

## LEGISLATIVE AND REGULATORY UPDATE

**JULY 13, 2017**

**9:00 – 10:00 AM**

**ACPE UAN:** 0107-9999-17-076-L03-P 0.1 CEU/1.0 hr  
0107-9999-17-076-L03-T 0.1 CEU/1.0 hr

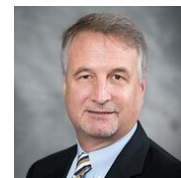
**Activity Type:** Knowledge-Based

**Learning Objectives for Pharmacists and Pharmacy Technicians:** *Upon completion of this CPE activity participants should be able to:*

1. Discuss the implications of the repeal of the Affordable Care Act of 2010 (ACA) and its potential impact on Medicare Part D, PBM transparency and the Medicaid Federal Upper Limits (FULS)
2. Review the 2017 developments with Specialty Pharmacy preferred networks and credentialing requirements
3. Evaluate the evolving changes with Direct and Indirect Remuneration (DIR) in the Medicare Part D Program
4. Discuss the evolving regulatory environment as state compounding standards move into compliance with FDA and USP mandates
5. Summarize California AB 1114 and the implications for pharmacists being paid as providers under the medical benefit

**Speaker: Mark Kinney, RPh**

Mark E. Kinney is an advocacy professional providing state and federal legislative/agency representation for community pharmacy. He is presently employed as the Vice President of Government Affairs for the Independent Pharmacy Cooperative (IPC), based in Sun Prairie, Wisconsin. IPC serves 2700 member pharmacies in all fifty states. He holds a degree in pharmacy from the University of Colorado, School of Pharmacy. Mark has over 15 years of state and federal legislative experience and has been a registered lobbyist in Washington D.C., Colorado, Wyoming, and Wisconsin. He recently represented community pharmacy on a number of important issues, including: Medicare and Medicaid reimbursement, pedigree requirements and drug compounding.



**Speaker Disclosure:** Mark Kinney reports no actual or potential conflicts of interest in relation to this CPE activity. Off-label use of medications will not be discussed during this presentation.



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# Legislative and Regulatory Update

Mark Kinney, RPh

## Disclosure

- Mark Kinney reports no actual or potential conflicts of interest associated with this presentation

## Learning Objectives

*Upon successful completion of this activity, pharmacists and pharmacy technicians should be able to:*

1. Discuss the implications of the repeal of the Affordable Care Act of 2010 (ACA) and its potential impact on Medicare Part D, PBM transparency and the Medicaid Federal Upper Limits (FULS).
2. Review the 2017 developments with Specialty Pharmacy preferred networks and credentialing requirements.
3. Examine the evolving changes with Direct and Indirect Remuneration (DIR) in the Medicare Part D Program.
4. Discuss the evolving regulatory environment as state compounding standards move into compliance with FDA and USP mandates.
5. Summarize California AB 1114 and the implications for pharmacists being paid as providers under the medical benefit.

## Current Political Environment

- It is all about healthcare: AHCA
- Budget: The New Foundation for American Greatness
- Medicaid Block Grants
- Congress & Administration in deregulation mode
  - Less agency oversight of Part D Plans and other market participants
  - Exception may be prescription drug prices
    - Senator Wyden and Senate Finance
    - Introduced C-THRU Act of 2017
    - Entire supply chain transparency?

## Accountable Care Act of 2010 Repeal & Replace

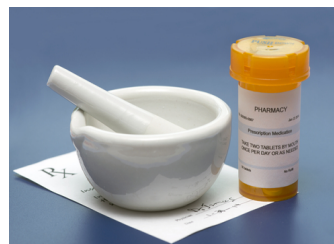
The Accountable Care Act of  
2010 pharmacy related provisions:

- Donut Hole Implications
- PBM Transparency
- Essential Health Benefits AHCA
- Defined Average Manufacturer Price (AMP)
  - Used to calculate Medicaid Federal Upper Limits (FULs)



## Specialty Pharmacy Trends

- Credentialing
  - URAC
  - ACHC
- Definition
  - CMS, States, Commercial
  - Drug Wholesalers
- Managed Care and Preferred Networks



## Direct and Indirect Remuneration (DIR) in the Medicare Part D Program

- CMS Finds PART D Plans Benefit From Higher Direct Indirect Remuneration (DIR) <sup>1</sup>
  - Part D plans benefit essentially by shifting costs to the catastrophic phase of the benefit, where plan liability is limited.
- Concerns over the DIR impact to not only pharmacies, but to patients as well.
- H.R. 1038, the "Improving Transparency and Accuracy in Medicare Part D Drug Spending Act." Senate companion bill (S. 413).
- CMS Guidance

<sup>1</sup> CMS Medicare Part D – Direct and Indirect Remuneration (DIR) 1/19/2017

## Regulatory Developments in Compounding

- Title 21 USC 353a
- Pharmacy Compounding 503a & 503b
- FDA Guidance:
  - Will require 503a pharmacies to obtain a valid "patient-specific prescription" for each drug compounded, despite existing federal law which states that a licensed pharmacist can compound "in limited quantities before the receipt of a valid prescription order for such individual patient." <sup>1</sup>
- State Regulations & New USP Standards



<sup>1</sup> FDA: Office Use Compounding Guidance January 2017

## Pharmacist As Provider Innovation

- Medical vs Drug Benefit Reimbursement

- Activity in the States

- California AB 114
- Washington State
- Montana
- Ohio



- Federal Legislation

- The Pharmacy and Medically Underserved Areas Enhancement Act of 2017 S.109 & Companion Bill H.R. 592
- Question For The Record (QFR) HHS Nomination Hearing

## Opioid Addiction Legislation

- Comprehensive Addiction & Rehabilitation

- Act (CARA) of 2016

- CMS Rulemaking

Include benzodiazepines, other drugs.



- In forty-five state Medicaid “lock-in” programs, the beneficiary has the clear ability to choose both the in-network prescriber and pharmacy.<sup>1</sup>

<sup>1</sup> Centers for Medicare and Medicaid Services, Center for Medicaid and CHIP Services, Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2014 Annual Report Prescription Drug Fee-For Service-Programs: September 2015: page 21

## U.S. Court of Appeals for the Eighth Circuit Issues a Ruling in Pharmaceutical Care Management Association v. Gerhart

- The U.S. Court of Appeals for the 8<sup>th</sup> Circuit (three judge panel) overruled a Federal District Court decision finding that ERISA preempts the recently passed Iowa MAC law. <sup>1</sup>
  - Expansive ruling that may impact many state laws.
  - Arkansas MAC legislation
- The Iowa Attorney General's office petitioned the 8<sup>th</sup> Circuit for an "en banc" hearing.
- Arkansas District Court U.S. District Judge Brian Miller Act 900.

<sup>1</sup> *Pharm. Care Mgmt. Ass'n v. Gerhart*, No. 15-3292 (8th Cir).

## Questions?

Mark Kinney, RPh