country is permitted, and, if not permitted, obtain any appropriate export licenses or other U.S. government permissions prior to exporting any product to sanctioned countries.

• According to U.S. regulations, no U.S. persons or entities may conduct business transactions with individuals and entities on the SDN List without a license from OFAC.[13]

• According to U.S. regulations, no U.S. persons or entities may conduct business transactions with individuals sanctioned by the Department of State for engaging in proliferation activities.[14]

• The Export Administration Regulations (EAR) require that providers have an export license from BIS prior to exporting a synthetic nucleic acid that is controlled by an Export Control Classification Number (ECCN) and is capable of encoding a protein.[15]

• U.S. persons or entities may not export, reexport, or transfer (in-country) an item subject to the EAR without a license if, at the time of export, reexport, or transfer (in-country) the exporter knows that the item will be used in the design, development, production, stockpiling, or use of biological weapons in or by any country or destination, worldwide.[15]

• In accordance with the EAR, providers must not conduct business with persons and entities on the DPL.[15]

• In accordance with the EAR, exports to persons or entities on the Entity List are subject to licensing requirements and policies in addition to those elsewhere in the EAR.[15]

• The presence of a party on the UL in a transaction is a ''red flag'' that should be resolved before proceeding with the transaction.[15]

In order to avoid violating U.S. laws and regulations, providers are encouraged to check the individual placing the order and the individual's affiliated institution (when applicable) against the most recent versions of these lists of proscribed entities before filling each order.

The U.S. Government recommends that providers utilize a ''Best Match'' approach to identify sequences of pathogens and toxins on the Commerce Control List for international orders. This screen is in addition to the ''Best Match'' sequence screen for Select Agent and Toxin sequences.

Contacting the U.S. Government

In cases where *follow-up screening* cannot resolve concerns raised by *customer screening* or *sequence screening, or when providers are otherwise unsure about whether to fill an order*, the U.S. Government recommends that providers contact relevant agencies as described in Section VII of ''Screening Framework Guidance for Synthetic Nucleic Acid Providers.''

Customer and Sequence Screening Software and Expertise

Providers should be aware that commercially available customer screening software packages may not necessarily address all aspects of customer screening recommended by the U.S. Government.

The U.S. Government recommends that:

• Synthetic nucleic acid providers select a sequence screening software tool that utilizes both a global and local sequence alignment technique.

• Synthetic nucleic acid providers have the necessary expertise in-house to perform the sequence screenings, analyze the results, and conduct the appropriate follow-up research to evaluate the significance of dubious sequence matches.

Records Retention

The U.S. Government recommends that:

• Companies retain electronic copies of customer orders for at least eight years based on the statute of limitations set forth by U.S. Code Title 18 Section 3286.[18] The following information should be archived: Customer (and end-user, if different) information (name, organization, address, and phone number), order sequence information, and order information (date placed and shipped, shipping address, and receiver name).

• Providers develop, maintain, and document their sequence screening protocols within company records.

• Providers develop, maintain, and document protocols to determine if a sequence hit qualifies as a true sequence of concern.

• Providers keep records of hits that required follow-up screening, even if the order was ultimately filled.

If an order involves an export, according to the EAR, both the provider and customer are required to maintain documentary evidence of the transaction and are prohibited from misrepresenting or concealing material facts in licensing processes and all export control documents.[15]

[18] Section 3286 specifies that no person shall be prosecuted, tried, or punished for any noncapital offense involving certain violations unless the indictment is found or the information is instituted within 8 years after the offense was committed. This statute of limitations applies to Title 18 Section 175(b) (possession of biological agents with no reasonable justification).

Dated: November 19, 2009.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. E9–28328 Filed 11–25–09; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Evaluation of the GuideLines Into Decision Support (GLIDES).'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by January 26, 2010.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Evaluation of the GuideLines Into Decision Support (GLIDES)

With this project AHRQ proposes to evaluate how the translation of clinical knowledge into clinical decision support can be routinized in practice and taken to scale in ways that improve the quality of healthcare delivery for children in the U.S. Previously in the GLIDES project, AHRQ designed and implemented decision support tools based on guidelines for the prevention of pediatric overweight and obesity and the management of chronic asthma in

the pediatric population (publication forthcoming). In this phase of the project, conducted for AHRQ through a contract with Yale University and Nemours, physicians will be surveyed about their experiences with the decision support tools developed in the previous phase. The participating study institutions (Yale University and Nemours) are geographically and organizationally diverse, and include a wide range of patients from a variety of social, economic and ethnic backgrounds. This project directly addresses AHRQ's mission of improving health systems practices, in particular for priority populations, including low-income groups, minority groups, women, children, and individuals with chronic diseases. See 42 U.S.C. 299(c)(1)(B).

The evaluation plan includes a physician survey component and an extraction of electronic medical record data. Participating physicians will be surveyed about their experiences with the decision support tools developed for this project. This will allow AHRQ to evaluate the fulfillment of knowledge transformation goals and the effectiveness of the decision support tools in improving the quality of health care at the chosen sites. Without such an evaluation, it would be difficult to determine whether this project has met AHRQ's goals of enhancing the ''quality, appropriateness and effectiveness of health services.'' *See* 42 U.S.C. 299(b); 42 U.S.C. 299a(a)(1). Consequently, it is necessary to collect this information to fulfill AHRQ's mission.

Method of Collection

Self-administered questionnaires will be used to elicit physicians' general opinions of guideline-based care and clinical decision support tools on a five point Likert-type scale. Results from low-utilizing physicians will be compared to high-utilizing physicians to determine whether general opinions of guidelines and technology correlate with actual practice. Results will also be analyzed by demographic characteristics included in the survey questionnaire to determine whether opinions vary by age, degree of computer experience and skill, level of training and professional degree. These analyses will be important to future studies and decision support designers because they will help us understand whether interventions need to be targeted differently to different audiences. For example, senior level specialists may have less desire or need for clinical decision support tools than novice generalists have. In-person qualitative interviews lasting approximately 30 minutes will be conducted with key personnel at each site (including physicians, nurse practitioners, and respiratory therapists). Participants will remain anonymous in the transcribed interviews. The interviews will be analyzed using standard qualitative techniques to explore barriers and facilitators to using the clinical decision support tool. The Human Investigation Committee (HIC) at Yale University has reviewed this protocol. The HIC found the survey study to be exempt from review under 45 CFR 46.101(b)(2). The HIC approved the interview study and required signed informed consent from participants.

Electronic medical record data will be extracted into an electronic spreadsheet for analysis. This extraction will occur at regular intervals to ensure continued maintenance and uptake of the tool. Utilization of the decision support tools at the provider and site level will be assessed based on the rate of electronic chart documentation. This is important to determine the rate of uptake of the intervention, as well as to determine whether there are any flaws in the design of the tool. Congruence of actual practice with guideline recommendations will be assessed based on automatically generated disagreement flags in the electronic medical record as well as by manual chart review. This data collection, including the manual chart review, will be performed by project staff and will not impose a burden on the participating sites. In addition, project staff will directly observe a random sampling of clinicians using the tool in clinical settings to determine how the tool affects workflow. These observations will not require any effort, time or action on the part of the clinicians themselves and will not impose a burden on the participating sites. Signed informed consent will be obtained prior to any observations. The Human Investigation Committee at Yale University has reviewed this protocol. It approved the medical record review, approved direct observation of clinicians and interviews of clinicians, required signed informed consent from clinicians, granted a waiver of informed consent from patients per 45 CFR 46.116(d), and granted a waiver of HIPAA authorization.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research. The Asthma Management and Clinical Decision Support System Usability and User Satisfaction Survey (asthma questionnaire) will be completed by 172 health care professionals across 3 sites and is expected to require about 6 minutes to complete. The Obesity Prevention and Clinical Decision Support System Usability and User Satisfaction Survey (obesity questionnaire) will be completed by 82 health care professionals across 2 sites and is expected to require about 6 minutes to complete. The in-person interviews will be conducted with a total of 50 clinicians at 3 sites and are expected to last 30 minutes each. The total burden is estimated to be 51 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be $2,781.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of sites	Number of responses per site	Hours per response	Total burden hours
Asthma questionnaire—Yale	2	31	6/60	6
Asthma questionnaire—Nemours	1	110	6/60	11
Obesity questionnaire—Yale	1	57	6/60	6
Obesity questionnaire—Nemours	1	25	6/60	3
In-person interviews—Yale	2	15	30/60	15
In-person interviews—Nemours	1	20	30/60	10
Total	5	na	na	51

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of sites	Total burden Hours	Average hourly wage rate *	Total cost burden
Asthma questionnaire—Yale	2	6	$59.83	$359
Asthma questionnaire—Nemours	1	11	59.83	658
Obesity questionnaire—Yale	1	6	47.25	284
Obesity questionnaire—Nemours	1	3	47.25	142
Interviews—Yale	1	15	53.54	803
Interviews—Nemours	1	10	53.54	535
Total	5	51	na	2,781

* Based upon the mean of the average wages for other physicians and surgeons, general pediatricians, and pediatric trainees (asthma questionnaire), and general pediatricians and pediatric trainees (obesity questionnaire), National Compensation Survey: Occupational wages in the United States 2008, ''U.S. Department of Labor, Bureau of Labor Statistics,'' and Yale Pediatric Residency Program, 2008.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost for this research. Since this project will not exceed one year the total and annualized costs are identical. The total cost is estimated to be $5,703.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$1,406	$1,406
Data Collection Activities	416	416
Data Processing and Analysis	780	780
Publication of Results	1,601	1,601
Project Management	200	200
Overhead	1,299	1,299
Total	5,703	5,703

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ' s estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 16 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–28210 Filed 11–25–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0563]

Draft Guidance for Industry and Food and Drug Administration Staff; Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act.'' This guidance is intended for manufacturers, retailers, importers, and FDA staff. The guidance describes FDA's current thinking regarding the appropriate preliminary timetable for its review of applications for Modified Risk Tobacco Products (MRTPs) under the Federal Food, Drug, and Cosmetic Act (the act), as modified by the Federal Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 25, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance document may be sent. See the