

Morgan Lewis

**UNDERSTANDING THE INTERRELATIONSHIP
OF PRICING METHODOLOGIES AND HOW
ONE PRICE MAY AFFECT ANOTHER**

ACI Rx Drug Pricing Boot Camp

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HYPO #1 (Self-Administered Drug Pricing)

Assume the launch of a new drug that is generally self administered (i.e., covered under Medicare Part D, not Medicare Part B). Assume further that drug is priced at \$10,000 per month, and that drug is used to treat chronic condition.

HYPOTHESIS #1 (Self-Administered Drug Pricing) (cont'd)

Business Issues:

- Is drug used for life-saving treatment or debilitating condition?
- Is drug in a competitive space?

In other words, will there be strong pressures to discount product?
Price reporting issues are most likely to be present when discounting practices are variegated and complex.

HYP0 #1 (Self-Administered Drug Pricing) (cont'd)

Regulatory Issues:

- Is the drug in its own (or limited) class or category based on USP model formulary?
 - o If yes, then Part D plans may be required to include.
 - o If no, then Part D plans will have some negotiation power.
- If discounting to Part D plan, will it affect the “negotiated price” (the pharmacy’s price, net of any discounts offered to the consumer)? This affects the amount of the donut hole discount that must be offered.

HYPO #1 (Self-Administered Drug Pricing) (cont'd)

- When does seeking formulary placement using rebates affect best price?
 - o Not when offered to Part D plans.
 - o Not when offered to commercial PBMs, unless:
 - (a) discount is passed along to pharmacies or providers;
 - or (b) it is a rebate on the PBM's mail order pharmacy.But what documentation will you have regarding how the rebate is applied?
- What about discounts to Kaiser?

HYPO #2 (“Part B” Drug Pricing)

Assume the launch of a new drug that is an infusion product administered in a physician’s office (i.e., covered under Medicare Part B, not Medicare Part D). Assume further that drug is priced at \$10,000 per month, and that drug is used to treat chronic condition.

HYPO #2 (“Part B” Drug Pricing) (cont’d)

Business Issue:

- Is drug used for a common condition or an orphan indication? Will physicians using the drug treat a large number of patients or only a handful?

If physicians have little “throughput” with the product, then there could be a significant cost of the “float” for them to keep it in inventory (unless shipping only occurs after the patient is scheduled).

HYP0 #2 (“Part B” Drug Pricing) (cont’d)

Regulatory Issues:

- Part B drugs are reimbursed at ASP (based on two quarters previous) plus 6%.
- Even if throughput is quick, what about claims processing lag? Does 6% compensate physicians for the float and for any issues in terms of challenging payment denials?
- Is there such a significant price differential between classes of trade, such that ASP + 6% may not cover the costs of the drug to some classes of trade?
- Is there a competitor product for which claims are paid faster?

HYPO #2 (“Part B” Drug Pricing) (cont’d)

- What steps can be taken to improve claims processing or otherwise ensure a shorter float period?
 - o Get a HCPCS code.
 - o Have a reimbursement support department helping with coverage denial challenges.
 - o Extend favorable finance terms.

HYPO #2 (“Part B” Drug Pricing) (cont’d)

- What happens if the manufacturer tries to raise prices?
 - Lag means that there will be a smaller gap between cost and reimbursement.
- What happens after there is a generic competitor on the market?
 - Combined sales data setting reimbursement rate means that there will always be a race to the bottom.

HYPO #3 (GPOs)

Manufacturer is negotiating an agreement with a GPO, involving the payment of administrative fees on a percentage of sales basis.

HYPO #3 (GPOs) (cont'd)

Business/Operational Issue:

- What will the distribution chain look like? How can the manufacturer ensure that there are no duplicate discounts?

HYPO #3 (GPOs) (cont'd)

Regulatory Issues:

- Is there automatically an exclusion of administrative fees from best price consideration if the GPO safe harbor is met?
 - o NO. “We believe that to propose a categorical exclusion of administrative fees of 3 percent or less if they fall within the GPO safe harbor provisions would be inconsistent with our guidance regarding an actual determination of the amount of bona fide service fees.”

HYPO #3 (GPOs) (cont'd)

- o ALSO “We do not believe that for the purposes of the Medicaid drug rebate program, administrative services related to the administration of a rebate contract would qualify as bona fide service fees because these fees are not associated with the efficient distribution of drugs or our interpretation of the bona fide service fee guidance.”

HYPO #3 (GPOs) (cont'd)

- Bona fide service fee requires:
 - o fair market value
 - o bona fide, itemized service actually performed
 - o Manufacturer would otherwise need to perform (or contract for) in absence of agreement; and
 - o Fees not passed on to client or customer of entity.

Are these all met with a 3% fee? What are the services?
Why is 3% FMV?

HYPO #3 (GPOs) (cont'd)

- For purposes of ASP calculations under Medicare Part B, are GPO fees categorically excluded?
 - Maybe. “[A]t this time we believe it is premature for us to provide specific guidance with respect to treatment of fees paid by manufacturers to PBMs and GPOs in the ASP calculation (other than to specify, as we proposed, that PBM and GPO fees that meet the definition of “bona fide service fees” are excluded from the calculation of ASP). Instead, we will continue to consider the comments received and to study the matter further. . . **In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP**, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices. These assumptions should be submitted along with the ASP data.”

HYPO #3 (GPOs) (cont'd)

- What Anti-Kickback Statute concerns are there and what precautionary steps are needed? Must fall within the GPO safe harbor, which requires that the GPO enter into an agreement with its members that either:
 - o sets admin fees at 3% or less;
 - o explains how they are calculated (fixed sum or fixed percentage); or
 - o identifies maximum fee.
- Discount safe harbor applies to sales to members.

In other words, manufacturer's compliance is contingent upon the GPO's Compliance.

HYPO #4 (Purchased Services)

Manufacturer is entering into a transaction with a distributor. Distributor is insisting on a payment for “inventory management services.”

HYPO #4 (Purchased Services) (cont'd)

Business Issues:

- Who has the bargaining power? The manufacturer or the distributor? Is the product in a competitive space?
- Is the product sold through specialty distributors, where typically there are a lot of value-add services being delivered?

HYPOTHESIS #4 (Purchased Services) (cont'd)

Regulatory Issues:

- Does the payment reflect a bona fide service fee?
 - o What are the services?
 - o What is the fair market value?
- Does it matter if this is a Part D drug or a Part B drug?
 - o Possibly. Healthcare Reform Law new definition of AMP specifically lists payments for “inventory management services” (among others) as a type of “bona fide service fee” excluded from AMP calculation. CMS does not *have* to have a unified definition of bona fide service fees across price reporting systems.

HYPO #4 (Purchased Services) (cont'd)

- Anti-Kickback Statute implications. Is the personal services safe harbor met? Need:
 - o Written agreement
 - o Detailed description of services
 - o Timing of provision of services
 - o Minimum one year term
 - o FMV compensation set out in advance that does not account for Federal healthcare business
 - o Services serve a commercially reasonable business purpose

But often these arrangements are based on a percentage of sales . . .

HYPO #5 (Research Grants)

Manufacturer provides a research grant to a physician who happens to be a key opinion leader and is an individual who writes lots of prescriptions for manufacturer's product.

HYPO #5 (Research Grants) (cont'd)

Business/Operational Issue:

- Is the manufacturer's organizational structure such that individuals with sufficient ability to judge whether a study is good science are evaluating whether to fund a research grant?

HYP0 #5 (Research Grants) (cont'd)

Regulatory Issues:

- Is the grant truly not tied to a sale?
 - o Ensuring that grants function is separated from Sales & Marketing helps to establish that one is not connected with the other.
- If the grant is tied to a sale, how is it included in the AMP and Best Price calculation?
 - o Depends on documentation. Should seek to comply with discount safe harbor, which also facilitates MDRP calculations.

HYPO #5 (Research Grants) (cont'd)

- Could the grant be construed as payment for services? If so, could it be viewed as a bona fide service fee? What would the service be? How would you determine fair market value?
- If a payment for services, does the personal services safe harbor apply?

HYPO #6 (Bundled Sales)

Manufacturer launches a new product, which is well received. Manufacturer seeks to leverage off of the sales volume of the new product to sell an older product. If a customer buys 10 units of older product and 5 units of new product, customer receives a 10% discount on new product.

HYPO #6 (Bundled Sales) (cont'd)

Business Issue:

- Which purchasers likely need to purchase both products? Do they purchase less than an optimal amount without incentives?

If these are drugs sold directly to physicians, this strategy works best when the two drugs at issue are used for the same disease state (e.g., Aranesp & Neulasta).

HYPOTHESIS #6 (Bundled Sales) (cont'd)

Regulatory Issues:

- Bundling Rule.
 - o “Bundled sale means an arrangement . . . under which the . . . price concession is conditioned upon the purchase of the same drug, drugs of different types . . . or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.”
 - o “[T]he discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement.”

HYPOTHESIS #6 (Bundled Sales) (cont'd)

- So what about the hypo? Take the dollar value of the discount and allocate to price for both products.
- May apply to ASP (if based on manufacturer's reasonable assumptions), but no formal rule for VA.

HYPO #6 (Bundled Sales) (cont'd)

- Discount safe harbor
 - o Overall requirement of transparency in pricing structure and notification to buyer of potential responsibility to accurately report price concessions as and when appropriate to Medicare and Medicaid.

HYPO #7 (Stacked Discounts)

Manufacturer sells to wholesaler at WAC minus 3 percent. Wholesaler sells to chain pharmacy. Chain pharmacy gets a separate discount (through a chargeback process) of 25 percent of WAC.

HYPOTHESIS #7 (Stacked Discounts) (cont'd)

Business Issue:

- Are there any efficiencies to be recognized through direct shipping to customer?

HYP0 #7 (Stacked Discounts) (cont'd)

Regulatory Issues:

- Could discounts be aggregated, resulting in a new best price?
- “*Stacking*” discounts. CMS has implied that there is a presumption that discounts available to a wholesaler or distributor are also available to the ultimate purchaser. Would therefore need to aggregate.
- Less likely to be relevant with the increase in the minimum unit rebate amount.

HYPO #7 (Stacked Discounts) (cont'd)

- Steps to avoid stacking issue (which may require “reasonable assumptions”):
 - o Direct sales to customer
 - o Payment to wholesalers of bona fide service fees, rather than price concessions (where appropriate)
 - o Contractual limitations on passing discounts onto customers
- VA – Include if discounts given through chargebacks.

HYPO #8 (Coinsurance Support Programs)

Manufacturer has a coinsurance support program. Patients, irrespective of income, receive a voucher of up to \$100 or the limit of their coinsurance.

HYPO #8 (Coinsurance Support Programs) (cont'd)

Business/Operational Issues:

- Will pharmacies accept this arrangement, or will they find this to be problematic under their agreements with managed care organizations?
- Do in-house or hire a 3PL? Which department will be responsible for administering the program?

Some MCOs require that discounts be applied to the total amount of the cost of a good, and not just the portion of the cost for which the patient is liable.

HYPO #8 (Coinsurance Support Programs) (cont'd)

Regulatory Issues:

- PAP exception? To qualify, it need be true that:
 - o Focus is on assistance to low-income individuals
 - o Manufacturer unilaterally establishes the amount of the subsidy
 - o the entire amount is available only to the patient
 - o the pharmacy may collect a bona fide service fee
- What about if no means testing?
- What about if lower of set dollar amount or the patient's coinsurance?

HYPO #8 (Coinsurance Support Programs) (cont'd)

- What if offering free drug instead?
- Could this be a stacking discount?
- ASP – would only exclude if excluded under Best Price.
- VA – not a sale to a wholesaler, so would be excluded.

HYPO #8 (Coinsurance Support Programs) (cont'd)

- Anti-Kickback Statute implications
 - o This does not qualify under OIG's "outside of Part D" guidance.
 - o So need to either: (a) exclude anyone who has (or should have) federal healthcare insurance; or (b) work through an independent tax-exempt organization.

HYPO #9 (Nominal Sales)

Manufacturer sells drugs to a cancer hospital at 5 percent of AMP when hospital uses such drugs for indigent patients.

HYPOTHESIS #9 (Nominal Sales) (cont'd)

Business Issue:

- Will manufacturer be able to verify who is receiving the product?

Should maintain and exercise audit rights. Should verify systems to avoid commingling.

HYPO #9 (Nominal Sales) (cont'd)

Regulatory Issues:

- Nominal price only covers discounts of 10% or less to:
 - o A 340B covered entity
 - o An intermediate care facility for the mentally retarded (ICF/MR)
 - o A State-owned or operated nursing facility
 - o A tax-exempt or State entity that, though not a 340B entity, provides 340B-type services to a 340B-type patient population [but note that there is no agency interpretation of these criteria]
 - o A public, nonprofit, or educational institution-based entity, providing family planning services to students
 - o Other safety net providers determined by CMS [none yet determined]

HYPOTHESIS #9 (Nominal Sales) (cont'd)

- Cancer hospitals only recently became 340B entities (and still don't qualify for orphan drugs at 340B pricing).
- Is it worth risking setting a new Best Price for any other entities?

HYPO #9 (Nominal Sales) (cont'd)

- VA – requires only that the price be less than 10% of AMP.
- ASP – same rules as best price.
- Can always eliminate all residual risk by providing entity product for free.
- Anti-Kickback Statute – discount safe harbor could apply.

HYPO #10 (Returned Goods)

Manufacturer routinely receives returns of goods that have expired or are close to expiring.

HYPOTHESIS #10 (Returned Goods) (cont'd)

Business Issues:

- What kind of limitations are there on returns (e.g., how close to expiration; condition of package, etc.)
- What value does the manufacturer attribute to the returned goods (i.e., WAC from what time period?)

HYPOTHESIS #10 (Returned Goods) (cont'd)

Regulatory Issues:

- AMP guidance – if returned in good faith (*i.e.*, based upon a policy not designed to distort AMP), then excluded from calculation.
- BP rules – expressly included, but question of whether there is actually a transaction in most cases, or whether it is simply a reversal of a prior transaction.
- ASP – returns are excluded from calculation.
- VA – generally excluded from the calculation.

HYPO #11 (Inpatient Drugs)

Manufacturer is launching a product for which the labeled indication is inpatient use. Manufacturer is considering whether it is necessary or helpful to participate in the Medicaid Drug Rebate Program.

HYPO #11 (Inpatient Drugs) (cont'd)

Business Issue:

- Are there uses that are not labeled, but supported by compendia, involving administration in other settings?

If there are other settings where a manufacturer's product could be used, if even for an off-label indication, then it may be easier to decide to seek MDRP coverage.

HYPO #11 (Inpatient Drugs) (cont'd)

Regulatory Issues:

- If a drug is used only in the inpatient setting and there is no separate reimbursement under Medicaid for the drug, then it is not a “covered outpatient drug” subject to the MDRP under the statute.
- Consequence of not participating means that Medicaid programs cannot consider the product to be a covered outpatient drug and get matching Federal funds (which is only critical if separate payment is available).

HYPO #11 (Inpatient Drugs) (cont'd)

- If a manufacturer elects to participate in MDRP, then must participate in 340B and VA programs.
- If participate in ASP, then, though ambiguous, arguably manufacturer must participate in MDRP.
- Manufacturer *may* participate in VA program, even if it does not participate in MDRP or 340B.

HYPO #12 (Single vs. Dual Pricing)

Manufacturer is in discussions with the VA regarding sales to the Big 4 and participation in the Federal Supply Schedule. Manufacturer is contemplating whether single pricing or dual pricing is better.

HYPO #12 (Single vs. Dual Pricing) (cont'd)

Business Issues:

- How much business does the manufacturer expect to generate with the Big 4 or the other governmental agencies?
- Is the manufacturer expecting large year-to-year price increases?

Balance between revenue stream issues and administrative simplicity.

HYPO #12 (Single vs. Dual Pricing) (cont'd)

Regulatory Issues:

- Under single pricing, prices are capped at the prior year's FCP plus CPI-U.
- Under dual pricing, price cap can reflect all increases to the tracking customer's price.
- Over time, the cut in the potential Big 4 price can be substantial.
- But the burden of monitoring the tracking customer discounts, notifying VA, and working with wholesalers to constantly update VA pricing can be significant.