

Track III-A

Creating Relationships with Prescription Drug Plans and Managed Care Organizations

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Part D is for Dollars

- Follow the money by tracing the relationships Nopharm creates with Part D Plans
 - Volume discount and market share discount agreements
 - Fletch Kramer rebate to all 5 PDPs in Region 1 of any Myphan costs above “stop loss” levels through reduction in Myphan non-Medicare costs in commercial book of business
 - Training to customer staff regarding pharmacy management and DUR programs
 - Formulary management software
 - Data purchase agreement
 - Nominal price Myphan discount agreement with a PBM that has PDP members
 - Grants

Application of 2003 OIG Final Compliance Program Guidance

- The compliance measures adopted by a pharmaceutical manufacturer should be tailored to fit the unique environment of the company (including its organizational structure, operations and resources, *as well as prior enforcement experience*).
- No specific OIG Part D Compliance Guidance for manufacturers, but expect possible supplemental guidance.

Integrity of Data Used For Government Reimbursement.

- False Claims Act liability possible if government reimbursement for product depends, in whole or in part, on information generated or reported by the manufacturer, *directly or indirectly*, and the manufacturer has knowingly failed to generate or report such information completely and accurately
 - In the commercial context, this reflects the impact of proper disclosure of best price and rebate calculations for government programs
 - Part D rebates are exempt from a manufacturer's best price calculation, but PDP Sponsors are reimbursed by the government

Disclosure of Pricing Information

- PDP Sponsors must provide beneficiaries with access to negotiated prices net of price concessions, i.e. direct and indirect subsidies, rebates, remunerations and any other price concessions plans obtain from pharmacies and manufacturers.
 - Classification, therefore, of price concessions by a PDP Sponsor will be important in determining the beneficiary negotiated price
 - PDP contracts should require that the PDP properly calculate and report price concessions to CMS

Nopharm Price Concessions

- Rebate and Discount arrangements questions you should ask:
 - Are the PDP rebates and discounts better than those rebates and discounts offered under Nopharm commercial contracts?
 - Did Nopharm offer rebates and discounts to commercial customers in order to secure Part D formulary status?

Nopharm Swapping?

- “Discounts are typically based on volume and improvements on incremental sales for ALL agreements.”
- If incremental volume and sales dollars occur within the commercial business, Nopharm will give a better discount on the Part D business.
- If incremental volume and sales dollars occur within the Part D business, Nopharm will give a better discount on the commercial business

Fletch's PDP Swap

- “In exchange for Myphan formulary status in all 5 PDPs, Nopharm will rebate any Myphan costs above “stop loss” levels through a reduction in Myphan non-Medicare costs”
- Assume “stop loss” levels are Part D stop loss levels
 - As Myphan Part D costs increase, Nopharm will increase commercial rebates to commercial parent of PDP
- Assume “stop loss” levels are commercial stop loss levels
 - As Myphan commercial costs increase, Nopharm will increase commercial rebates to commercial parent of PDP, but only if PDP has Myphan on formulary

Recommendations to Avoid Swapping Allegations

- Are there procedural ways to avoid the appearance of swapping?
- Is trying to avoid the “appearance” of swapping just form over substance?
- What about the sales force?
- What role should compliance have in swapping issues?

Integrity of Data Used For Government Reimbursement

- Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers.

Operation Brightlight as Possible Nopharm Price Concession

- Training agreements with customer staff regarding pharmacy management and DUR programs
 - Offered at nominal price as a public service
 - Offered by sales and marketing staff
 - Widely available from commercial technology vendors

Brightlight Concessions

- Questions you should ask about Training Agreements
 - Do these free programs relieve PDP of a business expense it would otherwise have to pay for itself?
 - If this is a service offered to a customer, why shouldn't this be structured to fit within the service contract safe harbor?
 - Is this really just a disguised price concession?

Brightlight Concessions

- Part D effect of disguised price concession
 - Offered to PDP to induce commercial formulary status?
 - If so, swapping.
- Commercial contract effect of disguised price concession
 - Should have been included in commercial best price calculation
 - Anti-kickback concern since no safe harbor protection

Recommendations to Revise Training Agreement Offer

- How can this program change so it's not a disguised price concession, if that's what you think it is?
- What role does compliance have in preventing disguised price concessions?

Service Fee or Price Concession?

- What effect if Nopharm moves out of the Training business and instead pays PDPs for the administrative services the PDPs perform?
- “Bona fide service fees” mean expenses that are for an *itemized service actually performed* by an entity *on behalf of the manufacturer* that would have generally been *paid* for by the manufacturer *at the same rate* had these services been performed by other entities.

Service Fee or Price Concession?

- Current ambiguity over whether service fee has to be retained by entity receiving the fee.
 - Current Medicaid reforms
 - ASP guidance
 - Part D?
- How can compliance contribute to service fee analysis?

Possible Nopharm Concessions

- Senior Plan Data Purchase Agreement
 - If have rebate agreement with Senior Plan, wouldn't that require submission of Myphan utilization data?
 - If already paid for it once, then appears that this data payment is simply a price concession and should be reported in Nopharm best price
 - If payment only occurs at the PDP level, then no best price impact since exempt from best price, but appears to be an inducement in exchange for formulary status under kickback statute

Agreements to purchase data from your customers

- Red flag
- How can such an agreement be structured successfully?
- Should compliance keep track of all data purchase agreements?

Possible Nopharm Concessions

- Long term PBM contract with certain “nominal” pricing arrangements for Myphan
- Nominal prices are exempt from best price calculations, right?
- But see current Medicaid reform statutory language requiring that nominal prices can only be exempt from best price if offered to community health centers and other “safety net providers”

Nominal Price Offers

- Should these be used in rebate agreements?
- If so, what parameters should exist?
- Should compliance keep track of all nominal price deals?

Possible Nopharm Concessions

- What effect does a price concession offered to a PBM have on the PDPs price concession reporting obligations?
- PBM acting as PDP sponsor, or affiliated with the PDP sponsor, must pass through and report 100% of rebates
- PBM not the entity acting as the PDP sponsor reporting to CMS, PBM may retain some of the rebate, at which point the PDP sponsor only reports that amount of the rebate the PBM passes through to the PDP.

What role does Manufacturer have in PBM Rebate Treatment?

- Isn't a PBM an independent actor with its own independent duty to its customer?
- Should a PBM tell a manufacturer how the PBM is administering the rebates it receives from the manufacturer?
- What if PBM won't tell manufacturer anything?

Kickback Concerns

- Integrity of the Data reported for calculating government reimbursement addresses whether the payment is accurate.
- Anti-kickback issues arise regarding whether the payment was appropriate.
- Not just the offer or payment of anything of value for patient referrals is at issue, but also *the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program.*

Manufacturer Kickback Checklist

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of a formulary process?
- If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, is the information complete, accurate, and not misleading?
- Does the arrangement or practice have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees?

Manufacturer Kickback Checklist

- Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?
- Does the arrangement or practice have a potential to increase the risk of over-utilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Possible Brightlight Kickbacks

- Pharmacy Management and DUR programs offered at nominal price as public service
 - Inducement in exchange for formulary placement of Myphan?
 - Possibly skews clinical decision making and integrity of formulary process
 - Possible disguised price concession to circumvent Medicaid best price
 - Is information accurate and free from bias or does it have built-in bias towards Myphan?

Possible Brightlight Kickbacks

- Formulary Management Program
 - Manages formularies through web-based tool for clinical indications and clinical trial results
 - Additional discounts offered to managed care plan if Myphan co-pays were established at levels less than competitor products
 - Volume discounts available if co-pay differential maintained and volume increases occur over previous quarter.

Possible Brightlight Kickbacks

- Formulary Management Program offered free of charge as a public service
- Is this a free good contingent on the purchase of Myphan?
 - Include in Myphan best price calculation
- Is this an inducement offered in exchange for Myphan formulary status?
 - Structure to fit within Service safe harbor
 - Requires charging a fair market value for the service
- Effect on clinical decision making and built-in bias of program to Myphan

Possible Nopharm Kickback

- HMO USA medical staff Phase IV Studies
 - “Approval of proposal was subject of some debate within the Company given the potential lack of new scientific data”
 - “Sales force ultimately prevailed”

OIG and Phase IV Research

- Post- marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug.
- Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing.
- Research contracts that originate through the sales or marketing functions—or that are offered to purchasers in connection with sales contacts—are particularly suspect.

Phase IV Study

Recommendations to Nopharm

- What essential changes in Nopharm Phase IV standard operating procedures should occur?
- Should compliance office monitor or otherwise keep track of all Phase IV studies?

Possible Nopharm Kickbacks

- Unrestricted education grants
- When reviewing grant policies and procedures, ask two questions:
 - Are the grant functions separated from sales and marketing functions?
 - Do objective criteria exist for making grants that do not take into account the volume or value of purchases made by or anticipated from a grant recipient?
- What is the role of compliance in the grant world?

PharGo: The Great Unknown

- OIG concerned that extraordinary incentive bonuses and expense accounts intentionally motivate sales force to induce sales through lavish entertainment or other remuneration depending upon the size and resources of the company and the complexity of the sales task

PharGo Incentives

- Mary-Kay like motivational techniques
- Commissions are based on percentage of total sales and PharGo's achievement of certain sales thresholds
- “Special Deals” not reviewed by compliance
- Grants for staff training
- Price reporting issues
- Anti-kickback issues
- Can a contract sales force be structured to fit within compliance requirements?

Any other Nopharm problems?

- Save formulary and P&T issues for next part of discussion
- Any other issues with Nopharm's relationships with PDPs or managed care organizations?

Track III-B

Medicare Part D

The Formulary Development Process

Formularies and Formulary Support Activities

- OIG suspicious of remuneration from a manufacturer or its agents directly or indirectly to person in a position to influence formulary decisions related to the manufacturer's products
- Neither price negotiations nor formulary support activities may trump decisions on clinical safety or efficacy

Nopharm Interactions with P&T Committee Members

- Advisory Committee Membership
- Speaker Agreements
- Total CME outsourcing arrangement
- Dr. Gary Miller, national key opinion leader on several PDP P&T committees, serves as speaker and consultant

Nopharm Advisory Committee Membership

- Key element of eligibility for membership on a Nopharm advisory committee is formulary decision-making authority
- Liberal per diem reimbursement rates and resort locations for meetings make it worthwhile for physicians to participate
- Unclear how much meeting time is spent “receiving” input from Advisory Committee versus “pushing” information out to them

Recommendations to Restructure Advisory Committee Process

- Name the key changes needed for Nopharm's compliance in this area.
- Does a “magic number” exist that represents the right number of members for an advisory committee?
- How should compliance office be involved in advisory committee issues?

Nopharm Speaker Program

- Created as part of Operation Brightlight
- Train 100 internists, 100 endocrinologists, and 100 neurologists about Myphan and all of its uses
- Speaker lists shown at selection process meetings internally at Nopharm included prescribing volume and P&T committee affiliation

Nopharm Speaker Program Risks

- Should speakers from “off-label” specialties be trained?
- How should speakers be selected?
- Is P&T Committee membership a disqualifying factor?

Total CME Outsourcing

- Proprietary database used by Total CME company recruits physicians with an impact on formulary decisions
- Total CME owned by former Nopharm Sales and Marketing Director
- Should P&T Committee Membership disqualify a physician?
- Should fact that company is owned by former sales rep disqualify it?

Dr. Gary Miller

- Speaks frequently and serves as consultant for Nopharm
- Nationally known internist and member of number of formulary committees for several PDPs
- Is something inherently wrong with Dr. Miller serving as a speaker and consultant for Nopharm?

Advance PCS Consent Order and P&T Relationships

- P&T Committee members shall disclose annually in writing whether any financial relationship exists with a pharmaceutical manufacturer
- Changes to the annual written disclosure must be provided prior to a formal or adhoc P&T meeting
- Members with financial relationships with a manufacturer shall recuse themselves from voting on that manufacturer's product under consideration for any action by P&T Committee

Other Nopharm Compliance Issues

- Any other compliance issues raised by Nopharm's interaction with P&T Committee members?