Update on CMCS Medicaid Pharmacy Program

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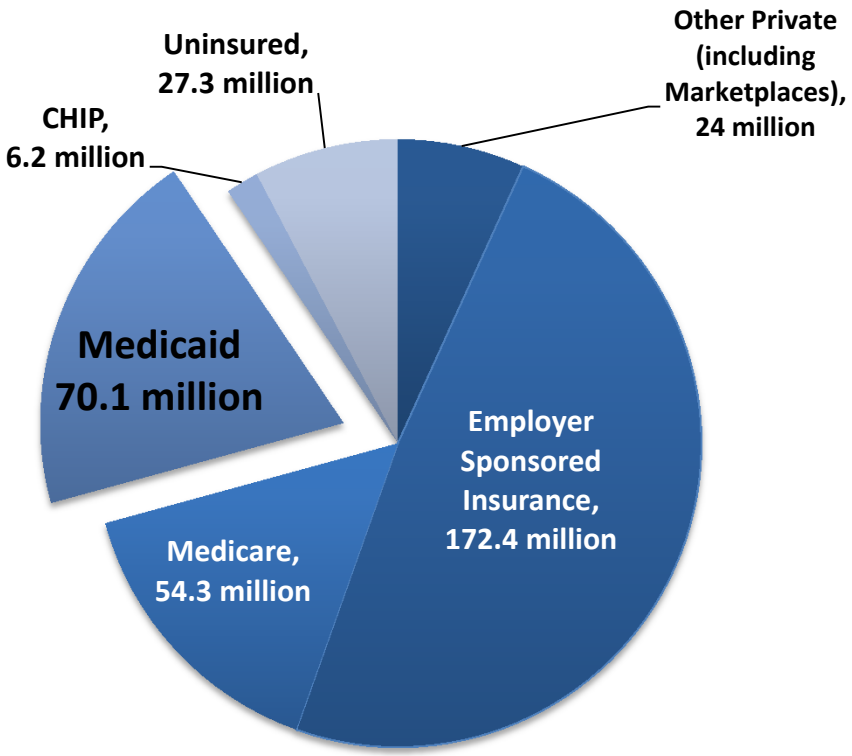
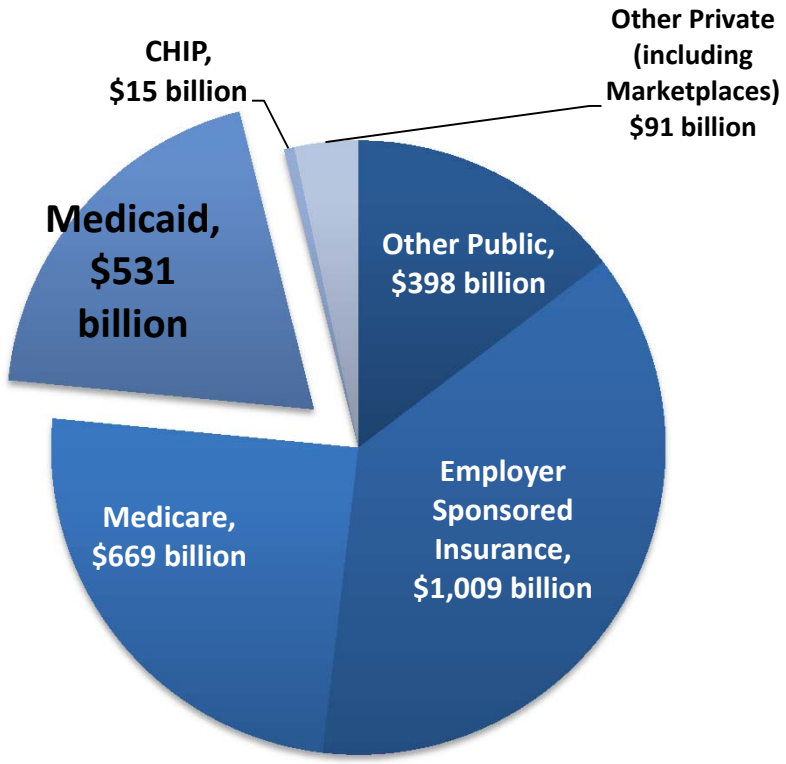
Medicaid is a Major and Growing Part of Health Coverage and Spending

Health Coverage, CY 2015



Health Expenditures, CY 2015

Total = $2.7 trillion



Source: CMS, Office of the Actuary, http://cms.hhs.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2012.pdf

CMCS Division of Pharmacy

Policy

- COD Regulation
- Reimbursement
  - NADAC, FULs
- SPAs
- Specialty Drugs
- Quality/DUR
- MCOs
- 340B
- PADs
- ABPs/Expansion

Operations

- Rebate Program
  - Utilization Data
  - AMP, BP Calculations
- BPD
- DRP

Medicaid Pharmacy Regulation Issues

- Official Publication Date
- Medicaid Proposed Pharmacy Regulation
  - Manufacturer Issues
    - AMP Definition, 5i drugs, pediatric drugs, LE drugs
  - Pharmacy Issues
    - AAC, FULs, professional dispensing fee
  - Subregulatory guidance to states on reimbursement changes; new manufacturer rebate agreement, release of new FULs

National Average Drug Acquisition Cost (NADAC) Approach

1. Survey pharmacies
2. Collect acquisition costs
3. Acquisition cost database
4. Scrub, review and analyze data
5. Compute national average drug acquisition costs
6. Publish reference file
7. Statistical reliability
8. Confidentiality

NADAC: Survey Pharmacies

- Random nationwide sample
- 2,000 – 2,500 pharmacies monthly
- Voluntary
- Independent and Chain pharmacies in all states (excludes closed door pharmacies)
- Invoice purchase records from most recent 30 day period
- Discounts, Rebates, Chargeback's, Free Goods
  - Typically not included on invoice
  - Typically not correlated to individual drug products or invoices

NADAC: Collect Acquisition Costs

- Electronic or hard copy records acceptable
- Copies, not originals
- No special formatting needed
- Purchase records may come directly from wholesalers
- Mail, fax or email
- Typically takes less than 30 minutes of non-pharmacist time to complete/prepare

NADAC: Publish Reference File

- NADAC rates published on a weekly and monthly schedule:
  - **Weekly** updates occur for brand products to reflect changes in published pricing and updates for brand and generic products due to help desk calls
  - **Monthly** updates occur to reflect the results of the ongoing monthly acquisition cost survey for brand and generic products
- Posted in excel file on CMS web site
  - NADAC rates posted on NDC level
  - NADAC rates calculated at drug group level
    - average for brand
    - average for generics

States Reimbursing at Average Acquisition Cost (AAC)

State	Ingredient Cost	Dispensing Fee
Delaware	NADAC	$10.00
Alaska	NADAC	Tiered based on in state location (range: $13.36 - $21.28)
Nevada	NADAC	$10.17
Alabama	AAC	$10.64
Idaho	AAC	Tiered based on total dispensing volume (range: $11.51 - $15.11)
Iowa	AAC	$10.12
Louisiana	AAC	$10.51
Oregon	AAC	Tiered based on total dispensing volume (range: $9.68 - $14.01)
Colorado	AAC	Tiered based on total dispensing volume (range: $9.31 - $13.40)

MCOs and Medicaid Pharmacy

- MCOs may adopt approaches to prescription drug coverage that are different from the states FFS drug coverage such as different prior authorization, PDLs, other limitations etc.
- MCOs may reimburse pharmacies differently from Medicaid FFS
- States must ensure the access standards at 438.206 are met for its contracts with MCOs (no specific access standards like TriCARE)
- ACA added the requirement for states to collect rebates on MCO drug claims
  - Challenges that states are facing collecting utilization data from MCOs

Medicaid Expansion & Alternative Benefit Coverage

- Medicaid expansion population may receive prescription drug benefits via Medicaid MCOs; follows rules of the exchanges

- Floor of prescription drug coverage for traditional Medicaid is different from floor for Medicaid expansion group

- Alternative Benefit prescription drug coverage is at least the greater of: 1 drug per USP category/class or the same # drugs per USP category/class as state's benchmark plan and have a process in place that will permit the beneficiary access to clinically appropriate drugs (1/1/17: P+T Committee)

Medicaid Expansion and Alternative Benefit Coverage

- CHANGE: Publish up to date list of all covered drugs including tiers structure in a manner that is accessible to plan and prospective enrollees
- CHANGE: Must allow enrollees to access prescription drug benefits at in network retail pharmacies unless drug is subjected to restricted distribution by FDA; cannot require mail order

Proposed MCO Regulation

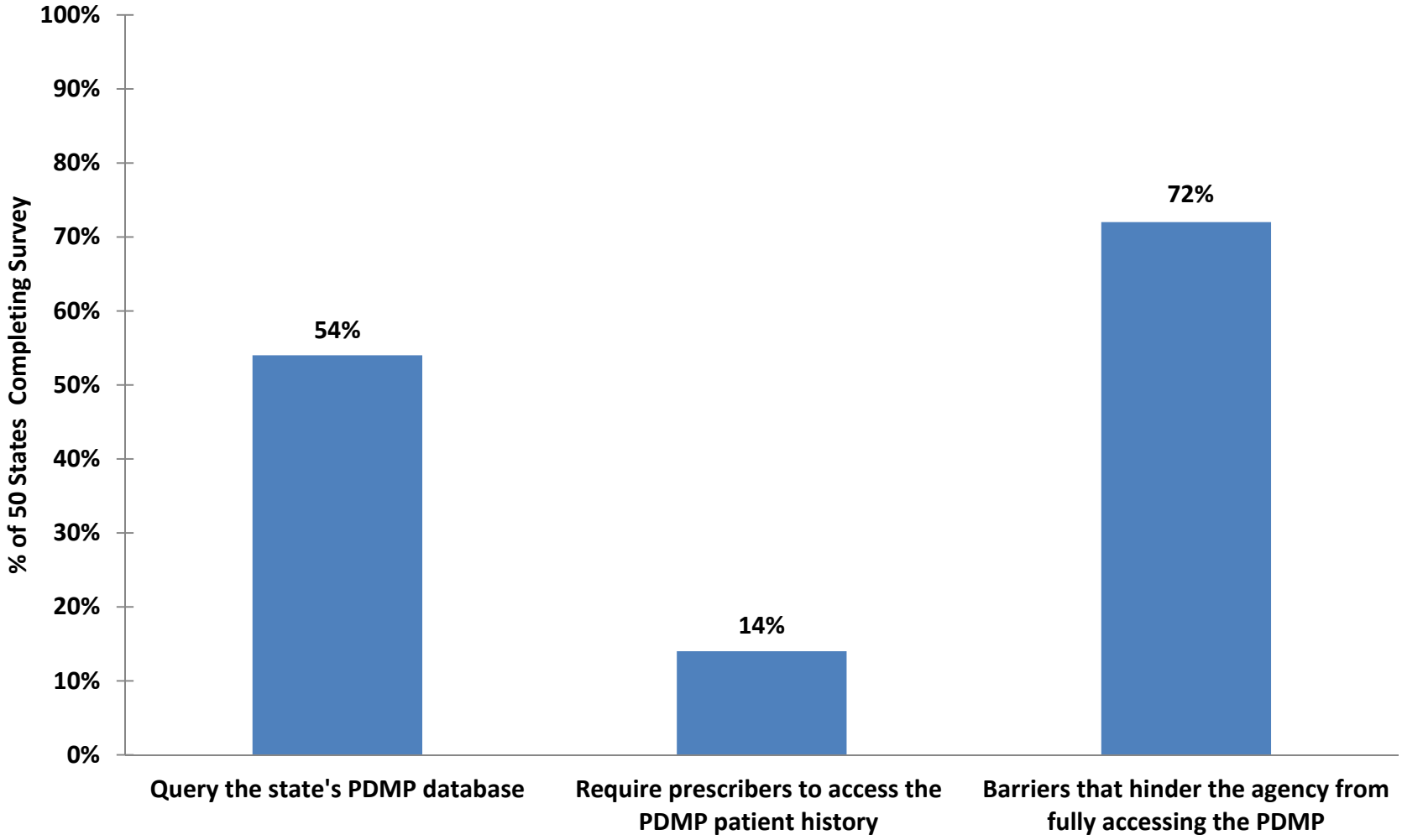
- MCO (including PIHPs & PAHP) contractually required to provide covered outpatient drugs:
  - Scope of coverage equal to 1927 coverage
  - Report drug utilization for rebates
  - Establish procedures to exclude 340B claims data from utilization data
  - Operate a DUR consistent with 1927 and provide description of activities on an annual basis
  - When establishing own formulary conduct PA program that complies with 1927(d)(5)

Quality: DUR Background

- Section 1927(g) requires that States shall provide for a drug use review program (pro DUR, retro DUR, educational interventions) to ensure that:
  - Drugs are appropriate;
  - Medically necessary;
  - Not likely to result in adverse medical results;

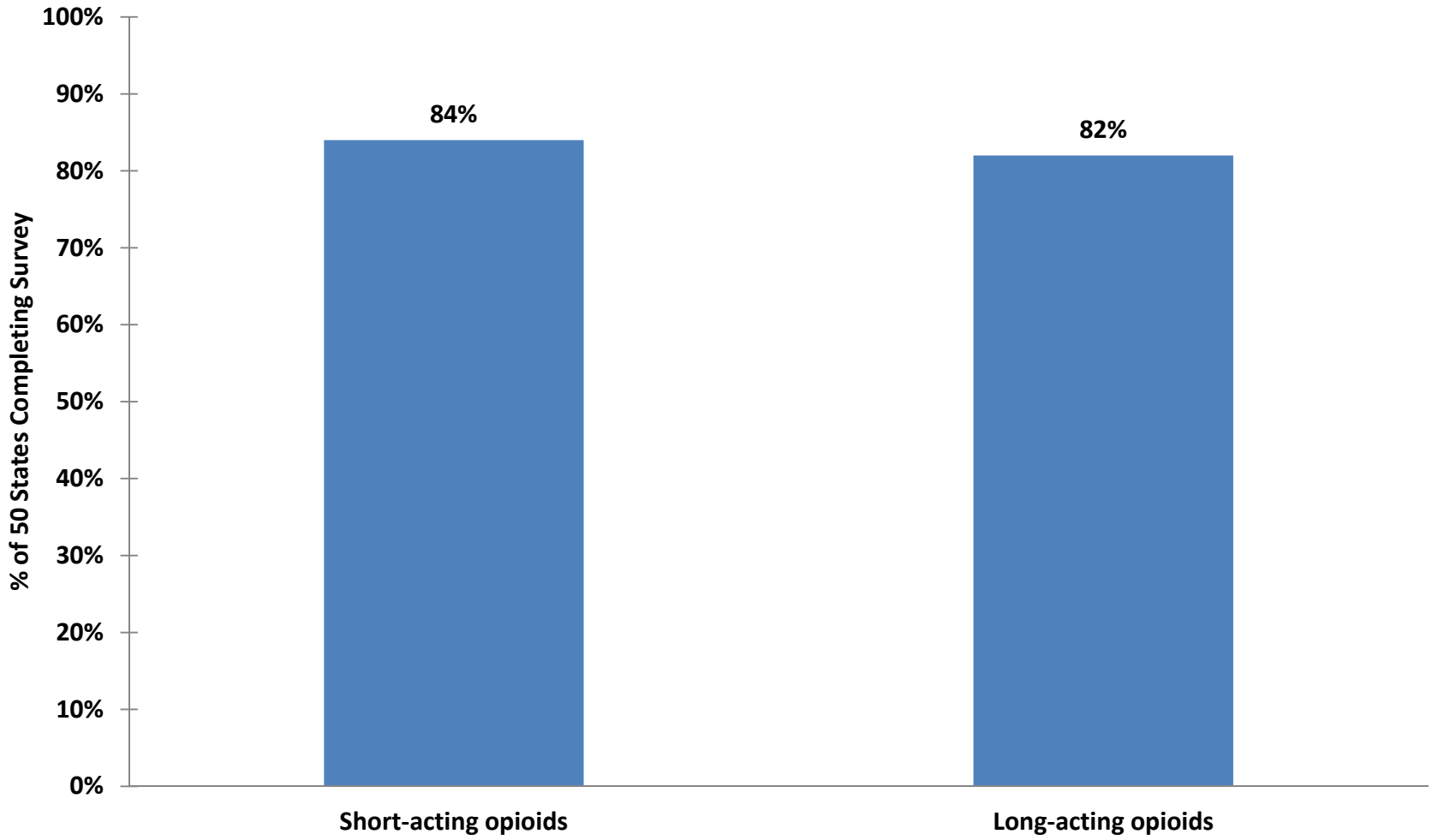
  We appreciate that all states responded in time to our 2014 survey!

Status of Prescription Drug Monitoring Program (PDMP)



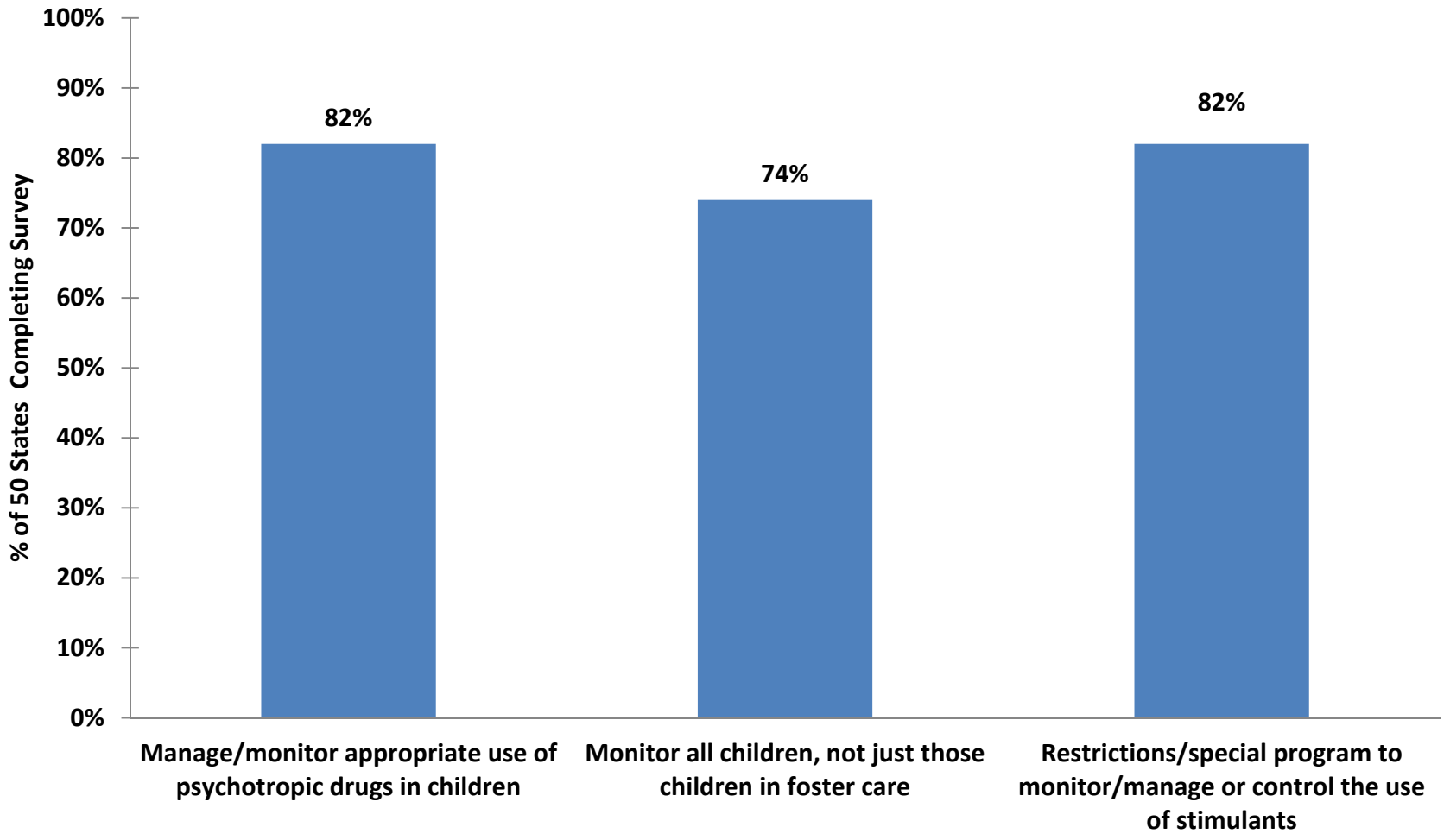
Source: State Comparison/Summary Report FFY 2013

POS Edits Limiting Quantity of Opioid



Source: State Comparison/Summary Report FFY 2013

Psychotropic Drugs/Stimulants



Source: State Comparison/Summary Report FFY 2013

Child and Adult Voluntary Core Set: In Different Stages of Maturity

- Child Core Set: CMS has spent the past five years (2010-2014) working with states to understand the 24 Child Core Set measures and to refine the reporting guidance
  - *Immunizations, HPV vaccine, ADHD medication follow up, MTM for asthmatics*
- Adult Core Set: New program. 2013 was first year of reporting. As with any new reporting program, the early years focused on working with states to understand the Core Set measures, refine the reporting guidance, and improving data quality.
  - *Vaccinations, smoking cessation, antidepressant MTM, antipsychotic medication adherence, annual monitoring for patients on persistence medications, hemoglobin A1c control, diabetes control, HIV viral load suppression*
- *Increased Use of Pharmacy MTM and Quality Measures*

Other Key Program Issues

- MCO Rebates and Supplemental Rebates
  - Number of States Collecting Supplemental Rebates on MCO drugs
- Physician Administered Drugs
  - Continue to get questions from states/MCO drugs
  - In 2011, the OIG conducted a study on the status of the states' compliance regarding collection of manufacturer rebates for physician-administered drugs.
  - In 2014, the OIG's Division of Audit began performing audits and issuing penalties regarding the non-compliance of rebate collection for physician-administration drugs.
- ABP Drug Coverage
  - New standards for ABP drug coverage under expansion

Other Key Program Issues

- 340B
  - Program Issues/Duplicate Discounts
  - Orphan Drug Issues
  - New Guidance
- High Cost Drugs/Generic Drug Prices
  - HCV drug access issues
- Specialty Drugs/Biosimilars
  - Guidance to state and manufacturers – biosimilars considered single source under the rebate program
- BPD/DRP
  - Avoiding disputes at the front end; resolving them at back end; same manufacturers appear to have issues

HHS Pharmaceutical Forum

- HHS Pharmaceutical Forum: Innovation, Access, Affordability and Better Health
- Opportunity to dialogue with government, states, manufacturers and payers on the importance of ensuring access to drugs
- Investigate potential value based purchasing arrangements that can be utilized by payers to reduce costs of drug treatments
- Nov 20th, Washington DC: purchasing strategies, VBP, consumer access to medications

State Release on HCV Drugs

- Recognizes challenges states have with covering new, high cost drugs, balanced with patients need to have access
- Provides guidance to states regarding Medicaid Coverage related to HCV Treatments, specifically Direct Acting Antiviral (DAA) drugs.
- Describes practices that concern CMS with respect to restricting access.
- Describes coverage policies with respect to FFS and Medicaid MCOs.

Manufacturer Letter on HCV Drugs

- Recognizes that manufacturer have key role in making drugs affordable
  - Sent to four manufacturers of HCV drugs
- Stresses the importance of access to DAA drugs, especially to the Medicaid program and patients
- Requests manufacturers of these drugs to share their ideas about how to make DAA drugs more affordable to payers, including Medicaid, through value-based purchasing type arrangements

HHS Opiate Reduction Priorities

- Improve opioid prescribing practices to reduce overdoses and reduce opioid use disorders
- Expand distribution and use of naloxone (to reverse overdose deaths)
- Expand Medication-assisted Treatment (MAT) so as to decrease opioid use disorders and overdoses
- Congress looking at Methadone use in state PDLs
  - Held webinar with states in early September to urge PDL review

Recommendations/Action Plan

- PDMPs (Prescription Drug Monitoring Programs)
- Guidelines (CDC is developing opioid prescribing guidelines)
- Naloxone – NIDA (NIH) supporting research trials on efficacy of prescribing take home naloxone for high risks individuals
- MAT – use of buprenorphine, methadone, ER naltrexone - in combo with counseling and behavioral therapy

Questions/Discussion

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