

**PART D:
Compliance Considerations**

“What we wish we knew 4 years ago!”

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Objectives

- **Review Corrective Action Plans for Part D and potential risks for us.**
- **Evaluate performance and share best practices for the PBM and internal operations.**
- **Discuss the integration of Medicare Advantage Part C and Part D Compliance Program Requirements.**
- **Discuss how to structure Part D Fraud, Waste, and Abuse Requirements & Reporting.**

Corrective Action Plans – What Can We Learn?

- Plan has a Compliance Plan as required but the Plan “is not adhering to the provisions found in the Plan.”
- Plan does not have “procedures in place designed to detect, correct, and prevent FWA.”
- CAP submitted by Plan and accepted by CMS. However, Plan “failed to fulfill its obligation under the CAP regarding formulary review process.”
- Notice in Network Pharmacies instructing enrollees to contact their plan to obtain a coverage determination or request an exception was not displayed.

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CAP... What can we learn?

- Internet Website must meet CMS guidelines regarding a current formulary that is updated a least monthly for Part D.
- Drug Utilization Management (DUM) narrative was not in associated P&Ps and description was not sufficient.
- Timely Notification Coverage Determinations and Case Files to IRE.

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CAP... What can we learn?

- **Being able to verify submission of prescription drug event (PDE) data for Part D payment reconciliation.**
- **P&Ps must state PDE data must be submitted to CMS by May 31 following end of a coverage year in order to be processed for payment reconciliation.**
- **Provide proper notice and timeliness of notifying LIS enrollees.**
- **Provide LIS Rider and EOC timely to LIS enrollees.**

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CAP... What can we learn?

- **Maintain accurate tracking in a log a member's LIS eligibility.**
- **Maintain accurate tracking in a log of members who are auto- or facilitated enrolled.**
- **Fail to successfully exceed a 95% LIS match rate.**
- **Assure the LIS requirements are documented in P&Ps.**
- **Develop and implement internal controls (including audits) to ensure compliance.**

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CAP... What can we learn?

- **Assure a system is in place to communicate other payer information on a primary claim to the pharmacy and receive transactions used to adjust TrOOP.**
- **Train appropriate staff on TrOOP policies and procedures regarding the requirements.**
- **For a beneficiary with mid-year plan changes:**
 - **The gross covered drug spend and TrOOP balance is calculated and a notice of the TrOOP status is sent to the beneficiary.**
 - **Each month that claims are adjudicated for the beneficiary during the coverage year, the information is sent to the new plan of record.**

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Oversight - Part C and Part D

- **How are we doing? Let's examine two major areas:**
 - **Pharmacy Benefits Manager (PBM)**
 - **Internal Operations**

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Best Practices – What Works?

- **Pre – PBM Contract**
- **Don't be afraid to negotiate! Or, hire someone to do it for you.**
- **Know ahead of time who to escalate issues to if you are not happy.**
- **Be specific in your expectations and get them in the contract so that there is no misunderstanding... otherwise...There may be an extra charge!**

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Best Practices... PBM Contracts

- **What should be included?**
- **Performance Guarantees that meets, at a minimum, CMS standards for:**
 - **System Availability**
 - **Claim Response Time**
 - **Customer Service Call Center Measures**
 - **Timely and Accurate ID Cards**
 - **Timely eligibility updates, and...**
- **Provide for revocation of contract if CMS or Plan Sponsor determines that the PBM has not performed satisfactorily.**
- **Be prepared to certify data, where necessary.**

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Best Practices... Account Manager

- **The individual must:**
 - Be a seasoned Account Manager who knows Part D!
 - Meet regularly with you or your designee (Pharmacist) to manage the business
 - Be proactive and willing to advocate on your behalf
- **Ask for a new one if you are not satisfied!**

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Best Practices... Full Time Pharmacist

- **If you don't have one, get one!**
 - Must have someone to manage the day to day. It cannot be you unless you have nothing else to do and Part D is your only responsibility... (Yeah, RIGHT)!
 - Formulary compliance is on CMS' radar so it must be managed everyday.
 - Must review the key indicators to assure compliance.

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Best Practices... Reporting Expectations

	MA-PDP	Frequency
• Who does what?	Reversals	Quarterly
	Medication Therapy Management Programs	Semi-Annually
• By when?	Generic Dispensing Rate	Quarterly
	Grievances	Quarterly
• How do we assure quality?	Prior Authorization, Step Edits, and Non-Formulary Exceptions	Quarterly
	Appeals	Quarterly
	Call Center Measures	Quarterly
• And, accuracy?	Overpayments	Semi-Annually
	Rebates, Discounts, and Other Price Concessions	Quarterly
	Prescription Data Event (PDE)	Monthly
	Plan Comparison Files	PBM directly to HPMS

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Best Practices... Audits

- **First Tier, Downstream, and Related Entities**
- **Audit First Tier (PBM):**
 - On-site: Corporate, Mail Order Services
 - PBM produces records of auditing of downstream entities (pharmacies and Pharmacist)
 - Obtain evidence that “it” happens... work papers, sign-in sheet, data, etc.
- **Trust but Verify!**

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Key Indicators - Part D Dashboard

	Q1-2	Q3-4
MTM Enrollment # (%)	173 (9%)	
MTM Contacts # (%)	45 (26%)	
	Q1	Q2
Appeals #	1	0
Audited Pharmacies #	610	590
Pharmacies with Rights Notice	552 (90.5%)	540 (91.5%)
Corrections with Rights Notice	58 (9.5%)	50 (8.5%)
Call Center Beneficiary % 30 sec	81%	86%
Call Center Beneficiary % Abandon	1%	1%
Rejections due to Step Therapy #	162	180
Rejections due to Prior Auth #	230	218
Rejections due to Quantity Limits #	193	132
Prior authorization denial %	0%	2%
Non-Formulary denial %	24%	22%
Grievances #	0	0
% Standard	na	na
% Expedited	na	na
% Generic Fill Rate - HPMS	73%	72%

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Dashboard...

<i>Part D Data</i>		Jan	Feb	Mar
\$ Total Plan Cost		\$397,477.62	\$382,759.70	\$451,002.82
# Total Rx Count		6216	5885	6747
# Utilizing Members		1495	1548	1604
# Rx PMPM		4.16	3.8	4.21
\$ Plan Cost PMPM		\$265.87	\$247.26	\$281.17
% Generic Fill Rate		70.00%	70.00%	69.30%
% Formulary Compliance		95%	95%	94.8%
Call Center Reasons:	Benefits	26.7%	26.1%	25.5%
	Claims	31.7%	31.8%	32.5%
	Home Delivery	7.5%	7.8%	8.7%
	Member Eligibility	17.9%	17.8%	17.0%

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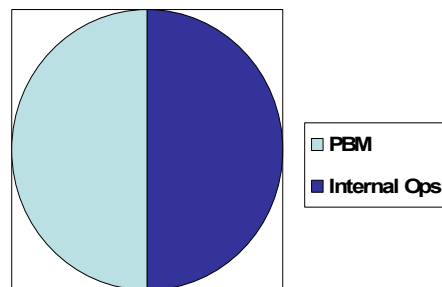
Best Practices... Rotate Measures

- **We can't measure everything all the time!**
 - Consider creating a multi-year cycle and change the indicators each periodically.
 - Always continue to measure areas with performance issues.

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It is not just about the PBM!

- **Part D Oversight – As Compliance Officers, what are you doing to provide oversight of the Plan's responsibility?**
- **Critical Success Factor = Oversight of Internal Part D Operations**



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Internal Part D Operations

- **Key Topics**
 - PDE, PDE, PDE.....
 - PDE Reconciliation
 - LIS
 - TrOOP
 - Best Available Evidence

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Devil in the Details...

- **Procedures in place for reconciliation of monthly reports (Drug Data Processing System, Cumulative Beneficiary Summary, PDE Accounting Reports, P2P files, Part D Payment Reconciliation Report) to ensure PDE data maintained by CMS and organization internal records correspond.**
- **Is your organization applying or prepared to apply correct LIS levels to enrollees referring to Weekly/Monthly Transaction Reply Report to establish correct premium, cost sharing, and deductible levels with correct effective dates for prior, current, or prospective enrollees?**

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CMS is watching... Annual Readiness Checklist

- **Annual Attestations**
 - **50% to 60% Increase in Questions 2009-2010**
 - **25% of Questions (2010) on Part D Operations**
- **Attest to compliance. If non-compliance, commit to date of compliance.**
- **Demonstrate compliance if report non-compliance.**
- **Be able to describe how meeting requirement with supporting documentation.**

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Part D Operations Infrastructure

- **What's the best infrastructure to support Part D operations effectively?**
- **Who in your organization does the day to day? What is the role of Compliance Officer?**
- **What works and does not? If you have other lines of business, is it integrated or a separate unit?**
- **Success stories?**
- **Challenges?**
- **Resource needs?**

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Part C & Part D Compliance Program Requirements

- **What components should be integrated into overall compliance program? For all lines of business?**
 - Employee Compliance Training
 - Specialized Compliance Training
 - Policies & Procedures
 - Code of Conduct
 - Internal Compliance Audit
- **Board of Directors involvement?**
- **What is your experience?**

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Fraud, Waste, and Abuse Program

- **Is Part D Fraud, Waste, and Abuse (FWA) requirements integrated into the overall Compliance Program or separate Part D FWA Program?**
- **Multiple “actors” on stage**
 - Part D Sponsor (Billing Part B vs. Part D)
 - PBM (Prescription Drug Switching)
 - Pharmacy (Prescription Drug Refill Errors)
 - Enrollees (Prescription Stockpiling)
 - Prescriber (Script Mills)
 - Wholesale (Submitting false pricing or rebate info)
- **Share best practices**

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Fraud, Waste, and Abuse Program

- **Regardless if it is integrated or separate, have your reported anything to the MEDIC?**
- **If so, great! If not, what is not working?**
Review monthly or quarterly reports:
 - **Top Members by drug cost; drug cost and controlled substances**
 - **Top Prescribers by drug cost; drug cost and controlled substances**
 - **Member/Pharmacy combinations**
 - **Provider/Pharmacy combinations**

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FWA.. Sample Reports

Top 10 Members – Highest \$\$\$ for Controlled Substances

<u>MBR ID</u>	<u>FIRST</u>	<u>MI</u>	<u>LAST</u>	<u># CLMS</u>	<u>COST</u>
821456	John	A	Doe	3	\$23,222
723457	Mary	B	Rae	17	\$18,056
173458	Pete	C	Me	10	\$16,529
423459	Regina	D	Fay	8	\$6,225
143460	Steve	E	Sow	11	\$5,311
623491	Joan	F	Lay	14	\$5,207
523662	Henry	G	Tee	9	\$5,165
223463	Sally	H	Dawn	4	\$4,821
823464	Ken	I	Sound	11	\$4,776
054237	Kathy	J	Tomas	6	\$3,986

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Summary / Questions

- **CMS has a road map! Look at the CAPS!**
- **Take control of your PBM Relationship!**
- **Develop your Performance Measures and make sure you monitor them!**
- **It's not just about the PBM! You are the Plan Sponsor!**
- **Regardless of whether the Compliance Plan is integrated or not, make sure you have all the elements!**
- **There are a lot of "actors" when you are looking at FWA. Don't forget to look at the total picture.**

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Resources

Part D Formulary Questions
partdformularies@cms.hhs.gov

Part D Benefit Questions
partdbenefits@cms.hhs.gov

Part D Manual
<http://www.cms.hhs.gov/PrescriptionDrugCovContra>

Part D Questions
Part D Account Managers

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