

PHARMACEUTICAL COMPLIANCE FORUM
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Managed Market
Considerations for HUB
and Specialty Pharmacy
Arrangements

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Agenda

- Panel Introductions
- Evaluating the Role of Compliance in Key Managed Markets Risk Areas
 - Specialty Pharmacy Arrangements
 - Co-pay Assistance (Cards and Vouchers)
 - Patient Assistance Programs
 - Reimbursement Assistance Services
 - HUB Services
- Compliance's Role with Legal on Key Issues
- Lessons and Take-aways

Panel Introductions

- Terra Buckley – Celgene Corporation
- Greg Sherman – Gilead Sciences
- Lisa Walkush – Grant Thornton LLP



True or False?

- There are no federal legal/compliance risks involving Managed Markets because it involves only dealings with private payors.
 - Key policy reasons why Managed Markets arrangements may raise risks:
 - Effect on prescribing decisions
 - Effect on federal health care program payments
 - What laws are potentially implicated?
 - Federal Anti-Kickback Statute
 - Federal Civil Money Penalty Statute
 - False Claims Act
 - HIPAA
 - State Laws



Key Managed Markets Risk Areas

- Issues that may raise legal/compliance risk:
 - Specialty Pharmacy Arrangements
 - Co-pay Assistance (Cards and Vouchers)
 - Patient Assistance Programs
 - Reimbursement Assistance Services
 - HUB Services



Specialty Pharmacy Arrangements

- Who evaluates the criteria by which specialty pharmacy solutions are determined?
- Who evaluates the selection of SPs?
- Who considers the services and compensation to be paid?
- Who monitors the performance of the SPs under the services agreement?
- What are some best practices?

Co-Pay Assistance

- Who evaluates the criteria by which patient access solutions are determined?
- Who evaluates the appropriateness of each solution?
- Who is involved in selection and contracting of third party vendors?
- Who monitors vendor performance?
- What are some best practices?

Patient Assistance Program Donations

- Who evaluates the criteria by which donations are determined and made?
- Who evaluates the selection of charity foundations?
- Who monitors the performance of the donation agreements?
- What internal resources are used?
- What are some best practices?

Reimbursement Assistance

- Who evaluates the types of reimbursement assistance provided to patients and prescribers?
- Who evaluates the conditions under which reimbursement assistance may be furnished?
- Who considers who may provide the services?
- Who monitors the performance of the services?
- What are some best practices?

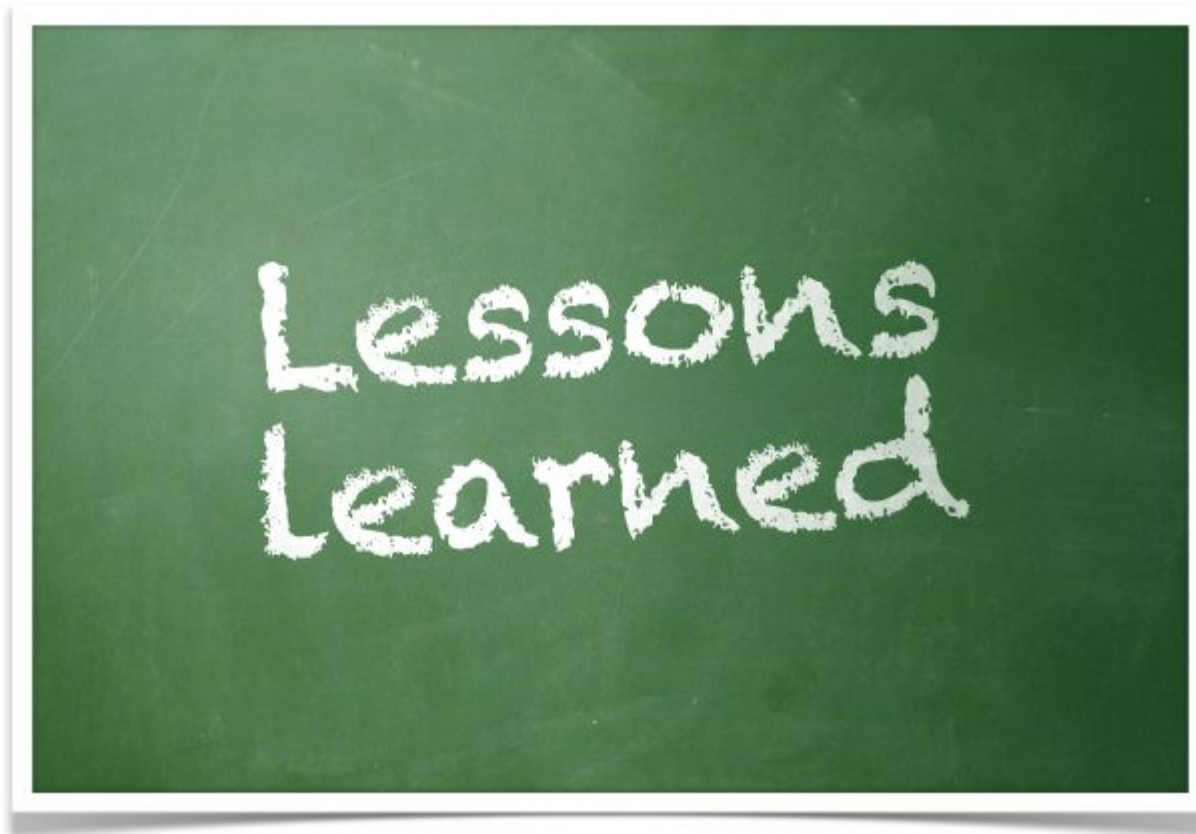
HUB Services Arrangements

- Who evaluates selection of a HUB?
- Who determines the requirements for the HUB services?
- Who considers the services and compensation to be paid?
- Who monitors the performance of the HUB under the services agreement?
- What internal resources are used?
- What are some best practices?

How do Legal and Compliance Interact?

- What are the legal/compliance factors for key risks?
- Who takes the lead on:
 - Initiation of the arrangement?
 - Contract review?
 - Monitoring?
 - Auditing?
 - Oversight of third parties?





Lessons/Considerations

- Today's Compliance Departments must expand their purview and focus
 - Look beyond HCPs and federal health care programs
 - Monitor more than just policies and transactions
 - Must seek insights into what is really going on (*i.e.*, intent)
- Monitor All Trends and Developments
 - Focus on case law, including from the pharma and provider industries
 - Lookout for new DOJ and OIG guidance
 - Take note of all new CIA terms and developments
- Use outside resources for evaluation and benchmarking

Questions?

