

recommended by a urologist based on current standard of care, before consideration of PROGENSA PCA3 ASSAY results. A PCA3 score <25 is associated with a decreased likelihood of a positive biopsy. Prostatic biopsy is required for diagnosis of cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PROGENSA PCA3 ASSAY (U.S. Patent No. 7,008,765) from The Johns Hopkins University & The Stichting Katholieke Universiteit, The University Medical Centre Nijmegen, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 1, 2013, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of PROGENSA PCA3 ASSAY represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PROGENSA PCA3 ASSAY is 936 days. Of this time, 383 days occurred during the testing phase of the regulatory review period, while 553 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective or if an exemption is not required, the date an institutional review board under section 520(g)(3) of the FD&C Act (21 U.S.C. 360j(g)(3)) approved the clinical investigation of the device in humans:* July 24, 2009. FDA has confirmed the applicant's claim that no investigational device exemption (IDE) was required under section 520(g) of the FD&C Act for human tests to begin. Institutional review board (IRB) approval was required under section 520(g)(3) of the FD&C Act and became effective on July 24, 2009.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 10, 2010. FDA has verified the applicant's claim that the premarket approval application (PMA) for PROGENSA PCA3 ASSAY (PMA 100033) was initially submitted August 10, 2010.

3. *The date the application was approved:* February 13, 2012. FDA has verified the applicant's claim that PMA

P100033 was approved on February 13, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 745 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 29, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 26, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 27, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of Inspector General**

**Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs**

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

**ACTION:** Notice.

**SUMMARY:** This Supplemental Bulletin updates the OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees that published in the **Federal Register** on November 22, 2005 (70 FR 70623).

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

Patients who cannot afford their cost-sharing obligations for prescription drugs may be able to obtain financial assistance through a patient assistance program (PAP). PAPs have long provided important safety net assistance to such patients, many of whom have chronic illnesses and high drug costs. Many PAPs also present a risk of fraud, waste, and abuse with respect to Medicare and other Federal health care programs. We issued a Special Advisory Bulletin regarding PAPs in 2005<sup>1</sup> (the 2005 SAB) in anticipation of questions likely to arise in connection with the Medicare Part D benefit. In the 2005 SAB, we addressed different types of PAPs and stated that we believed lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.<sup>2</sup> We also noted in the 2005 SAB that we could only speculate on fraud and abuse risk areas, because the Part D benefit had not yet begun. This Supplemental Special Advisory Bulletin (Supplemental Bulletin) is based on experience we have gained in the intervening years; it is not intended to replace the 2005 SAB, nor does it replace other relevant guidance, such as the 2002 OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries.<sup>3</sup>

We continue to believe that properly structured PAPs can help Federal health care program beneficiaries. This Supplemental Bulletin provides additional guidance regarding PAPs operated by independent charities (Independent Charity PAPs) that provide cost-sharing assistance for

<sup>1</sup> OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 FR 70623 (Nov. 22, 2005), available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf>.

<sup>2</sup> The 2005 SAB focused on PAPs under the then-upcoming Part D program, but the guidance also referenced co-payment assistance programs for drugs covered under Medicare Part B. Although these Medicare programs differ, and the types of PAPs may differ, the principles set forth in the 2005 SAB and herein apply regardless of which Federal health care program (as defined in section 1128B(f) of the Social Security Act (the Act)) covers the drugs.

<sup>3</sup> The 2002 OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries is available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

prescription drugs. To address some of the specific risks that have come to our attention in recent years, this guidance discusses problematic features of PAPs with respect to the anti-kickback statute, section 1128B(b) of the Act,<sup>4</sup> and the provision of the Civil Monetary Penalties Law prohibiting inducements to Medicare and Medicaid beneficiaries (Beneficiary Inducements CMP), section 1128A(a)(5) of the Act.<sup>5</sup> 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.

## II. The Anti-Kickback Statute and the Beneficiary Inducements CMP

The anti-kickback statute makes it a criminal offense 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. 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 give or 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 5 years, or both. OIG may also initiate administrative proceedings to exclude a person from Federal health care programs or to impose civil monetary penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.<sup>6</sup>

Two remunerative aspects of PAP arrangements require scrutiny under the anti-kickback statute: donor contributions to PAPs (which can also be analyzed as indirect remuneration to patients) and PAPs’ grants to patients. If a donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor’s federally reimbursable items, the statute could be violated. Similarly, if a PAP’s grant of

financial assistance to a patient is made to influence the patient to purchase (or to induce the patient’s physician to prescribe) certain items, the statute also could be violated. A determination regarding whether a particular arrangement violates the anti-kickback statute requires an individualized evaluation of all of the relevant facts and circumstances, including the parties’ intent. For PAPs, the nature, structure, sponsorship, and funding of the particular PAP are factors relevant to the analysis.

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person that offers or transfers remuneration to a Medicare or State health care program (as defined under section 1128(h) of the Act) beneficiary that the benefactor 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 may be made, in whole or in part, by Medicare or a State health care program. OIG may initiate administrative proceedings to seek such CMPs and exclude such person from the Federal health care programs. A subsidy for cost-sharing obligations provided by a pharmaceutical manufacturer through a PAP may implicate the Beneficiary Inducements CMP, if the subsidy is likely to influence a Medicare or State health care program beneficiary’s selection of a particular provider, practitioner, or supplier, such as by making eligibility dependent on the patient’s use of certain prescribing physicians or certain pharmacies to dispense the drugs.

## III. Independent Charity PAPs

Longstanding OIG guidance, including the 2005 SAB, makes clear that pharmaceutical manufacturers can effectively contribute to the safety net by making cash donations to independent, *bona fide* charitable assistance programs. The 2005 SAB sets forth a number of factors that we continue to believe are fundamental to a properly structured Independent Charity PAP. See 70 FR 70626. Many of these factors relate to the independence of the charity, as discussed further below. In this Supplemental Bulletin, we expand on our previous guidance in that regard, focusing on three areas: Disease funds, eligible recipients, and the conduct of donors.

### A. Disease Funds

As we explained in the 2005 SAB, we recognize that *bona fide* independent charities may reasonably focus their

efforts on patients with particular diseases (such as cancer or diabetes) and that, in general, the fact that a pharmaceutical manufacturer’s donations to an independent charity are earmarked for one or more broad disease funds should not significantly raise the risk of abuse. At the time, however, we also expressed our concern that, in some cases, charities might define their disease funds so narrowly that the earmarking effectively results in a donor’s subsidization of its own products. Over the past several years, we have become aware that some Independent Charity PAPs are, in fact, establishing narrowly defined disease funds and covering a limited number of drugs within those funds. To address this development, we discuss and expand on some of the safeguards that we originally set forth in the 2005 SAB to reduce the risk of abuse. We reiterate here that an Independent Charity PAP must not function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries’ drug choices.

One of the points we made in the Independent Charity PAPs section of the 2005 SAB was that pharmaceutical manufacturers and their affiliates should not exert any direct or indirect influence or control over the charity or its assistance program. We also stated that donors should not influence the identification of disease funds<sup>7</sup> and that we would be concerned if disease funds were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. These were merely examples—not an exclusive list—of improperly narrow approaches to defining disease funds. For example, we also are concerned about disease funds defined by reference to the stages of a particular disease, the type of drug treatment, and any other ways of narrowing the definition of widely recognized disease states. A charity with narrowly defined disease funds may be subject to scrutiny if the disease funds result in funding exclusively or primarily the products of donors or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donors’ products.<sup>8</sup>

<sup>7</sup> The 2005 SAB used the term “disease categories.” Our experience since 2005 suggests that the term “disease fund” is more accurate in this context.

<sup>8</sup> This is true even if the charity has obtained a favorable advisory opinion, because favorable opinions related to PAPs typically are based upon the charity’s certifications that: (1) No donor or affiliate of any donor has exerted or will exert any

<sup>4</sup> 42 U.S.C. 1320a–7(b).

<sup>5</sup> 42 U.S.C. 1320a–7(a)(5).

<sup>6</sup> 42 U.S.C. 1320a–7(b)(7) and 42 U.S.C. 1320a–7(a)(7).

We also are increasingly concerned about Independent Charity PAPs that choose to establish or operate disease funds that limit assistance to a subset of available products. Through our advisory opinion process, we have seen Independent Charity PAPs seeking to cover few drugs, such as by covering copayments only for expensive or specialty drugs. We are concerned that funds limited in this manner may not be beneficial to patients or Federal health care programs. Beneficiaries should not be tied to a particular product, or to a subset of available products, to receive or continue their assistance. Although we recognize that a patient prescribed an expensive drug may have a greater need for financial assistance than a patient prescribed a less expensive alternative, we are concerned that limiting PAP cost-sharing support to expensive products may steer patients in a manner that is costly to Federal health care programs and may even facilitate increases in drug prices. Moreover, whether a drug is “expensive” is a relative question that depends, in part, on the financial resources of the consumer; even a generic drug can be expensive for some patients. Finally, limiting assistance to certain drugs may steer patients away from potentially more beneficial products because assistance is available for one treatment and not another. Consequently, a fund will be subject to more scrutiny if it is limited to a subset of available products, rather than all products approved by the Food and Drug Administration (FDA) for treatment of the disease state(s) covered by the fund or all products covered by the relevant Federal health care program when prescribed for the treatment of the disease states (including generic or bioequivalent drugs).<sup>9</sup>

direct or indirect influence or control over the charity or any of the charity's programs; (2) the charity will define its disease funds in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (3) the charity's disease funds will not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. If the arrangement does not in practice comport with the facts presented in the advisory opinion, then the arrangement is not protected by the opinion. All of our advisory opinions are available on the OIG Web site at: <http://oig.hhs.gov/compliance/advisory-opinions/index.asp>.

<sup>9</sup> An Independent Charity PAP is not required to provide assistance for drugs prescribed off-label. However, we would expect a truly independent charity to treat all its funds equally. Thus, if the Independent Charity PAP offered assistance for all drugs covered by Medicare in Fund A, but limited assistance offered for Fund B to FDA-approved uses, the funds could be subject to scrutiny to determine whether either coverage determination was made to benefit a donor.

The 2005 SAB acknowledged that, in rare circumstances, there may be only one drug covered by Part D for the disease(s) in a particular disease fund or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the disease(s) in a particular disease fund. The 2005 SAB noted that, in these unusual circumstances, the fact that a disease fund includes only one drug or drugs made by one manufacturer would not, standing alone, be determinative of an anti-kickback statute violation. A determination of an anti-kickback statute violation can be made only on a case-by-case basis after examining the applicable facts and circumstances, including the intent of the parties. Notwithstanding the need for an individualized analysis, a disease fund that covers only a single product, or the products made or marketed by only a single manufacturer that is a major donor to the fund, will be subject to scrutiny. When determining whether an anti-kickback violation occurred, we would consider, among other factors, whether the disease fund in question appears to be narrowly defined in a manner that favors any of the fund's donors.

While we understand that many charities have limited resources and seek to use them to assist patients with the greatest financial need, assessing a patient's financial need is a separate concern from determining which drugs to include in a disease fund. Narrowly defining disease funds or limiting disease funds to provide assistance only for expensive drugs can result in steering patients to the drugs for which assistance is available. This type of steering increases the likelihood that the donors could use the PAPs as improper conduits to provide a subsidy to patients who use the donors' own products. This potentially increases costs to the Federal health care programs in cases where a lower cost, equally effective drug is available. Moreover, the ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support.

In short, disease funds should be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products; disease funds should not be defined for the purpose of limiting the drugs for which the Independent Charity PAP provides assistance.

### *B. Eligible Recipients*

It has come to our attention that some Independent Charity PAPs have started operating, or seek to operate, funds that provide financial assistance only to Federal health care program beneficiaries. We do not believe that the mere fact that a fund serves only Federal health care program beneficiaries increases risk to the Federal health care programs. In fact, we issued a favorable advisory opinion to an Independent Charity PAP that intended to develop a fund to serve only Medicare beneficiaries.<sup>10</sup> The safeguards regarding defining disease funds and recipient eligibility described in the 2005 SAB and in this Supplemental Bulletin, when properly implemented, should sufficiently protect Federal health care programs.

Regardless of whether a fund is available to all patients or is limited to Federal health care program beneficiaries, the Independent Charity PAP must determine eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. Some Independent Charity PAPs base their eligibility criteria on the poverty guidelines, which take into account family size, for determining financial need. As we explained in the 2005 SAB, Independent Charity PAPs also have the flexibility to consider relevant variables beyond income. Other variables Independent Charity PAPs may choose to consider, for example, are the local cost of living and the scope and extent of a patient's total medical bills. We are not recommending or requiring any particular method for assessing financial need. We do, however, want to emphasize that the cost of the particular drug for which the patient is applying for assistance is not an appropriate stand-alone factor in determining individual financial need; it is likely one of many obligations that affects the patient's financial circumstances. We also note that generous financial need criteria, particularly when a fund is limited to a subset of available drugs or the drugs of a major donor, could be evidence of intent to fund a substantial part of the copayments for a particular drug (or drugs) for the purpose of inducing the use of that drug (or those drugs), rather than for the purpose of supporting financially needy patients diagnosed with a particular disease.

<sup>10</sup> See Modification of OIG Advisory Opinion 07-06, available at: [http://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn07-06\\_mod.pdf](http://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn07-06_mod.pdf).

### C. Conduct of Donors

Thus far, this Supplemental Bulletin has focused on the conduct of Independent Charity PAPs. Similarly, when we have issued favorable advisory opinions regarding Independent Charity PAPs, the focus has been on the charities that requested the opinions—not the donors.<sup>11</sup> In requesting an opinion, a charity certifies to actions it will take to ensure the independence of the PAP from the donors. The charity is not in a position to certify as to the actions of the donors with parties outside the arrangement. For example, an advisory opinion issued to an independent charity regarding the PAP it operates typically states that the charity has certified that it will provide donors only with reports including data such as the aggregate number of applicants for assistance, the aggregate number of patients qualifying for assistance, and the aggregate amount disbursed from the fund during that reporting period. Thus, the charity would not give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP. The procedures described in these certifications are a critical safeguard and a material fact upon which we have relied in issuing favorable advisory opinions regarding Independent Charity PAPs. These opinions do not address actions by donors to correlate their funding of PAPs with support for their own products. Such actions may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute.

### IV. Conclusion

OIG continues to believe that properly structured, Independent Charity PAPs provide a valuable resource to financially needy patients. We also believe that Independent Charity PAPs raise serious risks of fraud, waste, and abuse if they are not sufficiently independent from donors. This Supplemental Bulletin reiterates and amplifies our guidance, based on practices and trends we have seen in the industry. We recognize that some charitable organizations with PAPs have received favorable advisory opinions

<sup>11</sup> An advisory opinion has no application to, and cannot be relied upon by, any individual or entity other than the requestor of the opinion. Thus, a donor is not protected by an advisory opinion issued only to the entity to which it donates. See section 1128D(b)(4)(A) of the Act (42 U.S.C. 1320a-7d(b)(4)(A)); 42 CFR 1008.53.

that may include features that are discouraged in this Supplemental Bulletin. We are writing to all Independent Charity PAPs that have received favorable opinions to explain how we intend to work with them to ensure that approved arrangements are consistent with our guidance. We anticipate that some opinions will need to be modified. We will post any such modifications on our Web site with the original opinions, consistent with our current practice. Favorable advisory opinions will continue to protect the arrangements described in the opinions until we issue any final notice of modification or termination to the requestors of those opinions. It is our intent that there be no disruption of patient care during this process. Should donors or PAPs continue to have questions about the structure of a particular organization or transaction, the OIG Advisory Opinion process remains available. Information about the process may be found at: <http://oig.hhs.gov/faqs/advisory-opinions-faq.asp>.

Dated: May 16, 2014.

**Daniel R. Levinson,**  
Inspector General.

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## DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2013-0065]

### Agency Information Collection Activities: Submission for Review; Information Collection Request for the Department of Homeland Security (DHS), Science and Technology, National Capital Region Secure Delivery Technology Program

**AGENCY:** Science and Technology Directorate, DHS.

**ACTION:** 30-Day notice and request for comment.

**SUMMARY:** The Department of Homeland Security (DHS), Science & Technology Directorate (S&T) invites the general public to comment on data collection forms for the National Capital Region (NCR) Secure Delivery Technology program. This is a new Paper Reduction Act collection without an OMB control number. Secure Delivery Technology is responsible for improving the efficiency and effectiveness of deliveries to General Services Administration (GSA) facilities in the NCR.

Information collected by Federal Protective Service (FPS) personnel to ensure secured deliveries in the NCR

includes the delivery driver's name and license number. The information collected is used by FPS personnel to verify the identity of the driver at the delivery central screening facility and final destination locations, along with providing an auditable trail for post-delivery analysis should an event occur that requires forensics.

DHS invites interested persons to comment on the "National Capital Region Secure Delivery Technology Driver Log" form and instructions (hereinafter "Forms Package") for the S&T NCR Secure Delivery Technology. Interested persons may receive a copy of the Forms Package by contacting the DHS S&T PRA Coordinator. This notice and request for comments is required by the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35).

**DATES:** Comments are encouraged and will be accepted until June 30, 2014.

**ADDRESSES:** Interested persons are invited to submit comments, identified by docket number DHS-2013-0065, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Please follow the instructions for submitting comments.

- **Email:** [Jonathan.Mcentee@hq.dhs.gov](mailto:Jonathan.Mcentee@hq.dhs.gov). Please include docket number DHS-2013-0065 in the subject line of the message.

- **Mail:** Science and Technology Directorate, ATTN: National Capital Region Secure Delivery Technology Program, 245 Murray Drive, Mail Stop 0202, Washington, DC 20528.

**FOR FURTHER INFORMATION CONTACT:** Jonathan Mcentee, [Jonathan.Mcentee@hq.dhs.gov](mailto:Jonathan.Mcentee@hq.dhs.gov), 202-254-6139. (Not a toll free number).

**SUPPLEMENTARY INFORMATION:** The Department is committed to improving its information collection and urges all interested parties to suggest how these materials can further reduce burden while seeking necessary information under the Paper Reduction Act.

DHS is particularly interested in comments that:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- (3) Suggest ways to enhance the quality, utility, and clarity of the information to be collected; and

- (4) Suggest ways to minimize the burden of the collection of information