

Walgreens



Risk and Fraud in Retail Pharmacies

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1



Agenda

- 01** Risk & Fraud: A Common Landscape
- 02** Days of Supply & Proof of Delivery
- 03** COVID-19: Post-PHE Enforcement
- 04** Walgreen Co. Corporate Integrity Agreement
- 05** Specialty Pharmacy
- 06** Compliance Operations at Walgreens
- 07** Publicizing Requirements & Fostering Partnerships

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2

2

Our Prescription Calls for Enabling Innovation with Integrity

The Walgreens Pharmacy and Healthcare Compliance team has developed a best-in-class pharmacy and healthcare compliance program aimed to enable, support and grow the business, while building in essential compliance guardrails to minimize and detect risk.



We are an effective partner: We support our core business to help achieve its objectives in a compliant manner with the benefit of the full context of risk for ongoing and new activities.



We champion the business: Responsible for fostering innovative business solutions through leveraging deep understanding and decades worth of experience with the company, coupled with our institutional knowledge to help guide our business partners with agility.



We help operationalize Compliance: Responsible for administration of the Corporate Integrity Agreement (CIA) Audit and implementation of all related obligations, including corrective actions, promotion of awareness and monitoring of actions taken after deployment of modifications.



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3

3

Risk & Fraud in Retail Pharmacy: A Common Landscape

Pharmacy benefits are processed in real-time.

- Majority of prescription drug claims have been submitted (“adjudicated”) in real-time for decades.
- Most third-party plans respond immediately to a pharmacy’s coverage request for a drug.
- Compared to medical benefits where claims are submitted after the fact and any remaining amount due is invoiced to the patient.

Certain types of drug products carry higher risks than others.

- Certain high-cost products carry higher likelihood of audit: Injectable Type 2 Diabetes Non-Insulin; Insulin Pens; Migraine Medications.
- Certain products carry significant regulatory, legal and public relations risks (e.g. Reproductive Health & Gender Affirming Care).
- Specialty drugs are higher risk due to their higher cost and involvement from other industry players.

Certain issues are pain-points across the retail pharmacy industry.

- Shifting trends in consumer behavior since COVID-19 towards shipping and delivery and away from brick-and-mortar.
- Resumption in enforcement of rules and regulations waived during COVID-19, including quantity and frequency allowances, and waiver of Proof of Delivery.
- Good Faith Dispensing and operational changes to account for injunctive relief and controlled substances.

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4

4

Clinical & 3rd Party Days Supply: Claim Submission Risks

Comparing Clinical Days Supply vs. Third-Party Days Supply

- Clinical days of supply relates to how long prescribed medication will last for the patient.
- Many third-party plans have days of supply limitation at retail; frequently shorter than clinical days of supply.
- Frequently occurs with Unit of Use products that are manufactured in packaging that cannot be opened.

Real Time Example: Fluticasone Nasal Spray

- Frequently prescribed (approx. 200k new prescriptions per month).
- Unit of Use product: fixed amount of 120 doses set by manufacturer.
- Typically prescribed for 2 inhalations per day which lasts patient 60 days.
- Plan rejects claim stating patient is limited to 30 or 34 days of supply

Compliance Risk: Documentation & System Limitations

- Many pharmacy fulfillment systems lack ability to submit two days of supply to PBMs.
- Many systems require a team member to manually annotate prescription image and/or call plan for an override.
- Potential dollar value associated with loss enlarges with expensive products and auto refill programs.

Best Practices to Mitigate Audit Risk & Reduce Loss

- Develop robust written standards, policies and SOP's.
- Train/coach team members on plan requirements and how to be compliant.
- Develop process to track and/or annotate the clinical days of supply so future dispenses are based thereon.
- Monitoring for high-risk products (including targeted monitoring and training).



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5

5

Proof of Delivery: A Frequently Audited Condition of Payment

- Where required by the plan, Proof of Delivery (“POD”) is a condition of payment and numerous government payors require obtaining & retaining patient or patient representative signature.
- Medicare Part B and many Medicaid Fee-for-Service plans require patient signature for POD.
- Without POD, the amount paid by MPB or Medicaid is subject to recoupment.
- Proof of Delivery records should be retained for ten (10) years plus the current year.
- Pharmacy providers should have robust recordkeeping and documentation procedures for retention of executed Proof of Delivery disclaimers/signature logs.



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6

6

COVID-19 Pandemic: Post-PHE Enforcement Status

- Majority of government payors waived Proof of Delivery (POD) requirements during duration of Public Health Emergency (PHE); some state waivers expired sooner.
- All state and federal payors resumed enforcing POD requirements after federal PHE expired in May 2023.
- Certain state Medicaid plans removed quantity limitations on products during COVID-19, allowing for early refill and not blocking claims through reject that would have otherwise been Refill Too Soon (RTS).



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OIG Audits, Settlements and Enforcement Actions



Corporate Integrity Agreements

Provider Types: Home Health, Specialty Rx, Physician Offices, Health Systems, Manufacturers

Allegations fall into three main buckets:

- Submission of claims inducing patient referrals or usage of specific medical devices;
- Billing for unnecessary therapy and/or unneeded testing;
- Improper procedures designed to enlarge billing reimbursements.



Audit Activity

Types: Medicare Advantage, Pricing/Rebate Invoicing/Cost Reporting, Drugs of Concern, COVID-19

- Medicare Advantage: audit of high risk diagnosis codes and whether medical records support the claim.
- Pricing: rebate invoicing-related and bad debt audits: CMS is payor of last resort.
- Drugs of Concern: Controlled substances paid by Medicare/Medicaid plans.
- COVID-19: Testing and treatment services, telehealth, lab tests.



Enforcement Actions

Telemedicine Fraud, Diversion, Illegal Distribution and Fraudulent Nursing Diplomas

- Telemedicine fraud (S.D. Florida), pharmaceutical fraud (claims related to diverted HIV medication) and illegal opioid distribution.
- Operation Nightingale: Multi-state (DE, NY, NJ, TX, FL) coordinated law enforcement action to apprehend individuals engaged in a scheme to sell false and fraudulent nursing degree diplomas and transcripts.



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Walgreen Co. Corporate Integrity Agreement

- Walgreens entered into settlement with Dept. of Justice and related Corporate Integrity Agreement (CIA) with Office of Inspector General (OIG) on January 11, 2019, resolving False Claims Act allegations.
- CIA grew out of three main third party billing-related FCA allegations:
 - Insulin Pens:
 - Most insulin pens are pre-packaged with (5) pens and a medication guide—the packaging was not originally intended to be broken open.
 - Many Medicaid FFS plans have a 30 to 34 days supply limitation.
 - Insulin Pens also require administration of priming dose (varies by product), which duration of days of supply.
 - Prescription Savings Club: Dispute about Usual & Customary (U&C) pricing vs. PSC pricing for prescription drugs and applicability to government payors.
 - Wisconsin Medicaid: Documentation of required diagnosis codes from prescriber related to attention deficit disorder medications.



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9

9

Walgreen Co. Corporate Integrity Agreement: Key Terms, Part I



Compliance and Ethics Officer and Committee, Board of Directors Compliance and Management Compliance

- Walgreens has appointed and maintained a Chief Compliance Officer throughout the duration of the CIA.
- Walgreens makes quarterly reports regarding compliance to the Audit Committee of the Walgreens Board of Directors.
- Walgreens formed a Compliance Steering Committee which meets quarterly.



Written Standards

- Walgreens has developed and enforced its robust Policies and Procedures, in addition to related Standard Operating Procedures and Job Aids.
- Walgreens has continued to update its written standards throughout the duration of the CIA.



Training and Education

- Walgreens deploys an annual Corporate Integrity Agreement Training to all Pharmacy Team Members.
- Walgreens also provides Board Member training to any new member of the Board of Directors.
- Walgreens maintains records of completed training.



Independent Review Organization Claims Review

- Walgreens has engaged in an annual Independent Review Organization Claims Review, following agreed upon procedures (AUP), where an independent auditor reviews claims billed by our retail and specialty pharmacies.

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10

Walgreen Co. Corporate Integrity Agreement: Key Terms, Part II

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Risk Assessment and Internal Review Process

- Walgreens has developed and implemented a centralized annual risk assessment and internal review process to identify compliance risks.
- Led by the Walgreens Internal Audit Department.



Disclosure Program

- Walgreens deployed a compliance hotline, compliance inbox and publicized the ways in which to raise/escalate a compliance issue to the Walgreens Support Center (corporate headquarters) in Deerfield, IL.
- Any report made by a team member is not nonretaliatory.



Ineligible Persons Screening

- Walgreens screens any prospective Covered Persons and any current Covered Persons against the OIG Exclusion List. Walgreens also requires any Covered Person to immediately disclose if they become a part of the Exclusion List.



Reportable Events

- Walgreens is required to disclose the reportable events, which include (1) a substantial overpayment, (2) a probable violation of law, (3) employment of a Covered Person and (4) the filing of a bankruptcy.



Notification of Government Investigation or Legal Proceeding

- Walgreens is required to disclose any ongoing investigation or legal proceeding that is conducted by a governmental entity or its agents involving an allegation that Walgreens has committed fraud or a crime.



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11

Specialty Pharmacy: Unique Opportunities & Unique Risks

- More companies involved in this market; usually do not act alone, typically partner with pharmaceutical companies to provide products to patients.
- Patient Financial Assistance programs present risks where program is owned by pharmacy or pharmaceutical company has an interest.
- Specialty drugs (e.g. biologics, cancer medications, HIV medications) are more expensive, therefore having higher reimbursement opportunity but also carry higher risk and likelihood for audit.
- Many of the pharmacy-related Corporate Integrity Agreements reached with the OIG involve specialty pharmacies and improper relationships, disallowed incentives, inadequate records and excessive billing to government payors.



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12

12

Promoting Compliance and Fostering Partnerships

- Publicizing applicable requirements and how to operationalize to chainwide and to centralized audiences is a key facet of driving compliance with applicable written standards.
- Regular, consistent engagement with employees at all levels of operations functions to broaden awareness and obtain the “buy in” from the business that is essential for an effective program.
- Flexible, adaptable and broadly disseminated reference materials and continually improving training modules are highly useful in helping team members handle issues in real-time.

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Pharmacy Compliance Focus Areas	Days of Supply	<ul style="list-style-type: none"> Insulin Pens: Include the priming units per dose as directed in the Insulin Storage Chart. Insulin Vials: To calculate DOS, use the total number of units and divide by the total daily dose. *Must add contain 100 units/ml (U-100) Eye and Ear Drops: IC+ should automatically calculate the correct DOS. Always follow the manufacturer/inuse (opened) guidelines in calculating DOS. Most solutions/suspensions have a dosage delivery system of 20 drops/mL. Use as Directed: Use as Directed (TDD) must never be used as standalone directions. Accurate directions must be provided to ensure patients take/use their medication properly. Anesthetics: prescriptions with any clarification(s) obtained from prescriber, patient, and/or insurance. 	Additional Resources Days of Supply Job Aid Insulin Storage Chart Unit of Use Job Aid Hardcopy Data Entry sRx Data Entry Proof of Delivery Job Aid WebSDL Reference Guide
	Proof of Delivery (or Patient Counseling)	<ul style="list-style-type: none"> Immediately scan the signed Proof of Delivery (POD) or Proof of Patient Counseling (PPC) disclaimer into Signature Scan application in IC+ by clicking on Application → Scan Signature. If Signature Scan status is "Unable to read barcode," Re-use scan image into patient profile. Then scan the Patient Images in addition to attempting troubleshooting steps and open a ticket: Support → Fix → Service Desk → Pharmacy → Issues → Script Problems → Other Script Problems → Proof Of Delivery Images Not Saving When Scanned. Run Proof of Delivery Report twice per week using this File Path: Support → 3rd Party → Third Party Reference → Electronic Signatures → Audit Request Form. Delivery button on register must only be used for delivery/mail/bedside delivery prescriber(s). 	
	IC+ Billing Tips	<ul style="list-style-type: none"> Pay Codes: Pay Code 9 (Plan Requested Brand to be Dispensed) (DAW 9) must be used when the Plan requires brand or list of available generic product. If insurance rejects when submitting Per Code 9, then use Pay Code 2 (Subst Allowed-Pr Request Drop Dispensed) and immediate prescription status insurance requires brand name. Co-Pay Waiving: Medicare Part D does not allow for waiving of co-pays (except for as listed in the Medical Part D Co-pay Waiving Submittal). SDL Reverse: After using WebSDL (Submit Direct Link), if the prescription is updated in IC+ for any reason, the SDL claim will reverse automatically and the SDL must be re-done. SDL Best Practices: <ul style="list-style-type: none"> The pharmacy should never use WebSDL when the prescription is in TPR status in IC+. Ensure 9PM puts the prescription in Ready status in IC+ before billing in WebSDL. 	

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13

Operationalizing Compliance & Identifying Actionable Opportunities

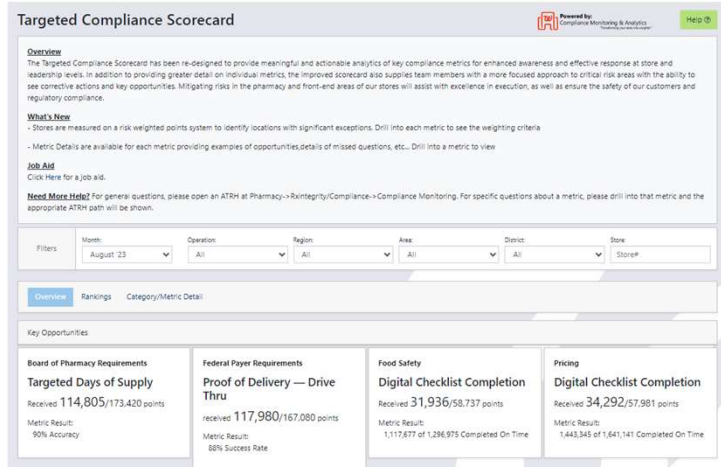
Targeted Compliance Scorecard tracks both Front End and Pharmacy metrics.

• Front End metrics:

- Food Safety
- Pricing
- Age Restricted Products
- FE Pull & Quarantine/Recalls
- Environmental Health/Safety

• Pharmacy metrics:

- Board of Pharmacy Requirements
- Federal Payer Requirements
- Inventory
- Privacy
- Specialty





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14

14

Using BOP & Payer Metrics to Help Operationalize Compliance

Category	# of Points	% of Points	Metric	Metric Result	Points
 <p>Board of Pharmacy Requirements</p> <p>State specific rules and regulation that govern the dispensing and billing of prescription products. These regulatory guidelines ensure Walgreens is in compliance with all Board of Pharmacy requirements.</p>	255,089 _{/344,930}	74.0%	Immunizations Processed as Cash	13,106 Cash Billed Rxs	28,664 _{/41,770}
			Improper use of UTD in SIG	3,425 Error(s) Found	39,291 _{/43,520}
			Overdue GCO Alerts	2,388 Overdue Alerts	-2,388
			Regulatory Inspections	210 Audit(s) with exceptions	-2,505
			Targeted Days of Supply	90% Accuracy	114,805 _{/173,420}
			VAR Scan Rate	97% Scanned In	77,222 _{/86,220}
 <p>Federal Payer Requirements</p> <p>Statutes, laws and regulations that govern the dispensing and sale of prescription products billed to Federal Healthcare Payers. These guidelines ensure Walgreens is in compliance with all requirements to be able to bill Medicare, Medicaid and all other Federal Healthcare Programs.</p>	230,122 _{/293,563}	78.4%	Insulin Pump Billing Accuracy	8,865 of 10,276 Billed Correctly	15,980 _{/22,035}
			Invalid waiving of Co-Pay (Medicare Part D)	5,752 Error(s) Found	35,804 _{/43,520}
			Proof of Delivery — Drive Thru	87% Success Rate	117,980 _{/167,080}
			Training	99% Training Completion	60,358 _{/60,928}



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15

15

Measuring Compliance in Inventory Control, Protecting Patient Privacy & Specialty Pharmacy Standards

Category	# of Points	% of Points	Metric	Metric Result	Points
 <p>Inventory</p> <p>This metric ensures pharmacies are maintaining inventory policies and procedures to support inventory control, patient safety, and pharmacy regulatory requirements.</p>	90,694 _{/174,120}	52.1%	Assembly 2D Scan Rate	42% 2D Scan Rate	14,246 _{/87,130}
			Delete Aged Rx Rate	96% Successfully Resolved	34,448 _{/43,470}
			Expired Product Return	8,400 Return(s) Completed	42,000 _{/43,520} ↓
 <p>Privacy</p> <p>Walgreens has an obligation to protect the privacy and security of its patients' information. Therefore, Walgreens has policies, procedures, and training in place that outline safeguards that must be followed to prevent impermissible use or disclosure of patient information.</p>	60,804 _{/60,928}	99.8%	Quarterly Compliance Walk	No Walks	
			Training	99% Training Completion	60,804 _{/60,928}
 <p>Specialty</p> <p>Providing the highest quality care is of utmost importance when serving our specialty patients. In order to ensure our team members, provide this level of clinical oversight, as well as ensure we stay compliant to regulatory and accreditation standards, the following audits have been created. The results of these audits will help to uncover opportunities and ensure consistency across community-based specialty locations</p>	8,285 _{/8,990}	92.2%	Compliance Audits	277 of 300 Audit(s) Passed	2,770 _{/3,000}
			Monthly Accreditation	283 of 300 Audit(s) Passed	2,830 _{/3,000} ↓
			Patient Management Audits	537 of 598 Audit(s) Passed	2,685 _{/2,990}






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Compliance Alerts: Flagging & Correcting Non-Compliance

-  Compliance Alerts flag the following Compliance Risks chainwide, including, but not limited to Days Supply, Claim Processing Procedures and Pay Codes.
-  Compliance Alerts have also been used to drive improvements in metrics such as Proof of Delivery, Manufacturer Savings Cards and COVID-19 billing.
-  Compliance Alerts are flexible and easy to tailor/develop and help correct the issue and coach around the requirement.

Click here for a job Aid specific to this type of audit

Alert Information

Store#: 1342
 Audit Date: 08/18/2023
 Due Date: 08/21/2023
 Reference ID: 5100056-8818-4410-8300-85377964299
 Audit Description: Days Supply Discrepancy
 Status: New
 Requirements: All prescriptions billed to a third party must comply with an accurate Days of Supply (DOS) in order to satisfy various pharmacy regulatory requirements. In addition to third party requirements, patient safety obligations and at times to ensure customer service satisfaction.

Image

Orig. Date: 09/18/2023
 Patient Name: [REDACTED]
 Patient Phone: [REDACTED]
 Date of birth: [REDACTED]

TOUJEO SOLOSTAR 300U/ML PEN 1.5ML
 INJECT 35 UNITS UNDER THE SKIN DAILY.

Qty: 4.500 Orig Refills: 0
 Substitution Allowed
 Drug Class: PC

MARK LIST, PER
 DEA #: FL3479842
 6215 S CLIFF AVE
 SIOUX FALLS, SD 571088596

Script Information

Rx #: [REDACTED]
 Patient Name: [REDACTED]
 Drug name: TOUJEO SOLOSTAR 300U/ML PEN 1.5ML
 Rx Sig: INJECT 35 UNITS UNDER THE SKIN QD
 Submitted Qty / Days Supply: 4 for 34 days

Correct Calculation

$34.500 \times 300.0 \text{ UNITS} = 10350.0 \text{ total units} / (35.00 \text{ units} \times 1 \text{ times per day}) = 295.71 \text{ total units per day} = 35 \text{ Days Supply}$

Annotations

1. Has this Prescription been sold to the patient? *

Yes No

Thank you for attending!

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