REVELATION PHARMA

WHY LEVERAGE A PSO SYSTEM?

WHAT VALUE DOES IT ADD TO MY PHARMACY?

REVELATION PHARMA

1

SETTING THE STAGE

- What is PSO?
  - Patient Safety Organization (PSO)
    - Patient Safety and Quality Improvement Act (PSQIA) of 2005
      - *Framework for creation, operation, and legal protections.*
    - Encourage reporting and learning from errors without fear of liability in support of Continuous Quality Improvement Programs
- Revelation Pharma - national network of compounding pharmacies driving quality and industry excellence.
    - *Quality Excellence > CQI*
- Alliance for Patient Medication Safety (APMS)
  - APMS is a federally listed Patient Safety Organization (PSO)
  - Provides CQI Program

REVELATION PHARMA

SLIDE 2

2

USE CASES
Meeting Regulatory Standards

- PSO Participation is voluntary, however
  - **22 States Require CQI Program**
    - AL, AR, CA, CT, FL, IN, IA, KS, KY, MD, MA, MO, MT, NH, NC, ND, OK, OR, RI, VA, WV, WY *NABP 2024 Survey of Pharmacy Law*
- Outsourcing facilities and cGMP standards
  - Quality management and continuous improvement "inherent" cGMP principles
  - **Require systems for quality assurance (QMS), which include monitoring and evaluating drug quality, and compliance**
    - *"21 CFR 211.192 — Investigations of discrepancies"*
    - *ICH Q10 Pharmaceutical Quality Systems*
  - Investigation and Corrective Actions: Deviations, Non-conformances, out-of-specifications (OOS) results, implementing Corrective and Preventative Actions (CAPAs)
    - **Lessons learned from CAPA activities, encouraging proactive identification and resolution of issues**
      - Mitigation of risk (Quality-Related Events – QRE) ICH Q9
    - **addressing root causes and reoccurrences for sustained / effective quality outcomes**
  - **Complaint Handling** – customer complaints, adverse events, recalls

REVELATION PHARMA | **SLIDE 3**

3

USE CASES
Achieving Accreditation Standards

- Accreditation Commission for Healthcare (ACHC) Pharmacy Compounding Accreditation Board (PCAB).
- PCAB - TCRX5-ALL: *The pharmacy lacks evidence of a written, effective, ongoing performance improvement plan. Quarterly and Annual reports were not in evidence. Data is available but not analyzed effectively.*
  - *APMS PSO / CQI Program contains effective tools for assessments and trending data by period*
  - *Network pharmacy enrolled in APMS PSO, maintained CQI certification and received accreditation with POA*
- National Boards of Pharmacy (NABP) Verified Pharmacy Program (VPP)
- 91.00 Reporting: *Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*
  - *Network pharmacy enrolled in APMS PSO, maintained CQI certification and adequately addressed inspection deficiencies*
- Joint Commission, Centers for Medicare & Medicaid Services (CMS) require quality improvement programs

REVELATION PHARMA | **SLIDE 4**

4

USE CASES
PSO System and CQI Functions

- CQI Certification with active PSO participation
- Success Rates% - Quality Systems Performance
- Contributing Factor Analysis and Trending
- QRE Types and Analysis
- Monthly / Quarterly / Annual Assessments

QRE Type

Contributing Factors

Available Reports

Select A Report

Corrective Actions/Recommendations

Training/competency/roles/responsibilities changer or adjustment: 18 QREs, 32.73%

Independent double check/read back/labeling shelf placement/educate staff: 3 QREs, 5.45%
Medication product - change vendor for active or inactive ingredient(s): 0 QREs, 0%
Staffing - change schedules/assignments/skill mix/other: 0 QREs, 0%

Patient profile update (eg Allergy, intolerance, reaction, other): 5 QREs, 9.09%
Refer Patient to medical care/consultation: 0 QREs, 0%
Environmental factors (e.g. improve lighting, physical space, reduce interruptions, other): 0 QREs, 0%
Pharmacy management factor - address safety culture, policies & procedures: 3 QREs, 5.45%
No actions planned: 4 QREs, 7.27%

Dispensing workflow or process change: 6 QREs, 10.91%

Software change - add modify, alert or other equipment repair/replace: 0 QREs,
: 0 QREs, 0%
: 1 QREs, 1.82%
Other: 7 QREs, 12.73%

Sent product for laboratory analysis: 0 QREs, 0%
Amended labeling or packaging: 8 QREs, 14.55%

QRE REPORTS
All Reports
R Type
QRE Type
QRE By Day of Week
QRE By Time of Day
Where Was QRE Discovered
Where Did QRE Occur
New R vs Refill R
Severity Level
Contributing Factors
Corrective Actions/Recommendations
Possible HIPAA
QRE Success Rate
Error Percentage
HIPAA Report
Reached the Patient

REVELATION PHARMA

SLIDE 5

5

USE CASES
Protection Afforded

LEE SILSBY COMPOUNDING PHARMACY

LEE SILSBY COMPOUNDING PHARMACY

FDA INSPECTIONS 2017, 2019, 2022

Inspection 1 Documentation in Patient Profiles; Manual Logs

Inspection 2 Improved systems for tracking; however, lacked advance controls and systems

Inspection 3 Active reporting to PSO; maintaining CQI program and certification through AMPS PSO

- ✓ 483 observations
- ✓ Opportunity for more effective CQI

- ✓ No observations
- ✓ Question of data integrity

- ✓ No observations
- ✓ Demonstrated PSO participation
  - ✓ Tracking / Resolutions
- ✓ PSO data protection

REVELATION PHARMA

SLIDE 6

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REVELATION PHARMA

WHY LEVERAGE A PSO SYSTEM?

WHAT VALUE DOES IT ADD TO MY PHARMACY?

REVELATION PHARMA

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REVELATION PHARMA

THANK YOU FOR YOUR TIME AND CONSIDERATIONS

QUESTIONS?

REVELATION PHARMA

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