

Legislative and Regulatory Update

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POLITICAL LANDSCAPE: 2020

- Election
 - Unclear approval numbers for President, with strong base
 - Numerous Democratic candidates
 - Increasing House retirements
 - Senators up for (re)election: 22 R seats v. 12 D seats
- Context
 - President Trump & Administration
 - Economy?
 - Geopolitics
 - UFO



HEALTH POLICY LANDSCAPE

- Surprise Medical Billing and Drug Pricing
- The Affordable Care Act
- Setting the Stage for the 2020 Election
 - Health Care Reform 2.0
 - Price Controls & Competition



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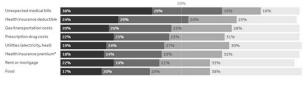
SURPRISE MEDICAL BILLING

1 in 6 insured patients get a surprise bill for out-of-network care

Large majority are worried about being able to afford surprise medical bills for them and their family

How worried, if at all, are you about being able to afford each of the following for you and your family?

Very worried Somewhat worried Not too worried Not at all worried



Source: Karen Pollitz et al., An examination of surprise medical bills and proposals to protect consumers from them, KAISER FAMILY FOUNDATION (June 2019).

SURPRISE MEDICAL BILLING

- Benchmark Payment Rate
 - Senate HELP (S. 1895)
 - House E&C (H.R. 3630)
- Arbitration Backstop
 - House E&C (H.R. 3630)
 - Senate HELP Chairman Lamar Alexander (R-TN) and Sen. Bill Cassidy (R-LA) in negotiations over adding an arbitration backstop to Senate HELP bill
- Other Approaches
 - House Ed. & Labor and House W&M considering possible approaches



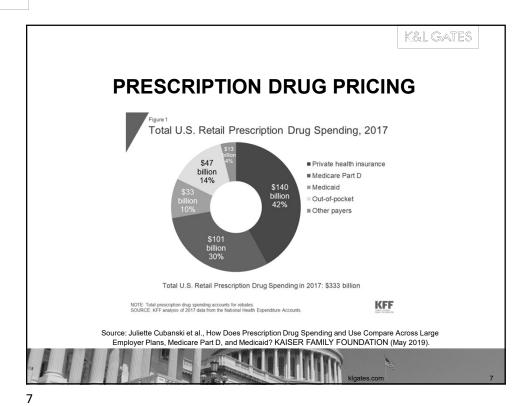
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POLITICAL LANDSCAPE

- Senate HELP in negotiations over arbitration backstop
 - Provider groups pushing against benchmark payment rate
- House committees still working on their proposals
 - House Ed. & Labor and House W&M expected to release legislation
 - House E&C Chairman Frank Pallone (D-NJ) launched an investigation into private equity firms' role in surprise medical billing
- Administration also considering surprise billing initiatives





PRESCRIPTION DRUG PRICING

- Medicare
 - Negotiation of Drug Prices
 - House Speaker Nancy Pelosi's (D-CA) draft
 - Other key proposals (Medicare Drug Price Negotiation Act S.99)
 - Payment of rebates to Part B and D
 - Senate Finance measure
 - Redesigning Part D benefit structure
 - Senate Finance measure
 - Disclosure Requirements
 - Senate Finance measure

Source: Rachel Sachs, Understanding The Senate Finance Committee's Drug Pricing Package, HEALTH AFFAIRS (July 2019); Peter Sullivan, Pelosi draft plan would allow negotiation on 250 drugs per year, THE HILL (September 2019).



PRESCRIPTION DRUG PRICING

Reporting

- Drugmaker reports on price increases
 - Senate HELP (S. 1895)
 - Senate Finance measure
 - House E&C (H.R. 2296)
 - House W&M (H.R. 2113)
- PBM proposals (spread pricing, FTC reports, rebate disclosures)
 - Senate HELP (S. 1895)
 - Senate Finance measure
 - Other committee proposals (H.R. 2376, H.R. 2296, S. 1227)

Source: Danielle Parnass, BGOV OnPoint: Drug Pricing Bills, BLOOMBERG GOVERNMENT (September 2019)



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PRESCRIPTION DRUG PRICING

- Generics, Patents
 - Access to samples for generics
 - Strengthening Health Care and Lowering Prescription Drug Costs (H.R. 987)
 - Senate HELP (S. 1895)
 - Pay for delay in patent settlements
 - Included in H.R. 987
 - Generic exclusivity parking
 - Included in H.R. 987
 - Senate HELP (S. 1895)
 - Sham citizen petitions
 - Senate HELP (S. 1895)

Source: Danielle Parnass, BGOV OnPoint: Drug Pricing Bills, BLOOMBERG GOVERNMENT (September 2019)



POLITICAL LANDSCAPE

- House Democratic Medicare negotiation bill
 - House Speaker Nancy Pelosi's (D-CA) approach
 - Allows direct negotiations without arbitration
- Senate committees still working on drug price proposals
 - Finance Chairman Chuck Grassley eyes broader package, House Republican support unclear
- Administration also working on drug pricing initiatives
 - President Trump expected to announce initiatives in the fall

Source: Peter Sullivan, Pelosi draft plan would allow negotiation on 250 drugs per year, THE HILL (September 2019); Danielle Parnass, BGOV OnPoint: Drug Pricing Bills, BLOOMBERG GOVERNMENT (September 2019).



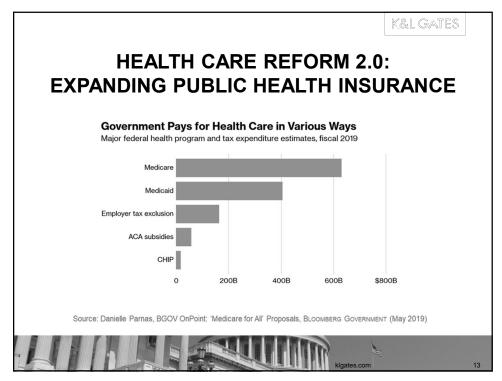
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AFFORDABLE CARE ACT

- Litigation
 - Texas v. United States
 - Litigation Continues
 - Cost-Sharing Reduction and Risk Adjustment
 - Non-ACA Plans (Short-Term Plans and AHPs)
 - Contraceptive Mandate
 - Section 1557
 - Provider Conscience Rule
- Legislation
 - What happens in aftermath of Texas v. United States?
 - Increasing interest in Health Care Reform 2.0





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HEALTH CARE REFORM 2.0: EXPANDING PUBLIC HEALTH INSURANCE

- Medicare-for-All
 - Comprehensive single-payer benefits system
- Public Plan Option
 - Public plan option for individuals and employers
- Medicare Buy-In Option
 - Option to buy into Medicare for eligible individuals



MEDICARE-FOR-ALL

- Comprehensive single-payer benefits system
 - Benefits available to every resident; provided free of charge, with no cost-sharing, deductibles, co-insurance, or co-payments
 - Largely replace current forms of private health insurance
- Key Proposals
 - Medicare for All Act of 2019 (H.R. 1384)

Rep. Pramila Jayapal (D-WA), 106 Original Cosponsors (all Ds)

Medicare for All Act of 2019 (S. 1129)

Sen. Bernie Sanders (I-VT), 14 Cosponsors (all Ds), including Sens. Cory Booker (D-NJ), Kirsten Gilibrand (D-NY), Kamala Harris (D-CA), and Elizabeth Warren (D-MA)



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PUBLIC PLAN OPTION

- An alternative to private health insurance
 - Government health plans offered in the individual market
- Key Proposals
 - Medicare-X Choice Act of 2019
 - H.R. 2000, Rep. Antonio Delgado (D-NY), 13 Cosponsors (all Ds); S. 981, Sen. Michael Bennet (D-CO), 11
 Cosponsors (all Ds), including Sens. Cory Booker (D-NJ), Kamala Harris (D-CA), and Arny Klobuchar (D-MN)
 - CHOICE Act
 - H.R. 2085, Rep. Janice Schakowsky (D-IL), 17 Cosponsors (all Ds); S.1033, Sen. Sheldon Whitehouse (D-RI), 5 Original Cosponsors (all Ds)
 - Choose Medicare Act
 - H.R. 2463, Rep. Cedric Richmond (D-LA), 5 Cosponsors (all Ds); S. 1261, Sen. Jeff Merkley (D-OR), 14 Original Cosponsors (all Ds), including Sens. Cory Booker (D-NJ), Kamala Harris (D-CA), and Kirsten Gilibrand (D-NY)
 - Medicare for America Act
 - H.R. 2452, Rep. Rosa DeLauro (D-CT), 15 Original Cosponsors (all Ds)
 - Keeping Health Insurance Affordable Act of 2019
 - S. 3, Sen. Benjamin Cardin (D-MD), 0 Cosponsor



MEDICARE BUY-IN

- Expands access to Medicare for older adults (50-64)
 - Enrollment managed by Medicare or ACA marketplace
 - Coverage includes Medicare, Medicare Advantage, Medicare Part D, and Medicare Supplement Insurance
- Key Proposals
 - Medicare at 50 Act (H.R. 1346)
 Rep. Brian Higgins (D-NY); 29 Original Cosponsors (all Ds)
 - Medicare at 50 Act (S. 470)
 Sen. Debbie Stabenow (D-MI); 19 Original Cosponsors (all Ds), including Sens. Cory
 Booker (D-NJ), Kamala Harris (D-CA), Kirsten Gilibrand (D-NY), Amy Klobuchar (D-MN)



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POLITICAL LANDSCAPE

- Trump Administration and Republicans oppose proposals to expand public health insurance
- Democrats divided on options to expand public health insurance, but building support ahead of 2020
 - o Medicare-for-All
 - o Public Plan Option
 - o Medicare Buy-in
- Industry coalition opposes health care reform 2.0, but changing tide?
 - American Hospital Association, American Medical Association, America's Health Insurance Plans, and Pharmaceutical Research and Manufacturers of America

Source: INSIDE HEALTH POLICY, Warren, Other Key Dem Presidential Hopefuls, Push ACA Reform Bill (April 2019); Danielle Parnas, BGOV OnPoint: 'Medicare for All' Proposals, BLOOMBERG GOVERNMENT (May 2019).



THE 2020 ELECTION

Medicare-for-All

- o Sen. Bernie Sanders (I-VT) focused on a single-payer system
 - Sens. Cory Booker (D-NJ), Kamala Harris (D-CA), Kirsten Gilibrand (D-NY), and Elizabeth Warren (D-MA) co-sponsored Medicare-for-all legislation

Public Plan Option

- Sens. Kamala Harris (D-CA), Amy Klobuchar (D-MN), Cory Booker (D-NJ), and Kirsten Gillibrand (D-NY) co-sponsored Medicare-X legislation
- o Joe Biden's health care plan includes a public plan option

Medicare Buy-In Option

o Candidates generally supportive of Medicare buy-in legislation

Source: INSIDE HEALTH POLICY, Warren, Other Key Dem Presidential Hopefuls, Push ACA Reform Bill (April 2019); Kevin Uhrmacher et al., Where 2020 Democrats stand on Medicare-for-all, The Washington Post (May 2019).



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THE 2020 ELECTION

Price Controls

- Medicare Part D Negotiation
 - Sen. Bernie Sanders' (D-VT) Medicare Drug Price Negotiation Act (S. 99)
 - Sen. Amy Klobuchar's (D-MN) Empowering Medicare Seniors to Negotiate Drug Prices Act (S. 62)

Regulation Beyond Part D

- Sens. Kamala Harris (D-CA) and Klobuchar's (D-MN) Combatting Unreasonable Rises and Excessively (CURE) High Drug Prices Act (S. 3754)
- Sens. Kamala Harris (D-CA) and Klobuchar's (D-MN) Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act (S. 366)

Competition

- Government-manufactured Generic Drugs
 - Sen. Elizabeth Warren's (D-MA) Affordable Drug Manufacturing Act (S. 3775)
- Access to Generics
 - Sen. Amy Klobuchar's (D-MN) Preserve Access to Affordable Generics and Biosimilars Act (S. 64)
 - Sen. Amy Klobuchar's (D-MN) Short on Competition Act (S. 844)

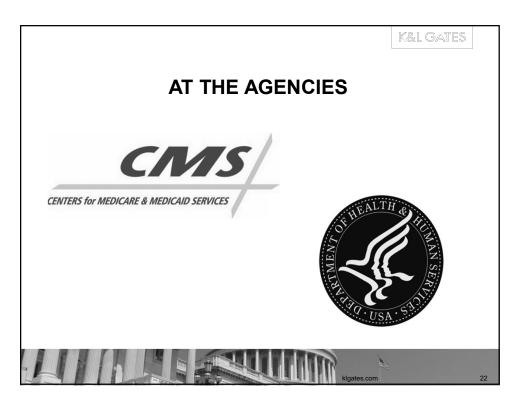


CR HOLDS OFF CUTS TO MEDICAID DSH

- Continuing Resolution (CR) funds the federal government through 11/21. The CR will:
 - Prevent Medicaid cuts, among other provisions
 - Delay the \$4 billion reduction in Medicaid disproportionate share hospital allotments scheduled to take effect Oct 1st
 - Extend the Certified Community Behavioral Health Clinic demonstration program through Nov 21st
 - Extend the current 100% Federal Medical Assistance Percentage under the Medicaid program.
 - Extends Community Health Centers, the National Health Service Corps, Teaching Health Centers that operate graduate medical education programs



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CMS PAYMENT SYSTEM PROPOSED RULE

- Improving Price & Quality Transparency in American Healthcare to Put Patients First
 - Patient-driven healthcare system
 - Making prices for items and services provided by all hospitals in the United States more transparent
 - Proposed changes also encourage site-neutral payment between certain Medicare sites of services.
 - Proposed rule proposes updates and policy changes under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System.
 - September 27, 2019 deadline for comments
- Increasing Price Transparency of Hospital Standard Charges
 - Proposed Definition of 'Hospital'
 - Proposed Definition of Hospital 'Items and Services'
 - Proposed Requirements for Making Public All Standard Charges for All Items and Services
 - Proposals for Monitoring and Enforcement
 - Overall Impact: CMS estimates that, compared to CY 2019, OPPS payments in CY 2020 will increase by approximately \$6 billion. This estimate includes estimated changes in enrollment, utilization, and case-mix.



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CMS PROGRAM INTEGRITY ENHANCEMENTS FINAL RULE

Program Integrity Enhancements to the Provider Enrollment Process Final Rule

- Addresses Waste Fraud and Abuse and creates several new revocation and denial authorities
- Establishes a new "affiliations" authority which will allow CMS to identify individuals and
 organizations that pose an undue risk of fraud, waste or abuse based on their relationships with
 other previously sanctioned entities.
- Allows authorities to revoke or deny, as applicable, Medicare enrollment if:
 - A provider or supplier circumvents program rules by coming back into the program, or attempting to come back in, under a different name (e.g. the provider attempts to "reinvent" itself);
 - A provider or supplier bills for services/items from non-compliant locations;
 - A provider or supplier exhibits a pattern or practice of abusive ordering or certifying of Medicare Part A or Part B items, services or drugs; or
 - A provider or supplier has an outstanding debt to CMS from an overpayment that was referred to the Treasury Department.
- CMS can now block providers and suppliers who are revoked from re-entering the Medicare program for up to 10 years.
- Effective November 4, 2019.



OPIOID CRISIS REMAINS A PRIORITY





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THE MONEY TREE CONTINUES TO BLOOM

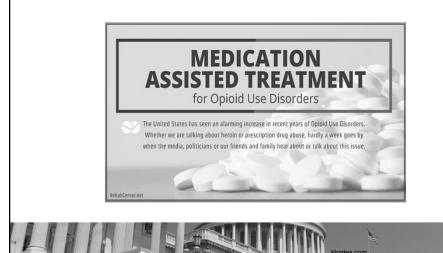
- Another \$1.8 billion in funding to states
- Expanding access to treatment and supporting near real-time data on the drug overdose crisis
- Centers for Disease Control and Prevention (CDC) = \$900 million in new funding 3yr
 agreement with states, territories, and localities to advance the understanding of the opioid
 overdose epidemic and to scale-up prevention and response activities
- Substance Abuse and Mental Health Services Administration (SAMHSA) = \$932 million to all 50 states as part of its State Opioid Response grants.
- Health Resources and Services Administration (HRSA) awarded nearly \$400 million in grants
 to community health centers, rural organizations, and academic institutions to help them establish
 and expand access to substance abuse and mental health services







ACCORDING TO HHS, APPROXIMATELY 1.27 MILLION AMERICANS NOW ARE RECEIVING MEDICATION-ASSISTED TREATMENT (MAT) OUT OF APPROXIMATELY TWO MILLION AMERICANS WITH OPIOID USE DISORDER



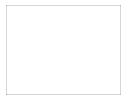
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EMPHASIS ON MAT = OPPORTUNITIES

- Emphasis continues on the expansion of MAT in hospital emergency departments and evidenced-based best practices to prevent overdoses and help patients recover.
- Increasing MAT initiation in the emergency department and warm hand-offs to MAT in the community
- Increasing direct warm hand-offs to community providers for MAT or abstinencebased treatment
- Increasing evidence-based opioid use disorder treatment and warm hands-offs for pregnant women
- Increasing the number of direct inpatient admissions for MAT initiation from the emergency department; and MAT initiation of OUD patients hospitalized
- Increasing warm hand-offs in primary care settings
- Increasing access to MAT in primary care settings





QUESTIONS?



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