
TEN KEY REGULATORY CONSIDERATIONS YOU DO NOT WANT TO OVERLOOK

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REIMBURSEMENT MATTERS

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- Various government and commercial payors may not have clear reimbursement criteria for combination products
- May need to retrofit antiquated reimbursement methodologies until law and policies “catch up” – do not expect consistency
 - Guidance pertaining to compounded product reimbursement may be relevant, depending on the context and whether there are multiple NDCs
- From a payor perspective, there may be resistance to covering a combination product that is more expensive than “compounding” (or otherwise combining) an alternative, if available

REIMBURSEMENT MATTERS

- Considerations:
 - Will combination product be covered under medical, drug or device benefit(s)?
 - Medicare
 - Will DMERCs or Carriers have authority over product reimbursement? What about interplay with Part D?
 - Will LCA (least costly alternative) policies apply?
 - Will “functional equivalence” apply? (Can it, post-MMA?)
 - Will “inherent reasonableness” apply?
 - If Part D applies, what restrictions will/can Plans implement? (interchange? prior authorization?)
 - How will combination product be classified by payors?
 - At least from a Medicare Part D perspective, there may be advantages to defining a new class, if appropriate

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COMMERCIAL CONTRACTING

- Do current discount/rebate contracts contemplate a combination product?
 - Consider whether contract changes need to occur (e.g., to definition of “product”/“new product”/new formulation language etc.) to avoid automatically discounting a combo product at the price of one of its components
- How will the product be characterized for therapeutic class purposes?
 - Consider whether will it be its own class (and will compounded products be included), or will product be bucketed under one or both components?
- MCOs/PBMs: Will combination products involving a device be subject to formulary?
- GPOs: Will there be any exclusivity or similar provisions?

- How will the combo product be priced relative to the component products, and what legal protection for the pricing might be available/structured into contract?
- What termination/amendment rights are maintained?
- What product warranties/indemnification are offered?
- Any unique pricing/discount/service fee mechanisms?

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GOVERNMENT PRICE REPORTING

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GOVERNMENT PRICE REPORTING

- Is a combination product an “covered outpatient drug” for purposes of Medicaid Drug Rebate reporting and/or Medicare ASP reporting?
- A “covered outpatient drug” is generally:
 - A prescription drug (and certain prescribed OTC drugs)
 - A prescription biological product, other than a vaccine; or
 - Insulin

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GOVERNMENT PRICE REPORTING

- A “covered outpatient drug” is not:
 - Any such product provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):
 - Inpatient hospital services
 - Hospice services
 - Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs
 - Physicians' services
 - Outpatient hospital services
 - Nursing facility services and services provided by an intermediate care facility for the mentally retarded.
 - Other laboratory and x-ray services
 - Renal dialysis
 - Any such product for which an NDC number is not required by the FDA or a drug or biological used for a medical indication which is not a medically accepted indication

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GOVERNMENT PRICE REPORTING

- A “covered outpatient drug” generally excludes the following (but states may choose to cover):
 - Agents when used for anorexia, weight loss, or weight gain
 - Agents when used to promote fertility
 - Agents when used for cosmetic purposes or hair growth
 - Agents when used for the symptomatic relief of cough and colds
 - Agents when used to promote smoking cessation
 - Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
 - Nonprescription drugs
 - **Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee**
 - Barbiturates
 - Benzodiazepines
 - Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the FDA

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GOVERNMENT PRICE REPORTING

- Considerations:
 - Need to understand how combination product will be reimbursed to understand whether Medicaid and/or Medicare price reporting obligations apply
 - Will any or all components of combination product be separately reimbursable?
 - If “excluded”, have any states chosen to cover anyway?
 - Is analysis different for components:
 - Is a combination product multiple “covered outpatient drugs”?
 - Is a combination product a mix of “covered outpatient drugs” as well as other non-covered product(s)?
 - For Medicare specifically – need to understand whether a Part B or a Part D drug
 - For Medicaid purposes – will baseline AMP reset?

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PAY ATTENTION TO BUNDLES

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- Medicaid Drug Rebate Guidance:
 - “*Bundled sale*” means an arrangement:
 - **regardless of physical packaging**
 - under which the rebate, discount, or other price concession is conditioned upon the purchase of
 - the same drug,
 - **drugs of different types** (that is, at the nine-digit National Drug Code (NDC) level)
 - **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
 - For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement
 - For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated

- 42 C.F.R. § 447.502 (emphasis added)

- Medicare Part B ASP Guidance:
 - “[W]e [CMS] are not establishing a specific methodology that manufacturers must use for the treatment of bundled price concessions for purposes of the ASP calculation at this time. 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. Our intent in not being prescriptive in this area at this time is to allow manufacturers the flexibility to adopt a methodology with regard to the treatment of bundled price concessions in the ASP calculation that, based on their particular circumstances, will best ensure the accuracy of the ASP calculation and not create inappropriate financial incentives.”
- 71 Fed. Reg. 69,624, 69,675 (Dec. 1, 2006)

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PAY ATTENTION TO BUNDLES

- Considerations:
 - Can pricing be reported under a single NDC if components of product are also available separately?
 - Can pricing be reported under a single NDC if components of product are not available separately?
 - If price reported under separate NDCs, how will allocation occur?
 - What if not all components are “covered outpatient drugs”?

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KICKBACK STATUTE CONSIDERATIONS

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- Under the federal health care program Anti-Kickback Statute (42 U.S.C. § 1320a-7b), it is a felony to:
 1. knowingly and willfully
 2. solicit, receive, offer or pay
 3. any remuneration (including kickbacks, bribes or rebates),
 4. directly or indirectly,
 5. overtly or covertly,
 6. in cash or in kind
 7. in return for referring an individual to a person for the furnishing or arranging for the furnishing of an item/service; or for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item for which Medicare or a State health care program may pay

5 KICKBACK STATUTE CONSIDERATIONS

- There are several statutory exceptions and regulatory “safe harbors” to the Anti-Kickback Statute, which, if complied with strictly, protect arrangements from prosecution under the Anti-Kickback Statute
 - Among other things, these safe harbors protect “discounts”, if structured properly

5 KICKBACK STATUTE CONSIDERATIONS

- A “discount” does not include:
 - “[s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, **unless the goods and services are reimbursed by the same Federal health care program using the same methodology** and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology”
 - 42 C.F.R. 1001.952 (emphasis added)

5 KICKBACK STATUTE CONSIDERATIONS

- In the preamble to the 1991 discount safe harbor regulations, the OIG states the following:
 - “Comment: Many commenters urged the OIG to expand this safe harbor provision to include a variety of other discounting practices where the benefit received relates to something other than the specific good or service purchased or provided...
 - ...Response: We believe that such an interpretation goes well beyond the legislative intent of this statutory exception, and vitiates its purpose. We believe that Congress did not intend to include within this provision the practice of a seller giving away, or reducing the price of, one good in connection with the purchase of a different good. Such arrangements, for the most part, do not represent price reductions where the value of the goods received can be measured and fully reported to the Medicare and Medicaid programs...
 - ...For example, in developing accurate pricing data to assist HCFA [now CMS] in setting the amount of reimbursement for IOLs, we found that bundled pricing arrangements similar to those suggested by our commenters were common, and made it difficult to determine the true acquisition cost of IOLs”
 - 56 Fed. Reg. 35,952 (Jul. 29, 1991)

5 KICKBACK STATUTE CONSIDERATIONS

- Considerations:
 - Facts and circumstances (from OIG Compliance Guidance for Pharmaceutical Manufacturers):
 - 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? 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 overutilization or inappropriate utilization?
 - Does the arrangement or practice raise patient safety or quality of care concerns?
 - Evaluate structure of all payment/discount relationships under AKS (not just end customers, but copromote partners, distributors PBMs, etc.)

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ANTI-TRUST CONSIDERATIONS

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- Sherman Act Section 1
 - Prohibits an agreement or understanding **among two or more parties** that results in an unreasonable restraint on competition (15 U.S.C. § 1)
 - Tying: An agreement by a party to sell one product [the tying product] but only on the condition that the buyer also purchase a different [the tied product] product

- Sherman Act Section 1 – Considerations:
 - Are there two parties?
 - Are there two separate products?
 - Are purchasers required to buy the tied product as a condition to the seller’s selling the tying product?
 - Is the tying product not available separately on commercially reasonable terms?
 - Does the seller have market power in the tying product?
 - Does the tied product market involve a “not insubstantial” volume of interstate commerce?
 - Does the seller of the tying product have a direct economic interest in the sale of the tied product?
 - Does the seller have any legitimate business justifications for the tying?
 - If so, is the tie-in the least restrictive alternative to achieve that justification?
 - Is there an anti-competitive effect in the tied product market?

- Sherman Act Section 2
 - Prohibits any person from monopolizing or attempting to monopolize “any part of the trade or commerce among the several States” (15 U.S.C. § 2)
 - Illegal monopoly under § 2 of the Sherman Act has two elements:
 - the possession of monopoly power in the relevant market *and*
 - the willful acquisition or maintenance of that power (distinguished from growth that comes as a consequence of superior products or superior business acumen)

- Sherman Act Section 2
 - Monopolization – Possession of Monopoly Power
 - Monopoly power has been defined by the Supreme Court as “the power to control prices or exclude competition.”
 - No magic number for when monopoly power is assumed. Courts have routinely held that 90% is enough to constitute a monopoly, they are less clear on whether anything under 30% would suffice.
 - Monopolization – Willful acquisition or maintenance of that power
 - *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978)
 - Willful acquisition and maintenance of monopoly power found when Lilly “bundled” products
 - Through a rebate program, Lilly bundled those products for which Lilly faced no competition with a product which faced significant competition

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ANTI-TRUST CONSIDERATIONS

- Sherman Act Section 2 – Considerations:
 - Do any of the products at issue have monopoly power?
 - What's the relevant market?
 - Geographic
 - Product
 - If one of the products has monopoly power, what is the effect of the bundle on competitors?
 - Will it force competitors out of market?
 - Is the purpose to “leverage” market share in a new product based on existing market share?

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STATE LAW PRICE REPORTING LAWS

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STATE LAW PRICE REPORTING LAWS

- In addition to federal price reporting, manufacturers must consider whether states price reporting requirements apply to combination products
 - Some requirements are statutory (e.g., VT, MN, ME)
 - Some requirements are contractual (e.g., state supplemental rebate agreement, state pharmaceutical assistance programs etc.)

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STATE LAW PRICE REPORTING LAWS

- Vermont's Pharmaceutical Marketer Price Disclosure Law (33 V.S.A. § 2005a)
 - Requires pharmaceutical marketers to disclose to Vermont doctors and other prescribers the prices of the drugs they market as well as the prices of others drugs in the same therapeutic class
 - “Short Form” and “Long Form” AWP disclosure:
 - “The disclosure of the AWP’s must be on a ‘per pill’ basis. **If the drug being marketed is in liquid, aerosol, injectible, or other non-pill form, then there is no disclosure requirement**, and the manufacturer is not required to provide a disclosure in accordance with this Guide. If one or more of the related drugs is in liquid, aerosol, injectible or other non-pill form, then the marketer shall list that drug and indicate that it is a “non-pill product”, and the AWP’s need not be disclosed for that related drug.”
 - VT Atty. Gen. *Guide To Vermont’s Pharmaceutical Marketer Price Disclosure Law, 33 V.S.A. § 2005a* (emphasis added)
 - Therapeutic Class:
 - “QUESTION: If there is a drug in the same therapeutic class with one that has a different delivery method, e.g., extended release versus immediate release, must the drug with the different delivery method be included in the price disclosure?”
 - ANSWER: If the extended release product, or other product with a different delivery method, is **listed as a different product by the three AWP sources**, then the drug with the different delivery method must be separately included in the price disclosure forms.”
 - VT Atty. Gen. *Pharmaceutical Marketers Price Disclosure Law and Guide: Questions and Answers 02-26-2005* (emphasis added)

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STATE LAW PRICE REPORTING LAWS

- Vermont (Vt. Stat. Ann. tit. 33, § 2010)/Maine (22 M.R.S.A. § 2698-B)
 - Similar statutes in VT and ME: generally require reporting of quarterly AMP, Best Price, and prompt pay to respective states
 - Both statutes apply to “prescription drugs”
- New Mexico (27 N.M.S.A. § 27-2e-1)
 - Statute generally requires reporting of AMP and WAC to NM (NM-price specific provisions modified by 11/9/07 Letter)
 - Applies to “prescription drugs”

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STATE LAW PRICE REPORTING LAWS

- Considerations:
 - Review definitions! (statutes/reg/contracts/other guidance...)
 - Need to review state supplemental rebate agreement and state pharmaceutical assistance program agreements:
 - Is a combination product automatically subject to any discount or rebate obligations?
 - Is there any notice requirement to state triggered by introduction of combination product (e.g., “new product” section in contract)
 - Does any allocation of discounts/pricing need to occur for state reporting or contract purposes?

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SALES AND MARKETING STATE LAWS

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- Currently, there are three “types” of state marketing/ disclosure laws:
 1. Laws that require companies to adopt a compliance program and/or marketing code of conduct that affects payments made to healthcare professionals (“HCP”) (e.g., CA, MA, NV)
 2. Laws that limit, or require manufacturers to establish limits regarding the payments that may be provided to HCPs (e.g., DC, MA, MN, CA)
 3. Laws that require certain payments provided to HCPs to be reported on an annual basis (e.g., DC, ME, MA, MN, VT, WV)

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SALES AND MARKETING STATE LAWS

- Considerations:
 - Important to review the extent that the scope of each such law would apply to the particular combination product (applicability may vary based on product/state)
 - How is “drug” or “prescription” (or similar term) defined?
 - Many states have similar definitions of “drug” but the use of “and” versus “or” can be relevant with respect to device carve out (see next section on state pricing laws for examples)
 - Is a device carved out of the definition?
 - Is a biologic included in the definition (explicitly or implicitly)?

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REP REGISTRATION STATE LAWS

- The District of Columbia requires registration of “pharmaceutical detailers”
 - A “pharmaceutical detailer” is:
 - Acting as a representative of a pharmaceutical manufacturer or labeler;
 - Communicating in person with a licensed health professional or an employee or representative of a licensed health professional located in DC;
 - In a non-conference setting;
 - For the purpose of selling, marketing, or promoting a prescription or over-the-counter pharmaceutical product for use in humans, or providing information about a pharmaceutical product for the purpose of selling, marketing, or promoting such product

- 17 D.C.M.R. § 8300.5

REP REGISTRATION STATE LAWS

- In DC, a “pharmaceutical product” is “a drug or biologic regulated by the federal Food and Drug Administration” D.C. Code § 3-1201.02(10A)(B)(iii)
- In DC, a “drug” is any substance:
 - a) recognized as a drug, medicine, or medicinal chemical in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, or official Veterinary Medicine Compendium or other official drug compendium or any supplement to any of them;
 - b) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal;
 - c) (other than food) intended to affect the structure or any function of the body of man or other animal; **and**
 - d) intended for use as a component of any items specified in subparagraph (A), (B), or (C) of this paragraph, **but does not include medical devices or their components, parts, or accessories**
 - D.C. Code § 47-2885.02 (emphasis added)

REP REGISTRATION STATE LAWS

- Florida requires registration of “complimentary drug distributors” (Florida Admin. Code 64F-12.008)
 - “Drug sample,’ or ‘complimentary drug,’ means a human prescription drug that is labeled ‘sample,’ ‘not to be sold,’ ‘complimentary,’ or other words to that effect, that is provided as a courtesy, that is not intended to be sold, and that is intended to promote the sale of the drug.”
 - Fla. Stat. 499.028
 - “Drug’ means an article that is:
 - a) Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;
 - b) Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;
 - c) Intended to affect the structure or any function of the body of humans or other animals; **or**
 - d) Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), **but does not include devices or their components, parts, or accessories.**
 - Fla. Stat. 499.003(19) (emphasis added)

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CORPORATE COMPLIANCE MATTERS

- When did you last update your corporate compliance program?
 - Are terms such as “drug” and/or “device” used in the policies in a way that would include combination products?
 - Have sales and marketing policies been updated to address issues specific to combination products (for example FDA issues, government price reporting...)
 - Revisit all “7 elements” of compliance to ensure that structure of program is tailored to include combination product issues

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CORPORATE COMPLIANCE MATTERS

- What industry ethical guidelines apply, and if more than one set is relevant, how are conflicts resolved?
 - PhRMA Code?
 - AdvaMED Code?



QUESTIONS AND ANSWERS

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