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Walgreens
INTERNAL AUDIT

Internal Audit Report

Date December 12, 2014

Subject Controlled Substance Order Monitoring Process Review

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Cc R. Ashworth, K. Carr, G. Fairweather, A. Gourlay, G. Hodge, D. Nobles, D. Pinon, J. Reed, P. Zagami

Background
On June 11, 2013, Walgreens entered into a Settlement and Memorandum of Agreement (Settlement Agreement) with the Department of Justice (DOJ) and the Drug Enforcement Administration (DEA).

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Conclusion

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Redacted – Attorney Client Privileged We recommend the following enhancements be made:

- Enhancing the Controlled Substance Order Monitoring application (CSOM application) to (1) require approval for ceiling limit overrides initiated by Pharmaceutical Integrity personnel and changes made to calculation parameters (K value), and (2) place a restriction as to the number of months a store/item ceiling limit can be in effect.
- Limiting user access to critical functionality within the CSOM application and administration capabilities of the CSOM application.
- Adding a system check within the Integrated Forecast System (IFS) to verify current data is being used by the CSOM application when calculating ceiling limits.
- Performing and formally documenting user acceptance testing to ensure that the IFS is calculating the ceiling limits as intended.
- Implementing a formal process to review and analyze the bi-weekly report provided by AmerisourceBergen of rejected Walgreens controlled substance orders.
- Monitoring store compliance with the stickering and retention of controlled substance prescriptions, the signoff and maintenance of the Rx Activity Logbook or Transaction Journals, the adherence to the Good Faith Dispensing and Target Drug Good Faith Dispensing policies, and completion of annual Good Faith Dispensing training.
- Creating a formal reporting and monitoring process to ensure adherence to the Settlement

Agreement's requirements on reporting suspicious orders to the DEA and responding to DEA requests.
- Streamlining the manner in which controlled substance prescriptions data is captured for removal from the pharmacy bonus calculation.
- Updating the Stickerless Prescription and Pharmacy Record Keeping procedures to reflect the requirements set forth in the Settlement Agreement.
- Confirming with the Legal department that Walgreens is in compliance with the Settlement Agreement's requirement regarding records request training.

Management is in the process of taking action to resolve the exception(s) noted above. See Attachment A for further details.

Objective
The purpose of our review was to identify, evaluate and test the policies, procedures, and processes implemented (operational / IT), as it pertains to retail pharmacies, as a result of the Settlement Agreement.

Scope

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Positive Findings
During the audit, we noted that, **Redacted – Attorney Client Privileged**
- A department of Pharmaceutical Integrity was established and staffed with personnel possessing pharmacy related training and management trained in diversion related issues.
- A robust system (CSOM application) exists that performs order tolerance and ceiling limit checks to help ensure stores are unable to acquire controlled substance or PSE merchandise in quantities that exceed expected quantities for their peer group.
- A CSOM application dashboard has been implemented and is being used by Pharmaceutical Integrity to centrally monitor controlled substance and PSE order activity, and if needed, take action to adjust store/item ceiling limits based on changing conditions.
- CSOS has been rolled out to the retail pharmacies.

- A dedicated email address has been established for which the DEA is able to submit requests for dispensing logs and PSE data, and encryption is used when emailing requested data back to the DEA.
- A formal process exists to help ensure controlled substance prescriptions are being excluded from applicable pharmacy bonus calculations.

The audit also found opportunities for improving controls. Findings, detailed recommendations along with Management responses are included in Attachment A.

We would like to thank Management for their assistance and cooperation during our review.

Attachment A

A. Controlled Substance Order Monitoring System

Background

Redacted – Attorney Client Privileged

Redacted – Attorney Client Privileged Orders of interest are reviewed by Rx Integrity, and if determined to be suspicious, are reported to the DEA.

To prevent stores from placing controlled substance and PSE orders that may be deemed suspicious, a "Tolerance Limit" and "Ceiling Limit" check is performed within Store SIMS. During these checks, orders are evaluated to determine if they should be flagged as "orders of interest" and reported to Rx Integrity via the Controlled Substance Ordering KPI application (CSOM application).

The CSOM application is used by Rx Integrity for many purposes, including but not limited to: (1) reviewing and addressing controlled substance & PSE "orders of interest", as identified by Store SIMS, (2) receiving and reviewing ceiling limit change requests made by field level management (i.e. district, store), (3) processing ceiling limit overrides and (4) making changes to factors used in calculating ceiling limits for the stores. To control the actions users can perform within the application, the CSOM application uses Authenticator to manage user access.

Tolerance Limit Check

The tolerance limit check is used to prevent stores from ordering their total allotment of a controlled substance or PSE item in one order. Should the store try and modify the quantity of an item ordered to exceed the tolerance limit, the quantity ordered for that particular item is systematically reduced to zero and is flagged as an "order of interest" to be reported to Rx Integrity for review.

Ceiling Limit Check

The purpose of the ceiling limit check is to address the risk of stores filling controlled substance and PSE prescriptions that would be considered excessive for the store when compared against their peer group. Data inputs received each week by the Integrated Forecasting System (IFS) to calculate the ceiling limits include the stores weekly Rx script count, weekly Rx sales, and Walgreens distribution center / ABC billings (controlled substance and PSE). Once calculated, the IFS will transmit the ceiling limits to the stores (Store SIMS).

Should the store attempt to modify the quantity of an item ordered to exceed the "quantity available" (ceiling limit – 6 weeks of accumulated receipts) , the quantity ordered for that particular item is systematically reduced to zero and is flagged as an "order of interest" to be reported to Rx Integrity for review.

Attachment A

Issues Related to the Controlled Substance Order Monitoring System

1. Ceiling Limit Parameter & Override Modifications

(1) While ceiling limit parameter modifications (e.g., K value changes) made by Rx Integrity personnel are required to be approved by the Senior Director of Pharmaceutical Integrity prior to being entered into the CSOM application, system approvals do not exist nor is a subsequent review performed to ensure that the change made was approved and entered accurately.

(2) In order to address changes to a store's external environment (e.g., a new hospital opens nearby, a competitor pharmacy in the area closes, etc.), Rx Integrity personnel have the ability to process a store/item ceiling limit override in the CSOM application. Store/item ceiling limit overrides initiated by Pharmaceutical Integrity personnel do not require pre-authorization by field level management (i.e. district, store) or a secondary approval by Pharmaceutical Integrity management. In addition, no subsequent review is performed after a change has been made to ensure the accuracy and integrity of the change.

Note: Ceiling limit override requests initiated by the stores via the CSOM application require system approval by field management prior to the request being passed to the Pharmaceutical Integrity department for review and approval.

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Recommendations

1. Rx Integrity should submit a change request to Applications Development – Business Services & Solutions to enhance the CSOM application to require a system-based secondary (one-over-one) approval prior to implementing any K value changes.

2. Rx Integrity should submit a change request to Applications Development – Business Services & Solutions to require a secondary (one-over-one) approval for ceiling limit changes exceeding certain thresholds (e.g., exceed 50% of the current value) and/or that are created with an expiration date greater than a predefined number of days (e.g., 90 days).

Until such programming changes are made, Rx Integrity management should generate and review reporting of all ceiling limit parameter changes and store/item ceiling limit overrides.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance

Rx Integrity will put together business requirements and a request to have the work completed by updating the system to a more automated process. Once prepared, the business case will be presented to the respective Executive Investment Council for spend approval. If approved, it will then be provided to the respective IT hub to determine whether the work will be performed based on capacity. If capacity exists it will then be prioritized against other work. Note: Legal / regulatory enhancements are given high prioritization.

In the meantime, Rx Integrity will create reporting of selected ceiling limit changes that the Rx Integrity Managers will review monthly. Report would be combined with the data elements required of #2 below to include both into one report "Ceiling Limit Parameter & Override Modifications" and "Ceiling Limit Override Expiration Date"

The fields would be:

- Store Number
- Item – Drug and Strength
- Previous Ceiling/Allocation
- New Ceiling/Allocation
- % Change in Allocation
- Current Total 6 Week Received Quantity (Including Open Orders)
- Override Date
- Expiration Date
- Override Duration

The report will be sent out monthly to the Rx Integrity managers for all orders that exceed predetermined thresholds. (Overrides for longer than 90 days to satisfy the "Ceiling Limit Override Expiration Date" piece, and overrides that increase ceiling more than 50% for the "Ceiling Limit Parameter & Override Modifications" piece)

Estimated Completion Dates
Report can be created by 3/31/2015

Creation of a business case with determination on funding approval and if applicable, IT timing determination for completion of work by 8/31/2015.

2. Ceiling Limit Override Expiration Date
The expiration date a user can enter into the CSOM application for a store/item ceiling limit override can be set to any time duration. Internal Audit (IA) observed that a user was able to enter a ceiling limit change on 11/13/14 with an expiration date of 11/13/18.

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Recommendation
Rx Integrity should submit a change request to Applications Development – Business Services & Solutions to program into the CSOM application a maximum time period that can be assigned to a ceiling limit override.

Until such programming changes are made, Rx Integrity management should generate and review reporting of the expiration dates entered for all ceiling limit overrides for appropriateness.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance
See response for issue A.1

Estimated Completion Date
See response for issue A.1

Attachment A

3. Access to Process Ceiling Limit Overrides

The Authenticator group CSOrderingKPIUser was intended to allow users view-only access to the CSOM application. During IA's review of this group, it was identified that users assigned to this group have the ability to process store/item ceiling limit overrides. At the time of our review, users with this access included individuals from the Asset Protection, IT, Rx Inventory, and Rx Purchasing departments.

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Recommendations

1. Rx Integrity should review those users assigned to the CSOrderingKPIUser group to ensure their access is appropriate based on job responsibility. For any users where current access is not appropriate, remove those users from the CSOrderingKPIUser Authenticator group until a view only Authenticator group is created (see recommendation (b) directly below).

2. Rx Integrity should submit a change request to Applications Development – Business Services & Solutions to create an Authenticator group allowing view-only access to CSOM application.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance

1. All users outside of Rx Integrity have been removed from the CSOrderingKPIUser group. Steven Mills, Sr BA Rx Integrity and Tasha Polster, Sr Dir Rx Integrity are the two team members that have access to add and remove users. Only users that are members of Rx Integrity team will be allowed access. The group will be updated with the hiring or moving of team members outside of the Rx Integrity group.

2. Requirements have been given to the Applications Development group who has requested additional funding. To create a new level of authorization – read-only – the estimate is $18,000. Due to the removal of individuals from the CSOrderingKPIUser group noted above and that various authenticator groups that have been established for the CSOM tool which provides for specific access based on employee roles and responsibilities, the view only access will not be requested.

Estimated Completion Dates

1. Removing users outside Rx Integrity – completed 2/12/2015

2. Application work - N/A

4. Access to Modify Ceiling Limit Parameters (i.e. K Values)

Users assigned to the Authenticator group CSOrderingKPICeilingAdmin have the ability to change the ceiling limit parameters (i.e., K values) through the CSOM application. In reviewing the users assigned to this group, IA noted that 12 of the 22 users should not have been assigned to this group as they do not work in Rx Integrity. This included individuals from IT, Rx Inventory and Asset Protection departments.

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Attachment A

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Recommendation
Rx Integrity Management should review the users assigned to Authenticator group CSOrderingKPICeilingAdmin, and remove those users that do not require such access.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance
All users outside of Rx Integrity have been removed from the Authenticator group CSOrderingKPICeilingAdmin on 2/12/2015. Steven Mills, Sr BA Rx Integrity and Tasha Polster, Sr Dir Rx Integrity are the two team members that have access to add and remove users. Only users that are members of Rx Integrity team will be allowed access. The group will be updated with the hiring or moving of team members from the team.

Estimated Completion Date
Completed 2/12/2015

5. Access to all CSOM application Functionality
Users assigned to the Authenticator group CSOrderingKPISuperUser are granted access to all functionality within the CSOM application. This includes access to process store/item ceiling limit overrides, modify ceiling limit parameters (i.e., K value), perform tasks designated as the responsibility of field level management (i.e. district, store), etc. In reviewing the users assigned to this group, IA identified several users outside of Rx Integrity that were assigned to this group including individuals from IT, Asset Protection and Rx Inventory departments.

Redacted – Attorney Client Privileged

Recommendation
Rx Integrity management should remove all users from the CSOrderingKPISuperUser group and assign the users to the specific Authenticator groups that provide the functionality they need based on their job responsibilities.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance
All users outside of Rx Integrity have been removed from the Authenticator group CSOrderingKPISuperUser on 2/12/2015. Steven Mills, Sr BA Rx Integrity and Tasha Polster, Sr Dir Rx Integrity are the two team members that have access to add and remove users.

Estimated Completion Date
Completed 2/12/2015

Attachment A

6. Administration of User Access

As the business owner of the CSOM application, only Rx Integrity management should be granting user access to certain groups for this application. In reviewing those individuals that have been granted administrative rights to add users to the Authenticator group's CSOrderingKPISuperUser and CSOrderingKPICeilingAdmin (see background section of issues 6 & 7 for information regarding these groups), IA noted there were two individuals(One from Asset Protection and one from Rx Inventory) that had been assigned administrative rights.

Redacted – Attorney Client Privileged

Recommendation

Rx Integrity management should review user listings of those that have been granted administrative access to key Authenticator groups of the CSOM application and update accordingly.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance

Only Rx Integrity management has administrative access to key Authenticator groups of the CSOM application.

Estimated Completion Date

Completed 2/12/2015

7. Rx Script Count File Validation

No validation is performed to ensure that the weekly store Rx Script Count file has been received by the IFS prior to calculating the ceiling limit. In the event the new weekly file is not received, the job to calculate the ceiling limits will not fail, but rather the old data (the last successful feed) will be used to calculate the ceiling limit.

Redacted – Attorney Client Privileged

Recommendation

A file validation check should be performed by the IFS to verify the date of the Rx script count file prior to calculating the weekly ceiling limits. If the file is not current, the job should fail and IT support should be notified.

In order for this change to be made, Pharmaceutical Integrity (business owner of the Controlled Substance Order Monitoring process) should initiate the process by submitting a request, with business requirements and prioritization, to IT Business Services & Solutions.

Attachment A

Management's Response –Joe Conlon, Director Business Services & Solutions
The team will look into a file delivery check and subsequent notification. The team will work with Rx Integrity team on requirements and determine funding. Based on whether the funding is approved by the requisite Executive Investment Council it will then go to the respective IT hub for a determination of when the work can be completed.

Estimated Completion Date
Creation of a business case with determination on funding approval and if applicable, IT timing for completion of work by 6/30/2015.

8. Ceiling Limit Calculation
During our review of the controlled substance monitoring process, IA noted that the Walgreens employee involved in defining the methodology, and creating the formulas used in calculating the ceiling limits, had a Ph.D. from the Illinois Institute of Technology in Management Science and was versed in Management and Computer Science with strengths in Statistics and Forecasting. In addition, it appears that User Acceptance testing was performed to verify that the ceiling limits were calculated correctly.

However, IA was unable to determine if the testing performed was adequate as no formal test plans were created nor documentation maintained to support the testing performed and conclusions reached.

Redacted – Attorney Client Privileged

Recommendation
User Acceptance testing should be performed, and appropriately documented, to ensure that the ceiling limits are being calculated accurately and that the regression model is working as intended. Specifically, we recommend that Rx Integrity management either contract with a third party firm, or work with Walgreens IT and other applicable Walgreens experts (e.g., Rx Inventory, etc.), to validate that the methodology applied and calculations programmed are appropriate and functioning as intended. To facilitate an audit trail, we recommend the related test support documentation be retained in the Change Management Automation Tool (CMAT).

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance
Rx Integrity will perform a random audit on 100 stores/items to verify the ceiling limits are calculated correctly, and work with Rx Inventory and Manager, Application Development - Build Inventory and Ordering to ensure that it is documented in the CMAT system.

It should be noted that our ceiling limit model is independent of ABC's operating model. ABC does not and will not share their ceiling limit algorithm with their customers.

Estimated Completion Date
11/30/2015

Attachment A

B. Controlled Substance Orders Rejected by AmerisourceBergen (ABC)

Background
Stores submit their Rx orders, including orders for controlled substances, to ABC, Walgreens primary pharmaceutical distributor. Redacted – Attorney Client Privileged

Redacted – Attorney Client Privileged

ABC has a system in place to flag orders that exceed set thresholds, and on a bi-weekly basis, provides Walgreens with a report that details this activity on a drug family basis. *Note*: A drug family is more specific than drug class (i.e. stimulant, depressant, opiate, and hallucinogen) in that all drugs in a drug family affect the body in a similar manner through means of similar chemical structure.

Issue
A process does not exist to review and analyze the bi-weekly reporting provided by ABC to determine why drug orders are being rejected. Based on a review of reports sent by ABC from the period of 7/11/14 – 10/9/14, approximately 1,850 orders were rejected per week.

Redacted – Attorney Client Privileged

Recommendation
Implement a process to review and analyze the bi-weekly ABC report with the intent of determining why orders that are deemed acceptable by Walgreens are being rejected.

This process should also include the creation of a report for Rx Integrity management that provides insight into the number of orders being rejected by ABC, the number of orders researched by the Rx Integrity department, conclusions reached based on the research performed, and any follow-up or remediation efforts required based on the results of the analysis.

Redacted – Attorney Client Privileged

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance
A weekly Order Monitoring Program (OMP) threshold report is received from ABC as a reference when a store calls asking why they are not receiving product.

For C2 Drugs: Rx Integrity will create a daily job that runs based on information we get from EDI (the CSOS system) and which will provide notification that a store will not receive an ordered drug as it hit ABC's OMP threshold. Rx Integrity will then determine whether this drug from that store has hit ABC's OMP threshold for the third time. Note: ABC will not consider any increase for a drug for a store until it has hit their OMP

threshold three times. If it has hit the threshold for a third time, Rx Integrity will provide an in depth questionnaire to the store to fill out to obtain more information on the drug being ordered. Once the questionnaire is received back, Rx Integrity analysts will review the responses from the stores, in addition to looking at store specific prescriber data, sales trends, etc., to ensure a request to ABC for an increase is warranted. If we deem that a request for increase is not warranted, Rx Integrity will make adjustments within the system to prevent orders from going to ABC that may trigger their OMP threshold.

We will start with C2 drugs. Once we deem this process works this will be expanded to all C3-C5 drugs and PSE. This process will reduce the risk of future rejections by ABC due to orders potentially hitting their ceiling limits. It needs to be highlighted that ABC does not reveal their ceiling limits, and we do not know what orders that they may send to the DEA.

Estimated Completion Dates
C2 implementation - 6/30/2015, C3-C5 and PSE implementation - 12/31/2015

Attachment A

Redacted – Attorney Client Privileged

Attachment A

Recommendations

1. To provide a reasonable level of assurance that the pharmacies across the chain are complying with documentation and retention requirements for controlled substance prescriptions, a formal monitoring program should be implemented. Due to the large number of Walgreens stores, the monitoring program should be based on a sampling methodology that balances the cost of implementing such a program against the potential cost on non-compliance. In addition, the program needs to include a mechanism by which the results are aggregated and reported to applicable management who has the authority to determine and direct necessary corrective actions.

2. Until such a program is implemented, Rx Integrity management should:

    a. Review the Compliance Checklist questions to determine if any changes should be made to help ensure compliance with the DEA Settlement.

    b. Request that the Compliance department provide the results of the quarterly Compliance Checklists. Where the compliance rate is not 100% for those questions pertaining to the Settlement Agreement, a process should be implemented to follow-up with applicable stores to understand the cause of non-compliance and remediate accordingly.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance

1. Rx Integrity management will meet with Asset Protection Solutions (APS) group management (Tim Gorman) to determine whether loss prevention personnel in the field can be utilized in performing audit activities on a sample basis and then reporting those results to Rx Integrity for review and follow-up. In the event that APS is unable to facilitate our independent monitoring request, we will hold discussions with the Chief Compliance Officer and the President, Pharmacy and Retail Operations to determine what type of independent monitoring can be put in place until it is determined if the new Store Walk program under development is implemented and can be utilized as an effective monitoring control (see note below on Store Walk Program).

2. Rx Integrity will also ensure that the questions on the Compliance Checklist are in compliance with the controlled substance stickering and prescription logbook requirements in the Settlement Agreement and request. The Compliance department to provide results to Rx Integrity for follow-up.

Note: Rx Integrity is currently working with Store Operations to incorporate checks on the Store Walks in addition to the Compliance Audit. The Store Walk is to create an alert when a store is not in compliance for the District Manager to follow up on.

Estimated Completion Dates

1. Discussions held with decisions made on an independent monitoring program by – 4/30/2015.

2. Compliance checklists updated and a process implemented for receipt of information by – 5/31/2015

Attachment A

D. Target Drug Good Faith Dispensing Policy

Background
Walgreens has implemented a Target Drug Good Faith Dispensing policy for the Pharmacists to follow and a Target Drug Good Faith Dispensing checklist for the Pharmacists to complete when certain controlled substance prescriptions (i.e. oxycodone, hydromorphone, methadone, and other district-specific controlled substances) are dispensed. The Target Drug Good Faith Dispensing checklist was created to aid Pharmacists in determining whether a prescription for certain drugs have been written for a legitimate medical purpose.

Issue
Based on discussions with Store Operations management, District Managers (DMs) and Pharmacy Supervisors (RxS) are expected to perform store walks of each store in their district approximately every 30-45 days. While specific questions are asked during these store walks pertaining to the Target Drug Good Faith Dispensing policy, no corporate reporting is generated to summarize the results from the visits as the walks were not established as an audit reporting vehicle.

Based on discussions held with the Compliance and Pharmacy Services departments, there is no monitoring performed outside of the Store Walk program to determine whether Pharmacists across the chain are adhering to the requirements set forth by the Target Drug Good Faith Dispensing policy.

Redacted – Attorney Client Privileged

Recommendations
A monitoring program, and related procedures, should be created to provide an adequate level of assurance that Pharmacists across the chain are adhering to the requirements set forth in the Target Drug Good Faith Dispensing policy.

Possible options to facilitate compliance monitoring include:

1. Work with Community Management leadership to leverage the existing Store Walk program in place and build a formal reporting mechanism whereby the results of those walks are provided to applicable management. As part of the monitoring program, roles and responsibilities should be defined within the Pharmacy Services as to who will monitor the store walk results.

2. Work with Compliance department leadership to (1) enhance the Compliance Checklist to include specific questions pertaining to adherence with the Target Drug Good Faith Dispensing policy and the Target Drug Good Faith Dispensing checklist and (2) for the Compliance department to provide those results to applicable management. As part of the monitoring program, roles, and responsibilities should be defined within Pharmacy Services as to who will monitor the Compliance Checklist results for issues.

3. Implement an independent monitoring program within Pharmacy Services to perform periodic reviews, on a sample basis, to identify and remediate non-compliance.

Attachment A

Management's Response – Rex Swords, Vice President, Pharmacy/Retail Operations and Planning

1. As noted within the management response for Finding C, Rx Integrity management will meet with Asset Protection Solutions (APS) group management (Tim Gorman) to determine whether loss prevention personnel in the field could be utilized in performing audit activities on a sample basis in the stores and then reporting those results to Rx Integrity for review. In the event that APS is unable to facilitate our independent monitoring request, we will hold discussions with the Chief Compliance Officer and the President, Pharmacy and Retail Operations to determine what type of independent monitoring can be put in place until it is determined that the new Store Walk program under development is implemented and can be utilized as an effective monitoring control (see note below on Store Walk Program).

2. Rx Integrity will work with Compliance Department leadership to (1) enhance the Compliance Checklist to include specific questions pertaining to adherence with the Target Drug Good Faith Dispensing policy and the Target Drug Good Faith Dispensing checklist and (2) for the Compliance Department to provide those results to Rx Integrity for follow-up.

Note: Rx Integrity is currently working with Store Operations to incorporate checks on the Store Walks in addition to the Compliance Audit. The Store Walk is to create an alert when a store is not in compliance for the District Manager to follow up on.

Estimated Completion Dates

1. Discussions held with decisions made on an independent monitoring program by – 4/30/15.

2. Compliance checklists updated and a process implemented for receipt of information by – 5/31/15

Attachment A

E. Monitoring of Good Faith Dispensing Training Completion

Background

Redacted – Attorney Client Privileged

Redacted – Attorney Client Privileged Walgreens has created two People Plus Learning based trainings for pharmacy personnel to take; specifically the Good Faith Dispensing Training and a separate acknowledgement of having read and understood the Good Faith Dispensing policy. Training completion can be tracked via the Key Performance Indicator (KPI) metrics available via StoreNet and it is store management's responsibility to ensure all training is taken as required.

Issue:
Based on a detailed review of the training data pertaining to 2013 and CY2014, IA identified the following:

- 2013 Training - IA noted that approximately180 active employees, at the time of our testing (September 2014), had not completed the Good Faith Dispensing training and that several thousand active employees had not completed the Good Faith Dispensing Policy Acknowledgement. The training was assigned throughout the year to a multitude of positions within the stores, including pharmacy personnel. Employees were given one month to complete the training once assigned.

- 2014 Training – IA noted, at the time of our testing (November 19th 2014), over 35,000 employees had not completed the Good Faith Dispensing training that was assigned in early October and was required to be completed by November 7th, 2014. .

Redacted – Attorney Client Privileged

Recommendation

Redacted – Attorney Client Privileged a centralized monitoring process should be implemented Redacted – Attorney Client Privileged This could be facilitated by Rx Integrity requesting a report from Walgreens Human Resources to identify employees who have not yet completed the required training and then working with Store Operations management to communicate non-compliance and reinforce the training requirement and its importance.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance
Rx Integrity team will work with LMS to get a report quarterly that shows noncompliance and then will work with the communication team to help drive execution down to store level by distributing reports down to store level of individual that have not completed the training. Rx Integrity will request reports quarterly to ensure new hire training is completed on time and will follow up through the communication team to ensure compliance.

Estimated Completion Date
3/31/2015

Attachment A

F. Reporting Suspicious PSE Orders to the DEA

Background

Redacted – Attorney Client Privileged

To facilitate compliance, the CSOM application is programmed to auto-generate an email to the stores requesting information regarding "orders of interest". The stores have two business days in which to respond. If no response is received within two days, the CSOM application will give Rx Integrity 24 hours to review and mark the order as "Response Received" (i.e. order considered non-suspicious). The following day, the CSOM application will send the orders in "Denied" status to the Rx Integrity mailbox for final review. Orders that are then deemed to be suspicious (PSE only) are then faxed electronically by Rx Integrity to the DEA.

Redacted – Attorney Client Privileged

Recommendation
A report should be created and monitored by Rx Integrity management to ensure that "orders of interest" are being evaluated and, if necessary, reported as suspicious to the DEA within required timeframes. Once a report has been created, a process should be implemented to review it on a daily basis to ensure compliance.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance

Redacted – Attorney Client Privileged

Walgreens no longer distributes controlled substances out of its distribution centers. This response is specific to PSE. To be able to effectively and efficiently monitor that Business Analysts are reviewing "orders of interest" within the required timeframes as outlined by the Settlement Agreement when stores respond to the auto-generated email, enhancements will need to be made to the CSOM tool to create a report.

Rx Integrity will put together business requirements. Once prepared, the business case will be presented to the respective Executive Investment Council for spend approval. If approved, it will then be provided to the respective IT hub to determine whether the work will be performed based on capacity and if capacity exists when it will be done based on other priorities.

Estimated Completion Date
Creation of a business case with determination on funding approval and if applicable, IT timing determination for completion of work by 6/30/2015.

Attachment A

G. Responding to DEA Requests for Controlled Substance Dispensing Logs

Background

Redacted – Attorney Client Privileged

Issue

In testing a random sample of 15 DEA requests from the period January 2014 – June 2014, IA identified that one of the requests had no evidence of information being provided to the DEA. Additionally, there were three requests for information provided to the DEA beyond the two day business requirement (responses were provided 6, 11, and 34 days after the request date).

Redacted – Attorney Client Privileged

Recommendation

At the time of our audit testing procedures (June 2014), Rx Integrity had just implemented a process, which utilizes an Access Database, to manage DEA requests. The process implemented requires each DEA request, upon receipt, to be logged into the Access Database and assigned to an Rx Integrity Business Analyst. The Access Database is used to maintain all relevant information (e.g. status of request, assigned date of completion, etc.) regarding the request.

As an enhancement to this process, Internal Audit recommends:

1. Due to the short timeframe in which DEA requests are to be generally responded to (two days), a daily report should be generated from the information contained within the Access Database of all outstanding DEA requests. This report should be used by Rx Integrity management to monitor for any potential issues in fulfilling requests in accordance with the Settlement Agreement.

2. Rx Integrity should ensure a mechanism exists to evidence that all DEA requests were responded to, along with the date of the response.

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance

1. Rx Integrity will look into developing an automated report to show if dates are missed. Depending on the cost of implementing the automated report, funding approval and IT assistance required, the report will then be implemented or if not, the weekly report referenced below will be continued to be used.

2. In the meantime, a weekly report is being generated for Rx Integrity Managers to review. The Rx Integrity analysts are in the system daily and log dates due for all requests that come in. As a best practice, the analysts communicate with the agents upon receipt of each request. This report will be updated to not only include the date the request was received but also include the date the DEA was responded to and how (e.g., fax, email, etc).

Estimated Completion Dates

1. Decision on automated report being approved for implementation by 6/30/2015

2. Report enhancement by 3/31/2015

Attachment A

H. Pharmacy Manager Bonus Calculation

Background
Per the requirements of the Settlement Agreement, "Beginning in 2014, Walgreens will exclude any accounting for controlled substance prescriptions dispensed by a particular pharmacy from bonus computations for Pharmacists and Pharmacy Technicians at that pharmacy". *Note*: Based on the bonus metrics in place for FY14, this requirement only had an impact on Pharmacy Manager bonus calculations.

One of the metrics used in calculating the Pharmacy Manager bonus that includes controlled substances is the "Average 90-day Adjusted Scripts" metric. In order to remove controlled substance script fills from the "Average 90-day Adjusted Script" metric, the following occurs:

- On a daily basis, Rx prescription information is extracted from the Enterprise Data Warehouse (EDW) and transmitted to the Pharmacy Strategic Analytics Server, housed at the Central Processing Office in Orlando.
- On a monthly basis, the Results department runs a query against the Pharmacy Strategic Analytics server to create an Excel spreadsheet summary, by store, of the total controlled substance prescriptions sold during the month.
- The monthly data is combined with the previous month's data in order to create a fiscal year-to-date total. After fiscal year-end, when the bonuses are calculated, the total controlled substance prescription total is subtracted from the "Average 90-day Adjusted Script" metric.

Issue
To determine if all controlled substance prescriptions are being captured by the Results department and properly extracted from the "Average 90-day Adjusted Script" metric, IA independently obtained controlled substance prescription information from the EDW and compared it to the data contained in the bonus system. Specifically, IA reconciled the total number of controlled substance prescriptions filled for the first three quarters of fiscal year 2014 (September 1, 2013 – May 31, 2014), per EDW, against the data contained in the Results department bonus system. Based on that reconciliation, approximately 1,700 controlled substance prescriptions (.002% of total controlled substances prescriptions filled) were not captured by the Results department and therefore not excluded from the "Average 90-day Adjusted Scripts" bonus metric.

Redacted – Attorney Client Privileged

Recommendation
The query used to extract the total controlled substance prescription data should be moved from the Strategic Analytics server to the EDW production environment. In doing so, this will ensure that the data used by the query is complete and secure, the queries used are subject to the IT change management process, and the extract query will consider any changes are made to the EDW.

Attachment A

Management's Response – Kyle Nelsen, Director Results
We will explore the ability to get a regularly scheduled monthly feed directly from EDW in the same format we currently receive. If we determine that EDW can feasibly provide the requested data and a sample file has been provided to verify the information provided will facilitate the bonus calculation process, Results will work with EDW to move the query from the Strategic Analytics server to the EDW production environment.

Estimated Completion Date
Determination of feasibility by 5/31/2015. If it is determined that the information can be provided as needed, the query will be moved to the EDW production environment prior to 8/31/2015

Attachment A

I. Stickerless Prescription Procedure on StoreNet

Background
Prior to the Settlement Agreement, Walgreens affixed a sticker, auto-generated from Intercom Plus, on CIII-CV controlled substance paper prescriptions in certain states based on state law. This sticker contains: (1) a serial number unique to each prescription; (2) the prescriber's name, address, telephone number, and DEA registration number; (3) the patient's name, address, and telephone number; (4) the prescription issue date; (5) the drug and quantity dispensed; and (6) the fill date.

Per the Settlement Agreement, "Walgreens pharmacies are to affix such a sticker to all paper controlled substance prescriptions in each state, regardless of the requirements of state law" and "Walgreens will maintain a paper file of such prescriptions organized chronologically by fill date." To notify the store locations affected by the new requirement, Pharmacy Services sent out a COMPASS communication in June of 2013 entitled "Change in Stickerless Procedures".

Issues
1. The Stickerless Prescriptions procedure, located on StoreNet, does not reflect the fact that all stores are required to follow this procedure regardless of state requirements. Instead, the procedure requires "All CIII-CV prescriptions will be stickered, filed, and handled according to state requirements".

2. In reviewing the COMPASS communication and responses from each store location, IA identified that two retail store locations have pharmacies (stores 1403 and 9409) which selected the "not applicable" option within the COMPASS application. Although this communication, and its associated requirements were applicable to their location, no follow-up was performed to determine why the two stores responded to the COMPASS communication as "not applicable".

Redacted – Attorney Client Privileged

Recommendations
1. The Stickerless Prescriptions procedure should be updated to clearly state that all CIII-CV prescriptions are to be stickered regardless of state requirements and filed and organized chronologically by fill date. In addition, we recommend the Director of Pharmacy Affairs perform a review to ensure no other policies that currently exist on StoreNet reference language that conflicts with the controlled substance stickering requirements set forth in the Settlement Agreement.

2. Pharmacy Services should follow-up with the two store locations to determine why they responded to the COMPASS communication as "not applicable".

Management's Response – Al Carter, Director Professional Affairs Central Pharmacy Operations
1. **Redacted – Attorney Client Privileged**

2. Follow-up occurred with both stores to confirm that the stores were in fact stickering all CIII-CV prescriptions. The stores both indicated that they were in fact stickering all required prescriptions.

Estimated Completion Dates

1. N/A

2. Complete

Attachment A

J. Rx Activity Log Book Procedures

Background
Per the Settlement Agreement, Walgreens pharmacies are required, for prescription refills, to follow the procedures outlined in the C.F.R. The Code requires there is documentation to support that refill information for a Schedule III or IV controlled substances was entered into the system accurately. In order to attest to this, each Pharmacist that was involved in the dispensing process for the refill is required to sign (full signature) the Rx Activity Logbook within 72 hours of the their shift.

Issue
While the Pharmacy Record Keeping policy on StoreNet specifies that each dispensing Pharmacist is to sign and date the Rx Activity Log Book, that procedure does not specifically mention certain requirements (e.g., format of signature, timeframe within which the review and attestation is to occur) Walgreens must adhere to with respect to the Settlement Agreement..

Redacted – Attorney Client Privileged

Recommendation
Update the Pharmacy Record Keeping procedure on StoreNet Redacted – Attorney Client Privileged

Redacted – Attorney Client Privileged

Management's Response – Al Carter, Director Professional Affairs Central Pharmacy Operations
The Pharmacy Record Keeping procedure will be updated as recommended and the change will be communicated to the stores in the March "News You Can Use" newsletter.

Estimated Completion Date
3/31/2015

Attachment A

K. DEA Records Request Training

Background
On occasion, the DEA will request the stores to provide certain records in order to aid their investigations. Per the Settlement Agreement, Pharmacists are to receive training that includes instructions on how to assist the DEA in obtaining records (e.g., copies of prescription hard copies).

Issue
While information does exist on the Rx Integrity department website instructing Pharmacy personnel on what to do in the event pharmacy records are requested by a DEA agent (i.e., DEA Visit Guidelines "Do's and Don'ts, DEA Prescription Request Records links), specific training has not been provided to Pharmacists detailing their responsibilities, and the associated procedures, for assisting the DEA in obtaining records.

Redacted – Attorney Client Privileged

Management's Response – Tasha Polster, Senior Director Pharmaceutical Integrity & Pharmacovigilance

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SNet → Rx Ops → Rx Integrity → DEA Inspection Resources → Request for Prescription Records Guide

Estimated Completion Date
Completed 2/20/2015

Every day I help people **get, stay and live well.**