- FDA, FTC and state regulation
- GDPR and other EU regulation
- Reimbursement
- Personnel management

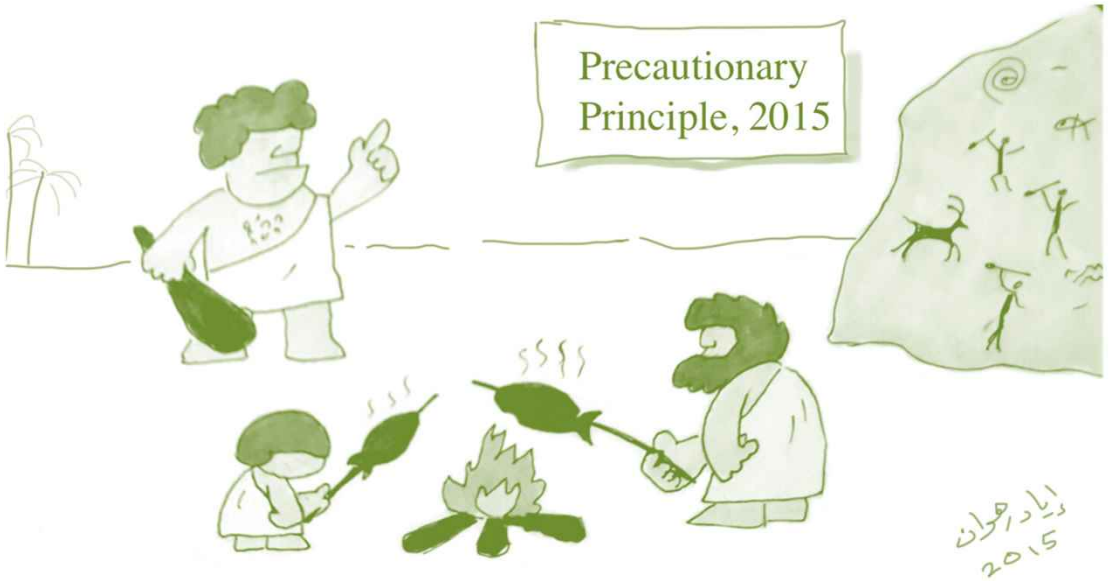
"We're looking for someone with your exact qualifications, but a mechanical version."

Liability

- Use of AI can present new and unexpected areas of malpractice, wrongful death, personal injury, and product liability.
- AI that produces errors or outcomes worse than traditional methods of care may produce liability to the provider and the vendor.
- Providers may face liability for using AI or for not using readily-available AI.
- Vendors may face product liability for AI that meets the definition of a device (devices are products; whereas software as a service solutions that are not devices may not be products subject to product liability laws.
- Providers and vendors must address and allocate the risks associated with AI, which is typically a zero-sum tug of war.

Risk Mitigation

- **Insurance**
- **Disclaimers**
- **Limitations on liability**
- **Security requirements**



"We must abandon the use of fire to avoid potential systemic ruin!"

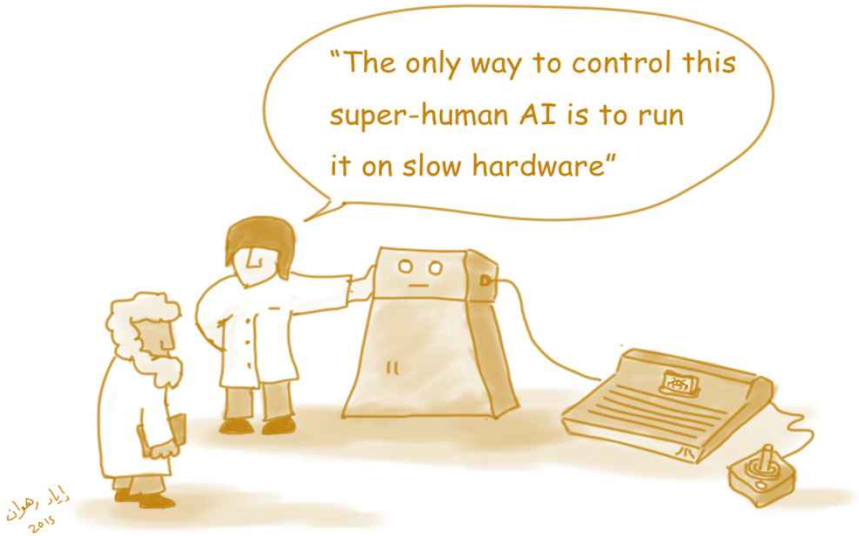
Data Rights

Key Questions Regarding Data Rights

- Who “owns” what?
- Is patient consent required?
- Is the data secure when stored, created or transmitted?
- Is de-identified data re-identifiable?
- What disclosures are required or advisable?
- What is the minimum necessary amount of
- Data for an AI app?

Security

- The HIPAA Security Rule requires covered entities (CE's) and business associates (BA's) to update their security risk analysis in response to environmental or operational changes affecting the security of electronic health information.
- CE's and BA's must assess the security risk posed by an AI technology through a security risk analysis and mitigate any risks revealed by the analysis.



Super intelligent machines containment strategies: stunting.

Access Discrimination

- AI that interacts with patients (i.e., virtual assistants, online chatbots, etc.) may be noncompliant with non-discrimination laws such at the ADA, Section 504 of the federal Rehabilitation Act, and Section 1557 of the Affordable Care Act.
- Recent lawsuits against hospitals have alleged that patient communication practice were discriminatory against the hearing impaired.
- AI providers may need to provide alternatives for patients who cannot access or use an AI technology because of language, disability or other barriers.

AI Regulation in the United States

- No general legislation controlling AI.
- AI issues addressed (if at all) through state and federal laws that might vary by industry, sector, and by how an algorithm is used.
- In 2016, Obama administration released the National Artificial Intelligence Research and Development Strategic Plan:
  - Intended only as guidance, the report did not create any legal precedent.
  - Recommended researchers to "design these systems so that their actions and decision-making are transparent and easily interpretable by humans, and thus can be examined for any bias they may contain, rather than just learning and repeating these biases".
- In 2017, NYC passed the first U.S. algorithmic accountability bill, effective 1/1/18:
  - Required creation of task force to recommend how information on City automated decision systems may be shared with the public and how City agencies address harm caused by agency AI; task force to present recommendations in 2019.

FDA Regulation

- FDA regulates software that meets the definition of a “device” under the FDA law.
- 2016 21st Century Cures Act clarified that FDA has regulatory authority over digital health, which includes AI systems that use machine learning (standard or deep) to provide diagnostic information for patients but not over software that encourages a healthy lifestyle, serves as an EHR, assists in displaying or storing data or provides only limited clinical decision support.
- December 2017 FDA issues draft guidance that it considers clinical decision support software a “device” if it makes a treatment recommendation that could not be reached independently by a clinician or other user (i.e., software that analyzes lab results using a proprietary algorithm).
- FDA revamped the de novo request process, which allows the developer of a low- to moderate-risk device without a predicate to submit a request to the FDA to make a risk-based classification of a device into class I or II. Once that de novo request is granted, the device can then serve as a predicate for 510(k) premarket approval of similar devices in the future, which is how a good chunk of AI software has been approved to date.

Future FDA Regulation

- FDA developing several AI initiatives:
- Medical Device Development Tools program: a pathway for FDA to qualify tools that medical device sponsors could use in the development and evaluation of their devices — issued last August. For a device to pass qualification, it must be determined by the FDA that it "produces scientifically plausible measurements and works as intended within the specified context of use."
- National Evaluation System for Health Technology (NEST): attempts to move medical devices from discovery to market as quickly as possible, by applying advanced analytics to data tailored to the devices and shifting to more active surveillance to better detect safety issues. NEST designed to leverage real-world data to generate better, more widely applicable evidence representative of a diverse U.S. population.
- ACR Data Science Institute and Lung-RADS Assist: new approach to validate and monitor AI algorithms; built to detect and classify lung nodules in lung cancer screening programs using real-world data through the capture of performance metrics within a national registry. A model for how AI algorithms can be monitored in clinical practice to ensure ongoing patient safety while establishing a pathway to increase the efficiency of the FDA premarket review process.

Future FDA Regulation (con't)

Software Precertification Program (SPP)

- In 2017 FDA launched pilot program to "pre-certify" eligible digital health developers who demonstrate a "culture" of quality and organizational excellence.
- Designed to provide qualified developers with an efficient premarket pathway for software-based medical devices.
- Pre-certified developers would be able to market certain devices without additional FDA review or with streamlined review.
- Program will eventually be bundled with the NEST and Medical Device Development Tools platforms, but is still in development phase with details of how long it would take for a company to successfully pass the program TBD.

FTC Regulation

Competition and Consumer Protection Focus

- Recently held its 7th (of 9 planned) hearing on AI seeking facts and perspectives on AI threats to competition and consumer protection and how to regulate such threats.
- For antitrust, concern is with algorithms that engage in or enable anti-competitive behavior (e.g., price sharing/coordination).
- For consumer protection, the concern is algorithmic bias (biased data sets, encoded social prejudices, inadequate data on minorities and other disadvantaged groups, intentional prejudice and proxy variables).
- Sense that FTC has sufficient authority to address consumer protection matters within its jurisdiction.
- Hands off approach to further regulation for now.

California Regulation

- Consumer Privacy Act (CCPA) of 2018 establishes for CA residents and businesses beginning in 2020 many of the same privacy protections as the EU's GDPR.
  - CA residents have right to:
    - request a business to provide them with the personal information the business collects about the resident, the purpose of the collection and who it's shared with
    - request a business stop selling their personal information
    - request a business to delete any personal information about the resident
  - Excludes from its jurisdiction: patient health information under CMIA and HIPAA, nonprofits, providers under CMIA, or covered entities under HIPAA so effects on health care attenuated.
  - Effective 7/1/19, a new "bot" law prohibits "any person to use a bot to communicate or interact with another person in California online, with the intent to mislead the other person about its artificial identity for the purpose of knowingly deceiving the person about the content of the communication in order to incentivize a purchase or sale of goods or services in a commercial transaction."
  - Requires clear, conspicuous disclosure.

EU Regulation of AI

- In December 2018 the EU published draft ethical guidelines for AI development and use
- The guidelines introduce a new standard for “trustworthy AI” – AI developed with an “ethical purpose” that respects fundamental rights, applicable regulations, core principles and values.
- Five “principles” or high-level norms are in the draft, all vague and lofty (e.g., do good, avoid harm, be fair, be transparent, etc.) that developers should incorporate into their systems.
- Ten values are then stated, which are more concrete guidelines on how to uphold the principles but are still very general at this point (be accountable and nondiscriminatory, design for all, protect privacy, test and manage systems, be fair, etc.).
- The principles and values could provide the basis for new rules or legislation.

GDPR

- Applies when the controller or processor is established in the EU or when the processing activities relate to data subjects in the EU.
- Article 22 of the GDPR prohibits "solely" automated decisions which have a "significant" or "legal" effect on an individual, unless they are explicitly authorized by consent, contract, or member state law. Where permitted, there must be safeguards in place, such as a right to a human-in-the-loop, and a non-binding right to an explanation of decisions reached.
- Article 22 only applies when a decision is based solely on automated processing – including profiling – which produces legal effects or similarly significantly affects the data subject. Article 22 is enforceable law.
- GDPR guidance re algorithmic bias in profiling systems, requires use of appropriate mathematical or statistical procedures for profiling, implementation of technical and organizational measures to prevent racial, ethnic, religious, political, genetic or health discrimination. This AI guidance is nonbinding.

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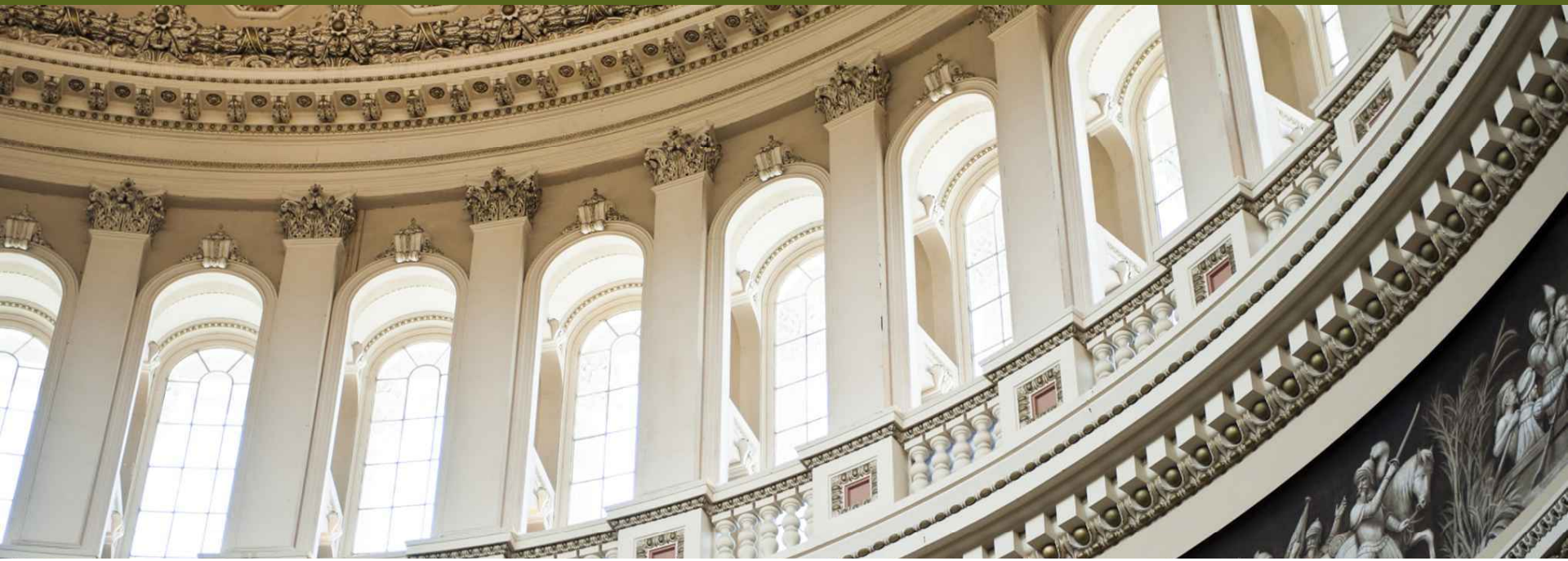

The National Symposium on Health Law and Policy

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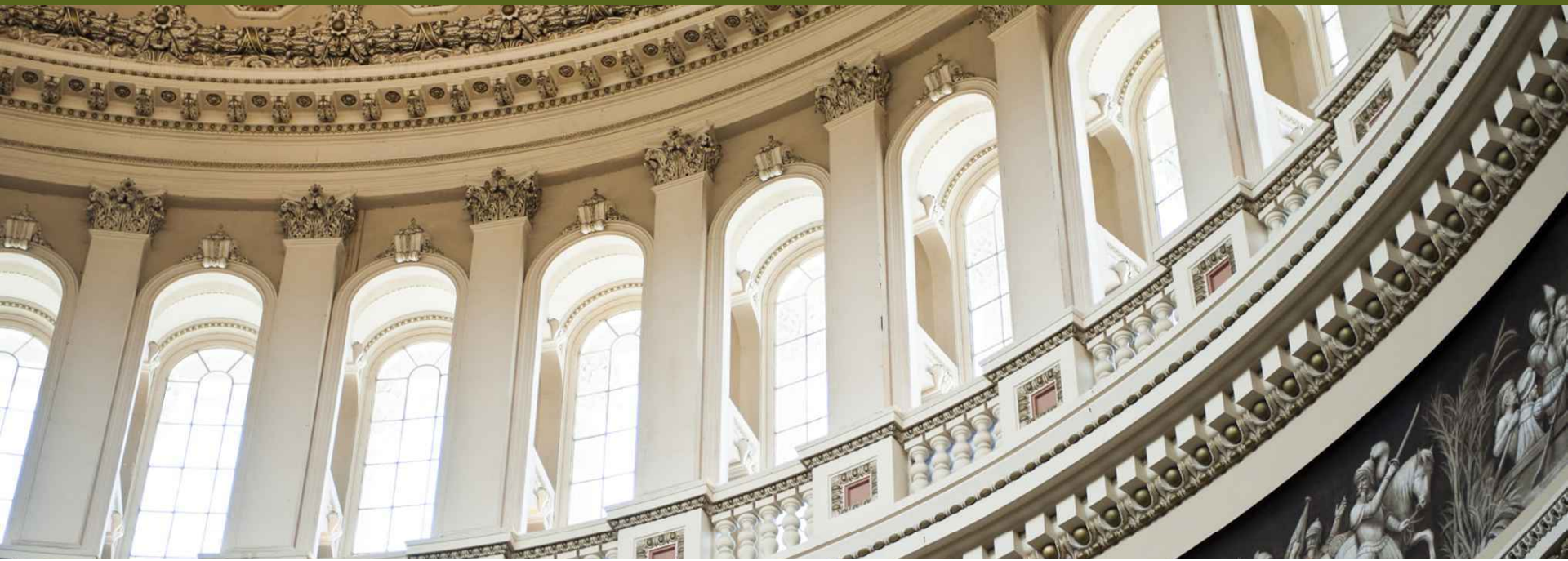
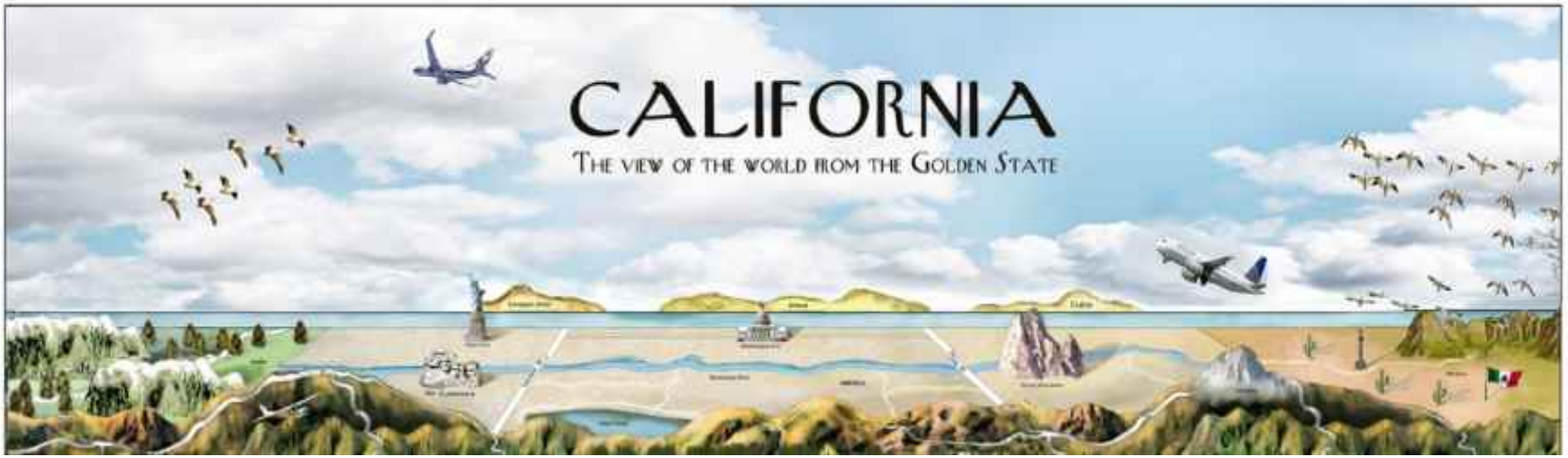


Health Care Policy: The View from California

Carmela Coyle – President & CEO, California Hospital Association

The View from California



Health Care Reform

- Single payer
- Rate setting
- Medicare for all
- Through the ACA

Affordability

Cost Containment  Affordability

Payer/insurers

Providers

Input prices – drugs, MRIs, etc.

Affordability

- **Coverage expansion**
  - California individual mandate
  - Undocumented individuals (up to age 26)
  - Enhanced ACA subsidies (400-600% of poverty)
- **Access**
  - Behavioral health
- **Value**
  - New payment models (global budgets)
- **Legal and regulatory reform**
  - Seismic
  - Duplicative regulation
  - More

Drug Pricing

Governor Newsom signs first-in-the-nation executive order to create the largest single purchaser for prescription drugs and allow private employers to join the state in negotiating drug prices.

State to negotiate for all Medi-Cal drugs
(from 2 million to 13 million beneficiaries)

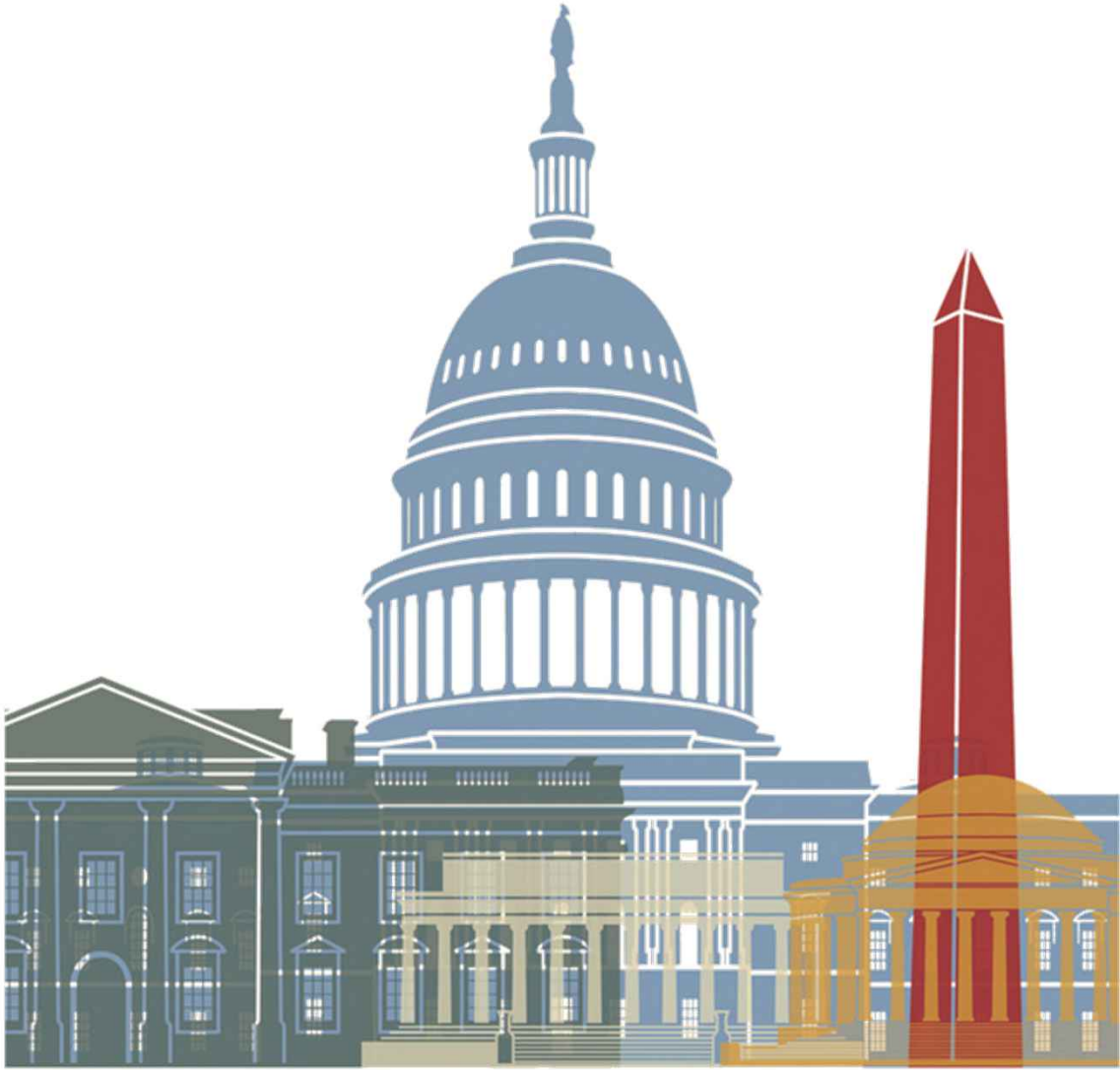
Pricing Transparency

- “Surprise” bills
- On the side of the patient
- California a leader/model
  - California state Supreme Court decision
  - California 2016 law

California Congressional Leadership

Echoes in Washington, DC

- Affordability
- Drug pricing
- Price transparency
- Surprise billing
- Medicare for all



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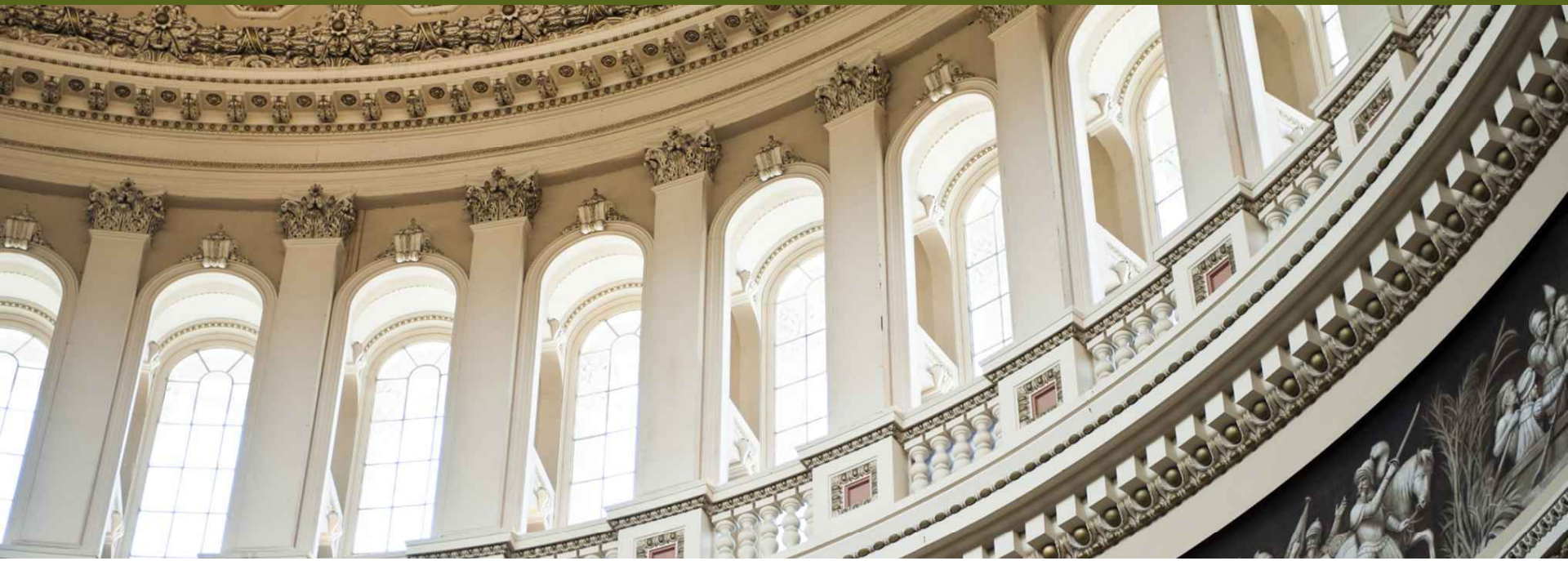

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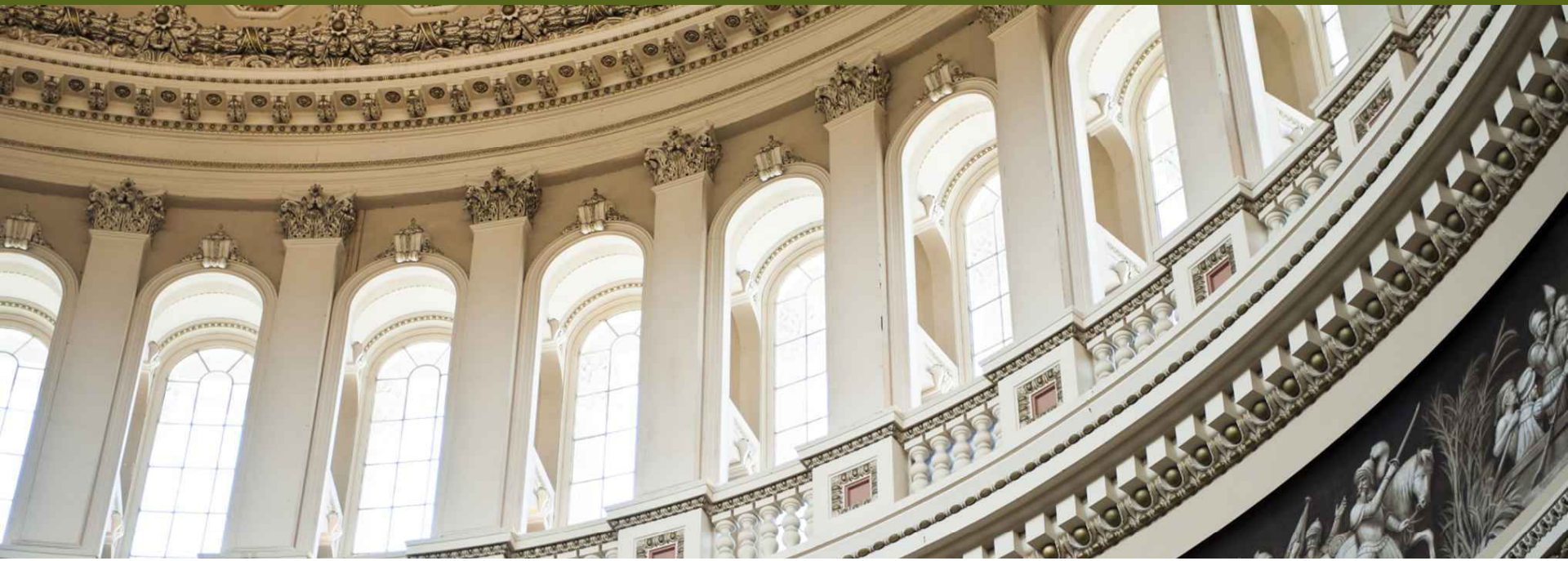


Washington Update

Steven Speil – Executive Vice President, Federation of American Hospitals

Democratic Base Stirred

She’s Back

New “Freedom Caucus”

When given eight issues to choose from, health care rose to the top as the deciding vote factor for Congress on election day.

Congressional Vote Among Health Care Voters: 17% R – 83% D	*Ranked by First Choice*	First Choice	Combined Choice
Health care		24%	37%
The economy and jobs		17%	28%
Changing how things work in Washington		17%	30%
Immigration		14%	33%
Abortion		5%	12%
Taxes		5%	13%
Guns		4%	16%
Foreign policy and terrorism		3%	11%

Source: POS Post-Election Survey.

Democrats Drive With Health Care

Importance of Health Care Priorities for Congress to Work On

Ranked by % Extremely/Very Important	Extremely/Very Important
Lowering prescription drug costs for as many Americans as possible	82%
Making sure the Affordable Care Act's protections for people with pre-existing health conditions continue	73%
Protecting people with health insurance from surprise high out-of-network medical bills	70%
Repealing and replacing the 2010 Affordable Care Act	43%
Implementing a national Medicare-for-all plan, in which all Americans would get their insurance from a single government plan	39%

Source: January 2019 KFF Health Tracking Poll.

Weaponize Pre-Ex

ACA Suit Haunts GOP

Blasting Drug Firms Resonates

Witches Brew Of Challenges

ACA Fixer-Upper

Single Payer Leaves Wilderness

Testing Health Care Terms

Terms Ranked by Mean Rating	%80-100	MEAN
Medicare-for-all	43%	62
The Affordable Care Act	28%	50
A single-payer health care system	21%	50
Obamacare	29%	47
Socialized medicine	19%	44
Government-run health care	19%	41

Arguments for Medicare-for-all: Net Oppose

Ranked by Net Difference (Favor – Oppose)	Favor	Oppose	Net Difference
Lead to delays in people getting some medical tests and treatments	**26%**	**70%**	**-44%**
Threaten the current Medicare program	**32%**	**60%**	**-28%**
Require most Americans to pay more in taxes	**37%**	**60%**	**-23%**
Eliminate private health insurance companies	**37%**	**58%**	**-21%**

Source: January 2019 KFF Health Tracking Poll.

Support for a Single Payer Health Care System

And, if you learned that virtually all health care costs would be covered, but it would eliminate employer provided health plans and there would only be one government plan, would you favor or oppose a single payer health care system?

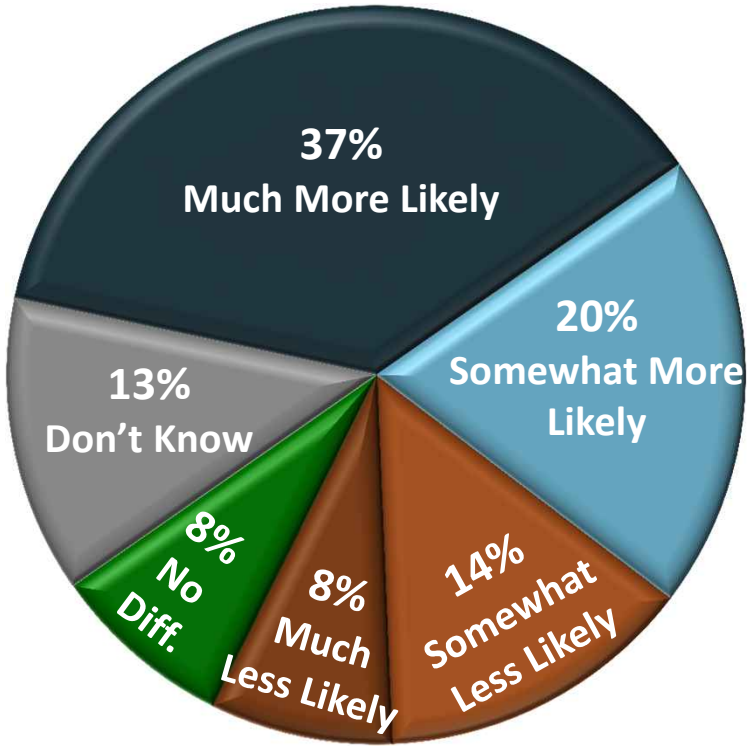
Here is a different question wording from a different pollster that confirms Democrats are more likely to support a Medicare-for-all candidate.

When thinking about your vote for the Democratic primary for the 2020 presidential election, would each of the following make you more or less likely to support a candidate, or would it make no difference either way?

(Asked Only Among Democrats)

The candidate supported a Medicare-for-all health system, where all Americans would get their health insurance from the government, over preserving and improving the Affordable Care Act.

Total More Likely	57%
Total Less Likely	22%



Source: January 2019 Morning Consult + Politico Poll.

Center Moves To Public Option

Providers United & Speaking Out

Americans are more frustrated by health care costs than coverage or access issues

Ranked by % Very/Somewhat Frustrating

	Very/ Somewhat Frustrating
Hospital fees and unexpected hospital bills	74%
Insurance costs, like premiums, copays and deductibles	71%
Out-of-pocket costs for prescription drugs	64%
Insurance does not cover emergency room or urgent care visits	64%
Out-of-pocket costs for routine visits to a doctor	62%
Insurance networks are too narrow, covering too few doctors and specialists	58%
Not being able to get an appointment with your physician or specialist	55%
Obtaining health insurance	51%
Not knowing what king of health care provider you need to see	49%

Source: Ispos Public Affairs; October 2018.

Out-Of-Pocket Sticker Shock

Toxic Anecdotes

Surprise Bills or Gaps in Coverage

menu

BILL CASSIDY, M.D.
UNITED STATES SENATOR FOR LOUISIANA

Contact

ALERT: SENATOR CASSIDY'S NEW IDEAS TO LOWER HEALTH CARE COSTS

Newsroom Press Releases

09.18.18

Cassidy, Bipartisan Colleagues Release Draft Legislation to End Surprise Medical Bills

WASHINGTON—U.S. Senators Bill Cassidy, M.D. (R-LA), Michael Bennet (D-CO), Chuck Grassley (R-IA), Tom Carper (D-DE), Todd Young (R-IN), and Claire McCaskill (D-MO), members of the bipartisan Senate health care price transparency working group, today released draft legislation to protect patients from surprise medical bills. The draft bill is intended to jumpstart discussions in Congress about how to best stop the use of balanced billing to charge patients for emergency treatment or treatment provided by an out-of-network provider at an in-network facility.

Recent examples of patients receiving surprise medical bills include a patient who received a bill of nearly $109,000 for care after a heart attack, and a patient who received a bill for $17,850 for a urine test.

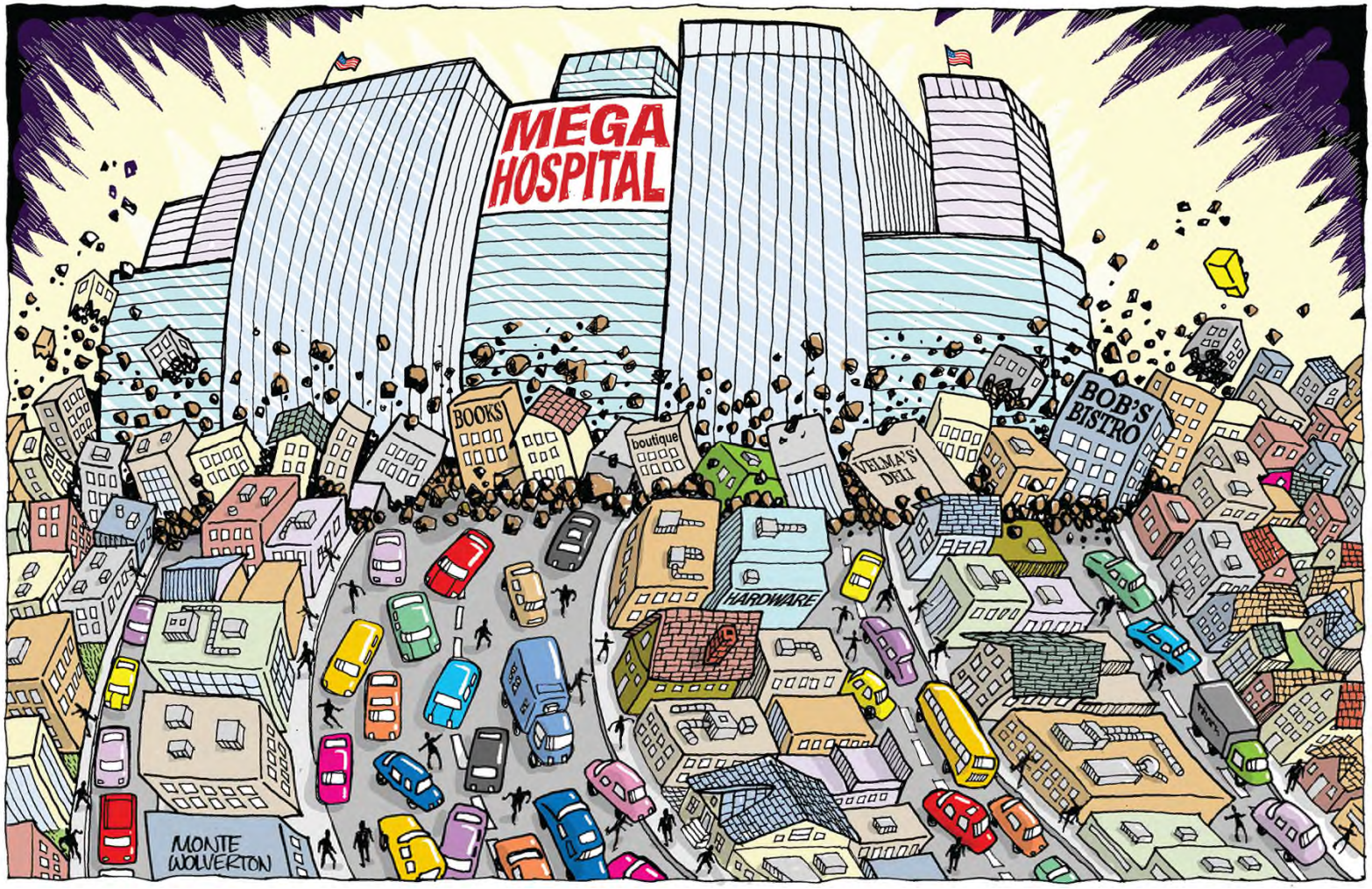
"Patients should have the power, even in emergency situations when they are unable to negotiate," **said Dr. Cassidy**. "Our proposal protects patients in those emergency situations where current law does not, so that they don't receive a surprise bill that is basically uncapped by anything but a sense of shame."

Waivers Roll Back Medicaid

Big Pharma Scapegoating PBMs

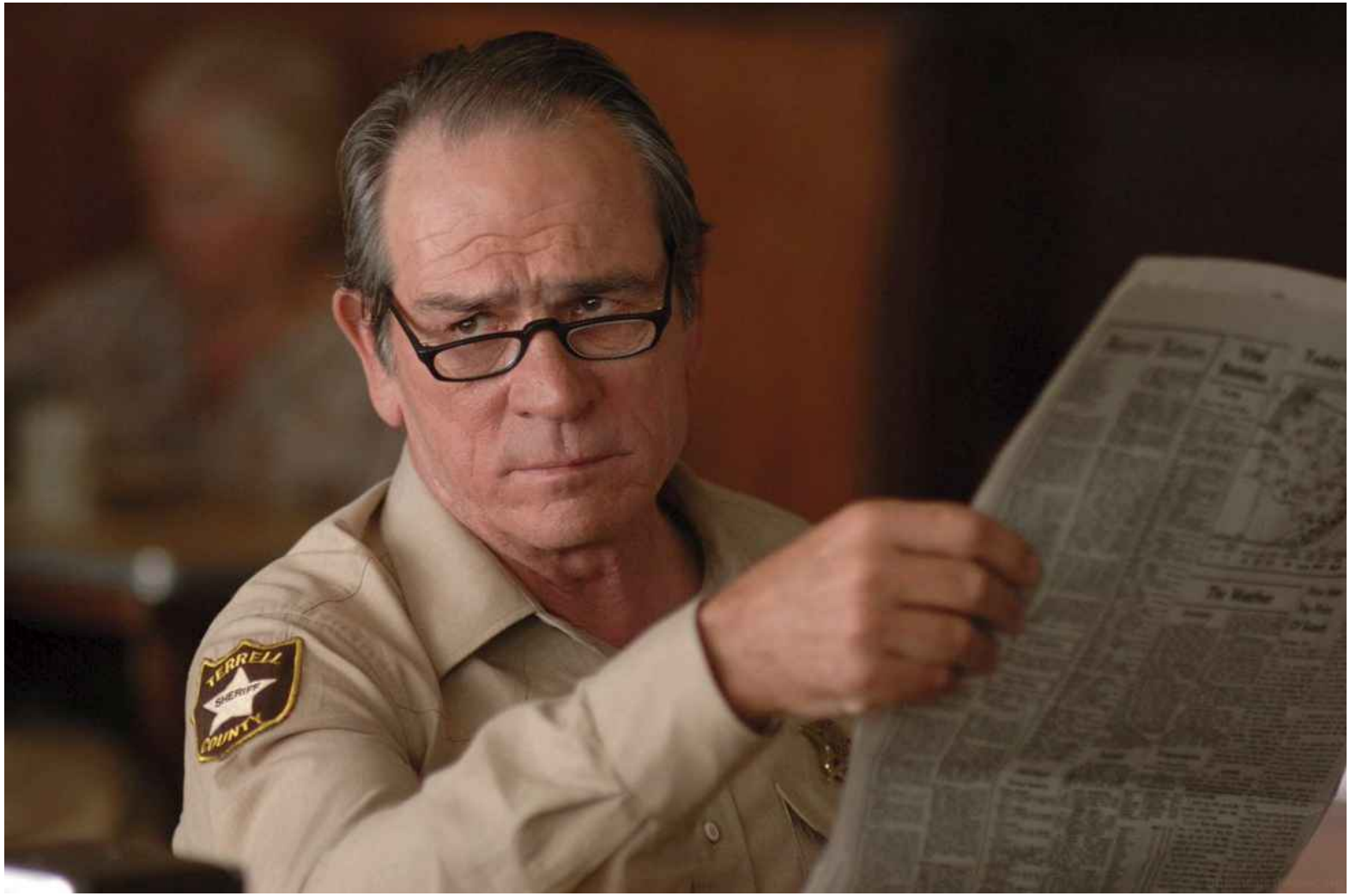
Casting Blame At Hospitals Too

Consolidation Price Mythology



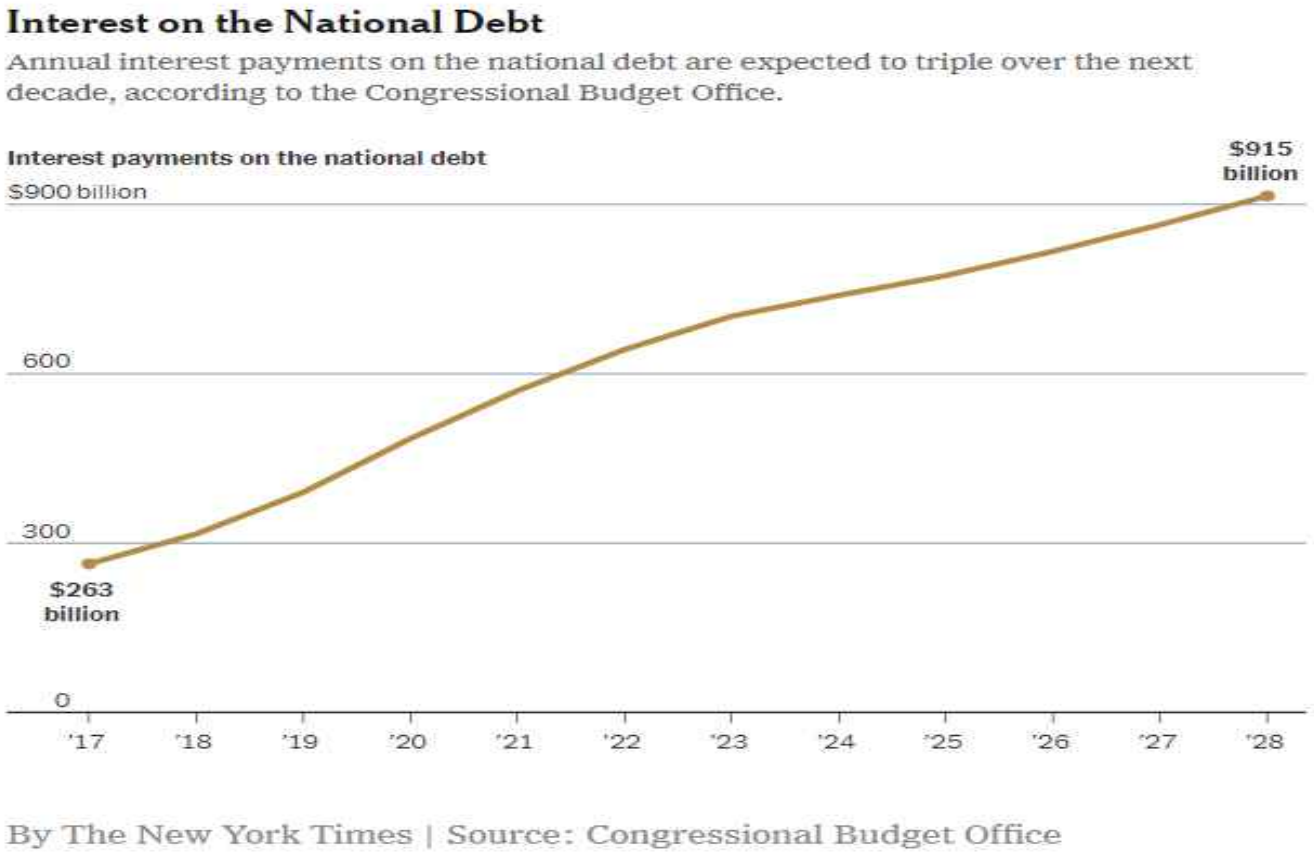
Insurers Claim Hands Tied

Oh Really?



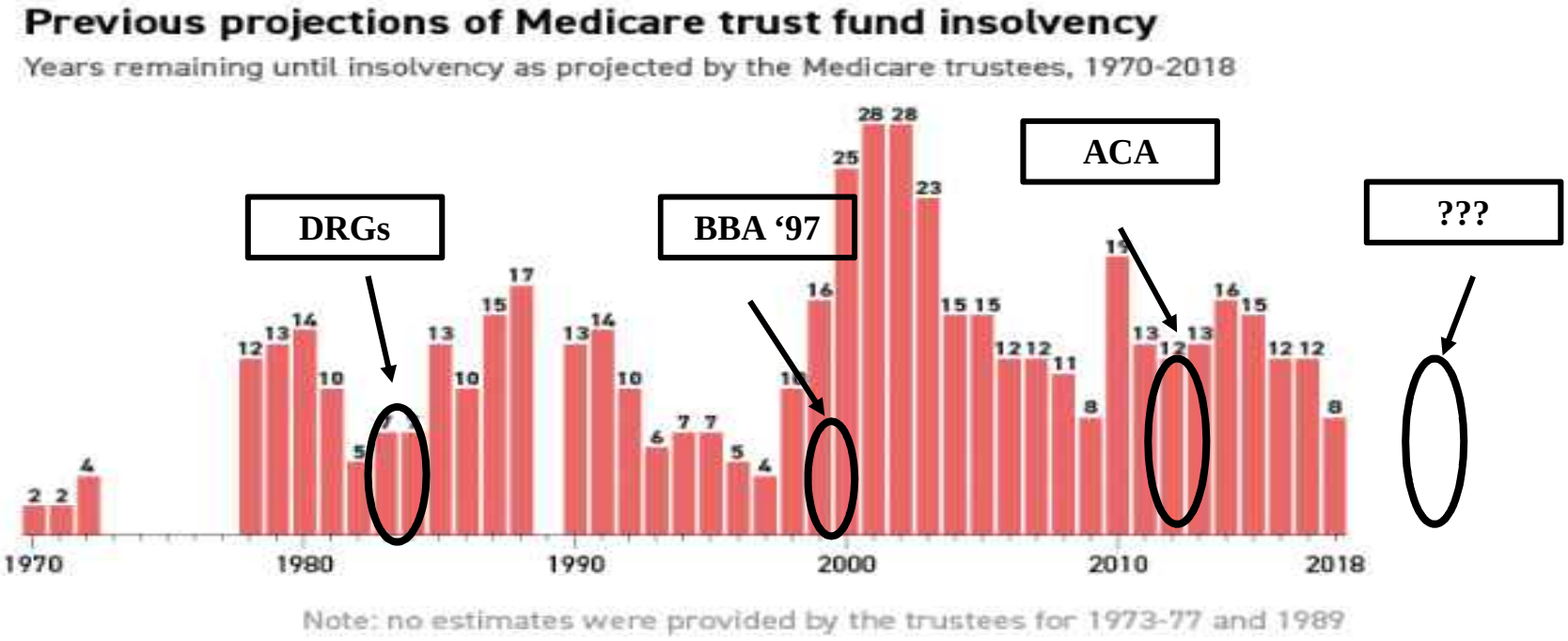
CMMI: Expanding Agenda and Authority

Deficits Existential Threat



Pay Go Rules

Part A Leading Indicator



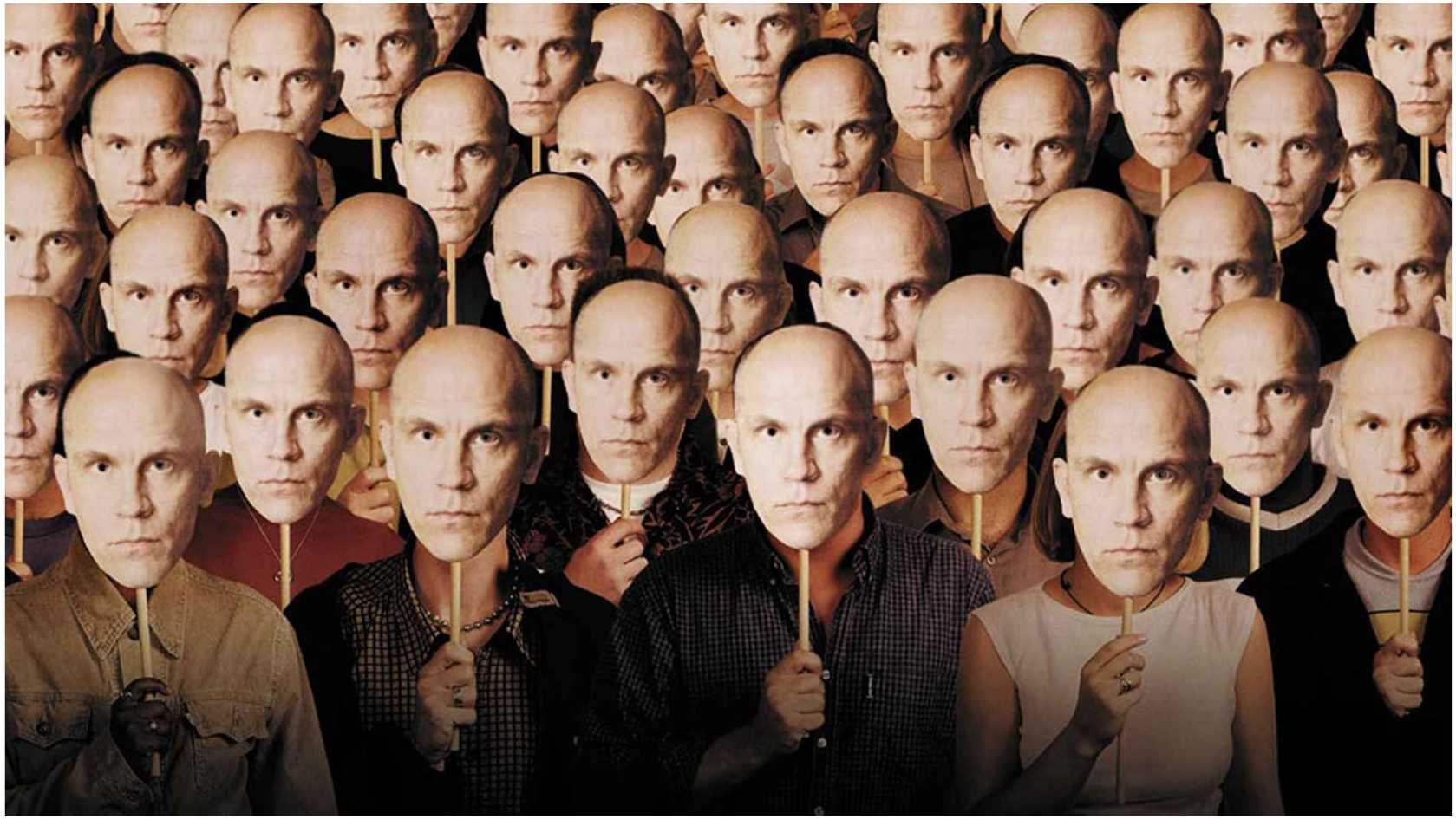
Tucker Doherty/POLITICO

Congress’s Piggy Bank

Bad Debt Always On List

Policymakers Push One Size Fits All

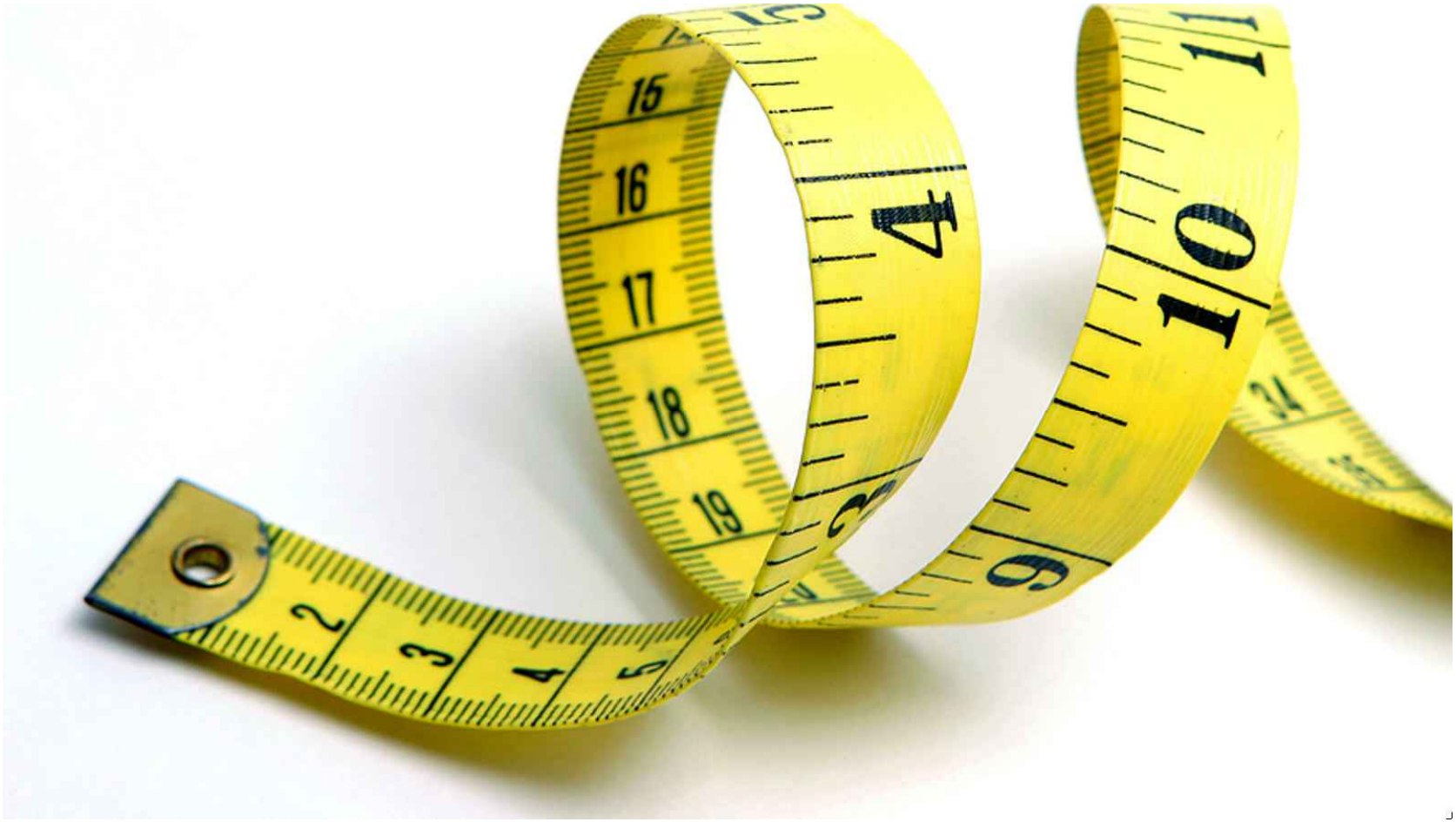
PAC Same Site Payment Too



Telehealth Works

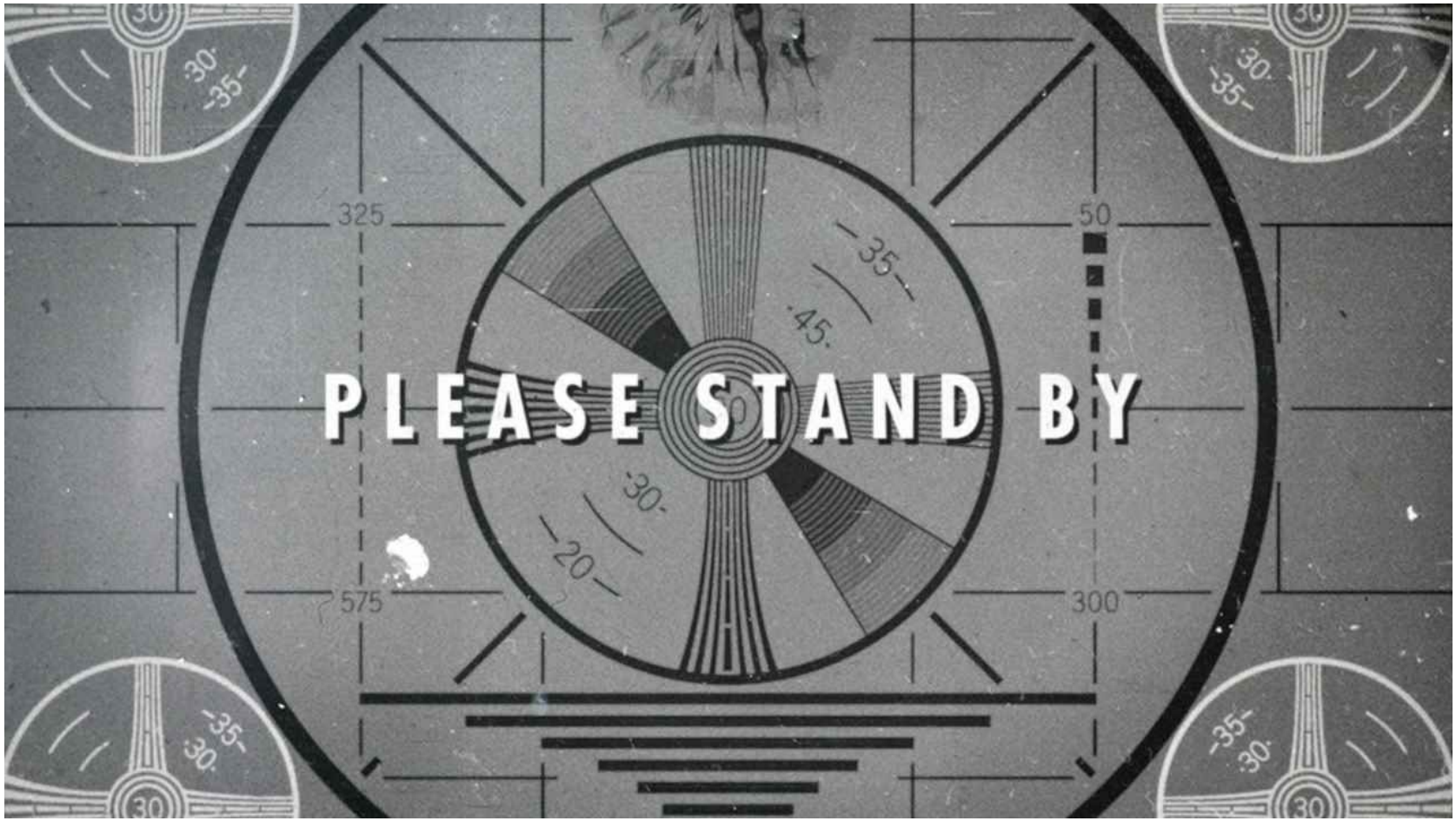
Hospitals On Interoperability

Getting It Right



Focus HCAHPS

Mueller Exposé



361 Days To Iowa Caucuses

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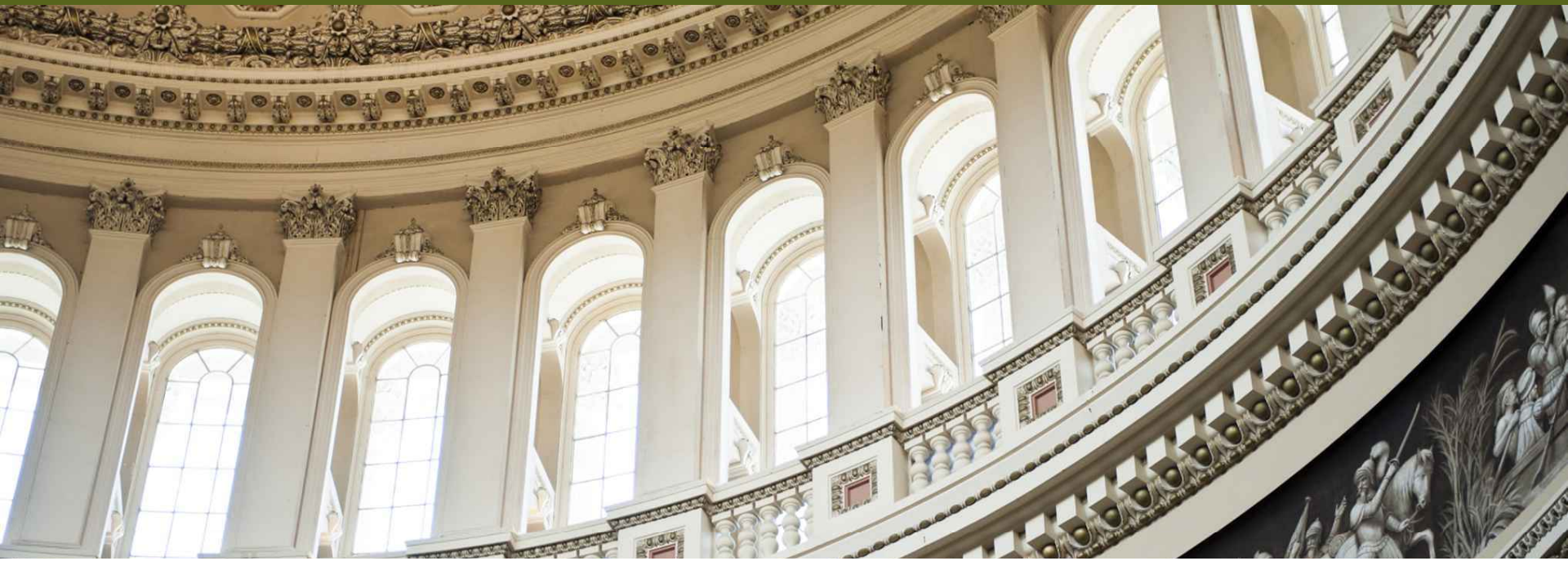

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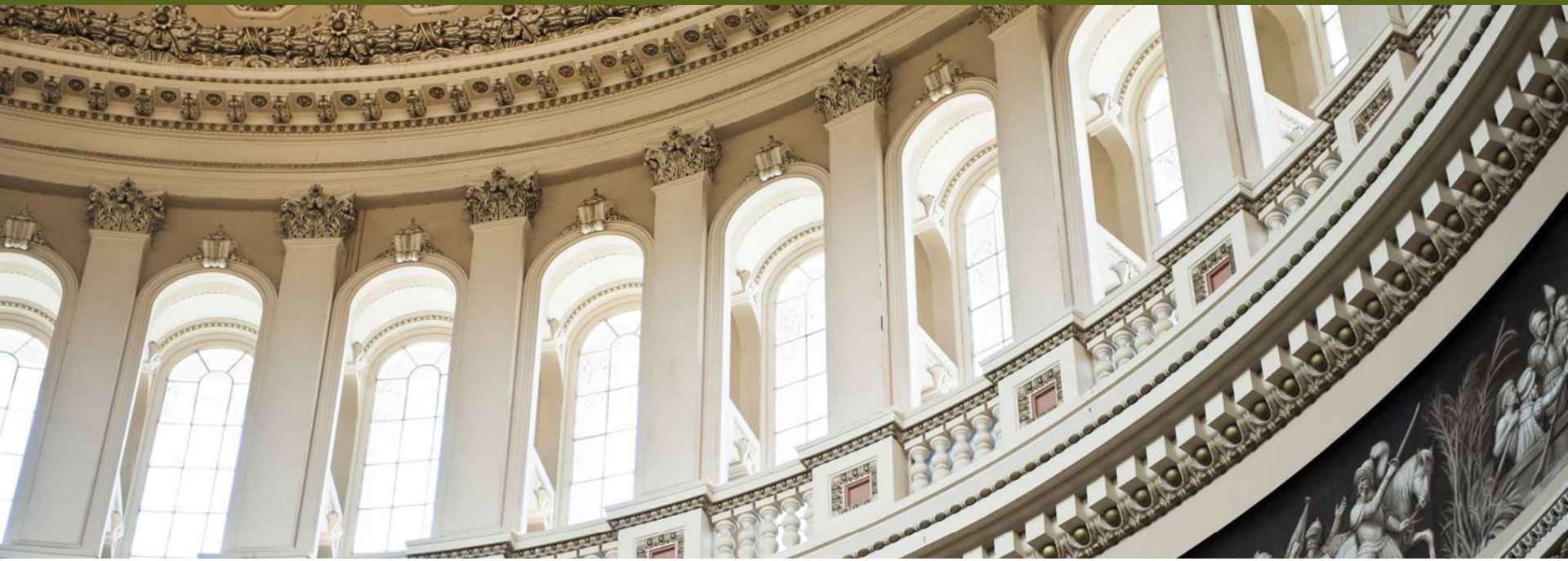
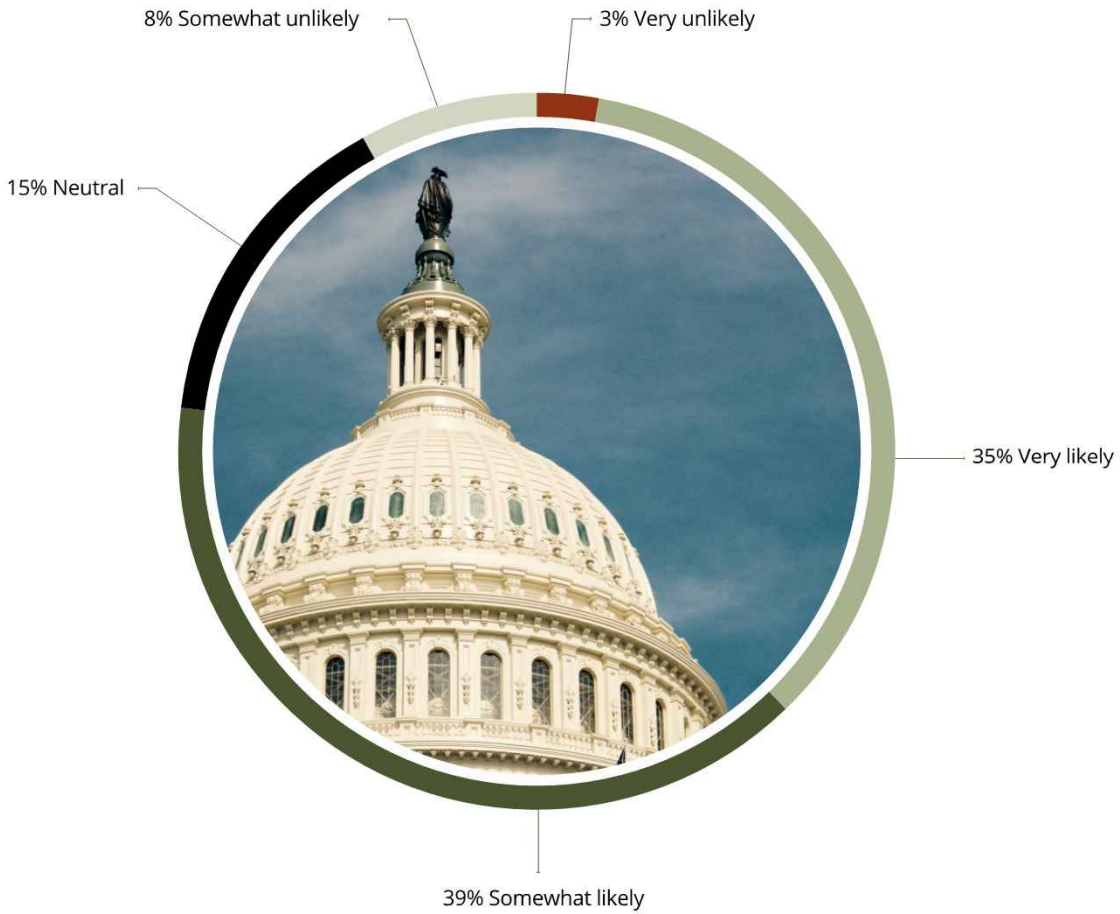


HLB Health Law & Policy Survey Results

John Hellow, Monica Massaro, Katrina Pagonis, Mark Reagan
Hooper, Lundy & Bookman, P.C. Panel Discussion

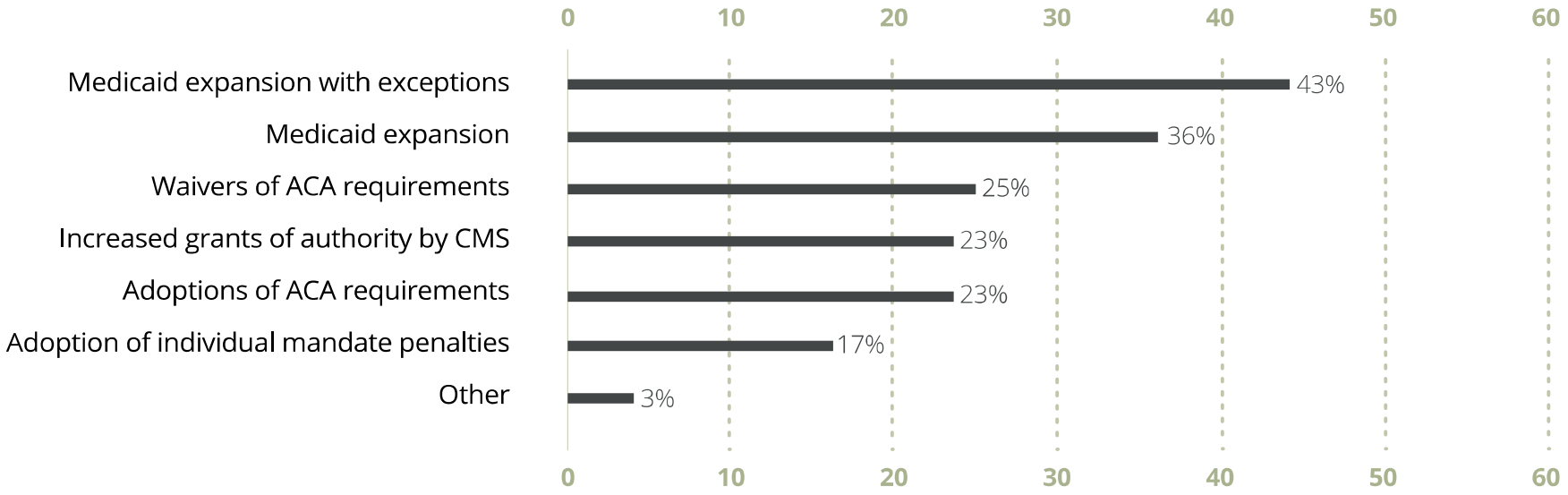
Question 1

How likely are we to see any significant changes in federal health care reform within the next two years?



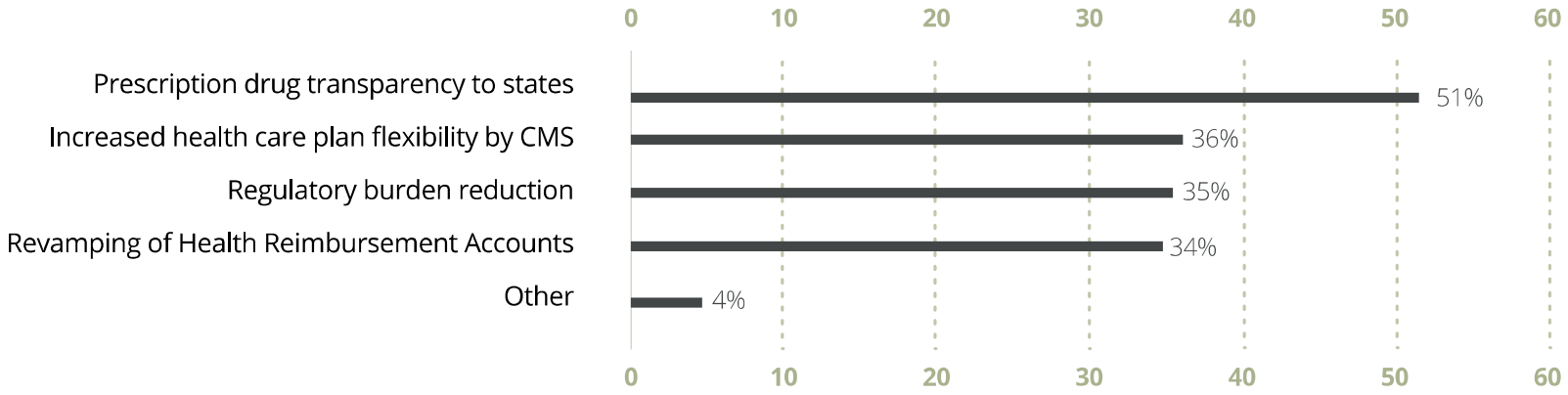
Question 2

At the state level, what are some likely changes around health care reform in the next two years?



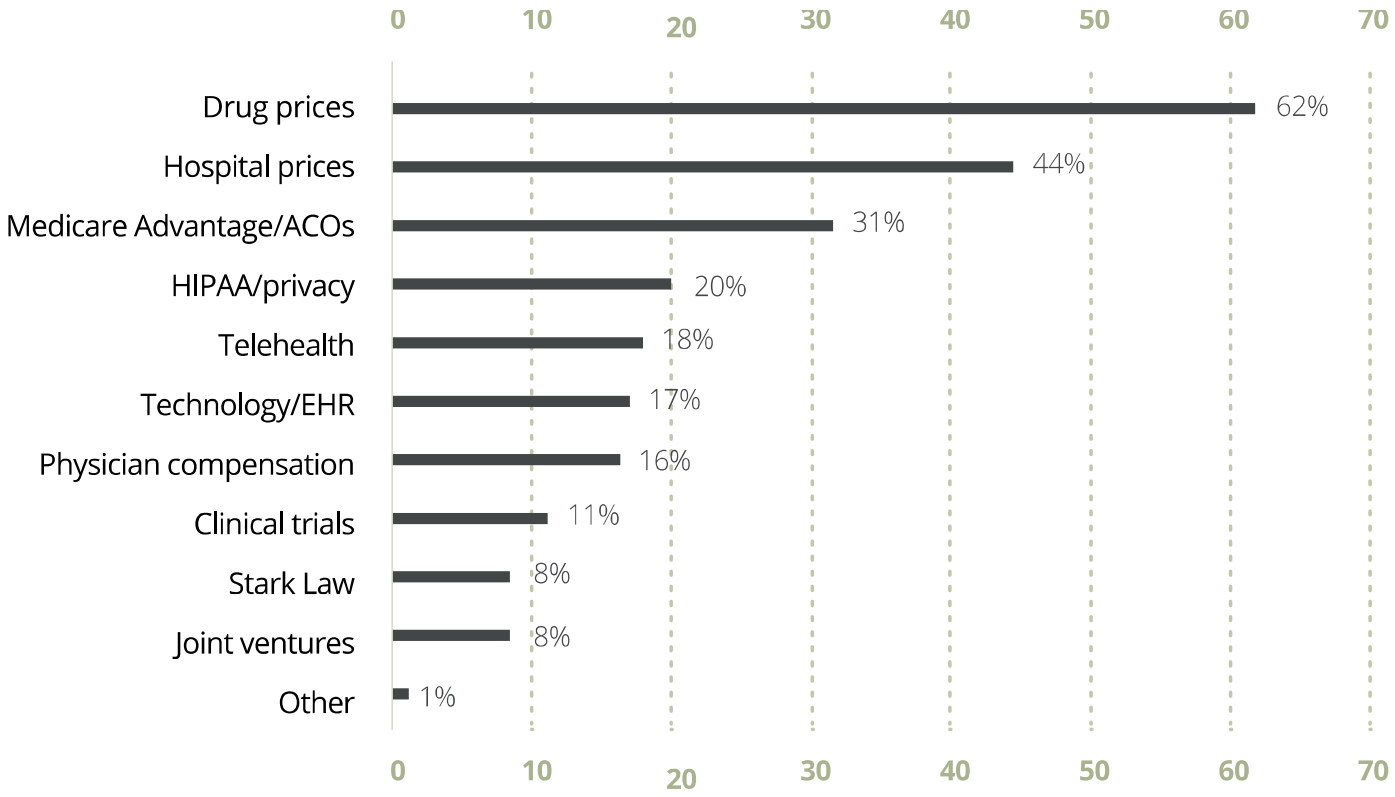
Question 3

Beyond the ACA, what are the top areas for health care reform under the current administration?



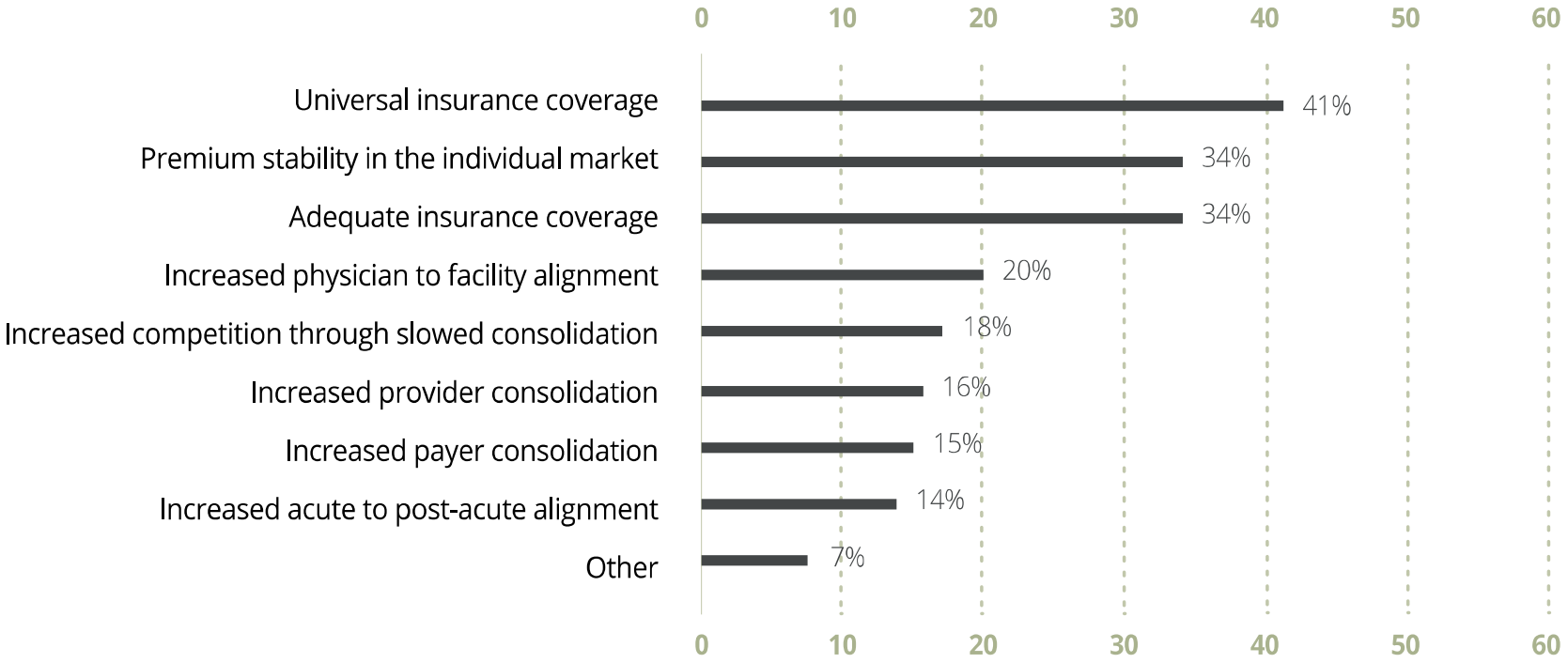
Question 4

Which of the following areas do you believe will most likely experience increased enforcement over the next two years?



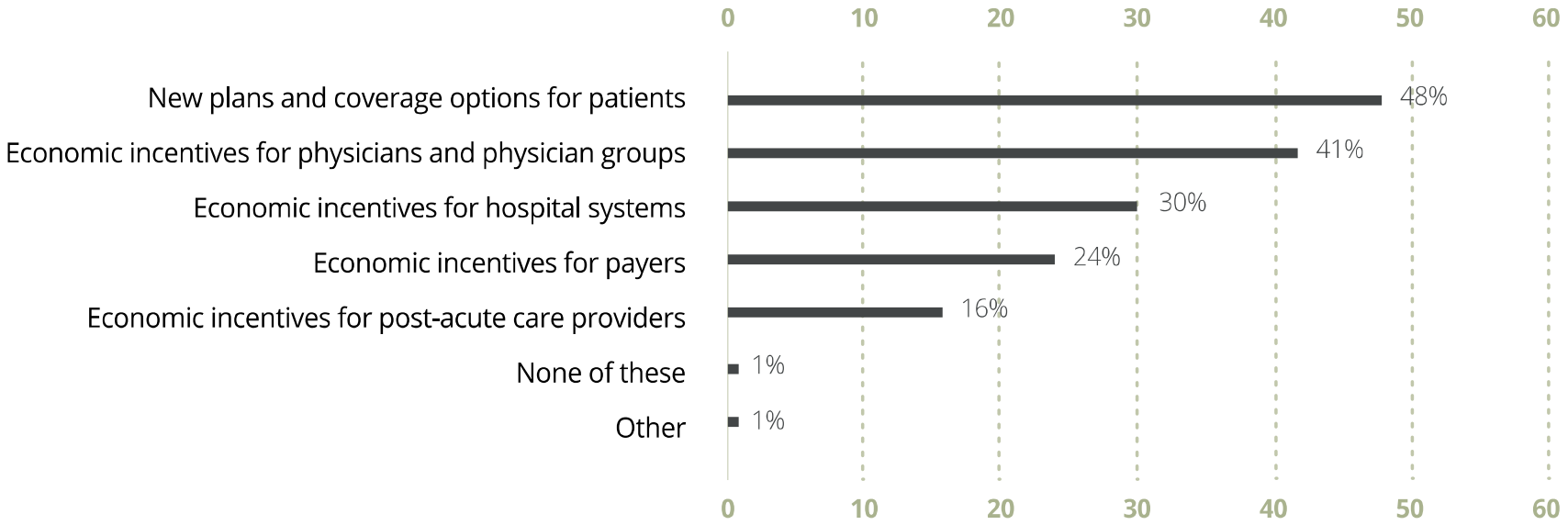
Question 5

Which of the following are most necessary to reduce the overall cost of health care?



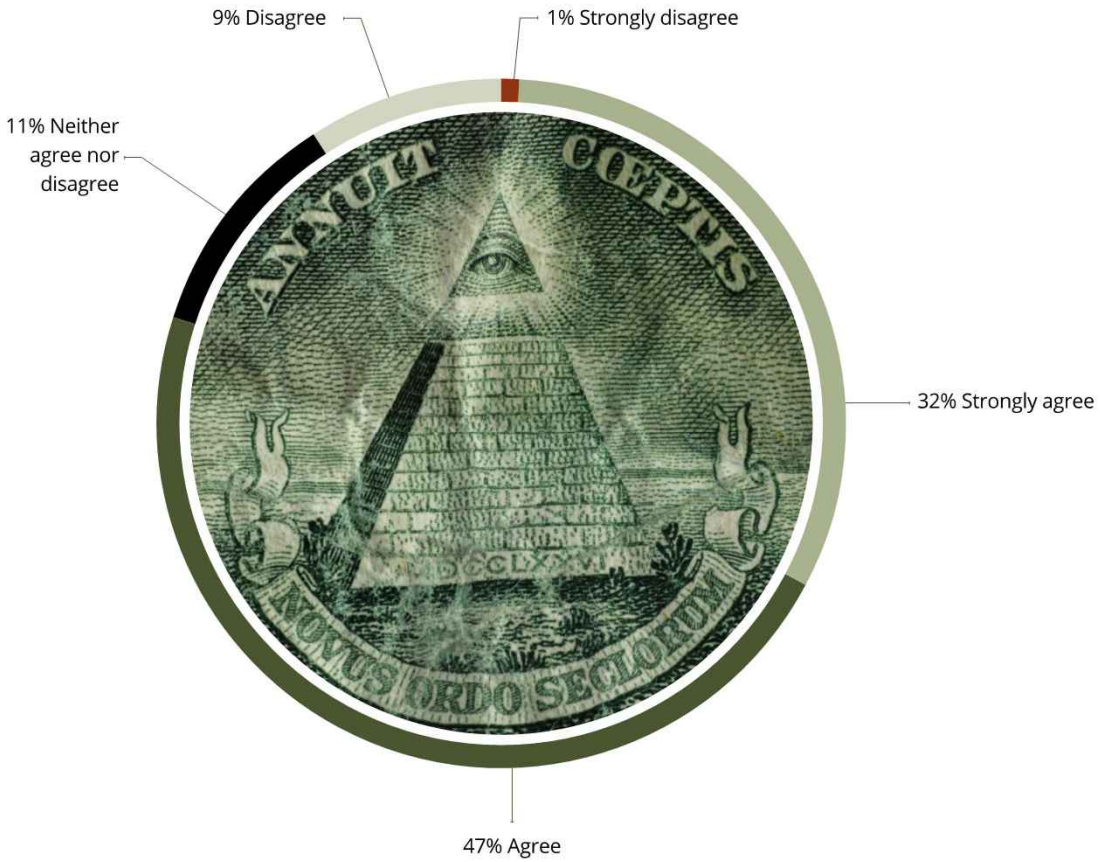
Question 6

Which of the following do you believe will be the most impactful payment developments in managed care over the next two years? Select up to two:



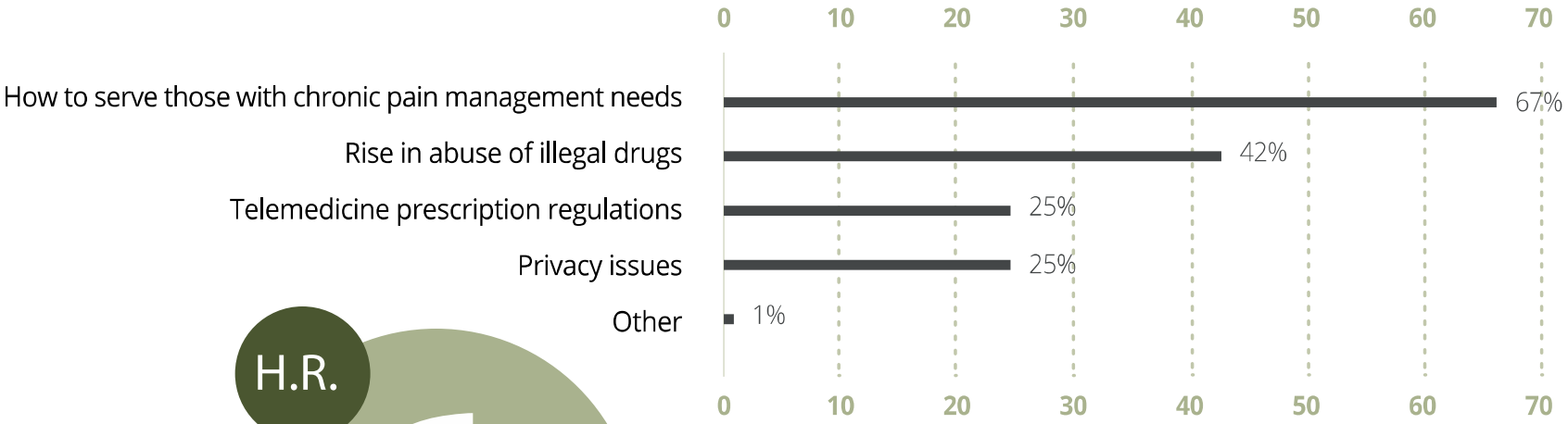
Question 7

Please state your level of agreement with this statement: Efforts to control prescription drug pricing will have significant impact on the market within the next two years.



Question 8

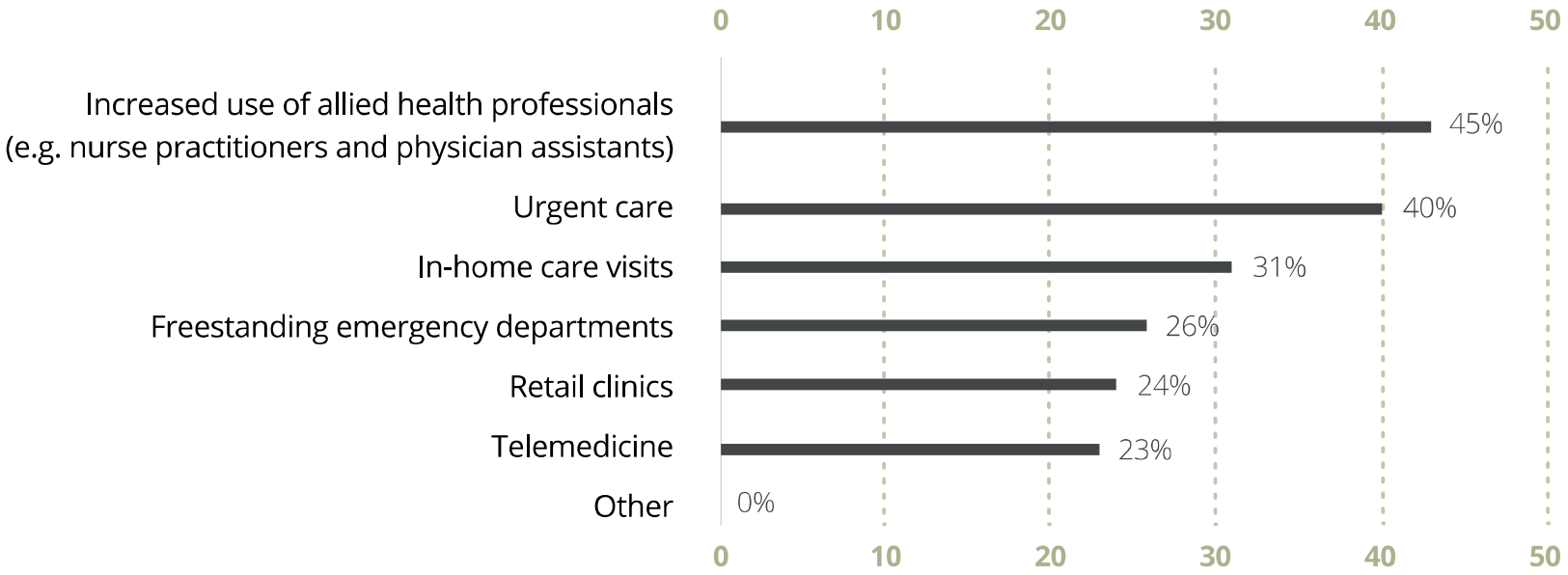
With the passage of HR 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which of the following do you expect to arise as challenges?



H.R. 6

Question 9

Where is the biggest growth opportunity for newer high touch points? Please select all that apply:

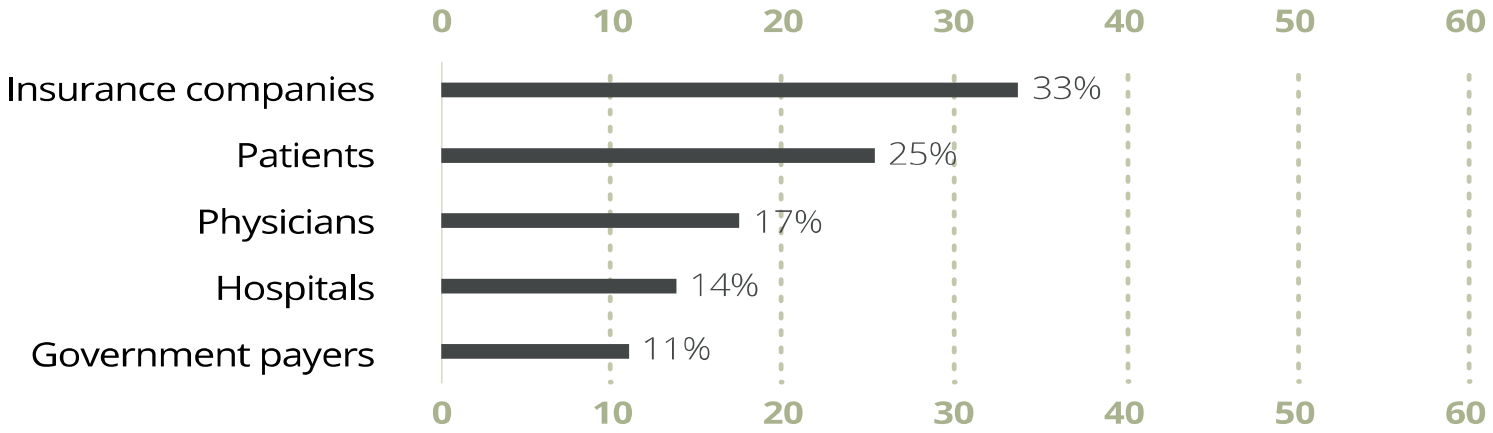


Question 10

To what extent do you do you believe that regulatory barriers are currently hindering the growth of telemedicine?

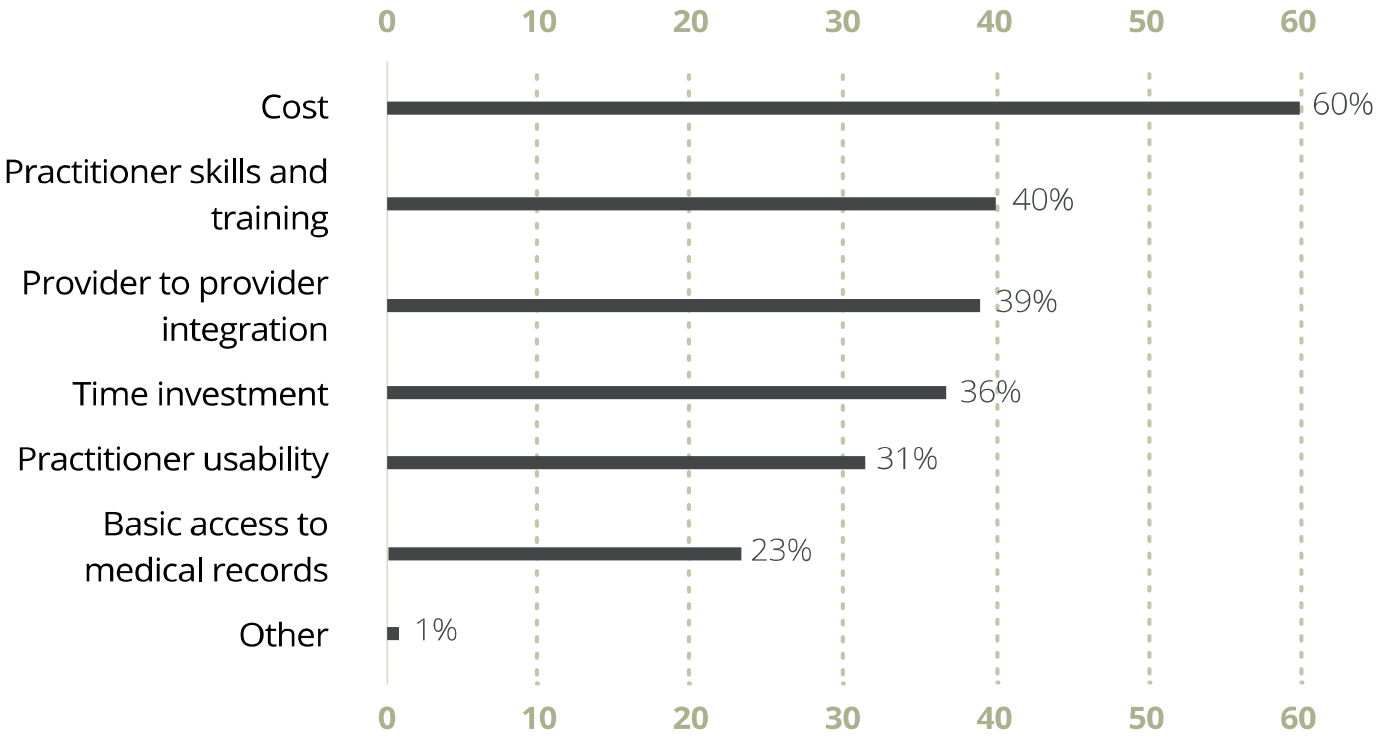
Question 11

Which party do you believe has the most to gain from physician alignment?



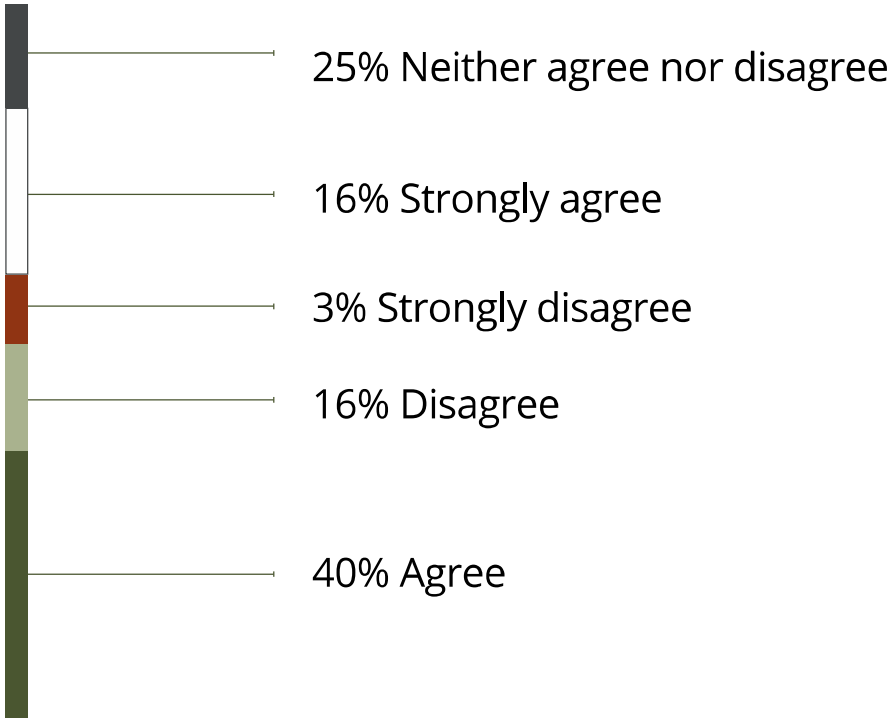
Question 12

From the provider, supplier and payer sides, what are the greatest challenges of health care's ever-increasing reliance on electronic systems? Please select all that apply:



Question 13

Please indicate your level of agreement with this statement: In the move toward value-based care, large hospitals are better able to manage post-acute care than smaller systems.



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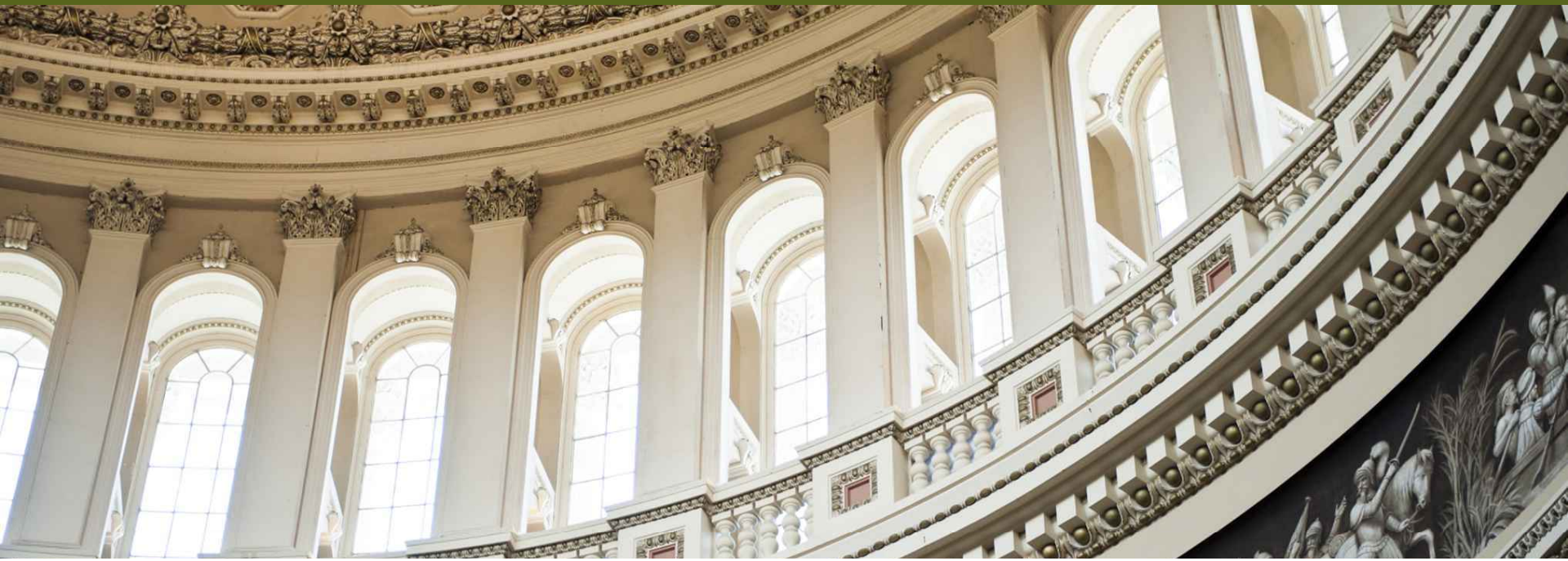


The National Symposium on Health Law and Policy

AMERICA'S PHYSICIAN GROUPS

AMERICA'S PHYSICIAN GROUPS:

Accelerating the Movement to Value

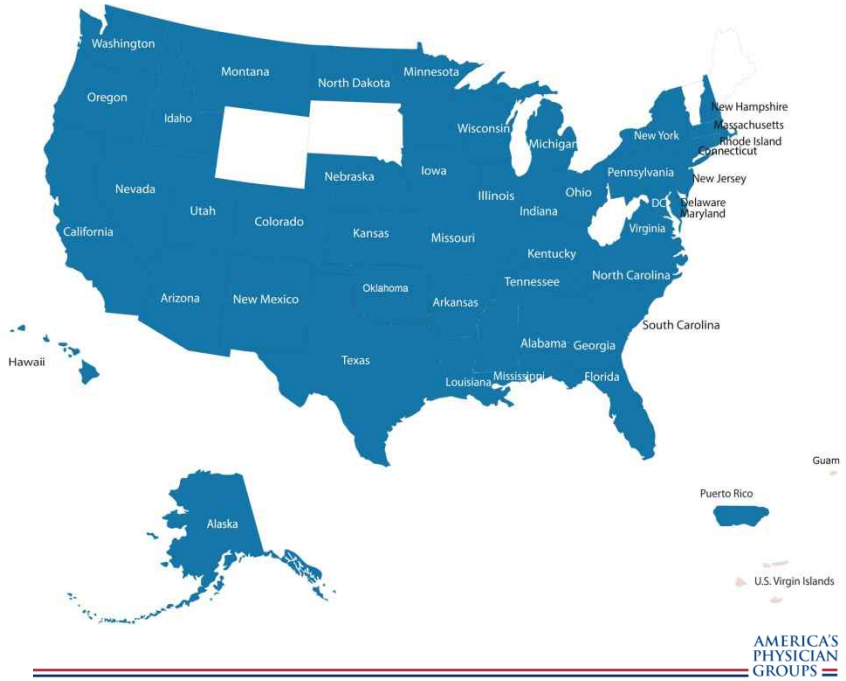
National Health Law and Policy Symposium

February 11, 2019

AMERICA'S PHYSICIAN GROUPS

Overview

- Introduction
- The Environment, from 40,000 feet
- Policy and Politics
- What is the best model?
- APG at work
- Conclusion; Q and A



WHO WE ARE

- 300+ physician organizations
- 45 states
- Capitation is the destination
- Taking Responsibility for America's Health

Overview

- Introduction
- The Environment, from 40,000 feet
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- What is the best model?
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The Environment, from 40,000 feet

- Value Movement, its really happening
- A word about MACRA
- Demographics still matter
- Moving from Acute to Chronic Care and its implications

Overview

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Policy and Politics

- Repeal and Replace
- Pharma dominating the discussion
- New APMs coming
- Ah yes, Medicare for All and Single Payer

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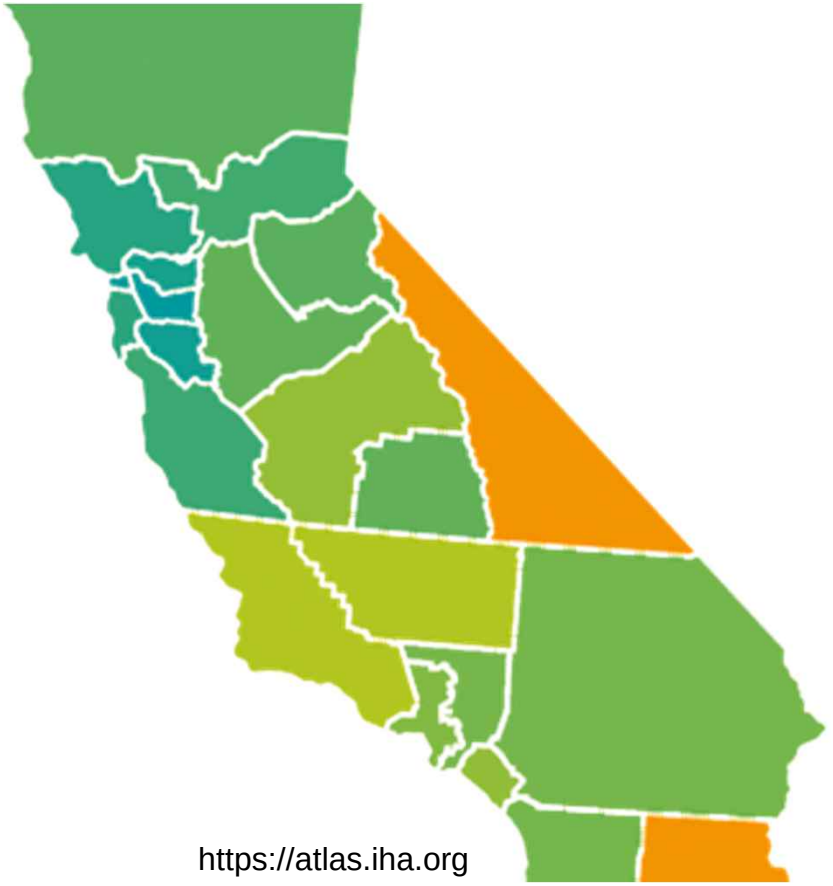
Atlas Coverage

Who's Included: 29 million Californians
(75% of state's enrolled pop)

- Commercial HMO
- Commercial PPO
- Medicare FFS
- Medicare Advantage
- Medi-Cal
- 19 regions

Data Partners:

- 10 health plans
- CMS
- CA Department of Health Care Services



https://atlas.iha.org

Atlas Measures

Clinical Quality

- Cancer Screenings: Breast, Cervical Over- and Under-Screening, Colorectal
- Diabetes Measures: Blood Sugar Testing, Control <8%, Poor Control >9%, and Kidney Monitoring
- Asthma Medication Ratio
- Appropriate Use of Imaging for Low Back Pain
- Avoidance of Antibiotics for Acute Bronchitis
- Clinical Quality Composite

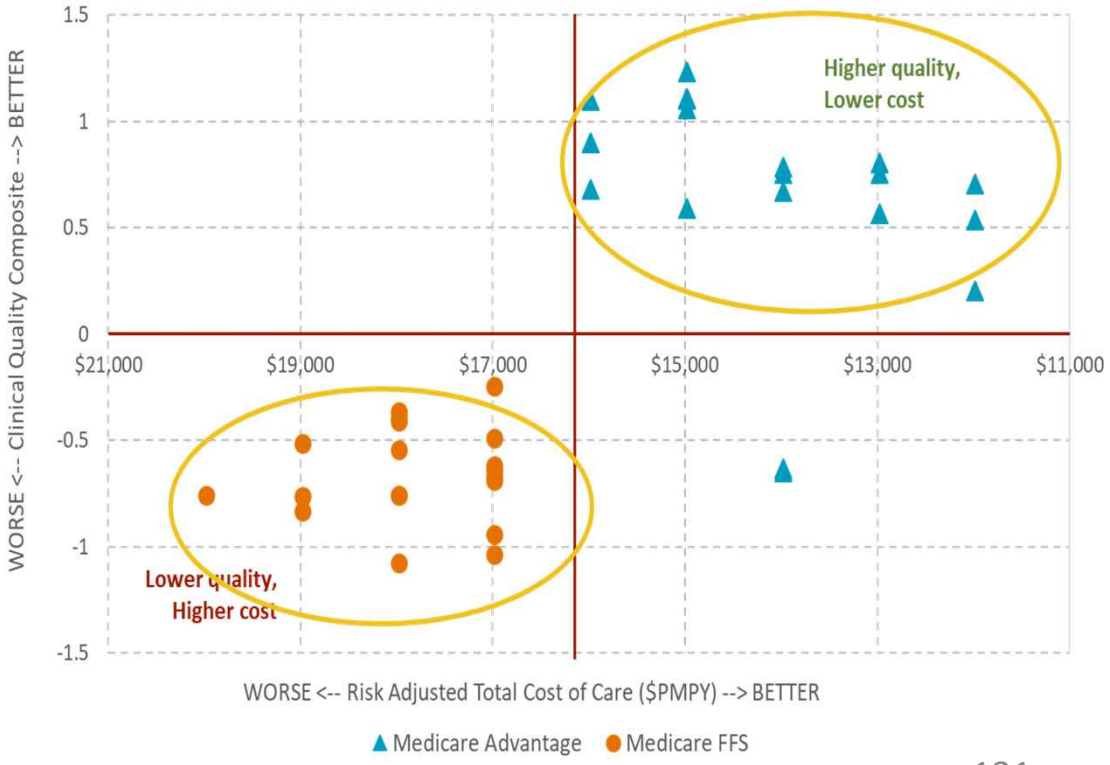
Hospital Utilization

- Emergency Department Visits
- Inpatient Bed Days, Discharges, and Average Length of Stay
- All-Cause Readmissions
- Frequency of Selected Procedures for several cardiac procedures, orthopedic surgeries, and other surgical removals
- Hospital Utilization Composite

Total Cost of Care

- Risk-Adjusted Cost (average per member per year)
- Observed (unadjusted) Cost
- Service categories: inpatient facility, outpatient facility, pharmacy, professional, and capitation

VALUE OF MEDICARE ADVANTAGE



Source: The California Regional Health Care Cost & Quality Atlas, Commercial HMO and PPO 2015 data

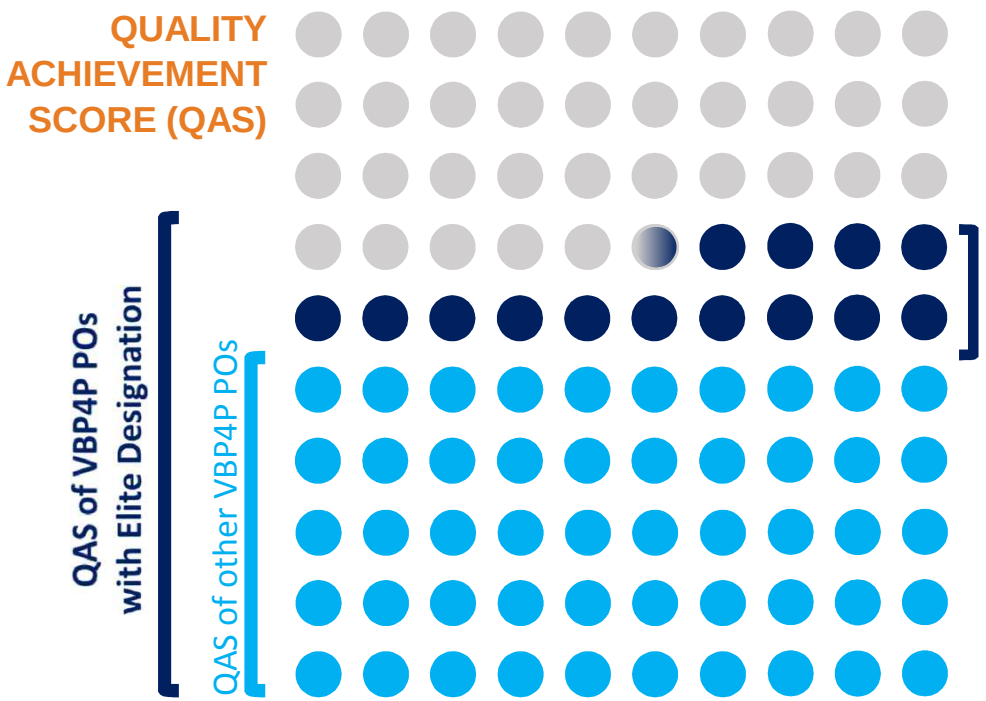
AMERICA'S PHYSICIAN GROUPS

Summary Stat

Capitated-Integrated is:

- Medicare Advantage has a $4,450 lower total cost of care pmpy than Original Medicare.
- Think of the implications

APG SOE® Elite Performance



MY 2016 VBP4P Physician Organizations who achieved **APG's SOE Elite Designation**, on average, performed

31% better

when compared to other VBP4P participating Physician Organizations

AMERICA'S PHYSICIAN GROUPS

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APG at Work

Mission

Initiatives

- Third Option
- New Risk Models
- Risk Evolution Task Force
- Dear Gavin: in the single payer debate, capitated-integrated is the answer to the cost problem

Overview

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Conclusion

“We must, indeed, all hang together or, most assuredly, we shall all hang separately.”

Benjamin Franklin

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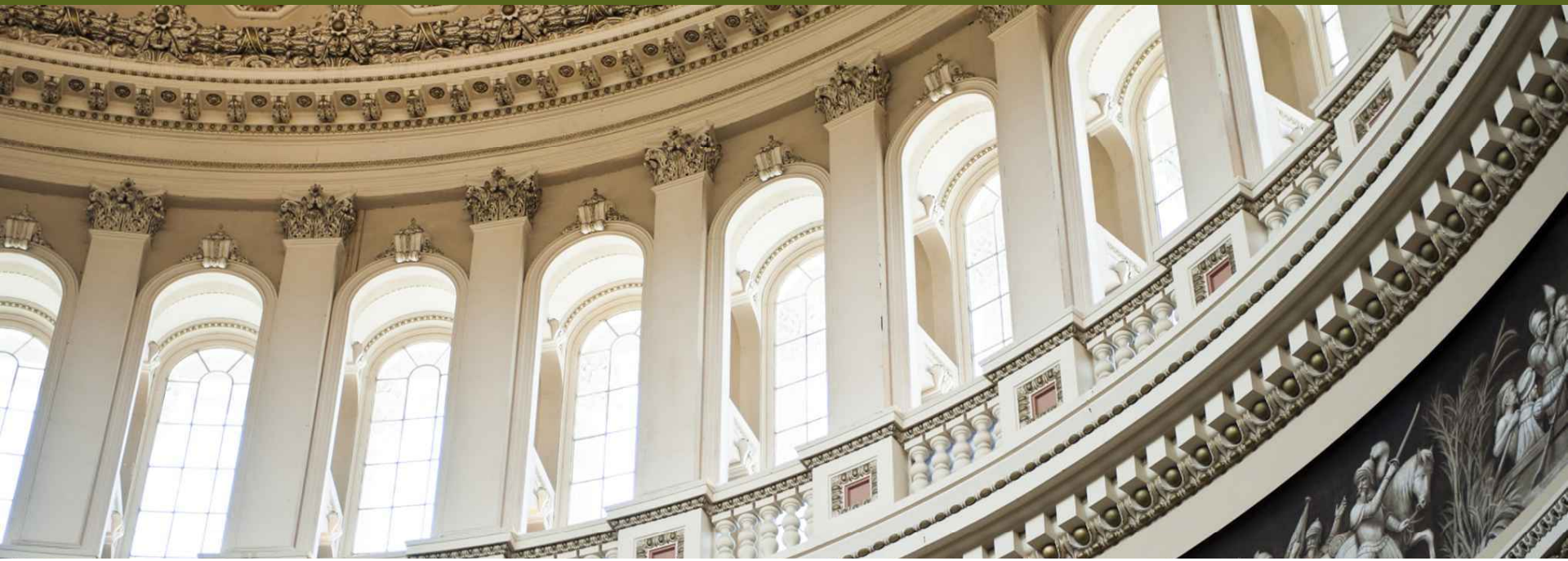

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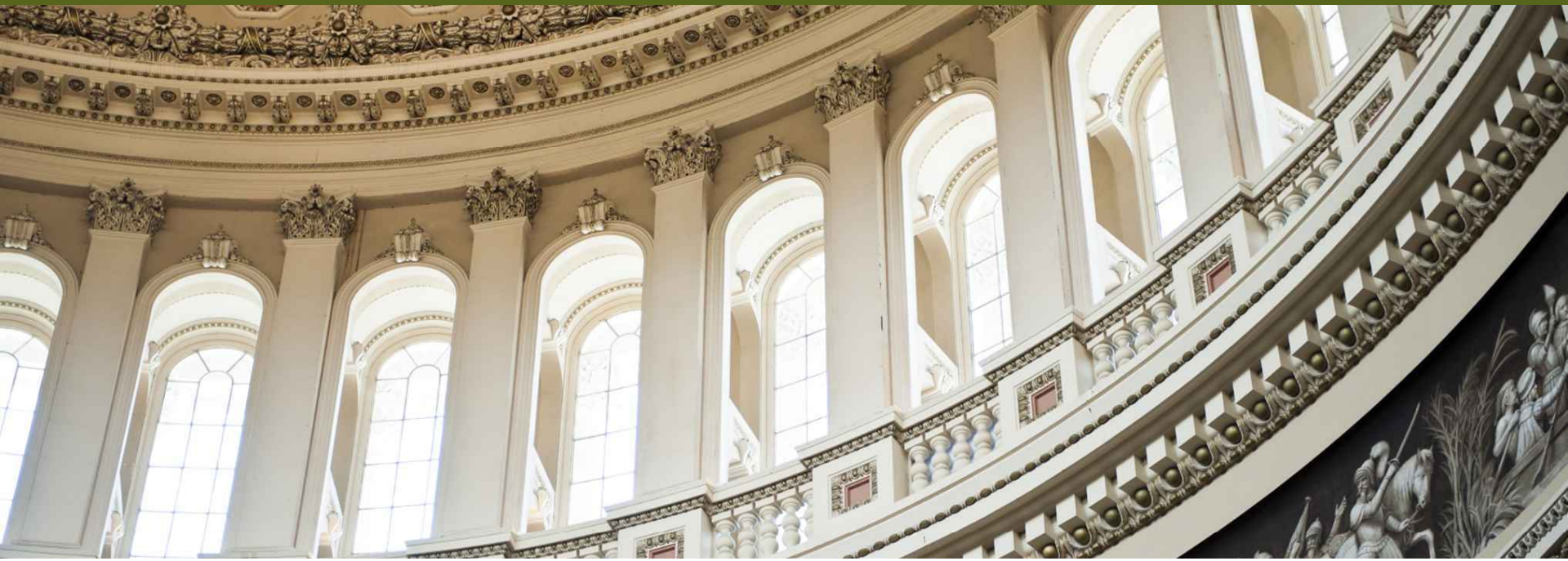
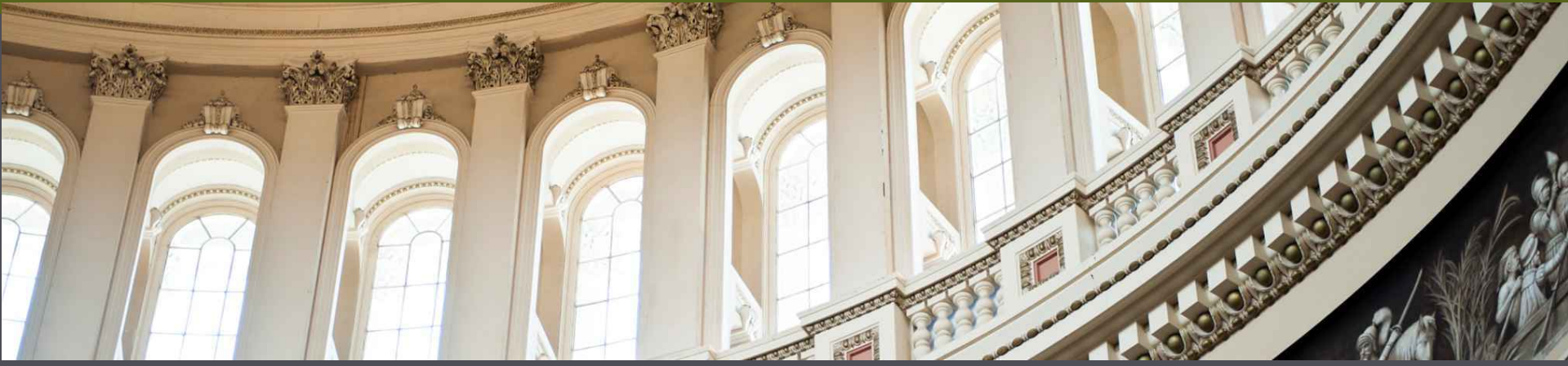


Fraud and Abuse Enforcement Trends

David Schumacher & Precious Gittens – Hooper, Lundy & Bookman, P.C.



Agenda

1	Current Enforcement Landscape
2	False Claims Act
3	Parallel Criminal Investigation
4	Opioid Crisis
5	Coming Attractions
6	Compliance Tips

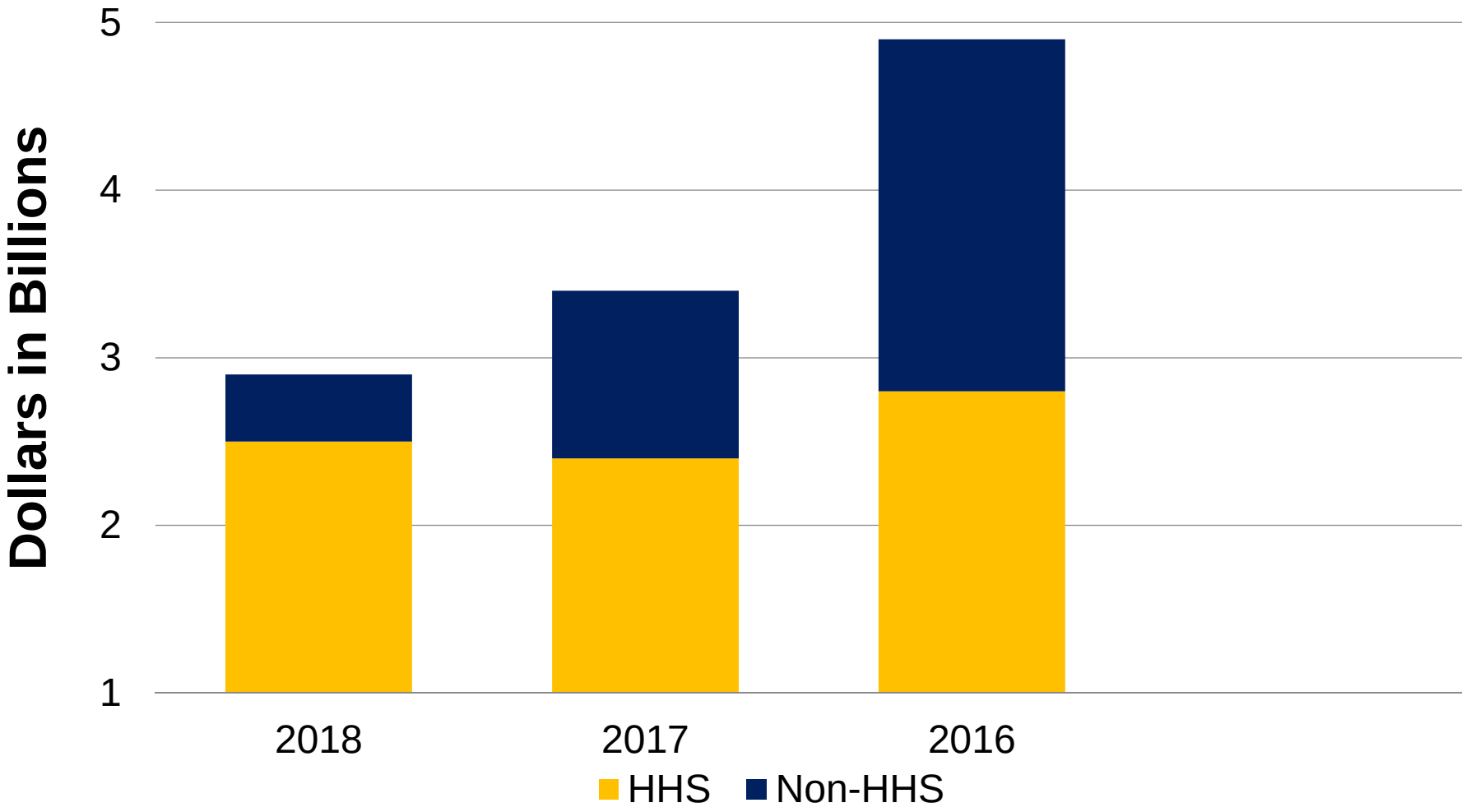
Current Enforcement Landscape

- DOJ: Aggressive as Ever
- Whistleblowers: Emboldened
- State Enforcement: On the Rise
- UPICs/MACs and Private Payors

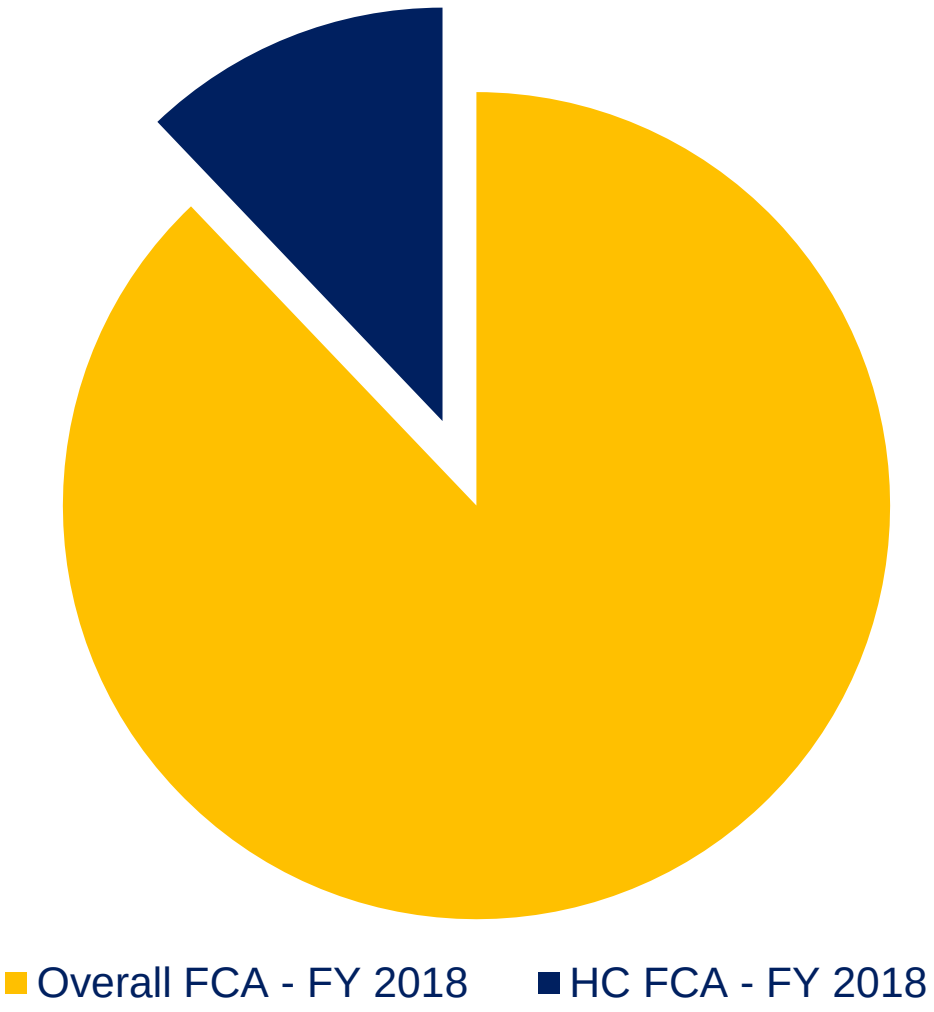
FY 2018 False Claims Act Statistics

- FCA judgments and settlements totaled more than $2.8B
- More than $2.5B from health care cases
- $1.9B of $2.5B from qui tam cases
- More than $266M awarded to relators (whistleblowers)
- Decrease in non-healthcare cases
- Increase in healthcare cases

HHS v. Non-HHS Recoveries



HHS Recoveries



DOJ False Claims Act Recoveries

Policy Issues Outside of Dollars

- **Continued Focus on Alleged Violations of the Anti-Kickback Statute**
  - Former hospital chain Health Management Associates paid over $260M to resolve false billing and kickback allegations; one subsidiary pled guilty to conspiracy to commit health care fraud
  - William Beaumont Hospital paid $84.5M to resolve allegations of improper relationships with eight referring physicians intended to induce patient referrals
- **Emphasis on holding individuals accountability**
  - $114M judgment against three individuals for paying kickbacks disguised as “handling fees” to physicians for referrals to Health Diagnostic Laboratory (HDL) and Singulex
  - $150M Insys FCA settlement and former executives plead guilty in connection with opioid kickback scheme
  - $5.5M judgment against neurosurgeon Dr. Sonjay Fonn, and his fiancé for kickbacks
- **DOJ Movement to seek dismissal of unmeritorious cases**

Recent FCA Dismissals: *U.S. ex rel. Health Choice v. Bayer Corp, et al.*

- 11 identical “white coat marketing” pharma cases
- Professional Relator
- DOJ always retains control of *qui tam*—including ability to dismiss
- DOJ moves to dismiss all 11 cases:
  - Questions allegations: educational, not kickbacks
  - Burden on DOJ to respond to discovery
- Relator’s Opposition

Who said this about the False Claims Act?

- The FCA is "**patently unconstitutional**" and it's "not even a close question"
- The FCA is a "**devastating threat** to the Executive's constitutional authority and to the doctrine of separation of powers"
- Whistleblowers were "**private bounty hunters**"
- The FCA is "**dangerous** . . . "**there is simply no way to cage this beast**"

DOJ Criminal Division, Fraud Section FY 2018 Report - Health Care Fraud (HCF) Unit

- 309 individuals charged
- 205 individuals convicted by plea or at trial
- 40% increase in number of individuals charged
- 20% increase in number of convictions
- Focus on/Increase in opioid prosecutions
- 67 individuals charged with opioid-related crimes
- 56% increase in “opioid defendants”
- Launch of Appalachian Regional Prescription Opioid Strike Force in Oct. 2018
- Overall “Impact on Investment” of $100 to $1 for FY 2018

The Travel Act in Health Care Fraud Enforcement

Kickbacks Beyond the Reach of the AKS

- Federal criminal statute that bars the use of the U.S. mail, or interstate or foreign travel, to the engage in certain unlawful activity, such as commercial bribery, in violation of state law
- Not limited to federal health care programs
- Creates federal jurisdiction when there is criminal activity that violates a specified state law, rather than a federal law, and the activity is directed from, or crosses, state lines
- Used to convert a violation of state law, such as commercial bribery or solicitation of patients, into a federal crime
- Simple acts such as using a telephone, the mail, email or internet to facilitate payments for patient referrals may serve as the basis for a Travel Act prosecution
- Biodiagnostic Laboratory Services in New Jersey. Press Release, U.S. Attorney, http://bit.ly/2gYvwwM
- Forest Park Medical Center (FPMC) in Texas. Press Release, U.S. Attorney of N.D. Tex., http://bit.ly/2xgsWMi

Opioid Crisis

- **Federal and State Enforcement**
- **DOJ Opioid Task Force**
- **Criminal and Civil Cases**
- **Insys Therapeutics & Perdue Pharmaceuticals**
- **Rehab Industry**
- **Hospitals and Pharmacies**

Looking Ahead: Pricing Enforcement

Looking Ahead: Pricing Enforcement

- **Recent federal activity on hospital and drug pricing**
- **Likely a precursor to enforcement**
- **Pharma/patient assistance cases**
- **Recent CA hospital pricing class action**
- **Recent Mass. hospital/outpatient surprise billing settlement**

New And Revised DOJ Policies

- Executive Order 13777
- Former U.S. AG Jeff Sessions Memo
- Former U.S. AAG Rachel Brand Memo
- Director, DOJ Civil Fraud Section Michael Granston Memo
- Then-Acting AAG Jesse Pannuccio remarks
- Deputy Attorney General Rod Rosenstein remarks
- Deputy Associate Attorney General Stephen Cox remarks

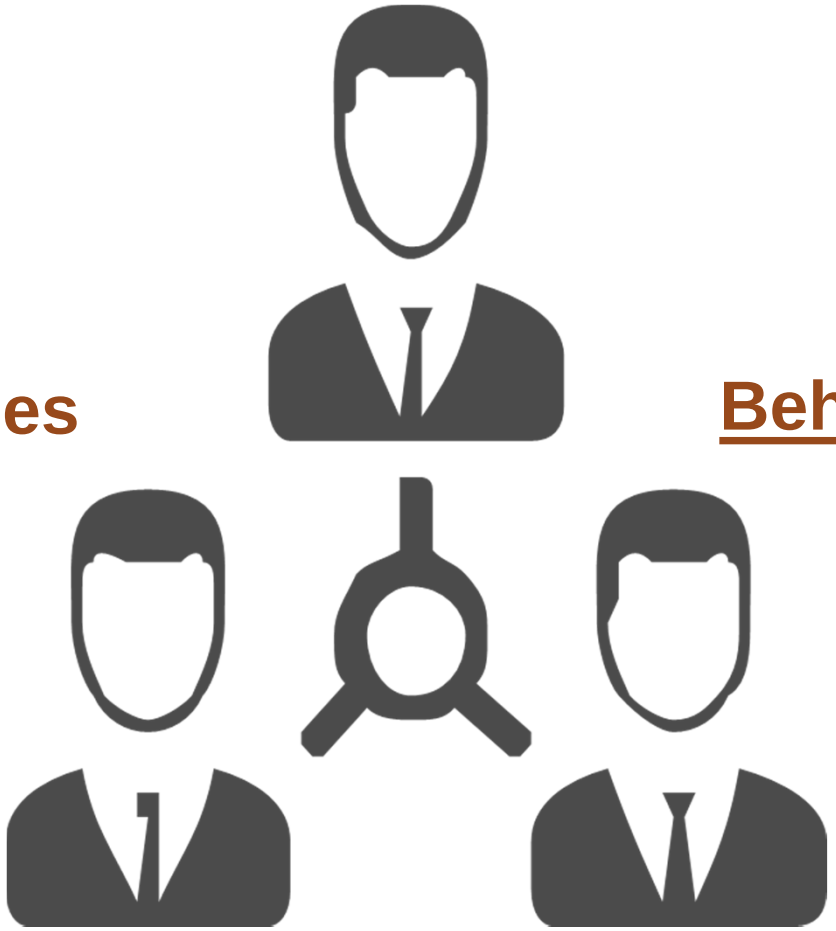
WHAT DOES IT ALL MEAN TO YOUR BUSINESS?

Defending Your Compliance Program

Concepts

Values

Behavior



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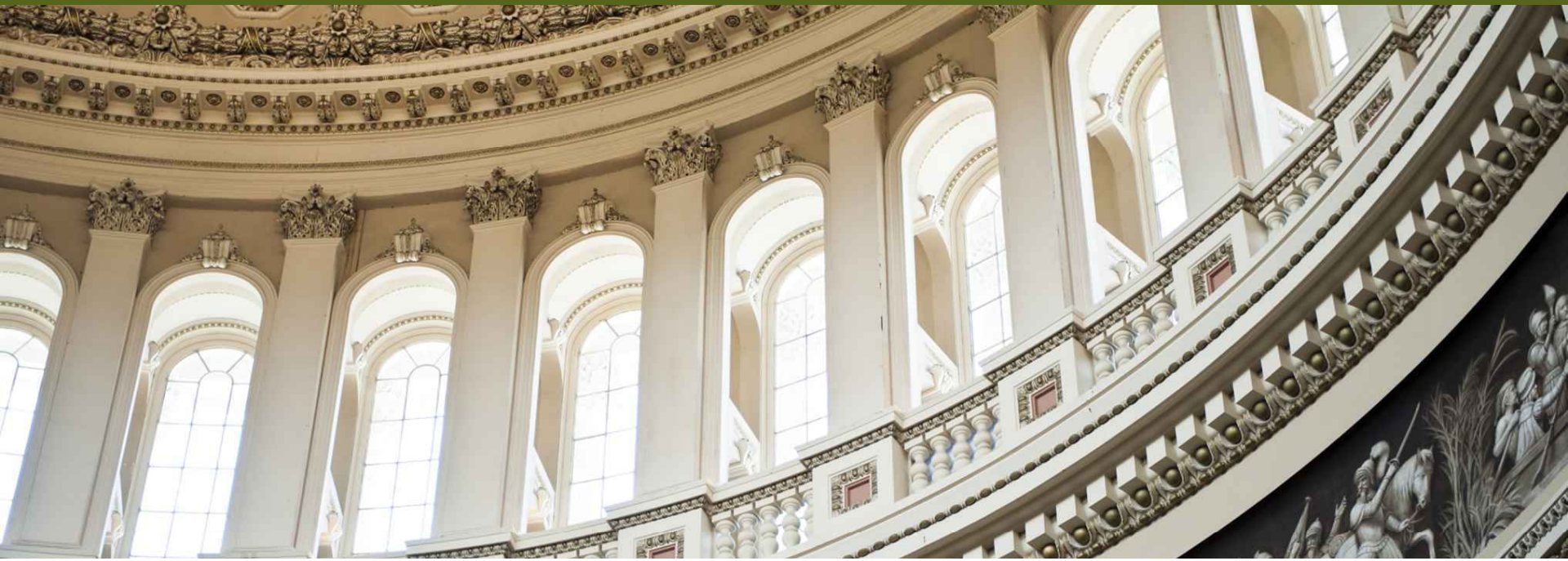

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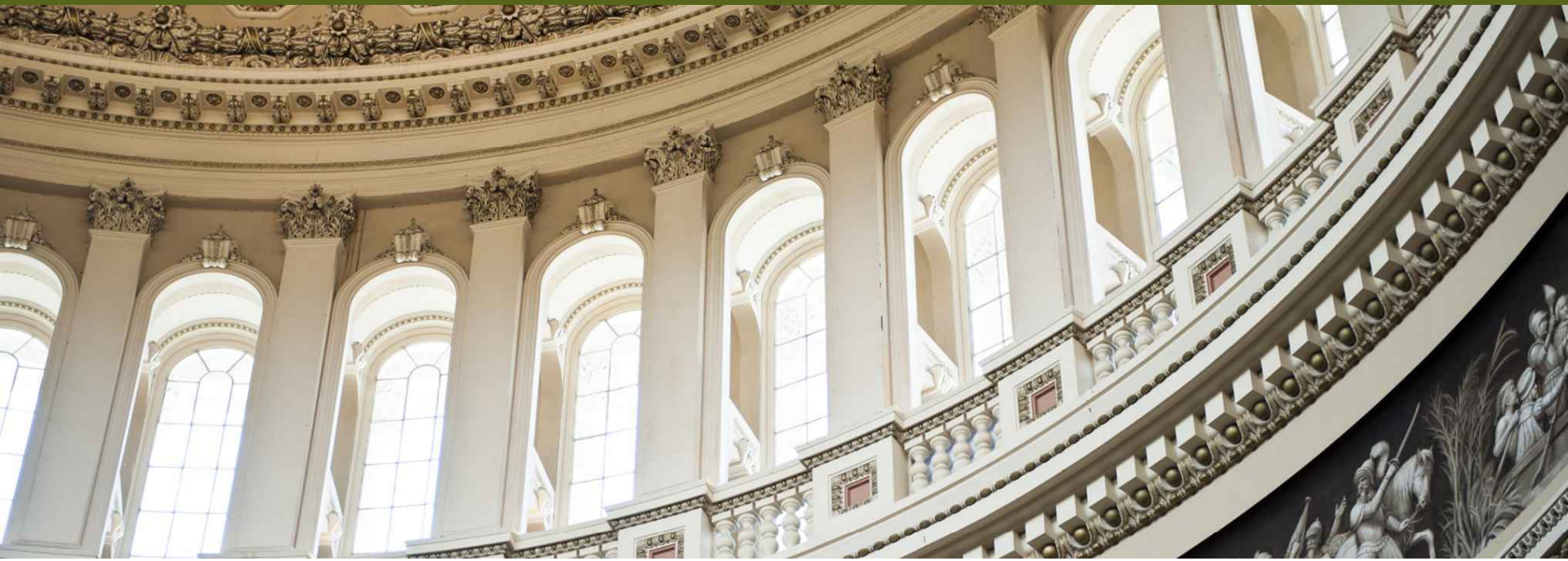


Policies to Battle the Opioid Epidemic: Current and Future Efforts

Alicia Macklin & Monica Massaro

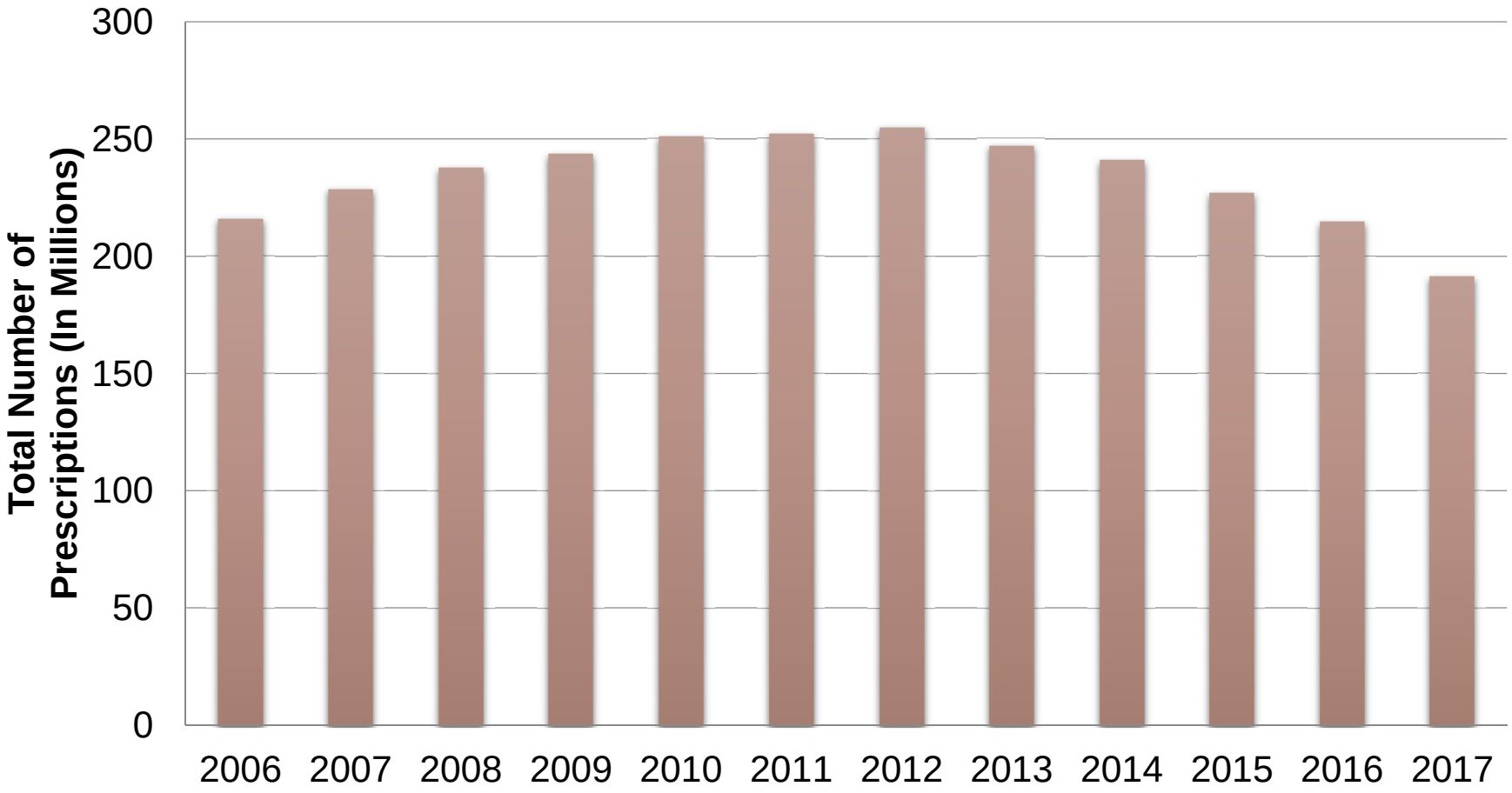
"The ongoing opioid crisis lies at the intersection of two substantial public health challenges – ***reducing the burden of suffering from pain and containing the rising toll of the harms*** *that can result from the use of opioid medications."*

Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use; National Academies of Sciences, Engineering, and Medicine, 2017.

How Did We Get Here?

- **Liberalization of Opioid Prescribing**
  - Changes to pain management
  - Emergence of standards recommending improvement of pain scores
  - Aggressive marketing
  - Limited provider time and resources
  - Limited coverage for non-opioid therapies
- **Pressure to Address Opioid Crisis**
  - Growing public awareness
  - Medical and policymaking organizations urge caution
  - Federal and state regulatory action

Total number and rate of opioid prescriptions dispensed, United States, 2006-2017



Data from Centers for Disease Control & Prevention (CDC): https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

Containing Rising Toll of Harms

SUPPORT for Patients and Communities Act

H.R. 6 – 115th Congress (2017-2018)

One Hundred Fifteenth Congress
of the
United States of America

AT THE SECOND SESSION
Begun and held at the City of Washington on Wednesday,
the third day of January, two thousand and eighteen

An Act

To provide for opioid use disorder prevention, recovery, and treatment, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT for Patients and Communities Act".

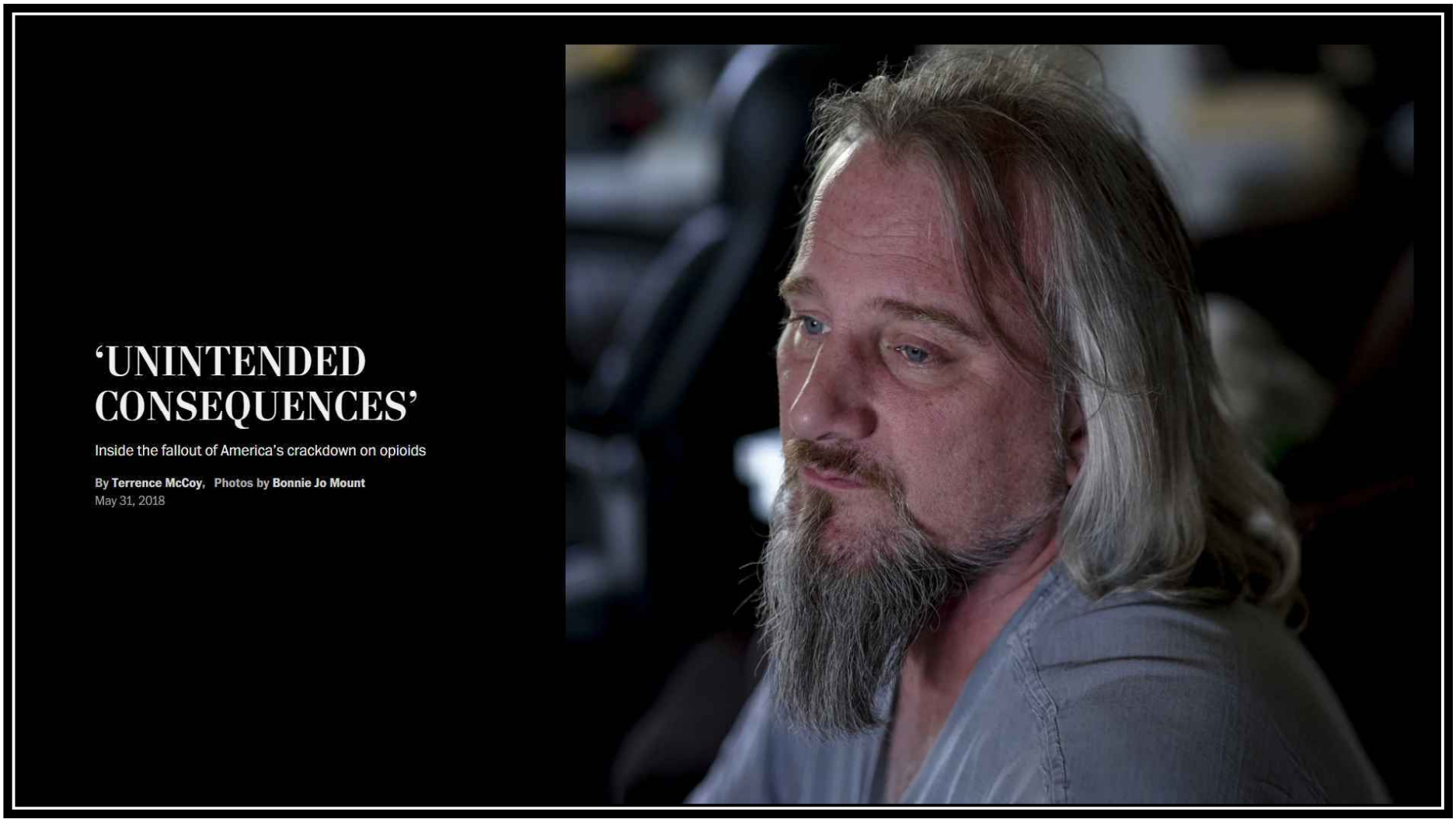
Highlights of the SUPPORT Act

- Expanded Access to Medication Assisted Treatment
- Partial Repeal of IMD Exclusion
- Best Practices for Recovery Residences
- Expanded Potential for Telemedicine
- All-Payor Drug Anti-Kickback Law

SUPPORT Act – Care Coordination and Privacy

- Did **not** align substance use treatment privacy law with the HIPAA privacy rules
- **Striking the right balance –**
  - Sharing substance use disorder information
  - Protecting patient privacy
- **Future regulatory movement?**
  - HIPAA Request for Information (December 14, 2018)
  - SAMHSA proposed rulemaking on broad changes to Part 2 (Expected March 2019)
    - Remove barriers to coordinated care
    - Permit additional sharing of information among providers

Chronic Pain Management



Source: T. McCoy, Unintended Consequences: Inside the fallout of America’s crackdown on opioids, The Washington Post, May, 31, 2018.

HHS 5-Point Strategy To Combat the Opioid Crisis

1

Better addiction prevention, treatment, and recovery services

2

Better data

3

Better pain management

4

Better targeting of overdose reversing drugs

5

Better research

Source: *https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html*

Pain Management Best Practices Inter-Agency Task Force Draft Report

- **Mission of Task Force**:
  - Determine whether there are gaps or inconsistences between best practices for pain management
  - Propose updates to best practices and recommendations to Congress to address such gaps and inconsistences.
- **Common Barriers and Obstacles to Best Practices for Pain Management**
  - Stigma: Patients and Providers
  - Lack of Education
  - Workforce
  - Research
  - Access to Care: Regulatory/Legislative Limits; Medication Shortages; Coverage Issues

Draft Report available at: https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html

Payment and Access Issues for Non-Opioid Treatment

Evidence Based Non-Opioid Treatment Options

- **Consistent focus on gaps in non-opioid treatment**
  - Previous policies have neglected both acute and chronic pain management
  - Coordinated and collaborative care is integral
  - Must eliminate barriers to access and coverage of non-opioid treatment options
  - Changes must align with current evidence based practice/clinical practice guidelines
  - Best practice may differ by population, setting and specialty
- **Multidisciplinary approach with varying aspects of care:**
  - Non-Opioid Medications
  - Restorative Movement Therapies
  - Interventional Procedures
  - Complementary and Integrative Health
  - Behavioral health/psychological interventions
- **Adequate reimbursement is necessary to account for physician time**

Access to Non-Opioid Medications

- **Task Force Recommendation (Section 2.2- 2a):**
  - Use of nonopioid medications (e.g., oral and IV acetaminophen, oral and IV NSAIDs, long-acting local anesthetics, dexmedetomidine), with nonpharmacologic treatments, should be used as first-line therapy whenever possible in the in-patient and out-patient settings.
  - **Considerations:**
    - Must have coverage and timely access
    - Copays can be a barrier to access even if these are covered
    - Must include risk assessment and proper monitoring
    - Stakeholders have pushed back, that physicians lack reimbursement, creating unintended incentives to opioid prescribing in post-surgery and chronic pain
- **Task Force Recommendation (Section 2.2- 4b):**
  - Provide coverage and reimbursement for buprenorphine treatment approaches
  - **Noted challenge by physicians in getting authorization for pain**

Promoting Nonpharmacologic Approaches

- **Nonpharmacologic Response: Physical and occupational therapy**
  - CDC and others have recognized this, updating their opioid prescribing guidelines that non pharmacologic therapy is preferred for chronic pain
  - Can be used as the primary pain treatment or in conjunction with other treatment
- **Task Force Recommendation (Section 3.3.2-4a):**
  - *Payors should reimburse pain management using a chronic disease management model.* CMS and private payors should reimburse integrative, multidisciplinary pain care by using a chronic disease management model in the manner they currently reimburse cardiac rehabilitation and diabetes chronic care management programs. In addition, reimburse care team leaders for time spent coordinating patient care.
- **Challenges remain:**
  - Workforce shortages in rural and underserved areas must be addressed
  - Education of primary care providers on nonpharmacologic options can promote referral to proper provider when appropriate

CDC's Guideline for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf

Draft 2020 Medicare Advantage and Part D Call Letter Proposes Opioid and Pain Policies

- **Non-Opioid Pain Management Supplemental Benefits**
  - Peer support services and cognitive behavioral therapy
  - Non-Medicare covered chiropractic services
  - Acupuncture
  - Therapeutic massage
- **Improving Access to Opioid-Reversal Agents**
  - Lower beneficiary cost-sharing (i.e., copays or coinsurance) for naloxone
  - Co-prescribing of naloxone when clinically appropriate
- **Improving quality metrics to track trends in Medicare Part D opioid overuse**
  - Implement the revised PQA opioid overuse measures that better align with the CDC Guideline for Prescribing Opioids for Chronic Pain
- **Comments due March 1, final 2020 Rate Announcement published by April 1**

Data Tracking to Inform Policy

- **MedPAC Report to Congress March 2019 on three items:**
  1. How Medicare pays for opioids and non-opioid alternatives in inpatient and outpatient settings;
  2. Incentives under the PPS for prescribing opioids and non-opioids; and
  3. How Medicare tracks opioid use
- **They found:**
  1. Limited data on what hospitals pay for drugs and the amounts they prescribe, indicating no clear signal that incentives exist (for opioids or alternatives)
  2. CMS does not operate opioid tracking in Part A & B, only through data available in the Part D Program
- **They will likely look into recommendations such as:**
  1. Requiring prescription drug event (PDE)-type reporting in hospitals
  2. Requiring hospitals to report prescribed drugs on Part A and Part B claims
  3. Incorporate opioid use disorder (OUD) in CMS' Hospital-Acquired Condition Reduction Program
- **Prescribing practices will continue to be scrutinized**
  - Facilities and providers should be prepared with policies and procedures

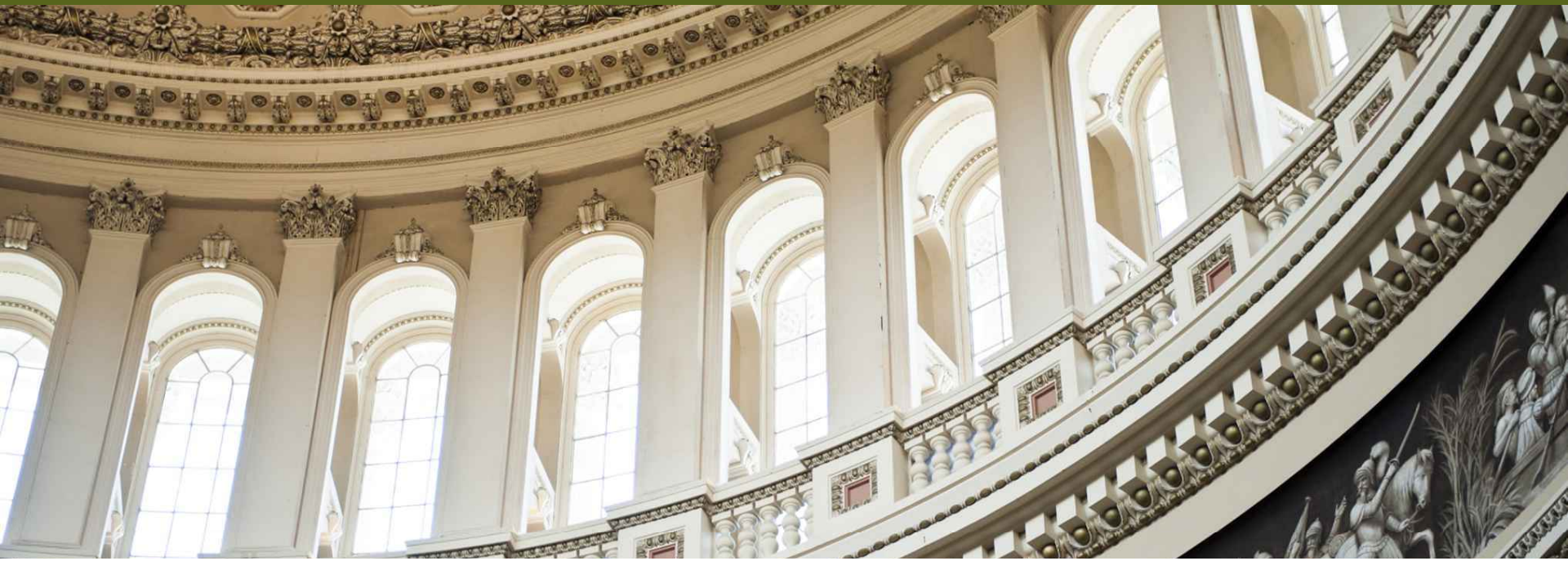
What’s Next

Policy Opportunities in 2019 and Beyond

- Will there be an appetite for a bipartisan Opioid 2.0 in Congress this year?
  - 42 CFR Part 2 depending on the progress of agency rulemaking
- Funds for the opioid epidemic continue to be necessary
  - In recent years, the epidemic has continued to receive increased funding
  - “Easy bipartisan issue” to add as a sweetener to other legislative efforts in the future
  - Has been compared to funding for the Ryan White HIV/AIDS Program
  - Funding tends to focus on grants for programs to contain harms, not addressing prevention
- March & May recommendations to Congress expected, followed by hearings
- Expect opioid and pain treatment being addressed in 2020 payment rules
- CMS's National Committee for Quality Assurance (NCQA) measures
- State level action happening simultaneously

HLB
HOOPER, LUNDY & BOOKMAN, PC
HEALTH CARE LAWYERS & ADVISORS

Presented by
Hooper, Lundy & Bookman, P.C.



The National Symposium on Health Law and Policy

Issues in Health Care: Payor Perspective

Keith Fontenot, Executive Vice President of Policy and Strategy

America's Health Insurance Plans

Keith Fontenot

EVP, Policy and Strategy, AHIP

February 11, 2019
Laguna Niguel, CA

Who is AHIP?

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage and health-related services that **improve and protect the health and financial security of consumers, families, businesses, communities and the nation**.

2019 AHIP Priorities

Medicare Advantage & Part D

Advocate and defend the benefits, services, and value MA/Part D deliver to seniors, people with disabilities, and taxpayers.

High-Priced Drugs

Focus attention on the consequences of out-of-control prescription drug prices and advocate solutions that lower costs.

Value of Private Plans

Demonstrate the value we deliver to consumers and patients every single day.

Taxes

Fight to delay, reduce, or repeal the taxes, fees, and assessments that raise premiums and costs for consumers.

Medicaid Managed Care

Promote managed care as a solution that serves the people who depend on it and the taxpayers who fund it.

Affordable Care Act Coverage

Advocate for solutions to deliver strong, stable markets and affordable choices for consumers.

Employer Coverage & Supplemental Protection

Promote the strength and stability of the coverage and benefits that Americans get through their jobs.

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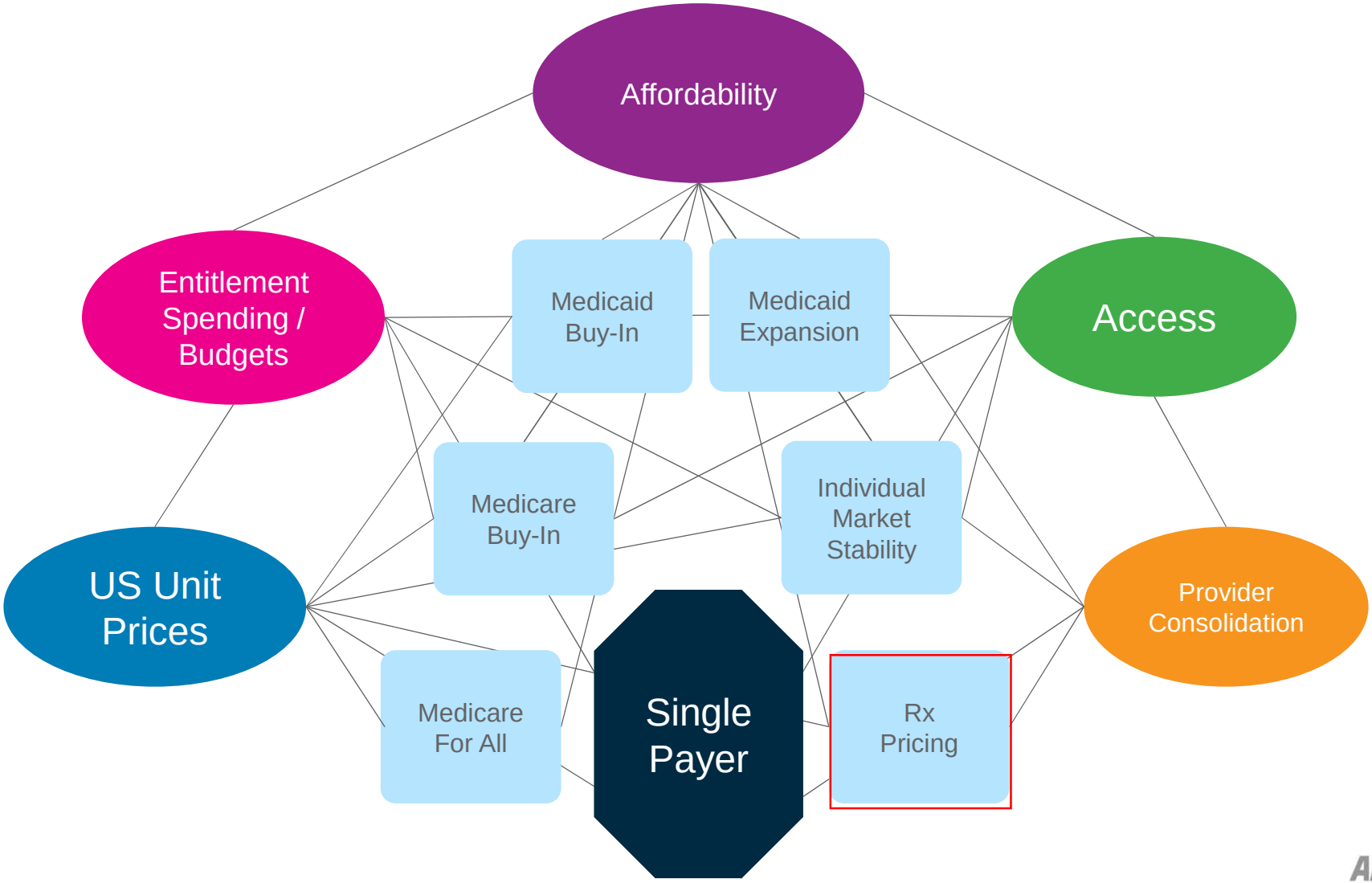
Connected Issues Drive Health Care Debate



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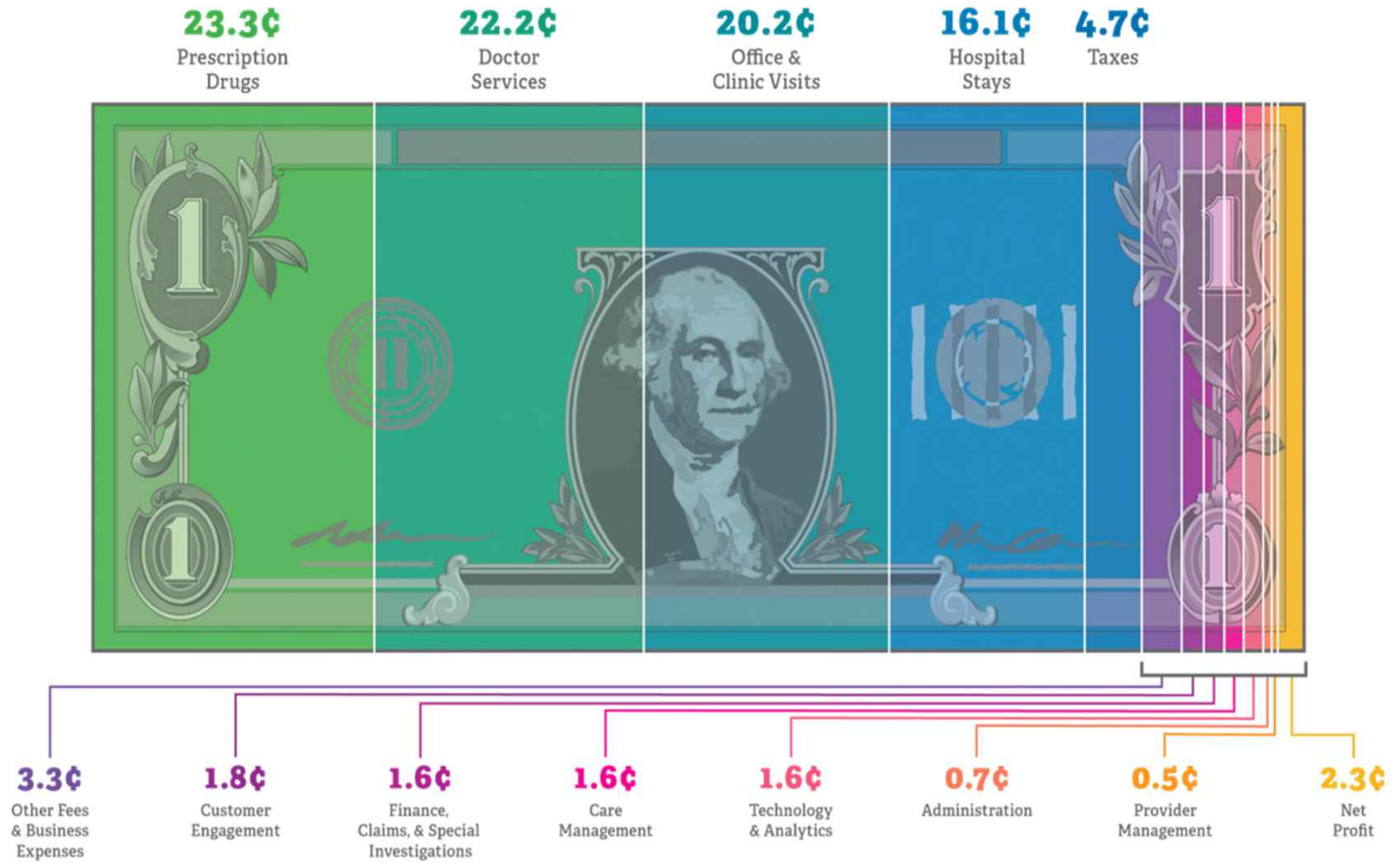
Where Does Your Health Care Dollar Go?



Source: https://www.ahip.org/wp-content/uploads/2017/03/HealthCareDollar_FINAL.pdf

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Where Does Your Health Care Dollar Go?

- **23.3¢ on Prescription drugs**—payments for outpatient prescription drugs and for prescription medicines administered in a physicians office or clinic
- **22.2¢ on Physician services—**payments for all non-drug related inpatient and outpatient services provided by a physician
- **20.2¢ on Office and clinic services—**payments for all non-drug related outpatient services provided—excluding physician services
- **16.1¢ on Hospital stays—**payments for all services provided during a hospital stay, including the administration of prescription drugs, but excluding payments to physicians

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Health Insurance Markets and Populations

Medicaid

66 million

(Source: CMS 2018)

Individual Market and Exchanges

18 million

(Source: HHS, 2016)

Employer Sponsored

155 million <65yo

(Source: CNBC, 2016)

CHIP

6.5 million Children

(Source: CMS 2018)

TRICARE

9.4 million

(Source: DoD 2015)

FEHB

8.3 million

(Source: OPM 2018)

Medicare

64 million

(Source: CMS 2019)

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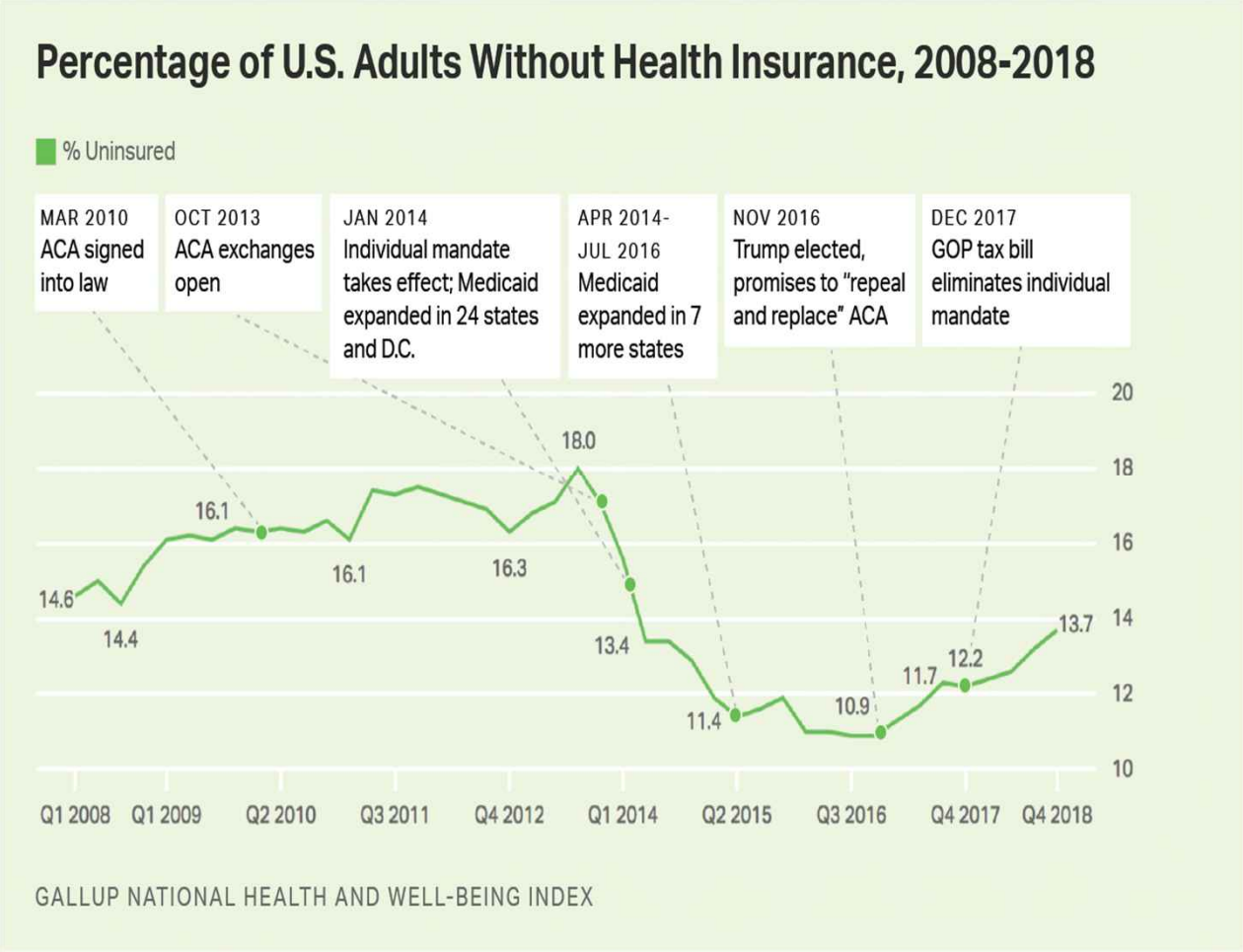
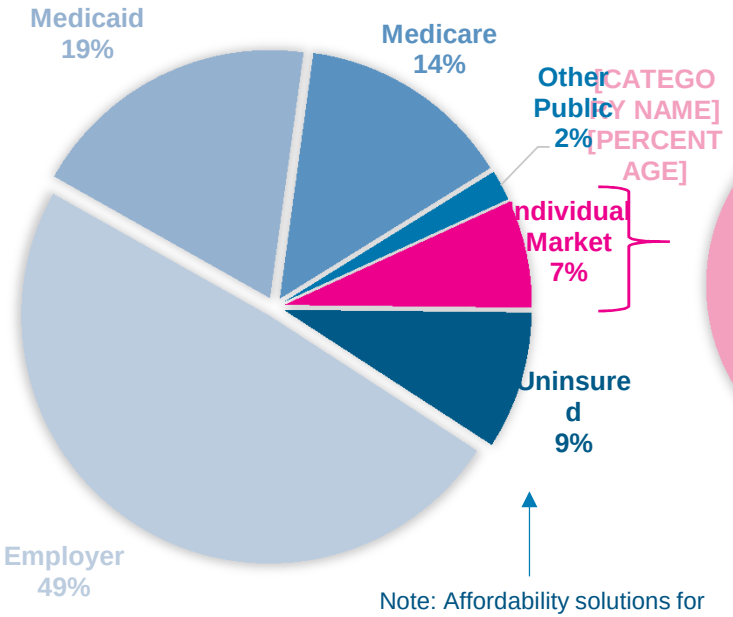
U.S. Uninsured Rate Has Risen

The uninsured rate in the United States recently increased to 13.7 percent. (Gallup)



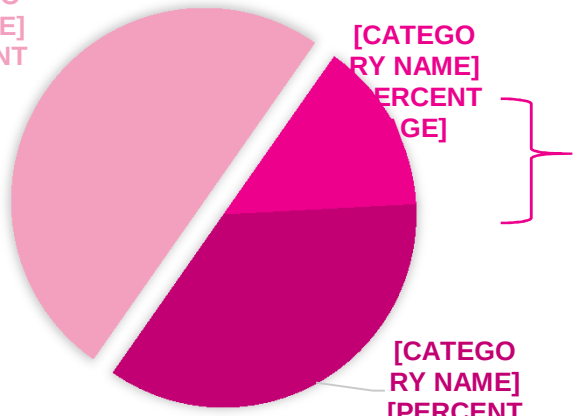
Individual Market Premium Affordability

COVERAGE SOURCE
(APX. 320 MILLION PEOPLE)



Note: Affordability solutions for those making >400% FPL may also help approximately 3.9 million uninsured people with income >400% of FPL.

INDIVIDUAL MARKET
(APX. 18 MILLION PEOPLE)



Note: Thorough data is not available on how many of these individuals continue to be insured in the individual market off-exchange going into the 2019 plan year.

Approximate number of Americans who buy their own insurance with no help with premiums

8 million

Policy Developments and Premiums

Policy Levers that Can Increase or Decrease premiums	Potential Impact on Individual Market Premiums[i]	Known	Unknown
Individual Mandate	**(+) 3-10%**	Repealed 2019	State mandates and long term impact
Cost-Sharing Reductions	**(-) 20%** on average **(-) 7-38%** for silver plans	Not funded as of 10/17, "silver-loading" strategies in place in most states	CMS Request for comment about silver loading in 2021 and beyond
Reinsurance	**(-) 4-12%**	In place in a limited number of states, no national reinsurance program	Limited number of states with 1332: Implemented: AK, OR, MN, NJ, ME, MD, WI,…
Health Insurer Tax	**(-) 3%**	2019 Moratorium	Future relief for 2020 and beyond
Association Plans	**Expected increase**	Goal is to significantly expand availability of association plans	Full impact on individual and small group markets
Short Term Plans	**Expected increase**	Final Rule	Attractiveness to existing exchange enrollees versus currently uninsured.
Medical Trend	**6%**	2018 claims experience	2019 medical trend

[i] Estimated 2019 premium impacts: individual mandate—5% chosen for AHIP data work as a conservative estimate, based on recent analysis estimating an impact of between 3-10% (Wyman); CSRs (CBO and KFF); reinsurance – 12% chosen for AHIP data work based on $15 billion in reinsurance funding, based on recent analysis estimating an impact between 4-12% depending on program type and funding amount (Avalere); HIT (Wyman); and medical trend (PWC).

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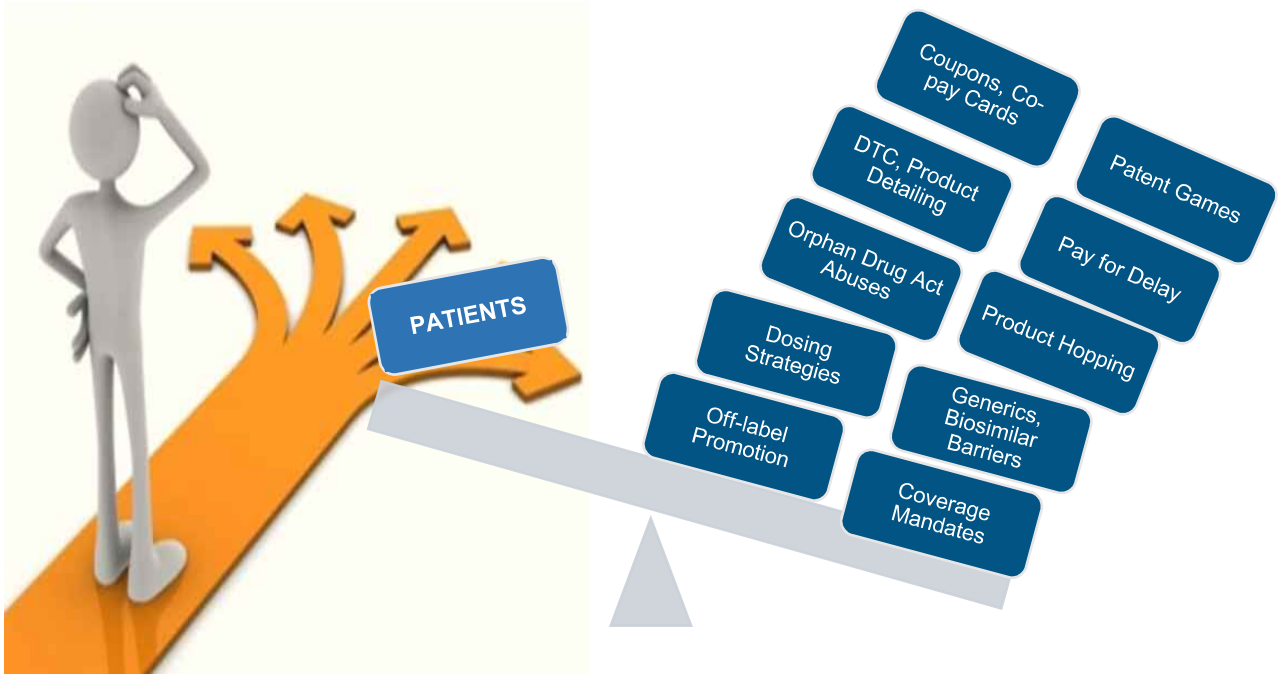
2020 NBPP Proposed Rule

- New flexibility regarding prescription drugs:
  - Permits Mid-year formulary changes in the case of a new generic
  - Permits classification of brand name drugs as “non-EHB” when a medically appropriate, generic drug is available and only count cost of generic drug towards out of pocket max
  - Permits plans to not count drug manufacturer coupons towards out of pocket max
- Modifies premium adjustment percentage
  - Changes how the Administration would measure “premium growth,” which is part of the formula for adjusting the applicable percentages, the maximum out-of-pocket limit, the ACA’s employer mandate penalty, and certain other ACA policy parameters
  - Under prior policy was based on employer market, proposing to incorporate individual market premiums
  - CMS estimates $900M less spent on premium tax credits and a 100,000 reduction in enrollment
- Seeks comment on the need to auto-reenrollment and CSR silver loading. Any policy changes effective for the 2021 plan year

An Unbalanced Pharmaceutical Market

Competition → Transparency → Value



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Growing and Unsustainable Rx Spending

U.S. spending on prescription medicines is projected to reach over $600 billion in 2021

$610 billion (2021)

$450 billion (2016)

$330 billion (2013)

Source: Medicines Use and Spending in the U.S. – A Review of 2016 and Outlook to 2021, IMS Institute

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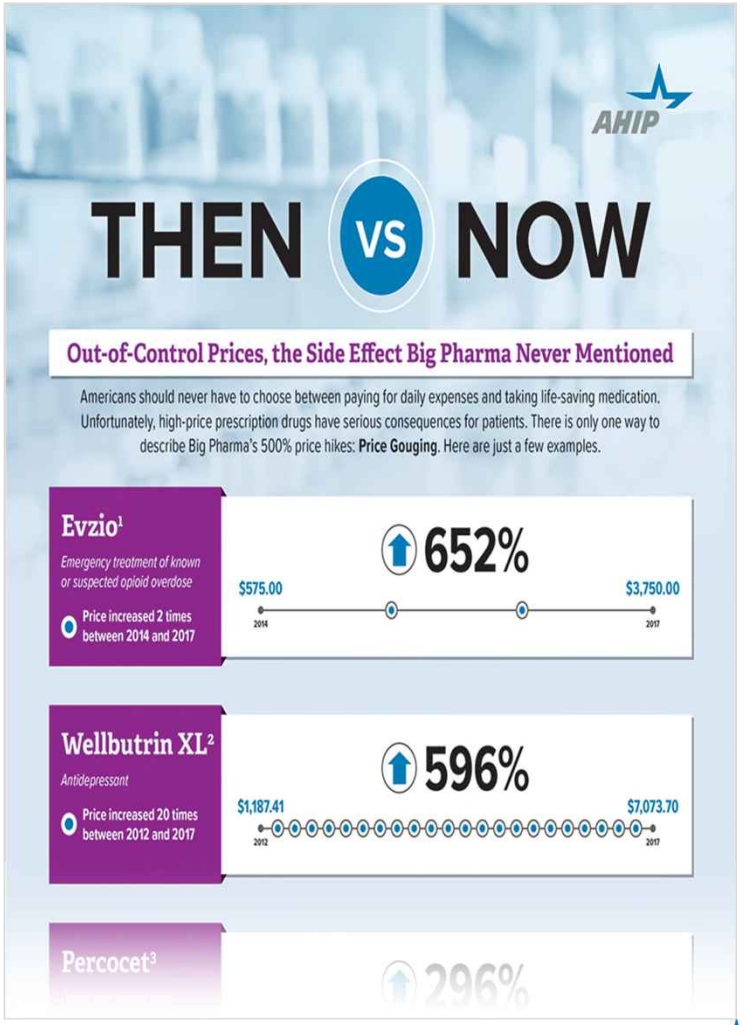
Price Increases for Brand Name Drugs

Brand Name Drug	Percentage Price Increase since 2014 (Cumulative)
Evzio	652%
Wellbutrin XL	596%
Percocet	296%
Humira	248%
Enbrel	245%
Byetta	229%
Rebif	215%
Avonex	193%



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Significant Interest in New Congress to Curb Drug Prices -- Some Have Potential for Bipartisan Support

Promote Generic and Biosimilar Drug Competition

(CREATES, Pay-for-Delay)

Import Cheaper Brand Name Drugs from Other Countries

Direct Medicare Negotiation with Manufacturers to Lower Drug Prices in Part D

Cap patient out-of-pocket drug costs in commercial plans and Part D

Bolder ideas

(Benchmark drugs in U.S. to foreign prices, curtail or eliminate drug patents/market exclusivity)

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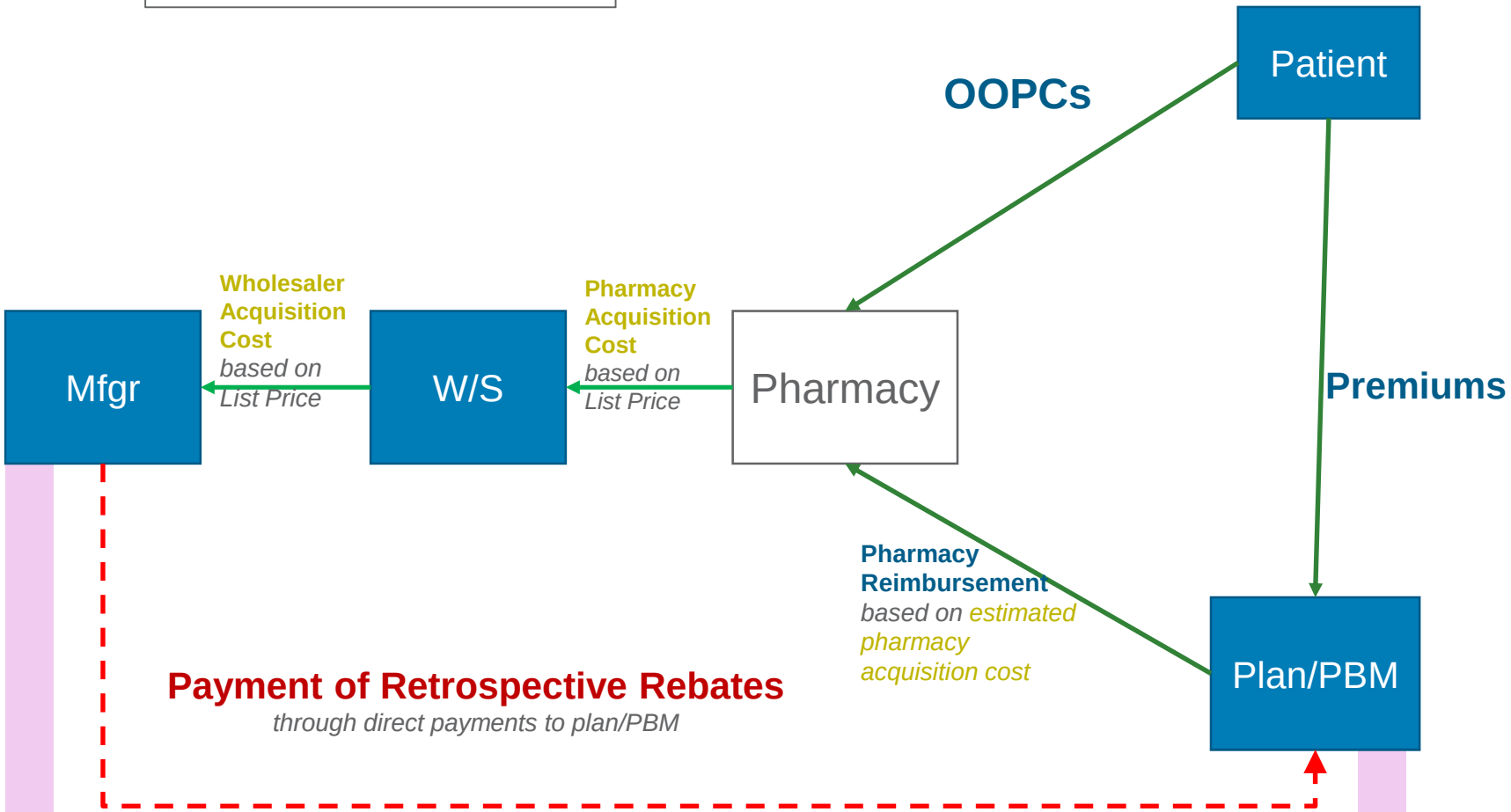
Paying for Prescription Drugs

Current Structure



PLAN/PBM NEGOTIATES WITH DRUG MANUFACTURERS FOR A REBATE AMOUNT

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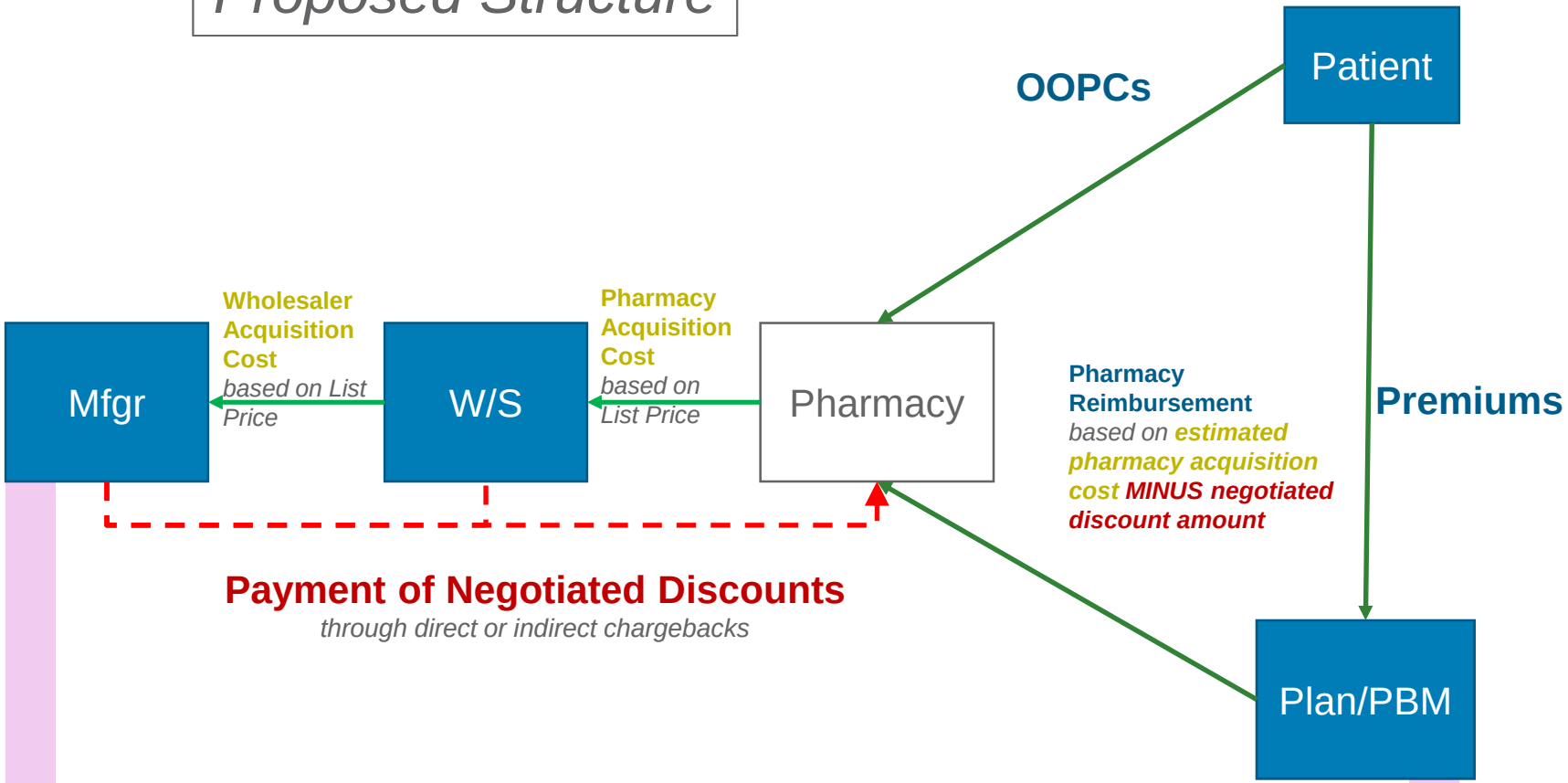
Paying for Prescription Drugs

Proposed Structure



PLAN/PBM NEGOTIATES WITH DRUG MANUFACTURERS FOR A DISCOUNT AMOUNT

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Estimated Impacts of Proposed Safe Harbor Regulation

Table 1: Estimated Payer Costs (+) or Savings (−) for Calendar Years 2020-2029 in Billions

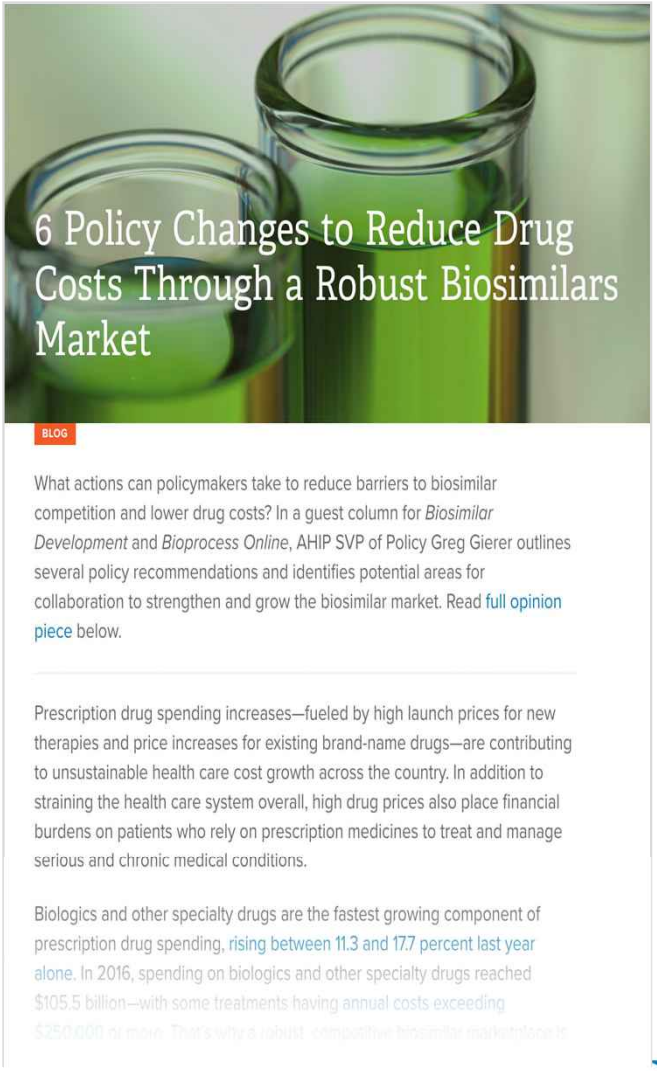
Calendar Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2020-29
Total Drug Spending (NHE)	**$10.2**	**$10.3**	**$10.9**	**$11.2**	**$12.8**	**$13.9**	**$15.0**	**$16.1**	**$17.5**	**$19.0**	**$137.0**
Household	**−2.5**	**−2.9**	**−3.2**	**−3.6**	**−4.1**	**−4.4**	**−4.8**	**−5.4**	**−5.9**	**−6.4**	**−43.3**
Out-of-Pocket (OOP)[1]	−5.3	−6.2	−7.2	−7.9	−8.8	−9.5	−10.5	−11.6	−12.7	−13.6	−93.2
Premium	2.7	3.2	3.9	4.3	4.7	5.1	5.7	6.1	6.8	7.3	49.9
Federal Government	**13.5**	**14.3**	**15.3**	**16.1**	**18.4**	**20.0**	**21.6**	**23.5**	**25.6**	**27.8**	**196.1**
State Government	**−0.1**	**−0.2**	**−0.2**	**−0.3**	**−0.4**	**−0.4**	**−0.5**	**−0.6**	**−0.6**	**−0.8**	**−4.0**
Private Business	**−0.7**	**−0.8**	**−0.9**	**−1.0**	**−1.2**	**−1.2**	**−1.3**	**−1.4**	**−1.5**	**−1.7**	**−11.8**

[1] Includes spending paid directly by the consumer at the point-of-sale.

Note: Totals do not necessarily equal the sums of rounded components.

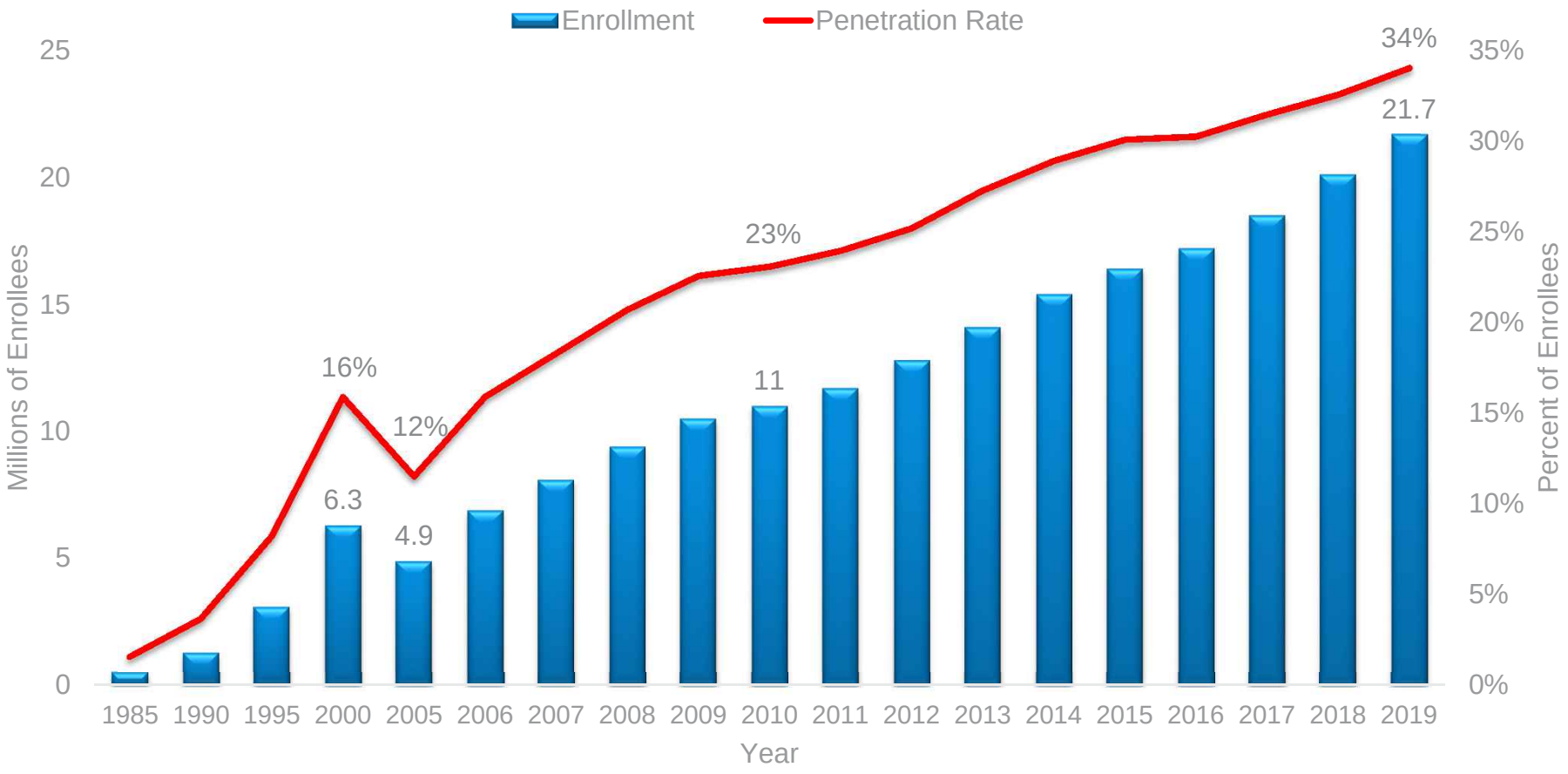
Public Policy Changes to Ensure A Competitive Biosimilars Market

- Encourage competition and innovation
- Shorten the exclusivity period for biologics to promote greater price competition and earlier access to biosimilars
- Remove barriers at the state level that restrict the use and approval of biosimilars
- Prohibit abuse of the patent process
- Reform reimbursement for Medicare Part B covered drugs
- Expand funding and research on treatment effectiveness
- Interchangeability



Medicare Advantage

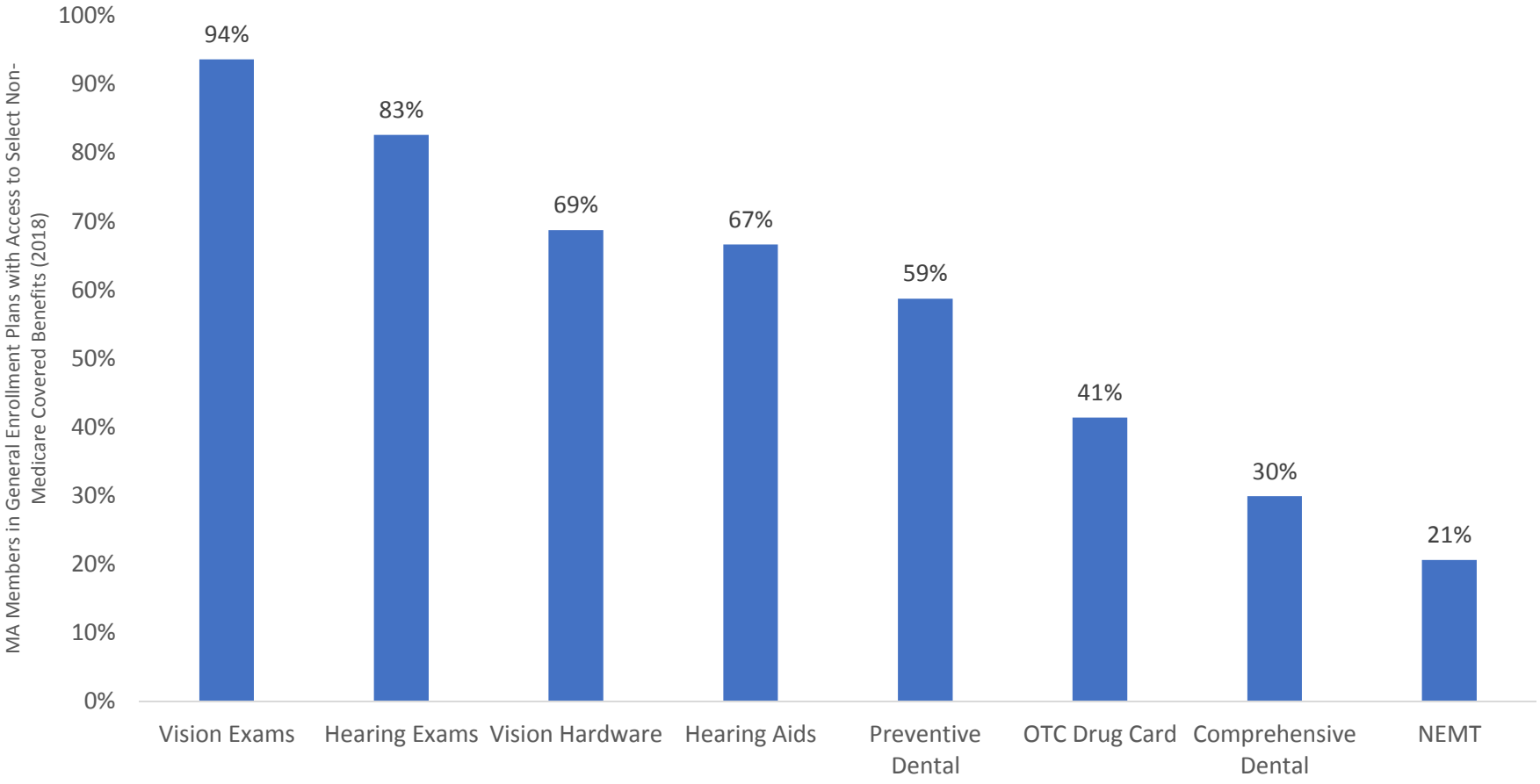
State of the Program



Key MA Elements for Beneficiaries

- Out-of-pocket cap
- Most MA plans offer a consolidated package of health and prescription drug coverage
- Over half of enrollees are in MA plans that offer drug coverage for no additional premium
- Plans offer additional (or “supplemental”) benefits for items and services not covered by Medicare
- Plans provide disease management and care coordination

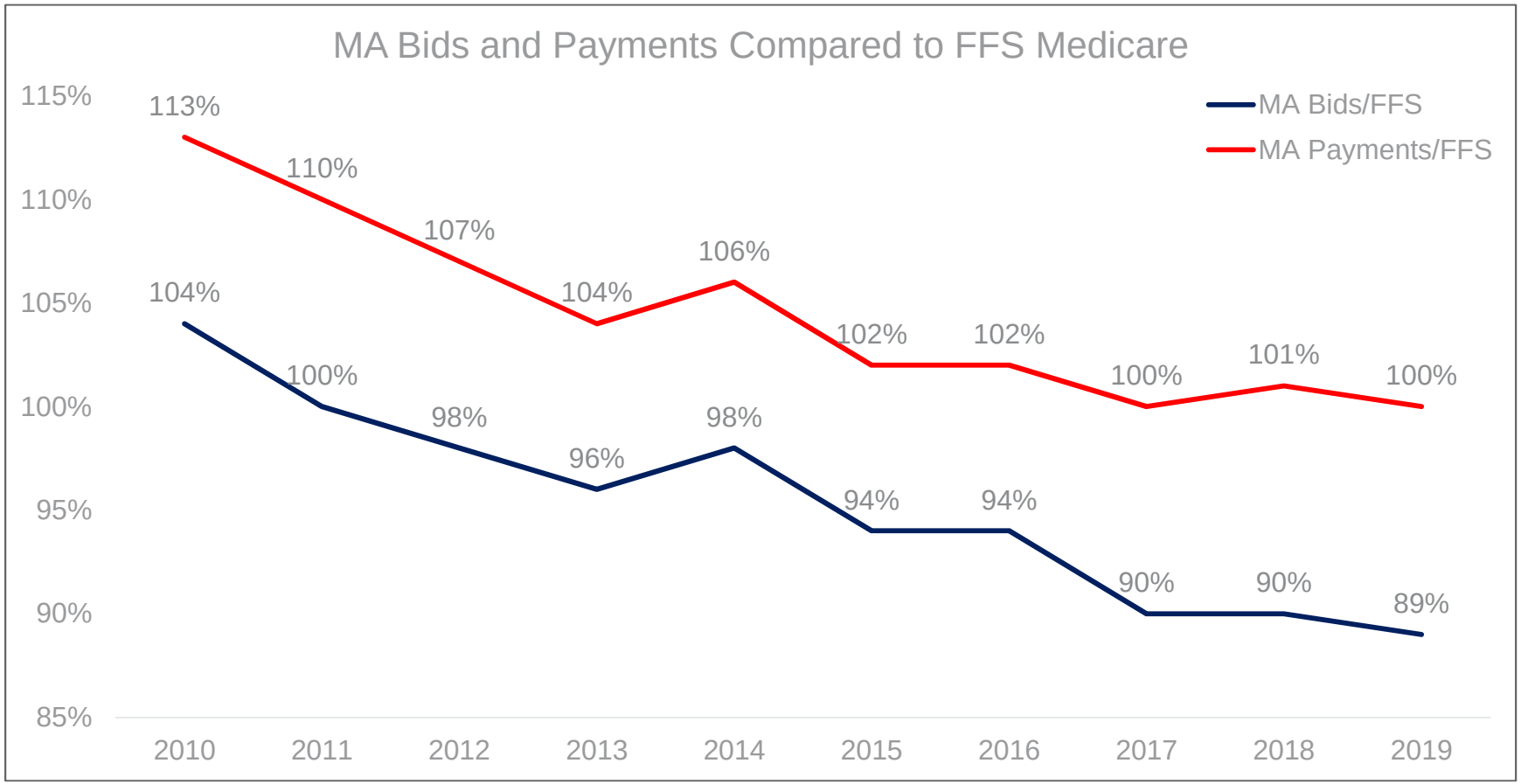
Common Supplemental Benefits



MA v FFS: Quality

- A recent study found MA outperforms FFS on 16 of 16 quality measures
- MA enrollment growth is associated with slower cost growth in FFS Medicare, saving taxpayers' money
- Satisfaction rates are 90%
- New research has shown MA enrollees recovering from hip fractures spent nearly a week less in nursing facilities after hospital discharge compared to FFS, and were less likely to be readmitted to the hospital
- Additional research has shown that more than half of MA enrollees make annual preventive care visits to their doctor, compared to just one-third in FFS

MA v FFS: Gov't Cost



Single Payer, Medicare For All

- Medicare-for-All proposals offer few details, and mean different things to different audiences
- Health care works for hundreds of millions of Americans
- One-size-fits-all, single-payer models mean the federal government would have control over health care – not patients
- Single payer means eliminating choice and raising costs, and further politicizing health care at a time we need real solutions
- Implications for Providers - Commercial reimbursement rates are 200% higher than Medicare FFS

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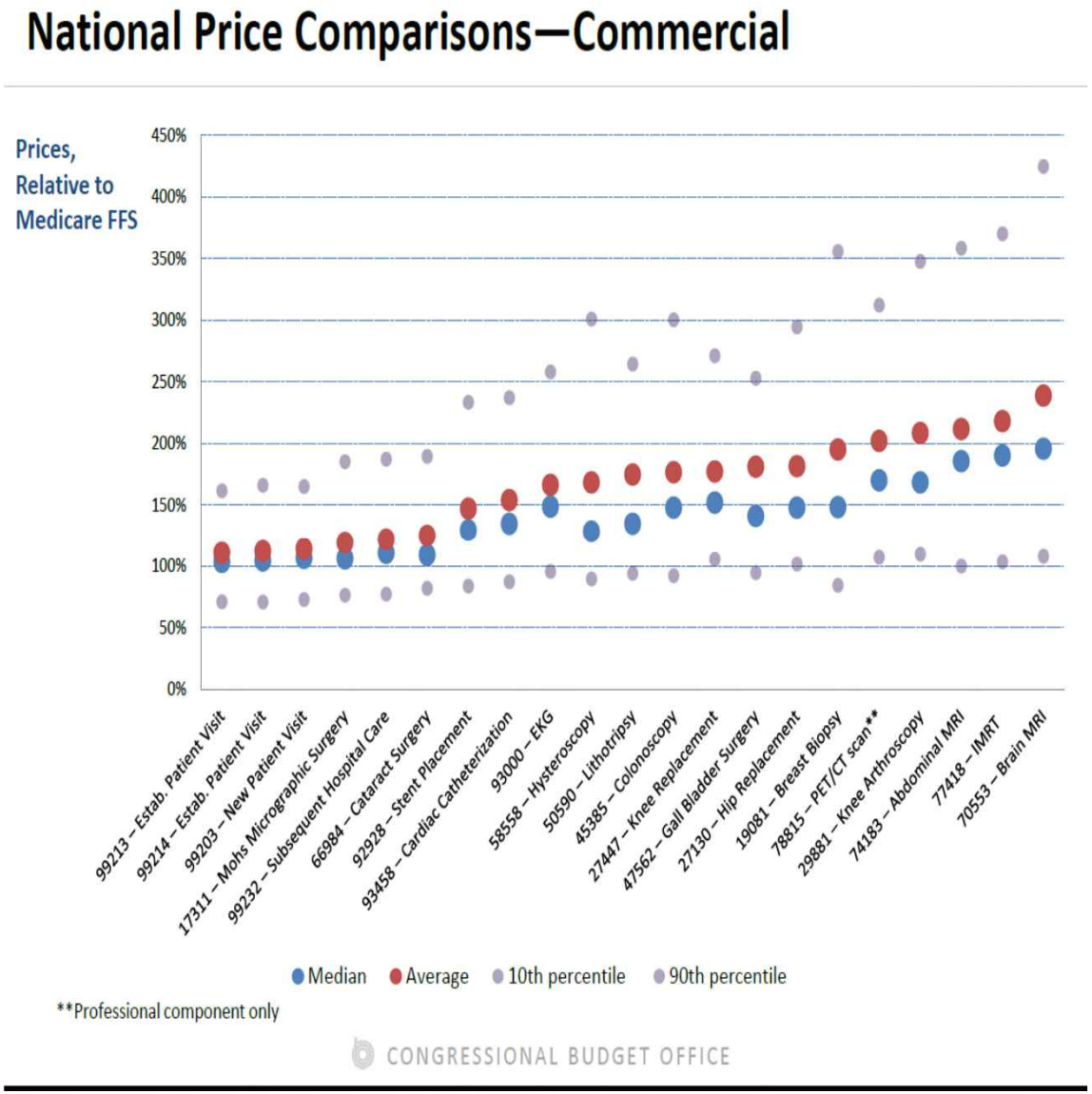
Commercial Price – 1.7 – 2.6 Times Medicare



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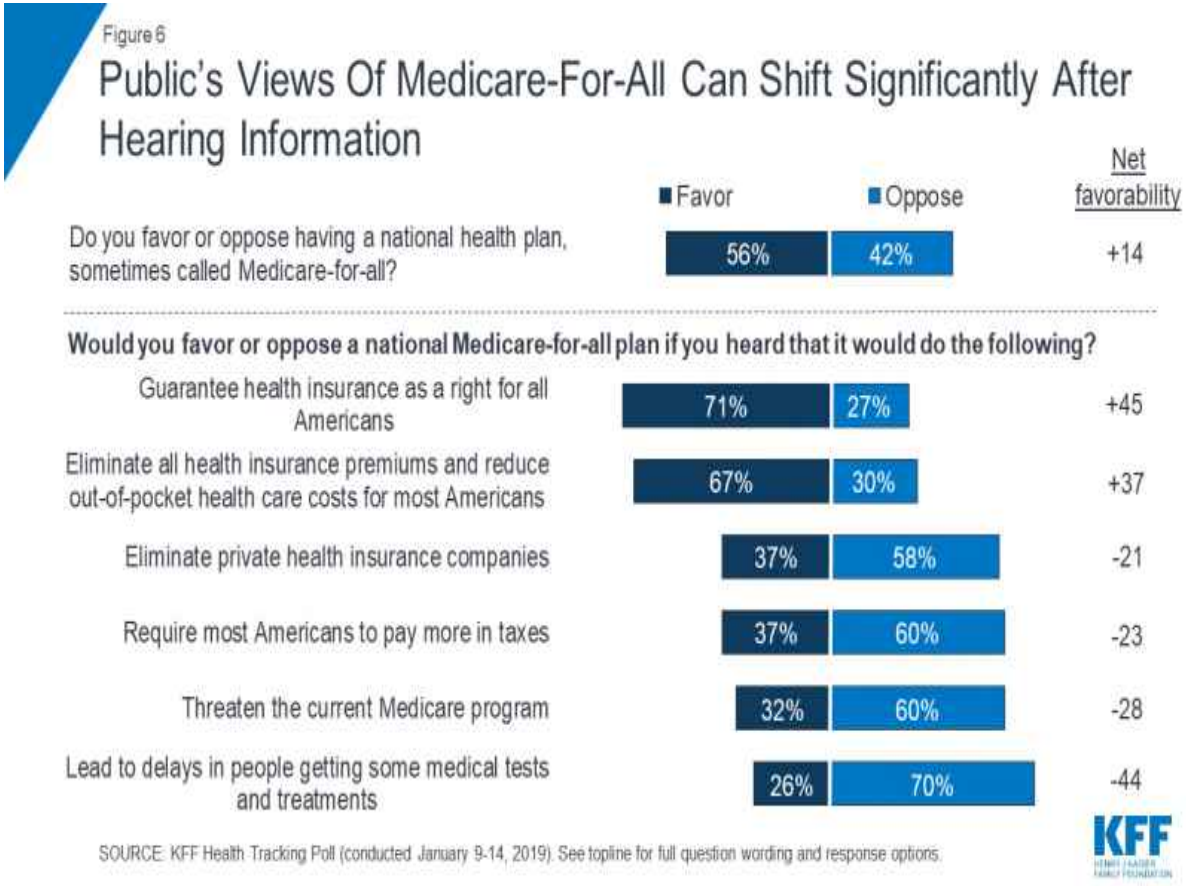
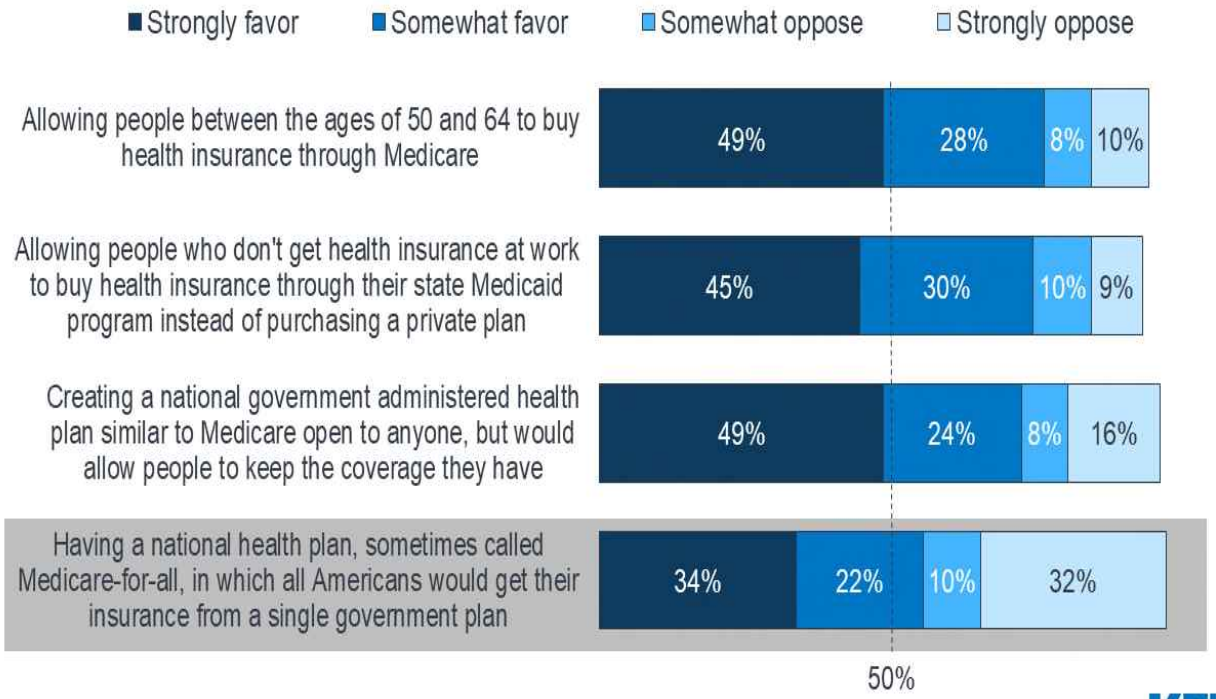
Public's Attitudes on Various Buy-in Proposals



Public's Attitudes on Proposals to Expand Medicare and Medicaid

Figure 4

Public's Attitudes On Proposals To Expand Medicare and Medicaid



SOURCE: KFF Health Tracking Poll (conducted January 9-14, 2019). See topline for full question wording and response options.

KFF
HENRY J KAISER FAMILY FOUNDATION

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Medicaid Buy-in

- States are looking to address:
  - Affordability
  - Bare counties
  - Health insurance provider competition
  - Unsubsidized population
  - Uninsured
- Allow people who are not currently Medicaid eligible levels to buy into a Medicaid plan

Plan Design and Benefits

- Wide range of benefits and little-to-no cost-sharing
- If on the Exchange, would need to be designed to meet QHP standards
- Off-Exchange not subject to the same coverage and rating requirements
- Sometimes income-related premium contributions beyond Medicaid current requirements

Program Implementation

- Political Support
- Regulatory Hurdles (i.e. 1115 waiver, 1332 waiver)
- Funding & Risk
- Health Care Provider Participation
- FFS vs. MCO
- Market Disruption
- State Medicaid Agency Capacity

Market Impact

- Could affect the risk pool or provider participation
- Off-Exchange could cause a significant number of people to leave the marketplace to purchase those plans
  - Could destabilize the pool and raise premiums
  - Could cause people to lose plans they currently have
- There is also the potential of cost-shifting from Medicaid buy-in plans to commercial market plans

Alternatives

Increase Enrollment/Improve the Risk Mix

- Marketing and outreach for those already eligible
- Promote continuous coverage
- Promote health and wellness/social determinants of health
- Protect non-medical, consumer-oriented benefits and services

Lower Costs for Consumers

- Promote state-based premium assistance programs
- State-based reinsurance (i.e. 1332 waiver)
- Tax Changes (i.e. Tax-deductible premiums, HSA flexibility)
- Promote lower list prices, transparency, competition, and value in prescription drug pricing
- Protect consumers from surprise out-of-network bills
- Curb inappropriate steering/third-party payments
- Support efforts to address over/under/misuse of goods and services – maximize health care dollars
- Support efforts to target fraud, waste, and abuse
- Expand telehealth, wellness programs, and other innovative approaches
- Eliminate taxes/fees that harm consumers and increase premiums

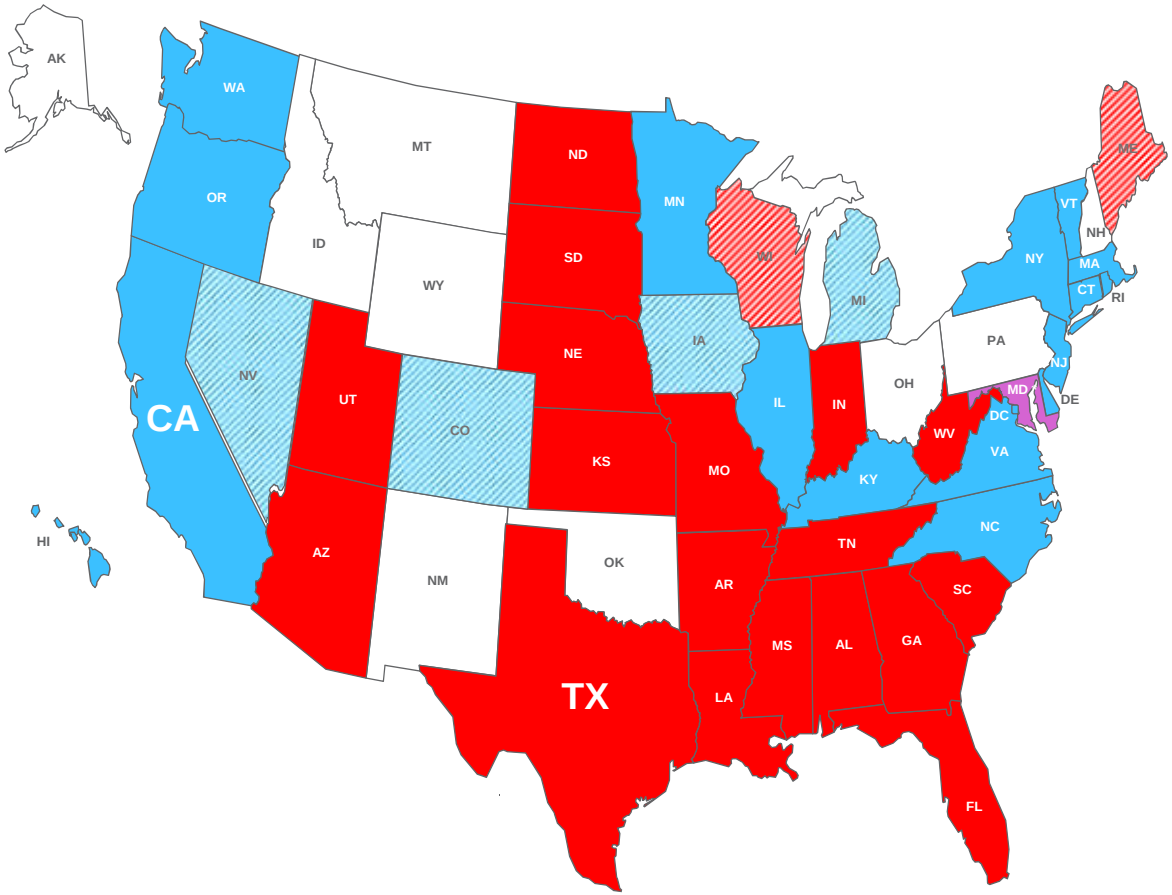
AHIP

Texas v. United States (ACA Litigation)

- Lawsuit challenging the constitutionality of the individual mandate, and the entire Affordable Care Act, filed in the federal district court of the Northern District of Texas
- District Court found the zeroed-out mandate penalty unconstitutional and invalidated all of the ACA
- Decision stayed pending resolution of appeal pending in the Fifth Circuit
- Government's failure to defend ACA in whole has led to intervention by California and 16 other states and pending motion by Democratic-led House
- AHIP amicus involvement at 5th Circuit
- 5th Circuit or Supreme Court as ultimate decider?

Texas v. United States (ACA Litigation)

Plaintiff and Intervening States



Plaintiff States
(18 states, 2 Governors):

TEXAS (lead state), Alabama, Arkansas, Arizona, Florida, Georgia, Indiana, Kansas, Louisiana, Maine (Paul LePage as Governor)*, Mississippi (Phil Bryant as Governor), Missouri, Nebraska, North Dakota, South Carolina, South Dakota, Tennessee, Utah, West Virginia, Wisconsin*

*ME & WI: Newly-elected Governors have signaled a desire to withdraw as Plaintiffs.

Intervenor Defendant States
(20 states and DC):

CALIFORNIA (lead state), Colorado*, Connecticut, District of Columbia, Delaware, Hawaii, Illinois, Iowa*, Kentucky, Massachusetts, Michigan*, Minnesota, Nevada*, New Jersey, New York, North Carolina, Oregon, Rhode Island, Vermont, Virginia, Washington

*CO, IA, MI, NV: Recently filed motion to join as Plaintiffs.

MARYLAND: Filed separate lawsuit (Maryland v US) asking court to validate the ACA – case dismissed without prejudice on 2/1.

AHIP

Texas V. US – Implications and Timeline*

- There is currently no impact as the decision has been stayed
- Timing of appeal and events beyond are uncertain
  - Responses to House intervention motion due Feb. 8, otherwise overall timing of appeal – including merits briefing – remains uncertain
  - CA-led states (and House) have asked to expedite the case – TX-led states and Fed. Gov. oppose
- May depend on Fifth Circuit's ultimate disposition
  - Decision that affirms district court's decision invalidating either ACA or even preexisting condition/community rating provisions (along with individual mandate) almost certain to be reviewed
  - Decision that overturns district court opinion on either constitutionality of individual mandate or severability from rest of ACA may not be reviewed
- Timing variable and dependent on lower courts
  - Possible that Supreme Court could review during October 2019 Term and issue decision by June 2020
  - Otherwise, review likely during October 2020 Term, with decision by June 2021

Current as of February 5, 2019

AHIP

Outlook

- Major legislative items:
  - FY 2019 funding
  - Budget Caps Deal
  - FY 2020 funding
- By Fall all thoughts turn to 2020
- Regulations continue…
- Surprise Billing
- Prescription Drugs

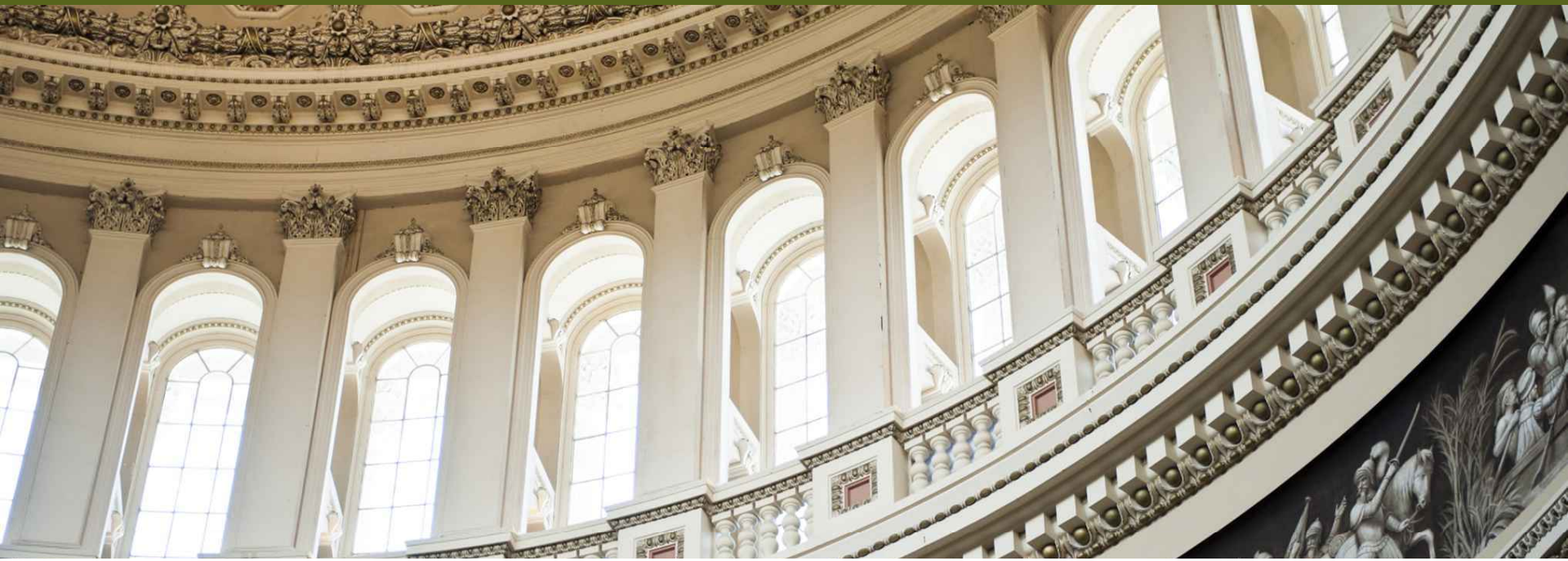
Issues in Health Care: Payor Perspective

Keith Fontenot
EVP, Policy and Strategy, AHIP

February 11, 2019
Laguna Niguel, CA

HLB
HOOPER, LUNDY & BOOKMAN, PC
HEALTH CARE LAWYERS & ADVISORS

Presented by
Hooper, Lundy & Bookman, P.C.



The National Symposium on Health Law and Policy

Speaker Biographies

Carmela Coyle

President & CEO
California Hospital Association

Carmela Coyle began her tenure as President & CEO of the California Hospital Association, the statewide leader representing the interests of more than 400 hospitals and health systems in California, in October 2017.

Previously, Coyle led the Maryland Hospital Association for nine years, where she played a leading role in reframing the hospital payment system in Maryland and moving to a value-based methodology. Maryland is now considered a national leader in health care policy and innovation.

Prior to 2008, Coyle spent 20 years in senior policy positions with the American Hospital Association (AHA), including 11 years as the senior vice president of policy, where she served as a national media spokesperson and led AHA's policy development and strategy planning activities. Earlier in her career, she worked for the Congressional Budget Office in Washington, D.C., advising members of Congress and their staff on the economic and budgetary implications of legislative policy.

CALIFORNIA HOSPITAL ASSOCIATION

1215 K Street, Ste. 800
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916.443.7401

AMERICA'S PHYSICIAN GROUPS

Taking Responsibility for America's Health

Donald H. Crane
President and CEO
America's Physician Groups

Don Crane is the President and CEO of America's Physician Groups, the nation's leading professional association representing medical groups and independent practice associations practicing coordinated care. It is the nation's largest trade association that explicitly promotes capitation as the payment model for its members, all of whom accept various forms of risk-based capitation or other population-based payment. These groups are in the forefront of the healthcare reform and represent the care model and payment methodologies adopted by federal legislation for the entire nation.

Mr. Crane has served as President and CEO of the organization since 2001. During his tenure America's Physician Groups has expanded from being a division of a regional hospital trade association consisting of 40 member groups to a national professional association consisting of nearly 300 physician organizations in 45 states, Washington, DC and Puerto Rico. Under Mr. Crane's leadership, America's Physician Groups has become a leading voice in federal and California advocacy.

America's Physician Groups' mission is to provide advocacy and education for physicians, and to lead the coordinated care movement across the nation. In that quest America's Physician Groups has embarked on an extensive educational effort to spread and scale the experience of its members in the delivery of risk-based coordinated care. This work involves tapping the acumen of the organization's members as faculty in a wide variety of educational programs, including conferences in California and Washington, D.C., and regional meetings in multiple locations around the country.

A seasoned healthcare attorney, Mr. Crane has served as corporate counsel for several major integrated health systems. Mr. Crane speaks regularly on healthcare issues to a wide variety of physician groups, hospitals, and other professional meetings. He is a

frequent guest lecturer on healthcare management issues to graduate students at major universities.

Mr. Crane serves on the Board of Directors of the National Coalition on Health Care. He is also the Editor-in-Chief of the *Journal of America's Physician Groups*, a magazine that reports on business trends, legislation, and industry initiatives impacting coordinated care.

In 2016 Mr. Crane received the prestigious Mathies Award for Vision and Excellence in Healthcare Leadership.

Mr. Crane received his B.A. from the University of California at Berkeley and his J.D. from Loyola University of Los Angeles.

Keith J. Fontenot

Keith J. Fontenot is the Executive Vice President for Policy and Strategy at America's Health Insurance Plans (AHIP), the national trade association representing the health insurance industry. He leads AHIP's policy development, regulatory, and research agenda for Federal programs (including Medicare Advantage, Part D, Medicaid and the Exchanges), as well as the individual, small group and employer sponsored markets, including supplemental coverages.

Mr. Fontenot brings to AHIP over three decades of expertise in policy development, regulatory and legislative work in health and income security programs, and the Federal budget. Prior to coming to AHIP he was Managing Director of Public Policy and Government Relations at Hooper, Lundy and Bookman, PC, and he also held positions as a Visiting Scholar in Health and in Fiscal policy at the Brookings Institution, and was a principal at Fontenot Consulting LLC.

He left government in 2013 after serving as the Associate Director for Health at OMB from 2009-2013, where he was responsible for managing policy and the budget for the nearly $1 trillion HHS budget for health-related programs, and was integrally involved in the development, negotiation and implementation of the Affordable Care Act. From 2007-2009 he was the Deputy Assistant Director for Health and Income Security at the Congressional Budget Office (CBO), where he guided CBO's efforts to prepare for possible health reform legislation, oversaw estimates of the costs of legislation, and led the development of innovative policy options for congressional consideration in health reform. Prior to that Mr. Fontenot held a number of senior positions in government, including: Chief of the Health Financing Branch at OMB, Deputy Associate Commissioner for Policy and Research at the Social Security Administration, and Chief of the Income Maintenance Branch at OMB. Mr. Fontenot holds a M.A. in public policy from Duke University, and a B.A. from the Old Dominion University.

Mark Parkinson

President & Chief Executive Officer

Mark Parkinson is the President and CEO of the American Health Care Association (AHCA), which represents over 13,600 skilled nursing facilities and assisted living centers.

Parkinson served as the 45th Governor of the State of Kansas. Prior to that, he was the owner and operator of long term care facilities in Kansas and Missouri. Under Parkinson's leadership, AHCA focuses on delivering policy solutions to the Hill and CMS, with a special emphasis on quality care. AHCA is now the largest association in long term care and is at record membership.

His vision has brought Parkinson recognition. He has been named a Top Association CEO by CEO Update and a top lobbyist for 2013, 2014, 2015,2016 and 2017 by *The Hill*, a leading Capitol Hill newspaper. Parkinson also has the distinction of being selected as one of the "100 Most Influential People in Healthcare" by *Modern Healthcare* in 2015.

Senior Vice President, Policy

Steven Speil

In his capacity as Senior Vice President, Health Finance and Policy, Mr. Speil manages the Federation's broad portfolio of payment policy issues. He serves as the association's chief liaison with the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration) and the Medicare Payment Advisory Commission. Working closely with the senior finance and policy executives in the Federation's member companies, Mr. Speil develops and carries out both issue-specific and general strategic plans designed to advance the finance and paymentrelated regulatory and legislative interests of the Association where they matter most - in the dynamic healthcare marketplace.

Prior to joining the Federation, Mr. Speil served as Associate Vice President, Policy Coordination and Communication, for the Health Industry Manufacturers Association (now AdvaMed), the national trade group representing the medical technology industry. Before moving to Washington, Mr. Speil held a succession of increasingly responsible management and policy positions in Massachusetts, including Legal Counsel to the Lieutenant Governor, Legislative Counsel for the Executive Office of Health and Human Services, Executive Director of the Disabled Persons Protection Commission, and Legal Counsel and Policy Director in the Office of State Health Planning. Mr. Speil also taught health law and policy as an Assistant Professor at Simmons College Graduate Program of Health Administration.

His federal experience includes service in the Food and Drug Administration's Office of Legislative and Congressional Affairs, and the Environmental Protection Agency's Office of General Counsel.

Mr. Speil earned a J.D. degree from American University's Washington College of Law; a Masters in Public Health degree in Health Administration from the University of North Carolina School of Public Health; and a Bachelor of Arts degree in Anthropology/Zoology from the University of Michigan.

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Chair of Government Relations & Public Policy

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Washington, D.C. 20004
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mcorry@health-law.com

PRACTICES

Government Relations & Public Policy

EDUCATION

University of Dayton, Ohio, B.A., 1971

Martin A. Corry is the Chair of the Government Relations & Public Policy department of Hooper, Lundy & Bookman, PC.

Mr. Corry represents clients on health care matters before Congress and the Executive branch on legislative, regulatory and administrative matters. He also provides strategic advice and counsel to clients on broad public policy and program goals as well as specific client business needs.

Mr. Corry was formerly the Special Assistant to the Administrator of the Centers for Medicare and Medicaid Services (CMS), where he assisted in planning, developing and implementing program initiatives related to healthcare financing and quality health care. He has also advised the Administrator on policies, procedures and critical issues.

Mr. Corry has also served as Director of Federal Affairs and AARP's (American Association of Retired Persons) Chief Federal Lobbyist, where he represented AARP before the Congress and the Executive branch, including Congressional leadership and senior Administration officials, on extensive issues from Social Security and Medicare to pensions, tax policy, federal budget and finance, as well as diverse consumer issues.

Presentations & Speaking Engagements

Regulatory Hotspots: A Leading Edge Legal View from D.C. and Beyond
Davie, Florida, September 11, 2015

HLB Webinar Recording Now Available: SGR Legislation - Key Implications for Providers
April 23, 2015

HLB Webinar: SGR Legislation - Key Implications for Providers
Webinar, April 23, 2015

Outlook to 2016: What the Coming Years Mean for Health Care
December 17, 2014

Outlook for Health Care Policy in the Lame Duck Session and Beyond: Implications for Legislation and Regulatory Action
Webinar, November 21, 2014

News

Application Due Soon for Two New Rounds of Residency Slot Redistribution
July 15, 2018

CMS Proposes Changes to Telehealth Reimbursement, Stark, Substance Use Disorder Treatment Reimbursement, and Evaluation & Management Reimbursement in the CY 2019 Physician Fee Schedule Proposed Rule
July 14, 2018

Congress Passes Sweeping Tax Reform Bill
December 21, 2017

Senate Moves to Proceed on Affordable Care Act Repeal Legislation
July 26, 2017

HLB's Marty Corry and Keith Fontenot Featured: ACA Watch: What BigLaw Lobbyists Think Happens Next
June 28, 2017
Health Law 360

A New Outlook for Health Care Reform Under the Trump Administration
November 17, 2016

CMS Issues Final Rule with Comment Period to Implement Site-Neutrality For New Off-Campus Provider-Based Departments
November 3, 2016

CMS Releases Final Rule Implementing MACRA with 2017 Resources
October 18, 2016

National Health Care Spending Trends and Implications
August 1, 2016
Health Law Perspectives

Martin A. Corry

MACRA Proposed Rule: A Deeper Dive into Medicare's New Physician Payment System
June 1, 2016

CMS Releases MACRA Proposed Rule
May 3, 2016

MACRA: Time to Double Down on an Alternative Payment Strategy?
April 15, 2016

Congressional Committee Seeks Comments Regarding Medicare Site Neutral Payment Policies
February 5, 2016

HLB 2016 Health Policy Outlook
January 8, 2016

D.C. District Court Rules That U.S. House Of Representatives Has Standing To Pursue Claims Regarding Cost-Sharing Reductions
November 25, 2015

Congress Eliminates OPPS Payments for Many New Hospital Off-Campus Outpatient Departments And Promotes Site-Neutral Payment Policy – Section 603 of the Bipartisan Budget Act of 2015
October 30, 2015

CMS Issues RFI Seeking Comments Regarding MACRA Payment Reforms
September 28, 2015

Making Way for MACRA: Positioning Your Organization For Payment Reform
August 12, 2015

King v. Burwell Decision: The ACA Provides Subsidies on all Exchanges
June 25, 2015

Q: *How Would the Administration's 2016 Budget Affect Providers?* **A:** *It Depends…*
February 10, 2015

OUTLOOK 2015: Physician Payments, Managed Care Quality, RACs Top LIst
January 9, 2015
BNA's Medicare Report

Courts Issue Opposing Opinions Regarding Federal Tax Credits in States with Federal Health Benefits Exchanges
July 23, 2014

HHS Seeks Comments on Reference Pricing
June 9, 2014

Martin A. Corry

CMS Proposes New Marketplace Network Adequacy Requirements for 2015 under the Affordable Care Act
February 5, 2014

Health Care Reform

Weekly Health Policy Update September 28, 2018
September 28, 2018

HLB Weekly Health Policy Update September 19, 2018
September 19, 2018

HLB Weekly Health Policy Update September 5, 2018
September 5, 2018

HLB Weekly Health Policy Update August 2, 2018
August 2, 2018

HLB Weekly Health Policy Update July 24, 2018
July 24, 2018

HLB Weekly Health Policy Update July 24, 2018
July 24, 2018

HLB Weekly Health Policy Update July 12, 2018
July 12, 2018

HLB Weekly Health Policy Update June 29, 2018
June 29, 2018

HLB Weekly Health Policy Update June 21, 2018
June 21, 2018

HLB Weekly Health Policy Update June 14, 2018
June 14, 2018

HLB Weekly Health Policy Update June 7, 2018
June 7, 2018

HLB Weekly Health Policy Update May 24, 2018
May 24, 2018

HLB Weekly Health Policy Update May 17, 2018
May 17, 2018

Martin A. Corry

HLB Weekly Health Policy Update May 10, 2018
May 10, 2018

HLB Health Policy Update April 27, 2018
April 27, 2018

HLB Weekly Health Policy Update April 17, 2018
April 17, 2018

HLB Weekly Health Policy Update April 9, 2018
April 9, 2018

HLB Weekly Health Policy Update March 26, 2018
March 26, 2018

HLB Weekly Health Policy Update March 14, 2018
March 14, 2018

HLB Weekly Health Policy Update March 7, 2018
March 7, 2018

HLB Health Policy Update February 27, 2018
February 27, 2018

HLB Weekly Health Policy Update February 15, 2018
February 15, 2018

HLB Health Policy Update February 9, 2018
February 9, 2018

HLB Weekly Health Policy Update January 30, 2018
January 30, 2018

HLB Weekly Health Policy Update January 22, 2018
January 22, 2018

HLB Weekly Health Policy Update January 16, 2018
January 16, 2018

HLB Weekly Health Policy Update January 8, 2018
January 8, 2018

HLB Weekly Health Policy Update December 12, 2017
December 12, 2017

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PRECIOUS MURCHISON GITTENS

Partner

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Washington, D.C. 20004
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PRACTICES

Compliance

False Claims Act

Fraud & Abuse, Stark, Anti-Kickback Counseling and Defense

Litigation, Mediation, Arbitration

Medicare, Medicaid, Other Governmental Reimbursement & Payment

White Collar Criminal Defense

EDUCATION

Howard University, B.A., *magna cum laude,* 1998

Georgetown University Law Center, J.D., 2001

- Member, *Georgetown Journal on Poverty Law & Policy*

BAR ADMISSIONS

2008, District of Columbia

2001, Maryland

Precious Gittens is a former federal prosecutor and is Co-chair of the firm's Fraud & Abuse Practice Group. She is Certified in Healthcare Compliance (CHC) by the Compliance Certification Board (CCB). Ms. Gittens advises organizations on compliance matters, including the development, implementation, and evaluation of compliance plans. She assists audit committees and boards of directors in conducting internal investigations and represents healthcare organizations in response to government investigations and enforcement actions. Ms. Gittens advises clients concerning false claims, anti-kickback and self-referral matters, and self-disclosures to the Office of Inspector General. She specializes in preparing management for civil and criminal proceedings and has handled substantial litigation matters involving the False Claims Act, health care fraud, contract and regulatory disputes, and business torts.

Ms. Gittens has previously served as Assistant United States Attorney with the United States Attorney's Office for the District of Columbia (2002-2007), where she prosecuted cases involving a wide variety of criminal white collar matters involving mail and wire fraud, conspiracy to commit bank fraud, embezzlement, uttering, false statements, tax evasion, and visa fraud. She served as lead prosecutor in over a dozen jury trials and over two dozen bench trials, conducted numerous federal and local grand jury investigations, and briefed and argued before the District of Columbia Court of Appeals.

Ms. Gittens received her B.A. Degree from Howard University, graduating *magna cum laude* and her J.D. Degree from Georgetown University Law Center, where she was a recipient of the *Michael Feldman Advocacy Award* and the winner of *William W. Greenhalgh Trial Advocacy Competition*.

Court Admissions

- 2016, United States District Court for the District of Colorado
- 2014, Supreme Court of the United States
- 2010, United States Court of Appeals for the District of Columbia Circuit
- 2010, United States District Court for the District of Maryland
- 2009, United States District Court for the District of Columbia
- 2008, District of Columbia
- 2001, Maryland

Representative Matters

- Advise national social service organization on complex regulatory matters, including regulatory compliance, payment and operational issues, in connection with the expansion of its chronic disease prevention programs.
- Represent molecular diagnostics company in response to Civil Investigative Demand issued by the DOJ pursuant to the federal False Claims Act.
- Represent diagnostic laboratory company in responding to subpoenas issued in connection with DOJ investigation of federal health care offenses.
- Represent skilled nursing facilities in conducting audits and internal investigations for alleged false claims and kickback arrangements.
- Assist healthcare management services company in conducting compliance oversight activities, including audits and internal investigations, in connection with operation of hospitals.
- Defend founders of physician-owned distributorship in federal false claims prosecution, and in parallel government investigation.
- Defended Executive Director of ambulatory surgery center in mail fraud prosecution.
- Represented managed health care services company in connection with state and federal health care fraud investigations, including response to congressional request for information concerning drug utilization by Part D beneficiaries and negotiated drug prices.
- Represented provider in payment dispute with health plan that was seeking to offset alleged overpayments.
- Provided strategic advice to food and beverage company threatened with deceptive trade practices law suit by consumer health and nutrition advocacy organization focused on the labeling and marketing of products.
- Assisted audit committee of a professional bar association in connection with accounting and internal compliance deficiencies identified by whistleblower.
- Represented home health care agency in billing dispute with the Centers for Medicare & Medicaid Services, resulting in full reinstatement of provider's Medicare enrollment and billing privileges, *nunc pro tunc* revocation

date.

Professional Affiliations

- Executive Council, Assistant United States Attorneys Association of the District of Columbia
- Executive Committee, The Barristers
- Women's White Collar Defense Association (WWCDA), District of Columbia Chapter
- Member, National Association of Criminal Defense Lawyers
- Master Member, William B. Bryant American Inn of Court (*invitation-only professional organization specializing in trial advocacy*)
- Member, Advisory Committee, Pan American Development Foundation
- Member, American Bar Association, Health Law and Criminal Justice Sections
- Member, American Health Lawyers Association
- Member, Health Care Compliance Association
- Member, Society of Corporate Compliance and Ethics

Community/Civic Activities

- Faculty, Harvard Law School Criminal Justice Institute Trial Advocacy Workshop
- Faculty, Emory Law School Kessler-Eidson Trial Techniques Program
- Instructor, National Institute for Trial Advocacy (NITA)
- Admissions Interviewer, Georgetown University Law Center Alumni Admissions Program
- Troop Advisor, Girls Scouts Nation's Capital Cadette Troop 4461
- Former Administrative Hearing Examiner, District of Columbia Office of Police Complaints

Honors & Awards

- Recognized as a *Top Rated Health Care Attorney in Washington, DC* by *Super Lawyer* (2016-2017)
- Selected as a recommended attorney by The Legal 500 in the health care service provider category (2016)
- Recipient, *The National Law Journal* and *Legal Times* "2014 Washington, D.C. Rising Star" Award
- Recipient, *The Network Journal* "40 Under Forty" Achievement Award

Presentations & Speaking Engagements

Federal Bar Association Qui Tam Conference
Washington, D.C., February 28, 2019

HCCA 4th Annual Healthcare Enforcement Compliance Conference
Washington, DC, November 4-7, 2018

American Health Lawyers Association 2018 Annual Meeting
Chicago, IL, June 25-27, 2018

Health Care Compliance Association 22nd Annual Compliance Institute
Las Vegas, NV, April 15-18, 2018

- *Government Investigations and Parallel Proceedings* (with Patric Hooper), California Hospital Association's Hospital Compliance Seminar, Pasadena, CA, February 2018
- *Moving Beyond the Seven Elements of Compliance: Measuring Compliance Program Effectiveness*, 2017 Health Care Fraud and Abuse Update (seminar presented by HLB/FTI Consulting), Los Angeles, CA and Boston, MA, October 2017
- Post-*Escobar: False Claims Act and Qui Tam Actions*, The Dale Baker Conference on Health Reform, San Francisco, CA, October 2016
- *Overpayments–Report and Return Rule for Medicare Parts A & B: The 60-Day Vulture Comes Home to Roost*, The Dale Baker Conference on Health Reform, Daytona Beach, FL, October, 2015
- *Regulatory Hotspots: A Leading Edge Legal View from D.C. and Beyond*, South Florida Hospital & Healthcare Association Program, Davie, FL, September 2015
- *Leadership Growth: Receiving and Acting on Feedback – Women, Influence & Power in Law* – By Invitation Only Executive Leadership Forum(an *InsideCounsel* advanced leadership development and training program designed for in-house counsel and their outside counsel partners), April 2015
- *Improv for Lawyers: A CLE to Enhance Negotiation Skills*, Corporate Counsel Women of Color 10th Annual Career Strategies Conference, Beverly Hills, CA, October 2014
- *Collaboration Between General Counsel and Board of Directors*, Corporate Counsel Women of Color Ninth Annual Career Strategies Conference, (Panelist), Washington, D.C., September 2013
- *How to Avoid Law Firm Overbilling*, Association of Corporate Counsel New Jersey (NJCCA) Chapter Continuing Legal Education Spring Program, West Orange, NJ, May 2013
- *Back to Basics: Effective Opening Statement*, ABA Section of Litigation Annual Conference, Washington, D.C., April 2012

News

Super Lawyers Recognizes Outstanding HLB Attorneys:
June 7, 2018

Precious Murchison Gittens Selected as a Member of Health Law 360 Advisory Board
March 19, 2018
Health Law 360

Legal 500 Recognizes HLB's Expansion
May 28, 2016

Precious Murchison Gittens Joins HLB: Former Federal Prosecutor Joins Firm at Critical Time for Health Care Providers
March 24, 2015

Health Law Perspectives

Health Law Perspectives, September 2015
September 15, 2015

Other Publications

A Sharpened Focus on Remediation in Federal Investigations
Compliance Today, April 2018

Publications

Contributing Author, California Hospital Association's *Hospital Compliance Manual* (Ninth Edition, 2018)

Contributing Author, California Hospital Association's *Hospital Compliance Manual* (Seventh Edition, 2016)

Health Law Perspectives, *New Guidance for Defendants in DOJ Investigations*, September 2015

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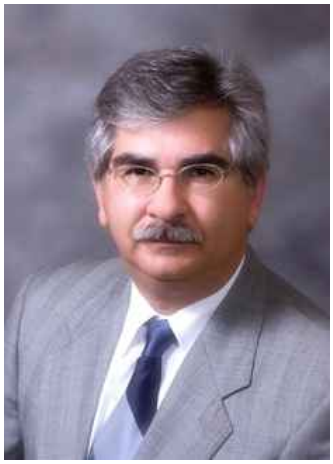

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PRACTICES

Administrative Law

Compliance

False Claims Act

Government Relations & Public Policy

Health Care Technology

Managed Care

Medicare, Medicaid, Other Governmental Reimbursement & Payment

Provider & Supplier Operations

Public Agency Law

Recovery Audit Contractor (RAC) Appeals

EDUCATION

Oakland University, B.A., 1977, *with honors*

Saint Louis University, M.H. A., 1981

Saint Louis University School of Law, J.D., 1982, *cum laude*

BAR ADMISSIONS

1982, California

John R. Hellow has specialized in Medicare and Medicaid payment policy issues since 1982. He has represented hospitals in a wide variety of Medicare and Medicaid payment disputes before federal and state administrative agencies, and has gained extensive experience in advising clients on reimbursement and other regulatory implications of their business transactions. In 1983 Mr. Hellow began representing hospitals in Medicare group appeals and was primarily responsible for representing 700 hospitals in successful challenges to Medicare's Malpractice Rules and labor/delivery room day policy. He has represented a group of 1400 hospitals in a challenge to Medicare outlier payments.

Mr. Hellow's current practice has focused on defending providers in Medicare False Claims Act disputes involving cost reporting and anti-kickback related issues. From 1999 until 2003 he was lead regulatory defense counsel in the largest federal health care fraud investigation in U.S. history, where he helped negotiate criminal, civil and administrative settlements of all pending issues with the Centers for Medicare and Medicaid Services and the Department of Justice's Criminal and Civil Divisions. He is also a member of the firm's Fraud & Abuse Practice Group.

Mr. Hellow is lead regulatory payment counsel for some of the country's leading hospital companies. He is payment counsel to the Federation of American Hospitals where he has primary responsibility for directing industry comments on federal program payment related reform under Medicare and Medicaid, hospital charging practices, including charity care and discounted services and upcoming pay for performance initiatives.

Mr. Hellow has represented hospitals in the United States Courts of Appeals for the District of Columbia, Federal Circuit, Ninth Circuit, Sixth Circuit, Eleventh Circuit and Eighth Circuit, in the United States Court of Federal Claims, and in the United States District Courts for the District of Columbia, Eastern District of

Michigan, Western District of Missouri, Central District of California, Northern District of California, Minnesota, Eastern District of Texas, Arizona, Utah and Southern District of Florida, and before the PRRB. Mr. Hellow is an advanced member of the Health Financial Management Association.

Mr. Hellow received his B.A. degree in History and Political Science, *with honors* from Oakland University in 1977. He received his Masters in Health Care Administration from St. Louis University in 1981 and his J.D., *cum laude* from Saint Louis University School of Law in January, 1982. Mr. Hellow was the Symposium Editor of the St. Louis University Health Law Review, and Note and Comment Editor of the St. Louis University Law Review during 1980 – 1981.

Professional Affiliations

- American Health Lawyers Association
- California Society of Healthcare Attorneys
- Hospital Financial Management Association

Honors & Awards

- Southern California *Super Lawyer* 2004-2018.
- Recognized as a top attorney by Chambers & Partners in California, 2014.
- Recognized by *Best Lawyers* (2012-2019).

Presentations & Speaking Engagements

BHC 2017 Annual Conference on Current Healthcare Developments
Las Vegas, NV, November 2-3, 2017

California Hospital Association Hospital Finance & Reimbursement Seminar
Sacramento, Glendale, Costa Mesa, CA, June 7, 20, 21, 2017

The 2016 Conference on Health Reform
San Francisco, CA, October 27-28, 2016

HLB Webinar Recording Now Available: SGR Legislation - Key Implications for Providers
April 23, 2015

HLB Webinar: SGR Legislation - Key Implications for Providers
Webinar, April 23, 2015

Robert Roth, HLB Washington, D.C. Managing Partner, Chairs AHLA Institute on Medicare and Medicaid Payment Issues
Baltimore, MD, March 25-27, 2015

HFMA San Diego Program
Del Mar, December 2, 2014

The 2014 Conference on Health Reform
San Francisco, California, October 23-24, 2014

News

Application Due Soon for Two New Rounds of Residency Slot Redistribution
July 15, 2018

Southern California Super Lawyers Named
February 1, 2018

Best Lawyers in America Recognizes 15 HLB Attorneys
August 16, 2017

Senate Moves to Proceed on Affordable Care Act Repeal Legislation
July 26, 2017

The Better Care Reconciliation Act of 2017 - A First Look
June 23, 2017

Federal Court Permanently Enjoins CMS' Policy Reducing the Hospital-Specific Medicaid Disproportionate Share Hospital Limit
March 6, 2017

HLB Announces 2017 Southern California Super Lawyers
January 20, 2017

A New Outlook for Health Care Reform Under the Trump Administration
November 17, 2016

CMS Issues Final Rule with Comment Period to Implement Site-Neutrality For New Off-Campus Provider-Based Departments
November 3, 2016

John R. Hellow

HLB Attorneys Author In-Depth Analysis of the CMS Final Rule Implementing the 60-Day Report and Return Statute for Medicare Parts A and B
March 17, 2016
BNA's Health Law Reporter

CMS Finalizes 60-Day Report and Repayment Rule
February 11, 2016

Congressional Committee Seeks Comments Regarding Medicare Site Neutral Payment Policies
February 5, 2016

D.C. District Court Rules That U.S. House Of Representatives Has Standing To Pursue Claims Regarding Cost-Sharing Reductions
November 25, 2015

HLB Receives 2016 Top Tier Honors from Best Lawyers®
November 3, 2015

Congress Eliminates OPPS Payments for Many New Hospital Off-Campus Outpatient Departments And Promotes Site-Neutral Payment Policy – Section 603 of the Bipartisan Budget Act of 2015
October 30, 2015

King v. Burwell Decision: The ACA Provides Subsidies on all Exchanges
June 25, 2015

HLB Recognized as a Top Law Firm in the U.S. by Chambers & Partners
May 20, 2015

Supreme Court Hears Oral Argument in ACA Subsidies Challenge
March 5, 2015

Lloyd Bookman Named Los Angeles Health Care Lawyer of the Year
August 26, 2014

Courts Issue Opposing Opinions Regarding Federal Tax Credits in States with Federal Health Benefits Exchanges
July 23, 2014

HHS Seeks Comments on Reference Pricing
June 9, 2014

HLB Again Achieves Top-Tier Ranking in Chambers Review of Leading Health Law Firms
May 23, 2014

CHA Annual Finance & Reimbursement Seminar

John R. Hellow

Appeals Court Decision Opens Door to Favorable DSH Treatment
April 9, 2014

The Affordable Care Act: A Comprehensive Overview
March 1, 2010

Health Law Perspectives

Application Due Soon for Two New Rounds of Residency Slot Redistribution
Health Law Perspectives

Other Publications

HLB Attorneys' In-Depth Analysis of the CMS's Final Rule Implementing the 60-Day Report and Return Statute for Medicare Parts A and B
BNA's Health Law Reporter, March 16, 2016

***BNA Health Care Fraud Report**: Tick, Tick, BOOM: CMS's Proposed 60-Day Rule Would Create Intense Time Pressure for Providers to Identify, Report, Return Overpayments*
2011

HLB
HOOPER, LUNDY & BOOKMAN, PC
HEALTH CARE LAWYERS & ADVISORS

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Associate

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Suite 1600
Los Angeles, CA 90067
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PRACTICES

Academic Medicine

Administrative Law

Behavioral Health & Community-Based Care

Business Transactions

Compliance

Fraud & Abuse, Stark, Anti-Kickback Counseling and Defense

Medical Education

Medical Staff Operations & Disputes

Real Estate

EDUCATION

Cornell University, BA 2006

University of Southern California Law School, JD 2009

University of California, Los Angeles Fielding School of Public Health, Master of Public Health 2016

BAR ADMISSIONS

2009, California

Alicia Macklin is an associate in the firm's regulatory and business departments, where she assists health care providers, including hospitals, physicians, and health services companies with a broad range of compliance, licensing and certification, and reimbursement issues.

Ms. Macklin received a B.A. in psychology, *Phi Beta Kappa*, from Cornell University in 2006, and her J.D. from the University of Southern California Law School, where she was Executive Senior Editor of the *Southern California Law Review*. In 2016 she graduated from the University of California, Los Angeles Fielding School of Public Health with a Master of Public Health.

Presentations & Speaking Engagements

HLB 2019 Medical Staff Update Seminar
March 5, 2019 - Oakland Marriott City Center, CA; March 12, 2019 - Westin Los Angeles Airport, CA

HLB 2019 Medical Staff Seminar Update
VIP Registration
March 5, 2019 - Oakland Marriott City Center, CA; March 12, 2019 - Westin Los Angeles Airport, CA

Hooper, Lundy & Bookman's 2018 Medical Staff Update

Hooper, Lundy & Bookman's 2018 Medical Staff Update

Hooper, Lundy & Bookman's 2017 California Managed Care Update
The Potential Impact of Health Reform, Changing Provider Contracts and Regulation on Managed Care Providers
Berkeley: August 22, 2017 Los Angeles August 24, 2017

Hooper, Lundy & Bookman 2017 California Managed Care Update - Berkeley
The Potential Impact of Health Reform, Changing Provider Contracts and Regulation on Managed Care Providers
DoubleTree by Hilton Hotel, Berkeley Marina, August 22, 2017

- Los Angeles County Bar Association 13th Annual Healthcare Compliance Seminar - Stark Law Updates, October 12, 2017
- EMTALA - Essentials and Trouble Spots Webinar, California Hospital Association, February 2018

News

President Trump signs the SUPPORT for Patients and Communities Act (H.R. 6)
October 26, 2018

Telehealth Updates - California
September 25, 2018

CMS Proposes Changes to Telehealth Reimbursement, Stark, Substance Use Disorder Treatment Reimbursement, and Evaluation & Management Reimbursement in the CY 2019 Physician Fee Schedule Proposed Rule
July 14, 2018

Connecticut Permits Prescribing Limited Controlled Substances via Telemedicine
July 5, 2018

The Better Care Reconciliation Act of 2017 - A First Look
June 23, 2017

Stark Law: New Self-Disclosure Protocol
April 6, 2017

Publications

The Fraud Exception to the Parol Evidence Rule: Necessary Protection for Fraud Victims or Loophole for Clever Parties?, 82 S. CAL. L. REV. 809 (2009)

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HOOPER, LUNDY & BOOKMAN, PC
HEALTH CARE LAWYERS & ADVISORS

MONICA (HERR) MASSARO

Manager of Government Relations & Public Policy

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mmassaro@health-law.com

PRACTICES

Academic Medicine

Clinical Research

Government Relations & Public Policy

EDUCATION

University of Pittsburgh, B.A., 2009

George Mason University, MPP, 2015

Monica Massaro is the Manager of Government Relations & Public Policy at Hooper, Lundy & Bookman, P.C.

Ms. Massaro represents various health care clients at the legislative and executive branches of the federal government. In addition to lobbying, her in-depth knowledge of Medicare payment allows her to provide expert advice on such areas as the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA) and how it impacts the future of Medicare payment.

Prior to joining HLB, Ms. Massaro spent six years working in government affairs at the American Physical Therapy Association (APTA), most recently serving as Manager of Congressional Affairs. Ms. Massaro represented the association as a lead lobbyist charged with management and strategy of the policy priorities for the over 90,000 member organization before Congress and Federal Government Agencies. During her time at APTA, Ms. Massaro handled a range of issues including Medicare Part A and B payment reform, health care workforce and education, small business, and rural health care.

In addition, Ms. Massaro has significant experience planning and carrying out grassroots and grasstops advocacy strategies and organizing successful Congressional fly-in days. She also has key experience managing coalitions of stakeholders on various issues to identify and implement common policy goals.

Ms. Massaro earned her B.A. in Political Science and Urban Studies from the University of Pittsburgh and her Masters of Public Policy from George Mason University with a focus in health policy.

Professional Affiliations

- Women in Government Relations
- Association of Government Relations Professionals

News

CMS Releases Final Rule Implementing MACRA with 2017 Resources
October 18, 2016

MACRA Proposed Rule: A Deeper Dive into Medicare's New Physician Payment System
June 1, 2016

CMS Releases MACRA Proposed Rule
May 3, 2016

HLB 2016 Health Policy Outlook
January 8, 2016

Health Care Reform

Weekly Health Policy Update September 28, 2018
September 28, 2018

HLB Weekly Health Policy Update September 19, 2018
September 19, 2018

HLB Weekly Health Policy Update September 5, 2018
September 5, 2018

HLB Weekly Health Policy Update August 2, 2018
August 2, 2018

HLB Weekly Health Policy Update July 24, 2018
July 24, 2018

HLB Weekly Health Policy Update July 24, 2018
July 24, 2018

HLB Weekly Health Policy Update July 12, 2018
July 12, 2018

HLB Weekly Health Policy Update June 29, 2018
June 29, 2018

Monica (Herr) Massaro

HLB Weekly Health Policy Update June 21, 2018
June 21, 2018

HLB Weekly Health Policy Update June 14, 2018
June 14, 2018

HLB Weekly Health Policy Update June 7, 2018
June 7, 2018

HLB Weekly Health Policy Update May 24, 2018
May 24, 2018

HLB Weekly Health Policy Update May 17, 2018
May 17, 2018

HLB Weekly Health Policy Update May 10, 2018
May 10, 2018

HLB Health Policy Update April 27, 2018
April 27, 2018

HLB Weekly Health Policy Update April 17, 2018
April 17, 2018

HLB Weekly Health Policy Update April 9, 2018
April 9, 2018

HLB Weekly Health Policy Update March 26, 2018
March 26, 2018

HLB Weekly Health Policy Update March 14, 2018
March 14, 2018

HLB Weekly Health Policy Update March 7, 2018
March 7, 2018

HLB Health Policy Update February 27, 2018
February 27, 2018

HLB Weekly Health Policy Update February 15, 2018
February 15, 2018

HLB Health Policy Update February 9, 2018
February 9, 2018

Monica (Herr) Massaro

HLB Weekly Health Policy Update January 30, 2018
January 30, 2018

HLB Weekly Health Policy Update January 22, 2018
January 22, 2018

HLB Weekly Health Policy Update January 16, 2018
January 16, 2018

HLB Weekly Health Policy Update January 8, 2018
January 8, 2018

HLB Weekly Health Policy Update December 12, 2017
December 12, 2017

HLB Weekly Health Policy Update November 14, 2017
November 14, 2017

HLB Weekly Health Policy Update November 7, 2017
November 7, 2017

HLB Weekly Health Policy Update October 31, 2017
October 31, 2017

HLB Weekly Health Policy Update October 25, 2017
October 25, 2017

HLB Weekly Health Policy Update October 17, 2017
October 17, 2017

HLB Weekly Update October 11, 2017
October 11, 2017

HLB Weekly Health Policy Update October 3, 2017
October 3, 2017

HLB Weekly Health Policy Update September 22, 2017
September 22, 2017

HLB Weekly Health Policy Update September 15, 2017
September 15, 2017

HLB Weekly Health Policy Update September 6, 2017
September 6, 2017

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Partner

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PRACTICES

- Academic Medicine
- Antitrust and Unfair Business Practices
- Behavioral Health & Community-Based Care
- Clinical Research
- Compliance
- False Claims Act
- Health Care Technology
- Life Sciences
- Litigation, Mediation, Arbitration
- Managed Care
- Medical Education
- Medicare, Medicaid, Other Governmental Reimbursement & Payment
- Post-Acute and Long-Term Care Services & Supports
- Telemedicine

EDUCATION

- University of California, Berkeley, B.A., 2001
- Johns Hopkins Bloomberg School of Public Health, M.P.H., 2005
- Georgetown University Law Center, J.D., 2005
- Yale Law School, L.L.M.,

Katrina Pagonis is co-chair of the firm's regulatory department and a nationally recognized expert on implementation of the Affordable Care Act's market reforms, including the federal regulation of government-sponsored and private managed care plans and the establishment and operation of Health Insurance Exchanges ("Marketplaces") like Covered California. Ms. Pagonis regularly advises clients on the impact of health care reform, as well as emerging health care reform proposals (from repeal-and-replace to single payer) at the state and national levels. She also provides regulatory and strategic advice to health care providers concerning managed care issues more generally, including out-of-network reimbursement, network configuration (narrow and tiered networks), reference pricing and cost-sharing limits, managed care contracting, and enrollment assistance activities.

In addition, Ms. Pagonis regularly assists health care providers—including hospitals, long-term care providers, suppliers, pharmacies, hospices, physicians and medical groups—with a broad range of regulatory and Medicare/Medicaid reimbursement matters. She is an expert in site-neutrality initiatives for hospital outpatient services, meaningful use of electronic health records, health care technology, clinical trial agreements, antitrust, and internal investigations. Ms. Pagonis represents providers in government investigations and False Claims Act cases and assists providers that have credible information regarding potential overpayments with the investigation, identification, reporting, and returning of overpayments. Ms. Pagonis is a former judicial law clerk of the U.S. Court of Appeals for the Ninth Circuit and the U.S. District Court for the District of Nevada. Until 2012, she was a full-time professor of health law at Hamline University School of Law in St. Paul, Minnesota.

2006

BAR ADMISSIONS

2009, California

Professional Affiliations

- American Health Lawyers Association, *Chair of the Healthcare Reform Task Force*
- American Bar Association, *Health Law Section*
- California Society of Healthcare Attorneys

Community/Civic Activities

- Advisory Board Member, Health Law Institute at Mitchell Hamline School of Law (2016 – present)

Presentations & Speaking Engagements

MHA 2019 Outpatient Prospective Payment System Update
Burlington, MA, December 7, 2018

California Society for Healthcare Attorneys 2018 Annual Meeting & Seminar
Napa Valley, CA, April 13-15, 2018

BHC 2017 Annual Conference on Current Healthcare Developments
Las Vegas, NV, November 2-3, 2017

Hooper, Lundy & Bookman's 2017 California Managed Care Update
The Potential Impact of Health Reform, Changing Provider Contracts and Regulation on Managed Care Providers
Berkeley: August 22, 2017 Los Angeles August 24, 2017

Hooper, Lundy & Bookman 2017 California Managed Care Update - Berkeley
The Potential Impact of Health Reform, Changing Provider Contracts and Regulation on Managed Care Providers
DoubleTree by Hilton Hotel, Berkeley Marina, August 22, 2017

The American Health Care Act of 2017 (AHCA): The Political Calculus Moving Forward and the Potential Impact on Medicaid, the Exchange and Individual Insurance Markets
Teleconference, May 10, 2017

Obamacare - Trump Administration Changes - Legal Challenges
Los Angeles, CA, January 26, 2017

Katrina A. Pagonis

Trump's First 100 Days, Part I
Los Angeles, CA, January 17, 2017

The 2016 Conference on Health Reform
San Francisco, CA, October 27-28, 2016

Outlook to 2016: What the Coming Years Mean for Health Care
December 17, 2014

Outlook for Health Care Policy in the Lame Duck Session and Beyond: Implications for Legislation and Regulatory Action
Webinar, November 21, 2014

The 2014 Conference on Health Reform
San Francisco, California, October 23-24, 2014

HLB Webinar Recording Now Available: Meaningful Use - From the Carrot to the Stick
September 10, 2014

CSHA Annual Meeting and Spring Seminar, Squaw Creek
April 11, 2014

NBA Webinar
April 3, 2014

California Dental Association Dental Benefits Workshop, Sacramento
March 20, 2014

California Society for Healthcare Risk Management Conference, Napa
February 26, 2014

- *The ACA and the Transformation of the California Health Care Marketplace: Covered California*, California Society for Healthcare Attorneys (Squaw Valley, April 2014)
- *Affordable Care Act Webinar: How it Affects Lawyers and Small Businesses*, The National Bar Association (April 2014)
- *False Claims Act and 60-Day Reporting and Repayment Rule*, U.C. Hastings College of the Law, Guest Lecturer for Health Law II (March 2014)
- *Managed Care Contracting*, California Dental Association, Dental Benefits Workshop (Sacramento, March 2014)
- *Managed Care Webinar*, California Association for Health Services at Home (March 2014)
- *Access to Coverage and Care, the Exchanges, and Competition*, U.C. Hastings College of the Law, Guest Lecturer for Health Law II (February 2014)

- *Covered California and Providers*, LACBA Health Care Law Section (Los Angeles, December 2013)
- *Health Insurance Exchange Challenges and Solutions, Part V: Beyond January—Exchange-Related Issues on the Horizon, American Health Lawyers Association Webinar* (with Joel Hamme, Tim Jost, and Caitlyn Sweaney, October 2013)
- *Covered California: Issues on the Horizon for Providers*, Hooper, Lundy & Bookman Managed Care Seminars (Los Angeles & Berkeley, October 2013)
- *Covered California: Legal and Business Concerns for Providers*, Santa Clara University Law, Health Law I, Guest Lecture (October 2013)
- *Insurance Exchanges and Inherent Changes Being Implemented Throughout the Health Insurance Marketplace*, Dale Baker Conference on Health Reform (with Cliff King, Las Vegas, September 2013)
- *Covered California: Enrollment & Marketing Opportunities for Providers, Plans and Agents*, California Society for Health Care Attorneys Teleconference Presentation (September 2013)
- *Health Exchanges: Proactive Legal Strategies for Providers*, HLB-Strafford Webinar (with Martin Corry and Jack Ebeler, September 2013)
- *Covered California: What Providers Need to Know Today About California's Health Insurance Exchange*, Hooper, Lundy & Bookman Webinar (with Martin Corry and Amanda Hayes-Kibreab, September 2013)
- *Health Insurance Exchange Challenges and Solutions, Part II: Enrollment Assistance and Privacy and Security*, American Health Lawyers Association Webinar (with L. Cook and D. Madala, August 2013)
- *Enrollment Assistance in AAPI Communities: The Provider's Role*, Asian Health Care Leaders Association National Conference (July 2013)
- *The Exchanges: Managed Care Contracting under the ACA, The Summit by ReviveHealth* (New Orleans, May 15, 2013, with Glenn Solomon)
- *Covered California: Health Benefits Exchange, U.C. Berkeley School of Public Health, Guest Lecturer for Legal Issues in Health Care* (April 22, 2013)
- *Managed Care Special Topics: Preparing for the Medi-Cal Managed Care Rural Expansion, Hospital Council of Northern & Central California* (April 18, 2013, with Felicia Sze)
- *Covered California: Health Benefits Exchange, LACBA/LACMA, The New Health Care Landscape* (Los Angeles, March 7, 2013)
- *Wellness Programs: Current Landscape & Coming Changes, HFMA* (San Diego, February 28, 2013, with Johan Otter)
- *Insurance Exchanges and Inherent Changes Being Implemented Throughout the Health Insurance Marketplace (Or "Is it 2014 Yet?"), The Conference on Health Reform* (Las Vegas, September 21, 2012, with Cliff King)
- *Federalism and the Individual Health Insurance Mandate*, Hamline Law Alumni CLE (February 2012, with Morgan Holcomb)

- *Hot Topics in Health Law: Palliative Care Issues*, Ramsey County Bar Association CLE (St. Paul, MN, November 2009)

News

The ACA's Been Ruled Invalid. What's Next?
December 17, 2018
Law360

HHS-OIG Seeks Comments on Value-Based Care, AKS and CMP
August 31, 2018

CMS Proposes Changes to Telehealth Reimbursement, Stark, Substance Use Disorder Treatment Reimbursement, and Evaluation & Management Reimbursement in the CY 2019 Physician Fee Schedule Proposed Rule
July 14, 2018

Federal Agencies Respond To Questions Regarding Out-Of-Network Reimbursement For Emergency Care
May 3, 2018

HHS Updates Rules on Confidentiality of Substance Abuse Records
January 9, 2018

Congress Passes Sweeping Tax Reform Bill
December 21, 2017

Proposed Massachusetts Legislation Aims to Contain Health Care Costs: Highlights for Providers
October 25, 2017

Senate Moves to Proceed on Affordable Care Act Repeal Legislation
July 26, 2017

The Better Care Reconciliation Act of 2017 - A First Look
June 23, 2017

The American Health Care Act of 2017 (AHCA): The Political Calculus Moving Forward and the Potential Impact on Medicaid, the Exchange and Individual Insurance Markets
May 10, 2017

Federal Agencies Issue Revised Common Rule
February 22, 2017

HLB Announces Attorney Promotions
December 14, 2016

Katrina A. Pagonis

A New Outlook for Health Care Reform Under the Trump Administration
November 17, 2016

CMS Issues Final Rule with Comment Period to Implement Site-Neutrality For New Off-Campus Provider-Based Departments
November 3, 2016

Webinar Recording Available: CMS Proposed Rule - Provider-Based Departments and Site Neutrality
August 1, 2016

CMS Proposes Restrictive Implementation of Site Neutrality for New, Off-Campus Hospital Outpatient Departments
July 7, 2016

At a Glance: What Providers Need to Know About the Medicaid Managed Care Final Rule
April 27, 2016

HLB Attorneys Author In-Depth Analysis of the CMS Final Rule Implementing the 60-Day Report and Return Statute for Medicare Parts A and B
March 17, 2016
BNA's Health Law Reporter

CMS Finalizes 60-Day Report and Repayment Rule
February 11, 2016

Congressional Committee Seeks Comments Regarding Medicare Site Neutral Payment Policies
February 5, 2016

D.C. District Court Rules That U.S. House Of Representatives Has Standing To Pursue Claims Regarding Cost-Sharing Reductions
November 25, 2015

King v. Burwell Decision: The ACA Provides Subsidies on all Exchanges
June 25, 2015

Supreme Court Hears Oral Argument in ACA Subsidies Challenge
March 5, 2015

CMS Provides Flexibility in Certified EHR Technology for 2014
September 4, 2014

Courts Issue Opposing Opinions Regarding Federal Tax Credits in States with Federal Health Benefits Exchanges
July 23, 2014

HHS Seeks Comments on Reference Pricing
June 9, 2014

CMS Proposes New Marketplace Network Adequacy Requirements for 2015 under the Affordable Care Act
February 5, 2014

Proposed Rule Implementing 60-Day Overpayment Refund Statute for Medicare Part C and D Plans Published
January 13, 2014

Health Law Perspectives

Ready for Compliance with Revised Common Rule?
Health Law Perspectives, June 2018

Risks for Providers Under the Risk Adjustment Program
Health Law Perspectives, May 2014, May 1, 2014

Other Publications

HLB Attorneys' In-Depth Analysis of the CMS's Final Rule Implementing the 60-Day Report and Return Statute for Medicare Parts A and B
BNA's Health Law Reporter, March 16, 2016

Publications

Fraud & Abuse and the Exchanges: HHS Concludes that the Exchanges and Qualified Health Plans are not Subject to the Anti-Kickback Statute, Hooper, Lundy & Bookman, Health Law E-Alert (November 2013)

Covered California's Enrollment Assistance Program, Health Law Perspectives 15:6 (with Kaitlyn Halesworth, September 2013)

Medi-Cal, The Exchanges, and Bridge Plans, Health Law Perspectives 15:2 (with Felicia Sze April 2013)

Smallpox Vaccination from Jenner to Jacobson: The Police Power, Individual Liberty, & Government Responsibility (for 2013 submission)

Gostin, Jacobson v. Massachusetts: The Police Power and Civil Liberties in Tension, in Health Law and Bioethics: Cases in Context (Richard Saver et al. eds., 2009, with Lawrence O.)

Contextualizing Personalized Medicine Evidence-Based Medicine in the Genomic Era, O'Neill Institute for National and Global Health Law Personalized Medicine Forum (Washington, DC, June 2008, Paper Presentation with Patricia A. King)

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PRACTICES

Administrative Law
Business Transactions
Clinical Research
Health Care Technology
Health Information Privacy & Security
Life Sciences
Pharmaceuticals
Telemedicine

EDUCATION

Amherst College, B.A., 1987, *magna cum laude*

Stanford Law School, J.D., 1990

- Law Review

BAR ADMISSIONS

1990, Pennsylvania

1995, California

Stephen K. Phillips is a corporate and health care regulatory partner with a particular focus on health care technology and privacy. He is the chair of the firm's Technology Practice Group and was selected for *Nightingale's Healthcare News*' list of Outstanding Healthcare IT Lawyers. His practice focuses on:

- Health care technology transactions, including drafting and negotiating:
  - SaaS, software licensing and related service agreements between health care technology companies and health care providers.
  - HIE licensing, participation and data sharing agreements and policies.
  - Terms of use/service, privacy and related user documentation.
- Compliance counseling, including:
  - Fraud and abuse investigations and self-disclosures.
  - Privacy and security compliance program development, review and training.
  - Privacy breach response and reporting.
  - Telemedicine and Web-based service design.
  - Medical, dental and other professional practice act restrictions, including corporate practice laws and scope of license restrictions.
  - GPO and supply chain purchasing strategy.
- Business transactions, including:
  - Mergers, acquisitions, strategic partnerships and outsourcing agreements.
  - Development of employer clinics and onsite health centers.
  - Physician and dental practice group and practice management company formations.
  - Provider-professional arrangements, including those for medical directorships, professional service and consulting arrangements.

Mr. Phillips received a B.A. degree from Amherst College, *magna cum laude*, and his J.D. from Stanford University. Mr. Phillips is admitted to the California and Pennsylvania State Bar.

Prior to joining the firm in September 2006, he was the General Counsel and Compliance Program Chair for Neoforma, a public health care supply chain management outsourcer, from December 2000-March 2006, and the Chief Operating Officer and General Counsel for eCliniq, a provider of Web-based clinical solutions for heart care physicians, from July 1999-November 2000. Before joining eCliniq, he practiced corporate and health care law at several leading law firms, the most recent of which was Latham & Watkins from June 1996-June 1999.

Representative Matters

Development of onsite medical clinics for Cisco Systems.

Representation of major California hospital system in fraud and abuse investigations and OIG self-disclosures.

Representation of AIDS Healthcare Foundation in its acquisition of MOMS Pharmacy.

Representation of Coast Plaza Doctors Hospital in its sale to Avanti Hospitals.

Negotiation on behalf of the California Prison Healthcare Receivership of a clinical data repository and portal solution agreement with IBM, Oracle, Orion Health and Initiate Systems.

Representation of acute care hospitals, SNFs, professional medical corporations, dialysis facility, home health agency and private duty nursing companies in private acquisitions.

Representation of large primary care medical group in negotiations with prominent West Coast health system for establishment of medical foundation.

Representation of California hospital district in establishment of outpatient clinic and related physician practice acquisitions.

Representation of life science and medical device companies in sponsorship of clinical trials.

Representation of surgeon-owned implant development and distribution companies in formation, syndication and intellectual property development.

$200 million merger of Neoforma, Inc. and Global Health Exchange, LLC.

$5.6 million Series A venture capital financing for eCliniq Corp.

$600 million Outsourcing Agreement among Neoforma, VHA, Inc., University HealthSystem Consortium (UHC), HPPI and Novation LLC.

Stephen K. Phillips

Professional Affiliations

- American Bar Association*, Health Law Section*
- American Health Lawyers Association
- California Society of Healthcare Attorneys, *Immediate Past-President and Board Member*

Presentations & Speaking Engagements

Northeast Telehealth Resource Center's Northeast Regional Telehealth Conference
Portland, ME, June 5-6, 2018

California Hospice and Palliative Care Association 2017 Annual Conference
Palm Springs, CA, October 9, 2017

Healthcare Supply Chain Compliance: Minimizing Regulatory and Contractual Liability Risk
Webinar, May 31, 2017

HLB Webinar Recording Now Available: Privacy Breaches - How to Prepare and Respond
May 7, 2015

HLB Webinar: Privacy Breaches - How to Prepare and Respond
Webinar, May 7, 2015

HLB Webinar Recording Now Available: Technology Contracts: From Negotiation to Litigation with Your HIT Vendor (November 18, 2014)
November 18, 2014

HLB Webinar Recording Now Available: Managing the New HIE Environment: Privacy and Security Considerations for Providers (June 26, 2014)
June 26, 2014

News

Connecticut Permits Prescribing Limited Controlled Substances via Telemedicine
July 5, 2018

California Governor Signs Far-Reaching Consumer Privacy Legislation
July 2, 2018

The OIG Acts on Telehealth
June 21, 2018

Stephen K. Phillips

Proposed Massachusetts Legislation Aims to Contain Health Care Costs: Highlights for Providers
October 25, 2017

Managing Substance Use Disorder Information in ACOs and HIEs under Revised Part 2 Regs
October 24, 2017

HHS Issues Revised Rule on Confidentiality of Substance Abuse Records
January 25, 2017

HHS Proposes Revisions to Rules Governing Confidentiality of Substance Use Disorder Records
February 9, 2016

Proposed Meaningful Use Stage 3 Measures Available for Comment
March 25, 2015

Anthem Breach Spawns Lawsuits
February 12, 2015

Malware Attack Exposes Security Flaws, Leads to $150,000 HIPAA Breach Settlement
December 17, 2014

Meaningful Use, Stage 3: Competing Visions for “Interoperability,” and Continuing Criticism
October 20, 2014

CMS Provides Flexibility in Certified EHR Technology for 2014
September 4, 2014

California Court of Appeal Dismisses Claim based on Theft of Computer
July 28, 2014

September 23 Deadline to Comply with the New HITECH Regulations Is Fast Approaching
August 23, 2013

Health Law Perspectives

Ready or Not, EU’s General Data Protection Regulation (GDPR) Is Here
Health Law Perspectives , June 2018

Health Law Perspectives, June 2018
June 2018

Other Publications

INSIGHT: General Data Protection Regulation Applicability to the U.S. Healthcare Industry
Bloomberg Law, August 17, 2018

Publications

Issues in Negotiating Healthcare Technology Agreements, CSHA Annual Spring Meeting. (April, 2016).

Social Networking for Hospitals, Hospital Council of Northern and Central California. (June 2011).

Electronic Health Records: The $63,000 Question, CSHA Annual Spring Meeting. (April, 2011).

Stark Fundamentals, CSHA Annual Spring Meeting. (April 24, 2009).

New Privacy & Security Legislation: California's AB 211 & SB 541 and HITECH's HIPAA Amendments, CAHF Legislative Conference (March 30, 2009).

Privacy/HIPAA Legislation, HFMA PFS Roadshow in Nevada (March 27, 2009).

Pork, Penalties, and Privacy: How to Get Paid Under the HITECH ACT Without Getting Burned, Health Law Perspectives. (March 2009).

New Privacy Legislation: AB 211 & SB 541, HFMA PFS Roadshow in Sacramento. (January 9, 2009).

Stark Law Update, CHA Compliance Seminar. (December 11, 2008).

Tax Exemption Issues, CHA Compliance Seminar. (December 11, 2008).

Knox-Keene Licensure: Is It Right for Your Organization, CAPG. (November 4, 2008).

1206(d) and Medical Foundations: Regulatory Issues, Hooper, Lundy & Bookman Seminar. (September 23, 2008).

Connecting Californian to Their Medical Record: Legal Issues and Approaches, CSHA. (November 2, 2007).

Supply Chain Reengineering and Software Purchasing, CAHF. (Summer 2007).

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Confidentiality and Privacy Issues in Telemedicine, Bender's Health Care Law Monthly. (November 1996).

Information Systems and Physician Profiling in Managed Care, California Health Law News. (Fall 1995).

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PRACTICES

- Accountable Care/Hospital-Physician Integration
- Administrative Law
- Alternative Dispute Resolution
- Antitrust and Unfair Business Practices
- Behavioral Health & Community-Based Care
- Compliance
- False Claims Act
- Fraud & Abuse, Stark, Anti-Kickback Counseling and Defense
- Government Relations & Public Policy
- Litigation, Mediation, Arbitration
- Managed Care
- Medicare, Medicaid, Other Governmental Reimbursement & Payment
- Post-Acute and Long-Term Care Services & Supports
- Provider & Supplier Operations
- Recovery Audit Contractor (RAC) Appeals

EDUCATION

Stanford University, B.A., 1983

Mark E. Reagan is the Managing Shareholder of Hooper, Lundy & Bookman, P. C., the largest full service law practice in the country dedicated solely to the representation of health care providers. He is also a member of the firm's Fraud & Abuse Practice Group.

Throughout his legal career, he has represented long-term care facilities, hospitals, physician groups, home health agencies, hospices, medical product suppliers, trade associations, and other health-related entities in California and in numerous other states. His practice is devoted to counseling, litigation and trial and appellate work, before administrative agencies and all courts, with an emphasis on health care issues, including long-term care, managed care, health care fraud and elder abuse, licensing and certification, Medicare and Medicaid, false claims, anti trust, unfair competition, workers' compensation reimbursement, risk management and corporate compliance. He frequently testifies before the California State Legislature on these and other health related matters and assists clients with legislation and regulatory enactments.

Mr. Reagan serves as General Counsel to the California Association of Health Facilities, and the Massachusetts Senior Care Association, each the largest trade association primarily serving the long-term care profession in their respective states. He serves on the Legal Committee for the American Health Care Association, and was the chair of that group from 2006 through 2009. Mr. Reagan is a board member of the American Board of Medical Quality.

Mr. Reagan has handled numerous Medicare and Medicaid reimbursement/audit matters on behalf of health care providers and has assisted his clients in obtaining recoveries in excess of $300 million. He has been representing the long-term care industry in California in Medicaid rate litigation since 1990. He has handled numerous such Medicaid matters on behalf of the California Association of Health Facilities and has represented a consortium of skilled nursing facilities

Loyola Law School, J.D., 1989

BAR ADMISSIONS

1989, California

2017, Massachusetts

in Washington challenging Medicaid rate cuts. To date, he has handled 10 separate cases challenging the Medicaid rates and timeliness of payment made to these facilities. Seven of the 10 have resulted in successful injunctions and/or judgments.

He has also handled several false claims cases to successful conclusions, including *U.S. ex rel. Swan v. Covenant Care, Inc.,* 279 F.Supp.2d 1212, 1217 (E. D. Cal. 2002), in which the Court held that regulatory violations and other "quality of care" concerns cannot give rise to false claims liability as to skilled nursing facilities participating in the Medicare program. Mr. Reagan has had a number of published decisions throughout his career within the California appellate courts and Supreme Court as well as the United States District Courts and the Ninth Circuit Court of Appeals

Mr. Reagan is also a nationally recognized speaker, instructor and author on health related topics.

He received his B.A. degree in Economics and Communication from Stanford University in 1983. In 1989, he received his J.D. from Loyola Law School, Loyola Marymount University and was admitted to the California Bar that same year.

Representative Matters

Lemaire v. Covenant Care California, LLC, 234 Cal. App. 4th 860 (2015)

Plott Nursing Home v. Burwell, 779 F.3d 975 (9th Cir., 2015)

Valley View Health Care, Inc. v. Chapman, 992 F.Supp.2d 1016, E.D. Cal. (2014)

Nevarrez v. San Marino Skilled Nursing and Wellness Centre, 221 Cal. App. 4th 102 (2013)

Ruiz v. Podolsky, 50 Cal. 4th 838 (2010);

Alvarado v. Selma Convalescent Hosp., 153 Cal.App.4th 1292 (2007);

Hogan v. Country Villa Health Services, 148 Cal.App. 4th 259 (2007);

People v. Davis, 126 Cal.App.4th 1416 (2005);

Chamber of Commerce of U.S. v. Lockyer, 422 F.3d 973 (9th Cir. 2005);

Chamber of Commerce of U.S. v. Lockyer, 364 F.3d 1154 (9th Cir. 2004);

Covenant Care, Inc. v. Superior Court, 32 Cal.4th 771 (2004);

Chamber of Commerce of U.S. v. Lockyer, 225 F. Supp.2d 1199 (C.D. Cal 2002);

U.S. ex rel. Swan v. Covenant Care, Inc., 279 F.Supp .2d 1212 (E.D. Cal 2002);

Delaney v. Baker, 20 Cal.4th 23 (1999);

California Assn. of Health Facilities v. Department of Health Services, 16 Cal.4th 284 (1997).

Professional Affiliations

- American Board of Medical Quality
- American Health Care Association - *Past Chair and Member of Legal Committee, Member of Finance Committee, Serve on the Managed Care and Alternative Payment Model Subcommittees of the Finance Committee*
- American Health Lawyers Association
- California Association of Health Facilities (General Counsel)
- California Society for Healthcare Attorneys

Honors & Awards

- Martindale-Hubbell, AV Rated
- Recognized as a Northern California Super Lawyer from 2012-2018

Presentations & Speaking Engagements

HCCA's 23rd Annual Compliance Institute
Boston, MA, April 7-10, 2019

AHCA/NCAL 69th Annual Convention & Expo
CEO, Senior Executive, and Independent Owner Breakfast Program - (by invitation only)
San Diego, CA, October 7-10, 2018

AHCA/NCAL 69th Annual Convention & Expo, San Diego Convention Center
San Diego, October 7-10, 2018

Emerging Post-Acute Strategies: Managing the Transition from Acute to Post-Acute Care (Los Angeles)
LAX Westin, June 6, 2018

2018 California Society for Healthcare Risk Management Annual Conference
Napa, CA, March 7, 2018

CAHF Region IV Annual Leadership Meeting
Carson, CA, September 7, 2017

HLB Webinar Recording Now Available: SGR Legislation - Key Implications for Providers
April 23, 2015

HLB Webinar: SGR Legislation - Key Implications for Providers
Webinar, April 23, 2015

CAHF Annual Conference
Palm Springs, CA, November 10-12, 2014

AHLA Annual Meeting
New York, NY, June 29, 2014 - July 2, 2014

CAHF Spring Legislative Conference, Sacramento
March 17, 2014

AHCA Independent Owners Leadership Conference, Las Vegas
March 14, 2014

Long Term Care & The Law Conference, Las Vegas
February 19, 2014

News

Proposed CMS SNF Program Changes Dramatically Alter Current Reimbursement Methodologies
May 2, 2018

HLB Post-Acute/Long-Term Care Practice Chair Mark Reagan Admitted to the Massachusetts Bar
November 2, 2017

Proposed Massachusetts Legislation Aims to Contain Health Care Costs: Highlights for Providers
October 25, 2017

Senate Moves to Proceed on Affordable Care Act Repeal Legislation
July 26, 2017

The Better Care Reconciliation Act of 2017 - A First Look
June 23, 2017

At a Glance: What Providers Need to Know About the Medicaid Managed Care Final Rule
April 27, 2016

CMS Finalizes 60-Day Report and Repayment Rule
February 11, 2016

Ready or Not: *Here Comes the Joint Replacement Program*
February 10, 2016

Numbers Never Lie ... Or Do They? The Use Of Statistical Sampling In False Claims Act Cases
October 15, 2015
Health Law Perspectives

Legal 500 Ranks HLB as a Top Health Law Service Provider in the U.S.
June 15, 2015

What Health Care Providers Need to Know Today About Newly-Proposed Medicaid Managed Care Regulation
June 5, 2015

Armstrong Supreme Court Decision
April 1, 2015

U.S. Supreme Court Determines that Providers Cannot Challenge Medicaid Rates under 42 U.S.C. Section 1396a (a)(30)(A)
April 1, 2015

Armstrong Supreme Court Decision - Comprehensive Summary
April 1, 2015

CCI, Cal MediConnect & Managed Care: What Providers Need to Know Today
May 9, 2014

Health Law Perspectives

Health Law Perspectives, June 2018
June 2018

Proposed Massachusetts Legislation Aims to Contain Health Care Costs: Highlights for Providers
Health Law Perspectives, October 15, 2017

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PRACTICES

Compliance

False Claims Act

Fraud & Abuse, Stark, Anti-Kickback Counseling and Defense

Life Sciences

Medicare, Medicaid, Other Governmental Reimbursement & Payment

Pharmaceuticals

White Collar Criminal Defense

EDUCATION

Syracuse University, B.A. Political Science and Journalism 1993, *Magna cum laude,* Phi Beta Kappa

University of Virginia School of Law, J.D. 2000, William Minor Lyle Moot Court Semifinalist, Bracewell & Patterson Award for Outstanding Oral Advocacy, Journal of Law and Politics editorial staff

BAR ADMISSIONS

Massachusetts, First Circuit

District of Massachusetts

David Schumacher is a partner in Hooper, Lundy & Bookman's Boston Office. He focuses his practice on criminal defense, fraud & abuse compliance and defense, as well as other health care enforcement actions. He is a member of the firm's Fraud & Abuse Practice Group.

Mr. Schumacher was previously deputy chief of the Health Care Fraud Unit in the U.S. Attorney's Office for the District of Massachusetts. During his eight-year tenure as a federal prosecutor, Mr. Schumacher investigated some of the largest and most complicated health care fraud cases in the country. Mr. Schumacher investigated pharmaceutical and medical device companies, home health care organizations, medical equipment companies, laboratories, physicians, and other health care providers, in cases involving violations of the federal health care fraud statute, False Claims Act, Anti-Kickback Law, HIPAA criminal violations, and the Food, Drug and Cosmetic Act.

As a result of his investigations, Mr. Schumacher returned hundreds of millions of dollars to the federal government and convicted dozens of individuals of health care fraud charges, including several convictions following jury trials. Prior to joining the U.S. Attorney's Office, Mr. Schumacher practiced at one of the largest law firms in Boston, focusing his practice on white collar criminal defense and commercial litigation. Mr. Schumacher also spent six months as a Special Assistant District Attorney in Middlesex County.

Through his experience, Mr. Schumacher is uniquely qualified to represent health care provider organizations and individuals in the most complex investigations and prosecutions. Mr. Schumacher's experience is invaluable to clients in need of representation before state and federal regulatory and law enforcement agencies and departments. He is well-positioned to defend clients under investigation by the Department of Justice and U.S. Attorney's Offices, state Attorneys General, and federal agencies. Mr. Schumacher also has extensive experience litigating

qui tam whistleblower actions and conducting internal investigations. He is also available to provide compliance advice to health care providers and assist with the development of compliance plans.

Professional Affiliations

- Boston Bar Association, Health Law Committee, White Collar Crime Section Steering Committee

Honors & Awards

- Massachusetts *Super Lawyer* (2018)

Presentations & Speaking Engagements

HCCA's 23rd Annual Compliance Institute
Boston, MA, April 7-10, 2019

Massachusetts Hospice Association Annual Meeting
November 8, 2018

HCCA 4th Annual Healthcare Enforcement Compliance Conference
Washington, DC, November 4-7, 2018

CLE Healthcare Fraud & Abuse
Boston MA, October 1, 2018

American Health Lawyers Association 2018 Annual Meeting
Chicago, IL, June 25-27, 2018

New England Home Health & Hospice Conference and Trade Show
Neddick, ME, April 25-27, 2018

American Conference Institute 18th Annual Forum on Fraud and Abuse
Boston, MA, March 5-6, 2018

American Conference Institute 5th Advanced Forum on False Claims & Qui Tam Enforcement Conference
New York, NY, January 30, 2018

White Collar Crime Conference
Boston, MA, January 18, 2018

2017 Hospice & Palliative Care Federation of Massachusetts Education Conference
Norwood, MA, November 9, 2017

BHC 2017 Annual Conference on Current Healthcare Developments
Las Vegas, NV, November 2-3, 2017

Health Care Compliance Association's 3rd Annual Healthcare Enforcement Compliance Institute
Washington, D.C., October 29 - November 1, 2017

Hooper, Lundy & Bookman, P.C. and FTI Consulting, Inc. Present: 2017 Health Care Fraud & Abuse Update Seminar
Boston, MA, October 12, 2017

Hooper, Lundy & Bookman, P.C. and FTI Consulting, Inc. Present: 2017 Health Care Fraud & Abuse Update Seminar
Los Angeles, CA, October 5, 2017

Boston Regional HCCA Conference
Boston, MA, September 8, 2017

American Health Lawyers Association Annual Meeting
San Francisco, CA, June 28, 2017

Boston Bar Association Health Care Fraud Conference
Boston, MA, May 9, 2017

News

Healey Complaint Seeks Damages From Purdue Pharma
January 16, 2019
The Morning Edition - National Public Radio

David Schumacher Was Quoted in the Following Article: DOJ Moves to Dismiss 11 FCA Suits With Same Relators Alleging Nurse Educators Are Kickbacks
December 24, 2018
Report on Medicare Coompliance

David Schumacher Was Quoted in the Following Article: Caregivers or Marketers? Nurses Paid by Drug Companies Facing Scrutiny as Whistleblower Lawsuits Mount
October 2, 2018
STAT

David Schumacher Was Quoted in the Following Article: Trump Confronted with 'Unprecedented' Legal Issues After Cohen's 'Earth-Shattering' Plea, Lawyers Say
August 22, 2018
Boston Globe

David S. Schumacher

Payment Code Change May Hinder Medicare Whistleblowers
August 21, 2018
BNA Health Care Daily Report

Outside Law Firms See Boston as Market of Opportunity
November 2017
New England In-House

Without Motive, Murder Hard To Prove In Meningitis Trials
October 31, 2017
Health Law 360

What To Watch For In 2nd Meningitis Murder Case
September 18, 2017
Health Law 360

Pharmacist in Deadly Meningitis Outbreak Heading to Trial
September 17, 2017
Boston Globe (AP)

Judge Told Jurors In Meningitis Outbreak Case To Be Unanimous — But Verdict Form Shows Division
May 15, 2017
WBUR

NECC Verdict Could Serve as Blueprint for Other Trials
March 24, 2017
Boston Globe

Verdict Form Reveals Close Call In Meningitis Murder Case
March 23, 2017
Health Law 360

Pain Doctor Who Prescribed Large Amounts of Oxycodone Pleads Guilty to Fraud
March 16, 2017
Boston Globe

What Could Bermuda's Legal Strategy Against Lahey Clinic Be?
February 16, 2017
Boston Globe

Hooper, Lundy Adds DOJ Health Fraud Deputy in Boston
January 25, 2017
Health Law 360

Hooper, Lundy & Bookman Opens Boston Office
January 18, 2017

Publications

- *When Does a Health Care Case Go Criminal?,* American Health Lawyers Association 2018 Annual Meeting (June 25, 2018)
- *More Than Just Paperwork: Prior Authorizations, The Latest Enforcement Risk,* BNA Health Law Reporter (October 5, 2017)
- *Health Care Fraud Enforcement-A View From the Trenches*, American Health Lawyers Association 2017 Annual Meeting (June 28, 2017)
- *Recent Federal Law Enforcement Efforts to Combat Opioid Crisis*, American Health Lawyers Association, E-Alert (February 14, 2017)
- *Federal and State Enforcement*, MCLE New England, Massachusetts Health and Hospital Law Manual (2014, 2016, 2017)
- *Individual Accountability in Health Care Fraud Investigations*, U. S. Department of Justice, United States Attorney's Office Bulletin (November 2016)

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Health Care Technology

Medicare, Medicaid, Other Governmental Reimbursement & Payment

Telemedicine

EDUCATION

Brandeis University, B.A. *cum laude,* 2010

Boston College Law School, J.D., 2014

The George Washington University Law School, LL.M. Health Care Law, 2015

BAR ADMISSIONS

2014, Massachusetts

2014, Maryland

2016, Washington, D.C.

Jeremy Sherer is an associate in the Business Department of Hooper, Lundy & Bookman's Boston office. The broad focus of his practice integrates the transactional and regulatory components of health care law, with a particular emphasis on health care IT issues, including telemedicine.

Mr. Sherer has experience counseling clients on telemedicine implementation and reimbursement, accountable care/ACO issues, health information privacy and security, and mergers, acquisitions and other strategic affiliations. He also advises clients on compliance with Federal fraud and abuse statutes (the "Stark" Law, the "Anti-Kickback Statute," and the False Claims Act) and their state counterparts, as well as overpayment appeals and investigations.

Mr. Sherer received his B.A. *cum laude* in Politics from Brandeis University in 2010. He received his J.D. from Boston College Law School in 2014, where he was the Managing Editor of the *Boston College Law and Religion Program* and a quarterfinalist in the National Religious Freedom Moot Court Competition. During law school, he held internships with the U.S. Department of Health and Human Services Region I Office of the General Counsel in Boston, the Massachusetts Executive Office of Health and Human Services, and the Office of the Maryland Attorney General. He received his LL.M. in Health Care Law from The George Washington University Law School in 2015, where he was a research assistant to Professor Sara Rosenbaum.

Mr. Sherer was previously an associate in the health care group of Dentons US LLP in Washington, D.C.

Representative Matters

- CMS Appeal: Draft and file requests for redetermination and reconsideration on behalf of provider client in response to demand letters alleging CMS issued

overpayments to provider.

- Regulatory Opinion: Draft opinion letter for hospital system explaining updates to provider-based reimbursement standards and reimbursement implications for a specific facility.
- Compliance Audit and Investigation: Perform thorough compliance audit and FCA investigation for large medical device manufacturer, conduct on-site interviews, draft portion of audit report.
- State Law Analysis: Perform 20 state-specific analyses on the permissibility of using electronic signatures on Professional Services Agreements and evaluate potential Stark Law implications.
- Telemedicine Counsel: Counsel one of the nation's largest hospital systems on state-level telemedicine developments including scope of practice, physician-patient relationship establishment, and midlevel practitioner reimbursement issues.
- State Risk Assessment: Evaluate risk of opening substance abuse treatment facilities in six states by analyzing SAMHSA standards, state corporate practice of medicine, licensure and fee-splitting issues.

Professional Affiliations

- Boston Bar Association Health Law Section, Education Committee 2017-2018
- Boston College Law School GOLD Alumni Council
- Brandeis University Alumni Lawyers Steering Committee

Honors & Awards

- Named one of "12 Health Care IT Law Attorneys You Should Know" by Health Data Management, 2018
- *Super Lawyers*® "Rising Star," Health Care Law (2017, 2018)

Presentations & Speaking Engagements

HCCA's 23rd Annual Compliance Institute
Boston, MA, April 7-10, 2019

ABA 20th Annual Emerging Issues in Healthcare Law Conference
Orlando, FL, March 13-16, 2019

ABA 16th Annual Washington Health Law Summit
Washington, DC, December 10-11, 2018

4th Annual North Country Telemedicine Conference
Glens Falls, NY, November 7, 2018

Biomedical Informatics Bootcamp: Telehealth & Data Analytics of the Future - 2018
Stony Brook, NY, October 12, 2018

Boston Bar Association CLE: Telemedicine Today
Boston, MA, September 26, 2018

Northeast Telehealth Resource Center's Northeast Regional Telehealth Conference
Portland, ME, June 5-6, 2018

Boston Bar Association: Health Law Basics for New Lawyers
Boston, MA, March 16, 2018

News

CMS Overhauls Medicare ACOs
December 26, 2018

Telehealth Faces Legal Obstacles Before It Can Take Off
November 19, 2018
Bloomberg Law

President Trump signs the SUPPORT for Patients and Communities Act (H.R. 6)
October 26, 2018

Telehealth Updates - California
September 25, 2018

HHS-OIG Seeks Comments on Value-Based Care, AKS and CMP
August 31, 2018

CMS Proposes Changes to Telehealth Reimbursement, Stark, Substance Use Disorder Treatment Reimbursement, and Evaluation & Management Reimbursement in the CY 2019 Physician Fee Schedule Proposed Rule
July 14, 2018

Connecticut Permits Prescribing Limited Controlled Substances via Telemedicine
July 5, 2018

The OIG Acts on Telehealth
June 21, 2018

Kentucky Passes Telehealth Legislation
May 16, 2018
HLB Health IT Blog

Telemedicine Facing Increased Government Security
April 19, 2018
Bloomberg Law

Cyber Extortion Schemes Undermining Patient Care
February 8, 2018
BNA Health Care Daily Report

Texas Telemedicine Update: Texas Dispute with Teladoc Leads to Revisions to Telemedicine Clinical and Reimbursement Standards
December 11, 2017

How CVS and Aetna Can Use Data to Reduce Healthcare Costs
December 6, 2017
Digital Insurance

Jeremy Sherer Named Top Health Care IT Attorney by Health Data Management
November 20, 2017

Health Law Perspectives

Ready or Not, EU's General Data Protection Regulation (GDPR) Is Here
Health Law Perspectives , June 2018

Significant MassHealth Reform Commencing March 1, 2018
Health Law Perspectives, February 2018

Proposed Massachusetts Legislation Aims to Contain Health Care Costs: Highlights for Providers
Health Law Perspectives, October 15, 2017

Other Publications

Telemedicine in Massachusetts: An Update, Digital Health Legal, Vol. 5, Issue 10 (October 2018)
Telemedicine in Massachusetts: An Update
October 1, 2018

CMS Proposes to Expand Telehealth Reimbursement Under Medicare
ABA Health Law eSource, September 2018

Publications

- *Telemedicine Can Help to Combat Opioid Epidemic*, The Daily Journal (July 23, 2018)
- *Privacy Compliance Highlights from 2017 – What Providers Should Know,* Healthcare Financial Management Association Advisor, Vol. XLV, No. 3 (June 2018)

Jeremy D. Sherer

- *Health Law Basics for Massachusetts Lawyers,* New England In-House (November 2017)
- *More Than Just Paperwork: Prior Authorizations, the Latest Enforcement Risk*, Bloomberg BNA Health Law Reporter, 26 HLR 1441 (October 5, 2017)
- *Fraud, Abuse, and the Value-Based Payment Regime: Is New Thinking Needed?* American Bar Association Litigation Section, Summer 2016, Vol. 16 No. 4 (September 13, 2016)
- *DOJ Targets Individuals for Violations of False Claims Act and Anti-Kickback Statute,* Journal of Health Care Compliance, Vol. 18, No. 4 (July - August 2016) (co-author)
- *Value Based Reimbursement: The Rock Thrown into the Healthcare Pond,* Health Affairs Blog (July 8, 2016)
- *IRS ACO Ruling Analysis for NAACOS Members*, National Association of Accountable Care Organizations (June 10, 2016) (co-author)
- *The ACA 60-Day Overpayment Rule and Related Compliance Challenges*, Journal of Health Care Compliance, Vol. 17, No. 6 (November - December 2015)
- *DOJ Issues Memorandum on Individual Accountability for Corporate Wrongdoing: Implications for the Health Care Industry,* AHLA E-Alert (September 22, 2015)
- *Navigating CMS' Tangled Web of Stark Law Interpretation,* Law 360 (July 22, 2015) (co-author)

Other Material

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HEALTH CARE LAWYERS & ADVISORS

New All-Payor Kickback Statute: Eliminating Kickbacks in Recovery Act of 2018

ATTORNEYS

Alicia Macklin

PRACTICES

Academic Medicine

Administrative Law

Behavioral Health & Community-Based Care

Business Transactions

Compliance

Fraud & Abuse, Stark, Anti-Kickback Counseling and Defense

Medical Education

Medical Staff Operations & Disputes

Real Estate

Alicia Macklin
January 30, 2019

The federal opioids law (the "SUPPORT Act"),[1] signed by President Trump on October 24, 2018, covered a myriad of issues. Thus, it may have been easy to overlook a dramatic change to the fraud and abuse landscape – a new drug anti-kickback statute, the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") – that was included in the SUPPORT Act.

EKRA was originally proposed by Senators Marco Rubio (R-Fla) and Amy Klobuchar (D-Minn.) in an effort to target patient brokers who recruit patients for addiction treatment centers and receive payment in return. However, as discussed below, EKRA also expands potential criminal liability for remuneration to patients, as well as payments to third parties for referrals. And, this new federal anti-kickback statute is applicable to all payors, not just Federal payors. Thus, all providers must now keep EKRA in mind when structuring certain arrangements related to substance use treatment, and in reviewing existing arrangements.

What does the statute prohibit?

EKRA is an anti-kickback statute applicable to services covered by all payors and prohibits soliciting, receiving, paying or offering any remuneration, directly or indirectly, overtly or covertly, in cash or in kind,

1. in return for or to induce referrals to a recovery home, clinical treatment facility, or laboratory, or
2. "in exchange for an individual using the services of" a recovery home, clinical treatment facility, or laboratory.

A "clinical treatment facility" is defined as a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law. A "recovery home" is defined as a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders. Finally, the term "laboratory" is not limited

in any way to those laboratories involved in substance use disorder treatment, but rather, is broadly defined to encompass all laboratory facilities.

A violation of EKRA can result in a fine of up to $200,000, or imprisonment for 10 years, or both, for *each* occurrence.

Are there any exceptions to EKRA?

EKRA includes seven statutory exceptions and allows the Attorney General, in consultation with the Secretary of Health and Human Services, to create additional exceptions by regulation. The current statutory exceptions both track, and differ from, the Medicare and Medicaid anti-kickback statute ("AKS") exceptions and safe harbors.

Exceptions that mirror the AKS safe harbors

The majority of exceptions under EKRA are similar to AKS safe harbors –

1. **General Discounts**. Discounts obtained by providers if the reduction in price is disclosed and reflected in the costs claimed or charges made by the provider, under a health care benefit program.
2. **Special Discounts.** Discounts in the price of an applicable drug that is furnished to a beneficiary under the Medicare coverage gap discount program.
3. **Federally Qualified Health Centers ("FQHCs").** EKRA adopts, through cross-reference, the AKS's exception for remuneration between FQHCs and any individual or entity providing goods, items, services, donations, loans, etc. pursuant to a written agreement that contributes to the ability of the FQHC to maintain or increase the availability of services provided to a medically underserved population served by the health center entity.
4. **Personal Services and Management Contracts.** EKRA adopts, through cross-reference, the AKS's personal services and management contracts safe harbor.
5. **Patient Copayments or Coinsurance**. Waivers of copayment or coinsurance so long as such waivers are not routinely provided and are provided in good faith.

Exceptions that Differ from AKS safe harbors

EKRA includes a compensation exception, similar to the AKS, for certain bona fide employment and independent contractor arrangements. However, unlike the AKS, the EKRA exception requires that compensation not be determined by, or vary with, (1) referrals to a particular recovery home, clinical treatment facility, or laboratory; (2) the number of tests or procedures performed; or, (3) the amount billed or received from the health care benefit program. Until further regulatory guidance is provided, EKRA does not appear to permit productivity or incentive-based compensation tied to business generation.

"New" Exceptions

Finally, EKRA includes a new "alternative payment model" exception that is not found in the AKS safe harbors. This exception allows for payments made pursuant to an alternative payment model or pursuant to a payment arrangement used by a State, health insurance issuer, or group health plan if HHS has determined that such arrangement is necessary for care coordination or value-based case. Alternative payment models refer to (1) the shared savings program under Section 1899 of the Social Security Act, (2) a model created by the Center for Medicare and Medicaid Innovation other than a health care innovation award, (3) a demonstration under the Health Care Quality Demonstration Program, or (4) a demonstration required by federal law.

What are the implications of this new anti-kickback statute?

As mentioned above, perhaps the most important takeaway from EKRA is the expansion of potential criminal liability for kickbacks related to all payors (including, arguably under an expansive reading of the statute, even self-pay patients), not just federal healthcare payors. This expansion, coupled with EKRA's application to remuneration to patients, means that EKRA potentially implicates many common industry practices, such as assisting patients with transportation to a treatment facility, or routine waivers of coinsurance or copayments. In addition to applying to all payors, as written, EKRA is applicable to all laboratories, not just those working with substance use treatment facilities.

Given that EKRA is new, and there have been no enforcement actions or clarifying regulations promulgated to date, the statute's true impact is yet to be determined. Further, while EKRA provides that its prohibitions do not apply to conduct prohibited under the AKS, the statute does not address the federal AKS's safe harbors. Thus, it is unclear how a particular agency will reconcile the safe harbors with the EKRA exceptions.

It is important to keep EKRA in mind when structuring arrangements in the substance use disorder context (or arrangements involving clinical laboratories) and to reevaluate existing relationships with clinical treatment facilities, recovery homes, and laboratories. Hooper, Lundy & Bookman will continue to closely follow EKRA, its enforcement, and related regulations to determine the ultimate impact of the new drug anti-kickback statute.

To learn more about this issue, please contact Alicia Macklin at 310.551.8161 in the Los Angeles office, or your regular Hooper, Lundy & Bookman contact.

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[1] Shortly after the bill was signed into law, HLB issued a high-level summary of the Act.

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HIPAA RFI - HHS Office of Civil Rights Seeks Input on HIPAA Changes

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Amy Joseph and Alicia Macklin
January 30, 2019

On December 14, 2018, the Department of Health and Human Services ("HHS") issued a request for information ("RFI"), asking for feedback on how to change certain regulations issued pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"). The RFI seeks information on how best to remove obstacles to efficient care coordination while also protecting patients' health information, as well as how to encourage providers to share information for treatment and care coordination, making it easier to share information with parents and caregivers in dealing with the opioid crisis. Comments or information regarding changes to the HIPAA regulations must be submitted to HHS on or before February 12, 2019. Then, the agency will still need to go through the regulatory rulemaking process to implement any proposed changes after the RFI process is complete.

Specifically, the RFI requests comments and information on a number of potential changes to the HIPAA Privacy Rule, including changes that:

- encourage, incentivize, or require covered entities to disclose PHI to other covered entities;
- encourage covered entities, particularly providers, to share treatment information with parents, loved ones, and caregivers of adults facing health emergencies, with a particular focus on the opioid crisis and individuals with serious mental illness;
- seek to minimize regulatory burdens and disincentives to the adoption and use of interoperable EHRs, while still providing helpful information to individuals regarding disclosures of PHI; and
- eliminate or modify the requirement for covered entities to make a good faith effort to obtain individuals' written acknowledgment of receipt of providers' Notice of Privacy Practices.

While the RFI touches upon some care coordination issues present in the opioid epidemic context (such as coordination between multi-disciplinary teams and between substance abuse providers), the contemplated changes are only to

HIPAA RFI – HHS Office of Civil Rights Seeks Input on HIPAA Changes

HIPAA, and not 42 CFR part 2, the regulations that govern the confidentiality of alcohol and drug abuse patient records. However, HHS recently announced that it also intends to release a notice of proposed rulemaking on broad changes to 42 CFR part 2 to remove barriers to coordinated care and permit additional sharing of information among providers. That notice of proposed rulemaking is expected in March 2019. This move was likely triggered by a failed bill in Congress that would have aligned 42 CFR part 2 with HIPAA.

Regulatory Sprint to Coordinated Care

Notably, the HIPAA RFI discussed above follows on two other requests for information (or RFIs) issued this summer by CMS and the Office of Inspector General ("OIG"), as part of the Regulatory Sprint to Coordinated Care. In those RFIs, the applicable regulatory agencies acknowledged that current fraud and abuse laws may be potential barriers to value-based care and sought input regarding potential revisions to the federal physician self-referral statute (otherwise known as the Stark law), federal anti-kickback statute, and civil monetary penalties statute to better facilitate value based care.[1] Those RFIs along with this RFI, indicate a recognition by the federal government that some potentially unnecessary hurdles currently exist which may be hampering providers' ability to implement value-based care models or otherwise work together efficiently for care coordination of patients.

To learn more about this issue, please contact Amy Joseph at 617-532.2702 in the Boston office or Alicia Macklin at 310.551.8161 in the Los Angeles office or your regular Hooper, Lundy & Bookman contact.

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[1] Medicare Program; Request for Information Regarding Physician Self-Referral Law, 83 Fed. Reg. 29524 (June 25, 2018); Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 Fed. Reg. 43607 (Aug. 27, 2018).

President Trump signs the SUPPORT for Patients and Communities Act (H.R. 6)

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by Alicia Macklin, Jeremy Sherer, Andrea Frey, and Charles Oppenheim
October 26, 2018

On October 24, 2018, President Trump signed into law the bipartisan SUPPORT for Patients and Communities Act (H.R. 6 or the "Act"), which aims to combat opioid abuse with increased attention to treatment. The wide-reaching compromise legislation combines elements from a number of opioid bills, addressing issues from access to treatment and prevention programs to expanded law enforcement efforts to curtail drug trafficking. The Act, however, does omit several items that have been part of the national dialogue on opioid abuse. For example, it does not include amendments to 42 U.S.C. § 290dd-2 and the associated regulation at 42 C.F.R. Part 2 ("Part 2") that would align the Part 2 substance use treatment privacy law with the Health Insurance Portability and Accountability Act ("HIPAA") privacy rules to better facilitate the sharing of a patient's substance use disorder information among providers. In addition, the Act does not provide for a significant increase in spending for the opioid crisis.

This alert focuses on a number of key sections in the more than 600-page Act that are of particular relevance to providers and that illustrate the varied approach that Congress is taking to combat the opioid crisis. In particular, we have summarized below portions of the Act that address the federal Medicaid institutions for mental disease ("IMD") exclusion, Medicaid and Medicare coverage for medication assisted treatment ("MAT"), Medicaid and Medicare coverage for telehealth addiction treatment services, and the Act's new drug recovery anti-kickback provisions. We will continue to monitor the promulgation of regulations pursuant to the Act, as well as state initiatives and waivers that seek to take advantage of particular provisions of the Act.

Access to Substance Use Disorder Treatment Information (Sections 7051, 7052, and 7053)

The Act includes an iteration of "Jessie's Law," which promotes provider education and the development of best practices with regard to care coordination and privacy for patients with a substance use disorder history. Named for a Michigan woman in recovery from an opioid addiction who overdosed after a post-surgical oxycodone prescription, Jessie's Law requires HHS to develop best

practices for prominently displaying substance use disorder treatment information in electronic health records when requested by patients. HHS is also required to notify providers annually regarding permitted disclosures to family members, caregivers, and health care providers during emergencies (including overdoses). Lastly, Jessie's Law tasks HHS with identifying model programs and materials to train and educate providers, patients and families regarding the permitted uses and disclosures of patient records related to treatment for substance use disorders.

The provision does not alter existing Part 2 confidentiality requirements for records relating to the identity, diagnosis, prognosis, or treatment maintained by a federally-assisted substance use disorder program. Many providers argue that the strict confidentiality requirements under the Part 2 regulations are outdated and negatively impact patients suffering from substance use disorders by preventing providers from seeing the whole picture in a patient's medical history. Although the Part 2 requirements remain intact under the Act, the debate over patient privacy and substance use disorder records will surely continue and some will continue to advocate for alignment of Part 2 requirements with HIPAA.

Federal Medicaid IMD Exclusion (Sections 1013, 5012, 5051, and 5052)

The Act limits the federal IMD exclusion, providing a new option for state Medicaid coverage of certain services provided to IMD patients. The IMD exclusion is a federal Medicaid restriction that prohibits federal financial participation ("FFP") for individuals, between the ages of 21 and 65 years, in an IMD. An IMD is a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services. The IMD exclusion was originally intended to discourage institutionalization of people with mental illness, but many argue that it exacerbates the nationwide shortage of treatment beds.

- Medicaid Managed Care Coverage. The Act codifies in statute current Medicaid rules that permit Medicaid managed care organizations to make payments for adult enrollees in an IMD for a short stay of no more than 15 days in lieu of other services.
- New State Option for Coverage. The Act also creates a new state option to provide coverage for IMD services up to 30 days a year for individuals in need of substance use treatment centers. States that exercise this option must meet certain requirements to receive FFP, and the option is set to expire on September 30, 2023. The potential impact of this provision is unclear because many states have already secured federal waivers for Medicaid inpatient substance abuse treatment. In California, for example, the state has waiver authority to use federal Medicaid funds to pay for two 90-day stays for adults and two 30-day stays for adolescents in an IMD, for the purpose of substance use treatment services. Finally, the Act directs the Medicaid and CHIP Payment and Access Commission ("MACPAC") to submit a report on Medicaid payment to IMDs to Congress.

Medication Assisted Treatment (Sections 1006, 1014, 2005, and 3201)

The Act includes a number of provisions aimed at increasing access to and coverage of MAT, which is the treatment of a substance use disorder with FDA-approved medications in combination with counseling and

behavioral therapies. And, the Act also directs MACPAC to submit a report on current utilization control policies applied to MAT for substance use treatment under state Medicaid programs. The aim of the report is to identify the limits that exist on access to MAT, such as limits on quantity or requirements for prior authorizations.

- Increase Number of MAT Providers. The Act seeks to increase access to MAT by expanding the group of health care practitioners that can prescribe or dispense controlled substances for MAT without being registered with the Drug Enforcement Administration ("MAT qualified providers"). Under current law, only physicians and, until 2021, nurse practitioners and physician assistants are potentially eligible to be MAT qualified practitioners. The Act will also permit clinical nurse specialists, certified nurse midwives, and certified RN anesthetists to be MAT qualified providers from Oct. 1, 2018 to October 1, 2023 and will make permanent the eligibility of nurse practitioners and physician assistants to be MAT qualified providers. In addition, the Act will permit MAT qualified practitioners to immediately treat 100 patients at a time if board certified in addiction medicine or addiction psychiatry or in a qualified practice setting. And, certain qualified physicians will be permitted to prescribe MAT for up to 275 patients.
- Medicaid Coverage. The Act requires state Medicaid programs to provide MAT coverage from October 1, 2020 to September 30, 2025, unless the state certifies that implementing such coverage statewide would not be feasible because of a shortage of MAT qualified providers. MAT is defined as including all FDA-approved drugs and, with respect to providing such drugs, counseling services and behavioral therapy.
- Medicare Coverage. The Act creates a new Medicare benefit category titled "Opioid Use Disorder Treatment Services" and new type of Medicare provider "Opioid Treatment Program," or "OTP," for the purpose of furnishing MAT to Medicare beneficiaries. Payment for such services will be through a bundled payment for opioid use treatment services (including dispensing and administration of MAT medications, individual and group therapy, and counseling) furnished by OTPs during a particular episode of care.
- Incentives to Utilize MAT and Appropriate Use of Opioids in Emergency Departments. The Act also authorizes five-year grants to initiate MAT protocols, among other recovery support services, in emergency departments, and it establishes a three-year trial grant program aimed at prevention. Under the latter program, eligible hospitals and emergency departments would be able to use grant funds to target treatment approaches for painful conditions, train on protocols or best practices related to the use and prescription of opioids and alternatives to opioids for pain management in the emergency department, and develop or continue strategies to provide alternatives to opioids.

Telehealth (Sections 1009, 2001, and 3232)

The Act contains several Medicare and Medicaid provisions aimed at expanding coverage for telehealth services to treat substance use disorders.[1] However, given that these provisions, for the most part, direct federal agencies to issue guidance or regulations, the final impact of these provisions is unknown until such guidance and/or regulations are issued.

- Medicaid Substance Use Disorder Treatment via Telehealth. The Act directs CMS to issue guidance on the provision of substance use disorder treatment via telehealth to Medicaid beneficiaries. The Act also directs

CMS to outline options for FFP for education directed to providers serving Medicaid beneficiaries with substance use disorders using the so-called "hub and spoke" model, under which a physician at a "hub" facility provides services to patients located at a different, "spoke" facility. Finally, CMS will issue reports assessing efforts to reduce barriers to substance use disorder treatment and other services delivered via telehealth and remote patient monitoring for pediatric populations under Medicaid.

- Medicare Substance Use Disorder Treatment via Telemedicine. Beginning July 1, 2019, the Act exempts telemedicine services treating substance use disorders from certain statutory "originating site" requirements (i.e., geographic requirements) that apply to telemedicine services generally furnished to Medicare beneficiaries. Previously, to qualify for coverage, patients were required to be located in particular geographic areas to access treatment services from a provider at a distant site. The new exemption will allow providers to receive payment when substance use disorder services are provided to Medicare beneficiaries at any originating site – including the patient's home – regardless of geographic location. Providers should note, however, that no facility fee will be paid when the originating site is the patient's home.
- Special Telemedicine Registration. Finally, the Act directs the attorney general to issue regulations establishing a process for providers to obtain a special registration permitting them to prescribe controlled substances via telemedicine in emergency situations. Currently, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 prohibits practitioners from prescribing controlled substances without conducting at least one in-person medical evaluation of the patient. As a result, some patients requiring treatment in rural areas could not access necessary care, even when such treatment was available via telemedicine, because the practitioner had not first examined the patient in-person. It is unclear whether the implementing regulations will extend the registration process to all providers or only those with behavioral health or addiction treatment backgrounds and whether all controlled substances will be covered, or just medication used in the treatment of substance use disorders. Providers should monitor the development of this special registration, which will have a significant impact on efforts to combat the opioid epidemic and the scope of services available via telemedicine to Medicare and Medicaid beneficiaries. Finally, it should be noted that state e-prescribing laws may impose more restrictive requirements that will need to be satisfied even after regulations implement the special registration procedure

Drug Recovery Anti-Kickback Provisions (Section 8122)

The Act contains an anti-kickback provision applicable to all patients receiving substance use disorder treatment, not just federal healthcare program beneficiaries, that prohibits soliciting, receiving, paying or offering any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce referrals to a recovery home, clinical treatment facility, or laboratory, or "in exchange for an individual using the services of" a recovery home, clinical treatment facility, or laboratory. The new prohibition is very broad, and applies to remuneration to patients, thus potentially implicating many common industry practices, such as assisting patients with transportation to a treatment facility, or routine waivers of coinsurance or copayments.

- Definitions. A "recovery home" is defined as a shared living environment that is or purports to be drug and alcohol free, and uses peer support to promote sustained recovery from substance use. A "clinical treatment

facility" is defined as a medical setting (other than a hospital) that provides "detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law."

- Exceptions. The new prohibition also contains a limited number of narrow exceptions that permit certain types of "remuneration" under certain circumstances, such as certain discounts, and payments to an employee or independent contractor if it is not determined by and does not vary based on the number of individuals referred or tests or procedures performed; or amounts billed or collected, for the covered substance use disorder treatment services.

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In addition to the foregoing provisions that focus on treatment, Medicare and Medicaid coverage, and fraud and abuse, the Act includes provisions that address a myriad of other issues. For example, the Act reauthorizes the 21st Century Cures Act grants through 2021, which provide up to $500 million per year in funding. It also includes provisions that aim to stop the entry of illicit drugs, specifically fentanyl, its analogues, and other synthetic opioids, by increasing coordination between federal agencies and by authorizing grants to state and local agencies for the establishment or operation of public health laboratories to improve detection and testing. Although some may criticize the Act for its omissions (particularly with regard to funding and reforms to confidentiality rules), the Act is certainly a notable legislative response to the opioid epidemic that is likely to precipitate changes in the delivery of needed substance use disorder treatment care.

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[1] "Medicare telehealth services" are a specific set of services that must satisfy statutorily proscribed reimbursement standards in order to be covered by Medicare.

For more information, please contact Alicia Macklin or Charles Oppenheim in Los Angeles, Jeremy Sherer in Boston, Andrea Frey or Katrina Pagonis in San Francisco, Monica Massaro or Kelly Delmore in Washington, D.C., or your regular Hooper, Lundy & Bookman contact.