Mini Summit VI: Compliance Considerations in Patient Support Programs

November 4, 2014

Alison J. Fethke, Ropes & Gray LLP
Bradford J. Patrick, AbbVie Inc.
Ronald L. Wisor, Hogan Lovells US LLP

Agenda

- Patient financial support
  - Copay assistance update
  - OIG Advisory on Independent Charity PAPs
- Patient support program services
- Privacy aspects
- Case study

Patient Financial Support

Ron Wisor, Hogan Lovells US LLP
ron.wisor@hoganlovells.com
(202) 637-5658

Forms of Financial Support

- Copay coupons and savings programs
- Copay and premium assistance through independent charities
- Free product
  - Samples and free trial vouchers
  - “Quick start,” “bridge” and other “access” programs
  - Indigent Patient Assistance Programs (PAPs)

Compliance "Rules of Thumb" for Patient Financial Support

- Exclude federal program patients from copay programs
- Grants to bona fide independent charities may be used to *indirectly* support Part D copays or premiums
- Free product vouchers should –
  - Be for limited trial use
  - Not require ongoing use of the product
  - Be avoided for drugs with barriers to switching (at least for federal program patients)
  - Advise patients, pharmacist and prescriber not to seek reimbursement
- Free product PAPs should operate entirely outside the Part D benefit
  - Potential exceptions for cases of urgent clinical need?

Copay Coupon Class Actions

- Filed in March 2012 by four health and welfare funds in four different federal courts against nine drug manufacturers
  - S.D.N.Y., N.D. Ill., E.D. Pa., D.N.J.
  - Abbott, Amgen, AstraZeneca, BMS, GSK, Merck, Novartis, Otsuka America and Pfizer
- Legal Claims
  - Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1961 *et seq.*
  - Robinson-Patman Act commercial bribery, 15 U.S.C. § 13(c)
  - Tortious interference

The Plaintiff's RICO Allegations

- Based on 2 predicate acts (mail fraud and wire fraud) and 3 fraud theories –
  - *Misrepresentation Theory*: Caused pharmacists to misrepresent true charges by not accounting for copay subsidies
  - *Waiver Theory*: Routine and undisclosed copay waivers a scheme to defraud
  - *Benchmark Theory*: Manufacturers reported fraudulent benchmark prices (WAC and AWP) to reporting services that did not account for copay subsidies

Favorable Ruling on BMS's Motion to Dismiss

- In June 2013, District Court (SDNY) dismissed almost all of plaintiffs' allegations *with prejudice* –
  - Found the BMS program "open and notorious"
  - "[T]he mere existence of the BMS copay subsidy program is not a fraud on anyone because it involves no element of deception"
- On the Benchmark Theory only, granted leave to amend to add the requisite particularity (i.e., the "when, where and how" of the alleged scheme)

BMS Court: Plaintiff's Theories Fail as Matter of Law

- On the Misrepresentation Theory
  - No false statements that "an insured paid the co-pay unaided by a co-pay subsidy program"
  - Statements that patients satisfied copay no more deceptive than if patient got the money from "his rich uncle or a stranger on the street"
  - Failure to disclose subsidies cannot be fraud by omission absent a contractual duty to disclose
- On the Waiver Theory
  - Court found there "is not *actually* any waiver" because full copay collected every time, from either patient or manufacturer
- On the Robinson-Patman/Commercial Bribery Claim
  - No allegations of contractual or other duty owed by patients to insurers, rejecting claim that insured patients are agents of their insurer

Merck Case Survives Motion to Dismiss

- In June 2014, District Court (NJ) dismisses the RICO claims against Merck
- But allows a tortious interference claim to go forward because plaintiff alleged that PBM contracts with pharmacies required the collection of copays "directly from patients"
  - Sole basis for that allegation appears to be a single PBM manual that defines a copay as "[t]hat portion of the total charge for each prescription drug which a Member is required to pay the Pharmacy in accordance with the Member's Prescription Drug Program"
  - Plaintiff will have to spin that into contractual requirement to collect copays from directly from patients to avoid summary judgment

Beware of Growing Self-Help by Insurers

- To prohibit use of coupons by contracts or other means, such as
  - Prohibitions on coupon use by network pharmacies (e.g., UnitedHealth for specified drugs)
  - Contract provisions like the following:

> *Interference Utilization. Company shall not interfere with Payer A's claim adjudication process through programs developed by, administered by or through participation in by, Company or any third party working on behalf of Company and/or representing any Company Products. Such programs shall include but are not limited to co-pay card programs, or other programs with the intent of encouraging, through incentives directed to a Participant or a Provider, (i) the use of non-Formulary products, or (ii) directing the claim to another vendor (collectively "Interference Utilization"). Company shall pay Payer A an amount equal to the Rebate that would have been paid by Company to Payer A on the Interference Utilization had it been adjudicated by Payer A…Non-payment of a Rebate on Interference Utilization shall be a material breach of the Agreement and cause for Payer A to terminate the Agreement pursuant to _____.*

Exclusion of FHCP Beneficiaries

- OIG has made clear that manufacturer copay assistance to FHCP beneficiaries is impermissible under the AKS
- September 2014 OIG Special Advisory Bulletin & Report
  - Warns manufacturers they bear ultimate responsibility to administer coupon programs in compliance with law
  - Failure to take appropriate steps to ensure that copay coupons do not induce the purchase of drugs through FHCPs may be evidence of intent to induce within the meaning of the AKS
  - Report reviewed effectiveness of safeguards manufacturers have in place to ensure Part D beneficiaries do not use copay coupons
- Coupon lawsuits allege Medicare Part D and and managed Medicaid beneficiaries mistakenly report themselves eligible, and manufacturers don't enforce limitation

Increased Due Diligence to Assure FHCP Eligibility Restrictions

- More consistent notice of eligibility restrictions in all coupon promotions
- Vigilance by internal/external HUBs that undertake insurance verification
- Require pharmacies that administer coupons to confirm they have done an E1 review prior to use
- Use vendors that use BIN/PCN and benefit stage review prior to allowing use of coupons
- Require same process for each refill
- Audit HUB/vendor performance
- Tighten procedures for self-certification

Copay Coupons and ACA Exchange Patients

- In October 2013, then-HHS Secretary Sebelius wrote to Congress that HHS had concluded, in consultation with DOJ, that qualified health plans (QHPs) purchased through Affordable Care Act Exchanges are not "federal health care programs"
  - Thus, the provision of copay assistance to QHP patients would not be prohibited by the AKS
- In a November 4, 2013 FAQ, however, CMS –
  - Expressed concern that support of QHP enrollee cost sharing by "commercial entities" could skew the insurance risk pool
  - Stated that it "discourages" this practice and "encourages" QHPs to reject such third party payments
  - Indicates it intends to monitor this practice and, if necessary, take action
- CMS since has indicated that the FAQ does not apply to cost sharing payments from –
  - Indian tribes and tribal organizations
  - State and federal government programs or grantees (such as the Ryan White HIV/AIDS Program)
  - Not-for-profit foundations that make payments "based on financial status and do not consider enrollees' health status"

Independent Charity PAPs

- In response to recent controversy and public scrutiny of support provided by manufacturers to certain charities, in May 2014 OIG issued a supplemental Special Advisory Bulletin identifying two types of arrangements that will draw its scrutiny –
  - Disease funds limited to a subset of available products, rather than all approved products for the treatment of the disease state
  - Disease funds that cover only one product or the products of a single manufacturer that is a significant donor to the fund
- In the SAB, OIG also –
  - Cautions against overly generous financial need criteria
  - Warns that actions by donors to correlate PAP funding with support or their own products implicates the AKS
  - Indicates that previously issued advisory opinions may require modifications to be consistent with the updated guidance

Patient Support Program Services

Alison Fethke, Ropes & Gray LLP
Alison.Fethke@ropesgray.com
312-845-1320

PAPs– Support Services

- In addition to financial support, Benefits/ Services may include:
  - Educational Materials
  - Reimbursement Support
  - Nurse Support/Hotline
  - Case Management
  - Injection Training
  - Patient Mentoring
  - Sharps Disposal/Cold-Packs
  - Appointment & Medication reminders
  - Physician Locators

PAPs– Support Services

- Potential Risks/Legal Considerations
  - Anti-Kickback Statute/OIG Guidance identify key criteria in evaluating support services:
    - Do they provide any independent value to the referring physician?
    - Has the patient already selected the product?
    - Are they available equally to all patients and physicians?
    - Will they increase in utilization/costs?
    - Are they of nominal value ($10/$50 annual aggregate)?
    - Are they advertised?
    - Are any benefits in the form of cash?
    - Are they clinically justified?

PAPs– Support Services

- Potential Risks/Legal Considerations
  - FDA Promotional Regulations
    - Are support program materials promotional or non-promotional?
  - FCA/Off-Label considerations
    - Should the program be limited to on-label patients?
  - State Professional Licensure Requirements
    - Phone-based or in-person nursing services
  - State Corporate Practice of Medicine Laws
  - Privacy Laws

PAPs– Support Services

- Reimbursement Support Services
  - Reimbursement information typically provided about coding, coverage and payment
  - Assistance may also include:
    - Assessing coverage options and/or verifying coverage
    - Obtaining prior authorization
    - Assisting with appeals
    - Referrals to independent foundations/charities
  - FCA/Off-Label concerns raised by scope of reimbursement support
    - *Allergan* (2010) –support services (including hotline) to maximize reimbursement for off-label uses of Botox
    - *Genentech* (2011) – support services to appeal denials and provide free drug if appeal unsuccessful

PAPs– Support Services

- Best Practices and Questions to Consider
  - Tailor your program to your specific drug
  - Keep the focus on patients, and make available to all eligible patients (avoid targeting subsets)
  - Consider the cumulative value of all program benefits
  - Ensure the program requirements/guidelines and logistics are in sync
  - Consider auditing and monitoring to ensure compliance with program requirements
  - Vendors & Third parties – ensure compliance through contractual obligations
  - *Are your support services replacing a core service for the physician and/or office?*

Privacy Aspects – Compliance Side: Patient Support Programs

Bradford J. Patrick, Esq.
Brad.Patrick@abbvie.com
847-937-5588
@attorneybp

Today's Presentation

- This presentation is intended to aid discussion for continuing legal education purposes & is not legal advice
- I am presenting my own views and opinions today. I am not speaking on behalf of AbbVie
- Privacy laws vary by sector, state, country, region and other subdivisions so always consult with an appropriate expert

Outline

- Planning for Compliance Success: Marketing Opt-Ins & HIPAA Authorizations
- Quick Note: PSP & PV
- Quick Note: Global Organizations & the PSP

Planning for Compliance Success: HIPAA Privacy Rule & Marketing

- HIPAA/HITECH Final Rule modified definition of "marketing"; effective Sept. 23, 2013 (78 FR 5566)
  - Marketing= a communication that encourages the purchase or use of a product or service where covered entity receives financial remuneration from a third party for that communication
  - Up until this date, HIPAA formerly allowed covered entities to send communications discussing a particular drug or biologic without patient authorization, even if paid by third party

- Two Key Exceptions: How does your client look?

Planning for Compliance Success: "Currently Being Prescribed"

- Authorization not required for refill reminders and other communications about **a drug or biologic that is currently being prescribed** for the individual, *provided* any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication (no profit allowed)
  - "Currently being prescribed" not defined (prescription's validity period?)
  - Drug/Biologic Being Marketed: Does it need to be same active ingredient(s), dose, strength, and route of administration?

- "[W]here [a] drug manufacturer also provides [a] pharmacy with a financial incentive beyond the cost of making the communication to encourage the pharmacy's continued willingness to send such communications on behalf of the drug manufacturer, the exception would not apply and the pharmacy must obtain individual authorization." (78 FR 5597)

Planning for Compliance Success: Using Face to Face Exception

- Communications made face-to-face by a covered entity to an individual are permitted without authorization
  - Covers both verbal and written communications
  - Does not apply to communications over the phone, by email, or by postal mail

Planning for Compliance Success: Evaluate Today's Opt-In vs. Future

- I authorize [MANUFACTURER] and its contractors to use and/or disclose the personal health information I supply ("Personal Information") to (1) provide me with [NAME OF DRUG] informational and marketing materials via **SMS**, e-mail, direct mail, and/or telephone; (2) help improve, develop, and evaluate products, services, materials, and programs related to my condition or treatment; and (3) **enroll me in [PSP BRANDED NAME]** ("the Program"), **which includes nursing services**…, the option to join [various optional PSP services], **and includes disease management support**; and (4) communicate with me via telephone or e-mail referencing the Program. I understand [MANUFACTURER] and its contractors will not sell or rent **my personal information**, but that it **may be used, disclosed, and/or transferred** to other [MANUFACTURER] locations and/or to [MANUFACTURER'S] contractors **for the purposes described**, or as required by law.

- [Privacy statement link; period of validity; right to cancel and how to cancel; right to receive copy of authorization and privacy statement]

Planning for Compliance Success: Opt-In & Privacy Policy Content

- What's included *and* not included in the marketing opt-in will matter to your client
  - "For the purposes described"
  - What do you know about your vendors that are involved?
- State privacy laws apply – e.g., California 14pt font
- FTC interest: Deceptive trade practice for company not to follow its published privacy policies
  - What's your privacy policy on program website?
  - What privacy policy is given to your PSP enrollees?
- Inconsistencies in opt-in language across organization?
- Opt-In is not equivalent to HIPAA Authorization

Planning for Compliance Success: PSP & Authorization to Disclose

- Manufacturers are typically not covered entities and so HIPAA itself does not impose obligations, *unless* they seek data interaction w/covered entities, bus. associates

- Authorizations, vs. mere marketing opt-in, may be useful where PSP envisions PHI from 3rd party covered entities
  - Pharmacy fill history as PSP input?
  - Records from physician office as part of PSP design?
  - Not foolproof – covered entities may not accept

- Useful for health economics and outcomes research
  - "An authorization for uses and disclosures of [PHI] for future research purposes must adequately describe such purposes such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research." (Final Rule, at 78 FR 5612)

Quick Note – PSPs and PV: Compliance with Safety Reporting

- Involvement of pharmacovigilance in each PSP program operated by the company or its third party vendors

- Ensure appropriate agreements exist for safety data exchange (and auditing) between company & service providers
  - Does vendor have the experience, processes & personnel to enable compliance?

- Audit vendors (pre- and post-retention); audit internal functions

- Ensure appropriate, recurring training relating to safety reporting requirements and compliance with agreements
  - How AE reports will be collected, classified, distributed and managed
  - "Solicited" vs. "Spontaneous" AE reports – can matter legally (causality assessments akin to study reporting)

Quick Note – Global PSPs: Think Global, Act Local?

- Specific safety data processing and reporting obligations
- Myriad of conflicting drug advertising laws
- Collection, use and disclosure of patient and caregiver data must meet applicable local privacy laws and policies
- Transparent, clear & unambiguous in consents with patients & caregivers about intended data collection, use & disclosure
  - Global sharing can carry negative perception
- All required consents must be obtained, *locally*

Panel Case Study: Hypothetical PSP Proposal

Case Study Proposal: Current PSP

- Client markets/sells an innovator drug for treatment of multiple sclerosis that requires PA

- PSP today – 3 core elements:
  - Co-pay program for commercially insured patients that reduces co-pay for most to $5; monthly, annual caps on aggregate co-pay support are in line w/ competition
  - 24/7 Nurse Hotline: Basic product questions & safety
  - Insurance support by phone 9am-5pm that helps patients contact their insurance plans & doctors on coverage issues

- Client wants to increase PSP & calls you

Case Study Proposal: Co-Pay & Voucher Ideas

- Change to have annual & monthly caps higher than competition
- Offer vouchers to patients that are good for one month of drug at no charge (cannot be billed to any payor)
  - Client wants vouchers to be given to patients at any time (new or existing patients)

Case Study PSP Proposal: Insurance/Reimbursement Services

- Client's company personnel or a retained third party will staff an 8am-8pm phone line to assist patients with the process of gaining coverage for the drug
  - Choosing among commercial and federal program plans
  - Benefit verifications, prior authorizations
  - Assisting with claims, appeals
  - Assisting with patient assistance foundation applications
- Same as #1, with assistance provided to physician offices
- Contract with third party vendor to offer online services to physician offices such as benefit verification, prior authorization and e-Prescription

Case Study Proposal: Nursing Services

- 24/7 Nurse Hotline proposal: Nurses to make follow up phone calls to patients to check on product experience, other needs
- Nurse proposal #2: In-home visits to patients
- Nurse proposal #3: Add nurse to patient "free text" email & web chat functionality
- Nurse proposal #4: Add nurse to patient Facetime/Skype

Case Study Proposal: Patient Peer to Peer Network

- Current patients and caregivers can sign up as peer support for new and prospective patients

Case Study Proposal: Physician Office Support

- Provide access for office into client/third party vendor data system so that physician office can log in & see patient interactions with PSP

- Electronic health records: hire vendors to create software integration links between PSP platform and most popular EHR systems to enable interested physician offices to integrate relevant PSP records into office EHR systems

Case Study PSP Proposal: Marketing Contracts

- Contract with third party pharmacies for them to market PSP offerings to prescribed patients and to opt in patients to program by phone or by email confirmation

- Allow physician offices to enroll patients into PSP on their behalf after receiving verbal confirmation from patient that they want to enroll, and/or after receiving written confirmation

Thank You for Attending This Mini Summit Breakout