Free Prescription Drugs for Households with Incomes as High as $80,000

By Cindy Randolph / Free Medicine Foundation

For individuals needing assistance in affording prescription medication, help may only be a few minutes away. The Johnson's have no insurance, and can't afford the 5 prescriptions they must take daily. However, they get all of them free-of-charge, thanks to the efforts of Free Medicine Foundation and drug-makers.

Three of the Nation's largest drug makers send the Johnson's their cholesterol, thyroid, heart, pain and blood pressure medication FREE because they participate in these little-known patient assistance programs that are offered by pharmaceutical companies.

The Johnson's who found a Free Medicine Foundation brochure application in their doctor's office said, "It's the best-kept secret in town, we couldn't take our medications without them…we wouldn't be able to afford it." they said.

Although free medicine assistance has been around for over 50 years, most people have never heard about and do not know how to apply for free medicine. The "Free Medicine Foundation" mission is to inform the media and the public of assistance that may be available to thousands of Americans who don't even realize they qualify for such help. Free Medicine Foundation works tirelessly to match patients with hundreds of free or low-cost available programs by scouring available medicine plans to find plans that match applicant needs.

Cindy Randolph, spokesman for the Free Medicine Foundation organization, said that our efforts have proven successful and have helped hundreds of thousands of Americans. Free prescription drugs are available to individuals who are uninsured or underinsured – with no outpatient prescription coverage for some or all prescription drugs you need, (have maxed their insurance out and/or reached the "gap" or "donut hole"), and who meet certain established income criteria for each medication.

"This is an effort to help people who qualify and don't even know it," said Randolph. This includes Medicare beneficiaries who elect not to enroll in a Medicare drug plan. The Office of Inspector General ("OIG") notes that "manufacturer-sponsored Patient Assistance Programs (PAPs) need not remove all Medicare beneficiaries from their existing programs to be compliant with federal fraud and abuse laws. Because enrollment in Part D is voluntary, existing PAPs may continue to provide free or reduced outpatient prescription drugs to Medicare beneficiaries who have NOT yet enrolled in Part D." In addition, individuals who do not meet criteria for income for prescription drug coverage –including Medicare beneficiaries who enroll in the Medicare drug plan – May still qualify for free or low-cost prescription drugs.

Drug sponsors recognize that sometimes exceptions need to be made based on a patient's individual circumstances. Individuals who do not meet these criteria may still qualify if both they and their physician attest that the patient has special circumstances of financial and medical hardship, and their income is below an established limit. It's not just poor people who qualify. With each medication the income criteria varies from below the poverty level up to $39,200 for individuals, $52,800 for couples, and as high as $80,000 for a family of four.

Since 1993, Free Medicine Foundation, which is a national program to help patients across the country, access prescription medicines by helping to enroll them in patient assistance programs. The Free Medicine Foundation enrollment center is helping people in need across the united States of America.

According to Randolph, there are hundreds of programs that offer free or nearly-free prescription drugs to those who qualify. Most all prescription drugs are on a free or low-cost assistance program. The biggest issue is letting people know that such programs actually exist and that the process of enrolling is not that difficult.

People interested in attempting to enroll in one of the many programs can simply call 1-573-996-3333 or log on to www.FreeMedicine.com.

The online enrollment is also easy, but will require the individual to have a list of drugs they are taking handy. Applicants can apply for as many drugs as needed, there is no limit. Include a $5 per prescription application processing fee (refundable if no assistance is received) indicating which drugs you need. And once enrolled, patients can continue to receive medication indefinitely as long as programs exist and patient continues to qualify.

For people facing tough prescription drug costs, the Free Medicine Foundation assistance program is a much needed effort. For more information and to access an application, visit www.FreeMedicine.com.

Free Prescription Drugs

How Can People Who Can't Afford Their Medicines Get Them?

Visit: www.FreeMedicine.com *or call* **1-573-996-3333**

Free Prescription Drugs

Free Medicine Enrollment Form

Complete this form & mail along with your processing fee of $5.00 for EACH medication to:

✉ **Free Medicine Foundation • P.O. Box 125, Doniphan, Mo. Postal Code 63935-0125**

Phone: 1-573-996-3333 • Internet: www.FreeMedicine.com

FREE MEDICINE Foundation.com

An Answer to Prayer When You Can't Afford Your Medicine

Most medications are available through free programs. Apply for as many medicines as you need, there is no limit. Free Medicine Foundation offers a money back guarantee.

> *"If it wasn't for this program my nephew would not be here right now, this program saved his life and I would like to thank you for all that you do. He received help from you in the past when he couldn't afford his medicine. Thanks to your help, I am slowly crawling out from under my prescription medicine credit card debt." Cynthia H., Dallas, Texas*

Be sure to include the following items:

1. The name, address and phone number of the person taking the medication(s) and list all of your medication(s).
2. The name and address of the doctor who prescribes the medication(s).
3. Send a refundable $5.00 (one-time processing fee) for **EACH** medication requested to Free Medicine Foundation. It is payable by cash, money order or check to "Free Medicine Foundation" and mail with this completed form.

Please Print Clearly

First Name | M.I. | Last Name

Address (Street number / street name / apartment number / P.O. Box number)

Address Continued (Street number / street name / apartment number / P.O. Box number)

City | State | Postal Code | Today's Date

Phone number | Date of Birth | M ☐ F ☐ Gender | $ _____ Total monthly household gross income

Email Address _____@_____

Are You Diabetic? ☐ Yes ☐ No

Are you on Medicare? ☐ Yes ☐ No

How did you hear about us? _____

Visit www.FreeMedicine.com For Details On How You Can SAVE up to 95% On Your Prescription Medicine NOW!

	NAME OF MEDICATION	STRENGTH	DOSAGE	Times Per Day	DOCTOR'S NAME & ADDRESS
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

Please Make Copies of This Form if More Medicines Are Needed.

Available in Spanish Online at www. FreeMedicine.com

0105-3

Money Back Guarantee Policy: If you are determined ineligible by all applicable sponsors, and receive no medicine assistance, send a written request to Free Medicine Foundation. Include denial letters for all applicable medications within 4 months of original application and your processing fee will be fully refunded.

Total number of medications requested ☐ x $5 EACH = Amount due $_____

Must Include Processing Fee with this Application, it can not be processed without the correct fee enclosed.

Long Island
Drug company extends aid to LI man

BY RIDGELY OCHS
Newsday Staff Writer

March 23, 2006

A major, multimillion-dollar drug company has agreed to continue providing a Nassau man a pain reliever free of charge, thanks to the unflagging efforts of his former wife.

For the past eight years, James Rogers, 55, has relied on huge doses of the highly addictive narcotic OxyContin to relieve pain caused by an inoperable cyst on his brain stem. Withdrawal from the drug would kill him, his doctor has said.

Until recently, the drugmaker, Purdue Pharma, had provided the drug, which would cost Rogers $120,000 a year, free as part of a program for low-income people with no drug insurance.

But in December the company said it would no longer provide Rogers with OxyContin because he was eligible for the new Medicare Part D drug program. However, Rogers, who lives on disability and a small pension, could not afford the co-pays and deductibles required in many Medicare plans.

Rogers' former wife, Veronica Goldman, of Williston Park, spent months calling Purdue, health plans and politicians to find a way to continue the drug. Last week, she and Rogers learned that Purdue would extend free coverage for a year. After that, the drug company will re-evaluate his situation.

Purdue Pharma spokesman James Heins said the company plans to continue its program for those not eligible for Medicare Part D or for those like Rogers "who have a real problem."

"It showed a sense of responsibility; I give them credit for that," said Rep. Peter King (R-Seaford), whose office worked with the drug company.

Rogers said he is grateful but would feel better if he got a letter confirming the drugmaker's commitment.

An estimated 1 million people who relied on drugmakers' patient assistance programs have been similarly affected by Medicare Part D. Drug companies became worried in November when the U.S. Department of Health and Human Services inspector general's office warned that giving free drugs could be viewed as trying to influence Medicare patients to choose one company over another.

But shutting these programs down was not the intent of the federal Centers for Medicare and Medicaid Services, said spokesman Peter Ashkenaz yesterday.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

CMS Perspective
on
Pharmaceutical Company Patient Assistance Programs
January 25, 2006

- The decision to keep a patient assistance program is up to the pharmaceutical company, not the US government. The terms of the programs are determined by the company, without any government involvement.

- There is nothing in the law that prohibits a pharmaceutical company patient assistance program from providing drug assistance to Medicare beneficiaries, even those enrolled in a Medicare prescription drug plan, but that help has to be *outside* the Medicare coverage – just as it has been until now.

- No company needs to end its patient assistance program on account of the drug benefit starting. Lawful avenues exist for pharmaceutical companies and others to help Part D beneficiaries with their drug costs. Pharmaceutical company patient assistance programs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit. In these circumstances, the beneficiary obtains the patient assistance program drugs without using his or her Part D insurance benefit.

- Specifically, pharmaceutical company patient assistance programs **<u>can</u>** provide coverage for particular drugs that are included in the Medicare drug benefit. This assistance would remain independent of the Medicare drug coverage, as it was before 2006. Any assistance a pharmaceutical patient assistance program provides to a Part D enrollee for prescription drugs that would have been covered under his or her Part D plan would not count as an incurred cost that would be applied toward the enrollee's true out-of-pocket costs (known as "TrOOP") balance or total drug expenditures. In other words, beginning when a beneficiary's assistance under a patient assistance program became effective, no claims for payment for any covered outpatient prescription drug provided outside of the Part D benefit may be filed with a Part D plan or the beneficiary, and the assistance must not count toward the beneficiary's TrOOP or total Part D spending for any purpose.

- In fact, a company can continue its patient assistance program at a much lower cost than in the past, because most of the seniors eligible for pharmaceutical company patient assistance programs now have access to very comprehensive coverage through the Medicare program's Limited Income Subsidy.

- Nothing in any Office of the Inspector General (OIG) laws, regulations, or guidance prevents pharmaceutical company patient assistance programs from providing free or reduced price outpatient prescription drugs to uninsured patients and Medicare beneficiaries who have not enrolled in Part D.

- In addition, as outlined more fully in the OIG guidance, lawful avenues exist for pharmaceutical company patient assistance programs to assist financially needy Part D enrollees. The OIG has issued a Special Advisory Bulletin addressing the application of the fraud and abuse laws to pharmaceutical company patient assistance programs (see http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBlletinFinal-Final.pdf).

    - The Bulletin explains that pharmaceutical companies face a heightened risk of liability under the fraud and abuse laws if they assist Part D enrollees by paying all or a portion of the Part D cost-sharing amounts owed by the Part D enrollees for the company's products. For reasons explained more fully in the OIG's Bulletin, these types of cost-sharing subsidies pose all the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs.

    - The Bulletin also makes clear that pharmaceutical companies may choose to provide free or reduced price drugs to financially needy Part D beneficiaries, so long as the assistance program is properly structured and the free or reduced price drugs are provided entirely outside the Part D benefit. They may also choose to make cash donations to bona fide, independent charities that assist Medicare beneficiaries with drug expenses.

- For example, suppose Ms. Smith has qualified for a patient assistance program for a particular, costly cancer drug. She signs up for Part D for her other medications, but her income and assets are too high to qualify for the Part D low-income subsidy. The pharmaceutical company could continue to provide her cancer drug through their patient assistance program, so that Ms. Smith continues to face the same out-of-pocket costs for the cancer drug as she did before. Ms. Smith would not get coverage from her Part D plan for the cancer drug. Because the pharmaceutical company would only need to provide such coverage for Medicare beneficiaries with incomes that are limited but too high to qualify for the low-income subsidy, the company could continue the assistance program for people like Ms. Smith at a significantly lower cost than before Part D began.

- If a company chooses to do so, it can have a "win-win": significantly lowering the cost of its patient assistance program compared to before the drug benefit, so that it can help more people getting drugs they need, and at the same time they can make sure that all people who have depended on the pharmaceutical company's patient assistance program in the past can get the same or more help.

- OIG guidance states that companies may enter into data sharing agreements with CMS to facilitate plan tracking of beneficiary drug utilization. CMS will work with companies interested in pursuing a data sharing agreement in accordance to the OIG guidance.

HHS Orders Drugmakers To Phase Out Assistance Programs To Part D Recipients By 2

on Tuesday, November 15 @ 14:13:32 CST

$40 Billion, that's the price tag for the new Medicaid Part D drug program. Not only does there seem to be a problem in funding it, but what about those patients caught in the "donut hole" of coverage. This is when they reach $2000 in benefits and then have to pay the next $3000 till part D pays again. These patients have had assistance programs from drug manufacturers to help with the burden. But now HHS(Health and Human Services)is requiring all drug makers to discontinue any assistance programs to part D participants. This makes absolutely no sense! To learn more about the reasons click here.

HHS Orders Drugmakers To Phase Out Assistance Programs To Part D Recipients By 2007

Drugmakers will have a one-year grace period following the Jan. 1, 2006, start of the Part D benefit to transition Medicare beneficiaries away from manufacturer-sponsored PAPs to independent programs, according to a OIG special advisory bulletin.

Patient assistance programs ("PAPs") have long provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs.

PAPs are structured and operated in many different ways. PAPs may offer cash subsidies, free or reduced price drugs, or both. Some PAPs offer assistance directly to patients, while others replenish drugs furnished by pharmacies, clinics, hospitals, and other entities to eligible patients whose drugs are not covered by an insurance program.

Some PAPs are affiliated with particular pharmaceutical manufacturers; others are operated by independent charitable organizations (such as, for example, patient advocacy and support organizations) without regard to any specific donor or industry interests.

Many pharmaceutical manufacturers have historically sponsored PAPs that assist patients whose outpatient prescription drugs are not covered by an insurance program (including some Medicare beneficiaries), in obtaining the manufacturer's products for free or at greatly reduced cost.

Beginning on January 1, 2006, Medicare Part D will offer Medicare beneficiaries who elect to enroll broad coverage for outpatient prescription drugs. Accordingly, Medicare beneficiaries who enroll in Part D will no longer qualify under traditional PAP eligibility criteria. Part D enrollees will incur cost-sharing obligations (including deductibles and copayments), although many low-income beneficiaries will qualify for subsidies that will reduce or eliminate their financial obligations.1

Pharmaceutical manufacturers have expressed interest in continuing to assist Medicare Part D enrollees of limited means who do not qualify for the low income subsidy. The Office of Inspector General ("OIG") is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs,

The elimination of drugmaker-funded PAPs will alleviate concerns that cost-sharing subsidies provided by the programs pose a heightened risk of fraud and abuse under the federal antikickback statute of the Social Security Act, the OIG said.

"Consistent with our prior guidance addressing manufacturer cost-sharing subsidies in the context of Part B drugs, we believe such subsidies for Part D drugs would implicate the

antikickback statute and pose a substantial risk of program and patient fraud and abuse," the OIG bulletin states.

"Simply put, the subsidies would be squarely prohibited by the statute, because the manufacturer would be giving something of value to beneficiaries to use its product," the OIG adds. "Where a manufacturer PAP offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries incentives to locate and use less expensive, equally effective drugs."

The OIG notes that manufacturer-sponsored PAPs need not remove all Medicare beneficiaries from their existing programs to be compliant with federal fraud and abuse laws. Because enrollment in Part D is voluntary, existing PAPs may continue to provide free or reduced outpatient prescription drugs to Medicare beneficiaries who have not yet enrolled in Part D.

To view the OIG's special bulletin, click here

it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 56 businesses are expected to submit written requests in year one, the total burden hours for year one are 280.

In year two, FDA expects about one-half as many firms to request a labeling compliance extension. So for year two, 28 firms are expected to file a request for an extension to the labeling compliance date. Again, assuming that it will take 5 hours to complete each request, the total burden hours for year two will be 140.

Dated: November 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23040 Filed 11–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0343]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Requesting an Extension to Use Existing Label Stock after the *Trans* Fat Labeling Effective Date of January 1, 2006'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing an opportunity for public comment on this collection of information. Since this collection received emergency approval that expires on January 1, 2006, FDA is following the normal PRA clearance procedures by issuing that notice.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 2005 (70 FR 52108), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0571. The approval expires on January 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23041 Filed 11–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 12, 2005, 9 a.m.—5 p.m., EST.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Monday, December 12, from 9 a.m. to 5 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–800–369–6048 on December 12 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the December meeting will include, but are not limited to: A summary of the U.S. Court of Federal Claims' 18th Judicial Conference; a report from the ACCV Workgroup looking at proposed guidelines for future changes to the Vaccine Injury Table; and updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics and Evaluation Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail *clee@hrsa.gov*. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–2124 or e-mail *clee@hrsa.gov*.

Dated: November 15, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–23042 Filed 11–21–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing patient assistance programs for Medicare Part D enrollees.

FOR FURTHER INFORMATION CONTACT: Darlene M. Hampton, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (November 2005)

I. Introduction

Patient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means

who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs. PAPs are structured and operated in many different ways. PAPs may offer cash subsidies, free or reduced price drugs, or both. Some PAPs offer assistance directly to patients, while others replenish drugs furnished by pharmacies, clinics, hospitals, and other entities to eligible patients whose drugs are not covered by an insurance program. Some PAPs are affiliated with particular pharmaceutical manufacturers; others are operated by independent charitable organizations (such as, for example, patient advocacy and support organizations) without regard to any specific donor or industry interests.

Many pharmaceutical manufacturers have historically sponsored PAPs that assist patients whose outpatient prescription drugs are not covered by an insurance program (including some Medicare beneficiaries), in obtaining the manufacturer's products for free or at greatly reduced cost. Beginning on January 1, 2006, Medicare Part D will offer Medicare beneficiaries who elect to enroll broad coverage for outpatient prescription drugs. Accordingly, Medicare beneficiaries who enroll in Part D will no longer qualify under traditional PAP eligibility criteria. Part D enrollees will incur cost-sharing obligations (including deductibles and copayments), although many low-income beneficiaries will qualify for subsidies that will reduce or eliminate their financial obligations.[1] Pharmaceutical manufacturers have expressed interest in continuing to assist Medicare Part D enrollees of limited means who do not qualify for the low-income subsidy.

OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs, and OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws.[2] We have been asked whether the anti-kickback statute will be implicated if pharmaceutical manufacturer PAPs[3] continue to offer assistance to financially needy Medicare beneficiaries who enroll in Part D by subsidizing their cost-sharing obligations for covered Part D drugs. For the reasons set forth below and consistent with extant OIG guidance, we conclude that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute. However, in the circumstances described in this Bulletin, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions. In addition, we believe other arrangements described in this Bulletin, if properly structured, may pose reduced risk. Thus, we believe lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.

Given the importance of ensuring continued access to drugs for beneficiaries of limited means and the expedited time frame for implementation of the Part D benefit, we are issuing this Special Advisory Bulletin to identify potentially abusive PAP structures, as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse. This Special Advisory Bulletin draws on the government's prior fraud and abuse guidance and enforcement experience. However, because the Part D benefit has not yet begun, and any assessment of fraud and abuse is necessarily speculative, this Bulletin cannot, and is not intended to, be an exhaustive discussion of relevant risks or beneficial practices.

At the outset, it is important to note the following:

- PAPs need not disenroll all Medicare beneficiaries from their existing PAPs to be compliant with the fraud and abuse laws. Enrollment in Part D is voluntary; therefore, existing PAPs may continue to provide free or reduced price outpatient prescription drugs to Medicare beneficiaries who have not yet enrolled in Part D. The Centers for Medicare & Medicaid Services (CMS) anticipates instituting procedures that will help PAPs determine if PAP clients have enrolled in Part D.
- Occasional, inadvertent cost-sharing subsidies provided by a pharmaceutical manufacturer PAP to a Part D enrollee should not be problematic under the anti-kickback statute (*e.g.*, where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D).
- Nothing in the Part D program or in any OIG laws or regulations prevents pharmaceutical manufacturers or others from providing assistance (*e.g.*, through cash subsidies or free drugs) to uninsured patients. Nothing in this Bulletin impacts programs that assist uninsured patients.
- Nothing in this guidance should be construed as preventing pharmacies from waiving cost-sharing amounts owed by a Medicare beneficiary on the basis of a good faith, individualized assessment of the patient's financial need (or failure of reasonable collection efforts), so long as the waiver is neither routine, nor advertised. Financial need-based waivers that meet these criteria have long been permitted.[4] However, a pharmacy has not waived a cost-sharing amount if the amount has been paid to the pharmacy, in cash or in kind, by a

[1] *See* 42 CFR 423.782.

[2] This Bulletin focuses on the application of the Federal anti-kickback statute. Other potential risk areas, including, for example, potential liability under the False Claims Act, 31 U.S.C. 3729–33, or other Federal or State laws, are not addressed here. Moreover, this Bulletin focuses on arrangements that involve pharmaceutical manufacturers directly or indirectly subsidizing Part D cost-sharing amounts. Programs that subsidize Part D premium amounts pose risks under the anti-kickback statute that are not addressed here. Similarly, PAPs established by health plans that subsidize cost sharing or premium amounts under Part D raise different issues and may require a different analysis. While this Bulletin may provide some useful guidance for other kinds of PAP arrangements, such PAPs are not specifically considered here.

[3] For purposes of this Special Advisory Bulletin, a pharmaceutical manufacturer PAP includes any PAP that is directly or indirectly operated or controlled in any manner by a pharmaceutical manufacturer or its affiliates (including, without limitation, any employee, agent, officer shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)). Moreover, for purposes of an anti-kickback analysis, we would not consider a charitable foundation (or similar entity) formed, funded or controlled by a manufacturer or any of its affiliates (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) to be a *bona fide*, independent charity, because interposition of the entity would not sever the nexus between the patient subsidies and the manufacturer. Indeed, in most cases, the foundation would receive all of its funding from the pharmaceutical manufacturer (or its affiliates) and would provide subsidies only for the manufacturer's products.

[4] *See, e.g.*, section 1128A(i)(6)(A) of the Act; OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, August 2002, *http:oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.* The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a safe harbor specifically incorporating these criteria for waivers of cost-sharing amounts for Part D drugs. Additionally, the safe harbor protects cost-sharing waivers offered to individuals who qualify for the low income subsidy, even if the waivers are routine and do not follow an individualized determination of financial need, provided they are not advertised. *See* Section 1860D–42 of MMA, codified at 42 U.S.C. 1320a–7b(b)(3)(G).

third party (including, without limitation, a PAP).

II. The Federal Anti-Kickback Statute

The Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act),[5] makes it a criminal offense knowingly and willfully to 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. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible ''kickback'' transaction. For purposes of the anti-kickback statute, ''remuneration'' includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. OIG may also initiate administrative proceedings to exclude a person from Federal health care programs or to impose civil money penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.[6]

A determination regarding whether a particular arrangement violates the anti-kickback statute requires a case-by-case evaluation of all of the relevant facts and circumstances, including the intent of the parties. For PAPs, the nature, structure, sponsorship, and funding of the particular PAP are necessarily relevant to the analysis.

III. Patient Assistance Programs

As described more fully below, cost-sharing subsidies provided by pharmaceutical manufacturer PAPs pose a heightened risk of fraud and abuse under the Federal anti-kickback statute. However, there are non-abusive alternatives available. In particular, as discussed below, pharmaceutical manufacturers can donate to *bona fide* independent charity PAPs, provided appropriate safeguards exist. Moreover, this Bulletin discusses several other alternatives that may pose a reduced risk of fraud and abuse.

This section addresses in turn: pharmaceutical manufacturer PAPs, independent charity PAPs, manufacturer PAPs that operate ''outside of Part D''; ''coalition model'' PAPs, and bulk replacement programs.

A. Pharmaceutical Manufacturer PAPs

Analytically, pharmaceutical manufacturer PAPs raise two main issues in connection with the Part D program: (i) Whether subsidies they provide can count toward a Part D enrollee's true out-of-pocket costs (known as the TrOOP); and (ii) whether the subsidies implicate the Federal anti-kickback statute.[7]

As to the first issue, the Part D regulations make clear that beneficiaries may count toward their TrOOP assistance received from any source other than group health plans, other insurers and government funded health programs, and similar third party payment arrangements.[8] The preamble to the Part D regulations explains that cost-sharing assistance furnished by a PAP, including a manufacturer PAP, will count toward a beneficiary's TrOOP expenditures, even if the PAP does not comply with the fraud and abuse laws.[9] This approach relieves beneficiaries of the financial risk of accepting assistance from an entity that may be improperly structured or operated.

As to the second issue, the core question is whether the anti-kickback statute would be implicated if a manufacturer of a drug covered under Part D were to subsidize cost-sharing amounts (directly or indirectly through a PAP) incurred by Part D beneficiaries for the manufacturer's product. Consistent with our prior guidance addressing manufacturer cost-sharing subsidies in the context of Part B drugs,[10] we believe such subsidies for Part D drugs would implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse.[11] Simply put, the subsidies would be squarely prohibited by the statute, because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product. Where a manufacturer PAP offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries= incentives to locate and use less expensive, equally effective drugs.

It is impossible to predict with certainty the way in which abuse may occur in a new benefit program that is not yet operational. The following are illustrative examples of some types of abuse that may occur:

- Increased costs to the program. We are concerned that a manufacturer might use beneficiary cost-sharing subsidies, which help beneficiaries meet their TrOOP requirement, to increase the number of beneficiaries using the manufacturer's product who reach the

[5] 42 U.S.C. 1320a–7b(b).

[6] 42 U.S.C. 1320a–7(b)(7); 42 U.S.C. 1320a–7a(a)(7).

[7] In some cases, a subsidy for Part D cost-sharing obligations provided by a pharmaceutical manufacturer may also implicate the prohibition on offering inducements to beneficiaries, as set forth in section 1128A(a)(5) of the Act, if the subsidy is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier, such as a physician or pharmacy. We have interpreted ''provider, practitioner, or supplier'' to exclude pharmaceutical manufacturers unless they also own or operate pharmacies, pharmaceutical benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. *See* Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, supra note 4.

[8] *See* 42 CFR 423.100; 42 CFR 423.464; 70 FR 4194, 4239 (January 28, 2005). We note that CMS is the proper agency to address questions about the mechanics of calculating TrOOP. In certain circumstances, knowing improper TrOOP calculations may give rise to liability under the False Claims Act, 31 U.S.C. 3729–33.

[9] *See* 70 FR 4194 at 4239.

[10] *See, e.g.*, OIG Advisory Opinion Nos. 02–13 and 03–3 (unfavorable opinions involving proposals from pharmaceutical manufacturer PAPs to subsidize Part B cost-sharing amounts). We note that the cost and utilization management features of the Part D program, while important, do not sufficiently mitigate the risks.

[11] Some in the industry have asserted that cost-sharing subsidies for Part D drugs differ from cost-sharing subsidies for Part B drugs so long as the subsidies are given to patients who are in a Part D ''coverage gap'' (*i.e.*, a benefit period during which the beneficiary pays 100% of the cost of the drugs). To support their position, they contend either that beneficiaries in the coverage gap are functionally ''uninsured'' or that the situation is comparable to providing free drugs to financially needy beneficiaries so long as no Federal health care program is billed for all or part of the drug, a practice we previously permitted in the context of subsidies for Part B drugs. *See* OIG Advisory Opinion Nos. 02–13 and 03–3. Under Part D, a ''coverage gap'' is a period of insurance coverage. *See* CMS Frequently Asked Question ID 4855, *http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=4855* (regarding prescription drug benefit coordination of benefits and TrOOP). During the coverage gap, beneficiaries remain enrolled in their Part D plans and have a continuing obligation to pay Part D premiums; Part D plans continue to receive the monthly per-enrollee direct subsidy from the Medicare program. Moreover, subsidies during the coverage gap are not like furnishing free drugs where no Federal health care program is billed. Sufficient spending during the coverage gap qualifies the beneficiary to reach the catastrophic coverage portion of the Part D benefit, at which point the Medicare program resumes payment for most of the costs of the beneficiary's drugs. In this regard, the different structures of the Part B and Part D benefits are crucial to the analysis.

catastrophic benefit in any given coverage year and to hasten the point during the coverage year at which beneficiaries reach the catastrophic benefit. This is of particular import because Medicare will make cost-based payments during the catastrophic coverage benefit.[12] We know from experience that cost-based reimbursement is inherently prone to abuse, including by vendors that sell products reimbursed on a cost basis. Similarly, we are concerned about the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices. Inflated prices could have a ''spillover'' effect on the size of direct subsidies, reinsurance payments, and risk corridor payments paid by Medicare to Part D plans in future years,[13] potentially resulting in higher costs to the Medicare program.

• Beneficiary steering and anti-competitive effects. Subsidies provided by traditional pharmaceutical manufacturer PAPs have the practical effect of locking beneficiaries into the manufacturer's product, even if there are other equally effective, less costly alternatives (and even if the patient's physician would otherwise prescribe one of these alternatives). Subsidizing Medicare Part D cost-sharing amounts will have this same steering effect. Moreover, as we have previously noted in the Part B context, cost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions. We are concerned that pharmaceutical manufacturers may seek improperly to maximize these profits by creating sham ''independent'' charities to operate PAPs; by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products (discussed in more detail below); or by manipulating financial need or other eligibility criteria to maximize the number of beneficiaries qualifying for cost-sharing subsidies.

These risks are necessarily illustrative, not exhaustive, of the potential risks presented by pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts.

Cost-sharing subsidies offered by a pharmaceutical manufacturer PAP to the dispensing supplier differ in two important respects from a provider's or supplier's unadvertised, non-routine waiver of cost-sharing amounts based on a patient's financial need, which has long been permitted. First, the subsidies result in the dispensing supplier receiving full payment for the product and avoiding the risk of non-collection, thus providing the supplier with an economic incentive to favor the subsidized product and a disincentive to recommend a lower-cost alternative, such as a generic. In addition, the availability of PAP assistance is typically advertised and may influence a beneficiary's choice of product (through the prescribing physician acting on behalf of the beneficiary). Moreover, once a beneficiary is enrolled in a pharmaceutical manufacturer PAP, the beneficiary is effectively locked into using the pharmaceutical manufacturer's product, since the beneficiary risks losing financial assistance if he or she switches products, even if an equally effective, but less expensive, product would be in his or her best medical interests.

A definitive conclusion regarding whether a particular manufacturer PAP violates the anti-kickback statute would require a case-by-case analysis of all of the relevant facts and circumstances, including the intent of the parties. However, for the reasons noted above, we believe that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts raise substantial concerns under the anti-kickback statute.

B. Independent Charity PAPs

Long-standing OIG guidance makes clear that pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, *bona fide* charitable assistance programs.[14]

Under a properly structured program, donations from a pharmaceutical manufacturer to an independent, *bona fide* charity that provides cost-sharing subsidies for Part D drugs should raise few, if any, anti-kickback statute concerns, so long as:

(i) Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) exerts any direct or indirect influence or control over the charity or the subsidy program;

(ii) The charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary (*i.e.*, the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);

(iii) The charity awards assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;

(iv) The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and[15]

(v) The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.[16]

[12] *See* 42 CFR 423.329. For purposes of calculating payments under catastrophic coverage, the cost of a beneficiary's drug is based in part on the plan's negotiated price (*i.e.*, a price that is set by the plan based on negotiations with pharmaceutical manufacturers and pharmacies).

[13] *See* 42 CFR 423.329; 42 CFR 423.336.

[14] In-kind donations of drugs to independent charity PAPs pose additional risks not yet directly addressed in prior OIG guidance, and we have insufficient experience with them to offer detailed guidance here. While in-kind donations have the potential benefit of increasing the value of donations (because marginal costs of drugs are generally low), they also have the effect of creating a direct correlation between the donation and use of a particular donor's product, thereby weakening important safeguards of an independent charity PAP arrangement. Moreover, there would appear to be difficult accounting and valuation issues raised by the use of in-kind product to subsidize Part D cost-sharing obligations, both for purposes of calculating TrOOP and for purposes of determining the amount of in-kind drug that equals the Part D cost-sharing amount owed.

[15] We recognize that what constitutes an appropriate determination of financial need may vary depending on individual patient circumstances. We believe that independent charity PAPs should have flexibility to consider relevant variables beyond income. For example, PAPs may choose to consider the local cost of living; a patient's assets and expenses; a patient's family size; and the scope and extent of a patient's medical bills.

[16] We have previously approved a *bona fide* independent charity PAP arrangement that included only limited reporting of *aggregate* data to donors in the form of monthly or less frequent reports containing *aggregate* data about the number of all applicants for assistance in a disease category and the number of patients qualifying for assistance in that disease category. *See* OIG Advisory Opinion No. 02–1. No individual patient information may be conveyed to donors. Moreover, neither patients nor donors may be informed of the donation made to the PAP by others, although, as required by Internal Revenue Service regulations, the PAP's annual report and a list of donors may be publicly available. *See* OIG Advisory Opinion No. 04–15. Reporting of data that is not in the aggregate or that is patient specific would be problematic, as would reporting of any data, whether or not in the

Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices.[17]

We recognize that some *bona fide* independent charities reasonably focus their efforts on patients with particular diseases (such as cancer or diabetes) and that some of these charities permit donors to earmark their contributions generally for support of patients with a specific disease. In general, the fact that a pharmaceutical manufacturer's donations are earmarked for one or more broad disease categories should not significantly raise the risk of abuse. However, we are concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products. For example, we would be concerned if disease categories were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases. This type of arrangement would present an elevated risk of fraud and abuse because of the increased likelihood that the PAP would function as an improper conduit for manufacturers to provide funds to patients using their specific drugs. To avoid this risk, pharmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories,[18] and pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.[19]

C. PAPs Operating Outside Part D

CMS has issued guidance stating that PAPs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit.[20] In these circumstances, the beneficiary obtains drugs without using his or her Part D insurance benefit. Beginning when a beneficiary's assistance under a PAP became effective, no claims for payment for any covered outpatient prescription drug provided outside of the Part D benefit may be filed with a Part D plan or the beneficiary, and the assistance must not count toward the beneficiary's TrOOP or total Part D spending for any purpose. For the reasons noted in connection with pharmaceutical manufacturer PAPs discussed above, PAPs that provide assistance outside the Part D benefit only during the coverage gap (*i.e.*, ''wrapping around'' the Part D benefit) pose a heightened risk of abuse. However, while it is difficult to assess the application of the fraud and abuse laws to PAPs that operate outside Part D absent a specific set of facts, it would appear that PAPs that furnish free outpatient prescription drugs entirely outside the Part D benefit pose a reduced risk under the anti-kickback statute, provided that:

(i) The PAP includes safeguards that ensure that Part D plans are notified that the drug is being provided outside the Part D benefit so that no payment is made for the subsidized drug by any Part D plan and no part of the costs of the subsidized drug is counted toward any beneficiary's TrOOP;

(ii) The PAP provides assistance for the whole Part D coverage year (or the portion of the coverage year remaining after the beneficiary first begins receiving the PAP assistance);[21]

(iii) The PAP assistance remains available even if the beneficiary's use of the subsidized drug is periodic during the coverage year;

(iv) The PAP maintains accurate and contemporaneous records of the subsidized drugs to permit the Government to verify the provision of drugs outside the Part D benefit;

(v) Assistance is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to the providers, practitioners, or suppliers used by the patient or the Part D plan in which the patient is enrolled; and

(vi) The arrangement complies with any then-existing guidance from CMS.

In addition, to promote quality of care, we believe it would be important for PAPs that provide free drugs outside the Part D benefit to coordinate effectively with Part D plans so that the plans can undertake appropriate drug utilization review and medication therapy management program activities.

D. ''Coalition Model'' PAPs

We are aware of nascent efforts by some in the industry to develop arrangements through which multiple pharmaceutical manufacturers would join together to offer financially needy Part D enrollees a card or similar vehicle that would entitle the enrollees to subsidies of their cost-sharing obligations for the manufacturers' products, typically in the form of discounts off the negotiated price otherwise available to the enrollee under his or her Part D plan. It is premature to offer definitive guidance on these evolving programs. Although these programs would operate so that the manufacturers effectively underwrite only the discounts on their own products, we observe that the risk of an illegal inducement potentially may be reduced if: (i) The program contains features that adequately safeguard against incentives for card holders to favor one drug product (or any one supplier, provider, practitioner, or Part D plan) over another; (ii) the program includes a large number of manufacturers, including competing manufacturers and manufacturers of both branded and generic products, sufficient to sever any nexus between the subsidy and a beneficiary's choice of drug; and (iii) each participating pharmaceutical manufacturer offers subsidies for *all* of its products that are covered by *any* Part D plan formulary. Other safeguards may also be needed to reduce the risk of an improper inducement. Moreover, a program under which Part D enrollees pay a portion of their drug costs out-of-pocket would tend to reduce the risk of abuse by preserving the beneficiary's incentive to locate and purchase equally effective, lower cost drugs.

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aggregate, related to the identity, amount, or nature of subsidized drugs.

[17] For further guidance on establishing compliant independent charity PAPs, see OIG Advisory Opinion Nos. 04–15, 02–1, 98–17, and 97–1 (favorable opinions issued to *bona fide*, independent charities that accept industry funding).

[18] Nothing in this Bulletin should be construed as preventing a charity from obtaining educational materials from donors that the donors generally make available to practitioners or the general public (*e.g.*, clinical information about drug products).

[19] We recognize that, in rare circumstances, there may only be one drug covered by Part D for the diseases in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular category. In these unusual circumstances, the fact that a disease category only includes one drug or manufacturer would not, standing alone, be determinative of an anti-kickback statute violation. Such a determination could only be made on a case-by-case basis after examining all of the applicable facts and circumstances, including the intent of the parties. We note that it would be important for the PAP program to cover additional products or manufacturers as they become available.

[20] *See* CMS Frequently Asked Question ID 6153, *http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=6153* (regarding PAPs providing assistance with Part D drug costs to Part D enrollees outside of the Part D benefit and without counting towards TrOOP).

[21] We note that our position that PAPs operating outside the Part D benefit should provide assistance for the remainder of the coverage year is consistent with our observation in several advisory opinions that manufacturers ''may provide free drugs to financially needy beneficiaries, so long as no Federal health care program is billed for all or part of the drugs.'' OIG Advisory Opinion Nos. 02–13 and 03–3.

IV. Bulk Replacement Models

Bulk replacement'' or similar programs, pursuant to which pharmaceutical manufacturers (or their affiliated PAPs) provide in-kind donations in the form of free drugs to pharmacies, health centers, clinics, and other entities that dispense drugs to qualifying uninsured patients, are different from traditional PAPs that provide assistance directly to patients. These programs potentially implicate the Federal anti-kickback statute if the free drugs are given to a recipient that is in a position to generate Federal health care program business for the donor manufacturer. Whether a particular bulk replacement program complies with the fraud and abuse laws would require a case-by-case analysis. In undertaking any analysis, we would consider, among other factors, how the program is structured and whether there are safeguards in place: (i) To protect Federal health care program beneficiaries from being steered to particular drugs based on the financial interests of their health care providers or suppliers; (ii) to protect the Federal health care programs from increased program costs; and (iii) to ensure that bulk replacement drugs are not improperly charged to Federal health care programs. Additionally, bulk replacement as a means of subsidizing only the Medicare Part D cost-sharing amount potentially raises substantial risks related to accounting for the amount of replacement drug that would be equivalent to the cost-sharing amount owed by the beneficiary; properly attributing that amount to specific beneficiaries; and properly calculating TrOOP.

V. Transitioning From Existing Pharmaceutical Manufacturer PAPs

OIG is mindful of the importance of a smooth, effective transition for beneficiaries who are currently participating in pharmaceutical manufacturer PAPs and elect to enroll in Medicare Part D. While most such enrollees are likely to qualify for the low-income subsidies available under Part D, we are concerned that there may not be sufficient independent charity PAPs available before the January 1, 2006 start date of the Part D program to accommodate beneficiaries of limited means who may need an alternative PAP arrangement. We recognize the importance of not unnecessarily burdening or alarming beneficiaries. We believe that manufacturers will play an important role in ensuring an effective transition.

With respect to pharmaceutical manufacturer PAPs that are in existence prior to the date of publication of this Special Advisory Bulletin, during the initial calendar year of the Part D benefit, OIG will take into consideration in exercising its enforcement discretion with respect to administrative sanctions arising under the anti-kickback statute whether the PAP is taking prompt, reasonable, verifiable, and meaningful steps to transition patients who enroll in Part D to alternative assistance models, such as independent charities.

In addition to taking steps to transition beneficiaries to other programs, pharmaceutical manufacturer PAPs can reduce their fraud and abuse exposure by taking one or more of the following steps: (i) Adjusting financial need criteria to reflect the lower drug costs incurred by Part D enrollees (*i.e.*, liability for premiums and cost-sharing amounts only, instead of the total cost of the drugs); (ii) where possible, subsidizing other drugs in the same class as the manufacturer's products covered by the PAP if a beneficiary's physician prescribes an alternate product; and (iii) checking CMS eligibility files, to the extent available, on a reasonably regular basis to determine whether PAP patients have enrolled in Part D and should be transitioned to other assistance programs. Occasional, inadvertent cost-sharing subsidies provided to a Part D enrollee should not be problematic (*e.g.*, where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D). Notwithstanding a pharmaceutical manufacturer's compliance with the foregoing, the Government will take enforcement action in cases where there is evidence of unlawful intent.

The potential variability of PAPs, the fact that the Part D program is not yet operational, and the fact that it is not possible to predict all future or potential fraud and abuse schemes with certainty, make it difficult to provide comprehensive general guidance on the application of the anti-kickback statute to PAPs for Part D enrollees at this time. We intend to monitor the situation closely and may issue further guidance, if needed. Nothing in this Bulletin should be construed as precluding any form of lawful assistance not described in this Bulletin.

VI. OIG Advisory Opinion Process

OIG has an advisory opinion process that is available to individuals and entities, including pharmaceutical manufacturers, that want assurance that they will not run afoul of the fraud and abuse laws.[22] OIG advisory opinions are written opinions that are legally binding on OIG, the Department, and the party that requests the opinion. To obtain an opinion, the requesting party must submit a detailed, written description of its existing or proposed business arrangement. The length of time that it takes for OIG to issue an opinion varies based upon a number of factors, including the complexity of the arrangement, the completeness of the submission, and how promptly the requestor responds to requests for additional information. Further information about the process, including frequently asked questions, can be found on the OIG Web page at *http://oig.hhs.gov/fraud/advisoryopinions.html*.

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse, and waste in the Department's programs and to promote efficiency and economy in departmental operations. OIG carries out this mission through a nationwide program of audits, investigations, and inspections. The Health Care Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by OIG.

Daniel R. Levinson,

Inspector General.

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BILLING CODE 4150–04–P

DEPARTMENT OF HOMELAND SECURITY

[DHS–2005–0054]

Office of State and Local Government Coordination and Preparedness; SAFER Grant Program

AGENCY: Office of State and Local Government Coordination and Preparedness, DHS.

ACTION: Notice and request for comment.

SUMMARY: Pursuant to the Paperwork Reduction Act, the Department of Homeland Security (DHS) solicited comments on the proposed collection of information in connection with the Staffing for Adequate Fire and Emergency (SAFER) Grant Application.

[22] Section 1128D(b) of the Act; 42 CFR part 1008.

You may wish to adapt the following document to send to those programs which require a letter certifying your patient's need for assistance.
Should also present a well-documented evaluation, providing sufficient evidence and information to help a review committee in making its decision. You might wish to mention a family illness, financial hardship, job turnover, divorce, catastrophic event or other factor... demonstrate financial hardship.

[Date: _____]

[Pharmaceutical Program Address]

[Patient Name:]

[Patient Address:]

To Whom It May Concern:

This above-named patient is being treated for _____ [clinical diagnosis].

The patient has been under my care for _____[period of time].

Enclosed is a prescription for _____ [drug] ___ mg [dosage].

In accordance with your eligibility criteria, this patient is currently unable to afford to pay for this drug due to financial hardship. The patient also has no insurance coverage to help pay for the cost of this drug, and is ineligible for any public assistance funding.

Please forward [an application / medication / samples] to this office at: [address here]

Call me with any questions at [office phone # here]. We greatly appreciate the free medications your company makes available to the patients we serve.

Thank you for your assistance.

Signed,

_____ [doctor's original signature here]
Doctor's Name typed out here

Doctor's DEA #: _____

Attachments: