Interactive Workshop Case Study

The Pharma Biotech
and
Device Colloquium

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Workshop Faculty

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Workshop Agenda

- Approach
  - Case Study (3 Different Assignments)
  - Working Group Focus
  - Brief Lecture/Breakout/Whole Group Discussion

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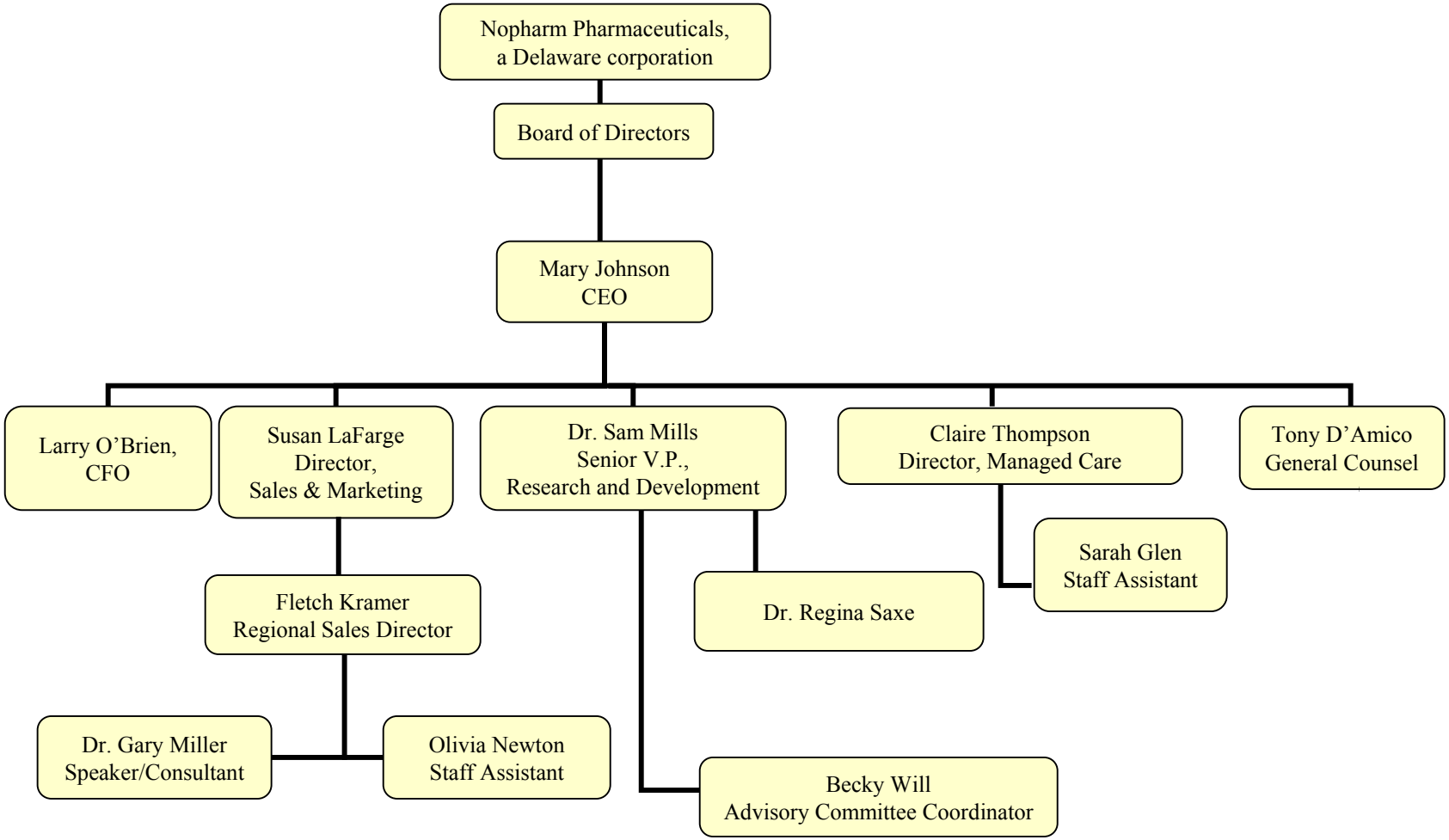
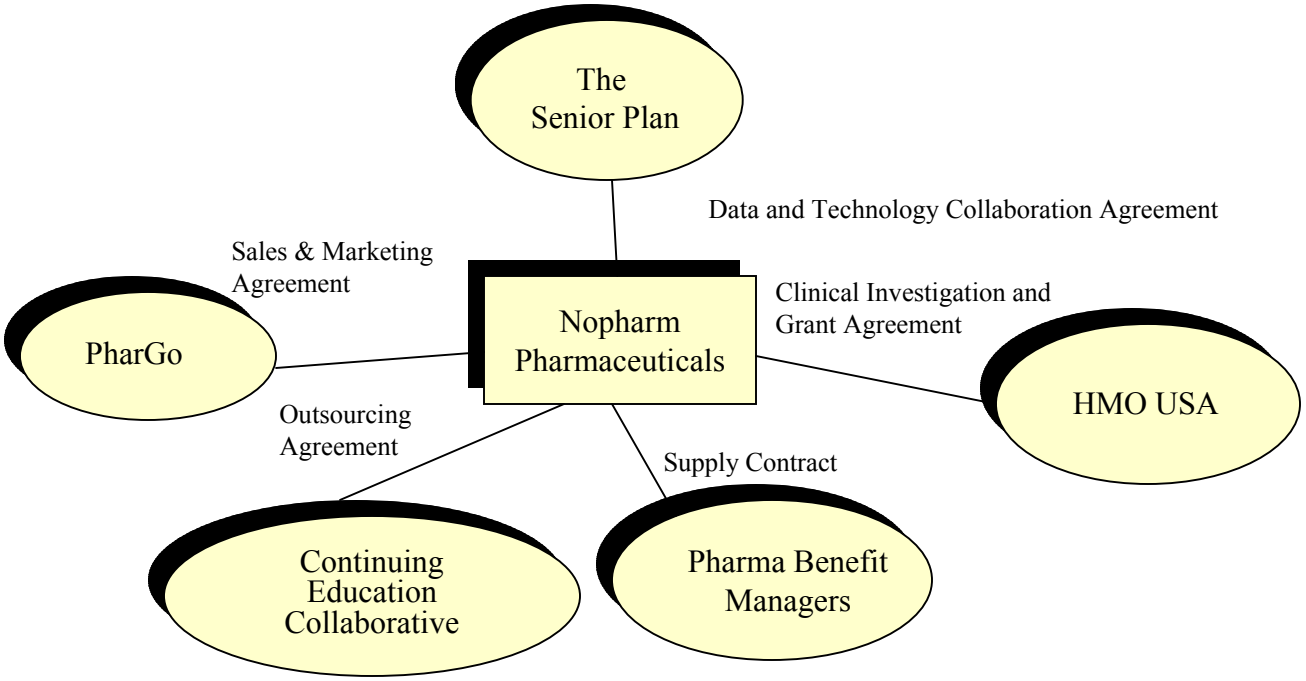
Nopharm Pharmaceuticals Organizational Chart



Nopharm Pharmaceuticals Significant Relationships



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Medicare Part D:
A Compliance Overview

Medicare Part D

- Part D Drugs are defined as those which need a prescription, have FDA approval, and include: drugs, biologicals, vaccines, insulin, and certain medical supplies.
  - Part D is to "wrap around" Part B (which is largely "incident to") drug coverage.
  - MMA doesn't define dispensing fees, but they are mentioned when reimbursing for the cost of the drug + a dispensing fee.
  - Final regulations define dispensing fees as just costs related to transfer of drug possession from pharmacy to beneficiary, including charges associated with mixing drugs, delivery, and overhead, including a reasonable profit.
- Unlike past Federal Medicare benefits, the Part D drug benefit will be administered by private CMS contracted entities (Sponsors) who either offer (1) stand alone Prescription Drug Only Plans (PDPs) or (2) Medicare Advantage Plans which cover Medicare medical benefits and the defined Part D drug benefits (MA-PD).

Competitive Cornerstone of the Final Regulations

Competition among Sponsors via "bidding" to CMS for reimbursement as well as competitive negotiations for prescription drug prices are cornerstones of the Part D program.

- CMS is expressly prohibited from interfering with these competitive negotiations among private entities.
- Part D provides that these negotiated prices with manufacturers will be excluded from Medicaid "best price" calculations.

Part D Drug Coverage

- Sponsors must offer at least “qualified prescription drug coverage” which is either standard or alternative.
- Standard coverage is “defined” as that provided by Part D or is “actuarially equivalent.”
- Alternative Coverage can be either basic alternative in that it is actuarially equivalent to defined standard coverage or “enhanced” to offer supplemental benefits.
- These options provide for flexibility in benefit design.

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Part D Defined Standard Coverage

Standard Benefit	Beneficiary Cost Sharing	Beneficiary out-of-pocket costs	Plan Payment Percentage	Plan Payment
Annual Deductible $0-$250 for Covered Part D Drugs	100%	$250	0%	$0
Initial Benefit[1] $251-$2,250	25%	$500	75%	$1,500
No Coverage of Costs $2,251-$5,100 (Doughnut Hole)	100%	$2,850	0%	$0
Catastrophic Coverage (After enrollee has incurred OOP costs greater than $3,600)	The greater of (1) 5%, (2) $2 for generic/multi-source, or (3) $5 for other drugs.[1]	Same as at left	95%	

1 Actuarial Equivalence: Plans can't offer less of a benefit, but could offer actuarial equivalents to decrease enrollee cost sharing, lower co-insurance, or increase the initial $2,250 coverage limit. Plans can't offer "enhanced" coverage unless they also offer standard coverage.

Compliance Program Implications - Contracting

- Manufacturers should review contracting strategies, operations, and systems.
  - Conduct a risk assessment of the contracting area to determine whether controls are adequate.
  - Increased rebating as a consequence of the competitive cornerstone of the program.
  - Increased visibility of the rebate agreements.
  - In the past, it was up to PBM plan sponsors to decide whether to perform a claims and/or rebate audit.
  - Now as a matter of proper oversight of delegation, Sponsors must perform ongoing oversight reviews, and CMS/OIG will have access to this information as a contractual condition.

Compliance Program Implications – Admin. Services

- Manufacturers should review clinical and administrative programs offered to Sponsors.
  - Manufacturers should also review their DUR, generic substitution, and therapeutic interchange, and other administrative and clinical programs.
  - In the past, even if Plan Sponsors audited PBMs, the focus was on the accuracy of claims/rebates. Now, the focus must also include any delegated administrative or clinical functions.

Compliance Program Implications - Audit

- Manufacturers should review their internal audit programs/protocols to ensure that they prepare departments for an audit of Part D benefit requirements by a Sponsor and/or CMS.
  - The addition of the Part D benefit will require education for CMS on how outpatient drug data, systems and processes work.
  - At the same time, past business partners will need to be trained on CMS audit protocols not those defined by business contract or standard operating procedure (e.g. PBMs).

Compliance Program Implications - Records

- Manufacturers should review and modify accordingly any record retention policies, procedures, and processes.
  - CMS will have the right to audit the books, contracts, medical records, and patient care documentation of not only the Sponsor, but also any subcontractor.
  - This right is in effect for 10 years from the end of the final CMS contract period or completion of an audit, whichever is later.

Compliance Program Implications – P&T

- Manufacturers should review relationships with Sponsor's formulary P&T committees.
  - There will be increased scrutiny of Sponsors' formulary documentation and P&T committee member independence.
  - This could be magnified due to beneficiary protection to ensure that vulnerable populations are not disadvantaged by formulary control techniques and decisions.

Compliance Program Implications - Sales

- Manufacturers should review marketing and sales processes and procedures with Sponsors.
  - Marketing and Sales under the Part D Program largely consists of Sponsors marketing to individual beneficiaries and employer groups.
  - However, manufacturers that market directly to Sponsors should ensure that their programs are compliant with PhRMA, OIG, and forthcoming CMS requirements.

Compliance Concepts – False Claims (and others) Risk "*actually paid*"

means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, 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) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug.

Compliance Risk – Calculating Reinsurance Payment Amounts

The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross covered prescription drug costs (includes amounts “actually paid”) incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold.

Risk-Sharing Arrangements

Increase in payment to PDP if adjusted allowable risk corridor costs are above upper limit of risk corridor.

- Costs ("actually paid") between first and second threshold upper limits. If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the Part D plan for the year, CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent) of the difference between the adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

Risk-Sharing Arrangements (cont'd)

- Costs above second threshold upper limits. If the adjusted allowable risk corridor costs for the Part D plan for the year are greater than the second threshold upper limit of the risk corridor for the Part D plan for the year CMS increases the total of the payments made to the Part D sponsor offering the Part D plan for the year by an amount equal to the sum of:
  - (A) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent) of the difference between the second threshold upper limit and the first threshold upper limit; and
  - (B) 80 percent of the difference between the adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.