**DRH Response to OMB Comments Dated 10/31/2012 – Revised 02/25/2013**

* **The title of this ICR - Evaluation of U.S. Family Planning Guidelines - Phase II – does not appear to accurately reflect the information being collected.  Please clarify how the methods and instruments proposed will serve to evaluate the guidelines. For example, in the Provider Survey, only the last 3 questions mention the US MEC and it is unclear how these questions will help CDC understand how, and to what extent, the guidelines have been used thus far.**

Every question on each survey was carefully selected to serve either as an evaluation measure relevant to one or more of the three U.S. family planning guidelines (i.e., 2010 *U.S. Medical Eligibility Criteria for Contraceptive Use*, the forthcoming 2013 *U.S. Selected Practice Recommendations for Contraceptive Use*, or the forthcoming 2013 *Guidance for Providing Quality Family Planning Services)*, or to measure characteristics of respondents, which will be used to better understand the extent to which the currently available guidance is being used, and to target dissemination efforts.

Although a specific family planning guideline may not be explicitly mentioned in each of the questions, as noted by the reviewer (except for the last 3 questions on the Phase II provider survey), the questions measure content addressed in one or more of the guidance documents.

For example, the 2010 *U.S. Medical Eligibility Criteria for Contraceptive Use* includes evidence-based recommendations for the safe use of contraceptive methods for women and men with specific characteristics and medical conditions. Examples of recommendations included in this guidance are the safety and effectiveness of intrauterine devices for adolescents and nulliparous women, the safety and effectiveness of injectables for adolescents, and the safety and effectiveness of combined hormonal contraceptives for women with bariatric surgery via restrictive procedures, but not for those with bariatric surgery via malabsorptive procedures.

Thus, questions on the Phase II provider survey that seek information on provider attitudes and practices related to these recommendations (i.e., survey numbers 13, 14, 15, 18, 19, and 20 ) serve to evaluate the diffusion, uptake and impact of the *U.S. Medical Eligibility Criteria for Contraceptive Use* on provider attitudes and practices.

To help clarify how the survey questions will assist CDC’s Division of Reproductive Health and the Office of Population Affairs to evaluate the 3 sets of U.S. family planning guidelines discussed in our information collection request, Table 1 summarizes the various constructs included in our instruments, the survey number on each survey that measures the construct (if applicable), as well as the U.S. family planning guideline(s) that the survey construct serves as an evaluation measure.

**Table 1. Summary of survey constructs, survey numbers measuring each construct, and relevant U.S. family planning guidance document**

| **Survey Construct** | **Survey Number** | **Evaluation Measure for:** |
| --- | --- | --- |
| **Phase 1 Provider Survey** | **Phase 2 Provider Survey** | **Phase 2 Administrator Survey** | **2010 US MEC\*** | **2013 US SPR\*** | **2013 QFPS\*** |
| *Safety Attitudes*  |  |  |  |  |  |  |
| COCs for women with certain characteristics | 15 | 13, 14 | -- | X | -- | -- |
| IUDs for women with certain characteristics | 16, 17 | 15 | -- | X | -- | X |
| DMPA for women with certain characteristics | 18 | 16 | -- | X | -- | -- |
| ‘Quick Start’ for COCs  | -- | 17 | -- | -- | X | X |
| ‘Quick Start’ for DMPA | -- | 17 | -- | -- | X | X |
| ‘Quick Start’ for implants | -- | 17 | -- | -- | X | X |
| ‘Quick Start’ for IUDS | -- | 17 | -- | -- | X | X |
| *Practices* |  |  |  |  |  |  |
| DMPA for adolescents | 19 | 19 | -- | X | -- | -- |
| COC for postpartum women | 20 | 20 | -- | X | -- | -- |
| IUDs for nulliparous women | 21, 22 | 21 | -- | X | -- | X |
| ‘Quick Start’ for COCs  | -- | 23 | -- | -- | X | X |
| ‘Quick Start’ for DMPA  | -- | 24 | -- | -- | X | X |
| Contraceptive counseling practices | -- | 18 | 13 | -- | -- | X |
| Required exams and tests  | -- | 22 | -- | -- | X | X |
| Recommended follow up | -- | 25 | -- | -- | X | -- |
| Emergency contraception  | -- | 26 | -- | -- | X | X |
| Dispensing year’s supply of pills at 1 visit | -- | 27 | -- | -- | X | X |
| Contraceptive method availability | 14 | -- | 9 | X | -- | X |
| Cervical cancer screening | -- | 29, 30 | -- | -- | -- | X |
| Family planning services provided | -- | -- | 10 | -- | -- | X |
| Referral practices | -- | -- | 11 | -- | -- | X |
| Preconception care services | -- | -- | 12 | -- | -- | X |
| *Sources of Information/Tools* |  |  |  |  |  |  |
| Preferred provider tools | 23 | -- | -- | X | X | X |
| Preferred continuing education sources | 24 | 28 | -- | X | X | X |
| *Awareness of Guidelines* |  |  |  |  |  |  |
| Awareness of US MEC, US SPR, or QFPS | 25 | 31 | 25 | X | X | X |
| Awareness of US MEC provider tools | -- | 32 | -- | X | -- | -- |
| Recommended new topics | -- | 33 | -- | X | -- | -- |
| *Health center systems and programs* |  |  |  |  |  |  |
| Hours of services | -- | -- | 14 | -- | -- | X |
| Educational materials provided | -- | -- | 14 | -- | -- | X |
| Adolescent services | -- | -- | 14,15 | -- | -- | X |
| Information technology | -- | -- | 16 | -- | -- | X |
| Community education programs | -- | -- | 17, 18 | -- | -- | X |
| Quality improvement systems | -- | -- | 19, 20 | -- | -- | X |
| Referral arrangements and networks | -- | -- | 21 | -- | -- | X |
| Staff training | -- | -- | 22 | -- | -- | X |
| *Demographics/Training* |  |  |  |  |  |  |
| Role | 1 | 6 | 23, 24 | Not specific evaluation measures, but used to better understand use of guidelines and to target dissemination efforts. |
| Clinical focus | 2 | 7 | 2 |
| Funding sources | 3 | 2 | -- |
| Setting | 4 | 1 | 1, 4 |
| State | 5 | 3 | 3 |
| # of clients | 8 | 9 | 5 |
| % provide family planning services | 9 | 10 | 6 |
| Time spent on family planning | 10 | -- | -- |
| Gender | 11 | 5 | -- |
| # providers in practice/clinic | -- | 4 | -- |
| Patient characteristics | 13 | 12 | 7 |
| # days formal family planning training | 6 | -- | -- |
| Years since last formal training | 7 | 8 | -- |
| Trained in LARC insertion | 12 | 11 | 22 |
| Health care network linkages | -- | -- | 8 |  |

\*US MEC=*U.S. Medical Eligibility Criteria for Contraceptive Use*; US SPR=*U.S. Selected Practice Recommendations for Contraceptive Use*; QFPS=*Guidance for Providing Quality Family Planning Services* (revised Title X programmatic guidelines).

* **Please provide some more background on Phase I and how the methods and instruments proposed in the Phase II ICR map on to the earlier approval (we searched for the earlier approval in the system but the OMB control number given was 0920-0008 – Emergency Epidemic Investigations; would the program confirm that 0920-0008 is the correct OMB number?).**

Our Phase 1 data collection efforts are described in detail in the PDF attachment titled “SOW\_Final\_Phase 1” including background, purpose, and scope of work. Briefly, Phase 1 consisted of a mailed survey to a sample of 4,000 private- and public-sector family planning providers in the United States. Private-sector providers included office-based physicians (obstetrician/gynecologists, family practice physicians, and pediatricians specializing in adolescent medicine) sampled from the American Medical Association (AMA) Physician Masterfile. Public-sector providers included practitioners providing services at Title X-supported clinics, sampled from the Office of Population Affairs directory. Anticipating non-response, a reminder postcard was sent to those who had not responded to the first mailing after ~2 weeks. A second copy of the survey was sent to those who had not responded to the first survey or reminder postcard after ~2 weeks. Phone calls were made to those that had not responded to any of the contact attempts to encourage participation.

Methods described in our Phase II information collection request are similar to those implemented in Phase 1, with a few additions (e.g., expanded type of respondents to include providers in non-Title X publicly funded health centers and administrators of publicly funded health centers, online data collection option). Table 1 above shows how the instruments complement one another between and within phases.

Our Phase I data collection effort was approved by CDC’s Epidemic Intelligence Service office on December 3, 2009 as EPI-AID 2010-024: *Surveillance of U.S. Family Planning Providers’ Use of Contraception Guidelines and Practices Related to Contraceptive Use for Women with Specific Characteristics or Medical Conditions*. As such, the data collection was covered under OMB No. 0920-0008 for emergency epidemic investigations. Data collection began December 7, 2009 and ended March 5, 2010. Please see PDF attachments titled “Emergency Epidemic Investigation OMB Form\_EPI-AID 2010-24” and “Call for EPI-AID\_Phase 1” for more details.

* **Please provide additional detail on and timing related to the guidance mentioned in the Private and Public Sector Cover Letters (C1 and C2): “The information gathered will be used to develop educational materials and tools for providers related to family planning service provision, and to help plan for the implementation of forthcoming national guidance on the provision of quality family planning services.”  Part A mentions that materials are likely to be released in late 2012 or early 2013; is that still the case? It would be helpful to understand which survey questions are intended to relate to the impact of the US MEC and which questions are intended to inform the forthcoming guidance documents.**

Both forthcoming family planning guidance documents (i.e., *U.S. Selected Practice Recommendations for Contraceptive Use* and *Guidance for Providing Quality Family Planning Services)* are currently in CDC clearance. **We expect that both documents will be released in early 2013**.

To help the reviewer understand which survey questions are intended to be evaluation measures for the U.S. MEC versus the forthcoming family planning guidance documents, please see Table 1 above.

* **Screenshots of surveys available online must be provided.**

Screen shots of both Phase II survey instruments are attached. These screen shots are in draft form and have not yet been finalized.

* **Please delete the following bullet from the Administrator Survey Cover Sheet (E2): “Your complete answers are essential to helping us support publicly-funded family planning service providers in the future.”**

The bullet has been deleted from E2. Please see revised version.

* **Are the proposed samples intended to be nationally representative?**

Yes, the proposed samples are intended to be nationally representative. The sample frames will represent a complete census of the target samples. For example, to sample private-sector physicians specializing in obstetrics and gynecology, family medicine, and adolescent medicine (specialties that provide the bulk of family planning services in the United States), we will use the AMA Physician Masterfile, which includes information on AMA member and nonmember board-certified physicians residing in the United States and United States territories. To sample public-sector family planning providers and health center administrators, we will use the Guttmacher Institute Database of Publicly-funded Family Planning Health Centers, which is regularly updated and maintained by the Guttmacher Institute. After data collection, to ensure that the data are nationally representative, data will be weighted to account for the probability of selection into the sample, as well as nonresponse bias. This information has been added to section B1.

* **Please provide additional information in Part B about planned non-response bias analyses.**

As stated above, in analyses, data will be weighted to account for the probability of selection into the sample, as well as nonresponse bias.

In addition, we will know basic information about each of the sampled physicians and health centers, which will be analyzed to understand general differences between respondents and non-respondents. For example, for the publicly-funded family planning health centers, we will know the type of health center (e.g., Planned Parenthood, hospital, community health center). For physicians, we will know background information such as specialty, gender, and graduation year from medical school.

This information has been added to section B3.