American Health Lawyers Association
New Year: New Medicare Advantage, Part D, Medicaid Managed Care, and Affordable Care Act

January 8, 2019

Moderator: Jeremy Earl
McDermott Will & Emery LLP
Washington, D.C.
jearl@mwe.com

Emily A. Moseley
Strategic Health Law
Chapel Hill, NC
emoseley@strategichealthlaw.com

Annie Hsu Shieh
Central Health Plan of California
Diamond Bar, NC
ahsu@centralhealthplan.com

Jen McDowell
Express Scripts, Inc.
St. Louis, MO
JBMcDowell@express-scripts.com






AHLA

Agenda

- Medicare Advantage
  - Reducing Burdens
  - Benefits Flexibility
  - Fiscal Stewardship
- Part D
  - Opioids
  - Drug Pricing and Costs
- Medicaid Managed Care
  - Scope of program
  - Proposed Rule
  - Opioids and Drug Pricing
- Affordable Care Act

MEDICARE ADVANTAGE

The State of Medicare Advantage 2019

- MA Enrollment Projected to Increase

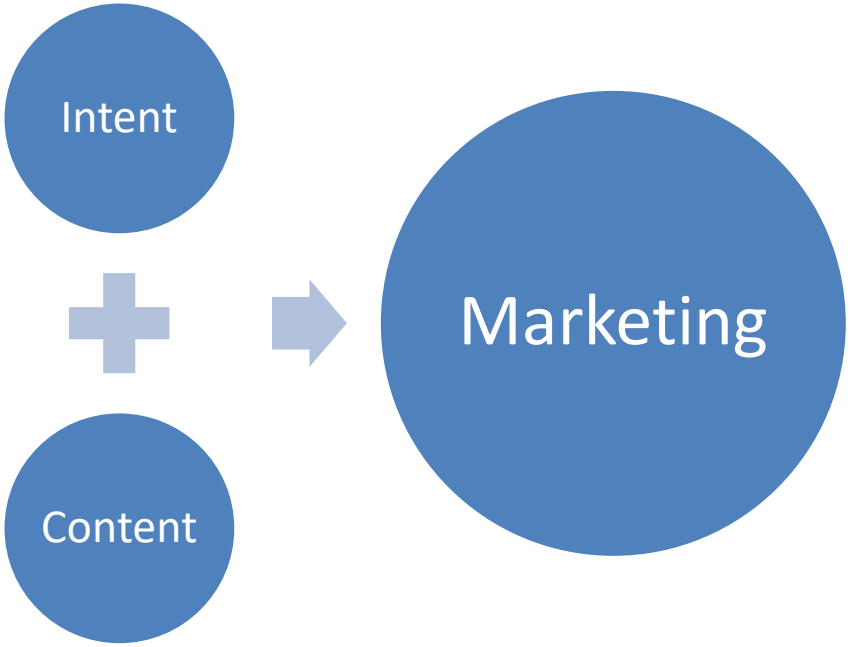
	2017	2018	2019
Projected Enrollment	18,463	20,357	22,574
Actual Enrollment	18,689	20,241	
Growth Percentage	7.79%	8.30%	11.53%

- MA Premiums Projected to Decrease

	2017	2018	2019 Proj.
Weighted Avg. Premium	$31.91	$29.81	$28.00
Percent Change	-2%	-7%	-6%

Reducing Burdens

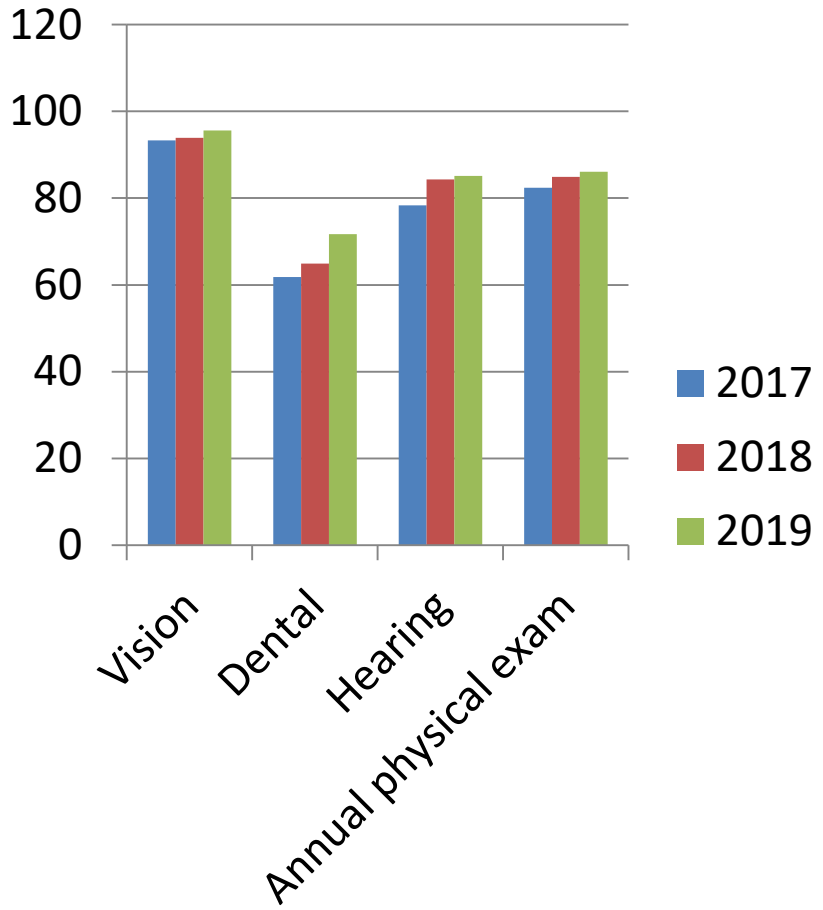
- Preclusion List
- FDR training & oversight
- Marketing & open enrollment
- Lengthening mandatory timeframes
- MLR reporting



If both standards aren't met, it's communication

Benefits Flexibility

- Uniform benefit requirement
- Supplemental benefits – "primarily health related"
- Telehealth expansion
- Part B prior authorization



Mandatory Supplemental Benefits

Fiscal Stewardship

- Star Ratings
- Risk Adjustment
- Encounter Data

Average Star Rating	2015	2016	2017	2018	2019
	3.92	4.03	4.02	4.06	4.08

Time Period	Forecast (in Millions of Encounters)
March 2018	66
CY 2018	800
CY 2013 - 2018	4,000

Protecting Enrollees Through Surveillance & Compliance

- Annual ANOC/EOC Timeliness & Accuracy Review
- Summary of Benefits Retrospective Review
- Retrospective Review of Advertising Materials
- Accuracy of Online Provider Directories
- Ensuring Compliance with Network Adequacy Standards
- 2019 Program Audits

PART D

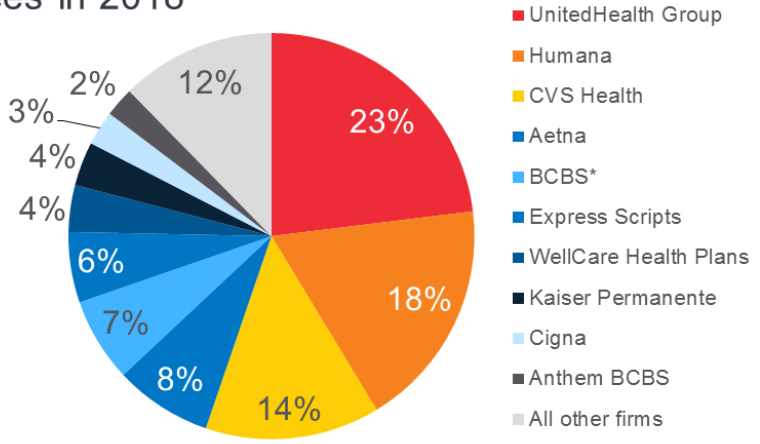
AHLA

Part D

- 43 Million Enrolled
- MA plans must offer, but 58% of enrollees are in a stand-alone prescription drug plan
- 12 Million receive premium and cost-sharing assistance.

Figure 1

Three firms—UnitedHealth, Humana, and CVS Health—cover over half of all Medicare Part D enrollees in 2018

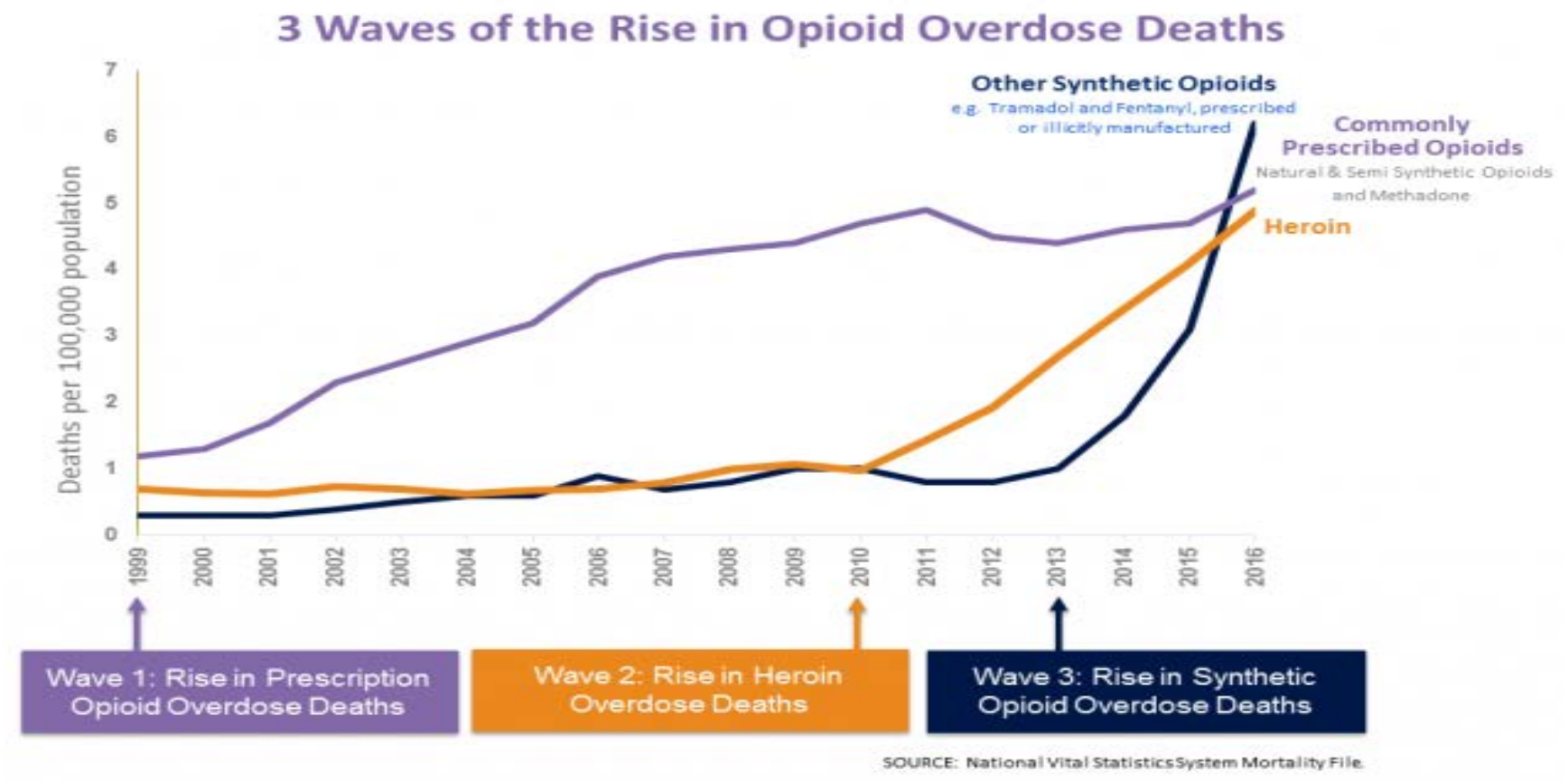


Total Part D Enrollment, 2018 = 43.4 million

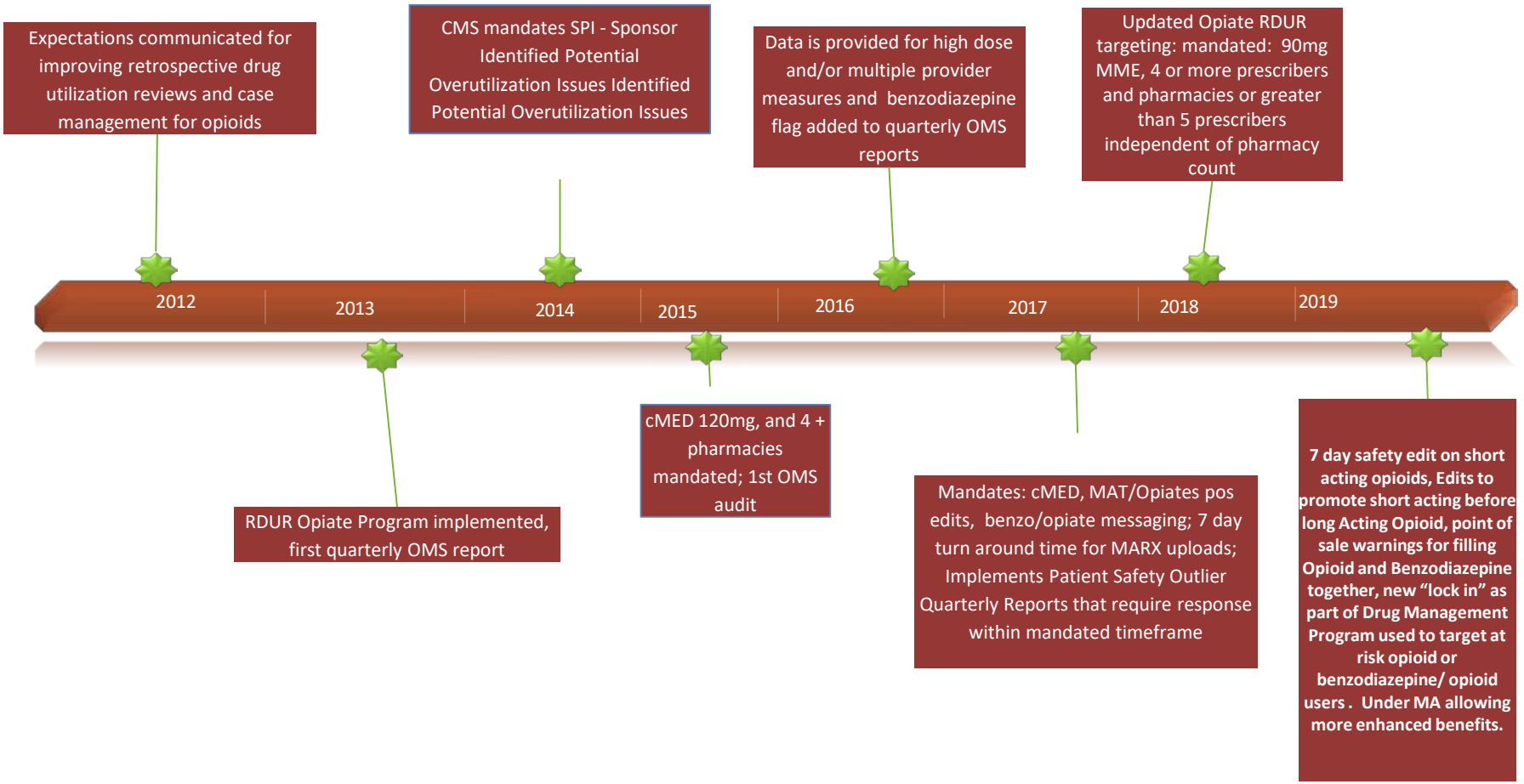
NOTE: Includes enrollment in the territories and employer-only group plans. *BCBS excludes Anthem BCBS, which is a separate plan sponsor.
SOURCE: KFF analysis of CMS 2018 Part D plan files.

KFF HENRY J. KAISER FAMILY FOUNDATION

Public Health Crisis: Opioids



Evolution of Medicare Part D and Opioid Controls



Controlling Access

Point of Sale Edits

Naïve Patients	Chronic Users	Concurrent Users
Hard safety edit to limit first time Rx fill to 7 day supply	Soft edit: 90mg Hard edit: 200 mg Care Coordination and Safety Edits	Safety edits for opioids +benzodiazepines or buprenorphine Duplicative use of long-acting opioids

"Lock In" for High Risk Users

Plans are asked to identify members at risk for adverse drug outcomes from opioids using the following criteria:

- use of opioids with an average MME greater than or equal to 90 mg for any duration during the most recent six months **and**
- either 3 or more opioid prescribers and 3 or more opioid dispensing pharmacies or 5 or more opioid prescribers, regardless of the number of dispensing pharmacies
- Optional: any MME and 7 or more prescribers or pharmacies
- Exempted beneficiaries: hospice/end-of life care, long-term care facility (with single pharmacy), and cancer patients

Lock-In

KEY: Prescriber outreach, case management, coordination of care.

- After identification, (detailed) notice, case management, and waiting-period, Plan can limit access through:
  - Pharmacy lock-in and,
  - As a last resort, prescriber lock-in.
- Maximum 12- month lock-in (renewable)
- Data disclosure and sharing among CMS and plans
- Special enrollment period for low-income subsidy eligible beneficiaries is not available for those who are identified as potentially at-risk.

Fiscal Stewardship: Drug Costs

"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.

AHLA

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

Drug Price Blueprint

AHLA

May 16, 2018 RFI

"Millions of Americans face soaring drug prices and higher out-of-pocket costs, while manufacturers and middlemen such as pharmacy benefit managers (PBMs) and distributors benefit from rising list prices and their resulting higher rebates and administrative fees."

AHLA

Meanwhile…

- Closing the Donut Hole
- ~~Pharmacy Gag Clauses~~
- Indications Based Formulary
- Part B Step Therapy
- OIG RFI Regarding the Anti-Kickback Statute and Beneficiary Inducement CMP
- Proposed Regulation to Require Drug Pricing Transparency

November 30, 2018 Proposed Rule

Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

AHLA

MEDICAID MANAGED CARE

Medicaid Population

- Just under 73 million individuals or 1 in 5 Americans are enrolled in Medicaid/CHIP
- Diverse and varied range of beneficiaries
  - Children
  - Aged & Disabled
  - Expansion Adults
    - Increasing number of states seeking expansion
    - "The expansion of Medicaid through the Affordable Care Act to non-disabled working age adults without dependent children was a clear departure from the core, historic mission of the program."
      - CMS Administrator Seema Verma

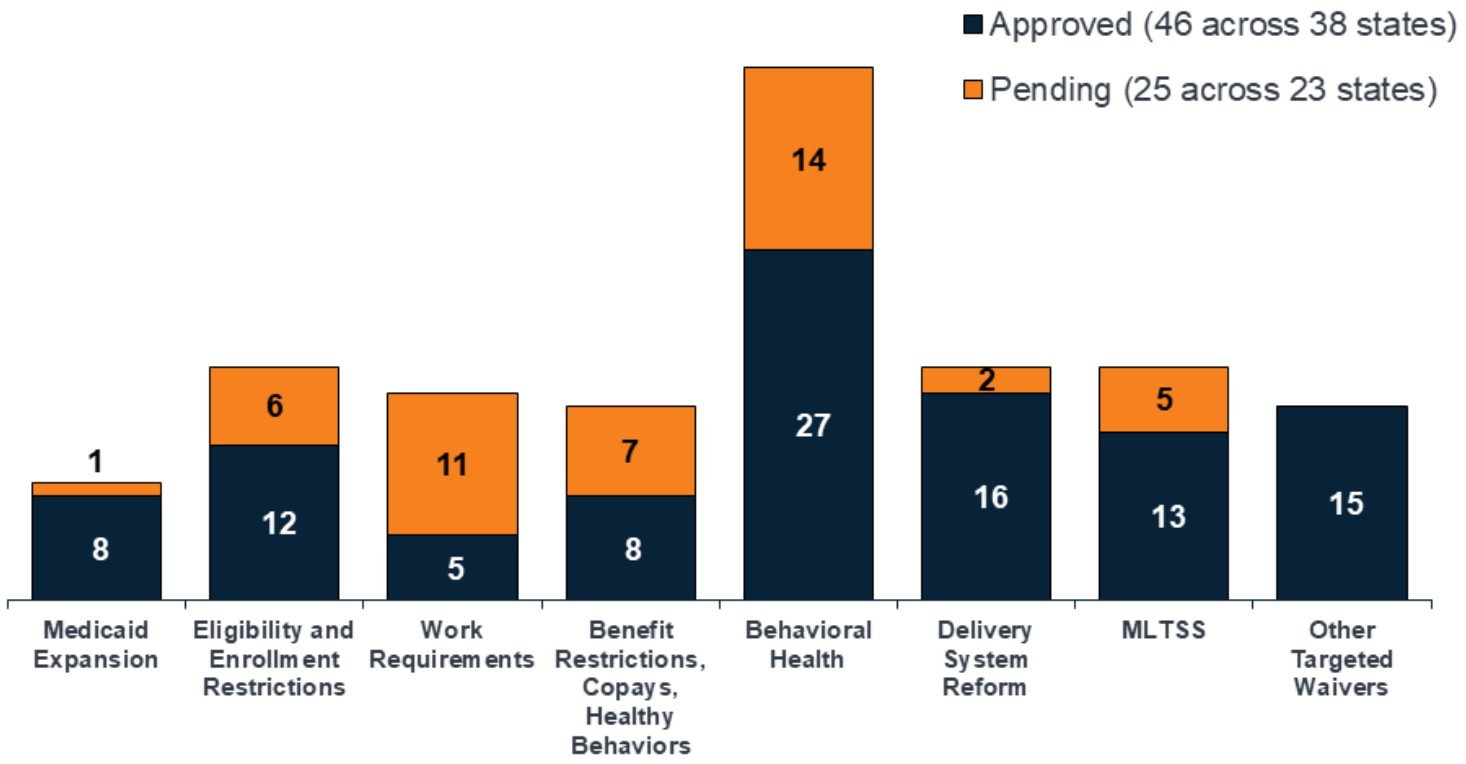
Section 1115 Waivers

- “The CMS sleigh has made deliveries to Kansas, Rhode Island, Michigan, & Maine this week to drop off signed #Medicaid waivers.”
- “Christmas came early for these Governors & we are proud to support local innovation all across this great country!”

AHLA

Waivers

Landscape of Approved vs. Pending Section 1115 Medicaid Demonstration Waivers, December 21, 2018



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.

KFF
HENRY J KAISER FAMILY FOUNDATION

Proposed Rules

- More than half of Medicaid Beneficiaries receive care from a Managed Care Organization (MCO)
  - CMS has committed to reviewing managed care regulations to prioritize beneficiary outcomes and to better met state priorities
  - Bipartisan Budget Act of 2018
- November 1, 2018 Proposed Rules
  - Dual Eligible Special Needs Plans (D-SNPS)
  - Unified Grievance and Appeal Processes
  - New Standards for Integration of Medicare and Medicaid benefits
  - Effective 2021

November 14, 2018 Proposed Medicaid Managed Care Rule

- Revisits 2016 Final Rule and 2017 Pass Through Payment Final Rule
  - Rate ranges and rate setting
  - Capitation rate development and actuarial soundness
  - Provider payment initiatives and minimum fee schedule directed payments
  - Pass-through payments
  - MLR
  - Provider directories
  - State flexibility on network adequacy
- Yet to come?
  - Oversight of Payment Risks
  - MLR
  - Program Integrity

Drug Pricing Transparency

- State-level initiatives
  - Monthly and annual reporting
  - Pharmacy pricing and rebates
  - Alternate pricing models for PBMS
- OIG survey on specialty drug pricing and reimbursement
  - Definitions
  - Amounts paid
  - Payment methodologies
  - Differences in reimbursement amounts

Opioids

- Professional practice restrictions
  - Day supply limits for opioid naïve patients
  - Co-prescribing of opioid antagonists for certain patient populations
  - Patient counseling, “pain contracts”
  - Consulting with Prescription Drug Monitoring Program databases
- Plan obligations
  - Prescriber and pharmacy lock-in programs
  - Expanded access to mental health/substance use disorder services
  - Expanded access to opioid antagonists and MAT
  - Retail pharmacy claim adjudication rules
- SUPPORT Act
  - Mandatory Medicaid coverage of medication assisted treatment
  - Funding for services in “institutions for mental disease” and home health care coordination services
  - Mandatory DUR edits, prescriber oversight

AHLA

AFFORDABLE CARE ACT

Cost-Sharing Reductions

- Payments suspended as of October 2017
- Issuers still required to offer plans with CSRs
  - Additional costs factored into premiums for silver plans
  - Increased premium tax credits in 2018 and 2019
  - CMS promotion of “unloaded” silver plans off exchange
- Individual mandate rendered moot by tax reform bill

Contraceptives

- Exemptions based on religious or moral objections
- Voluntary accommodation
- ERISA v. non-ERISA status
- Ongoing litigation in CA, PA, and MA

1557 Nondiscrimination

- Equal program access on the basis of sex
- Prohibiting discrimination on the basis of gender identity
  - Nationwide injunction in *Franciscan Alliance v. Burwell (Azar)*
  - But see cases in CA, WI, MN, et al.
- Trump Administration review of rules
  - OMB review in April 2018
  - Potential to address gender identity litigation
  - Relaxing of standards for notice/taglines

Association Health Plans

- Factors
  - Bona fide group or association
    - Primary purpose to offer/provide coverage and one substantial business purpose
    - Acting directly as an employer
    - Formal organizational structure
    - Control
  - Commonality of interest
  - Eligible participants are current/former employees or their dependents
  - Must meet nondiscrimination standards
  - Affiliation with health insurance issuer is prohibited
- Additional leeway for working owners

Short-Term Plans

- Short-Term, Limited Duration Plans
  - Maximum coverage period of 12 months
  - Extension of coverage up to 36 months total
  - Revised notice requirements

Fall 2018 Regulatory Agenda

- ACA
  - (PR) 2020 Notice of Benefit and Payment Parameters
  - (PR) Grandfathered plans
  - (FR) Risk adjustment methodology for 2018 benefit year
- Medicaid
  - (PR) Drug utilization review and value based payment for Medicaid covered drugs
  - (FR) State fair hearings and appeals
  - (FR) Medicaid fraud control unit
- Medicare
  - (FR) Medicare appeals (ALJ/MAC)
- OIG
  - (PR) OIG rebate safe harbor
  - (PRE) OIG IFR on Anti-Kickback and Beneficiary Inducement civil monetary penalties
- HIPAA transactions
  - (PR) Health care attachments
  - (PR) Rescission of standard unique health plan and other entity identifiers
  - (PR) Update retail pharmacy standards to D.0V201211
- (FR) Provider conscience
- (PR) Medicare secondary payer reporting
- (PR) HRAs and other account-based group health plans

AHLA

Any views or advice offered in this publication are those of its authors and should not be construed as the position of the American Health Lawyers Association.

“This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that the publisher is not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought”—from a declaration of the American Bar Association.