Manufacturer Patient Support Initiatives: Current Practices and Recent Challenges

Intersecting Worlds of Drug, Device, Biologics and Health Law

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Overview

- Current Manufacturer Patient Support Initiatives
  - Description
  - Key Structural/Operational Considerations
- Potential Legal Issues
- Summary Considerations/General Guidance

Manufacturer Patient Support Initiatives

- Increasingly Common
- Increasingly Integrated Program of Initiatives
- New Era of Uncertainty?

PAP Structural Considerations

- Different types.
  - Charitable foundation.
  - Free drug.
  - Coinsurance support.
  - Coupon.
  - Bulk replacement.

PAP Structural Considerations

(cont'd)

- PAP features
  - ➢ Which drugs are subject to policy?
    - Will PAPs for all of a company's drugs be subject to the same rules?

PAP Structural Considerations

(cont'd)

- PAP features *(cont'd)*
  - ➢ Which patients are eligible?
    - Carve out for Federal program beneficiaries, or separate PAP?
    - Graduated relief, based on income?
    - Carve-out for certain States?
    - Limitations on whether used for labeled indication?

PAP Structural Considerations

(cont'd)

- PAP features *(cont'd)*
  - ➢What is the benefit to be conferred?
    - Free drug?
    - Coinsurance support?
    - Coupon?
    - Interim product during benefits investigation?

PAP Structural Considerations

(cont'd)

- PAP features *(cont'd)*
  - ➢What procedures must be followed?
    - Qualify upon denial of coverage?
    - Coverage denial appeal requirement?
    - Reconsideration process for PAP denial?

Operational Issues

- Which group within the company owns PAP?
  - Marketing? Medical? Foundation?
  - Is the group responsible for donations to independent PAP foundations different from the group responsible for the company's own PAP?

Operational Issues *(cont'd)*

- How will patients get drug?
  - From pharmacy directly? How will manufacturer pay pharmacy?
  - From HUB?
  - Sent to physician? Comply with PDMA?

Considerations Specific to Coinsurance Support

- What is the amount?
  - Is it tied to coinsurance obligations, or is it capped at a fixed dollar?
  - Is there any consideration to patient financial status?

Considerations Specific to Coinsurance Support *(cont'd)*

- How is it administered?
  - ➢Direct relationship with manufacturer?
  - ➢Use of a coupon card?

Considerations Specific to Coinsurance Support *(cont'd)*

- How does patient enroll?
  - Doctor provides coupon card?
  - Patient applies to manufacturer through physician or through website?
  - How does the manufacturer ensure no Federal healthcare program beneficiaries, including patients with Medicare as secondary?
- Relationship with PBMs – is the coinsurance support in lieu of, or in addition to, rebating to PBMs/MCOs?

Reimbursement Support Services

- Reimbursement Support Services Encompass Wide Variety of Activities
  - Reimbursement Information
    - General information about coding, coverage and payment
    - Payor-specific information
    - Patient-specific information
  - Reimbursement Assistance
    - Assessing coverage options
      - Current insurance coverage
      - Co-pay assistance
      - Manufacturer PAP
      - Charitable foundation PAP
    - Verifying coverage
    - Obtaining prior authorization
    - Assisting with appeals
    - Interim supply of product

Reimbursement Support Services
(cont'd)

- Considerations
  - Who will provide the services?
    - Field representatives v. home office
    - Sales/marketing v. medical affairs
    - Manufacturer v. third party vendor
    - *Often combination with need for clear allocation of responsibility and definition of limits on information/services provided for each*
  - What services will be provided?
    - Reimbursement information
    - Reimbursement assistance
  - What potential limits apply to the services?
    - Anti-kickback statute
    - FDA promotional restrictions
    - False claims act (accuracy of information provided)
    - HIPAA/privacy laws
  - What operational issues exist?
    - Maintaining focus on patient
    - Exchange of information
    - Ensuring accurate information

Educational Materials/Tools

- Educational materials/tools encompass various informational materials or aids
  - Information about disease/condition
  - Aids for therapeutic compliance
  - Aids/information for managing therapy (drug interactions)

- Considerations
  - What information/tools will be provided?
  - Will the information/tools be promotional or non-promotional?
  - What patients will have access to the information/tools?
    - Only patients on manufacturer's drug?
  - How will information/tools be developed/validated?
    - Recognized third party standards?
  - What is independent value to patient?

Hotlines

- Hotlines (telephone or web-based) may provide information about disease/condition or drug

- Considerations
  - Who staffs hotline (*e.g.*, clinician)?
  - What information is provided?
    - Practice of medicine issues
      - Third party vendor expertise?
    - FDA promotional considerations
    - Application of medical information line guidelines
    - Adverse event reporting
  - How are privacy considerations addressed?
  - What is independent value to patient?

Potential Legal Issues: Anti-Kickback Statute Implications

- Anti-Kickback Statute.
  - Knowingly and willfully offering anything of value in exchange for Federal healthcare business.
  - Criminal statute.
  - Also derivative False Claims Act issues.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- No concern with Beneficiary Inducement Statute.
  - Inducing patients to purchase items or services from a particular provider or supplier.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- OIG's view of PAP.
  - Charitable foundation donations.
    - No manufacturer exerts any direct or indirect influence over the charity.
    - The assistance to beneficiaries is independent from any manufacturer's funding.
    - The assistance is not tied to use of a particular manufacturer's product, or the receipt of items or services from a particular provider.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- OIG's view of PAP *(cont'd)*
  - Assistance is rendered based on reasonable and uniform measures of financial need.
  - Limits on data to manufacturers.
  - BUT aggregate data about the number of applicants needing assistance with respect to a particular disease category is acceptable.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- Outside of Part D.
  - PAP notifies Part D plans to ensure that no payment is made from the Part D plan.
    - CMS data sharing agreement facilitates exclusion of drug utilization from Part D coverage.
  - The assistance is provided during the entire coverage year (or the remainder of the year, if the beneficiary enrolls mid-year).
  - Assistance is available, even if the beneficiary's need is periodic.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- Outside of Part D *(cont'd)*
  - PAP's assistance is accurately documented and capable of verification by the government.
  - Assistance is rendered based on reasonable and uniform measures of financial need.
  - The arrangement complies with any guidance from CMS.
  - Assistance is given without regard to providers or suppliers used by enrollee or Part D plan the beneficiary is enrolled in.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- Coinsurance support issues.
  - ➢ OIG would contend must exclude Federal healthcare program beneficiaries.
  - ➢ However, there still remains potential for "pull-through" allegation.
    - Especially true in buy and bill space.
    - Facts and circumstances-driven.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- Interim PAP.
  - Drugs furnished on a trial basis.
  - OIG deems acceptable, so long as there truly are no strings attached and drug available only for a very finite time.
- Coupons deemed acceptable by OIG, but only if applied to total value and not just to the coinsurance.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- Reimbursement support issues.
  - Only acceptable if no substantial, independent value conferred to physician or patient.
  - For example, benefits investigation should be deemed acceptable if checking only on availability of coverage for drug itself. It would likely be problematic if benefits investigation were to occur for a determination of the coverage of the overall treatment of a patient's illness, and not just the drug.

Potential Legal Issues: Anti-Kickback Statute Implications

(cont'd)

- Reimbursement support issues *(cont'd)*
  - Reimbursement guarantees expressly deemed problematic.
    - But OIG advisory opinions have made exceptions, where: (a) limited in duration; (b) availability of coverage has been made absolutely clear by Medicare; and (c) expense of product has limited purchases.
  - Free advertising of product, on behalf of customers, also deemed problematic.
  - Analytical framework could apply to education support, etc.

Potential Legal Issues: HIPAA

- Purpose is to ensure that covered entities guard the privacy and security of protected health information.
  - Manufacturers are generally not "covered entities" because they do not engage in electronic billing activities.
  - May become business associate by signing a BAA.
    - Obligations are not just contractual, but statutory, including compliance with security rules.
    - Lesson is - - Don't sign a BAA!

Potential Legal Issues: HIPAA *(cont'd)*

- FTC policy
  - FTC considers it a deceptive trade practice for company not to follow its published privacy policies.
  - Need to ensure that privacy policy on website or otherwise circulated to PAP beneficiaries is not too onerous for manufacturer to comply with in the long-term.

Potential Legal Issues: Price Reporting

- Medicaid Drug Rebate Statute liability – Average Manufacturer Price minus Best Price (or, if greater, 23.1%), multiplied by State utilization in a quarter equal rebate liability to a particular State for that quarter.
  - Pricing carries over to 340B (and possibly ASP) as well.

Potential Legal Issues: Price Reporting *(cont'd)*

- Final (but withdrawn) Rule PAP exception.
  - The drugs are given for free without any purchase requirement, or are based on the financial need of low income individuals and families.
  - The amount of the subsidy is determined by a manufacturer, without negotiation with any third party.
  - The entire amount of the free product or subsidy is made available to the individual patient, without any portion of the benefit being conferred on a third party, such as a retail pharmacy.
  - The pharmacy collects either no additional payment, or only a bona fide service fee.

Potential Legal Issues: Price Reporting (cont'd)

- Proposed Rule PAP exception.
  - Rebates and refunds are excludible from AMP and BP if retail community pharmacy does not receive any portion of the discount.
  - Copayment assistance programs are excludible from AMP and BP if they provide "free goods" not contingent on future purchases.

Potential Legal Issues: Price Reporting (cont'd)

- Final (but withdrawn) Rule Coupon exception.
  - The coupon is not contingent upon any purchases by individuals.
  - The amount of the subsidy is determined by a manufacturer, without negotiation with any third party.
  - The entire amount of the free product or subsidy is made available to the individual patient, without any portion of the benefit being conferred on a third party, such as a retail pharmacy.
  - The pharmacy collects either no additional payment, or only a bona fide service fee.

Potential Legal Issues: Price Reporting (cont'd)

- Propose Rule Coupon exception.
  - No impact on AMP or BP if full value goes to patient and no value goes to retail community pharmacy.
- Presumably same rules would apply to "5i" drugs.

Potential Legal Issues: Federal Civil False Claims Act

- Federal Civil False Claims Act (FCA)(31 U.S.C. §§3729 – 3733)
  - Prohibits any person from knowingly:
    - Presenting or causing to be presented a false or fraudulent claim for payment or approval
    - Making or causing to be made or used a false record or statement material to a false or fraudulent claim
  - Scope
    - "Knowingly" requires actual knowledge of the information or deliberate ignorance/reckless disregard of the truth or falsity of the information *but* no proof of specific intent to defraud
    - Claims resulting from violation of federal anti-kickback statute constitute a false or fraudulent claim
  - Civil money penalties ($5,000 to 10,000 as updated for inflation) plus 3 times the damages sustained by the government
  - *Other federal fraud statutes and numerous state analogues exist*

Potential Legal Issues: Federal Civil False Claims Act

(cont'd)

- Potential FCA Application under Government or Whistleblower Theories
  - ➢ False information regarding coverage, coding and other claims submission requirements knowingly provided to physicians or other health care providers submitting claims
    - *Sample Allegations:* Abbott Laboratories FCA action (settled 2003) included allegations that manufacturer counseled healthcare providers to submit to Medicare "unbundled" claims for enteral feeding products purchased under a discounted "bundled" rate from manufacturer. Manufacturer also allegedly distributed to healthcare providers a letter that could be used in the event of a government audit to establish a per-product cost for the bundled products that misstated the purchasing provider's actual cost or failed to mention that the provider obtained some products at no charge

Potential Legal Issues: Federal Civil False Claims Act

(cont'd)

- Potential FCA Application under Government or Whistleblower Theories
  - ➢ Claim results from violation of federal anti-kickback statute
    - *Sample Allegations:* TAP Pharmaceuticals FCA action (settled 2001) included allegations that manufacturer provided kickbacks in the form of free reimbursement consulting services to encourage use of its drug
  - ➢ Off-label promotion resulted in submission of claims for non-covered services
    - *Sample Allegations:* Pfizer Neurontin FCA action (settled 2004) included allegations that manufacturer promoted the drug Neurontin for uses not approved by the FDA and the marketing resulted in Medicaid reimbursement for unapproved uses (which was allegedly not allowed under the Medicaid reimbursement rules of certain states)

Potential Legal Issues: *Sample* Federal Health Care Fraud State

- Health Care Fraud Statute (18 U.S.C. § 1347)
  - Prohibits any person from knowingly and willfully engaging in scheme or artifice in connection with the delivery of or payment for health care benefits, items, or services:
    - to defraud any health care benefit program; or
    - to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program
  - Scope
    - No actual knowledge of the statute or specific intent to commit a violation needed
    - Health care benefit program is any public or private plan under which any medical benefit, item, or service is provided
    - Scheme or artifice to defraud is not defined but most formulations require an intent to deceive. *See, e.g., U.S. v. Sawyer,* 85 F.3d 713, 732 (1st Cir. 1996)
  - Damages
    - Fines or imprisonment (10 to life (depending on injury)) or both

Potential Legal Issues: Federal Promotional Restrictions

- Generally
  - Federal Food, Drug and Cosmetic Act and implementing regulations restrict how a manufacturer promotes its drug product
  - Patient support program activities undertaken directly by manufacturer or indirectly through third party vendors may be subject to restrictions

Potential Legal Issues: Federal Promotional Restrictions

(cont'd)

Potential Legal Issues: Federal Promotional Restrictions

(cont'd)

- Advertising: On-label or unbranded
- Educational Materials and Patient Tools: On-label or unbranded
- Hotlines:
  - On-label or unbranded
  - Respond to off-label questions (subject to uncertainty regarding unsolicited request)?
  - Same restrictions as medical information lines?
- Reimbursement Support Programs:
  - On-label
  - Off-Label
    - ✞ Respond to off-label questions (subject to uncertainty regarding unsolicited request)?
    - ✞ Promotion or scientific exchange?
- Patient Assistance Programs:
  - Limit support to on-label indications (physician or patient certify use)?
  - Offer drug to all patients without limits (physician certify medical necessity only)?

Potential Legal Issues: Common Law

- Tortious Interference with Contractual Relations
  - Common law tort
    - Improper interference by third party with contractual relationship of contracting parties
    - Third party improperly induces one party to a contract not to fulfill its obligations causing damage to other party
  - Contract between health plan and member
  - Potential argument that the structure of a patient support program could be interpreted as undermining the health plan's benefit design
    - Knowledge/acceptance of health plan mitigates
  - *Copayment assistance*
  - *Note*: Health plan may also revise benefit design (*e.g.*, increasing copayments or imposing prior authorization requirements) rather than bring legal action

Potential Legal Issues: State Regulation of Drugs and Marketing

- State Laws Governing Drug Coupons/Discount Cards
  - Some states regulate the provision of "discount cards" or other purchasing mechanisms that offer patients access to discounted prices on drugs
    - Laws may require that the cards or advertising surrounding the cards meet certain requirements/contain certain information (*e.g.*, card is not insurance)
  - Some states regulate or prohibit the provision of drug coupons
    - Laws may prohibit drug coupons altogether or provide that can only be distributed by or to certain parties
  - *Copayment assistance or free drug coupons*

Potential Legal Issues: State Regulation of Advertisements

- State Laws Regulating Direct-to-Consumer Advertising of Drugs
  - Some state laws regulate the advertising of drugs directly to consumers
    - Prohibit advertising of drugs for certain conditions
    - Require that the advertisements not be false or misleading
    - Require that advertisers be licensed/registered
  - Advertising of patient support activities referencing drug (and some limited oversight of unbranded disease awareness advertisements)
  - *Note:* Manufacturer would need to be aware/in compliance for general advertising of drug

Potential Legal Issues: State Professional Regulation

- State Corporate Practice of Medicine Laws
  - States generally impose some limitation on the ability of a business corporation to practice medicine or employ/contract with physicians and/or other clinical professionals to practice medicine
  - States limit how licensed professionals (including physicians and other nonphysician licensed professionals) can organize and provide services
  - Not issue if practitioners are not practicing medicine/nursing
  - *Employing/contracting with practitioners to staff hotlines*

Potential Legal Issues: State Professional Regulation

(cont'd)

- State Health Care Professional Licensure Laws
  - States generally prohibit the practice of medicine (or provision of clinical care) by individuals who are not licensed to provide such care
  - Individuals licensed in one state who provide care remotely to patients in another state could implicate state licensure laws
  - Not issue if practitioners are not providing care
  - *Operation of hotlines*

Potential Legal Issues: State Consumer Protection

- State Consumer Protection Statutes
  - State consumer protection statutes may prohibit unfair or deceptive acts or practices by businesses involving consumers
    - General prohibition/specific practices identified
  - Attorney generals typically have wide discretion in interpreting
  - Private plaintiffs may use
    - *Example:* Kaiser lawsuit against Pfizer for Neurontin marketing practices included allegation that practices violated the California Unfair Competition Law
  - *Broad scope of general prohibition permits wide latitude in application (or attempted application)*

Recent Litigation: Overview

- Recent Litigation Focuses on Patient Support Programs

- *Qui Tam* Litigation
  - Includes allegations involving reimbursement support programs
  - FCA, off-label promotion, anti-kickback statute

- Private Class Action Litigation
  - Focus on copayment assistance programs
  - Structure of programs

Recent Litigation: Qui Tam Litigation

- Allergan Allegations (2010 Settlement)
  - Company provided reimbursement support services to physicians to maximize reimbursement for off-label uses of Botox
    - Claims review and analysis, cost recoveries, presentations involving off-label coverage discussions
    - Hotline to instruct physicians on billing requirements to ensure a "clean claim"
  - Company operated reimbursement hotline through third party vendor to assist physicians in obtaining reimbursement for off-label uses of Botox
    - Drafting letters and providing supporting packets of off-label studies
  - *United States v. Allergan, Inc.*, No. 10cr00375 ODE (N.D. Ga. filed Sept. 1, 2010) and *United States ex rel. Beilfuss v. Allergan, Inc.*, No. 08cv1833 TWT (N.D. Ga. filed May 22, 2008)

Recent Litigation: Qui Tam Litigation *(cont'd)*

- Genentech Allegations (2011 Settlement)
  - Company provided reimbursement support services to providers in connection with denials of coverage for off-label uses of Rituxan
    - Assist with appeal from third party payor denial
    - Provide free doses of drug if appeal is unsuccessful
  - *United States ex rel. Underwood v. Genentech*, Inc., No. 03cv3983 PD (E.D. Pa. filed July 3, 2003)
- Eisai Allegations (Ongoing)
  - Company reimbursement support program for Ontak was a kickback because guaranteed reimbursement for off-label uses
    - Reimburse providers through credit invoice if third party payor denied coverage
    - Coach providers on claims submission for off-label uses
  - *United States. ex rel. Keeler v. Eisai, Inc.*, No. 09cv22302 KMW (S.D. Fla. filed Aug. 4, 2009)

Recent Litigation: Qui Tam Litigation *(cont'd)*

- Pfizer (Pharmacia) Allegations (Ongoing)
  - Company reimbursement support program for Genotropin was kickback to physicians because helped physicians obtain new patients and undertook tasks that physician or staff would otherwise have to do
    - Ensuring physicians/staff provide information necessary for coverage and assist with follow-up
    - Providing access to drug before coverage approval complete
  - *Note*: Court indicates that program was ***not*** a kickback in summary judgment opinion (now under appeal)
    - Oral arguments in May, 2012
  - *United States ex rel. Rost v. Pfizer*, No. 03cv11084 PBS (D. Mass. filed June 5, 2003)

Recent Litigation: Private Class Action Lawsuits

- *New England Carpenters Health and Welfare Fund v. Abbott Laboratories*, No. 12-01662 (N.D. Ill. filed March 7, 2012)
- *New England Carpenters Health and Welfare Fund v. GlaxoSmithKline*, No. 12-01191-CDJ (E.D.Pa. filed March 7, 2012)
- *New England Carpenters Health and Welfare Fund v. Astrazeneca*, No.12-01192-PD (E.D.Pa. filed March 7, 2012)
- *Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Merck & Co.*, No. 12-01379-PGS-LHG (D.N.J. filed March 7, 2012)
- *Plumbers and Pipefitters Local 572 Health and Welfare Fund v. Novartis Pharmaceuticals Corp.*, No. 12-01403 (D.N.J. filed March 7, 2012)

Recent Litigation: Private Class Action Lawsuits *(cont'd)*

- *American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan and Sergeants Benevolent Association Health and Welfare Fund v. Amgen, Inc. and Pfizer, Inc.*, No. 12-2237 (S.D.N.Y. filed March 27, 2012)

- *American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan and Sergeants Benevolent Association Health and Welfare Fund v. Bristol-Myers Squibb Co. and Otsuka American Pharmaceutical, Inc.*, No. 12-2238 (S.D.N.Y. filed March 27, 2012)

Recent Litigation: Private Class Action Lawsuits *(cont'd)*

Recent Litigation: Private Class Action Lawsuits *(cont'd)*

- Core Factual Allegations
  - Co-pay "subsidy" programs increase the overall burden of *private* health plans in providing benefits to members because the programs:
    - Apply to individuals who are privately insured under a prescription drug plan that requires personal cost sharing by the member for drug
    - Undermine the contractual insurance arrangement between the plans and the plans' members by reducing or eliminating the personal cost-share feature of the insurance contract
    - Cause the plans to pay for more units of expensive co-pay subsidy drugs than plans would have if the defendants had not interfered with the parties' performance of the contract
  - Co-pay "subsidy" programs also function as secondary insurance but do not comply with regulatory requirements for such insurance

Recent Litigation: Private Class Action Lawsuits *(cont'd)*

- Core Factual Allegations
  - Health plan member presents card to pharmacy along with health insurance card
    - Primary insurance is processed first
    - Co-pay card or coupon is processed second and entered into the computer as if it were a form of secondary insurance
  - Pharmacist determines the amount to be paid by the manufacturer and sends that information to an administrator who then reimburses the pharmacy on behalf of the manufacturer
  - Pharmacist charges the health plan the full amount of its usual payment for the branded drug and the health plan is not informed that a subsidy has been provided

Recent Litigation: Private Class Action Lawsuits *(cont'd)*

- Legal Allegations
  - ➢ Racketeering Influenced and Corrupt Organizations Act ("RICO")
    - Manufacturers (acting through third party vendors) defrauded health plans by interfering with cost-sharing provisions established by health plans
      - ✞ Health plans are paying for brand name prescriptions for which plans would not otherwise have had to pay
      - ✞ True cost for reimbursement of the routinely subsidized drugs is less than the amount represented by the manufacturers and pharmacies so that amount paid by plans is inflated
    - Manufacturers (acting with pharmacists) defrauded health plans by reporting and charging benchmark prices at the time of sale to health plans while failing to account for routine waiver of co-pays
    - Both alleged frauds were committed with others and accomplished through US mail and wire transfers

Recent Litigation: Private Class Action Lawsuits *(cont'd)*

- Legal Allegations
  - Robinson-Patman Act (15 U.S.C. § 13(c))
    - Seller cannot lawfully pay anything of value to someone who makes a decision to purchase a product that is paid for by another
    - "Subsidizing" co-pays to induce purchase of brand name drugs instead of less expensive alternatives causes payors to pay more for branded drugs
      - Co-pay subsidy is compensation
      - Consumers act on behalf of health plans
      - Consumers are not told that payors pay more for brand name drugs

Recent Litigation: Private Class Action Lawsuits *(cont'd)*

- Open Issues
  - ➢ Groundwork Laid for Other Causes of Action?
    - Illegal Kickbacks
      - ✞ Government health benefit programs/states with restrictions
      - ✞ Allegations that claims processed although purportedly excluded and manufacturers knew
    - Insurance Fraud
    - Unregulated Practice of Insurance
    - Consumer Protection
  - ➢ AWP Litigation as Precursor?

Summary Considerations

- PAPs.
  - Carefully consider OIG guidance.
  - Ensure that logistics and policy mesh.

Summary Considerations *(cont'd)*

- Coinsurance support.
  - If not excluding Federal healthcare beneficiaries, consider what makes circumstances unique.
  - Be particularly circumspect in "buy and bill" space, even when dealing with non-governmental payers.
    - Means testing?
    - Limit to labeled indication?
    - Payment to patient, not physician?
    - What does your email traffic say about motivation?

Summary Considerations *(cont'd)*

- Reimbursement Support.
  - Are you replacing a core service?
  - Owner Manual approach
- A lion can still attack a single zebra even if It's running in a herd.

General Guidance

- Era of Uncertainty
  - Application of certain federal and state laws uncertain
  - Significance of private class action lawsuits uncertain
  - Compliance *plus* avoidance of appearance of noncompliance
- Tailored Approach
  - Assess Risk
    - Nature of drug
    - Market/competition
    - Eligible patients
    - Range of support services to be offered
    - Structure of support services
  - Implement Risk Management Strategies
    - *Appropriate action often depends on specific facts and circumstances*

General Guidance *(cont'd)*

- General Principles
  - ➢ Information about programs publicly available
    - Ensure public *but* avoid targeted advertising that could raise concerns depending on nature of programs (*e.g.,* focus on federal health care program beneficiaries or on populations for which drug use would be off-label)
  - ➢ Focus on assisting patients (not physicians or other providers)
    - Patient awareness of condition
    - Patient access to drug
    - Patient health and safe and compliant use of drug
  - ➢ Compliance with FDA promotional restrictions
  - ➢ Consider overall/cumulative "value" of patient support initiatives

General Guidance *(cont'd)*

- General Principles
  - Compliance with OIG guidance where available
  - Auditing and monitoring programs to ensure compliance with requirements/restrictions
  - Contractual obligations on third party vendors
    - Standard of care
    - Reliance on expertise
    - Compliance with law
    - Indemnification and insurance

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