How to effectively work with your PBM during a CMS Audit

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**One Source.
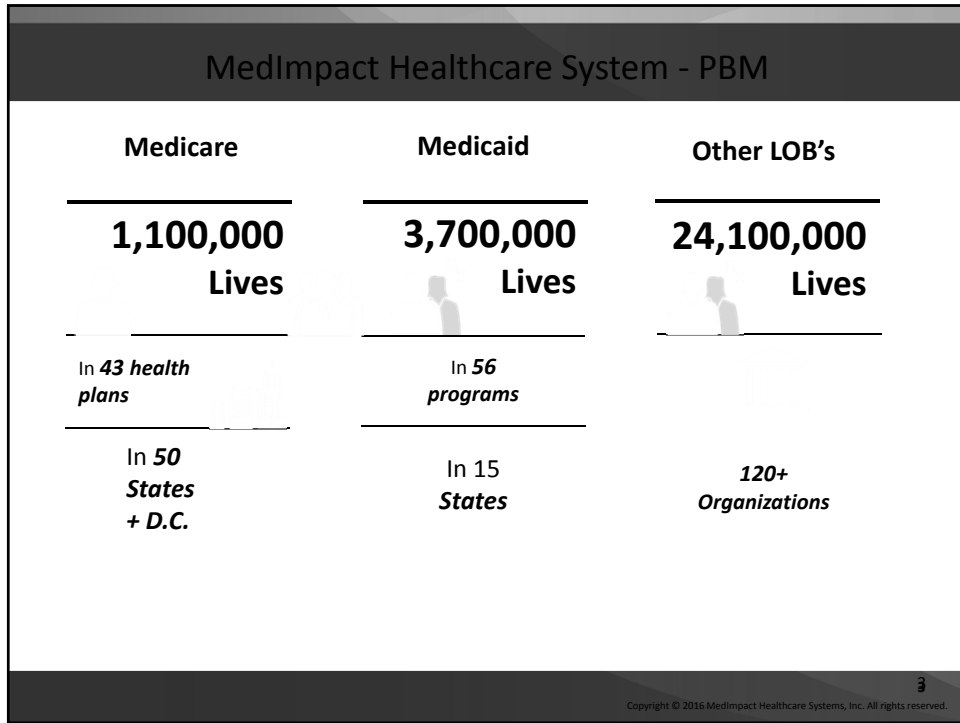Lower Cost.
Better Care.™**

Managing Trend Before It Happens™

MedImpact Healthcare Systems, Inc.

Founded in 1989

- Cover more than 51 million lives
- Privately held
- Corporate office in San Diego, CA
- Operations and data processing centers in San Diego, CA, and Tempe, AZ
- Member service center in Detroit, MI
- International Operations - China, Middle East
- SUNRx 340B
- MedImpact Direct - Mail order (front end)
- Medical Security Card – Cash discount card

URAC ACCREDITED PHARMACY BENEFIT MANAGEMENT

PQA Pharmacy Quality Alliance

2

MedImpact Healthcare System - PBM

Medicare	Medicaid	Other LOB's
1,100,000 Lives	**3,700,000 Lives**	**24,100,000 Lives**
In *43 health plans*	In *56 programs*	
In *50 States + D.C.*	In 15 *States*	*120+ Organizations*

3

MedImpact Corporate Compliance Org

REGULATORY COMPLIANCE
Licensing, bill assessments, research, HIPAA Privacy

FEDERAL/STATE PROGRAMS
Medicare Part D, Medicaid, Health Exchanges

CORPORATE COMPLIANCE
Compliance Program, Code of Conduct, Compliance Reporting, Training

COMPLIANCE ASSURANCE
Compliance monitoring and auditing, accreditation

EXTERNAL COMPLIANCE SUPPORT
Management of compliance audits (client, regulatory, third party)

4

What do PBM's Typically do?

- Manage pharmacy benefits
- Claims processing
- Formulary design
- Design pharmacy networks – (CVS, Walgreens, Independents etc..)
- Negotiate manufacturer rebates
- Clinical (pharma) programs
- Fraud, Waste & Abuse / Special Investigations Unit
- Cash discount card programs, trend reporting etc…

Part D Plan Sponsor – PBM Oversight

- Part D Plan Sponsors are subject to and will routinely be audited by CMS
- Part D Plan Sponsors have an obligation to audit their First Tier, Downstream and Related Entities (FDRs)
- Part D Plan Sponsors must undertake internal auditing to confirm compliance with Medicare regulations and sub-regulatory guidance, contractual arrangements, and applicable laws
- PBMs will:
  - Be asked to support Part D Plan Sponsors during CMS audits
  - Be the subject of the audit if the Part D Plan Sponsor is auditing the PBM as an FDR
  - Be asked to support Part D Plan Sponsor's internal audit efforts related to PBM functions

Communication between Part D Plan Sponsor and PBM

Establish an ongoing working relationships and frequent communication between PBM and Part D Plan Sponsor. PBM should:

- Regularly inform Part D Plan Sponsors of actions PBM is taking in relation to Health Plan Management System (HPMS) memos

- Communicate compliance issues to Part D Plan Sponsors for reporting to CMS

- Maintain log of communications

CMS Audits – Examples of Supported Audits by PBM

- CMS Program Audit

- CMS 1/3 Financial

- Transition Monitoring Program Analysis (TMPA)

- Data Validation (DV)

- Appeals Timeliness

- PDE Data Validation

- CMS Timeliness Monitoring

- Formulary Administration Analysis (FAA)

Top 5 Things That Will Cause Problems With Your CMS Audit

1. Don't communicate with your PBM early and often enough

2. Don't provide the actual audit announcement / share scope with your PBM

3. Don't share with CMS what the PBM provided to you

4. Haven't read the audit notification language in your contract with your PBM

5. Don't review the PBM documentation prior to providing it to CMS

Collaborate Before, During, After Audits

- PBM assigns an audit manager for responding to CMS audit requests/inquiries throughout the audit cycle

- Part D Plan Sponsors provide immediate notice to PBM when CMS audit notifications are received – timing is everything

- Part D Plan Sponsors and PBM discuss universe requirements prior to call with or submission to CMS

- Both Part D Plan Sponsor and PBM representatives participate in meetings/calls with CMS that involve PBM data

- Establish dedicated conference rooms to promote collaboration internally and externally as needed to fully understand the request and expectations from the Part D Plan Sponsor and/or CMS throughout the CMS audit

- Daily meetings between Part D Plan Sponsor and PBM to understand and assign document requests

- Daily meetings with cross-functional audit team to understand and assign document requests

- Part D Plan Sponsor provides draft audit reports to PBM so PBM has opportunity to provide comments and assist with responses

Establish and Use Trained Cross-Functional Audit Team

- Identify subject matter experts responsible for the various functional requirements who will be responsible for reviewing requests issued from CMS

- Train the audit team *in advance* to
  - Understand CMS deadlines and their significance
  - Know and be able to speak to CMS requirements with confidence
  - Understand and be prepared with respect to CMS key focus areas
  - Identify consistent system/reporting requirements as early as possible to support expedited turnaround times and complexity of system data pulls
  - Have a quality review process that has a standardized set of reporting and criteria definitions
  - Create a library containing information on historical impact analysis queries for given conditions

- Benefits
  - Provides more efficient and accurate responses
  - Limits strain on resources and relationships
  - Avoids distraction from day to day business operations

CMS Common Findings/Best Practices - 2016

More CMS 2016 Best Practices/Sponsor Tips*

"If you utilize delegated entities to perform any of the functions currently included in a program audit, ensure you are able to collect and consolidate the relevant universe data accurately. ***When performing internal audits, sponsors should practice the submission of the universe data from delegated entities and ensure their accuracy to prepare for a future audit and to ensure compliance with CMS requirements.*** If is important that both your organization and any delegated entities are prepared for all aspects of a CMS audit."

"The audit protocols are valuable resources for audit preparation and detail the process for audits. ***Sponsors are encouraged to perform practice audits, including practicing universe pulls.*** Practice audits will not only help you prepare for an actual CMS audit, but may help you improve your operations by exposing areas that are problematic or otherwise non-compliant with CMS regulations. Because audit findings may impact Medicare Advantage and Part D Star Ratings, routine self-audits are encouraged to improve operations."

*CMS 2016 Part C and Part D Program Audit and Enforcement Report dated May 9, 2017

Opioids Epidemic By The Numbers

IN 2016...

116 People died every day from opioid-related drug overdoses

11.5 m People misused prescription opioids[1]

42,249 People died from overdosing on opioids[2]

2.1 million People misused prescription opioids for the first time[1]

2.1 million People had an opioid use disorder[1]

17,087 Deaths attributed to overdosing on commonly prescribed opioids[2]

Opioid Epidemic

On October 26, 2017, President Trump directed the Department of Health and Human Services (DHHS) to declare the opioid crisis a public health emergency.

– Eric D. Hargan, Acting Secretary, DHHS issued the following:

DEPARTMENT OF HEALTH & HUMAN SERVICES   Office of the Secretary

Washington DC 20201

DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS

As a result of the consequences of the opioid crisis affecting our Nation, on this date and after consultation with public health officials as necessary, I, Eric D. Hargan, Acting Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists nationwide.

Date   10/26/2017

Eric D. Hargan
Acting Secretary

CMS Proposed Rule

CMS Proposed Rule (CMS-4182-P) was published in the Federal Register, Volume 82, No. 227, on November 28, 2017 (Public comment through 1-16-18):

- Implement statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), which amended the Social Security Act and includes new authority for Medicare Part D drug management programs, effective on or after 1-1-19.
  - Part D Plan Sponsors may establish a drug management program for "at-risk beneficiaries" (beneficiaries at risk for prescription drug abuse or misuse)
  - Limit at-risk beneficiaries access to coverage of controlled substances that CMS determines are "frequently abused drugs" to a selected prescriber(s) and/or network pharmacy(ies)
  - CMS proposes to exempt beneficiaries who have cancer or are in hospice or long-term care from the drug management program

America's Health Insurance Plans (AHIP)

Launched Safe, Transparent Opioid Prescribing (STOP) Initiative. Purpose is to support adoption of clinical guidelines for pain care and opioid prescribing.

- Work with federal and state leaders, as well as physicians and other providers, to address opioid crisis.
- Established the STOP Measure, which is an evidence-based methodology health plans can use to measure how provider practices compare to the Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain.   This measure helps health plans and providers collaborate to improve adherence to CDC guidelines, improve patient safety, and reduce the risk of opioid misuse.

Source: AHIP, Health Plans Launch New STOP Initiative to Help Battle Opioid Crisis in America, by Cathryn Donaldson, October 19, 2017; https://www.ahip.org/health-plans-launch-new-stop-initiative-to-help-battle-opioid-crisis-in-america

Pharmaceutical Care Management Association (PCMA)

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PCMA's President and CEO, Mark Merritt, spoke at a forum of national experts – "America's Opioid Epidemic: Strategies for Prevention" – and emphasized workable, near-term solutions to help combat the opioid epidemic:

- Require E-prescribing (e-Rx) for Controlled Substances

- Seven-Day Opioid Prescription Limits for Acute Pain

- Endorse the CDC's Guideline for Prescribing Opioids for Chronic Pain

- Improve and Integrate State Prescription Drug Monitoring Programs (PDMPs) and Require Prescribers to Check Them

- Give Medicare Part D Plans More Tools to Fight Pharmacy Opioid Fraud

- Achieve Timely and Flexible Implementation of the Comprehensive Addiction and Recovery Act (CARA)

Source: PCMA, PCMA Highlights PBM Solutions to Address the Opioid Crises, November 7, 2017; https://www.pcmanet.org/pcma-highlights-pbm-solutions-to-address-the-opioid-crisis/

17

Questions

18