

Schaner & Lubitz, PLLC

Venture Philanthropy Legal Report Spring 2014 #4

Disease Foundation Patient Assistance Programs: A Valuable Way To Help Patients That Must Be Done Right

Disease foundations searching for ways to ameliorate increasing health care burdens on their patient constituents often consider forming patient assistance programs (PAPs), which provide financial relief to needy patients. PAPs independently sponsored by disease foundations can accept contributions from pharmaceutical, biotechnology and health care companies. Such independently sponsored PAPs can help patients who receive insurance through federal government programs and are thus unable to take advantage of assistance provided by health care company sponsored PAPs.

However, there are tricky legal requirements to be met before an independent charity PAP can accept donations from companies offering health care products and services. Careful attention must be paid to these requirements from the outset.

We have extensive experience structuring, advising, and obtaining government approvals in this area. We also represent entities before offices of inspectors general, including the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG), which is the lead government entity in enforcing the legal requirements discussed in this article. We offer this article as a distillation of our navigation of the process by which the federal government reviews and approves a properly designed and operated PAP.¹

1. How Do PAPs Operate?

PAPs provide assistance to needy patients by helping them obtain necessary health care products and services. PAPs frequently operate in the chronic and terminal disease sectors, where patients are the neediest and for whom the high cost of medical care can be a debilitating obstacle. Some PAPs are sponsored directly by manufacturers of health care products or providers of health care services. These PAPs cannot provide assistance to patients who receive health insurance through any government program.

PAPs independently run by charities can provide such assistance to all needy patients, including patients receiving health care insurance through the government. As discussed further in this article, particularly in Section 7, disease foundation PAPs usually must be limited to providing financial assistance. Co-pay support for products and services are the most frequent type. Premium and deductible assistance, and direct financial reimbursement to patients, also can be features of disease foundation PAPs. However, to pass scrutiny, independent charity PAPs must meet certain criteria, which are discussed below. These criteria generally are identified below, in Section 5.

2. Federal Law Applicable To PAPs

The federal Anti-Kickback Statute (AKS), a criminal law, and its non-criminal companion, the Civil Monetary Penalties Law (CMP), demand that PAPs not participate directly or indirectly in steering patients who participate in any health care insurance program involving federal tax dollars toward any particular health care product or service. The AKS makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program, including Medicare and Medicaid. The CMP imposes fines and other administrative penalties on any person who offers or transfers remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence the beneficiary to order or receive from a particular provider, practitioner, or supplier any item or service for which payment

¹ The application of our experiences and recommendations as described in this article may well be different when they are applied to particular disease foundations and PAPs. None of the observations or recommendations in this article may be taken as legal advice.

may be made, in whole or in part, by Medicare or a State health care program.

A PAP receiving financial contributions from companies selling products or services reimbursable by a federal health care program risks accusation that it could be in violation of the AKS or the CMP, if the PAP in any way could be perceived as influencing a patient's choice of products or services toward those of any donor or any donor affiliates. PAPs that run afoul of the AKS or the CMP are subject to severe penalties. We discuss these penalties more in Section 9.

3. Two Kinds Of PAPs²

Many PAPs are operated by pharmaceutical and other companies in the health care industry. Such PAPs are viewed by the federal government as incapable of passing AKS and CMP scrutiny, because they steer patients toward health care products or services manufactured or sold by the PAP sponsor.

Independent charities, however, are not subject to the same automatic taint that manufacturer PAPs carry. As long as charity managed PAPs are truly independent of any manufacturer or provider of health care products or services, a PAP can receive and dispense financial assistance to eligible patients, even if the assistance originates from pharmaceutical manufacturers and other providers of health care products and services. True independence for purposes of the AKS and CMP is determined according to specific facts and circumstances. Consequently, many disease foundations, and potential donors from the health care industry, may be unwilling to involve themselves in an independent charity PAP without assurance that they are not going to violate the law.

4. The Value Of A Favorable Advisory Opinion

Fortunately, the federal government provides a means by which PAPs may pre-clear their programs to avoid violation of the AKS and CMP.³ Through a process that culminates in a federally issued advisory opinion, PAPs may petition the HHS OIG for individual review and approval of a PAP. Advisory opinions only may be relied upon by the particular entity that petitions and receives favorable approval. Thus, each independent charity considering whether to sponsor and operate a PAP also should think about whether it should go through the process to obtain a favorable advisory opinion.

The process is a long one, but a positive result can be extremely beneficial. A PAP that receives a favorable advisory opinion receives assurance that OIG will not seek to prosecute the PAP under the AKS or CMP as long as the PAP is operated according to the rules disclosed to and approved by OIG. By issuing a favorable advisory opinion, OIG is certifying that the risk of violating the AKS and CMP is minimal and thus acceptable such that no prosecution effort will be made, as long as the PAP operates according to the facts disclosed to and approved by it. A favorable advisory opinion can be a very attractive advantage to a PAP, particularly one that intends to approach potential donors from the health care industry.

5. OIG Endorsement Of Independent Charity PAPs

Independent charity PAPs have existed since at least the late 1990s. They received a boost when, in 2005, in connection with the expansion of Medicare to cover prescription drugs under Part D, the HHS OIG published a Special Advisory Bulletin explaining how independent charity PAPs receiving financial donations from for-profit entities that sell health care products and services appropriately can play a role in assisting financially needy patients.

<http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf>

Through its 2005 Special Advisory Bulletin, OIG formally recognized that PAPs operated by independent charities can assist federal health care program beneficiaries and obtain financial donations from manufacturers and other for profit health care entities so long as they observe certain restrictions.

² There are more than two kinds of PAPs. But for purposes of this article, which is intended to identify the value of independent charity PAPs in relation to their manufacturer/service provider PAP counterparts, there is no need to extend discussion here beyond these two types.

³ The advisory opinion process was created in 1996, pursuant to the Health Insurance Portability and Accountability Act (HIPAA).

These include: establishing objective, usually financial needs based, criteria for determining which patients may benefit from the program; not allowing donors to influence who may benefit or how patients may benefit through the PAP; and, limiting the kind of information that a PAP may report to its donors. These restrictions are discussed in detail in the 2005 Special Advisory Bulletin and must be carefully observed to ensure that a disease foundation PAP in fact is operating in a way that reduces the risk of any AKS or CMP violation.

On May 21, 2014, OIG issued a Supplemental Special Advisory Bulletin. Having had nearly a decade's worth of experience approving and policing independent charity PAPs, OIG has notified the disease foundation community that there are at least two features to a PAP that would pose an unacceptable risk of an AKS or CMP violation. For example, it would be inappropriate for an independent charity PAP to provide reimbursement for only one product, or products manufactured by only one manufacturer, because, if it did, a PAP would run an unacceptable risk of acting as a witting or unwitting vehicle through which a health care manufacturer or provider of services may be subsidized through federal tax dollars. <http://oig.hhs.gov/newsroom/news-releases/2014/charity.asp>. Relatedly, OIG also is requiring independent charity PAPs to certify that they will reimburse for usually lower cost generic and bioequivalent forms of health care products.

6. The Advisory Opinion Process

The advisory opinion process involves a lengthy petition to OIG. PAP sponsors must explain in great detail how the PAP will or does operate. In terms of independent charity PAPs, OIG is principally concerned with ensuring that donors do not have influence over PAP operations; that patients are eligible for and receive benefits in a scrupulously objective manner; and that donors participating in the health care industry do not receive information from the PAP that allows them to calibrate how their donations can influence sales of health care products or services or otherwise obtain a market advantage through such information.

OIG has published two checklists of topics affecting whether a favorable advisory opinion will be issued. The lists, which are found here, <http://oig.hhs.gov/compliance/advisory-opinions/index.asp>, are important reference tools, as are the regulations governing the advisory opinion process (42 C.F.R. Part 1008), which may be found here, <http://www.gpo.gov/fdsys/pkg/CFR-2013-title42-vol5/pdf/CFR-2013-title42-vol5-part1008.pdf>. In addition, potential petitioners or their counsel should be familiar with the OIG advisory opinion FAQs, found here, <http://oig.hhs.gov/faqs/advisory-opinions-faq.asp> and prior issued advisory opinions, see <http://oig.hhs.gov/compliance/advisory-opinions/index.asp#Advisory>. Discussion with entities and their representatives who have been through the process already also can be important.⁴

7. Advanced Issues

Creative minds seeking to maximize the value of an independent charity PAP for its patient community may be tempted to ask at least two questions. First, can an independent charity PAP receive and distribute in-kind donations of product? Second, can a PAP provide financial assistance for off-label use of health care products and services?

In-kind donations. The answer to this question is “no”. In its 2005 Special Advisory Bulletin, OIG noted that PAPs providing assistance to patients who are uninsured may receive in-kind donations of health care products and distribute them through pharmacies, clinics and similar channels. <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf> (Section IV. Bulk Replacement Models). However, in the same document OIG also noted that difficult questions arise if PAPs serving federal health care program beneficiaries accept and redistribute in-kind donations, because there is a heightened risk that these patients will be influenced to continue to use these products so that federal health care program payments to the manufacturer are triggered and also because valuation of the product for deductible purposes might be difficult. *Id.* at footnote 14. Although OIG was equivocal in the footnote, noting at that time that it had insufficient experience with the issue to provide detailed guidance,

⁴ The OIG advisory opinion process applies to many different types of health care arrangements other than PAPs; thus, in reviewing OIG advisory opinions it is important to be able to distinguish which analyses and principles apply to the independent charity PAP sector.

our experience since the Special Advisory Bulletin issued is that OIG will not permit independent charity PAPs to accept in-kind donations of health care products that are reimbursable by a government health care program.

Off-label Use. The answer to this question now appears to be “yes”. In its most recent Supplement to the 2005 Special Advisory Bulletin, OIG included a footnote indicating a softened position with respect to coverage of off-label use. OIG stated in the footnote (number 9) that while PAPs are not required to cover off-label use of a product, OIG would expect that PAPs treat off label coverage in a uniform fashion, so long as off-label coverage is provided with respect to all products covered by the PAP. Historically, independent charity PAPs pledged to OIG that they would only cover on-label use. See, e.g., OIG Advisory Opinion 10-07 available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10-07.pdf> (“For a patient to qualify for assistance under the Proposed Arrangement, the Specialty Medication must have been prescribed as part of an approved course of treatment for a Specified Disease, and must not be for an off-label use.”) (underscore added). And we have had the specific experience of having been informed by OIG that a request to cover off-label uses would not be approvable. Footnote 9 of the Supplement, however, indicates that off-label use can be covered, so long as such coverage is uniform among all products for the indication covered by the PAP.

8. The Effect of the Affordable Care Act

The effects of the Affordable Act are still working their way through the health care system, including independent charity PAPs. Initially, there were concerns that qualified health plans (QHPs) would themselves be federal health care programs thus vastly expanding the scope of the AKS and CMP. Then, in November 2013, HHS Secretary Sebelius publicly stated by letter that QHPs are not considered to be federal health care programs.

However, at the same time, CMS issued a statement generally discouraging third party provision of co-payment assistance to beneficiaries of QHPs, thus enabling many health care programs to deny payments when third parties, including independent charity PAPs, provided such assistance. More recently, on February 7, 2014, CMS issued guidance through an FAQ that payments from non-profit charities will be recognized so long as the payments are made by “private, not-for-profit foundations . . . on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status. In [this] situation, CMS would expect that premium and any cost-sharing payments cover the entire policy year.” <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf>.

The financial need requirement enunciated by CMS also is one OIG likely criterion for approval of an independent charity PAP. There are, of course, others, but, if an independent charity has any favorable advisory opinion letter from OIG that contains reference to financial need-based eligibility, the letter could prove helpful in establishing if necessary that any payment provided through such an approved PAP should be recognized by CMS and QHPs.

On May 24, 2014, after requests by multiple stake-holders concerned about a CMS issued interim regulation that did not specifically mention approval for payments from private non-profit foundations, Secretary Sebelius further clarified by letter that “existing guidance related to third-party payments of premiums and cost sharing made on behalf of Marketplace QHP enrollees by private, not-for-profit foundations is sufficient to put the public on notice that as a general matter, such payments are not prohibited by HHS's rules to the extent they are provided in a manner consistent with the February 7, 2014 FAQ.”

http://www.ahanews.com/ahanews/jsp/display.jsp?dcrpath=AHANEWS/AHANewsNowArticle/data/ann_052114_subsidies&domain=AHANEWS.

9. What Happens If A Disease Foundation Runs Afoul Of The AKS or the CMP?

Alleged violations of the AKS and the CMP are taken very seriously by the government. The AKS is a criminal statute, and violations involving criminal intent can result in arrest and prosecution by the federal government. In our experience, disease foundations are not within the category of likely criminal

offenders. Instead, they are much more likely to be subject to the CMP because of technical violations that arise from a lack of awareness of this complex area of the law.

CMP violations are handled by the enforcement section of the HHS OIG. <http://oig.hhs.gov/fraud/enforcement/cmp/>. Even though they are civil in nature, the investigative process can be lengthy and costly, resulting in substantial fines and public exclusion from the right to participate in the sector of the health care industry that receives payment from federal health care programs.

In short, obtaining a favorable advisory opinion and abiding by it is likely to be important to any disease foundation wishing to serve financially needy patients through providing co-pay, premium or direct reimbursement relief from the high cost of health care products and services.

10. Summary of the Usefulness of an OIG Advisory Opinion

An advisory opinion is not required by law in order to operate a PAP. However, the AKS and CMP are complicated federal legal enforcement tools; health care law in the age of the ACA is rapidly evolving; and, potential donors working in the health care industry are subject to rigorous oversight by law enforcement. Thus, a health care company donor will be much more likely to agree to participate if a charity has received a favorable advisory opinion, and an advisory opinion is a very valuable tool for any independent charity seeking to operate a PAP.

11. Structuring A Disease Foundation PAP

There are many considerations that go into structuring an independent charity PAP. One of the most important is choosing the relationship between the disease foundation and the PAP. To cabin risk, we often recommend that disease foundation PAPs should be organized as entities separate from their disease foundation sponsors. If a disease foundation has received recognition from the Internal Revenue Service as a tax exempt organization under Section 501(c)(3) of the Internal Revenue Code and is the sole member of the PAP, the PAP can be organized as a limited liability company and derive its tax exempt status from the disease foundation.

The PAP should have a separate board of managers, although some members of the parent disease foundation usually also serve on the PAP Board. Per the HHS OIG, no director, officer or employee of a healthcare industry company donating to the PAP can serve on the PAP Board. In addition, we would strongly recommend that regardless of whether a health care industry company is a donor to the PAP, no director, officer or employee of such a company should serve on the PAP Board if the company manufactures products or services reimbursable by any federal health care program. This is particularly the case if the product or service also is covered by the PAP.

About the Firm (for more information, please see www.schanerlaw.com):

Ken Schaner and David Lubitz had a desire to apply their many years of experience primarily to the representation of tax exempt organizations, but could not do so in their then positions as partners in a large law firm, where the fee structure is not generally compatible with representation of non-profit entities. Accordingly, they formed Schaner & Lubitz in 2008. Today, their clients include the Cystic Fibrosis Foundation, JDRF International, Michael J. Fox Foundation for Parkinson's Research, Foundation for Fighting Blindness, Multiple Myeloma Research Foundation, Crohn's & Colitis Foundation of America, Leukemia & Lymphoma Society, and a number of other disease related entities and other section 501(c)(3) organizations, including several large private foundations. The firm has worked on over 300 venture philanthropy transactions and other diverse, sophisticated matters. Leslie Brown, former counsel at Rees Broome PC, who brings a depth of corporate and association experience, joined the firm as counsel in 2014.

About the authors:

Ken Schaner has practiced law for more than 40 years. He began his legal career at the Internal Revenue Service, where he was part of the team that drafted the 1969 amendments to the tax code pertaining to exempt organizations. He was a founding partner of Swidler Berlin, LLP, where he also served as managing partner and head of the corporate practice, and then a partner at Bingham McCutchen, LLP before co-founding Schaner & Lubitz, PLLC.

David Lubitz has practiced law for more than 20 years. He has worked for or represented non-profit organizations throughout his legal career. David has worked as a law clerk to a United States District Judge, he has worked for the Legal Aid Society, overseas on U.S. government funded rule of law projects, and as an associate at Morgan, Lewis & Bockius in Washington, D.C. He was a partner at Swidler Berlin, LLP and Bingham McCutchen, LLP before co-founding Schaner & Lubitz, PLLC.

Leslie Brown has practiced law for nearly 15 years. Leslie began her legal career as an associate at the Washington, D.C. law firm, Shaw Pittman, LLP. Leslie then clerked for the Honorable Lynn J. Bush of the U.S. Court of Federal Claims, before serving as Counsel for nine years at Rees Broome, PC, where she served as the outside general counsel to numerous community associations across the D.C.-area. Leslie joined Schaner & Lubitz, PLLC as Counsel in June, 2014.