

with antimicrobial resistance development as a consequence of antimicrobial drug use in food-producing animals. The resistance-in-animals threshold represents the upper limit of acceptable levels of antimicrobial resistance in a food-producing animal species. This resistance threshold is derived through a risk assessment model that builds a link between the human health threshold and the resistance levels in animals. Therefore, exceeding the resistance threshold would be considered an unacceptable human health risk.

II. Comments

This discussion paper is being distributed at this time for consideration by the public in anticipation of the January 22 to 24, 2001, public meeting. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this discussion paper by April 9, 2001. Two copies of any comments are to be submitted, except that an individual may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the docket including transcript and comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the discussion paper may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm/>.

Dated: December 21, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for the opportunity for public comment

on proposed data collection projects (section 3506 (c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Ryan White CARE Act: Cross-Title Data Report Form (CTDR)—New

The Cross Title Data Report (CTDR) form, created in 1999 by the HIV/AIDS Bureau of the Health Resources Services Administration (HRSA), is designed to collect information from grantees, as well as their subcontracted service providers, funded under Titles I, II, III and IV of the Ryan White Comprehensive AIDS Emergency (CARE) Act of 1990, as amended by the Ryan White CARE Act Amendments of 1996 and 2000 (codified under Title XXVII of the Public Health Services Act). The purpose of the Ryan White CARE Act is to provide emergency assistance to localities that are disproportionately affected by the human immunodeficiency virus (HIV) epidemic and to make financial assistance available for the development, organization, coordination, and operation of more effective and cost-efficient systems for the delivery of essential services to persons with HIV disease. The CARE Act also provides grants to states,

eligible metropolitan areas, community-based programs, and early intervention programs for the delivery of services to individuals and families with HIV infection. All Titles of the CARE Act specify HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quantity and quality of care. Accurate records of the providers receiving CARE Act funding, the services provided, and the clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities.

Previously, grantees under each Ryan White CARE Act Title reported aggregate data on distinct Title-specific forms. The CTDR, an aggregate of these data collection forms, is designed to reduce the reporting burden for grantees with concurrent reporting responsibilities, and to eliminate title-specific reporting in order to reduce duplication among grantees and providers funded through multiple CARE Act Titles. The CTDR form collects data from grantees and their subcontracted service providers on six different areas: service provider information, client information, services provided/clients served, demographic information, AIDS Pharmaceutical Assistance and AIDS Drug Assistance Program, and the Health Insurance Program. Collected on an annual basis, the primary purposes of the CTDR are to: (1) Characterize the organizations from which clients receive services; (2) provide information on the number and characteristics of clients who receive CARE Act services; and (3) enable HAB to describe the type and amount of services a client receives. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected on the CTDR is critical for HRSA, state and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems.

The estimated response burden for CARE Act grantees is estimated as:

| Title under which grantee is funded | Number of grantees respondents | Responses per grantee | Hours to coordinate receipt of data reports from providers | Total hour burden |
|-------------------------------------|--------------------------------|-----------------------|--|-------------------|
| Title I only | 54 | 107 | 40 | 2,160 |

| Title under which grantee is funded | Number of grantees respondents | Responses per grantee | Hours to coordinate receipt of data reports from providers | Total hour burden |
|-------------------------------------|--------------------------------|-----------------------|--|-------------------|
| Title II only | 50 | 112 | 40 | 2,000 |
| Title III only | 303 | 1 | 8 | 2,424 |
| Title IV only | 63 | 1 | 16 | 1,008 |
| Total | 470 | | | 7,592 |

The estimated response burden for service providers is estimated as:

| Title under which provider is funded | Number of provider respondents | Responses per provider | Hours per response | Total hour burden |
|--------------------------------------|--------------------------------|------------------------|--------------------|-------------------|
| Title I only | 1,011 | 1 | 24 | 24,264 |
| Title II only | 836 | 1 | 40 | 33,440 |
| Title III only | 138 | 1 | 40 | 5,520 |
| Title IV only | 34 | 1 | 40 | 1,360 |
| Funded under multiple Titles | 491 | 1 | 48 | 23,568 |
| Total | 2,019 | | | 88,152 |

| | Number of respondents | | | Total hour burden |
|-------------|-----------------------|--|--|-------------------|
| Total | 2,489 | | | 95,744 |

Send comments to Susan G. Queen, Ph.D, HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 22, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the

HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Evaluation of the Scholarships for Disadvantaged Students (SDS) Program—New

The Scholarships for Disadvantaged Students (SDS) program was established in 1990 to provide financial assistance to health professions and nursing students from disadvantaged backgrounds. A primary tenet of the SDS program is that students who come from disadvantaged backgrounds will be most likely to practice in Medically Underserved Communities (MUCs) after graduation. In this way, the SDS program is working to alleviate health profession and nursing shortages across the country.

The evaluation of this program will include a mail survey directed at graduates of SDS-participating

institutions in the fields of allopathic and osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, pharmacy, nursing, allied health and behavioral and mental health. The survey will be directed at the 1996 graduates of allopathic and osteopathic medicine schools who participated in the SDS program in both 1996 and 2001. The survey will also be directed at the 1999 graduates of dentistry, veterinary medicine, optometry, podiatry, pharmacy, nursing, allied health and behavioral and mental health schools who participated in the SDS program in both 1999 and 2001. The information will identify the place and type of employment for each individual surveyed in order to determine whether or not the individual practiced in a MUC between July 1, 1999, and June 30, 2000. The data collected through this survey will be used to determine whether statistically significant differences exist between the rate at which disadvantaged versus non-disadvantaged individuals and SDS scholarship recipients versus non-recipients practice in MUCs after graduation. These data will also be used to determine whether differences exist in the rates at which individuals in different health professions work in MUCs. The results will be used to formulate programmatic and policy recommendations designed to strengthen the SDS program and increase its effectiveness.