Compliance Program Overview & FWA Requirements: Measuring Effectiveness

Vernisha Robinson-Savoy, MBA, MSM
Division of Analysis, Policy and Strategy
Medicare Parts C & D Oversight & Enforcement Group
Center for Medicare

Beth Brady, MBA, BA
Division of Plan Oversight and Accountability
Investigations and Audit Group
Center for Program Integrity

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Agenda

- CPE Audit Protocol: Highlights and Changes for CY 2015
- Measuring Effectiveness: Tracer Samples
- Fraud, Waste and Abuse (FWA) Monitoring & Auditing Expectations
- 2016 Compliance and FWA Training Requirements
- Questions

2015 Compliance Program Effectiveness Audit Protocol

- The CPE audit protocol has been modified significantly since CY 2014.
  - Reduced burden of uploading numerous documents prior to the audit
  - More outcomes-focused & results-oriented review
  - Use of "compliance tracers" to trace issues through the organization
  - Streamlined executive and employee interviews

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- Format for CY 2015
  - Compliance Tracers (Webinar and Onsite)
    - Five (5) compliance events to test the effectiveness of the compliance program
  - Compliance Interviews (Onsite)
    - Compliance Officer
    - Special Investigations (SIU)/ FWA Operations
    - Employees

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- The CPE Program Area Audit Process and Data Request is comprised of five (5) sections:
  - Audit Purpose and General Guidelines
  - Universe Preparation & Submission
  - Tracer Sample Selection
  - Audit Elements
  - Appendix A: Record Layouts

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- Sponsors are required to submit their universes and a completed CPE Self-Assessment Questionnaire (SAQ).

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- **Universe Preparation & Submission**
  - Appendix A: Record Layouts Format (Tables 1 through 5)
  1. *First Tier Entity Auditing and Monitoring (FTEAM)*
     - Include all first-tier entities for which auditing and monitoring events were initiated and/or re-opened during the audit period
     - Refer to sections 40 and 50.6.6 of the CPGs

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- **Universe Preparation & Submission**
  - Appendix A: Record Layouts Format (Tables 1 through 5)
  2. *Employees and Compliance Team (ECT)*
     - Include only current employees of the organization
     - Refer to sections 50.2.1, 50.2.2, 50.2.3, and 50.2.4 of the CPGs

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- **Universe Preparation & Submission**
  - Appendix A: Record Layouts Format (Tables 1 through 5)

  3. *Internal Auditing (IA)*
     - Include all audits started and/or re-opened during the audit period
     - Audits related to the sponsor's operational areas to ensure compliance with Medicare requirements
     - Open, Closed, In-Progress, etc.
     - Refer to 50.6.1, 50.6.4, 50.6.6, and 50.6.8 of the CPGs

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- **Universe Preparation & Submission**
  - Appendix A: Record Layouts Format (Tables 1 through 5)

  4. *Internal Monitoring (IM)*
     - Include all monitoring or regular reviews performed to confirm compliance and ensure corrective actions are undertaken and effective
     - Include all monitoring events started and/or re-opened during the audit period
     - Open, Closed, In-Progress, etc.
     - Refer to 50.6.1 of the CPGs

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- **Universe Preparation & Submission**
  - Appendix A: Record Layouts Format (Tables 1 through 5)

  5. *Fraud, Waste and Abuse Monitoring (FWAM)*
     - Include any monitoring efforts performed to identify trends and abnormalities of FWA
     - Use of data analytics, fraud alerts, reports on pharmacy and medical billing, investigations, etc.
     - Refer to 50.6.9 and 50.6.10 of the CPGs

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- Tracer Approach and Sample Selection
  - CMS will use a tracer approach to evaluate whether the Sponsor's compliance program, as a whole system, functions in a way that is effective to address non-compliance and FWA.
  - Each tracer will test every applicable compliance element.
  - Tracers will be performed in a "real-time" walkthrough with the Sponsor.

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- Five (5) tracer samples will be selected to review.
  - Tracers 1 & 2 will be selected from the FTEAM universe.
  - Tracer 3 will be selected from the IA & IM universes.
  - Tracers 4 & 5 will be selected from the FWAM universe and/or "external resources" *(e.g., CMS Account Manager, HPMS memos, CMS notices of non-compliance, provider or enrollee complaints, etc.)*.
- CMS will consider several factors when determining tracer selections including the scope of the Sponsor's Medicare program, business functions, staffing resources, compliance history, etc.

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- Tracers will be used to evaluate compliance with the following elements:

    1. Written Policies, Procedures and Standards of Conduct
    2. Compliance Officer, Compliance Committee, Governing Body
    3. Effective Training and Education
    4. Effective Lines of Communication
    5. Effective System for Routine Monitoring and Auditing
    6. Procedures and Systems for Promptly Responding to Compliance Issues
    7. Sponsor Accountability and Oversight of FDRs

Note: Well-Publicized Disciplinary Standards will not be reviewed during the CY 2015 audits.

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- Tracer Walkthroughs
  - In order to facilitate streamlined and comprehensive tracer discussions, Sponsors will build a PowerPoint presentation (PPT) for each tracer sample using a template provided by CMS.
  - Two (2) PPT templates (FDR and non-FDR) will be provided to Sponsors on the Thursday prior the start of Week 1.
  - Sponsors will have 3 business days to submit completed presentations for each of the 5 tracer samples.

2015 Compliance Program Effectiveness Audit Protocol (cont.)

- Presentations will guide the tracer discussions between the Sponsor and CMS.
  - 2 tracers will take place via webinar during Week 1
  - Remaining 3 tracers will be reviewed onsite during Week 2
- During the live review of the tracers, CMS will ask for Sponsors to show supporting documentation and screenshots to support their statements:
  - Policies
  - Meeting minutes
  - Training records
  - Audit reports, etc.

2015 CMS Compliance Program Effectiveness Audit

Sample Tracer Case Template Guide

Tracer [#]

Prepared by: [Sponsor's Name]

[Date]

Instructions for Completion

- Please include specific information using this PowerPoint template as a guide and responding to the specific requests listed within the template. The presentation focuses on various aspects of your organization as they relate to the operation and effectiveness of your compliance program.

- This presentation is an important part of the CPE tracer documentation. You must provide <u>at least</u> the information requested in the template; however, you are not limited to providing only this information, and we fully expect you to tailor the presentation to fully tell the story of the compliance issue and the operation of your compliance program.

- CMS will review all tracer documentation to determine that the compliance program elements were effectively met. You will need access to documents/data during the onsite review and may be requested to produce screenshots or upload documents outlined in the *CMS 2015 Audit Protocol: Part C and D Compliance Program Effectiveness (CPE) Program Area Audit Process and Data Request.*

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CPE Audit Element I
Detailed P&Ps and SOC distributed to personnel

- **Existence of Policies, Procedures, Work processes and Standards of Conduct (Pre-Issue)**
  - List and discuss all applicable policies, procedures and work processes that cover the business area/function and was in effect <u>at the time</u> the issue occurred/identified
    - Effective Date
    - Date of distribution to involved parties/appropriate personnel

- **Existence of Policies, Procedures, Work Processes and Standards of Conduct (Post-Issue)**
  - List and discuss all applicable policies, procedures, and work processes that cover the business area/function and was <u>reviewed</u> and <u>revised</u> as after issue identification and correction.
    - Revision date and/or Effective Date
    - Date of distribution to involved parties/appropriate personnel

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CPE Audit Element II
Issue considered or acted on by the Compliance Committee

- **Compliance Officer**
  - Provide a short narrative of Compliance Officer's role with addressing the issue

- **Compliance Committee**
  - Issue communicated to the Compliance Committee?
  - Issue considered or acted on by the Compliance Committee?
  - If issue was not shared with the Compliance Committee, provide a narrative why not.

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CPE Audit Element III
Compliance/FWA Training and Education Activities

- **Training and Education of Staff Involved with Compliance Issue**
  - How do you ensure employees are aware of the Medicare requirements related to their job function?
  - What types of training and education are made available to employees and/or FDRs on this topic or issue?
  - Additional training necessary and/or provided as a result of the issue? If so, to whom? When? What types of mechanisms were used? (i.e., classroom, webinar)
  - If training was not provided, please provide an explanation of rationale for not conducting training.

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CPE Audit Element IV

Appropriate communication between Compliance Officer and Staff/Management

- **Communication and Reporting Systems**
  - How was the issue communicated to the operational staff or business area involved?
  - Any communication or interaction with other internal staff, business areas, senior executives, etc.?
  - Any communication or interaction with FDRs?
  - Any communication or interaction with the CMS Account Manager?

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CPE Audit Element V
Formal Baseline/Risk Assessment

- **System to Identify Compliance Risks**
  - Was a formal risk assessment or baseline assessment completed for the Medicare C/D lines of business?
  - Was the operational area/FDR identified as a potential compliance risk or area of particular concern?
  - Any modifications made to the risk assessment after compliance issue was identified?

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CPE Audit Element VI
Timely Corrective Action Implemented and Effective

- **Corrective Actions**
  - Explain the detailed corrective actions that were taken regarding the identified issue.
  - A timeline indicating the corrective actions have been fully implemented or, if not fully implemented, when you expect the corrective action to be completed.
  - Which business areas or functions are responsible for overseeing the implementation and effectiveness of the corrective action?
  - If corrective actions were not taken, please provide an explanation of rationale for not implementing corrective action.

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CPE Audit Element VII
Sponsor Accountability and Oversight of FDRs

- FDR tracers will follow the same continuum through the elements of a compliance program as other tracers.
  - Detailed P&Ps to appropriate personnel
  - Issue considered or acted on by the Compliance Committee
  - Issue reported to the CEO/Board Audit Committee
  - Training and education of staff involved with the compliance issue
  - Appropriate communications between Compliance Officer and staff/management
  - Risk assessment
  - Monitoring/Auditing
  - Root cause analysis
  - Timely corrective action implemented and effective

CPE Audit Element VII (cont.)
Sponsor Accountability and Oversight of FDRs

- Documentation Sponsor may need to provide:
  - P&Ps related to oversight of FDRs
  - Reports and minutes from meetings between the Sponsor and FDRs
  - Minutes from compliance committee and board meetings
  - Proof that FWA and compliance training was provided to FDR
  - Records confirming FDRs were checked against the OIG/GSA exclusion databases
  - Monitoring and auditing reports from Sponsor and FDRs
  - Corrective action plans

2015 Compliance Program Effectiveness Audit Protocol

- CPE Tracer Results and Conditions
  - CMS will ensure all questions have been addressed before moving on to the next tracer.
  - Each tracer is considered an independent case and will be scored accordingly.
  - If deficiencies are found during the tracer walkthroughs, the applicable audit condition(s) of non-compliance will be cited.

Fraud, Waste and Abuse (FWA) Monitoring and Auditing

- Sponsors must perform *effective* monitoring in order to prevent and detect FWA.
  - Use of data analysis
  - Monitoring to detect unusual patterns, practices and trends
  - Analyze claims data
  - Identify problem areas at the FDR
  - Routinely generate and review reports on pharmacy billing, medical claims, etc.

Fraud, Waste and Abuse (FWA) Monitoring and Auditing (cont.)

- Sponsors must either establish a specific SIU or ensure FWA-related activities are conducted by the compliance department.
  - Reduce or eliminate fraudulent or abusive claims paid for with federal dollars
  - Prevent illegal activities
  - Identify providers and enrollees with overutilization issues
  - Work with or refer investigations to the NBI MEDIC

FWA Monitoring & Auditing Risk Assessment

Routine Monitoring and Auditing for FWA Detection

"… Sponsors must establish and implement an effective system for routine monitoring and identification of compliance risks [including FWA]…Risk areas identified through CMS audits and oversight, as well as through the sponsor's own monitoring, audits and investigations are priority risks. The results of the risk assessment inform the development of the monitoring and audit work plan."

http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf

FWA Monitoring & Auditing Work Plan

Work plan **_must_** include "process for responding to all monitoring and auditing results and for conducting follow-up reviews of areas found to be non-compliant to determine if the implemented corrective actions have fully addressed the underlying problems."

*Chapter 9, Section 50.6.3

Work plan **_may_** include:
- ✓ Announced or unannounced audits to perform and schedules
- ✓ Audit types, methods and resources
- ✓ Person(s) responsible
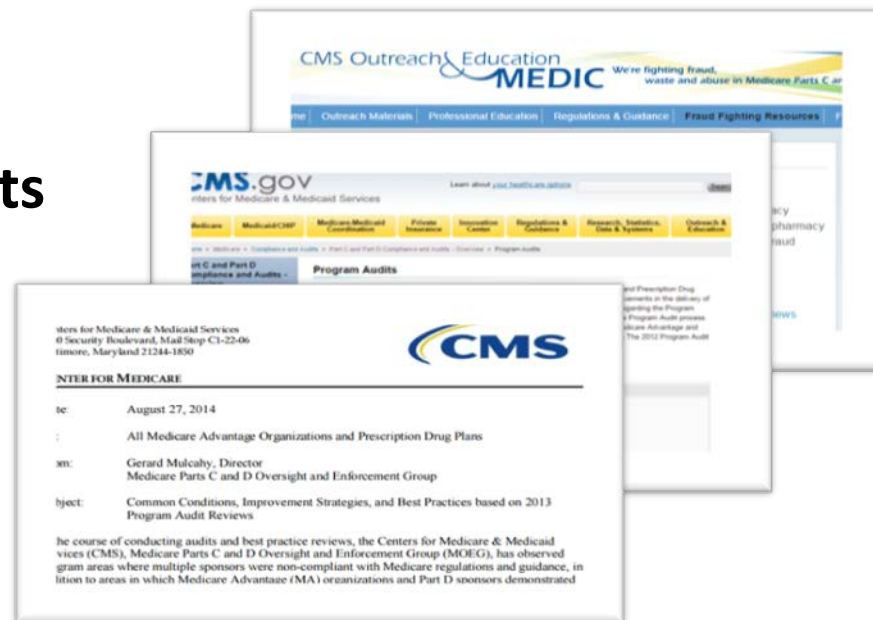- ✓ Final audit report due date

Audit findings may require follow up including referrals and corrective action.

FWA Monitoring & Auditing CMS Notifications

Work plans may incorporate CMS notifications

- **CMS Fraud Alerts**

- **Best practices from CMS audits**

- **High Risk Pharmacy and High Risk Prescriber Assessments**

FWA Monitoring & Auditing Requested Actions

High risk assessments are valuable supplements to plan sponsors' internal data analysis

Plan sponsors should routinely generate and review reports on pharmacy billing and medical claims, etc. based on data analysis to identify pharmacies and other FDRs that require further review*
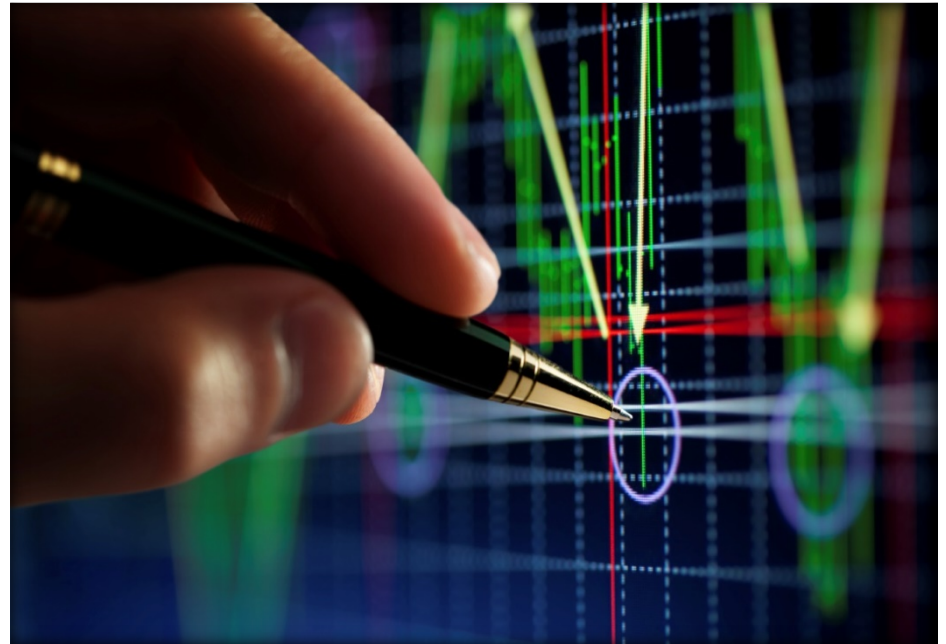
*Chapter 9, Section 50.6.9

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FWA Monitoring & Auditing Plan Sponsor Actions – Monitoring Internal Processes

Augment Monitoring Processes based on Program Requirements
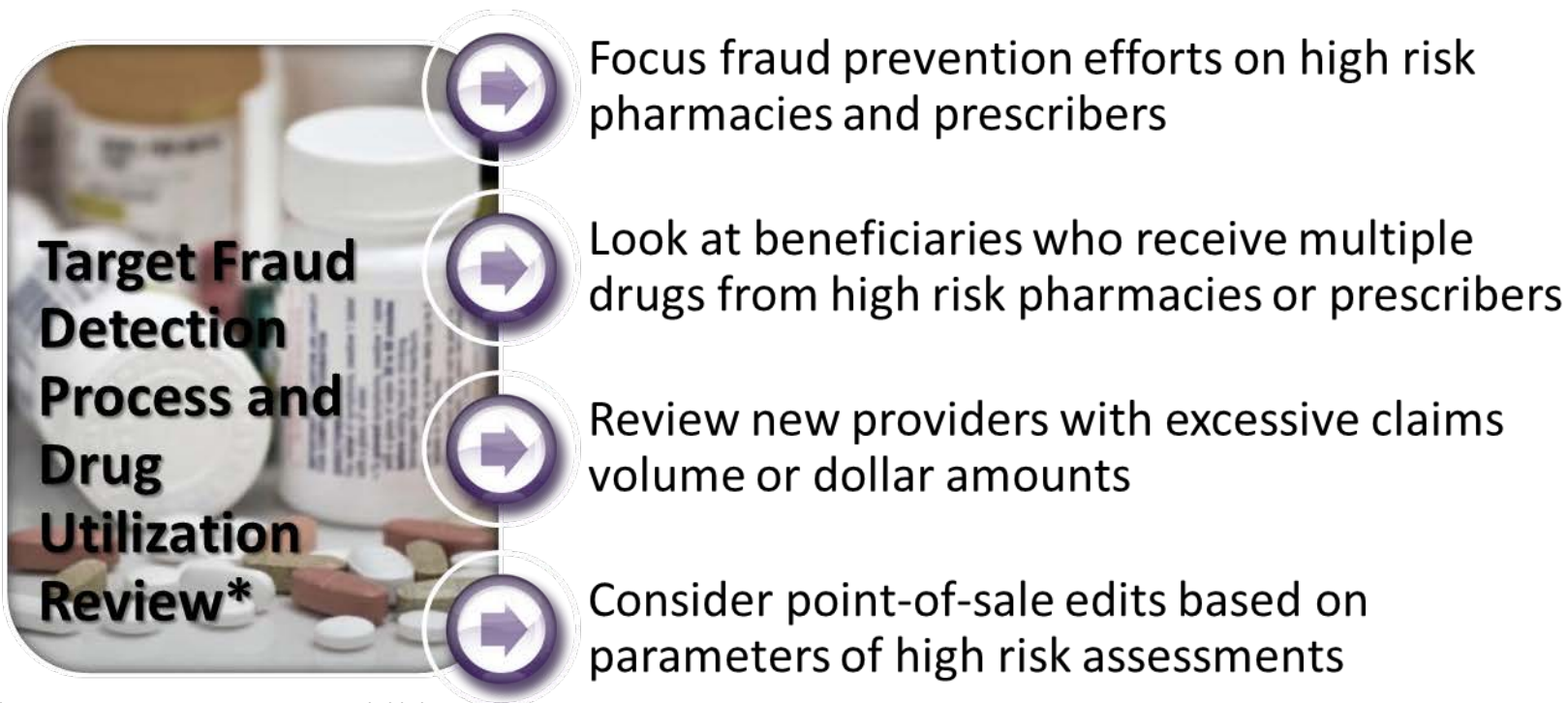
➡ Confirm existing monitoring processes align with current Part D program requirements

➡ Conduct routine proactive data analysis using data from high risk prescriber and pharmacy lists

FWA Monitoring & Auditing Plan Sponsor Actions – Fraud Detection & DUR

Target Fraud Detection Process and Drug Utilization Review*

Focus fraud prevention efforts on high risk pharmacies and prescribers

Look at beneficiaries who receive multiple drugs from high risk pharmacies or prescribers

Review new providers with excessive claims volume or dollar amounts

Consider point-of-sale edits based on parameters of high risk assessments

*Pursuant to 42 C.F.R. §423.153(b)(2)

FWA Monitoring & Auditing Plan Sponsor Actions – Internal Claims Data Analysis

Internal claims data analysis to identify trends and audit areas

Match office visit claims to high risk prescriber's prescription claims

Validate addresses to confirm legitimacy of outlier pharmacies

Investigate outliers based on analysis of internal claims data

Monitor links between outlier prescribers, pharmacies and beneficiaries
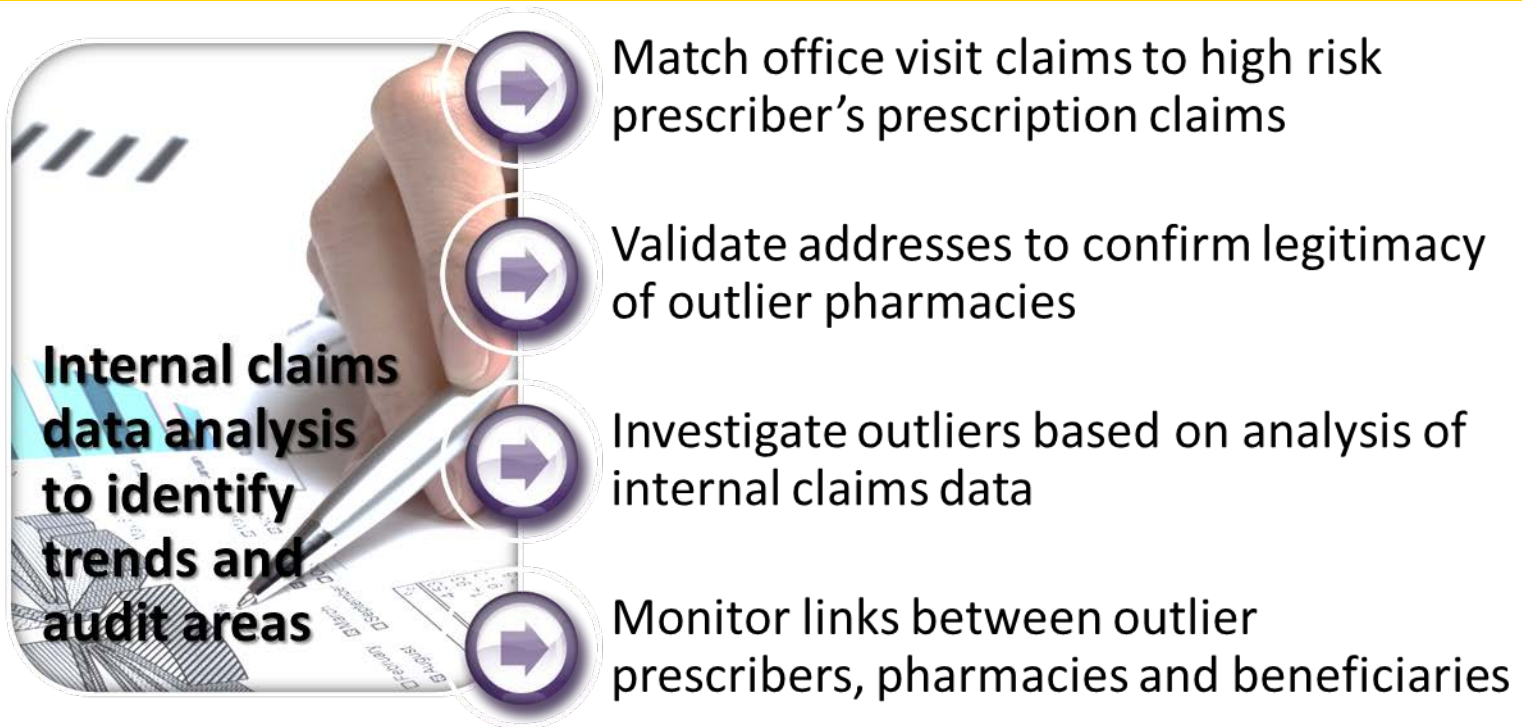
FWA Monitoring & Auditing Plan Sponsor Actions – Focused Data Analysis

Focused data analysis on outlier prescribers and pharmacies

- Conduct peer-to-peer comparison in same specialty and service area

- Watch for providers who bill same or similar items or services for most beneficiaries

- Create dashboard of normal values across time to watch developing trends

- Monitor standard data analysis reports to quickly identify suspects and schemes
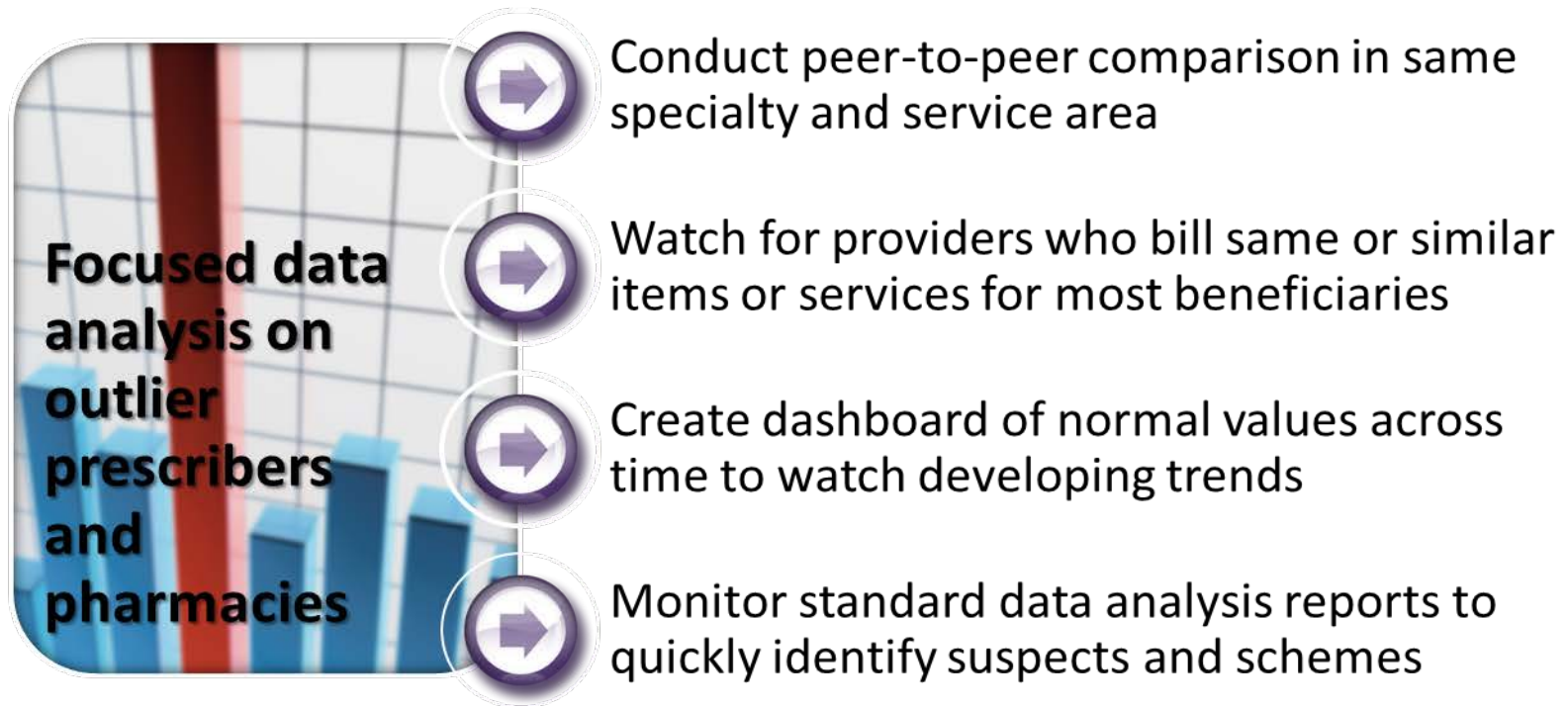
FWA Monitoring & Auditing Plan Sponsor Actions – Contractual Arrangements

Review contractual arrangements with identified prescribers

→ Review contracts with prescribers identified as high risk for FWA

→ Consider disciplinary measures, including contract termination, if warranted

FWA Monitoring & Auditing Action Reminders

Identification of prescriber or pharmacy in the high risk assessment alone does not prove FWA and is not grounds for plan sponsor to take action

Plan sponsor must conduct claims reviews and analysis per established protocols to confirm FWA and take action

Taking Action Against FWA

Administrative Actions

Prescriber Education
Prescriber memo with additional education and/or mandated training for prescribers

Procedural Changes
Modify procedures to identify outliers and continually monitor high-risk prescribers

Disciplinary Actions
Initial warning letters and further action that may include removal from provider network

Questions?

Vernisha Robinson-Savoy
vernisha.robinson-savoy@cms.hhs.gov

Beth Brady
elizabeth.brady@cms.hhs.gov