Evaluation of Genomic Applications in Practice and Prevention (EGAPP)
(OMB no. 0920-0751. Expiration date August 31, 2010)

Change Request
January 29, 2009

Summary

The Centers for Disease Control and Prevention (CDC) requests OMB approval of a *non-substantive* change request for the new data collection entitled "Determining Stakeholder Awareness and the Use and Impact of Products Developed by the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Model Project," (approved 08/6/2007; expiration date 8/31/2010). The proposed changes are a result of external events that impacted the timing of the information collection and therefore we request: 1) a rescheduling of information collections and reduction of the number of survey topics, 2) minor editorial changes to accommodate the survey interface and to enhance respondents' comprehension, and 3) an update to our information collection instruments posted on RegInfo.gov.

As we explain below in detail in the "Justification for Proposed Changes" section, the timing of this information collection is important because the useful lifespan of the products we are collecting information on is relatively short. Specifically, because the CYP450 evidence-based recommendation (the topic of information collection #1) was published December 2007, we would like data collection on this topic to occur in February 2009. Therefore, we request your decision on this *non-substantive change* as quickly as possible in order to ensure that all data collection on the CYP450 recommendation can occur within its useful lifespan.

Justification for Proposed Changes

Change 1: Rescheduling of information collections

In our original request, we planned to collect information from respondents about selected EGAPP products at two time periods: baseline (information collection #1) and 12 months later (information collection #2). Baseline was to begin 6 months after publication of the EGAPP Working Group recommendations for 2 genetic applications: (1) CYP450, and (2) HNPCC or *UGT1A1*. We originally estimated that the CYP450 recommendation would be released in August 2007, while release of a recommendation on *UGT1A1* or HNPCC was expected in October 2007. Due to external journal production issues and collaborations with CDC external partners, these recommendations were not published within the originally expected time frames. The CYP450 recommendation was published in December 2007, while the HNPCC and *UGT1A1* recommendations were not published until January 2009 (see **Appendix A: Summary of Changes in Product Release Dates**).

As a result, we propose to limit the scope of the first information collection to questions about CYP450. Questions about recommendations concerning HNPCC and *UGT1A1* will be delayed until the second information collection. Finally, to avoid an unacceptable level of burden for the second information collection, we will eliminate the questions about breast cancer management,

Factor V and Thombophilia, and Cardiogenomic profiling, which we originally planned to field in the second information collection.

Specifically, the original project plan and schedule included:

- Information collection #1: Baseline questions about the CYP450 products and HNPCC (Lynch Syndrome) products **OR** Baseline questions about the CYP450 products and the *UGT1A1* products.

- Information collection #2: 12-month follow-up questions about the CYP450 products **AND** baseline information collection on gene expression profiling for breast cancer management **or** Factor V and Thrombophilia **or** Cardiogenomic profiling.

  (For a summary in table form, see **Appendix A: Summary of Original Information Collection Schedule**.)

To accommodate the modified publication of these products, we propose to modify the information collection plan as follows:

- Information collection #1: Baseline questions about the *CYP450* products.

- Information collection #2: Baseline questions about the HNPCC (Lynch Syndrome) products and baseline questions about the *UGT1A1* products.

  (For a summary in table form, see **Appendix A: Summary of Modified Information Collection Schedule**.)

A critical reason why the schedule of data collection has changed is the longer than expected interval between publication of the CYP450 and subsequent recommendations. The EGAPP Working Group, who authors the recommendations upon which these information collections are based, is an independent panel supported by CDC, and as valued external partners, we are compelled to respect their decisions on timing of the release of their recommendations.

An additional, critical consideration is, again that the useful lifespan of an evidence-based recommendation, before an update is required, is often considered to be relatively short. This change will ensure that all data collection on the CYP450 recommendation can occur within its useful lifespan, and before updates are released, which could be confusing to respondents.

Impact of Proposed Changes on the Burden Estimate

The original burden estimate for each response was 10 minutes. The elimination of some questions, and the redistribution of remaining questions across information collection #1 and information collection #2, will result in decreased burden for information collection #1. Taking into account a range of response times for information collection #1 and information collection #2, the revised burden estimate for each response will decrease to an average of 8 minutes.

The number of respondents will not change. The overall total reduction in burden is estimated at 84 hours, as shown in the table below.

Table of Revised Burden Hours Including Change in Burden Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Total Burden Hours Based on Original Response Estimate (10 minutes)	Revised Burden Hours Based on Modified Response Estimate (8 minutes)	Change in Burden Hours
Healthcare Provider	1,740	1	290	232	-58
Policy/Payer Survey	100	1	17	13	-4
Purchaser Survey	31	1	0	4	+4
Policy Survey	50	1	8	7	-1
General Survey	770	1	128	103	-25
Total	2,691	1	443	359	-84

In the original ICR, the estimated total burden for the Purchaser Survey was recorded as zero (0) hours. The error has been corrected in the revised estimate of total burden hours, above.

Change 2: Minor editorial changes to accommodate the web-based interface and to enhance respondents' comprehension

The survey interface will be modified so that respondents will be routed to the appropriate set of questions for information collection #1 and the appropriate set of questions for information collection #2.

In order to accomplish the proposed data collection mentioned above, it was necessary to make minor editorial changes in some survey questions to make the originally submitted surveys compatible with the computer interface for survey delivery. Furthermore, we made a few minor editorial changes to enhance respondents' comprehension of survey questions. These minor changes are reflected in the surveys submitted with this change request. The surveys submitted with this request are for CYP450 which is the topic queried by the first information collection, however the questions for the second round of information collections will be nearly identical to these with the minor exception that they will ask respondents about HNPCC (Lynch Syndrome) and *UGT1A1* instead of CYP450. There will also be a slight difference in grammar between the two information collections given that the first asks respondents about only one topic and the second asks them about two; therefore, we will use the plural form of verbs in the lead-in text to the questions in the second information collection.

Of note, the survey instruments submitted with this change request show the surveys in their entirety, however as respondents complete each information collection, some questions may be skipped depending on how they answer preceding questions.

The survey interface also assesses whether respondents meet the criteria for participating. If necessary, the interface will re-route a respondent to another survey instrument, or indicate that the respondent should exit. **Appendix B: Exit Survey Text and Redirect Text** shows the text that a respondent would see in either of these circumstances.

Change 3: Uploading of approved surveys to RegInfo.gov to reflect the final approved data collection instruments.

When this project received initial approval, an earlier version of the survey instruments was uploaded on RegInfo.gov. The Notice of OMB Action, Terms of Clearance stated that the collection was: "approved consistent with revisions outlined in CDC memos submitted to OMB and included in the public docket." However, the posted surveys do not contained any submitted revisions as described.

The modified surveys attached with this change request contain these revisions, in addition to the minor editorial changes outlined in the section entitled "Change 2" above.

Attachment C1: Healthcare Provider Survey
Attachment C2: Policy/Payer Survey
Attachment C3: Healthcare Purchaser Survey
Attachment C4: Policy Survey
Attachment C5: General Survey

Appendix A: Changes in EGAPP Product Release Dates and Subsequent Changes to Information Collection Schedule

Summary of Changes in Product Release Dates		
Product	**Estimated Release Date**	**Actual Release Date**
CYP450 Guidelines	August 2007	December 2007
UGT1A1 and HNPCC (Lynch syndrome) Recommendations	October 2007	January 2009

Summary of Original Information Collection Schedule (*currently approved*)		
Survey Contents	**Information collection #1: February/March 2009**	**Information collection #2: February/March 2010**
CYP450 and	Baseline	12-Month Follow-up
HNPCC or *UGT1A1*	Baseline	n/a
Gene expression profiling for breast cancer management **or** *Factor V* and Thrombophilia **or** Cardiogenomic profiling	n/a	Baseline

Summary of Modified Information Collection Schedule (*proposed*)		
Survey Contents	**Information collection #1: February 2009**	**Information collection #2: February 2010**
CYP450	Baseline	n/a
HNPCC	n/a	Baseline
UGT1A1	n/a	Baseline

Note: For **Information collection #1** in **February, 2009**, only CYP450 will be included. On **Information collection #2** in **February, 2010**, both HNPCC (Lynch Syndrome) and *UGT1A1* will be included.

Appendix B: Exit Information collection Text and Redirect Text

The attached information collections reveal the minor editorial changes that we have made to the information collections, however they do not show the Exit Information collection text or the Redirect text respondents may see as they answer questions. In order to make sure the survey is conducted properly, some respondents may be asked to exit the survey or may be redirected to the appropriate survey. Below is the text that respondents who are redirected or asked to exit the survey may see.

Redirect text:

Based on your response to the previous question you are going to be re-directed to a different version of this survey. Please click the link below to go to the correct survey.

Exit survey text:

If you were directed to this page before completing all of the survey questions, we appreciate your willingness to provide us with feedback, however, based on your answer to the previous question, you do not fit the criteria of individuals from whom we are collecting information at this time. Thank you for your interest in EGAPP. Please click on the "next" button below and on the next page, please click on the "submit" button to exit this survey.