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.

[FR Doc. 05–23038 Filed 11–21–05; 8:45 am]

BILLING CODE 4150–04–P

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

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.

This notice extends the comment period by 30 days.

DATES: Comments are encouraged and will be accepted until December 22, 2005. This process is conducted in accordance with 5 CFR 1320.10

ADDRESSES: You may submit comments, identified by docket number DHS–2005–0054, by *one* of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- E-mail: *tom.harrington@dhs.gov*. Include docket number DHS–2005–0054 in the subject line of the message.
- Mail: Office of State and Local Government Coordination and Preparedness, Grants Program Office, 810 7th Street, NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Tom Harrington 202–786–9791 (this is not a toll free number).

SUPPLEMENTARY INFORMATION: DHS, as part of its continuing effort to reduce paperwork and respondents' burden, invites the general public to take this opportunity to comment on this proposed information collection as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)).

Currently, the Office of State and Local Government Coordination and Preparedness (OSLGCP) is soliciting comments concerning a proposed new collection, the SAFER Grant Application. The information collection was previously published in the **Federal Register** on August 16, 2005 at 70 FR 48170 allowing for OMB review and a 60-day public comment period. No comments were received. The purpose of this notice is to allow an additional 30-days for public comments.

Description: The SAFER Act 15 U.S.C.229(a) provides for $65 million in grant funding to be distributed directly to individual fire departments on a competitive basis. The law allows DHS to fund fire department staff and benefits on a decreasing cumulative value over the span of five years. The information collected through the program's application is the minimum necessary to evaluate grant applications authorized under the SAFER Grant Program or is necessary for DHS to comply with mandates delineated in the law.

Public Participation: Interested persons are invited to participate in this Information Collection Request by submitting written data, views, or arguments on all aspects of the proposed Information Collection Request. OSLGCP also invites comments that relate to the economic, environmental, or federalism affects that might result from this Information Collection Request. Comments that will provide the most assistance to the OSLGCP in developing these procedures will reference a specific portion of the Information Collection Request, explain the reason for any recommended change, and include data, information, or authority that support such recommended change.

Instructions: All submissions received must include the agency name and docket number DHS–2005–0054 for this Information Collection Request. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

Analysis:

Agency: Department of Homeland Security, Office of State and Local Government Coordination and Preparedness.

Title: Staffing for Adequate Fire and Emergency Response (SAFER) Grant Application.

OMB Control Number: NEW.

Frequency: Quarterly.

Affected Public: State, local or tribal government.

Estimated Number of Respondents: 7,000.

Estimated Time per Response: 17 hours per response.

Total Burden Hours: 149,000.

Total Cost Burden: None.

Dated: November 14, 2005.

Scott Charbo,

Chief Information Officer.

[FR Doc. 05–23047 Filed 11–21–05; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Triennial Status Report and Status Report Fee: General Notice

AGENCY: Bureau of Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of due date for Status Report and Fee.

SUMMARY: This is to advise Customs brokers that the Triennial Status Report Fee of $100 that is assessed for each license held by a broker whether it may be an individual, partnership, association or corporation, is due during the month of February 2006 along with the corresponding status report.

DATES: Due date for payment of the fee and status report: February 28, 2006.

FOR FURTHER INFORMATION CONTACT: Russell Morris, Broker Management Branch, (202) 344–2717.

SUPPLEMENTARY INFORMATION: In accordance with 19 U.S.C. 1641(g) and 19 CFR 111.30(d), each broker must file a written status report and pay the corresponding fee of $100 every three years. The report is due every three years regardless of the date the license was issued to the broker. The last status report and fee were due during the month of February 2003. Reports and fees must be filed during the month of February 2006, and be addressed to the director of the port that originally delivered the license to the broker. No reports or fees should be submitted directly to Customs and Border Protection Headquarters.

The elements that must be included in the report are prescribed in 19 CFR 111.30(d). While no particular format is required, a model report may be obtained from your local Customs and Border Protection port office.

Dated: November 15, 2005.

Jayson P. Ahern,

Assistant Commissioner, Office of Field Operations.

[FR Doc. 05–23061 Filed 11–21–05; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement Bureau

[File No. 1653–0029]

Agency Information Collection Activities: Extension of a Currently Approved Information Collection; Comment Request

ACTION: 60-day notice of information collection under review; immigration user fee.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE) submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until January 23, 2006.

Written comments and suggestions from the public and affected agencies