Patient Assistance Programs

Proactive Planning to Ensure Compliance

September 25, 2017

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Agenda

1. Why do we still need PAPs?
2. Government View of Patient Assistance Programs
3. PAP Compliance Planning in an Evolving World
ONGOING NEED FOR PATIENT ASSISTANCE PROGRAMS

- Failure of many states to expand Medicaid leaves many without coverage
- Remaining years of Medicare coverage gap (donut hole) leave vulnerabilities for Medicare beneficiaries
- In the commercial market, issuers use tiered drug benefit structures to manage costs
- Increasing drug prices and increasing deductibles and coinsurance even where coverage exists
Source of Health Insurance / BEFORE & AFTER HEALTH REFORM

• Among 289 Million People Under Age 65

PRIOR LAW

- Uninsured (57 M) 20%
- Other (15 M) 5%
- Nongroup (13 M) 4%
- Medicaid (35 M) 13%
- ESI (169 M) 58%

AFTER ACA (2024)

- Uninsured (24 M) 8%
- Other (15 M) 5%
- Nongroup (8 M) 3%
- Medicaid (48 M) 17%
- ESI (162 M) 56%

Note: ESI is Employer-Sponsored Insurance
Note: It is yet to be determined what the ultimate sources of coverage may be since the Supreme Court gave states discretion on whether to implement Medicaid expansion
NOTES: *NM, NV, and OR are federally-supported state-based Marketplaces in 2015.

Medicare Part D and the Coverage Gap / SUMMARY OF STANDARD PART D BENEFIT PACKAGE

- Medicare Part D plan sponsors must offer a “standard benefit” package or a benefits package that is “actuarially equivalent”

- Structure of the standard benefit package in 2016:
  - **Annual Deductible**: $320
  - **Initial Coverage**: Part D Plan covers the first $3,310 of drug costs, subject to 25% beneficiary coinsurance;
  - **Coverage Gap (“Donut Hole”)**: for branded drugs, beneficiary pays 45%, Part D Plan pays 5%; manufacturers give 50% discount
  - **Catastrophic Coverage**: after beneficiary incurs “true out-of-pocket” expenditures (TrOOP) of $4,700: Part D Plan covers 15%, Medicare pays 80%, beneficiary pays 5% coinsurance
Medicare Part D and the Coverage Gap / ACA PROVISIONS TO CLOSE THE “DONUT HOLE”

- **Coverage Gap**: originally included because costs of continuous coverage would exceed spending goals; very unpopular

- **Affordable Care Act**: phases out coverage gap by 2020 with:
  - (1) **Coverage Gap Discount Program (CGDP)**: Gradually increasing manufacturer discounts on branded and generic drugs
  - (2) gradually reducing beneficiary coinsurance for branded and generic drugs to 25% by 2020

- **Additional Payment Sources Count Toward TrOOP**
  - Manufacturer CGDP discounts
  - AIDS Drug Assistance Program (ADAP)
  - Payments by the Indian Health Service, an Indian tribe, or tribal organization
  - **BUT**: drugs provided or paid by PAPs still do not count toward TrOOP
“PAPs can continue to assist Part D enrollees through a properly structured program that operates entirely outside the Part D benefit. Under this approach, the beneficiary does not use his or her Part D benefit to obtain the drug and the cost of the drug is not applied toward the enrollee’s true out-of-pocket costs.”

“Many pharmaceutical companies have donated to bona fide independent charities that operate PAPs that serve financially needy Medicare and other patients. Nothing in the law prevents pharmaceutical companies from continuing to support these vital programs.”
Why is PAP Compliance More Important than Ever?

- Criticism that PAPs favor more expensive brand drugs
- Focus on Capitol Hill on drug pricing has resulted in publicity on the role of PAPs and criticism of drug company benefits from their operations
- Government enforcement focus on PAPs
  - DOJ subpoenas reportedly have been issued
  - OIG has revised its guidance
Types of PAPs

- Pharmaceutical Manufacturer PAPs
- Independent Charity PAPs
- PAPs operating outside Part D
- Coalition Model PAPs
- Bulk Replacement Model PAPs

*Compliance measures depend on type of PAP*
DHHS/OIG Perspective on Patient Assistance Programs

- Anti-kickback statute (Social Security Act (“SSA”) section 1128B(b)) makes it a criminal offense to--
  1. knowingly and willfully
  2. offer, pay, solicit, or receive any remuneration
  3. induce or reward referrals of items or services reimbursable by a Federal health care program
    - “Remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind
    - Civil Money Penalties (SSA section 1128A(a)(7))/Federal Health Care Program Exclusion
    - Safe Harbors, Advisory Opinions, Fraud Alerts/Special Advisory Bulletins
    - *There are no safe harbors for PAPs; there are Special Advisory Bulletins and many Advisory Opinions*
DHHS/OIG Perspective on Patient Assistance Programs

- Civil Money Penalties for Beneficiary Inducements (SSA section 1128A(a)(5))
  - For giving something of value to a Medicare or Medicaid beneficiary
  - That the giver knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service
  - For which payment may be made, in whole or in part, by Medicare or Medicaid
OIG Concerns with PAPs

- Subsidies tied to use of a particular manufacturer’s product can
  - Steer beneficiaries to particular drugs
  - Increase costs to Medicare
  - Provide a financial advantage over competing drugs
  - Reduce beneficiary incentives to locate and use less expensive, equally effective drugs
DHHS/OIG Perspective on Patient Assistance Programs /
COMMON FACTORS OF PAPs NOT VIOLATING OIG-ENFORCED LAWS

- No Donor or affiliate would exert direct or indirect control over program administrator or program
- Provider/practitioner selection done before patient applies for assistance
- Donors have no mechanism to know how their donations correlate to use of its prescription drugs or services
- Specified diseases addressed by program are defined according to widely accepted clinical standards
- Program assistance available for all appropriate drugs to treat patient’s condition, and covered by patient’s insurance (limit or prevent steering)
DHHS/OIG Perspective on Patient Assistance Programs / COUPONS

...the offerors of coupons ultimately bear the responsibility to operate these programs in compliance with Federal law. Pharmaceutical manufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D. Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the anti-kickback statute.”*

Specific OIG Concerns:
(1) Claims processing procedures fail to stop payment for coupons to Part D beneficiaries;
(2) Manufacturer notices to beneficiaries and pharmacies are inadequate; and
(3) Part D plans are unable to identify coupons and CMS and OIG cannot monitor the integrity of their use.

General Compliance Strategies

**DOS & DON’TS**

- **DO** choose a path and stick to it (Carve-out versus independence)
- **DO** review and update your policies and procedures in light of evolving OIG guidance and DOJ settlements
- **DO** focus on staff training on guidelines and communications, especially if staff interact with multiple PAP models
- **DO** ensure that there are adopted and followed –
  - robust patient eligibility guidelines and
  - verification procedures for financial need
- **DON’T** include only expensive specialty pharmaceuticals
Compliance Strategies

**DOS & DON’TS FOR MANUFACTURERS**

- **DO** be sure your carve-out mechanisms are effective (for Pharmaceutical Manufacturer PAPs)
- **DO** monitor those responsible for reviewing and approving PAP grants
- **DO** review and evaluate PAP structures, policies and compliance before making grants
- **DON’T** put all your eggs in one PAP basket
- **DON’T** earmark funds for particular products, stages or complications of diseases (as opposed to broad diseases)
- **DON’T** “exert influence” over independent charitable PAPs
Compliance Strategies

DOS AND DON’TS FOR INDEPENDENT PAPS

- DO be sure PAP guidelines don’t favor donor drugs
- DO consider funding a broad range of equally effective treatments
- DO seek multiple and diverse donors
- DON’T accept donations earmarked for particular drug products
- DON’T share specific information with pharmaceutical manufacturer donors that would enable them to correlate donations with sales
- DON’T include donors on your board
Compliance Strategies

Should you seek an OIG Advisory Opinion?

Pros –
- Certainty (until modified!)
- Ease of acceptance of your PAP for pharmaceutical manufacturers
- Best means of managing AKS risk

Cons –
- Long lead time (but many have been issued)
- Difficult to modify operations without going back to the OIG
- Open kimono
Compliance Strategies

- Should you seek an OIG Advisory Opinion?
- May 2014 OIG Supplemental Special Advisory Bulletin
  - Narrowly defined disease funds may be subject to scrutiny if the disease funds result in funding exclusively or primarily the products of donors or the disease fund is operating to induce the purchase of donor products.
  - OIG Footnote says “This is true even if the charity has obtained a favorable advisory opinion”
    - favorable advisory opinions related to PAPs typically are based upon the charity’s certifications and this would mean the arrangement does not in practice comport with the facts presented in the advisory opinion
Compliance Strategies

- Counsel Opinions/Involvement?
- Firewalls?
- Audits?
- Reporting to Part D plans?
Questions & Answers

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Appendix
DHHS/OIG Opinions on Patient Assistance Programs / PHARMACEUTICAL COMPANY PATIENT ASSISTANCE PROGRAMS

07-28-2009 Advisory Opinion 09-08 (concerning a proposed institutional patient assistance program that would make certain drug products available to people without prescription drug coverage through the provision of replacement stock to certain participating disproportionate share hospitals)

02-12-2008 Advisory Opinion 08-04 (concerning a proposal to offer a free trial prescription program to hemophilia A patients who are Federal health care program beneficiaries)

04-06-2007 Advisory Opinion 07-04 (concerning a pharmaceutical company's patient assistance programs, which will provide free outpatient prescription drugs to financially-needy Medicare Part D enrollees entirely outside of the Part D benefit)

11-09-2006 Advisory Opinion 06-21 (concerning a pharmaceutical company's proposal to establish a patient assistance program to provide outpatient prescription drugs to financially-needy Medicare Part D enrollees entirely outside of the Part D benefit)

11-02-2006 Advisory Opinion 06-19 (concerning a pharmaceutical company's proposal to establish a patient assistance program to provide outpatient prescription drugs to financially-needy Medicare Part D enrollees entirely outside of the Part D benefit)
DHHS/OIG Opinions on Patient Assistance Programs / PHARMACEUTICAL COMPANY PATIENT ASSISTANCE PROGRAMS, cont.

09-26-2006 **Advisory Opinion 06-14** (concerning a pharmaceutical manufacturer's proposal to establish a patient assistance program to provide the company's drugs to financially-needy Medicare Part D enrollees outside of the Part D benefit)

04-18-2006 **Advisory Opinion 06-03** (concerning a pharmaceutical company patient assistance program that provides free outpatient prescription drugs to financially-needy Medicare Part D enrollees entirely outside of the Part D benefit)

02-12-2003 **Advisory Opinion 03-3** (concerning a proposed modification to a drug company's patient assistance program to pay Medicare Part B cost-sharing amounts for financially needy beneficiaries following surgery)

10-04-2002 **Advisory Opinion 02-13** (concerning whether a proposed arrangement involving financial assistance by a non-profit foundation, which a pharmaceutical company proposes to establish and fund in order to subsidize cost-sharing amounts incurred by financially needy patients using its drug, would violate the administrative authorities related to the anti-kickback statute)
DHHS/OIG Perspective on Patient Assistance Programs / NONPROFIT/CHARITABLE PATIENT ASSISTANCE PROGRAMS

01-05-2015 *Advisory Opinion 14-11* (concerning a nonprofit, tax-exempt, charitable organization's proposal to provide assistance with copayment obligations to financially needy patients, including Medicare and Medicaid beneficiaries, diagnosed with Crohn's disease or ulcerative colitis)

12-02-2013 *Advisory Opinion 13-19* (concerning patient assistance programs that provide funding for premium assistance and certain other medical expenses to [disease redacted] patients in financial need.)

10-18-2011 *Modification of Advisory Opinion 07-18* (modifying *Advisory Opinion No. 07-18*, which was issued on 01-03-2008, to allow a patient assistance program to generally limit its funds to specialty pharmaceuticals and to enroll pharmacies as "Participating Pharmacies")

08-30-2010 *Advisory Opinion 10-12* (concerning a nonprofit, tax-exempt, charitable organization's proposal to provide financially-needy patients with grants to defray their cost-sharing obligations for drugs and/or devices to treat brain tumors and conditions incident to brain tumors)

05-27-2010 *Advisory Opinion 10-06* (concerning a patient assistance program that assists underinsured patients with their prescription drug co-payment obligations)
05-18-2009 Advisory Opinion 09-04 (concerning a nonprofit, tax-exempt, charitable organization's arrangement to provide financial assistance with cost-sharing obligations associated with certain advanced diagnostic testing owed by financially needy patients, including Medicare and Medicaid beneficiaries)

10-21-2008 Advisory Opinion 08-17 (concerning a nonprofit, tax-exempt, charitable organization's proposed arrangement to provide financial assistance to cover cost-sharing obligations associated with outpatient drug treatment owed by financially needy Medicare or Medicaid patients with a certain disease) Modification of Advisory Opinion 08-17; Second Modification of Advisory Opinion 08-17

02-01-2008 Advisory Opinion 08-01 (concerning a non-profit corporation's program that arranges for pharmaceutical manufacturer patient assistance programs to provide donated drugs to free clinics and Federally qualified health centers (FQHCs) for use by financially-needy patients who do not have any form of outpatient prescription drug insurance coverage)

01-03-2008 Advisory Opinion 07-18 (concerning the management by a health care industry consultancy of a charitable organization's arrangements to subsidize patient cost-sharing and premium obligations)
10-03-2007 **Advisory Opinion 07-11** (concerning a nonprofit, tax-exempt, charitable organization's proposal to establish a foundation to provide financially needy cancer patients with grants to defray their out-of-pocket treatment costs)

07-30-2007 **Advisory Opinion 07-06** (concerning the management by a health care industry consultancy of a charitable organization's arrangement to subsidize patient cost-sharing and premium obligations) **Modification of Advisory Opinion 07-06**

09-25-2006 **Advisory Opinion 06-13** (concerning a nonprofit, tax-exempt, charitable organization's proposal to provide financially needy persons who have [diseases redacted] with grants to defray the costs of premiums and cost-sharing obligations under Medicare Part B, Medicare Part D, Medicare Supplementary Health Insurance, and Medicare Advantage); **Modification of Advisory Opinion 06-13** (modifying Advisory Opinion 06-13 issued September 18, 2006 that concerned a nonprofit, tax-exempt, charitable organization's proposal to provide financially needy persons who have [diseases redacted] with grants to defray the costs of premiums and cost-sharing obligations under Medicare Part B, Medicare Part D, Medicare Supplementary Health Insurance, and Medicare Advantage)
DHHS/OIG Perspective on Patient Assistance Programs / NONPROFIT/CHARITABLE PATIENT ASSISTANCE PROGRAMS, cont.

09-19-2006 Advisory Opinion 06-10 (concerning a nonprofit, tax-exempt, charitable organization's practice of providing certain therapy management services and assistance with Medicare cost-sharing obligations to financially needy Medicare beneficiaries undergoing medical treatment for certain diseases)

06-30-2006 Advisory Opinion 06-08 (concerning a free clinic's practice of dispensing drugs on behalf of patient assistance programs ("PAPs") sponsored by pharmaceutical manufacturers that provide free drugs to financially-needy patients, including some patients enrolled in the Medicare Part D outpatient prescription drug benefit)

04-27-2006 Advisory Opinion 06-04 (concerning a nonprofit, tax-exempt, charitable corporation's proposal to provide financially needy Medicare beneficiaries with assistance with premiums and cost-sharing obligations under Medicare Part B, Medicare Part D, Medigap [as hereinafter defined], and Medicare Advantage)

11-05-2004 Advisory Opinion 04-15 (concerning grants provided by a nonprofit, charitable organization to financially-needy patients suffering from specific chronic or life-threatening diseases to defray the costs of prescription drug therapies)

04-04-2002 Advisory Opinion No. 02-1 (concerning a non-profit, tax-exempt, charitable corporation funded largely by drug companies that would provide financial assistance to subsidize, in whole or in part, the Part B cost-sharing amounts and Medigap premiums of financially needy Medicare beneficiaries suffering from relatively rare chronic diseases)