

individuals based on their responses to these questions.

(Comment 7) “Lilly suggests that the survey design be improved to better align with the research objectives, to avoid bias and to mitigate extreme respondent fatigue. Lilly recommends that FDA modify the data collection instrument to address the points noted above and seek additional public comment on the revised design.”

(Response) Given our responses and points of clarification above, we believe that the current design is rigorous and meets FDA’s research objectives. The design allows us to test and validate measurement items for consumers’ risk and benefit perceptions. By randomizing respondents to the various ads with different benefit and risk information, we have controlled for underlying differences in respondent

demographics and thereby have reduced the potential for selection bias (Ref. 4) and enhanced study validity. As we have described above, we also have designed the study to minimize respondent fatigue by testing only the most promising candidate items and by ensuring a survey length of no more than 30 minutes.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response <sup>2</sup>	Total hours
Pretest screener .....	2,000	1	2,000	0.03 (2 minutes) .....	60
Main study screener .....	20,000	1	20,000	0.03 (2 minutes) .....	600
Pretest .....	<sup>2</sup> 1,100	1	1,100	.5 (30 minutes) .....	550
Main Study .....	10,200	1	10,200	.5 (30 minutes) .....	5,100
<b>Total .....</b>					<b>6,310</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> With online surveys, several participants may be completing the survey at the time that the total target sample is reached. Those participants are allowed to complete the survey, which can result in the number of completes going slightly over the target number. Thus, if our target is 1,000, we have rounded up by an additional 100 to allow for some overage.

III. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. Lipkus, I. M., “Numeric, Verbal, and Visual Formats of Conveying Health Risks: Suggested Best Practices and Future Recommendations,” *Medical Decision Making*, 27(5), 696–713 (2007).
2. Aikin, K. J., J. L. Swasy, and A.C. Braman, “Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results,” FDA, Center for Drug Evaluation and Research, 19 (2004).
3. Horne, R., J. Weinman, and M. Hankins, “The Beliefs About Medicines Questionnaire: The Development and Evaluation of a New Method for Assessing the Cognitive Representation of Medication,” *Psychology and Health*, 14, 1–24 (1999).
4. Kunz, R., G. E. Vist, and A. D. Ochman, “Randomization to Protect Against Selection Bias in Healthcare Trials,” *The Cochrane Library*, Issue 2 (2008).

Dated: November 14, 2014.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy**

The Health Resources and Services Administration (HRSA) is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

Section 100.2 of the VICP’s implementing regulation (42 CFR Part 100) states that the revised amounts of an average cost of a health insurance policy, as determined by the Secretary, are to be published periodically in a notice in the **Federal Register** and filed with the United States Court of Federal Claims (the Court). This figure is calculated using the most recent Medical Expenditure Panel Survey—Insurance Component (MEPS–IC) data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation and Health Research and Educational Trust (KFF/HRET) Employer Health Benefits survey or other authoritative source that may be more accurate or appropriate.

In 2014, MEPS–IC, available at [www.meeps.ahrq.gov](http://www.meeps.ahrq.gov), published the

annual 2013 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$5,571. This figure is divided by 12-months to determine the cost per month of \$464.25. The \$464.25 shall be increased or decreased by the percentage change reported by the most recent KFF/HRET, available at [www.kff.org](http://www.kff.org). The percentage increase from 2013 to 2014 was published at 2 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy is \$473.54 for 2014.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is \$473.54 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the Court. Such notice was delivered to the Court on November 13, 2014.

Dated: November 13, 2014.

**Mary K. Wakefield,**  
*Administrator.*

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