Legal Considerations for Patient Assistance Programs

March 6, 2014

Robert D. Clark  Seth H. Lundy  S. Craig Holden
Ober|Kaler  King & Spalding  Ober|Kaler
(202) 326-5039  (202) 626-2924  (410) 347-7322
Topics

I. Health Insurance Exchanges and Plans (HIEs) And How They Work.

II. HIEs’ Impact On PAPs And Potential Risks.

III. PAP Developments/Risks and Mitigation Strategies.
I. Health Exchanges And How They Work

• HIEs created under the Affordable Care Act to provide individual and small business marketplaces for health insurance.

• HIEs provide consumers access to information about insurance products and insurance providers.

• Access to information = more competitive market

• Majority of plans offered through HIEs provide coverage for essential health benefits, at a minimum, and meet 1 of 4 levels of plan generosity based on actuarial value.
I. Health Exchanges And How They Work

• Federal regulations, criteria and systems

• HIE primary functions include electronic enrollment, eligibility determinations, individual plan enrollment, plan management, consumer assistance and accountability, and financial management.

• States develop laws, regulations, agencies and systems for state-run HIE

• Federal grants used by states for HIE creation and implementation.
I. Health Exchanges And How They Work

• Qualified individuals and small businesses (will) purchase of health insurance through HIEs.

• Certain individuals receive premium assistance in the form of federal tax credits to offset health insurance cost (affordable care).

• No obligation to enroll in HIE for coverage, and individuals, businesses and insurers may participate in the insurance market outside of HIEs.
I. Health Exchanges And How They Work

• 17 states establish and operate a HIE as a state exchange.

• 26 states and the federal district allow individuals to access the federal exchange operated solely by the federal government (federal HIEs)

• 7 states have a state exchange that is operated by the federal government in partnership with the state (federal-state partnership exchanges).
I. Health Exchanges And How They Work

- State HIE
- Federal HIE
- Federal-State Partnership HIE
I. Health Exchanges And How They Work

Original Timeline

- **Elect State Exchange**
  - Pushed Back – December 14, 2012

- **Certification**
  - Now none - Previously January 1, 2013

- **Elect Federal Partnership**
  - February 13, 2013

- **Set Up Exchanges**
  - October 1, 2013

- **Policies on Open Market**
  - January 1, 2014
I. Health Exchanges And How They Work

• March 31, 2014 – Individual open enrollment ends on HIEs

• Nov. 1, 2014 - Small Business Exchange (SHOP) to open, originally scheduled to open Nov. 1, 2013

• Jan. 1, 2015 - HIEs required to be self-sustaining (?)
I. Health Exchanges And How They Work

• The Good.
  – 12 states have 10 or more insurers enrolled
  – California, Connecticut, Kentucky, and Rhode Island state HIEs successful because state HIEs develop smaller, simpler, consumer-friendly HIEs
  – Connecticut to offer “HIE in a box” to other states
  – “Front end” functions on federal HIE functioning, allows individual electronic enrollment
  – 4 million enrollees in all HIEs combined announced by CMS on Feb. 25, 2014
I. Health Exchanges And How They Work

• The Bad.
  – Federal HIE unable to function Oct. 1, 2013, re-launched Nov. 30, 2013
  – 4 million enrollees out of 28.6 million potential enrollees
  – “Back end” function to pay subsidies to insurers not working

• The Ugly.
  – Maryland Health Connection fires lead contractor, meets enrollment goal after reducing goal by 40% in Feb. 2014
  – CoverOregon unable to process electronic applications as of January 2014, hires 500 people to process paper applications
II. Impact Of HIEs On PAPs
II. Impact Of HIEs On PAPs

• While the advent of HIEs should result in more covered individuals, the resulting level of coverage for these individuals may be decreased, leaving more people in need of co-pay assistance and alternate funding services.

• On a federal level, legal concerns regarding PAPs pertain to issues arising under the federal Anti-Kickback Statute and Civil Money Penalties Statute relating to prescriber and beneficiary inducements.

• These federal statutes apply to inducements relating to items reimbursed under “federal health care programs.”
II. Impact Of HIEs On PAPs

- HIEs are **not** “federal health care programs.”

  - HHS nonetheless raises concerns about the potential for affecting risk pools if providers were to pay or subsidize premiums for enrollees in a manner that steered certain types of enrollees to specific exchange-based plans.
II. Impact Of HIEs On PAPs

• Follow up CMS FAQ

• The Department of Health and Human Services (HHS) has broad authority to regulate the Federal and State Marketplaces (e.g., section 1321(a) of the Affordable Care Act). It has been suggested that hospitals, other healthcare providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces. HHS has significant concerns with this practice because it could skew the insurance risk pool and create an unlevel field in the Marketplaces. HHS discourages this practice and encourages issuers to reject such third party payments. HHS intends to monitor this practice and to take appropriate action, if necessary.
II. Impact Of HIEs On PAPs

• Some in industry continue to seek further clarification or disagreement.
  – Follow up letter of January 31, 2014 from Patient Services, Inc. sent to Secretary Sebelius without response to date.
  – February 12, 2014 letter from Senator Grassley to Secretary Sebelius expressing concern about the interpretation, also without response to date.

• The net result is that, absent further guidance, coverage through HIEs are effectively treated like private health plans.

• Caveat: Senator Grassley is challenging the Administration's interpretation.
II. Impact Of HIEs On PAPs

• Potential Issues Associated With HIEs:
  ➢ HIEs may limit coverage to preferred providers.
  ➢ HIEs may develop their own rules regarding patient assistance, much like Medicaid programs.
  ➢ The HIE or plans operating under the HIE potentially could prohibit patient assistance for covered individuals.
  ➢ Governmental authorities could take a position that assistance for some patients (e.g., those who participate in a HIE) could form an inducement for the prescription of a product in general, including for Federal Health Care Programs.
III. PAP Developments/Risks and Mitigation Strategies
III. PAP Developments/Risks and Mitigation Strategies

• With the advent of the Exchanges and expansion of insurance scrutiny of PAPs is already increasing.

• New media focus brings risks to the forefront.

• Key focus is on whether the PAP is being used to direct patients to a particular manufacturer’s drug.
  - Manufacturer Run PAPs
  - Charitable Foundation PAPs
III. PAP Developments/Risks and Mitigation Strategies

Patient Assistance in the Spotlight:

• Oct 22 2013 Article on Seeking Alpha Financial Website.
  – Focuses on arrangement between a major independent, charitable patient assistance foundation and a donor.
  – Raises questions about patient assistance generally.
    • Characterizes donations as a way to increase sales for manufacturers.
    • Calls into question OIG guidance as a “loophole”.
  – Note that the author had an undisclosed financial position at stake in trying to sell short the donor’s stock.
III. PAP Developments/Risks and Mitigation Strategies

Oct 22 2013 Article (Cont’d)

• Issues raised:
  – Size of the foundation and dollars involved.
  – “Co-pay assistance donation dollars are largely solicited from pharmaceutical and biotech companies whose expensive drugs are then purchased with those same donations.”
  – 80% of its donations come from just two drug companies.
  – Whether the foundation is sufficiently transparent as a charity
  – Degree of independence of the foundation and board
    • Focus on related services and consulting agreements of directors and managers
  – Co-operation of an Assistance Fund and a pharmacy
  – Propensity of single-drug funds
    • Ability to direct donations toward coverage for a donor’s products
III. PAP Developments/Risks and Mitigation Strategies

December 18, 2013 New York Times article: Shake-Up at Big Co-Pay Fund Raises Scrutiny on Similar Charities (by Andrew Pollack)

- Focuses on the same major independent, charitable patient assistance foundation
- Raises questions about patient assistance industry as a whole
  - “The bulk of the contributions to these charities come from the pharmaceutical companies themselves. The foundations not only help hundreds of thousands of patients a year, they also raise drug company sales and profits.”
- Acknowledges that the donations are legal, as long as they are not directed to pay for the donor’s own drugs
- Tracks many of the same issues as the Seeking Alpha article
III. PAP Developments/Risks and Mitigation Strategies

Implications of Media Attention

- Main stream media focus put spotlight on donors
- Raises issue that not all patient assistance programs and foundations are created alike
  - The level of compliance matters
- While the media focus was on patient assistance foundations, the same issues are present (in spades) with manufacturer operated assistance programs
- Media attention may lead to government interest:
  - Congressional investigations
  - OIG investigations
  - More limitations in OIG advisory opinions
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Run PAPs: A Current Look

➢ Risk Areas:

» PAP may be viewed as providing financial advantage to the manufacturer’s drug over competing drugs that induce its prescription.

» Could be seen as increasing costs to Medicare Part D or other payment programs by reducing enrollees’ incentives to locate and use less expensive, equally effective drugs.

» If PAP is marketed, it could be seen as a way to steer enrollees to particular drugs.
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Run PAPs (Continued)
  ❖ Control by manufacturer over the PAP criteria could be used to give preference to certain types of patients or prescribers that are more lucrative to the manufacturer (e.g., by having broad patient need criteria that exclude few patients and restricting coverage to those with insurance).
  ❖ See OIG Advisory Opinions: 06-14, 06-21 and 07-04.
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Run PAPs (Continued)

   ➢ Keys for Compliance:
     ❖ Provide assistance entirely outside of the Medicare Part D program.
     ❖ Limit to drugs that are not eligible for coverage under Medicare Part B, but which may be eligible for Part D coverage.
     ❖ Patient financial need should be determined in a reasonable, uniform, consistent manner.
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Run PAPs (Continued)

  ❖ Outlines OIG’s position on how pharmaceutical and independent charity PAPs and PAPs operating outside of Medicare Part D should be structured.

➢ OIG Advisory Opinions (e.g., 06-14, 06-21 and 07-04).
  ❖ Issued by Office of Chief Counsel to the Inspector General.
  ❖ Accessible online at http://oig.hhs.gov/compliance/advisory-opinions/index.asp.
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Supported Charitable Foundation PAPs: A Current Look

**Benefits of Charitable Donations**

“We accept that the majority of donors who make contributions to tax-exempt organizations and the majority of tax-exempt entities that solicit or accept donations – including donors and recipients with ongoing business relationships with one another – are motivated by *bona fide* charitable purposes and a desire to benefit their communities. . . . A business relationship between a donor and recipient does not make a tax-deductible donation automatically suspect under the AKS. On the other hand, a donation made for the purpose of inducing the recipient to refer Federally payable business to the donor would violate the Anti-Kickback Statute, regardless of whether the donation was direct or passed through an intermediary.”

- OIG Advisory Opinion 10-19 at 6–7
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Supported Charitable Foundation PAPs (Continued)

➢ Risk Areas:

✓ Charity may serve as an improper conduit for donors to provide funds to patients using the manufacturer’s products if funds are established for single product or single manufacturer disease states.

✓ Earmarked donations and narrowly-defined disease categories may effectively steer Medicare beneficiaries to particular products based on the availability of a subsidy.

✓ Even funds run by a charity may function as a co-pay waiver for all or nearly all patients using the donor manufacturer’s drug.
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Supported Charitable Foundation PAPs (Continued)

  ❖ Key risk factors include:

  ☐ Funds that include only a single eligible drug.

  ☐ Funds where the only donor is the manufacturer whose drug(s) constitute the vast majority of prescriptions of eligible drugs in the fund.

  ☐ Funds that in practice provide assistance to patients using only one drug.

  ☐ Open donations by manufacturers that provide unlimited donations for funds that cover predominantly or exclusively that manufacturer’s drugs.
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Supported Charitable Foundation PAPs (Continued)

➢ Resources: OIG Advisory Opinions 07-06 (and 2011 Modification), 07-11, 07-18 (and 2011 Modification), 08-17, 09-04, 10-06, 10-07, 10-12, 11-05.
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Supported Charitable Foundation PAPs (Continued)

➤ Keys for Compliance:

▶ Have an independent, bona fide charitable organization interposed between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing funding or benefit to any donor (so that the donation is unlikely to influence selection of provider, practitioner, supplier, product, insurance plan).

▶ Ensure that donors are not in a position to exert direct or indirect control over the organization and its program (organization has absolute, independent, and autonomous discretion as to use of contributions).
III. PAP Developments/Risks and Mitigation Strategies

• Manufacturer Supported Charitable Foundation PAPs (Continued)

- Structure charitable fund funds in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.
  
  ✓ “In rare circumstances where there may only be one product relevant to an otherwise properly delineated fund or only one manufacturer (including its affiliates) that makes all of the products relevant to an otherwise properly delineated fund, [the organization should certify that it] will use best efforts to cover additional products and manufacturers as they become available.” (Advisory Opinion 07-04 at 5 n.4).

- Ensure equal eligibility for patients based on reasonable, verifiable, uniform measure of financial need applied in consistent manner.
III. PAP Developments/Risks and Mitigation Strategies

• Key Takeaways

  ❖ PAPs are a recognized patient resource that will continue
  ❖ PAP reach should be unaffected by HIEs
  ❖ Nonetheless, PAPs will continue to face risks and scrutiny, so careful structuring and application is essential
Questions?