

United States is estimated to be approximately 34 million.<sup>1</sup> Therefore, assuming an annual contact lens exam for each contact lens wearer, 34 million people would receive a copy of their prescription each year under the Rule. At an estimated one minute per prescription, the annual time spent by prescribers complying with the disclosure requirement would be a maximum of 567,000 hours. [(34 million × 1 minute)/60 minutes = 566,667 hours]

As required by the FCLCA, the Rule also imposes two recordkeeping requirements. First, prescribers must document the specific medical reasons for setting a contact lens prescription expiration date shorter than the one year minimum established by the FCLCA. This burden is likely to be nil because the requirement applies only in cases when the prescriber invokes the medical judgment exception, which is expected to occur infrequently, and prescribers are likely to record this information in the ordinary course of business as part of their patients' medical records. The OMB regulation that implements the PRA defines "burden" to exclude any effort that would be expended regardless of a regulatory requirement. 5 CFR 1320.3(B)(3)(2).

Second, the Rule requires contact lens sellers to maintain certain documents relating to contact lens sales. As noted above, a seller may sell contact lenses only in accordance with a prescription that the seller either (a) has received from the patient or prescriber, or (b) has verified through direct communication with the prescriber. The FCLCA requires sellers to retain prescriptions and records of communications with prescribers relating to prescription verification for three years.

Staff believes that the burden of complying with this requirement is low. Sellers who seek verification of contact lens prescriptions must retain one or two records for each contact lens sale: Either the relevant prescription itself, or the verification request and any response from the prescriber. Staff estimates that such recordkeeping will entail a maximum of five minutes per sale, including time spent preparing a file and actually filing the record(s).

Staff also believes that, based on its knowledge of the industry, this burden will fall primarily on mail order and Internet-based sellers of contact lenses,

as they are the entities in the industry most reliant on obtaining or verifying contact lens prescriptions. Based on conversations with the industry, staff estimates that these entities currently account for approximately 10% of sales in the contact lens market<sup>2</sup> and, by extension, that approximately 3.4 million consumers—10% of the 34 million contact lens wearers in the United States—purchase their lenses from them.

At an estimated five minutes per sale to each of 3.4 million consumers, contact lens sellers will spend a total of 283,300 burden hours complying with the recordkeeping requirement. [(3.4 million × 5 minutes)/60 minutes = 283,333.3 hours] This estimate likely overstates the actual burden, however, because it includes the time spent by sellers who already keep records pertaining to contact lens sales in the ordinary course of business. In addition, the estimate may overstate the time spent by sellers to the extent that records (e.g., verification requests) are generated and stored automatically and electronically, which staff understands is the case for some larger online sellers.

*Estimated labor costs:* \$32,317,000 (rounded to the nearest thousand).

Commission staff derived labor costs by applying appropriate hourly cost figures to the burden hours described above. Staff estimates, based on its knowledge of the industry, that optometrists account for approximately 75% of prescribers. Consequently, for simplicity, staff will focus on their average hourly wage in estimating prescribers' labor cost burden.

According to Bureau of Labor Statistics from May 2008, salaried optometrists earn an average wage of \$50.58 per hour and general office clerical personnel earn an average of \$12.90 per hour.<sup>3</sup>

With these categories of personnel, respectively, likely to perform the brunt of the disclosure (for optometrists) and recordkeeping (for office clerks) aspects of the Rule, estimated total labor cost attributable to the Rule would be approximately \$32.8 million. [(\$50.58 ×

566,666.7 hours) + (\$12.90 × 283,333.3 hours) = \$32,317,000]

The contact lens market is a multibillion dollar market; one recent survey estimates that contact lens sales totaled \$2.37 billion from Jan 1, 2006 to Dec 31, 2006.<sup>4</sup> Thus, the total labor cost burden estimate of \$32.3 million represents approximately 1.5% of the overall market.

*Estimated annual non-labor cost burden:* \$0 or minimal.

Staff believes that the Rule's disclosure and recordkeeping requirements impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (e.g., prescription pads, patients' medical charts, facsimile machines and paper, telephones, and recordkeeping facilities such as filing cabinets or other storage).

**Willard Tom,**  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-0371.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### Proposed Project: HRSA AIDS Education and Training Centers Evaluation Activities (OMB No. 0915-0281)—Revision

The AIDS Education and Training Centers (AETC) Program, under the Title XXVI of the Public Health Service Act, as amended, Ryan White HIV/AIDS Program legislation, supports a network

<sup>1</sup> See Contact Lenses, Frequently Asked Questions, Nov. 2009, available at (<http://www.allaboutvision.com/faq/contactlens.htm>). See also Nichols, J. "Annual Report: Contact Lenses 2008," Contact Lens Spectrum, Jan. 2009, available at (<http://www.clspectrum.com/article.aspx?article=102473>).

<sup>2</sup> The FTC's February 2005 study, "The Strength of Competition in the Rx Sale of Contact Lenses: An FTC Study," cites various data that, averaged together, suggests that approximately 10% of contact lens sales are by online and mail-order sellers. The report is available online at (<http://www.ftc.gov/reports/contactlens/050214contactlensrpt.pdf>).

<sup>3</sup> Mean and median worker hourly wages for optometrists and general office clerks are drawn from the Bureau of Labor Statistics (BLS) Occupational Employment and Statistics Survey, May 2008, based on BLS-sampled data it collected over a 3-year period. See (<http://www.bls.gov/news.release/pdf/ocwage.pdf>) (Table 1).

<sup>4</sup> The Vision Council of America and Jobson Optical Research have conducted large scale continuous consumer research under the name VisionWatch, which reports on the vision care industry. The basis for this statistic is on file with the Federal Trade Commission.

of regional and cross-cutting national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV/AIDS. The AETCs' purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

As part of an ongoing effort to evaluate AETC activities, information is needed on AETC training sessions, consultations, and technical assistance activities. Each regional center collects

forms on AETC training events, and the centers are required to report aggregate data on their activities to HRSA and the HIV/AIDS Bureau (HAB). This data collection provides information on the number of training events, including clinical trainings and consultations, as well as technical assistance activities conducted by each regional center, the number of health care providers receiving professional training or consultation, and the time and effort expended on different levels of training and consultation activities. In addition, information is obtained on the populations served by the AETC trainees, and the increase in capacity

achieved through training events. Collection of this information allows HRSA and HAB to provide information on training activities and types of education and training provided to Ryan White HIV/AIDS Program Grantees, resource allocation, and capacity expansion.

Trainees are asked to complete the Participant Information Form (PIF) for each activity they complete, and trainers, are asked to complete the Event Record (ER). The estimated annual response burden to trainers as well as attendees of training programs is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
PIF .....	116,624	1	116,624	0.167	19,476.2
ER .....	18,070	1	18,070	0.2	3,614
Total .....	134,694	.....	134,694	.....	23,090.2

The estimated annual burden to AETCs is as follows:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Aggregate data set .....	12	2	24	32	768

The total burden hours are 23,858.2.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: April 7, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information 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 350(c)(2)(A) of Title 44, United

States Code, as amended by the Paperwork Reduction Act of 1995 Public Law 104-13, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (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, call 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 of other forms of information technology.

#### Proposed Project: Scholarships for Disadvantaged Students Program (OMB No. 0915-0149) Extension

The Scholarships for Disadvantaged Students (SDS) Program has as its purpose the provision of funds to eligible schools to provide scholarships to full-time students with financial need from disadvantaged backgrounds enrolled in health professions and nursing programs.

To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the Public Health Service (PHS) Act). A school must meet the eligibility criteria to demonstrate that the program has achieved success based on the number and/or percentage of disadvantaged students who graduate from the school. In awarding SDS funds to eligible schools, funding priorities must be given to schools based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working