Hot Topics for Health Plan Counsel

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2019 AHLA In-House Counsel Program

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Agenda

- **Medicare Advantage**:
  - Managing Rapid Growth and Legal Risk
- **Drug Pricing**:
  - Controlling Costs and Increasing Transparency
- **Medicaid**:
  - Expansion, Reform, and Payment Integrity
- **The Affordable Care Act**:
  - The Only Constant is Change
- **Provider Disputes**
  - Protections for Innovative Health Design

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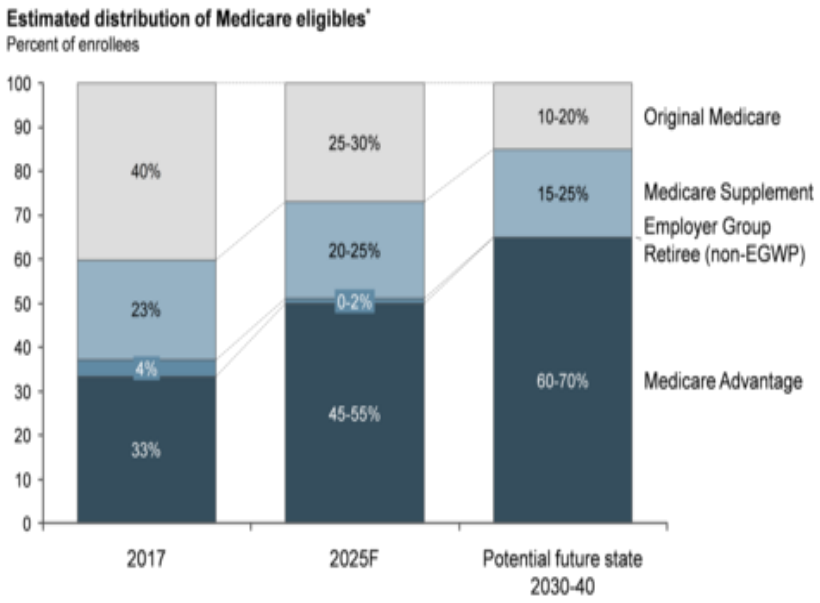
MEDICARE ADVANTAGE

RAPID GROWTH REGULATORY CHANGE LEGAL RISK

Medicare Advantage Growth



2004

- 13% of beneficiaries
- 5.3 million beneficiaries

2019

- 34% of Medicare beneficiaries
- 20 million beneficiaries

2025

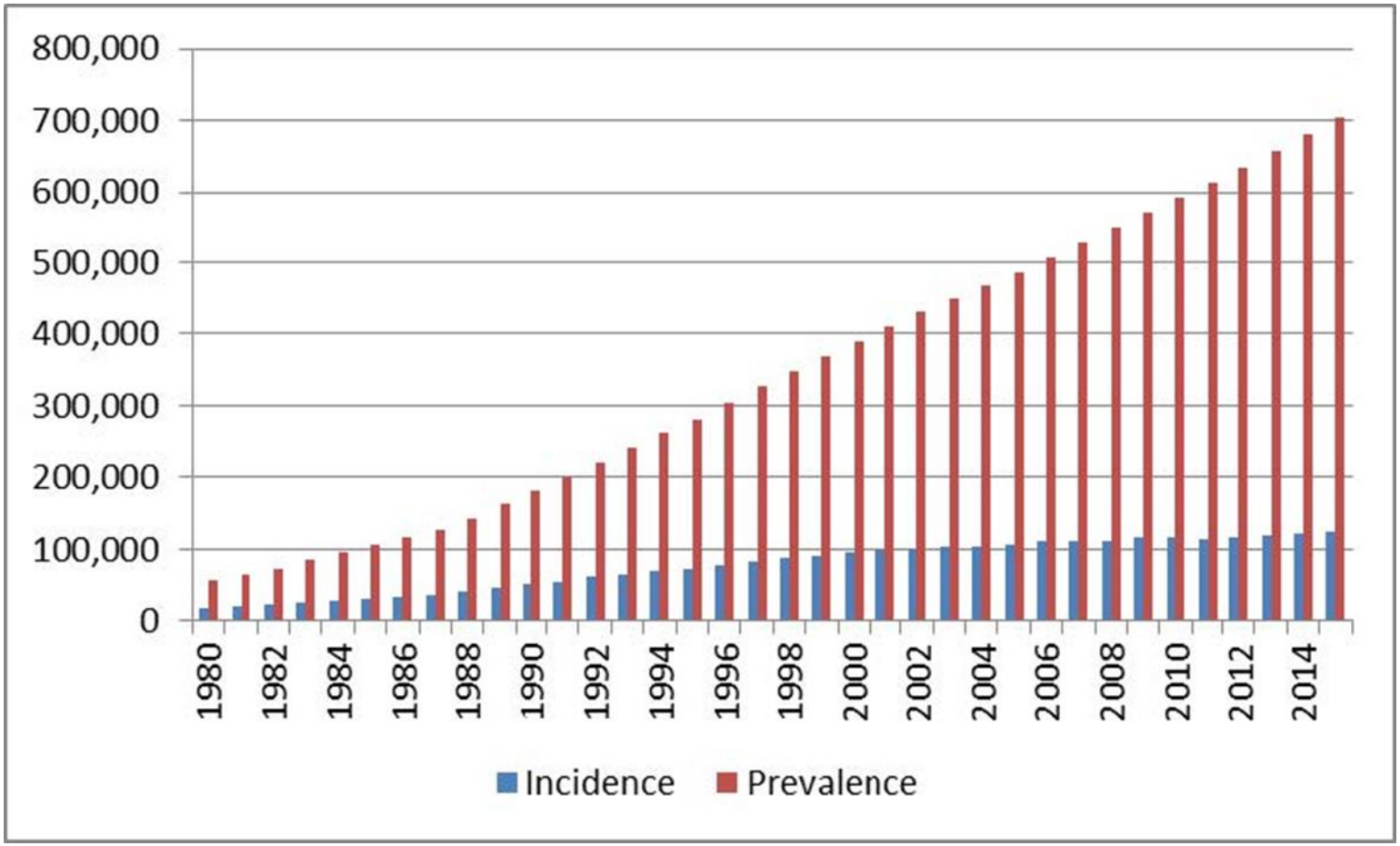
- 50% of Medicare beneficiaries
- 38 million

2040

- 70% of Medicare beneficiaries
- 60 million beneficiaries

https://dashealth.com/dr-news-item/medicare-advantage-marches-toward-70-penetration

Medicare Advantage and ESRD



Venture Capital Backed Health Plans

oscar

Founded: **2012**

Total funding amount: **$1.3B**

Clover

Founded: **2013**

Total funding amount: **$925M**

bright HEALTH

Founded: **2015**

Total funding amount: **$440M**

DevotedHealth

Founded: **2017**

Total funding amount: **$362M**

Source: www.crunchbase.com (accessed 3/11/2019)

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New Flexibility: Supplemental Benefits

Primarily Heath Related

- Diagnosis, prevent, or treat an illness or injury, compensate for physical impairment, ameliorate impact of injuries, reduce emergency and health care utilization (can include daily maintenance)
- Formerly: Prevent, cure, or diminish and illness or injury, excluding daily maintenance

Must be:

- Focused on healthcare needs
- Medically appropriate
- Recommended by a provider

Uniformity and Targeted Benefits

Specific supplemental benefits for specific medical conditions: i.e. tied to or have nexus to health status or disease state.

Equal treatment of enrollees with the same health status or disease state for whom such services and benefits are useful

Includes both access to services or reductions in specific cost sharing and/or deductibles for services or items

Benefit designs reviewed by CMS to ensure the overall impact is non-discriminatory

Special Supplemental Benefits for the Chronically Ill

Individuals with:

(1) one or more morbidities that is life threatening and limits overall function

(2) has a high risk of hospitalization and adverse outcomes, and

(3) requires intensive care coordination

Any enrollee with a chronic condition identified in Section 20.1.2 of Chapter 16(b) of the Medicare Managed Care Manual (e.g. chronic heart failure, dementia, ESRD, cancer, HIV/AIDs, drug/alcohol dependency, asthma)

Other criteria or social risk factors should not be used in determining eligibility.

Special Supplemental Benefits for the Chronically Ill (SSBCI)

SSBCI	Examples
Includes benefits that are not primarily health related May be offered non-uniformly to chronically ill enrollees Must have reasonable expectation of improving or maintaining health of enrollee with chronic condition, but need not affect permanent change in enrollee's condition	Meals, transportation for non-medical needs, pest control, indoor air quality equipment and services, and benefits to address social needs 2020 Final Call Letter clarified they can include capital or structural improvements.

Part B Benefits Via Telehealth (2020)

Members have option to receive in person and are advised of this option;

Contracted and credentialed providers, who comply with state licensing requirements;

Provide CMS information about cost, methods, and effectiveness upon request

Plans also may offer as supplemental benefits if do not want to comply with the requirements above or if benefit not covered by Part B (e.g. video dental consultation).

Plans given the discretion to determine what benefits are clinically appropriate to offer as telehealth benefits.

Plans may also maintain differential cost-sharing

84 Fed. Reg. 15680, 15829 (April 16, 2019)
(42 C.F.R. § 422.135)

Payment Integrity: Precluded Providers

- Are currently revoked from Medicare, are under an active reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or
- Have engaged in behavior for which CMS could have revoked the prescriber, individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. Such conduct includes, but are not limited to, felony convictions and Office of Inspector General (OIG) exclusions.

See 42 C.F.R. §§ 422.2, 423.100; 83 Fed. Reg. 16440 (April 16, 2018); 84 Fed. Reg. 15680-81, 15780-15797 (April 16, 2019).

Plan Sponsor Obligations

Screening | Beneficiary Notice | Denial of Claims | Provider Contracting

Effective January 1, 2019	Effective June 17, 2019	Effective January 1, 2020
Screen the Preclusion List monthly **Plans must follow beneficiary notification requirements** **60 days after sending notification to a beneficiary, deny a claim for an item or service provided or prescribed by a precluded provider**	**CMS consolidated the appeals process and timeframe for inclusion on the Preclusion List for providers**	**Update provider contracts with respect to non payment of for services rendered by providers on the Preclusion List.**

Provider Directories

Provider Directory Review:	52 plans and 10,504 provider locations 5,602 providers total: cardiology, oncology, ophthalmology, PCP
48.74% of provider directories were inaccurate	Percent of inaccurate locations ranged from 4.63% to 93.02%
Inaccuracies included:	Not at the location listed Incorrect phone number was incorrect, or Not accepting new patients
40 Plans subjected to Compliance Actions:	18 Notices of Non-Compliance 15 Warning Letters 7 Warning Letters with Request for a Business Plan

Risk Adjustment

United v. Azar

- **Overpayment regulation struck down (Sept. 2018).**
  - "Reasonable diligence" incorrectly applies a negligence standard to what essentially gives rise to a claim for fraud.
  - It is arbitrary for CMS to treat any incorrect diagnosis code as an overpayment, when for RADV audits only errors above a certain threshold are penalized (the FFS adjustor).
- **CMS moves for reconsideration based on new data underlying the November 1, 2018 proposed rule, then appeals. Appeal now held in abeyance.**

CMS Proposed Rule

- **CMS Proposed Rule**
  - 83 Fed. Reg. 54982 (Nov. 1, 2018)
  - CMS intends to extrapolate RADV audit results to calculate overpayments.
  - Rule would eliminate FFS adjuster from RADV.
  - Extended comment period.

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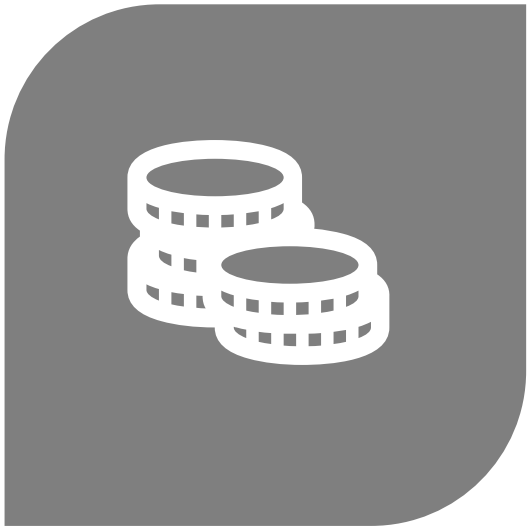

DRUG PRICING

CONTROLLING COSTS

INCREASING TRANSPARENCY

Drug Pricing

"I have directed my Administration to make fixing the injustice of high drug prices one of our top priorities. Prices **will** come down."

- President Donald J. Trump
- American Patients First (May 2018)

Section 1860D-11

(i) NONINTERFERENCE.—In order to promote competition under this part and in carrying out this part, the Secretary—

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

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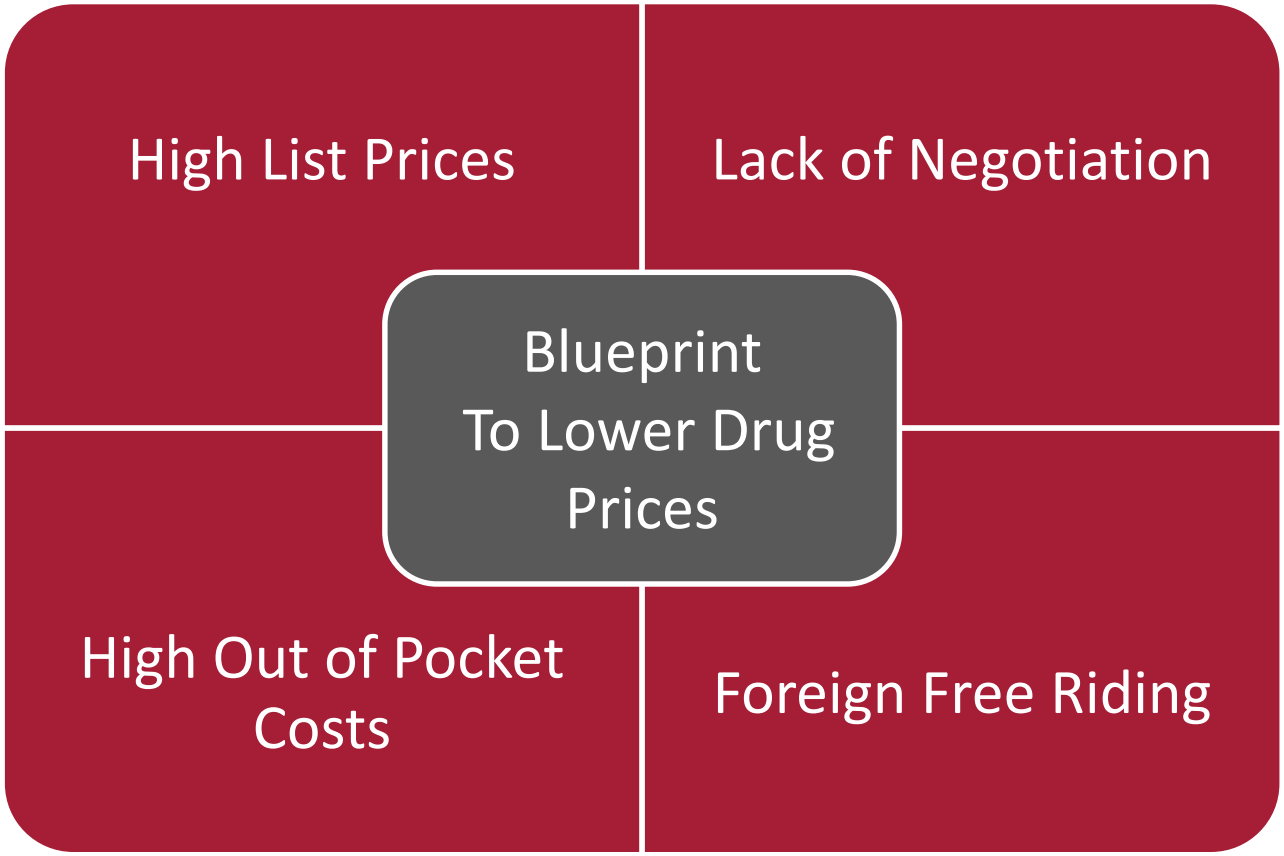
American Patients First

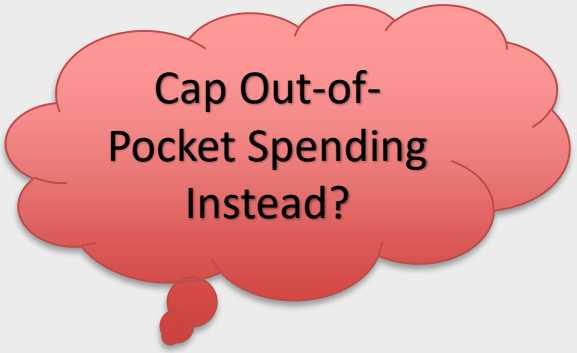


Part D: Round 1 (April 2018 Final Rule)

- Expedited Mid-Year Generic Substitutions
- Part D Tiering Exceptions
- Transition Supply Requirement
- Part D Meaningful Difference
- Pharmaceutical Manufacturer Rebate Pass Through

Part D: Round 2 (May 2019 Final Rule)

- Protected Class Drugs
- Real Time Benefit Tool
- EOB Inclusion of Negotiated Drug Price
- MA Plans & Part B Drugs
- Redefinition of Negotiated Price



Rebate Safe Harbor

- Amends the discount safe harbor to explicitly exclude reductions in price or other remuneration from a drug manufacturer to a Part D Sponsor, Medicaid managed care organization, or a PBM
- Creates two new safe harbors for: (1) a point-of-sale reductions in price on prescription pharmaceutical products passed through to patients at the point of sale and (2) certain PBM service fees
- Intended to reduce list price, limit out-of-pocket costs, lower government spending, and improve transparency
- If adopted, would be effective 2020 (or, maybe not).
- CBO estimates additional $177 billion in federal spending

84 Fed. Reg. 2340 (February 6, 2019)

Regulation to Require Drug Pricing Transparency

- Medicare and Medicaid
- Direct-to-Consumer TV ads
  - Prescription Drugs and Biological Products
  - Must include Wholesale Acquisition Cost (WAC or list price)
- Effective July 9, 2019 – unless challenged
- Enforcement mechanism: Private action under Lanham Act

84 Fed. Reg. 20732 (May 10, 2019)

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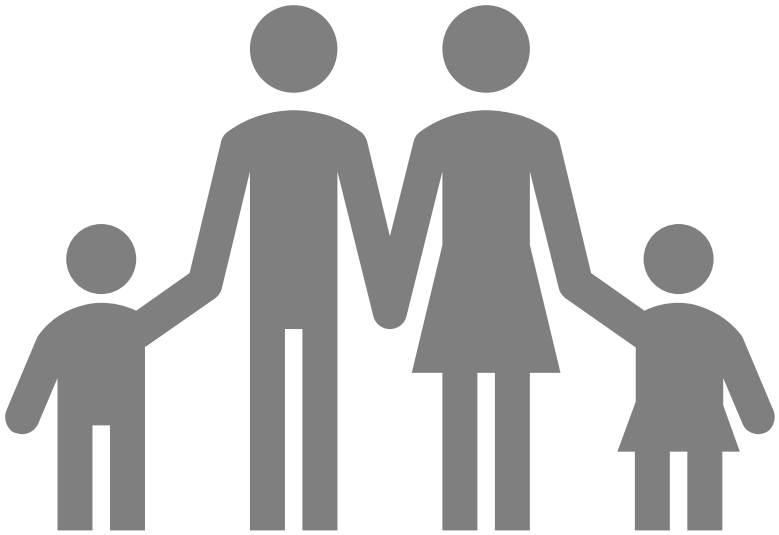
Beyond Part D: APM Examples

Referenced Based Pricing

- Instead of tiered formulary, drugs are divided into therapeutic classes
- Reference price set for commonly used drugs
- Plan pays reference price
- Members choose drug, but for higher cost drugs pay more

Netflix

- “Subscription” pricing for expensive hepatitis C medication
- RFIs for Medicaid and state employee health plans
- Also being eyed for Naloxone
- Regulatory challenges include Medicaid Best Price and Medicaid Drug Rebate Program



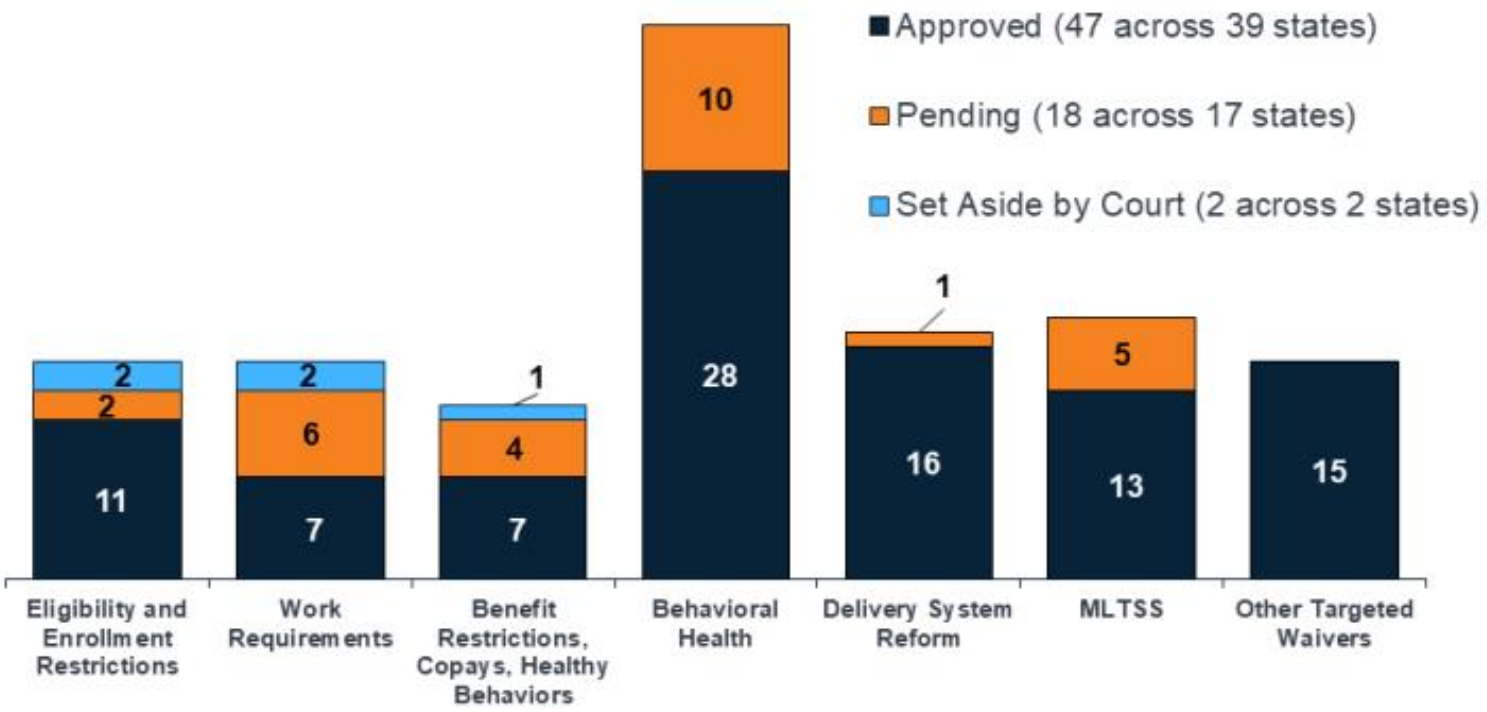
MEDICAID

EXPANSION, REFORM, AND PAYMENT INTEGRITY

Section 1115 Waivers

- State control and flexibility:
  - New focus on health outcomes, efficiencies to ensure program sustainability, coordinated strategies to promote upward mobility and independence, incentives that promote responsible beneficiary decision-making, alignment with commercial health products, and innovative payment and delivery system reforms
  - Not expanded coverage
- Litigation challenges and GAO criticism for lack of transparency

Landscape of Approved vs. Pending Section 1115 Medicaid Demonstration Waivers, April 18, 2019



NOTES: Some states have multiple approved and/or multiple pending waivers, and many waivers are comprehensive and may fall into a few different areas. Therefore, the total number of pending or approved waivers across states cannot be calculated by summing counts of waivers in each category. Pending waiver applications are not included here until they are officially accepted by CMS and posted on Medicaid.gov. For more detailed information on each Section 1115 waiver, download the detailed approved and pending waiver tables posted on the tracker page. "MLTSS" = Managed long-term services and supports.

November 14, 2018 Proposed Medicaid Managed Care Rule

- Quality rating system
- Capitation rate development
- Provider payment initiatives and minimum fee schedule directed payments
- Pass-through payments
- MLR
- Beneficiary Protections
- Network Adequacy

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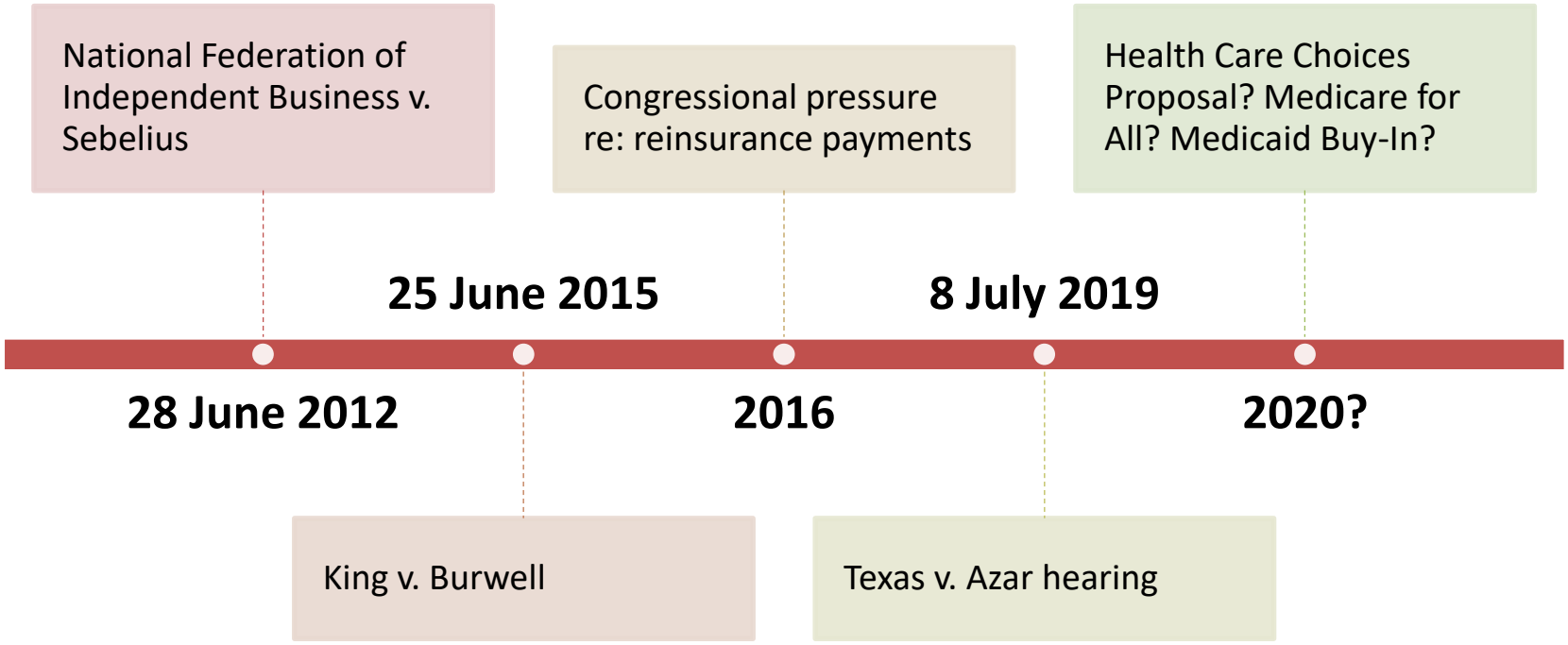
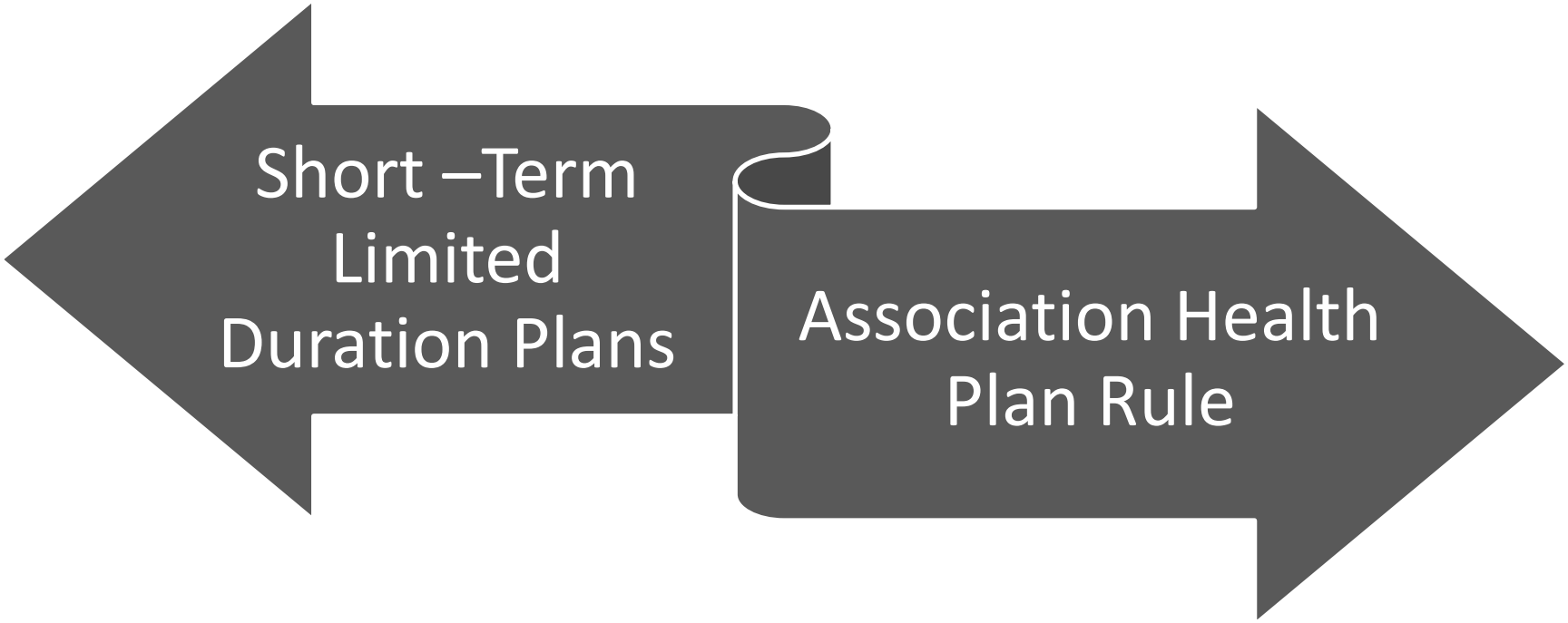
THE AFFORDABLE CARE ACT

THE ONLY CONSTANT IS CHANGE

Where Does the Pathway of Change Lead?



More change… and challenges.



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UNITED STATES V. ATRIUM HEALTH

The Antitrust Division's Effort To Protect Innovative Health Plan Designs

Final Judgment

- Filed on December 14, 2018 with consent of Atrium Health
- No findings of fact or conclusions of law
- Fundamental goal of Final Judgment is to remedy conduct that the Antitrust Division had challenged:

> the essence of this Final Judgment is to enjoin Defendant from prohibiting, preventing, or penalizing steering as defined in this Final Judgment;

Source: [Proposed] Final Judgment, p. 1

- Final Judgment accomplishes this goal by prohibiting Atrium from:
  (a) enforcing existing contractual restrictions on steering, or
  (b) negotiating or agreeing to future restrictions on steering

Scope of Final Judgment

- Covers all "Healthcare Services" and is not limited to the acute inpatient services challenged in lawsuit:

> H. "Healthcare Services" means all inpatient services (*i.e.*, acute-care diagnostic and therapeutic inpatient hospital services), outpatient services (*i.e.*, acute-care diagnostic and therapeutic outpatient services, including but not limited to ambulatory surgery and radiology services), and professional services (*i.e.*, medical services provided by physicians or other licensed medical professionals) to the extent offered by Defendant and within the scope of services covered on an in-network basis pursuant to a contract between Defendant and an Insurer. "Healthcare Services" does not mean management of patient care, such as through population health programs or employee or group wellness programs.

Source: [Proposed] Final Judgment § II(H)

Scope of Final Judgment, ctd.

- Generally prohibits Atrium from negotiating or enforcing contract terms that would prohibit, prevent, or penalize:
  - Narrow Network Benefit Plans
  - Tiered Network Benefit Plans
  - Plans with Reference-Based Pricing
  - Plans with a Center of Excellence Feature
  - Transparency Tools/Efforts
- Specifically prohibits Atrium from:
  - Negotiating or enforcing express prohibitions on steering or transparency,
  - Requiring prior approval for the introduction of new benefit plans (with the exception of "Co-Branded Plans"),
  - Requiring Atrium providers be included in the most-preferred tier of a tiered product

Source: [Proposed] Final Judgment § IV

What the Final Judgment does not address/prohibit:

- Restricting steering in plans that are Co-Branded (i.e., Atrium & an insurer) or feature a narrow network where Atrium is the most-prominently featured provider (e.g., Blue Local – Atrium)
- Requiring that Atrium be given an opportunity to review information that will be included in a transparency effort before it is disseminated, but only as long as such review does not delay the dissemination
- Prohibiting the dissemination of Atrium's confidential price or cost information
- Leveraging transparency in ways that are harmful to consumers

Key Takeaways

- USDOJ views steering mechanisms in benefit plan designs as strongly pro-competitive and is willing to litigate against providers who attempt to impede steerage in certain ways
- Use of market dominance by integrated health systems to protect referral patterns can violate the antitrust laws

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