TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section/Title/FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(4)(v)/Summary Report of Increased Frequency of Adverse Drug Experience	190	1.58	300	2	600
514.80(b)(5)(i)/Special Drug Experience Report/Form FDA 2301	190	0.13	25	2	50
514.80(b)(5)(ii)/Advertising and Promotional Materials Report/Form FDA 2301	190	2.11	772	2	1,544
514.80(b)(5)(iii)/Distributor's Statement Report/Form FDA 2301	530	0.14	56	2	112
Total					35,177

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting burden for § 514.80(b)(4)(iv)(A) is included in the reporting burden for § 514.80(b)(2)(i).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
514.80(e)[2]	530	28.22	19,385	0.5	9,693
514.80(e)[3]	530	4.06	2,379	10.35	24,623
Total					34,316

[1] Burden estimates were separated between Form FDA 1932 and Form FDA 2301 to reflect the difference in estimates for ''Hours per Respondent'' required.
[2] Recordkeeping estimates for § 514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3); Form FDA 1932.
[3] Recordkeeping estimates for § 514.80(b)(2)(iii), (b)(4), (b)(5), and (c); Form FDA 2301.

Forms FDA 1932 and FDA 2301 for this collection of information are currently approved under OMB control number 0910–0012 and will not change due to implementation of this regulation. The reporting and recordkeeping burden estimates in this document are based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The total annual response numbers are based on the 2000 fiscal year submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The numbers in tables 1 and 2 of this document are total burden associated with this regulation. Section 514.80(b)(3) and (b)(4)(v) are new information collection requirements over the current requirements.

Dated: April 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10932 Filed 5–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Health Resources and Services Administration

HRSA–03–099 Fiscal Year 2003 Competitive Cycle for the Bioterrorism Training and Curriculum Development Program (BTCDP) 93.996

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration announces that cooperative agreement applications will be accepted for the Bioterrorism Training and Curriculum Development Program for Fiscal Year 2003.

Purpose: The Bioterrorism Training and Curriculum Development Program consists of two discrete goals: (1) Provision of Continuing Education for practicing providers; and (2) Curricular Enhancement in health professions schools. Each area requires a separate application for funds.

Cooperative Agreements will be awarded to assist eligible entities to prepare a workforce of healthcare professionals to address the medical consequences of bioterrorism and other public health emergency preparedness and response issues. In this context, ''other public health emergencies'' includes other forms of terrorism (such as use of chemical, explosive, incendiary, or nuclear agents against the civilian population) as well as natural disasters and catastrophic accidents. Specifically, the goal of this program is the development of a healthcare workforce that possesses the knowledge, skills and abilities to: (1) Recognize indications of a terrorist event; (2) meet the acute care needs of patients, including pediatric and other vulnerable populations, in a safe and appropriate manner; (3) participate in a coordinated, multidisciplinary response to terrorist events and other public health emergencies; and (4) rapidly and effectively alert the public health system of such an event at the community, State, and national level.

Healthcare professionals provide a pivotal link to their communities. They disseminate accurate, responsible, trustworthy, and timely health related information to the public-at-large. This crucial component of the emergency response network helps to mitigate mortality and morbidity and to preserve public order while using resources effectively and efficiently. These professionals must be provided with the essential information needed to quickly identify a terrorist event; appropriately treat/respond to those in need of acute care; rapidly report such events to the public health authorities at the local, State and national levels, and participate in a coordinated and multidisciplinary response. The ability to meet the population's needs for acute

care during a public health emergency is dependent upon the rapid and coordinated efforts of appropriate community providers and local and State public health response systems.

Effective responses to public health emergencies require close collaboration among healthcare providers, medical specialists and other health professionals involved in patient care, the public health system, and the emergency response system. To achieve such a collaborative environment, it will be necessary to implement new models of undergraduate/graduate curricula and continuing education for health professionals that broaden public health knowledge and ensure that essential multidisciplinary and interdisciplinary collaborative responses to emergencies will occur.

It is expected that the training supported with these funds will involve a two-tiered approach—that will not only provide the discipline specific knowledge, skills and abilities needed to recognize, treat, and efficiently report instances of a terrorist event, but also will prepare the learners to participate in a multidisciplinary terrorist response. Each course of study shall include both discipline appropriate clinically oriented material and the team collaboration/coordination needed to respond to terrorist events. These activities will outline the integrated professional roles and responsibilities inherent in a community response and may include participation in drills, exercises and/or simulations.

Authorizing Legislation: These applications are solicited under section 319F(g) of the Public Health Service Act as amended by section 105 of the Public Health Security and Bioterrorism Response Act of 2002, Pub. L. 107–188 and the Consolidated Appropriations Resolution, 2003 (Public Law 108–7), which provides approximately $26 million to support the training of a workforce of healthcare professionals to address Bioterrorism and other public health emergencies.

1. *Eligible Applicants for Continuing Education:* The entities eligible to apply for this program are academic health centers; other public or private nonprofit accredited or licensed health professions schools; other educational entities such as professional organizations and societies; private accrediting organizations; other nonprofit institutions or entities including faith-based organizations and community'based organizations; and multi-state or multi-institutional consortia of various combinations of these eligible entities.

(a) The applicant must demonstrate the ability to provide training to the full range of health care providers in an entire State, in a region of a State, or in a multi-State region, either by its own efforts or through partnerships or subcontracts.

(b) Applicants shall demonstrate, through programmatic descriptions and letters of support, linkages and relationships with entities that provide emergency preparedness and response training, including but not limited to the State Designated Agency for Emergency Preparedness, HRSA Hospital Preparedness Program awardees, the CDC Health Preparedness and Response for Bioterrorism Program awardees and the Metropolitan Medical Response System Participants. A comprehensive coordinated multi-disciplinary approach must be undertaken to effectively meet the needs without replication and redundancy.

(c) Applicants must establish and maintain a programmatic advisory board with members including representatives from the HRSA Hospital Preparedness Program, the CDC Public Health Preparedness and Response for Bioterrorism Program, an academic health center, other health professions schools, and both health service providers and consumers from the area served by the program. This advisory board shall meet no less than twice a year.

Targeted Trainees

The targeted trainees are both hospital and community-based health care providers, including, but not limited to, those serving in public and private hospitals, Community Health Centers, Migrant Health Centers, Federally Qualified Health Centers, National Health Service Corps sites, and private and group practice.

ESTIMATED NUMBER OF CONTINUING EDUCATION HEALTH PROFESSIONS TRAINEES

Target profession	Annual number to be trained
NHSC Providers	500
Health Center Administrators	500
Allied Health Providers	5,000
Nursing	10,000
Medicine	10,000
Nurse Practitioners	1,000
Physician Assistants	1,000
Dentists	1,000
Pharmacists	1,250
Mental Health Providers	1,500
Public Health Providers	1,000
Others to include EMS and Veterinarians	5,250
Total	38,000

In selecting from among the most highly ranked applications, efforts will be made to balance awards to achieve broad professional and geographical distribution.

2. *Eligible Applicants for Curricular Enhancement:* The entities eligible to apply for this program are public or private nonprofit accredited or licensed health professions schools; other educational entities such as professional organizations and societies; and other nonprofit institutions or entities including faith-based organizations and community-based organizations. Eligible entities, if not a health professions school, must include in their application the participation (*i.e.*, through partnerships/subcontracts) of such a school to implement the curricular enhancement. In selecting from among the most highly ranked applications, efforts will be made to balance the distribution of awards across the following types of health professions schools: Medicine, Nursing, Mental Health, Allied Health, and others. These awards will develop best practice models by piloting both the professionally specific curriculum and the curriculum enhancement process to be widely disseminated to other academic institutions across the country upon project completion.

Applicants shall demonstrate through programmatic descriptions and letters of support that the funds awarded will be utilized to support multidisciplinary training consisting of no fewer than three health care disciplines.

Awardees will:

1. Adapt/refine existing curricula or if necessary, develop new curriculum addressing their students' knowledge, skills and abilities to:

(a) Recognize indications of a terrorist event in their patients;

(b) Provide acute care in a safe and appropriate manner;

(c) Rapidly and effectively alert the public health system of such an event at the community, State, and national level; and

(d) Coordinate their response as part of a multi-disciplinary team approach to a terrorist event.

2. Pilot and evaluate the curriculum; and

3. Incorporate the training into their required overall curriculum within two years.

Federal Involvement

Federal: Division of State, Community and Public Health, AHEC Branch staff will:

- Review all changes to the composition of all advisory committees and boards;
- Participate in an annual evaluation of the cooperative agreement program;
- Assist in planning and implementing project priorities by coordinating and facilitating the interchange technical and program information;
- Assist project staff in the development, compilation and dissemination of materials prepared by project personnel;
- Review for programmatic content all contracts and agreements among recipient medical or osteopathic schools, other health professional schools and community-based centers (unless such reviews are formally delegated to the recipient cooperating school); and
- Provide guidance concerning the content, structure and form of the annual progress report and final project report.

Funding Priorities and/or Preference

None.

Statutory Matching or Cost Sharing Requirement

None.

Administrative Special Consideration

Special consideration will be given to applicants who (a) develop new and innovative approaches to education and training using distance learning methodologies/telehealth, or (b) enhance or expand existing distance learning educational programs with the purpose of preparing health professionals and health professional students to deliver quality health care in medically underserved communities. A special consideration is another factor considered in making funding decisions that is neither a review criterion, preference, nor priority.

Review Criteria

Applications will be reviewed by a panel of peer reviewers using the following criteria:

(1) *Purpose, Need and Rationale:* The extent to which the purpose is consistent with the legislative purpose and is clearly described and the extent to which the need for the proposed project is thoroughly documented;

(2) *Project Effectiveness:* The extent to which potential effectiveness of the proposed project in carrying out the education purposes of the Bioterrorism Training and Curriculum Development Program is clearly described;

(3) *Project Plan:* The extent to which the project plan is clearly articulated and specifies measurable outcome objectives which are attainable within the stated time frame;

(4) *Linkages and Collaborative Efforts:* The degree to which the applicant describes a comprehensive coordinated multidisciplinary approach to the training of health professionals;

(5) *Project Management:* The extent that the applicant identifies activities and outcomes that are related to the outcome objectives given the proposed level of staff, resources available, length of the project period and institutional eligibility; and

(6) *Fiscal Plan:* The extent to which the fiscal plan describes the effective use of funds and resources to carry out the project.

Estimated Amount of Available Funds

It is estimated that $26 million will be available for fiscal year 2003.

Estimated Number of Awards

It is estimated that the number of awards may vary for Continuing Education from 15–25.

It is estimated that the number of awards may vary for the Curricular Enhancement from 10–12.

Estimated Average Size of Each Award

It is estimated that the average size of each award for Continuing Education may range from $900,000 to $1,500,000.

It is estimated that the average size of each award for Curricular Enhancement may range from $300,000 to $400,000.

Estimated Project Period

Applications will be submitted for two years. The first budget period will be September 1, 2003 to August 31, 2004; the second budget period will be September 1, 2004 to August 31, 2005, subject to the availability of funds and evaluation of recipient performance.

Application Requests, Availability, Deadline and Addresses

Application materials are available for downloading via the web at *http://bhpr.hrsa.gov/grants/default.htm*. Applicants may also request a hard copy of the application material by contacting the HRSA Grants Application Center, Grants Management Office, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879 or by calling (877) 477–2123 or by Fax at 1–877–477–2345. In order to be considered for competition, applications must be postmarked or submitted to the address listed above by the due date of June 16, 2003. Applicants should request a legibly dated U.S. Postal postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing. An application receipt will not be provided. Applications submitted after the deadline date will be returned to the applicant and not processed. Applicants should note that HRSA anticipates accepting grant applications online in the last quarter of the Fiscal Year (July through September). Please refer to the HRSA grants schedule at *http://www.hrsa.gov/grants.htm* for more information.

Projected Award Date: September 30, 2003.

FOR FURTHER INFORMATION CONTACT: Lynn Rothberg Wegman, Division of State, Community and Public Health, Bureau of Health Professions, HRSA, Room 9–105, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Wegman's telephone number is 301–443–1648.

Additional Information: Technical Assistance Workshops will be conducted at the following locations: Atlanta, GA; Boston, MA; Chicago, IL; Dallas, TX; Denver, CO; San Francisco, CA; and Washington, DC. Additional details, including the specific Dates for the workshops, may be obtained via the web at *http://bhpr.hrsa.gov/grants/default.htm*. Attendance at the workshops is optional and at the expense of the participant. Registration is required and may be completed by contacting Karen L. Ellis at (301) 315–2806 and Maria Smith at (301) 315–2844 or by registering on line at *http://meetings.Z-techcorp.com/meetings*.

Paperwork Reduction Act: The Application for the Bioterrorism Training and Curriculum Development Program has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. Should any data collection associated with the evaluation of this cooperative agreement fall under the purview of the Paperwork Reduction Act, OMB clearance will be sought. The OMB clearance number is 00915–0060.

The program is not subject to the provision of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Dated: April 18, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–10934 Filed 5–2–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

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

ACTION: Notice

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Pharmaceutical Manufacturers developed by the Office of Inspector General (OIG). Through this notice, the OIG is setting forth its general views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.

FOR FURTHER INFORMATION CONTACT: Mary E. Riordan or Nicole C. Hall, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

Background

Compliance program guidance is a major initiative of the OIG in its effort to engage the health care community in preventing and reducing fraud and abuse in federal health care programs. The purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements. In the last several years, the OIG has developed and issued compliance program guidance directed at the following segments of the health care industry: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; Medicare+Choice organizations offering coordinated care plans; hospices; nursing facilities; individual and small group physician practices; and ambulance suppliers.

Copies of these compliance program guidances can be found on the OIG Web site at *http://oig.hhs.gov/fraud/complianceguidance.html.*

Developing the Compliance Program Guidance for Pharmaceutical Manufacturers

On June 11, 2001, the OIG published a solicitation notice seeking information and recommendations for developing compliance program guidance for the pharmaceutical industry (66 FR 31246). In response to that solicitation notice, the OIG received eight comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts. In addition, we have taken into account past and ongoing fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration). In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, draft compliance program guidance for the pharmaceutical industry was published in the **Federal Register** on October 3, 2002 (67 FR 62057) for further comments and recommendations.

Elements for an Effective Compliance Program

This compliance program guidance for pharmaceutical manufacturers contains seven elements that have been widely recognized as fundamental to an effective compliance program:

- Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action.

These elements are included in previous guidances issued by the OIG. As with previously issued guidances, this compliance program guidance represents the OIG's suggestions on how pharmaceutical manufacturers can establish internal controls to ensure adherence to applicable rules and program requirements. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program. The document is intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers.

Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services is continuing in its efforts to promote voluntary compliance programs for the health care industry. This compliance guidance is intended to assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs[1] and in evaluating and, as necessary, refining existing compliance programs.

This guidance provides the OIG's views on the fundamental elements of pharmaceutical manufacturer compliance programs and principles that each pharmaceutical manufacturer should consider when creating and implementing an effective compliance program. This guide is not a compliance program. Rather, it is a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one. For those manufacturers with an existing compliance program, this guidance may serve as a benchmark or comparison against which to measure ongoing efforts.

A pharmaceutical manufacturer's implementation of an effective compliance program may require a significant commitment of time and resources by various segments of the organization. In order for a compliance program to be effective, it must have the support and commitment of senior management and the company's governing body. In turn, the corporate leadership should strive to foster a culture that promotes the prevention, detection, and resolution of instances of problems. Although an effective compliance program may require a reallocation of existing resources, the long-term benefits of establishing a compliance program significantly outweigh the initial costs.

In a continuing effort to collaborate closely with the pharmaceutical industry, the OIG published a notice in

[1] (Endnotes appear at end of document)