

Report to Congress

Report on Activities Related to “Improving Women’s Health”

As Required by the Affordable Care Act

(P.L. 111-148, Section 3509)



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I. EXECUTIVE SUMMARY

The Patient Protection and Affordable Care Act, P.L. 111-148 of 2010, includes provisions to improve the health of women. Section 3509, titled “Improving Women’s Health,” details specific requirements for various U.S. Department of Health and Human Services (HHS) agencies and offices related to women’s health. The Secretary of HHS, through the HHS Office on Women’s Health, is required to issue a report to Congress not later than one year after the date of enactment of this section, and every second year thereafter, describing the activities carried out under Section 229 of the Public Health Service Act (as amended).¹

The Affordable Care Act codifies the establishment of an Office on Women’s Health within the Office of the Secretary of HHS, as well as Offices of Women’s Health within four of its agencies; the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA). The Affordable Care Act gives these offices, all of which were already in existence, new authority, agency location, and protection from termination or reorganization without the direct approval of Congress.

The law charges the HHS Office on Women’s Health to establish the HHS Coordinating Committee on Women’s Health (CCWH) to coordinate the activities of these offices, and establish the National Women’s Health Information Center (NWHIC) to facilitate the exchange of information. Among the requirements, these offices must report on the status of their activities related to women’s health; establish women’s health-related goals and objectives; identify women’s health projects to be conducted or supported; consult with women’s health professionals and other groups on policies; and serve as a member of the CCWH.

Section 3509 also requires that the Director of the Office of Research on Women’s Health (ORWH) at the National Institutes of Health (NIH) report to the Director of NIH; and that the Substance Abuse and Mental Health Services Administration (SAMHSA) appoint an Associate Administrator for Women’s Services who reports to the SAMHSA Administrator.

The Affordable Care Act does not provide deadlines to complete these requirements, and it carries no specific authorization of appropriations other than such sums as necessary for each of the fiscal years 2010 through 2014.² There are no specific requirements for other HHS agencies and offices, other than to coordinate on activities for issues of particular concern for women; provide consultation on policies; and serve on the HHS Coordinating Committee on Women’s Health (CCWH), which is comprised of senior-level representatives from each HHS agency and office. The activities of other HHS agencies and offices are provided to demonstrate the Departmental cross-collaboration on women’s health initiatives and activities.

In addition to fulfilling the requirements of creating the HHS Coordinating Committee on Women’s Health (CCWH) and the National Women’s Health Information Center (NWHIC), the HHS Office on Women’s Health has made significant progress in providing expert advice and consultation to the Secretary; in monitoring the activities of HHS Federal agencies and offices and identifying needs; in coordinating efforts with the private sector, and in providing for the

exchange of information through publications and other means appropriate. As required under Section 3509, the HHS Office on Women's Health has filled the position of Deputy Assistant Secretary of Health (Women's Health) to head the Office and report to the Secretary and Assistant Secretary for Health, effective March 27, 2011.

AHRQ, CDC, FDA, and HRSA have all made progress in establishing Offices of Women's Health, headed by a Director who reports to the appropriate authority. Some of these agencies and offices are actively reorganizing and/or staffing their Offices of Women's Health. More progress and task completions are expected in subsequent reports to Congress. As required under Section 3509, AHRQ, CDC, FDA and HRSA have all reported to their respective authority on the current level of activity in each agency or office regarding women's health, and they have established women's health-related short-range and long-range goals and objectives in coordination with other agencies and offices as relevant and appropriate. They have also identified women's health projects that should be conducted or supported, and have consulted with women's health professionals and other groups as appropriate on policies. Continuing progress is expected on these requirements in the next reporting period. AHRQ, CDC, FDA, and HRSA representatives all served on the HHS Coordinating Committee on Women's Health (CCWH) during the reporting period.

In compliance with the requirements in Section 3509, the FDA has also made significant progress in providing information to women and health care providers on areas where disparities between men and women exist, and has begun the process of making annual estimates of funds needed to monitor clinical trials and analysis of data by sex. Further progress is expected in future reports.

The NIH Reform Act of 2006, P.L. 109-482, mandates that the ORWH reside within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), which is located within the Office of the Director of NIH. As such, the Director of ORWH reports to the Director of DPCPSI; however, the Director of ORWH is not precluded from reporting to the Director of NIH. The Substance Abuse and Mental Health Services Administration (SAMHSA) has appointed an Associate Administrator for Women's Services who reports to the SAMHSA Administrator. Various other HHS agencies and offices supported the activities described in Section 3509, including by serving on the HHS Coordinating Committee on Women's Health (CCWH).

This is the first of the required reports to Congress, and it provides a baseline summary of activities carried out by HHS agencies and offices in accordance with Section 3509, since March 23, 2010. Subsequent biennial reports will demonstrate the progression of activities carried out by HHS agencies and offices under Section 3509.

II. INTRODUCTION

On March 23, 2010, President Barack Obama signed the Protection and Affordable Care Act, P.L. 111-148, into law. This landmark legislation calls for changes to make health care more affordable, expand health coverage, make health insurers more accountable, and make the health system more sustainable.³ In terms of women's health, the Affordable Care Act is expected to increase women's access to health coverage and health care, and to strengthen the health system to serve women more effectively.

Section 3509 directs the U.S. Department of Health and Human Services (HHS) to make women's health a priority. Section 3509 calls for greater prioritization and authorization of women's health issues within HHS Federal agencies and offices; greater coordination of efforts across HHS Federal agencies and offices; and greater access to women's health information including on areas in which differences between men and women exist.

The past few decades have seen a greater focus on women's health, including improved understanding of sex and gender differences and the unique health needs of women.⁴ The increased participation of women in clinical trials research is critical to addressing gaps in knowledge about women's health.⁵ Women are more likely to suffer from multiple chronic conditions and are in greater need of health care services across their lifespan.⁶ Women are also more likely than men to be victims of sexual assault, intimate partner violence, and stalking.

Women, particularly those in minority populations, face additional social and economic barriers affecting their health and well-being.⁷ Women are more likely than men to live in poverty and are more likely to be underemployed.⁸ With lower average incomes, women are also impacted harder by the rising costs of health care.⁹ While most women ages 18-64 are covered by employer-based health care, women are nearly twice as likely as men to be covered as dependents; this makes women more vulnerable to loss of coverage if the wage earner loses his job.¹⁰ At the same time, women are the primary caregivers in society, and their access to health care and health-related knowledge affects the health of families and communities.¹¹

Improving the health of women has been one of the strategic priorities of the U.S. Department of Health and Human Services (HHS) for over 26 years. HHS is the U.S. government's principal agency for protecting the health of all Americans and providing essential human services. HHS improves women's health through the administration of over 300 programs in research, education, training, direct clinical service delivery, and policy development.¹²

The HHS Coordinating Committee on Women's Health (CCWH) was established in 1983 to advise the Assistant Secretary for Health (and in 1993, the Deputy Assistant Secretary for Health) on activities across HHS to safeguard and improve the health of all women in the United States.¹³ The HHS Coordinating Committee on Women's Health (CCWH) works strategically to improve awareness, increase collaboration, advance evidence-based programs and policies, support sex and gender-specific initiatives, and address gaps and disparities in women's health.¹⁴ CCWH is chaired by the Deputy Assistant Secretary for Health (Women's Health) and is

comprised of senior-level representatives from each of the HHS agencies and offices. For reference, **Appendix I** includes the HHS agencies and offices that comprise CCWH.

The activities described in this report are based on information provided by the CCWH members who represent each of the HHS agencies and offices, related to progress on meeting the requirements outlined in Section 3509 of the Affordable Care Act. This report provides baseline information on programs and activities since March 23, 2010.

III. AGENCY/OFFICE-SPECIFIC REQUIREMENTS

Section 3509 of the Affordable Care Act, titled “Improving Women’s Health,” has specific requirements for the following U.S. Department of Health and Human Services (HHS) agencies and offices: the HHS Office on Women’s Health (OWH), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

The activities described below reflect the progress of each agency and office on their agency- and office-specific requirements in the reporting period of one year since the enactment of Section 3509 (March 23, 2010-March 23, 2011). For reference, **Appendix II** includes information on commonly used acronyms, and **Appendix III** contains Section 3509 of the Affordable Care Act.

Office on Women’s Health (OWH)

The Office on Women's Health (OWH) was established in 1991 in the Office of the Assistant Secretary for Health, within the Office of the Secretary, to improve the health of American women by advancing and coordinating a comprehensive women's health agenda throughout the U.S. Department of Health and Human Services (HHS).¹⁵ The HHS Office on Women's Health is the primary agent for women's health issues, working to provide leadership to promote health equity for women and girls through sex/gender-specific approaches.¹⁶ OWH ensures that women’s health policy, practice and research are mutually informed and effectively integrated within HHS. OWH also is the main point of contact with other Federal agencies and the White House on issues related to women’s health; and OWH collaborates on programming, policies, and initiatives with both Federal and non-Federal partners on behalf of women and girls.

In addition to OWH’s national staff, OWH has a mature system of Regional Women’s Health Coordinators located in the ten HHS Regional Offices. These Coordinators provide expert advice and consultation based on the needs in each area. States and Territories have either established women’s health offices or designated a coordinator; these non-Federal staff work with OWH’s Regional Coordinators to provide greater focus on women’s health issues at the regional, State and local levels, while advancing the mission of OWH. This nationwide network of connections provides OWH a ready infrastructure for rapid dissemination of information and implementation of HHS programs that benefit women and girls.

The following sections describe the specific requirements in Section 3509 of the Affordable Care Act related to the HHS Office on Women’s Health (amending Part A of Title II the Public Health Service Act [42 U.S.C. 202 et seq.]). Progress on or completion of each requirement is described. When appropriate, current activities and next steps are also indicated.

Establishment of an Office

The requirements of Section 229(a) under Section 3509 [amending 42 U.S.C. 237(a)] have been fulfilled through the establishment of an Office on Women's Health in the Office of the Assistant Secretary for Health, within the Office of the Secretary. The Office has completed hiring for the position of Deputy Assistant Secretary for Health (Women's Health) who will report to the Secretary and Assistant Secretary for Health, effective March 27, 2011.

Women's Health-Related Goals and Objectives

OWH has fulfilled the requirements of Section 229(b)(1) under Section 3509 through the establishment of short-range and long-range goals and objectives on issues of particular concern to women, in coordination with other appropriate agencies and offices. OWH's five-year strategic plan, implemented in fiscal year 2009, reflects these short-range and long-range goals and objectives. The strategic plan, which was used as a model for other offices within the Office of the Assistant Secretary for Health, identifies four goals (see **Table 1**):

- 1) Develop and impact national women's and girls' health policy;
- 2) Develop, adapt, implement, evaluate and replicate model programs on women's and girls' health;
- 3) Educate, influence and collaborate with health and human services organizations, health care professionals, and the public; and
- 4) Increase OWH's organizational efficiency and performance.

OWH's strategic plan prioritizes its goals on issues of particular concern to women, and the means to address them: policy, programs, communication, collaboration, and performance. OWH continues to fund evidence-based interventions to address gaps in women's health that are not addressed at the national level by any other public or private entity. These interventions focus on disparities in women's health, including with regards to minority status, disability, geography, family history, socioeconomic status, multiple dimensions of chronic conditions, infectious diseases, and age as contributing risk factors.

Of particular note in terms of progress on these goals during the reporting period, OWH increased the percentage of women-specific *Healthy People 2010* objectives and sub-objectives that have met their target or are improving. As an example, of the 338 women-specific *Healthy People 2010* objectives or sub-objectives in 2007, 69.5% have met their target or are improving. This is a 3% increase over the baseline performance report.

Heart disease is the leading cause of death for American women. OWH's education programs helped to increase the percentage of women who are aware of the early warning symptoms and signs of heart attacks and the importance of accessing rapid emergency care by calling 9-1-1. Additionally, OWH worked to expand the number of users of OWH communication resources and to increase the number of girls ages 9-17 and women ages 18-85+ who participate in OWH-funded programs per million dollars spent annually, a measure that routinely exceeds OWH targets.

Table 1. HHS Office on Women’s Health Vision, Mission and Goals

<i>Vision</i>
All women and girls are healthier and have a better sense of well-being.
<i>Mission</i>
Provide leadership to promote health equity for women and girls through sex/gender-specific approaches.
<i>Goals</i>
<ul style="list-style-type: none"> • Develop and impact national women’s and girls’ health policy; • Develop, adapt, implement, evaluate and replicate model programs on women’s and girls’ health; • Educate, influence and collaborate with health and human services organizations, health care professionals, and the public; and • Increase OWH’s organizational efficiency and performance.

OWH’s progress and activities on these goals are described in greater detail under the applicable Section 3509 Affordable Care Act requirements, in the sections that follow.

Expert Advice and Consultation

OWH fulfilled the requirements of Section 229(b)(2), by routinely providing expert advice and consultation to the HHS Secretary on scientific, legal, ethical and policy issues relating to women’s health. OWH coordinates women’s health initiatives and programs for the entire Department. As such, OWH is uniquely positioned to look at all these activities across HHS, encompassing research, regulation, quality improvements, health services and prevention programs. OWH also advises the Assistant Secretary for Health on issues related to the advancement of women’s health. These activities are consistent with, and reflect OWH commitment to OWH’s strategic plan Goal 1.

Examples of efforts to provide expert advice and consultation to the HHS Secretary and Assistant Secretary for Health on scientific, legal, ethical, and policy issues relating to women’s health include the following:

- OWH has proposed establishing a *Federal Advisory Committee (FAC) on Women’s Health* to provide expert advice and evidence-based recommendations to the Secretary and Assistant Secretary for Health on a broad range of issues on the status of women’s and girls’ health. The FAC will address prevention, education, policy, and programmatic approaches. It will provide expert consultation on emerging women’s health issues, preventive and behavioral programs, and identification of relevant partnering and collaborative opportunities.

- OWH is a Departmental representative to the *White House Council on Women and Girls*, collaborating with other Federal leaders in proposing actions that affect the lives of women and girls, especially related to their health and well-being. *The White House Council on Women and Girls* was created on March 11, 2009, by President Barack Obama, and it is charged with taking into account the needs of women and girls in the policies and programs that are created.¹⁷
- OWH is a representative to the *Office of the Vice President's Working Group on Violence Against Women*, focusing on increased attention, policy actions, and programmatic changes for women and girls who experience family and partner violence.
- Since 1994, OWH has led the 40 member *Federal Interagency Working Group on Women's Health and the Environment*, to provide expert advice and consultation on environmental factors affecting women. The working group consists of representatives from HHS agencies and offices, as well as representatives from the Environmental Protection Agency, Department of Labor, Department of Defense, and the Consumer Product Safety Commission. The *Federal Interagency Working Group on Women's Health and the Environment* works to identify gaps related to women's health and the environment and to coordinate efforts across Federal agencies and offices. Originally formed to address breast cancer and the environment, some of the current initiatives include: dietary supplements used to treat menopausal symptoms, tobacco control interventions for women, workplace health and safety for women, mercury exposure for women, and environmental risk factors for lupus.
- OWH is collaborating with the *White House Office of National AIDS Policy*, which was tasked with creating a national strategy to coordinate efforts to reduce HIV infections in the United States, increase access to care and optimize health outcomes for people living with HIV/AIDS, and reduce HIV-related health disparities including gender/sex differences.¹⁸ The *National HIV/AIDS Strategy: Federal Implementation Plan* was released in July 2010, and OWH works collaboratively with the HHS Office of HIV/AIDS Policy to provide expert advice and consultation to the HHS Secretary and Assistant Secretary for Health on its implementation, including policy and programmatic recommendations for women and girls.
- OWH continues to lead and manage the *Chronic Fatigue Syndrome Advisory Committee (CFSAC)*. Research has shown that chronic fatigue syndrome (CFS) is three to four times more common in women than men, a rate similar to that of autoimmune conditions such as multiple sclerosis and lupus. CFSAC focuses on policy, research, education, and access to care for those with this condition. The Committee includes ex-officio representatives from the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), Social Security Administration (SSA), Agency for Healthcare Research and Quality (AHRQ), and the Centers for Medicare and Medicaid Services (CMS).

- OWH Regional Women’s Health Coordinators are leading efforts to articulate a comprehensive set of recommendations for services that promote successful transition of women and girls back into their communities after incarceration. This *Incarcerated Women’s Transition Project* was developed to define a best-practice model and a set of recommendations for gender sensitive services to meet the health and social needs of women and girls reentering their communities from correctional facilities.
- OWH Regional Women’s Health Coordinators are also leading efforts to establish and implement the *National Office on Women’s Health Leadership Institute Program*. This program will focus on educating and training Community Health Workers for higher level leadership roles in applying public health systems approaches to address health disparities at the community-level.
- In FY 2011, OWH funded a national survey of single-parent caregivers. Following this survey, OWH will develop policy-oriented activities to educate policymakers, researchers, and American families about this subset of caregivers and their unique needs. The survey builds upon recommendations from the OWH-commissioned *Literature Review of Existing Supports for Single Parent Caregivers* conducted in FY 2009 (www.womenshealth.gov/pub/owh/single-parent-caregivers.cfm).
- OWH launched *Project Connect: A Coordinated Public Health Initiative to Prevent Domestic and Sexual Violence*. The initiative funds statewide teams to develop policy and public health responses to violence against women. The initiative focuses on improving outcomes for maternal and child health and decreasing unplanned pregnancy, sexually transmitted infections, and poor pregnancy outcomes that result from domestic and sexual violence. This project demonstrates the connection between research, policy and practice. For example, grantees are changing practice and policy by requiring providers to assess and respond to violence and abuse with every patient and offer safety resources. OWH has supported the training of over 1500 adolescent, reproductive, and perinatal health providers in eight states and two Tribes. *Project Connect* is a multi-state initiative designed to educate public health professionals and build sustainable public health partnerships across the nation.

Monitoring HHS Activities

OWH has met the requirements of Section 229(b)(3). The Deputy Assistant Secretary for Health (Women’s Health), who serves as the Director of OWH, chairs the HHS Coordinating Committee on Women’s Health (CCWH). OWH monitors all HHS activities regarding women’s health and identifies needs for the coordination of activities throughout the Department, leveraging initiatives, programs, and resources to maximize the benefit for women and girls. These activities are also consistent with OWH’s strategic plan Goal 3. In meeting this goal, OWH considers both the general population of women and girls as well as those for whom specific challenges may exist. Examples include:

- OWH leads the *HHS Steering Committee on Violence Against Women (VAW)*. This committee is comprised of experts on Violence Against Women (VAW) from agencies and offices within HHS. The committee meets bi-monthly to collaborate on VAW issues, identify gaps in program initiatives, and propose strategies and solutions to address these gaps. The committee also produces an annual report on HHS VAW program and activities. The committee members provide critical guidance as health resource experts for the National Advisory Committee on Violence Against Women, which is chartered by the Department of Justice and co-chaired by the Attorney General and HHS Secretary.
- OWH is working collaboratively with HRSA to lead an *HHS Working Group for Worksite Lactation Support*. This working group, which is comprised of representatives from HHS agencies and offices, will develop implementation strategies to assure that lactation facilities and support are available to breastfeeding mothers across all HHS agencies and offices. The Affordable Care Act includes a provision for employers to allow reasonable break time for nursing mothers to express milk in a private place, other than a bathroom. The OWH/HRSA collaboration is assisting in the implementation of this provision.
- OWH is part of an HHS-wide effort to improve the nation's oral health by realigning existing resources and creating new activities to improve coordination and integration among HHS programs. OWH participates on the *HHS Oral Health Coordinating Committee (OHCC)*, engaging in monthly OHCC planning meetings. As part of the revitalized initiative, the OHCC is conducting an assessment of health care providers' understanding of the role of oral health in general health, to inform training and information development for providers and the public. Following the assessment, OWH will assist with creating HHS educational training materials to enhance awareness of health care providers and the public. In addition, OWH is working closely with staff from HRSA to coordinate efforts on oral health and pregnant women. In 2010, educational materials related to pregnancy and oral health were distributed at OWH exhibits.

Establishment of CCWH

As noted, OWH has fulfilled the requirements of Section 229(b)(4) through the establishment of the HHS Coordinating Committee on Women's Health (CCWH), composed of senior-level representatives from each of the HHS agencies and offices. In 1983, almost 8 years before OWH was established, the HHS Assistant Secretary for Health appointed the *Public Health Service (PHS) Task Force on Women's Health Issues* to "identify those women's health issues that are important in our society today and to lay out a blueprint for meshing those issues with the priorities of the Public Health Service."¹⁹

After two years of study, the PHS Task Force issued Volume I of *Women's Health: Report of the Public Health Service Task Force on Women's Health Issues*, which included their findings and a series of recommendations to address women's health. In response to those recommendations, the HHS Coordinating Committee on Women's Health (CCWH) was created to facilitate intradepartmental communication (see **Table 2**).

Table 2. Coordinating Committee on Women's Health Vision, Mission and Objectives	
<i>Vision</i>	
All women and girls lead safe and healthy lives.	
<i>Mission</i>	
Provide Department-wide leadership to address the health, safety and quality of life of women and girls.	
<i>Objectives</i>	
<ul style="list-style-type: none"> • Recommend and provide guidance on women's health policy, programming and evaluation efforts; • Collaborate and coordinate initiatives with Federal and non-Federal partners; • Deliver science-based and culturally competent health information and resources; • Identify and develop a coordinated response to emerging issues that affect women and girls' health and well-being. 	

The CCWH is chaired by the Deputy Assistant Secretary for Health (Women's Health). For reference, see **Appendix I** for the complete list of HHS agencies and offices that comprise CCWH.

Establishment of NWHIC

In 1994, women had no single resource for comprehensive information about the illnesses that affected them or the ways in which they could protect their health. As the Internet was expanding into households, OWH recognized an opportunity to reach millions of women through that vehicle. OWH and the U.S. Army Medical Research and Materiel Command (USAMRMC) established a partnership to plan, develop and operate the National Women's Health Information Center (NWHIC), which launched in 1998. Thus, OWH has met the requirements of Section 229(b)(5), and NWHIC contributes to OWH's strategic plan Goal 3.

Through NWHIC, OWH manages five websites, including two comprehensive websites (www.womenshealth.gov and www.girlshealth.gov); a micro-site for lupus (www.couldihavelupus.gov) and its Spanish equivalent (www.podriayotenerlupus.gov); and a micro-site for bone health (www.bestbonesforever.gov). Included below is more information on the scope, reach and usage of the sites and the public information that they support:

- The *womenshealth.gov* website offers access to more than 4,000 publications and 2,000 organizations covering more than 800 health topics from Federal and non-Federal sources. It provides health information and referrals to consumers of health services,

health professionals, researchers, educators, and students. The website contains fact sheets; frequently asked questions (FAQs); information on national health education campaigns; a calendar of national and local events; daily news on women's health topics; and online journals and dictionaries. During calendar year 2010, there were 10,440,743 user sessions on *womenshealth.gov*.

Feedback on *Womenshealth.gov*

"Your services have been invaluable for me. I have called the National Breastfeeding Hotline several times over my year of nursing and have always been helped by quality, knowledgeable, and friendly staff. You have been so supportive and I am very grateful. Your site has the best breastfeeding-related information on the web. Thank you again for providing such a wonderful service. I think more hospitals should share this and utilize this as a resource for ALL new mothers (I was told about it by my sister)." – Call Center and Womenshealth.gov website user

- The *girlshealth.gov* website motivates girls ages 10-16 to choose healthy behaviors by providing information on fitness, nutrition, stress management, relationships with friends and family, peer pressure, suicide, drugs, and self-esteem. It provides reliable, useful information on health issues that girls and young women face. The website uses an interactive, user-friendly format to keep them engaged and interested in learning more about their health. *Girlshealth.gov* is the #1 Google return when searching for "girls' health" and it had 956,951 user sessions during calendar year 2010.

Feedback on *Girlshealth.gov*

"I just wanted to let you know that I love this website! I go on it all the time! Thank you so much for a website that I can learn how to stay safe on the Internet and in-person. Thanks again!" – Girlshealth.gov website user

- The *couldihavelupus.gov* website and the Spanish-language website *podriayotenerlupus.gov* describe lupus, list symptoms of the disease to promote early diagnosis, and discuss how lupus affects women. The vast majority of people with lupus are women, and they face debilitating and potentially life-threatening health consequences as a result of this autoimmune disease. The websites, which are part of a *National Lupus Awareness Campaign*, provide a much-needed online community for women to share stories and connect with other women battling the disease. In FY 2010, there were 1,024,305 users of the lupus website.

In a partnership with the American Academy of Pediatrics (AAP), the National Osteoporosis Foundation (NOF) and other HHS agencies, OWH developed two unique initiatives that OWH manages and includes on *womenshealth.gov* and *girlshealth.gov*, to support health for adolescents and their parents:

- The *Best Bones Forever!* campaign, which is based on the 2002 information campaign named *Powerful Bones, Powerful Girls*. It was re-branded and renamed *Best Bones*

Forever! on September 2, 2009, to encourage girls, their friends, and parents to incorporate bone-healthy behaviors into daily life. By age 18, most young women have built most of their bone mass, which affects their chances of having frail bones and developing osteoporosis later in life. Women over 50 are nearly twice as likely as men to develop this debilitating disease. This national campaign focuses on calcium and vitamin D consumption and physical activity for girls ages 9 to 14. In FY 2010, OWH implemented social media outreach, exhibiting at various conferences and meetings, and continued enhancement of the campaign websites. Since its launch 18 months ago, there have been 248,197 user sessions on the website *bestbonesforever.gov*.

- The *BodyWorks* campaign, which began in 2006, is designed to help parents and caregivers of adolescents (9-13) improve family eating and activity habits. *BodyWorks: A Toolkit for Healthy Teens & Strong Families* focuses on the family as the most important environment to prevent obesity in girls. The toolkit's curriculum was originally developed for adolescent girls; but many parents also wanted their adolescent boys to participate. A "For Guys" toolkit was developed in 2010. The program uses a train-the-trainer model to distribute *BodyWorks* toolkits through community-based organizations, State health agencies, non-profit organizations, health clinics, hospitals and health care systems. An extensive evaluation of *BodyWorks* is planned for FY 2011-FY 2013. Currently over 3,500 trainers and 3,000 families throughout the country have participated in the program. The Spanish version of the *BodyWorks* toolkit was released in the summer of 2009, and 200 Spanish speaking trainers with at least 200 families have participated in the program.

Feedback on *BodyWorks* Campaign

"I am doing all I can to make other cities aware of this great program. Thanks for providing us with this valuable toolkit." – Parks and Recreation staff member, MS

Other immediate information sources for women that OWH manages as part of the National Women's Health Information Center (NWHIC) include the Information and Referral Helpline and the National Breastfeeding Helpline, described below:

- The Information and Referral Helpline offers a toll-free telephone number for callers at 1-800-994-9662 (or TDD, 1-888-220-5446). Information and Referral Specialists answer questions on women's and girls' health in either English or Spanish. Assistance includes person to person responses, mailings of relevant materials, and referrals to other information or help sources. During calendar year 2010, there were over 28,808 phone calls to the helpline, of which 1,277 were related to lupus.
- The National Breastfeeding Helpline is part of the Information and Referral Helpline. It offers trained breastfeeding peer counselors who provide information, support, and encouragement on breastfeeding questions and concerns. It uses the same phone numbers listed above for the Information and Referral Helpline (1-800-994-9662 or TDD, 1-888-

220-5446). Of the 28,808 phone calls to the helpline during calendar year 2010, 4,357 were related to breastfeeding.

OWH also manages the print materials that support the technology-based access tools at part of NWHIC and its websites. Some of these materials include:

- Printed publications in English and Spanish, which cover a variety of women's health topics. From the highly requested women's health calendar to the widely distributed *Lifetime of Good Health*, *womenshealth.gov* provides users with in-depth information on various women's health-related topics.
- The *womenshealth.gov*'s monthly newsletter, *Healthy Women Today*, featuring a range of information on women's health, including healthy recipes, news headlines, health observances, and announcements of new products. The *Spotlight on Women's Health* features interviews with people with inspirational health stories.

Private Sector Efforts

OWH has fulfilled the requirements set forth in Section 229(b)(6) by coordinating a number of efforts to promote women's health programs and policies with the private sector. As noted above, many of OWH's efforts include significant collaborations with both the public and private sectors in order to improve the reach, sustainability and effectiveness of its efforts, consistent with OWH's strategic plan Goal 3 and 4. These initiatives highlight OWH's central convening function between public and private entities, to make progress on women's health. Some of efforts with the private sector are described below:

- Over the last two years, the CCWH (led by OWH) reviewed and integrated the perspectives of a diverse group of about 1,000 public and private stakeholders to draft an *Action Agenda to Improve the Health of Women and Girls Beyond 2010*. The draft Agenda includes recommendations for specific actions to: a) ensure input from HHS' women's health experts in health care reform; b) systematically disaggregate data to identify and monitor health outcomes; c) position HHS as a leader in eliminating violence against women and girls; and d) focus HHS efforts on expanding capacity to provide culturally competent, quality health services for all women and girls.
- In October 2010, OWH led the *HHS Steering Committee on Violence Against Women (VAW)*, in convening the *National Domestic Violence Awareness Month* program with Federal speakers from the White House, Department of Justice Office of Violence Against Women, HHS Assistant Secretary for Health, Surgeon General, HHS Administration for Children and Families, Centers for Disease Control and Prevention, National Institutes of Health-National Institute of Child Health & Human Development, HHS Chief of Security, and the Employee Assistance Program. Business leaders and others from the private sector participated, including the Family Violence Prevention

Fund, Kaiser Permanente, Verizon Telecom and Second Chance Employment Services. This program was made available to viewers via a nationwide webcast.

- In FY 2010, OWH collaborated with HRSA to continue the four-year *National Business Case for Breastfeeding Campaign* to encourage businesses to offer lactation support for mothers who return to work. The goal of the program is to increase support to sustain breastfeeding for six months by women who return to work. The *Business Case for Breastfeeding Kit* is available in hard copy through the HRSA Resource Center and online (www.womenshealth.gov/breastfeeding). Hundreds of businesses in 30 states have adopted lactation support policies for their employees. OWH is partnering with CDC and the Surgeon General's Office to update the *HHS Blueprint for Action on Breastfeeding*. This new document will reflect the latest science related to breastfeeding.
- OWH collaborated with *text4baby™*, which was launched in 2010 by the *National Healthy Mothers, Healthy Babies Coalition*. This public-private partnership uses text messages to help pregnant women and new mothers access care, and it encourages healthy behaviors during pregnancy and through the first year of the infant's life. OWH continues to collaborate with the *National Healthy Mothers, Healthy Babies Coalition* as a public-private partnership.
- OWH contributed to several nationwide women's heart health initiatives during the reporting period. As a founding sponsor, with the National Institutes of Health's National Heart, Lung, and Blood Institute, of the *Heart Truth Campaign*, OWH is disseminating educational modules for health professionals on the science behind the campaign's messages. These modules are being updated and will appear on *Medscape* in FY 2011. In FY 2008-2011, the Primary Care Partnerships Program to Prevent Heart Disease in Women will have reached out to every public and private health care provider in Ohio, Delaware, and Western New York through seminars, grand rounds, office detailing, and motivational interviewing training. OWH also supports the *Heart Truth Champions* program in several cities with high heart disease rates to deliver educational information at seminars, programs and health fairs.
- In FY 2010, OWH initiated the development of a social marketing campaign on awareness and prevention of STDs among teen girls, 13 to 19 years of age. The campaign, in partnership with the Centers for Disease Control and Prevention (CDC), brings together Federal agencies, public health associations, community-based organizations, faith-based organizations, and other private sector entities to address the high rates of untreated STD's among U.S. teen girls.
- OWH developed *Communication Skills Building for Parents of Pre-Teens* (CSB) kits for parents of pre-teens meant to improve parent-to-child communication on difficult issues related to early adolescence. One of the two kits targets African American parents and will be completed by March 2011. The other kit targets Hispanic parents and will be completed by fall 2011. Kits contain a tip sheet for parents, facilitators' guide, and interactive DVDs. Before they are disseminated, facilitators will be trained by an OWH

contractor in communications skills building. Facilitators will then train public and private sector organizations that have direct access to parents and children. Examples of potential groups are the Girl Scouts of America and the National Hispanic Federation.

- In 2010, OWH engaged a contractor to provide program support for central and regional women's health projects, and logistical support and travel arrangements for critical meetings with women's health partners. The OWH contract provides a mechanism for supporting small projects and critical meetings of non-Federal women's health partnerships at the local, State, regional, and national levels. The number of health care professionals served during 2010 increased by nearly 21% from the previous year to a total of 13,816. There was also a 70% increase in requests for applications received for all of the funding opportunities released through this contract during 2010.

Exchange of Information

As previously noted, OWH provided for the exchange of information, through publications and other means appropriate, between OWH and recipients of grants and contracts, health professionals, and the general public during the reporting period. This exchange has allowed OWH to fulfill the requirements of Section 229(b)(7), and it further supports OWH's strategic plan Goals 2 and 3.

OWH translates the best science available in the fields of women's and girls' health into plain language so it is understandable to a wide audience. This credible, non-biased, accurate information reaches the general public, academicians, health professionals, State and local agencies, and others through various avenues. Some additional examples of information translation and dissemination include the following:

- OWH manages *Quick Health Data Online*, a dynamic and comprehensive database system that provides state- and county-level data for women and men from all 50 States, the District of Columbia, and the U.S. territories. Database elements include demographics, mortality, access to care, reproductive health, infectious and chronic disease, maternal health, mental health, and violence and abuse. OWH modified and expanded this system in FY 2009 and updates the data annually. In 2010, user sessions averaged 13,763 per month, with a high of 19,692 in March 2010. Free training sessions on how to create tables, graphs, and maps with the data are now offered several times a month.
- In early FY 2011, OWH created the *Federal Women's Health Web Council*, with members from throughout the Federal government. This collaborative Council works to ensure women's health information is easily accessible throughout the Federal government.
- In 2010, OWH and the Advertising Council completed the Congressionally supported first-ever *National Lupus Awareness Campaign*. This campaign is dedicated to

increasing awareness of lupus and improving early diagnosis and treatment among those who are at increased risk for this disease. The campaign, targeted toward young minority women who are most likely to be affected by lupus, provides people with lupus and their family members with information to help them take action for early detection. The campaign included TV and radio public service announcements, a website (*couldihavelupus.gov*), bulletin boards, and other media tools. It reached more than 30 million people during the first few months after the launch in 2009. The website has drawn over 1,187,457 user sessions. It is the Advertising Council's leading outdoor billboard, and it ranked #2 in network cable TV and #3 in total cable TV. This campaign was also featured on the *Oprah.com* website with outstanding public responses. The website will remain operational as an OWH microsite.

Return on Investment for the National Lupus Awareness Campaign

For the initial \$2,300,000 investment for the National Lupus Awareness Campaign, OWH received more than \$54,000,000 in free advertising.

- During the reporting year, OWH began developing the *HIV Prevention Gender Toolkit* focused on women and girls. The toolkit will be a user-friendly guide to assist program planners and providers to develop, implement, monitor, and evaluate gender responsive HIV prevention programs and support services for women and adolescent girls. The purpose of the toolkit is to increase awareness and understanding of: a) the effects of gender inequalities on women's/girls' vulnerabilities to HIV infection and access to HIV/AIDS prevention programs and support services; b) ways in which gender intersects with other key determinants of health such as socio-economic status, race and ethnicity, and how these determinants might increase women's/girls' vulnerabilities to HIV infection; c) the importance of integrating a gender perspective and utilizing gender analysis in developing, implementing, monitoring, and evaluating HIV prevention and support services for women and girls; and d) ways to offer HIV program planners and providers a resource on how to integrate a gender perspective in the design, implementation, monitoring, and evaluation of HIV prevention programs and support services for women and girls.
- OWH developed the *Make the Call; Don't Miss a Beat* campaign to inform women of the seven symptoms of a heart attack and the need to call 9-1-1. Television, radio, print, internet, and out-door ads have begun circulating nationwide for this two-year campaign. The first print ads appeared in the February 2011 issues of *Woman's Day* and *Prevention Magazine*. *USA Today* featured an exclusive news article the day of the campaign launch. Satellite and radio media tours were also conducted during the first week in February to celebrate *Heart Month*.

Feedback on *Make the Call, Don't Miss a Beat* Campaign

"OWH is doing the campaign we've been waiting for. It speaks directly to women about the symptoms and what to do about them." – WomenHeart Champion

Programs developed by OWH are typically intended to facilitate the exchange of information, and to translate research and best practices to usable actions at the community and/or population level to affect the health of women and girls. Some examples of current projects that support this objective include the following:

- In 2010, OWH launched a new prevention and awareness initiative titled *Coalition for a Healthier Community* (CHC), which builds on the lessons learned and strengths of the *Advancing System Improvements to Support Targets for Healthy People 2010* (ASIST 2010) model. The program's priority is to provide support to communities to implement evidence-based, gender-specific programs to address health issues identified by the community. This cooperative agreement uses a two-phase approach that allows one year for planning and up to five years for implementation and evaluation. The first phase requires an assessment by the community to determine issues that have a major impact on the health of women and girls, and then to develop a strategic action plan to address the identified issues.
- In 2010, OWH initiated a new multi-agency program intended to reduce smoking rates in young, low-socioeconomic status (SES) women, 40% of whom are now smoking. This target population will be reached at three levels: clinical interventions during pregnancy and one year after delivering a child, quit lines with free incentives, and media campaigns. OWH is partnering with the Health Resources and Services Administration (HRSA) and the Indian Health Service (IHS) to pilot test the program in FY 2011. Based on evaluation findings, the program will be expanded to Medicaid patients in FY 2012.
- Recognizing the critical role that health care providers play in the early diagnosis of lupus, in 2009, Congress directed and funded OWH and the Office of Minority Health (OMH) to develop a curriculum for health care provider education. This curriculum is slated to be completed in FY 2011; its release will complement the *National Lupus Awareness Campaign*, which encourages the public to visit their health care providers.
- In FY 2010, OWH initiated a new *Training Initiative on Trauma-Affected Women, Children, and Families*. The Initiative will be implemented using public health principles and gender-based approaches to conduct regional and national capacity-building training for providers from a broad array of service delivery systems. The primary focus is to assist service providers in recognizing the signs of trauma-affected women, children, and families, and to begin to make systems changes to promote and foster trauma-informed care.

Meetings, conferences, and events are effective tools to engage, collaborate with, and influence the policy, research, and practice related to the health of women and girls. OWH actively seeks the exchange of information among researchers, community providers, policy and education specialists, as well as the voices of consumers to inform the priorities of the Office. Some examples of meetings, conferences, and events include:

- OWH and UNAIDS, the Joint United Nations Programme on HIV/AIDS, collaborated to hold a two-day forum *Bringing Gender Home: Implementing Gender Responsive HIV/AIDS Programming for U.S. Women and Girls*. The forum was held June 10-11, 2010, in Washington, D.C., and focused on increasing leadership in gender-responsive programming for women and girls and implementing gender-sensitive HIV/AIDS strategies among health providers, U.S. policy makers, and U.S. governmental and non-governmental agencies. More than 275 people attended the forum.
- OWH, in collaboration with OHAP and OPA, held a meeting with over 150 national women leaders from HIV/AIDS organizations to discuss the *National HIV/AIDS Strategy: Federal Implementation Plan*, and its relevancy to women and girls. A diverse group of women leaders from across the country attended the meeting on September 10, 2010.
- OWH, in collaboration with ASPE, has planned a meeting in 2012 focusing on incarcerated women to explore a comprehensive gender-specific approach to increase re-entry success in the prevention of HIV/AIDS and other health issues. In FY 2012, OWH plans to provide HIV/AIDS prevention education to incarcerated or recently released women using a community-team approach with other community providers, including officials from correctional institutions.
- OWH convened the *2010 HIV and Violence Against Women National Conference*. This one-day event engaged over 300 service providers from across the United States, including in the fields of domestic violence, sexual assault, and HIV/AIDS, and it addressed the intersection between sexual and intimate partner violence and HIV/AIDS. This community-level training, implemented by five contractors, has reached over 5,200 individuals in approximately 10 states, in addition to the implementation of other new State and local policies and programs. Based on the outstanding results and need for more training, another conference will be convened in 2011.
- OWH played a significant role in the development, promotion, and organization of the launch event on January 20, 2011, for the *Surgeon General's Call to Action to Support Breastfeeding*. This "call to action" outlined steps to remove obstacles to breastfeeding.

OWH works closely with other offices and agencies to highlight the needs of specific populations, through public awareness activities focus on designated days or weeks in the year, such as:

- *National Women's Health Week (NWHW)*, which encourages women to make their health a top priority. In 2010, over 2,200 national, State, and local events raised awareness about the manageable steps all women can take to improve their health. The first-ever *Presidential Proclamation for National Women's Health Week* was issued in May 2010, and more than 100 governors, mayors, and Tribal leaders, as well as Congress issuing proclamations. Other components of NWHW include the *WOMAN Challenge* (Women and Girls Out Moving Across the Nation) and *National Women's Check-up Day*.
- *National Women's and Girls' HIV/AIDS Awareness Day (NWGHAAD)* is observed every March 10th since 2006. The observance was established by OWH in collaboration with the HHS Office of HIV/AIDS Policy (OHAP).

Reporting

In terms of the requirements set forth in Section 229(d), OWH has assisted the Secretary to prepare and submit this report to the appropriate committees of Congress not later than one year after the date of enactment of the Affordable Care Act.

Transfer of Functions

In fulfillment of the requirements under Section 229(e)(2), all functions exercised by the Office on Women's Health of the Public Health Service remain with the Office on Women's Health (established under Section 229 of the Public Health Service Act, as added by Section 3509).

Agency for Healthcare Research and Quality (AHRQ)

The Agency for Healthcare Research and Quality (AHRQ), within the U.S. Department of Health and Human Services, was established in 1989 as the Agency for Health Care Policy and Research, which changed in 1999 after reauthorization legislation.²⁰ AHRQ is the lead Federal agency on health care quality research. AHRQ's mission is to improve the quality, safety, efficiency, and effectiveness of health care for all Americans.²¹ Through its offices and centers, AHRQ supports research to help people make more informed decisions, and to improve the quality of health care services, including through measurable improvements in quality of life and patient outcomes, lives saved, and value gained for what is spent.²²

The following sections describe the specific requirements in Section 3509 of the Affordable Care Act related to the Agency for Healthcare Research and Quality (amending Part C of Title IX of the Public Health Service Act [42 U.S.C. 299c et seq.]).

Establishment of an Office

AHRQ continues to fulfill the requirements set forth in Section 925(a) under Section 3509 [amending 42 U.S.C. 299(b)-24(a)], which mandates the establishment of an Office of Women's Health and Gender-Based Research, headed by a Director who is appointed by the Director of AHRQ. AHRQ's existing Office of Priority Populations houses the Office of Women's Health and Gender-Based Research, and therefore has led the ongoing efforts to codify the mandated functions related to this office. The Office of Priority Populations is responsible for maintaining the Agency's focus on the health care of all priority populations, including women and minorities, inner-city, rural and frontier areas, low income groups, children, the elderly, and individuals with special health care needs, including those with disabilities and in need of chronic or end of life health care. This existing focus has been advantageous for the creation of an Office of Women's Health and Gender-Based Research by allowing for shared resources and economies of scale.

Within the Office of Priority Populations, there are four Senior Advisors, including the Senior Advisor for Women's Health and Gender Research, who have been working with the Director of Healthcare and Research Quality to update the job description of the Senior Advisor for Women's Health and Gender Research position to include the Agency-specific activities outlined in Section 3509.

Report on Current Level of Activities

The Senior Advisor for Women's Health and Gender Research reports directly to the Director of Priority Populations. In fulfillment of the requirements of Section 925(b)(1), publications during the reporting period have included the annual *National Healthcare Disparities Report*, *National Healthcare Quality Report*, and an annual budgeting report, all of which contained information specific to women's health.

Women's Health-Related Goals and Objectives

AHRQ continues to fulfill the requirements of Section 925(b)(2) to establish short-range and long-range goals and objectives within the Agency, and to coordinate with other appropriate agencies and offices on activities for issues of particular concern to women. As part of this ongoing coordination effort, the Senior Advisor for Women's Health and Gender Research commissioned a contract report to identify and evaluate the Agency's gender-sensitive and women-specific health services research portfolio from 2005 to 2010. AHRQ sponsored the Institute of Medicine (IOM) *Report on Women's Health Research* that was published in September 2010. The Agency's Senior Advisor for Women's Health and Gender Research plans to continue developing goals and objectives for 2011 that are based on the information that is outlined in the 2010 IOM and AHRQ reports related to women's health.

Additionally, with regard to Section 925(b)(2), the Priority Populations Senior Advisors have established networks within the Agency in order to more frequently communicate across the Agency's offices and centers regarding activities related to women's health. The Senior Advisor

for Women's Health and Gender Research also began collaborating with portfolio leaders in order to assess on-going work to promote women's health and gender research. Midway through 2010, another individual began serving as Senior Advisor for Women's Health and Gender Research. The current Senior Advisor for Women's Health and Gender Research's performance plan for 2011 includes the development of goals and objectives and building on the AHRQ-commissioned report and the IOM report. These objectives will assist AHRQ in the Agency's ongoing fulfillment of Section 925(b)(2) that requires regular reporting to the Director.

Women's Health Projects

AHRQ has fulfilled the requirements of Section 925(b)(3) through the extramural research activities of the Office of Priority Populations, by which the Senior Advisor for Women's Health and Gender Research has identified opportunities to promote women's health and gender research in her review of research requests and proposals. The Senior Advisor for Women's Health and Gender Research has also developed a "Special Emphasis Notice" to promote research on minority women through extramural funding. AHRQ expects that the "Special Emphasis Notice" will be posted in Spring 2011.

AHRQ anticipates that additional opportunities for project identification will arise through presentations of the spend plan budgets to the Senior Leadership Team, the Senior Advisor for Women's Health and Gender Research's collaboration with the AHRQ Women's Health Network, and the Senior Advisor for Women's Health and Gender Research's membership of Topic Triage, which prioritizes topics for the Effective Health Care Program.

Consultation with Women's Health Professionals

AHRQ has completed the requirements of Section 925(b)(4) through its consultation with a technical expert group that provided input for the 2010 AHRQ report commissioned by the Senior Advisor for Women's Health and Gender Research. The report, which also helped the Agency to fulfill the requirements of Section 925(b)(2), included a research portfolio of AHRQ's gender-sensitive and women-specific health services from 2005 to 2010.

In addition to the report, the Agency has consulted with workgroups that support the National Healthcare Quality and Disparities Reports, the U.S. Preventive Services Task Force, and the AcademyHealth Gender Research Special Interest Group. AHRQ has also provided technical consultation to the March of Dimes, the American Nurses Association, the Office of Communications and Knowledge Transfer, and individual contractors and grantees. Collectively, these collaborations allow for targeted dissemination and outreach efforts to key stakeholders. For example, the Senior Advisor for Women's Health and Gender Research presented to the State Medicaid Directors at their annual meeting in Fall 2010 on evidence to inform policies on Cesarean delivery.

AHRQ also plans to feature content from the Affordable Care Act on their website as it relates to their activities regarding women's health and gender research.

CCWH Membership

The Senior Advisor for Women's Health and Gender Research has fulfilled the requirements set forth in Section 925(b)(5) by serving as an active and responsive representative on CCWH.

Centers for Disease Control and Prevention (CDC)

The Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services, is the primary Federal agency for conducting and supporting public health activities in the United States.²³ In existence for over 60 years, CDC strives to protect health and promote quality of life through prevention and control of disease, injury, and disability. CDC is composed of the Office of the Director, the National Institute for Occupational Safety and Health, Center for Global Health, and five offices, including Public Health Preparedness and Response; State and Local Support; Surveillance, Epidemiology and Laboratory Services; Noncommunicable Diseases, Injury and Environmental Health; and Infectious Diseases.²⁴ CDC employs over 15,000 employees in more than 50 countries.

The following sections describe the specific requirements in Section 3509 of the Affordable Care Act related to the Centers for Disease Control and Prevention (amending Part A of Title III of the Public Health Service Act [42 U.S.C. 241 et seq.]).

Establishment of an Office

CDC's Office of Women's Health (OWH) was established in 1994 within the Office of the Director as a free-standing office. In 2005, OWH became a part of the Office of Strategy and Innovation within the Office of the Director. The mission of CDC's OWH is to promote and improve the health, safety and quality of life for women. CDC's OWH allows for greater collaboration and access to information on women's health, serving as an advocate for women's health issues and a catalyst for innovative research, disease prevention programs, and policy development.²⁵

As noted above, CDC has fulfilled the requirement in Section 310A(a) under Section 3509 [amending 42 U.S.C. 242(s)] by establishing an Office of Women's Health (OWH) in 2010 within the Office of the Associate Director for Program in the Office of the CDC Director. The position of Director of CDC's OWH was filled by Yvonne Green, R.N., C.N.M., M.S.N., effective January 2011. CDC's OWH is currently recruiting for two other positions: a Health Communication Specialist and a Program Specialist.

Report on Current Level of Activities

Section 310A(b)(1) requires CDC to report to the Director of CDC on the current level of the Centers' activities regarding women's health conditions. Once the positions listed above are filled, one of the main activities for CDC's OWH will be to develop a report to the Director that

will include the areas outlined in the legislation. In the meantime, a current staff member is conducting a review of CDC's programs focused on women's and girls' health as identified via the CDC Director's priorities.

Women's Health-Related Goals and Objectives

In accordance with the requirements of Section 310A(b)(2), CDC is continuing to establish short-range and long-range goals and objectives within the Centers regarding women's health. Agency and program goals and objectives have been identified, as demonstrated through *Healthy People 2020*, CDC's *Winnable Battles* initiative (a set of agency priorities) and CDC's QPR activities (periodic assessments of CDC's programs to ensure progress against one and four year goals). CDC's OWH will build on these processes and identify priorities already selected by the programs that focus on women's health.

CDC's OWH is also currently developing a strategic plan which will identify action steps to accomplish the requirements of Section 310A(b)(2). Recent reports such as *Women's Health Research: Progress, Pitfalls, and Promise* will be used to review progress and identify additional priorities. CDC's Office of the Associate Director for Program will provide consultation in drafting the strategic plan to ensure that it is consistent with the Agency's goals. CDC's OWH will continue to seek input on women's activities, programs, and projects within the Centers through the CDC/ATSDR's Women's Health Workgroup, comprised of representatives from the various centers, offices, and employee workgroups. Information shared through the internal CDC/ATSDR's Women's Health Workgroup helps to coordinate activities across the Agency in addressing women's health.

Women's Health Projects

CDC has fulfilled the requirements set forth in Section 310A(b)(3) to identify projects in women's health that should be conducted or supported by the Centers. Efforts are being made to identify specific women's health projects, initiatives, and projects via the Agency's *Winnable Battles* and QPR efforts. CDC's OWH will also investigate opportunities through the Affordable Care Act, the Prevention and Public Health Fund, and other pathways that will highlight, support, and augment new and ongoing work in women's health.

Consultation with Women's Health Professionals

CDC continues its efforts to fulfill the requirements of Section 310A(b)(4), which mandates the Agency to consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups as appropriate, on the policy of the Centers with regard to women's health. CDC's OWH met with the Society for Women's Health Research in August 2010. The Agency continues to work closely with the Federal *text4baby*TM workgroup and *National Healthy Mothers, Healthy Babies Coalition*, to better meet the informational needs of pregnant women and new mothers through mobile technology. CDC's OWH is currently meeting with the Girl Scouts to identify shared goals and opportunities to help keep girls and women staff and leaders healthy. As part of the strategic

plan development, CDC's OWH will identify and include new organizations, professionals, groups, and individuals who can help advance women's health.

CCWH Membership

In reference to the requirements set forth in Section 310A(b)(5), CDC's OWH has been a member of CCWH since its creation and during the reporting period the Director of CDC's OWH served as the representative. CDC's OWH participates in the monthly meetings; provides input on programmatic and policy issues; participates in small workgroups to address specific issues; provides reports, documents, and materials as requested; supports activities and provides guidance and recommendations from a CDC perspective; and co-sponsors events.

Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA), within the U.S. Department of Health and Human Services (HHS), is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, as well as the nation's food supply, cosmetics, and products that emit radiation.²⁶ FDA is also responsible for regulating the manufacturing, marketing, and distribution of tobacco products. Through its centers and offices, FDA seeks to accelerate innovations to make medicines and food safer, more effective and more affordable, while providing the public with accurate, science-based information.²⁷ FDA is led by the Commissioner of Food and Drugs who is appointed by the President of the United States with Senate confirmation.

The following sections describe the specific requirements in Section 3509 of the Affordable Care Act related to the U.S. Food and Drug Administration (amending Chapter X of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 391 et seq.]).

Establishment of an Office

FDA's Office of Women's Health (OWH) was created in response to a Congressional mandate in 1994, in the Office of Science and Health Coordination within the Office of the Commissioner, thereby fulfilling the requirements set forth in Section 1011(a) under Section 3509 [21 U.S.C. 399b]. The mission of FDA OWH is to protect and advance the health of women through policy, science, and outreach, and to advocate for participation of women in clinical trials.²⁸

Report on Current Level of Activities

The FDA has fulfilled the requirements of Section 1011(b)(1) by providing completed summaries to the Office of Commissioner of Food and Drugs on FDA OWH's analysis of clinical reviews. These summaries analyzed the efficacy and safety data as it related to women's participation in clinical trials. The data was analyzed by sex across various testing, and included

multiple therapeutic area clinical trials for women's participation in studies conducted since 1992. In addition, FDA OWH's funded studies from 1994-2009 were evaluated in FY 2009-2010 for contributions towards the participation of women in clinical trials and the understanding of sex differences. Specific areas included cardiovascular disease, oncology, medical devices, and diagnostic tests, and the National Center for Toxicological Research (NCTR) research areas and biologics.

FDA OWH's Research and Development program area continues to support studies to track the participation of women in clinical trials, and collaborates with FDA's centers to understand sex differences in disease prevalence and response to treatment. FDA OWH annually funds approximately 15 intramural studies (over 200 studies since the creation of the Office) on women's health and sex and gender differences.

Women's Health-Related Goals and Objectives

FDA OWH has fulfilled the requirement set forth in Section 1011(b)(2) to establish short-range and long-range goals and objectives within the Administration for issues concerning women's health. In order to achieve this requirement, FDA OWH began a strategic planning process adopted in 2010 that mapped a framework for achieving three key goal areas, advancing the science of women's health and strengthening outreach capacity over the short- and long-term. The three key goal areas include: a) informing FDA women's health regulatory policy development through advocacy and collaborative research; b) promoting integration of FDA consumer information into existing health promotion, clinical services, and public health programs and efforts; and c) providing expert consultation and on-going technical assistance to the FDA centers and offices in the area of consumer communications.

An-ongoing activity for FDA OWH is the development of health education fact sheets and brochures in 16 different languages to promote consumer understanding, and to encourage patient-provider dialogue in an effort to minimize the risks associated with FDA regulated products. FDA OWH's three newest publications (released in July 2010) are "Diabetes Medicines," "Insulin," and "Glucose Meters." At the Federal Citizen Information Center, public interest in these latest materials generated the most orders for a new publication in a two month period.

FDA OWH also maintains a list-serve of approximately 20,000 women's health, professional, and community connections. This allows the Office rapidly to issue both broad and targeted audience communications. FDA OWH conducts approximately 24 e-blasts per year, and uses *Twitter*. These are used as important outreach tools to announce FDA actions, recalls, and activities of importance to women and their families.

In November 2010, FDA OWH launched the *Women and Diabetes Public Service Announcement* (www.fda.gov/womensdiabetes). This video was created in English and Spanish, and provides key messages on the safe use of diabetes medicines, including where to find informational materials. Other important messages are currently under development and are expected to launch in April 2010. These four video episodes are for use in Spanish speaking populations, using an engaging novella infotainment format, to reduce cultural and language

barriers to raising awareness and educating underserved Hispanic/Latina women on safe medication use. Issues addressed in the novellas include record keeping of prescribed or over-the-counter medicines, reading labels, dangers of skipping or doubling doses, sharing medications, safe ways to take medication, and the importance of consulting your health provider (doctor, nurse or pharmacists) about safe use of these products.

Information on Sex Differences

Additionally, FDA OWH has fulfilled the requirement mandated in Section 1011(b)(3) to provide information to women and health care providers on those areas in which differences between men and women exist. The Office has completed and continues to fulfill this requirement in a number of ways, which include:

- FDA OWH conducted over 75 annual conferences nationwide, providing opportunities to increase awareness of sex differences and women’s health issues through the dissemination of over 50 FDA OWH health education fact sheets, brochures, poster sessions, presentations, and panel discussions.
- FDA OWH disseminated their publications through collaborative partnerships, utilizing various media (hard copy, web links, social media, video), special media promotions (e.g., features in *Dear Abby*), the Federal Citizen Information Center in Pueblo, CO, and through FDA Public Affairs Specialists nationwide.
- FDA OWH utilized research findings from the over 200 total OWH funded intramural studies on women’s health and sex differences to develop more than 150 scientific peer-reviewed publications.
- FDA OWH Research and Development and Outreach staff published and presented on their own program-specific projects. Examples include: contributing to “Enrolling Pregnant Women in Research—Lessons from the H1N1 Influenza Pandemic,” which was accepted for publication in the June 17, 2010 issue of *The New England Journal of Medicine*; staffing the publication “FDA Calls Attention to the Pregnancy Registry,” which was accepted for publication in the June issue of the *Journal of Women’s Health*; conducting a HRSA-FDA OWH Podium Presentation Abstract on the “Patient Safety and Clinical Pharmacy Services Collaborative,” which was accepted by the American Academy of Nurse Practitioners for their National Conference in June 2011; and facilitating meetings, workshops, and symposiums on topics related to women’s health such as breast cancer, mammography and imaging, and promoting adequate numbers of women and ethnic sub-populations in clinical research.
- FDA OWH conducted meetings, workshops, and symposia to: highlight the impact of FDA OWH funded intramural studies and findings to FDA staff; coordinate a Cross Center half-day *Seminar on Breast Cancer and Mammography/imaging*; and negotiate co-sponsorship with the Society for Women’s Health Research to hold a first-of-a-kind

patient recruitment and retention conference to broaden the understanding of the challenges and solutions for promoting adequate numbers of women and ethnic sub-populations in clinical research.

- FDA OWH conducted trainings to advance the science of women's health and sex and gender differences. For example, FDA OWH collaborated with the American Association of the Colleges of Pharmacy (AACP) in the development of an updated Women's Health Curriculum for use in approximately 120 U.S. Colleges and Schools of Pharmacy.
- FDA OWH, in partnership with HRSA's Patient Safety and Clinical Pharmacy Services Collaborative (PSPC), launched a new web-based training module for health professionals focused on improving patient-provider communications in 2011. The course addresses factors that impede communications such as patient low-health literacy and the subsequent difficulties in safe medication use resulting from poor comprehension. The course also instructs health professionals on the use of OWH consumer health materials as tools to be used in patient education to improve compliance, and ultimately health outcomes. CE credit was made available for physicians, nurses, and pharmacists.
- FDA OWH disseminated information through electronic communications such as the FDA OWH Pregnancy Registry website (www.fda.gov/pregnancyregistries), an online directory of pregnancy registries as a resource for medical professionals and women seeking medication exposure information.

Consultation with Women's Health Professionals

FDA OWH does not have regulatory authority and does not consult with outside organizations or regulated industry on Administration policy with regard to women, and therefore has not fulfilled the requirements of Section 1011(b)(4). FDA OWH has, however, responded to requests for guidance on product issues important to women's health. A recent example includes a meeting with UNAID to discuss participation of women in clinical trials. In addition, FDA OWH has held meetings and dialogue sessions with key stakeholders to discuss ways in which the FDA can better promote the health of the women and their families, and leverage its expertise and resources by working with outside organizations.

Most recently in September 2010, a Women's Health Update Meeting was held to discuss current and future FDA OWH activities in the areas of women's health research and educational outreach. Meeting participants included advocacy, academia, consumer groups, scientific experts, industry, public health providers, and other government agencies.

Annual Estimates of Funds Needed

FDA OWH continues its ongoing work to fulfill the requirements of Section 1011(b)(5), which mandates that the Office make annual estimates of funds needed to monitor clinical trials and

analysis of data by sex in accordance with needs that are identified. This effort is an FDA-wide initiative that will be enhanced by the clinical data standardization efforts that are ongoing within the Administration. Currently, this is a capital- and time-intensive process as the individual clinical studies within a regulatory submission must be reviewed for the participation of women and analysis of data by sex.

A recent project funded by FDA OWH involved the conversion of legacy data (in three domains), into two New Drug Application (NDA) submissions to the Center for Drug Evaluation and Research (CDER). The contractor recently completed the project and the data analysis is ongoing. This pilot project will serve to demonstrate how data standardization will help to facilitate the process of monitoring participation of women in clinical trials, as well as the analysis of the clinical trial data by sex.

CCWH Membership

During the reporting period, the Acting Director of FDA OWH served as an active representative on CCWH, thereby fulfilling the requirement of Section 1011(b)(6).

Health Resources and Services Administration (HRSA)

The Health Resources and Services Administration (HRSA) in the U.S. Department of Health and Human Services is the primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable.²⁹ HRSA was established in 1982 through the merging of the Health Resources Administration and the Health Services Administration. Through its six bureaus and 13 offices, HRSA provides guidance and financial support to health care providers in every State to provide health care to uninsured people, people living with HIV/AIDS, and pregnant women, mothers, and children.³⁰ The mission of HRSA is to improve health and achieve health equity through access to quality services, a skilled health workforce, and innovative programs.

The following sections describe the specific requirements in Section 3509 of the Affordable Care Act related to the Health Resources and Services Administration (amending Title VII of the Social Security Act [42 U.S.C. 901 et seq.]).

Establishment of an Office

HRSA continues to fulfill the requirements set forth in Section 713(a) under Section 3509 [amending 42 U.S.C. 914] of the Affordable Care Act requires that the Secretary establish an Office of Women's Health within the Office of the Administrator (OA) of HRSA. HRSA established an Office of Women's Health (OWH) in 2000, which is now organizationally located within HRSA's Maternal and Child Health Bureau (MCHB). HRSA will continue to administer programs and activities authorized by other legal authorities, as well as this section of the Affordable Care Act.

Report on Current Level of Activities

HRSA's OWH's mission is to work across all HRSA programs to ensure that women across the lifespan receive comprehensive, culturally competent, quality health care.³¹ HRSA's OWH provides ongoing expertise, updates, and reports on a variety of collaborative women's health-related activities to the Office of the Administrator (OA), as is required under Section 713(b)(1).

During this reporting period, examples of expertise and updates have included: a) the development and evaluation of mobile health technology for underserved populations; b) violence prevention activities for youth, pregnant women and families; c) health promotion and disease prevention and screening activities in primary care; d) integration of women's health in health professions training programs; e) development of women-specific models of engaging and retaining women living with HIV/AIDS in care; and f) global women's health strategic planning in support of the *Millennium Development Goals and the Global Health Initiative*.

Additionally, HRSA's OWH, in collaboration with other HRSA bureaus and offices, developed and published *Women's Health USA 2010 Data Book*. The *Women's Health USA Data Book* serves as a concise reference for the HRSA Administrator, senior policymakers, and program managers to identify priority focus areas on issues affecting the health of women. Data is analyzed by sex, race/ethnicity, age, geographic location, and other socio-economic variables. In 2011, HRSA's OWH will continue to provide expertise and updates on women's health policy and programming to the Administrator and senior leadership.

Women's Health-Related Goals and Objectives

Regarding the requirements of Section 713(b)(2), HRSA's OWH serves a cross-cutting role in support of this mission through coordination, collaboration, information sharing, and program support activities that address women's health across the lifespan. Several trans-HRSA activities related to women's health took place during this reporting period. These efforts have included:

- HRSA partnered with the *National Healthy Mothers, Healthy Babies Coalition* and other Federal and non-Federal partners to develop *text4baby™*, a free mobile education service that provides pregnant women and mothers with infants less than one year of age with free, brief evidence-based health messages. HRSA is leading a national evaluation of this and other trans-HRSA outreach and promotion activities.
- HRSA is continuing to support a Special Project of National Significance, *Enhancing Access to and Retention in Quality HIV/AIDS Care for Women of Color*. This project is a multi-site demonstration and evaluation of HIV service delivery interventions for women of color. The initiative funds 11 demonstration sites for up to five years in their efforts to design, implement, and evaluate innovative methods for enhancing access to and retaining women of color living with HIV/AIDS in primary medical care and ancillary services.

- HRSA, in collaboration with the Administration on Children and Families (ACF), awarded grants to States, territories and American Indian/Alaska Native Tribes to implement home visiting programs to pregnant women and families with young children. The purpose of this initiative is to promote maternal health, healthy child development, and school readiness, as well as to reduce the occurrence of domestic violence and child maltreatment.
- HRSA, in collaboration with the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the Institute of Medicine (IOM), is providing ongoing expertise in developing of a set of women's health preventive guidelines as outlined in the Affordable Care Act.
- HRSA supported the Spanish translation of *Bright Futures for Women's Health and Wellness* health education tools. These tools target consumers, primary care providers and communities in order to help young and adult women of all ages achieve better health.
- HRSA, in collaboration with the National Assembly of School-Based Health Care, supported the development of an online resource center and training module to assist school-based health center personnel to better address the needs of children in suddenly deployed military families.
- HRSA's OWH provided technical assistance through the International Visitors Program to 29 delegates from 5 countries on maternal health issues.
- HRSA supported nursing, dentistry, medicine, and other health professions' training and academic programs, and continues to support nurse midwifery and women's health nurse practitioner grant programs.
- HRSA contributed expertise to the *Global Health Initiative, Women, Girls and Gender Equality Principle Task Force* to develop a women- and girl-centered approach guidance document for partner countries.

In 2011, HRSA's OWH will continue to engage in strategic planning and coordinate with HRSA bureaus and offices, as well as other Federal partners, on activities within the Administration that relate to health care provider training, health service delivery, research, and demonstration projects for issues of particular concern to women in ongoing fulfillment of Section 713(b)(2).

Women's Health Projects

HRSA's OWH has identified several projects in women's health that could be conducted or supported by HRSA bureaus and offices in order to fulfill the requirements set forth in Section 713(b)(3), including: a) the adaptation of mobile health technology to improve chronic care disease management, obesity prevention, and smoking cessation among women and girls; b) violence prevention screening in primary care service sites; c) integration of violence prevention training among health professions education and training programs; d) increased awareness of Federally Qualified Health Centers' services among newly released female prisoners and detainees; e) partnerships with school-based health centers to improve resources and education for military families; f) life course strategic planning in maternal and child health programs; g) mentoring programs for young women considering careers in public health and interdisciplinary health professions training programs; h) global health partnerships to improve gender equality and health equity; i) alignment of performance, capacity or other women-specific measures with National Quality Forum measures for HRSA grant programs; and j) interdisciplinary efforts to support medical homes for women and girls.

In 2011, HRSA's OWH will continue to provide a leadership role in collaborating with HRSA's bureaus and offices to address ongoing efforts around these projects.

Consultation with Women's Health Professionals

In ongoing fulfillment of the requirements in Section 713(b)(4), HRSA's OWH consulted with a variety of non-Federal organizations and consumer groups to seek and provide input on the Administration's policy to provide culturally competent, comprehensive quality primary care to all women, as well as health professions' programs and education training opportunities. Discussions with organizations at HRSA-sponsored grantee meetings, forums, and webinars provided additional opportunities to network and share common goals to improve women's health outcomes. Consultation with expert groups to inform strategic planning, develop innovative solutions to reach underserved, hard-to-reach populations, and to build public-private partnerships around maternal and child health were particular highlights over the last year. In 2011, HRSA's OWH will continue to broaden the network of Federal and non-Federal partners to support HRSA's integrated approach to women's health and wellness across the lifespan.

CCWH Membership

The Director of HRSA's OWH actively served as an active member on the HHS Coordinating Committee on Women's Health (CCWH) during the reporting period, thereby fulfilling the requirement in Section 713(b)(5).

As part of this fulfillment, the member led committee efforts to develop the *CCWH Draft Action Agenda to Improve the Health of Women and Girls Beyond 2010*, served on the 2010 National Women's Health Week Planning Committee, and provided HRSA's OWH responses to numerous requests from the White House Council on Women and Girls. In addition, HRSA's OWH reported on and distributed HRSA publications and program announcements to CCWH,

and briefed HRSA leadership on critical updates from the HHS OWH and other agencies and offices represented on CCWH. In 2011, HRSA's OWH will continue to play an active role on CCWH.

National Institutes of Health (NIH)

The National Institutes of Health (NIH), within the U.S. Department of Health and Human Services, is the nation's medical research agency. NIH is made up of 27 institutes and centers, each with a specific research agenda, and is the largest source of funding for medical research in the world. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.³²

The Office of Research on Women's Health (ORWH) was established in 1990, and was the first office devoted specifically to women's health at HHS.³³ ORWH advises the NIH Director and staff on matters relating to research on women's health; strengthens and enhances research related to diseases, disorders, and conditions that affect women; ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH; and develops opportunities for and supports recruitment, retention, re-entry, and advancement of women in biomedical careers.³⁴

ORWH works collaboratively with the Advisory Committee on Research on Women's Health (ACRWH), comprised of physicians, scientists, and other health professionals who advise the Director of ORWH on relevant issues; and the Coordinating Committee on Research on Women's Health (CCRWH), composed of the NIH institute and center directors or their designees to assist the director of the Office in accomplishing its mission.

The following section describes the specific requirement in Section 3509 of the Affordable Care Act related to the National Institutes of Health (amending Section 486(a) of the Public Health Service Act [42 U.S.C. 287d(a)]), as well as other efforts taken by NIH in support of improving women's health.

Establishment of an Office

As previously noted, NIH has fulfilled the requirements of Section 3509(c), which amended Section 486(a) of the Public Health Service Act [42 U.S.C. 287d(a)], to require the Director of the Office of Research on Women's Health report to the Director of NIH. The NIH Reform Act of 2006 (P.L. 109-482) mandates that the ORWH reside within the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), which is located within the Office of the Director of NIH. As such, the Director of ORWH reports to the Director of DPCPSI; however, the Director of ORWH is not precluded from reporting to the Director of NIH. Section 3509(c) is the only statutory requirement directed to NIH under Section 3509.

Report on Current Level of Activities

In accordance with Section 486B of the Public Health Service Act [42 U.S.C. 287d(2)], beginning in 1994 and every two years thereafter, ORWH has compiled a biennial report detailing the activities of the Office and NIH with respect to women's health and sex differences research. In particular, in these biennial reports ORWH describes and evaluates the progress made during the preceding two fiscal years in research and treatment related to women's health and sex differences research conducted or supported by NIH; describes and analyzes the professional status of women physicians and scientists, including the identification of problems and barriers regarding advancements; summarizes and analyzes expenditures made by NIH related to women's health and sex differences research during the preceding two fiscal years; and makes recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate. This report is approved by ACRWH and is submitted to the Director of NIH for inclusion in the mandated biennial report on all NIH activities submitted to the President and Congress.

In addition, a collection of examples of women's health research advances was compiled in 2010 from submissions by every NIH institute, center, and programmatic office within the Office of the Director. This publication, *Highlights of NIH Women's Health and Sex Differences Research 1990-2010*, serves to illustrate the breadth and importance of women's health throughout the NIH research portfolio. Both of these documents are available in print and on the ORWH website.

Women's Health-Related Goals and Objectives

In accordance with the purpose of the ORWH as defined in Section 486(b)(6) of the Public Health Service Act [42 U.S.C. 287d(b)(6)], the ORWH recently conducted its third agenda setting process, which resulted in a three volume strategic plan representing the NIH agenda for conducting and supporting women's health and sex differences research over the coming decade. ORWH engaged the CCRWH, ACRWH, a variety of women's health research stakeholders, and the public throughout the formulation of the strategic plan, which was developed over the period of 2009-2010.

Following the tradition established by the ORWH from its inception, the research agenda setting process actively engaged members of the public, including women's health advocacy groups, public health officials, scientists, researchers, policymakers, clinicians, and individuals representing their own concerns or the perspectives of academia, government, or industry. The process included five regional meetings where input from 1,500 participants was received through public testimony, scientific workshops, and thirty-seven interactive working groups. These meetings encouraged an environment for interactive discourse on future priorities and innovative scientific approaches to advancing the field of women's health and sex differences research ranging from an increased focus on sex and gender in the clinical translation of basic research findings to the impact of behavioral, psychosocial, and societal factors on health and disease.

Over 140 advocacy and academic organizations and individuals presented oral and written testimony and were also active participants in the scientific working groups. Testimonies included personal expressions of the painful, life altering and debilitating effects of a wide range of diseases such as autoimmune diseases, pelvic floor disorders, and chronic pain syndromes as well as personal experiences of NIH career development programs and their beneficial effects on career advancement. The concerns and issues highlighted brought remaining gaps in knowledge and unmet needs in women's health information to the forefront, and underscored the ultimate goal of the research agenda, to improve the health of women and girls and enhance career development in women's health research careers. In addition, at each meeting, there were specific presentations and working groups on biomedical career development for women, and for women and men as researchers in women's health or related efforts.

The reports of the thirty-seven working groups yielded a total of 400 topical recommendations that were distilled into six major concepts to advance women's health and sex differences research. The resulting strategic plan, *Moving into the Future With New Dimensions and Strategies: A Vision for 2020 for Women's Health Research*, has been widely distributed, presented at a variety of venues, and has been acknowledged in a Senate resolution. The full written reports of the working groups (Volume II) and the entirety of the written public testimonies (Volume III) have been compiled as compendia to the strategic plan (Volume I). All three documents are available in print and on the ORWH website.

Women's Health Projects

In accordance with the purpose of the ORWH as defined in Section 486(b)(1) and (2) of the Public Health Service Act [42 U.S.C. 287d(b)(1) and (2)], the office routinely identifies projects and interdisciplinary approaches to research on women's health that should be conducted or supported by NIH, and recommends an agenda for conducting and supporting such research. This process is carried out in collaboration with the CCRWH and the ACRWH.

ORWH furthers its mission by partnering with the NIH institutes and centers (IC) to co-fund a wide variety of basic, clinical, and translational studies in all aspects of women's health and sex differences research each year. Examples include:

- ORWH's active collaboration with the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) on uterine fibroids research, an area that has historically been under-funded and disproportionately affects African American women. In addition to providing funding for research, in November 2010 ORWH was a key sponsor of the Advances in Uterine Leiomyoma Research: Third NIH International Congress, along with NICHD, other NIH ICs, AHRQ, CDC, HRSA, FDA, and the Office of Women's Health, Office of the Secretary.
- ORWH's longstanding funding partnership with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) for the Diabetes Prevention Project. ORWH recently provided additional funding to enable a major Gestational Diabetes Mellitus (GDM) awareness campaign, which in its initial phase has reached over three million

women. GDM is an important public health concern as it is diagnosed in 7% of all pregnancies.

- ORWH's support for sex differences research such as the Osteoarthritis Initiative and basic research on sex differentiation in the brain. ORWH was an active participant in the Institute of Medicine's 2010 meeting on Sex Differences and Implications for Translational Neuroscience Research, the proceedings of which have been published and will influence future research directions in neuroscience.
- ORWH's leadership, through the NIH Working Group on Women in Biomedical Careers, in the development and funding of a grant program aimed at supporting research on: a) causal factors explaining the current patterns observed in the careers of women in biomedical and behavioral science and engineering; and b) the efficacy of programs designed to eliminate sex/gender disparities and promote the careers of women in these fields.

Another ORWH mechanism for co-funding research with the NIH ICs is the Research Enhancement Awards Program, which supports meritorious research project grants on a variety of women's health topics in partnership with the ICs, which would otherwise not be funded. This program expands the number of scientific topics included in the NIH research portfolio on women's health and sex differences research.

ORWH continues to expand its two signature programs: Building Interdisciplinary Research Careers in Women's Health (BIRCWH) and the Specialized Centers of Research (SCOR) on Sex and Gender Factors Affecting Women's Health. These unique programs benefit the health of women and men, and girls and boys through sex differences research and interdisciplinary scientific collaboration. They also provide important support for early career scientists, both women and men, with an emphasis on mentoring and collaboration to increase the number of women's health investigators.

BIRCWH is a trans-NIH career development program that provides protected research time for junior faculty, known as BIRCWH scholars, and pairs them with senior investigators in an interdisciplinary mentored environment. A key goal of BIRCWH is to support the next generation of women's health researchers who are looking at complex health conditions that will lead to improvements in health for all women. BIRCWH scholar research areas cover a variety of topics including diabetes, cancer, depression, cardiovascular health, HIV/AIDS research, arthritis/musculoskeletal health, mental health, substance abuse, intimate partner violence, reproductive health and health disparities. In 2010, ORWH funded thirteen new and continuing BIRCWH programs nationwide, for a total of 29 active centers, with additional funding provided by many NIH Institutes and Centers. Since 2000, 407 scholars have been trained (~80% women) in the 41 centers, resulting in over 1300 publications, 750 abstracts, 200 NIH grants, and 85 awards from industry and institutional sources.

The SCORs are designed to increase innovative, interdisciplinary research focusing on sex differences and major medical problems that affect women through centers that facilitate basic, clinical, and translational research. The currently funded SCORs are collaborative and

interdepartmental, and include research on pregnancy, substance abuse, the urinary tract, osteoporosis, depression, and pain. The bulk of the funding is provided by ORWH, with five ICs and the FDA contributing as well. In FY 2010, the SCOR investigators reported publishing 150 journal articles, 214 abstracts and presentations, and 44 other publications (including book chapters). In addition, one of the many inter-SCOR collaborations is a joint effort between the University of California–San Francisco and the Washington University in Saint Louis, Missouri SCORs, which is looking at the connection between chronic urinary tract infections and urinary system dysfunction in an attempt to better understand and relieve the burden of these conditions that disproportionately affect women.

Another ORWH signature program is the Advancing Novel Science in Women’s Health Research (ANSWHR) program, which promotes pursuit of new concepts and interdisciplinary research approaches to women’s health sex difference research. This program has had broad appeal and is evolving into an important scientific pathway for both early-stage investigators and veteran researchers to test nascent scientific concepts relevant to women’s health research and the study of sex and gender differences. These investigator-initiated grants address unresolved questions to expand the knowledge base in a variety of areas relevant to women’s health research. In FY 2010, ANSWHR was reissued with 23 IC partners and 16 awards were made. Close to 200 applications were received for the most recent submission round. In total, more than 60 grants have been supported since the program was launched.

In the future, the BIRCWH, SCOR, and ANSWHR programs will incorporate the goals of the new NIH strategic plan for women’s health and sex differences research, *Moving into the Future With New Dimensions and Strategies: A Vision for 2020 for Women’s Health Research*.

Information on Women’s Health and Sex Differences

ORWH is actively engaged in information dissemination to both the scientific community and members of the public through the development, production, and distribution of print and electronic materials including fact sheets, booklets, and podcasts on a wide array of topics. The office sponsors a number of seminar series and scientific conferences each year and staff members provide oral and poster presentations, and distribute ORWH materials as well as those contributed by other ICs, at many community and professional events.

ORWH also maintains an active website and an online women’s health information portal developed in collaboration with the National Library of Medicine (NLM). Employing new media to disseminate health information to a wider audience, the NLM-ORWH Women’s Health web portal provides researchers and consumers with the latest information in a centralized location about significant topics in women’s health from scientific journals, peer-reviewed sources, NIH ICs and health news sources (www.womenshealthresources.nlm.nih.gov).

ORWH creates and manages a variety of online resources on women’s health and sex/gender differences. For example, ORWH, in collaboration with the FDA Office of Women’s Health, has developed and launched the first online education course on *Sex and Gender in Human Health*. Recently, a second course, *Sex and Gender Differences in Health and Behavior*, has

been added. Together, the two courses comprise a total of twelve modules (<http://sexandgendercourse.od.nih.gov/>).

CCWH Membership

During the reporting period, the Associate Director for Research on Women's Health (NIH) and Director of the Office of Research on Women's Health served as an active member on CCWH.

Substance Abuse and Mental Health Services Administration (SAMHSA)

The Substance Abuse and Mental Health Services Administration (SAMHSA) was established in 1992 within the U.S. Department of Health and Human Services. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities. Through its centers and offices, SAMHSA seeks to improve the delivery and financing of prevention, treatment, and recovery support services for substance abuse and mental illness in the United States, improving health and reducing health care and other costs to society.³⁵

The following section describes the specific requirement in Section 3509 of the Affordable Care Act related to the Substance Abuse and Mental Health Services Administration (amending Section 501(f) of the Public Health Service Act [42 U.S.C. 290aa(f)], as well as other efforts taken by SAMHSA in support of improving women's health.

Associate Administrator for Women's Services

The Substance Abuse and Mental Health Services Administration (SAMHSA) has fulfilled its only statutory requirement under Section 3509, Section 3509(d) (and Section 501(f) of the Public Health Service Act [42 U.S.C. 290aa(f)]), by appointing an Associate Administrator for Women's Services (AAWS). In further compliance with the requirement of Section 3509(d), the AAWS reports directly to the SAMHSA Administrator.

The Associate Administrator for Women's Services (AAWS) has established and chairs the SAMHSA Women's Coordinating Committee (SWCC) to identify substance use and mental health needs, and to coordinate the provision of behavioral health services for women managed through SAMHSA's Center for Mental Health Services, the Center for Substance Abuse Prevention and the Center for Substance Abuse Treatment. In addition, the AAWS has established SAMHSA's Advisory Committee for Women's Services (ACWS) to provide advice to SAMHSA on mental and substance use disorder needs and services specific to women and girls.

Women's Health Projects

The following projects represent some key activities that SAMHSA undertook during the reporting period to address the behavioral health needs of women:

- SAMHSA presented and piloted the *Trauma Peer Engagement Guide for Women* to assess its usability in three peer-communities and to seek broader comment on the needs for information and best practices for peers working with women who have experienced violence and trauma;
- SAMHSA developed the publication *Addressing the Needs of Women and Girls: Developing Core Competencies for Mental Health and Substance Abuse Service Professionals* (2011);
- SAMHSA conducted technical assistance sessions to grantees that provide residential treatment, recovery support, and family services for pregnant and postpartum women who face alcohol and other drug problems, as well as their children. Technical assistance is provided to build community capacity to provide high quality comprehensive services for women, and evidence based practices and support around program sustainability;
- SAMHSA hosted the *National Conference on Women, Addiction, and Recovery*;
- SAMHSA developed the online course *Introduction to Women with Substance Use Disorders*;
- SAMHSA conducted the *Women's Addiction Services Leadership Training*;
- SAMHSA trained all Mental Health America (MHA) staff to help inform MHA's national campaign to promote trauma informed care with an emphasis on women and girls;
- SAMHSA served on the planning committee for the first Institute of Medicine (IOM) *Global Health Forum on the Prevention of Violence for Women and Children*; and
- SAMHSA collaborated with the U.S. State Department's Bureau of International Narcotics and Law Enforcement in developing an international curriculum for substance abuse provider organizations serving women.

Collaboration with HHS Agencies and Offices

SAMHSA continues to collaborate with other HHS agencies on initiatives that promote the health and well-being of women and girls. Examples of collaborations during the reporting period include:

- SAMHSA collaborated with the NIH and others in translating behavioral health research to practice as it relates to women, including the development of curricula for health care professionals and providers;
- SAMHSA participated as a member of the Federal Roundtable on Women and Girls and Trauma;
- SAMHSA chaired the Federal Partners Intergovernmental Committee on Women and Trauma to develop a joint agenda for Federal action to contribute to public health support for women and girls with trauma;
- SAMHSA provided recovery services through policy support of, and collaboration with, the State Women's Services Coordinators/Women's Services Network (WSN), a specialty network of the National Association of State Alcohol and Drug Abuse Directors (NASADAD), under the auspices of the National Treatment Network and in collaboration with the National Prevention Network.
- SAMHSA co-sponsored a monthly webinar series with the HHS OWH titled *Region V The Impact of Trauma on Women and Girls Across the Lifespan*;
- SAMHSA collaborated with the National Institute on Drug Abuse and the World Health Organization (WHO) on the development of guidelines for the management of substance use disorders among pregnant women;
- SAMHSA provided technical assistance on trauma and women's services through onsite focus groups at the Navy Consolidated Brig in Miramar, California; and
- SAMHSA collaborated with the Krieger Foundation and the Mayor's Office in Baltimore City, Maryland to provide training and other technical assistance to shelter and health department programs on maternal health and infant mortality.

Information on Women's Health and Sex Differences

Additionally, SAMHSA uses publications and social media to disseminate information related to women and girls. Some examples of product and program innovations include:

- SAMHSA's *SAMHSA/CSAT Treatment Improvement Protocols for Women*;
- SAMHSA's Fetal Alcohol Spectrum Disorders Center for Excellence *What You Need to Know* series that targets women across the socio-economic spectrum, including women who are incarcerated and special populations;

- SAMHSA’s website on women’s substance abuse treatment issues (<http://womenandchildren.treatment.org>);
- SAMHSA’s publication *Family-Centered Treatment for Women with Substance Use Disorders-History, Key Elements and Challenges*; and
- SAMHSA’s publication *Funding Family-Centered Treatment for Women with Substance Use Disorders*.

CCWH Membership

A representative from SAMHSA served as an active member of CCWH during the reporting period, and has provided the Department with expertise on women’s behavioral health needs and services.

IV. OTHER HHS AGENCIES/OFFICES

While Section 3509 of the Affordable Care Act does not have specific requirements for other U.S. Department of Health and Human Services (HHS) Federal agencies and offices, it specifies that OWH, AHRQ, CDC, and HRSA coordinate with other appropriate agencies and offices on activities for issues of particular concern for women; and AHRQ, CDC, HRSA, and FDA consult with health professionals on policies. It also requires that the HHS Coordinating Committee on Women's Health include senior-level representatives from each of the HHS Federal agencies and offices.

The following HHS Federal agencies and offices contributed to or supported efforts under Section 3509, including but not limited to serving as members of the HHS Coordinating Committee on Women's Health. The activities described below reflect the reporting period of one year since the enactment of Section 3509 of the Affordable Care Act (March 23, 2010-March 23, 2011). For reference, **Appendix II** includes information on commonly used acronyms.

Administration on Aging (AoA)

The Administration on Aging (AoA) is the Federal agency designated to carry out the provisions of the Older Americans Act of 1965 (OAA, as amended P.L. 109-365) in order to advance the concerns and interests of older people and their caregivers.³⁶ The mission of AoA is to develop a comprehensive, coordinated, and cost-effective system of home and community-based services to enable older people to maintain their dignity and independence in their homes and communities.³⁷ AoA is the lead partner of the National Aging Network, consisting of 56 State Units on Aging (SUAs), 629 Area Agencies on Aging, 244 Tribal organizations, and 2 Native Hawaiian organizations. AoA serves as an advocate for older persons within the U.S. Department of Health and Human Services (HHS), and coordinates activities between Federal agencies and offices to assure a continuum of improved services.

While all older Americans and their family caregivers are eligible to receive services through the OAA Programs, AoA gives specific attention to those individuals who are in the greatest economic and social need. Given this focus and the demographics of the aging, AoA provides services to more women than men. According to the U.S. Census Bureau, there were 22.7 million women 65 years or older and 16.8 million men 65 years or older living in the United States in 2009. That statistic represents a sex ratio of 135 women for every 100 men, which increases with age. At age 85 there are approximately twice as many women as men, and half of all women over age 75 live alone.³⁸

At the direction of the Secretary, AoA has developed partnerships within HHS and other Federal agencies to enhance the health and independence of older persons and individuals with disabilities to streamline their access to long-term care services and support systems. In collaboration with the Centers for Medicare and Medicaid Services (CMS), AoA has worked on *Care Transitions Interventions* for individuals with multiple chronic conditions in an effort to

reduce hospital readmission rates around an acute care episode. Women represent 62% of the 9 million dual-eligible Medicare and Medicaid beneficiaries, and AoA has worked closely with CMS's Federal Coordinated Health Care Office to streamline programs for dual-eligible beneficiaries.

AoA has also collaborated with the National Education and Resource Center on Women and Retirement Planning (the Center), which is maintained by the Women's Institute for a Secure Retirement (WISER). The Center provides user-friendly financial education and retirement planning tools for low-income women, women of color, and women with limited English-speaking proficiency.³⁹ WISER tailors educational financial tools and information to meet the needs of target populations. Through the Center's one-stop-gateway, women have access to comprehensive, easily understood information that promotes opportunities to plan for income during retirement and for long-term care. The Center conducts workshops nationwide on strategies for accessing financial and retirement planning information targeted to women and disseminates online newsletters, over 150 fact sheets, booklets, and special reports tailored to the specific needs of hard-to-reach women. Over the past two years, the Center has established an interactive website that contains important information for women on a range of financial issues including investments, pensions, social security, and long-term care. The Center has also planned a series of nationwide webinars designed to assist women in taking active roles in planning for their retirement and long-term care.

Regarding other AoA initiatives, AoA awarded \$100 million in Recovery Act funding for Nutrition Grants that provide meals to older Americans in need, serving more than 21 million meals to over 1.1 million seniors. Of those served, 66% of home delivered meal recipients and 65% of congregate meal recipients were women. In October, AoA launched a newly enhanced Eldercare Locator Program. The Eldercare Locator is a free nationwide public service providing older adults and caregivers with information about aging services in their community. The Eldercare Locator has been redesigned to better serve the 76 million baby boomers (of which 38 million are women) that are approaching 65 this year. Service features now include on-line chat with an Information Specialist and access to a database of publications and other resources for older adults and caregivers. The new Eldercare Locator Call Center partners with the National Association of Area Agencies on Aging, the National Center on Senior Transportation (NCST), Family Caregiver Alliance (FCA), and National Council on Aging (NCOA) to provide the most pertinent and up-to-date information on aging to consumers.

During the reporting period, a representative of AoA actively participated on the HHS Coordinating Committee on Women's Health (CCWH). AoA regularly collaborated with CCWH members on the planning and conduct of meetings and conferences, and by providing technical consultation, as requested. During this reporting period, AoA also continued to be involved in the refinement and implementation of objectives contained in the CCWH *Draft Action Agenda to Improve the Health of Women and Girls Beyond 2010*.

Administration for Children and Families (ACF)

The Administration for Children and Families (ACF) within the U.S. Department of Health and Human Services (HHS) provides national leadership and direction to plan, manage, and coordinate the administration of comprehensive and supportive programs nationwide for vulnerable children and families.⁴⁰ ACF funds State, territory, local, and Tribal organizations to provide family assistance, child support, child care, Head Start, child welfare, and other programs related to children and families.

Within the Family and Youth Services Bureau (FYSB), ACF's Family Violence Prevention and Services Program awards grants to State, territory, and Tribal agencies for the provision of shelter and other services to victims of family violence and their dependents, including battered women's shelters.⁴¹ ACF's Family Violence Prevention and Services Program also funds five national resource centers that provide information and technical assistance via toll-free telephone numbers.

As part of the HHS Steering Committee on Violence Against Women, ACF's Family Violence Prevention and Services Program coordinated with the HHS Office on Women's Health (OWH) on activities during the reporting period for issues of particular concern to women, specifically dating and domestic violence.

ACF's Family Violence Prevention and Services Program Director also served as an active member of the HHS Coordinating Committee on Women's Health (CCWH) during the reporting period. In that capacity, she collaborated on projects and strategic planning to advance women's health initiatives, supported annual conferences related to women's health, participated in briefings on women's health for international visitors, and worked on a range of other programmatic initiatives to address violence against women.

Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services (CMS) is the U.S. Federal agency that administers Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). CMS is the Federal agency relied upon to provide critical health care coverage to women and their children across the lifespan. CMS has a long-standing commitment to promoting and leveraging the policies, educational initiatives, and other services sponsored by the HHS Office of Women's Health (OWH). Either as direct beneficiaries or as caregivers to children, aging parents, and extended family members, women represent the majority constituency for CMS. As a result, a close working relationship between CMS and OWH, and other Federal agencies with whom CMS actively networks through the OWH-sponsored Coordinating Committee for Women's Health (CCWH), provides a foundation for CMS to reach its goals. CMS strives to achieve its three-part aim of better quality of care and better health outcomes for U.S. individuals, families, and communities at lower-costs.

In 2010, CMS' collaboration with OWH included an internal assessment on current disparities in healthcare access and services experienced by America's most vulnerable citizens, and

projections for the beneficiary support demands going forward. The increase in need for beneficiary support is a result of:

- Enhanced coverage policies within the Affordable Care Act initiated in 2010, extending coverage to 32 million additional individuals, the majority who are women; and
- A shift in population cohorts as the first of the 76 million baby boomers reach age 65 in 2011. Medicare population growth is expected to increase from 35 million in 2000 to 72 million by 2030, representing 20 percent of the total U.S. population. Additionally, their life expectancy is higher than of any previous generation.

Reflecting this internal assessment and strategic planning, CMS' participation in OWH initiatives focused in two priority areas during the reporting period:

- Proactive involvement in the completion of the CCWH *Draft Action Agenda to Improve the Health of Women and Girls Beyond 2010* requested by Secretary Sebelius. Specifically, CMS' contribution focused on: a) outreach to increase CHIP enrollment among qualifying children with an emphasis on outreach to minority ethnic and racial groups; and b) raising awareness about and ensuring inclusion of the health care needs of older women in all components of the *Draft Action Agenda*.
- Assisting in the selection and initial design and development of a new research project to identify the unique needs of single-parent caregivers. Current information indicates that this population of caregivers, the majority of whom are women, face intense emotional, financial, and physical stress as a result of the demands of caring for children and parent(s) in their role as single head of household. These stresses may cause life-long emotional strains that diminish their overall health status and increase their burden of dependency on the U.S. health systems.

Most importantly, as a result of the close collaborative work of CMS and OWH in 2010, there is a greater awareness and understanding of the impending, irreversible rate of population aging in the U.S., and its potential impact on health care needs and costs and age-related spending policies for HHS. Overall, this work manifested itself in a new, highly focused, progress-driven collaboration between CMS and OWH. CMS has committed the time of a senior-level full-time employee to support OWH efforts strategically to assess current Federal sector resources dedicated to the health and well-being of older women in the U.S. and its territories, to the senior employee will help identify and implement short- and long-term strategic priorities to leverage Federal agencies resources for more effective, cost-saving outcomes in women's health services.

During the reporting period, a representative of CMS served as an active member on the HHS Coordinating Committee for Women's Health (CCWH).

Indian Health Service (IHS)

The Indian Health Service (IHS), within the U.S. Department of Health and Human Services (HHS), is responsible for providing Federal health services to American Indians and Alaska Natives. The provision of health services to members of Federally-recognized Tribes grew out of the special government-to-government relationship between the Federal government and Indian Tribes (based on Article I, Section 8 of the Constitution). IHS is the principal Federal health care provider and health advocate for Indian people, and its mission is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.⁴² IHS provides a comprehensive health service delivery system for approximately 1.9 million American Indians and Alaska Natives who belong to 564 Federally recognized Tribes in 35 states.

During the reporting period, IHS, in coordination with other agencies and offices, consulted with women's health professionals and other groups to develop a new policy and protocol addressing sexual assault of American Indian and Alaska Native females, males, children, adolescents, adults, the elderly and special populations (LGBT), in accordance with Tribal Law and Order Act of 2010 [25 U.S.C. 2801 et seq.].

The Tribal Law and Order Act of 2010 requires: "The Director of the Indian Health Service in coordination with the Director of the Office of Justice Services, and the Director of the Office on Violence Against Women of the Department of Justice, and in consultation with Indian Tribes and Tribal Organizations, and in conference with Urban Indian Organizations, shall develop standardized sexual assault policies and protocol for the facilities of the Service (IHS), based on similar protocol that has been established by the Department of Justice."⁴³ The new policy and protocol are expected to be announced during the reporting period (by March 23, 2011).

A representative from Indian Health Service (IHS) served as an active member on CCWH during the reporting period.

Office of Adolescent Health (OAH)

The Office of Adolescent Health (OAH) was established in 2010 within the Office of the Assistant Secretary for Health to coordinate adolescent health programs and initiatives across the U.S. Department of Health and Human Services (HHS). The Office supports multi-disciplinary projects focused on improving adolescent health, including adolescent girls, and works in partnership with other HHS agencies to support evidence-based approaches to adolescent health promotion and disease prevention.⁴⁴ OAH, with ACF and ASPE, oversaw a comprehensive review of the scientific evidence base to identify programs that have been shown through rigorous evaluation to have impacts on teen pregnancy or related sexual behaviors. Twenty-eight evidence-based models were identified as having met the standards and therefore eligible for replication under the Teen Pregnancy Prevention (TPP) Tier I funding announcement. Study reviews and results posted were on the OAH website during the reporting period.

The Office is responsible for implementing and administering this new TPP grant program to support evidence-based prevention approaches to address the high rates of teen pregnancy. OAH is also responsible for implementing the Pregnancy Assistance Fund, supporting pregnant and parenting teens and women, as authorized in the Affordable Care Act (Sections 10211 - 10214).

- On April 1, 2010 OAH issued a funding announcement for the replication of evidence based programs (Tier 1). In September 2010, this resulted in the award of 75 new cooperative agreements with total funding of \$75 million.
- On April 7, 2010 the office issued a joint announcement with the Administration on Children and Families (ACF) to support research and demonstration projects to test additional or innovative approaches to teen pregnancy prevention (Tier 2). In September 2011, this resulted in the award of 19 new OAH supported cooperative agreements totaling \$15.2 million, and ACF awarded 13 new projects totaling \$10 million in funds through the Affordable Care Act.
- OAH also issued an announcement jointly with the Centers for Disease Control and Prevention (CDC) for a teen pregnancy initiative entitled, *Integrating Services, Programs and Strategies through Community-wide TPP programs* (Tier 2). In September 2010, 8 community-based awards were made with \$9.8 million in TPP funds.
- On September 28, 2010, in a series of two stakeholder calls with the White House, OAH announced 17 new grants to States and Tribal entities were announced under the Pregnancy Assistance Fund. List of the projects is available on the Office of Adolescent Health Website (www.hhs.gov/ash/oah/assistance/2010_projects.html).

The Acting Director of OAH served as an active member of the HHS Coordinating Committee on Women's Health (CCWH) during the reporting period.

Office of the Assistant Secretary for Financial Resources (ASFR)

The Office of the Assistant Secretary for Financial Resources (ASFR) provides advice and guidance to the Secretary of the U.S. Department of Health and Human Services (HHS) on all aspects of budget, financial management, grants and acquisition management, and the American Recovery and Reinvestment Act coordination.⁴⁵ ASFR provides direction on these activities across the Department.

During the reporting period, a representative of ASFR served as an active member on the HHS Coordinating Committee on Women's Health (CCWH). As a member of CCWH, the representative attended monthly CCWH meetings and contributed to discussions on women's health. As a liaison to the Budget Office, they also provided periodic updates on budget matters regarding women's health.

During the reporting period, the representative of ASFR coordinated with other CCWH members on issues of particular concern to women to produce “Women’s Health” tables in the *Moyer Material*. The tables provide estimates of funding on women’s health within the various HHS Federal agencies and offices, and are submitted as a supplement to the President’s Budget.⁴⁶

Office of the Assistant Secretary for Planning and Evaluation (ASPE)

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is the principal advisor to the Secretary of HHS on policy development. ASPE is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis.⁴⁷

During this reporting period, ASPE reported on relevant activities regarding women’s health to the Secretary of HHS and the HHS Coordinating Committee on Women’s Health (CCWH), including the reporting requirements under Section 3509 of the Affordable Care Act.

ASPE also commissioned an Institute of Medicine (IOM) study to examine existing prevention guidelines, identify gaps that may exist in recommended preventive services for women, and highlight specific services and screenings that could supplement currently recommended preventive services for women. The U.S. Department of Health and Human Services (HHS) will use the information and recommendations from this study in its development of the comprehensive guidelines required under the Affordable Care Act addressing preventive services for women, which are due to be published in August 2011.

A representative of ASPE served as an active member on the HHS Coordinating Committee on Women’s Health (CCWH) during the reporting period.

Office of Disease Prevention and Health Promotion (ODPHP)

The Office of Disease Prevention and Health Promotion (ODPHP) is located in the Office of the Assistant Secretary for Health within the U.S. Department of Health and Human Services (HHS). ODPHP was created in 1976 by Section 1701 of the Public Health Service Act (PHSA) [42 USC 300u], which authorized the Secretary to formulate national goals, and a strategy to achieve such goals, for health information and health promotion, preventive health services, and education in the appropriate use of health care.⁴⁸ ODPHP is directed to: coordinate all activities within the Department which relate to disease prevention, health promotion, preventive health services, and health information; coordinate such activities with similar activities in the private sector; maintain a national health information center; and support related projects and research.

The mission of ODPHP is to provide leadership for a healthier America by initiating, coordinating, and supporting disease prevention and health promotion activities, programs, policies, and information for the U.S. Department of Health and Human Services (HHS) through collaboration with HHS agencies and other partners in prevention.⁴⁹

During the reporting period, ODPHP worked to establish women's health-related short-range and long-range goals and objectives, and to identify women's health projects. In December 2010, ODPHP launched *Healthy People 2020*, including 40 topic areas with measurable objectives and targets, and more than 1,000 population-based measures. Hundreds of the *Healthy People 2020* objectives collect data by sex and gender, and serve to identify disparities between men and women, tracking the data for these objectives through the decade. Additionally, ODPHP manages *healthfinder.gov* (www.healthfinder.gov), one of HHS' consumer websites. In 2011, *healthfinder.gov* will be identifying on its website the evidence-based interventions specific for women.

A representative of ODPHP served as an active member on the HHS Coordinating Committee on Women's Health (CCWH) during the reporting period.

Office of Global Health Affairs (OGHA)

The Office of Global Health Affairs (OGHA) promotes the health of the world's population by advancing the Secretary's global strategies and partnerships.⁵⁰ OGHA is the point of coordination for global health policy, security, and initiatives within the USG. The Office supports the Secretary and HHS leadership by providing strategic direction for global health, which allows for a consistent approach across government sectors and multilateral organizations.

OGHA works with HHS Operating and Staff Divisions to ensure that HHS's international activities are coordinated and that they align with the Secretary's vision for HHS's Global Health priorities. OGHA also works closely with other relevant stakeholders including other U.S. government departments and agencies to ensure that HHS international activities are consistent with U.S. domestic priorities. In addition, the Office represents the Secretary and HHS in discussions of international matters with representatives from foreign governments and multilateral organizations, including but not limited to: the World Health Assembly, the United Nations (UN), the Pan American Health Organization (PAHO), and the Global Fund to Fight AIDS, Tuberculosis, and Malaria Board (Global Fund).

During the reporting period, OGHA has had a number of achievements which directly and indirectly benefited the health and welfare of women and girls. Some specific examples of OGHA's work to transform health care are:

- OGHA supported HHS's ability to gather information about other countries' experiences with various health care models, including discussions with the Netherlands, France, Denmark, the United Kingdom, and the European Union, and through the Organization for Economic Cooperation and Development.
- OGHA encouraged and promoted adoption of health information technology globally including *eHealth* and *mHealth*, through participation in conferences and coordination of Departmental activities.

- OGHA assisted in the launching of the *Global Alliance for Clean Cookstoves*, which is a public-private interdepartmental partnership to promote respiratory health.

In addition to these specific accomplishments, one of the key areas of focus of OGHA is Maternal and Child Health (MCH), and other health issues which specifically affect women and girls. Currently, HHS provides technical assistance, resources, and programmatic support in MCH in over 75 countries, has staff working on the ground in over 54 countries, and spends over \$300 million annually on its global MCH programs. OGHA helps coordinate HHS' global MCH implementing agencies and offices, including CDC, NIH, HRSA, SAMHSA, ACF, and FDA.

OGHA also supports the health and well-being of women and girls through its coordinating work with other USG agencies, on the implementation of the *Global Health Initiative* (GHI). GHI is a USG investment to improve health outcomes in partner countries through strengthened health systems and integrated services. GHI recognizes that women are the gateway to healthy families and thus the first principle is a focus on women, girls, and gender equality. With a particular focus on improving the health of women, newborns, and children around a world, GHI is working to improve measurement and evaluation by collecting sex- and age-disaggregated data, as well as health statistics to monitor progress and evaluate effectiveness of programs on women, girls, and gender equality and health.

OGHA will continue this important work to improve the health and well-being of women and girls through many forums, both domestic and international. To that end, the office is currently leading the development of a Department-wide *Global Health Strategy* that will allow us to proactively advance the President's overarching global health agenda. This strategy has begun with an unprecedented comprehensive inventory of our current programs, budgets, and activities, and will include our work in pandemic planning, combating bio-terrorism, and implementing the GHI.

The Senior Advisor to the Director of OGHA served as an active member on the HHS Coordinating Committee on Women's Health (CCWH) during the reporting period.

Office of HIV/AIDS Policy (OHAP)

The Office of HIV/AIDS Policy (OHAP) is located in Office of the Assistant Secretary for Health within the U.S. Department of Health and Human Services (HHS). OHAP advises the Assistant Secretary for Health and senior HHS officials on: the appropriate and timely implementation and development of HIV/AIDS policy; the establishment of priorities; and the implementation of HIV/AIDS programs, activities, and initiatives across HHS health agencies.⁵¹ OHAP is responsible for several Federal HIV/AIDS initiatives, including the *National HIV Testing Mobilization Campaign* and *AIDS.gov* (the internet gateway for Federal domestic HIV/AIDS information).

During the reporting period, OHAP worked to develop short-range and long-range goals and objectives in coordination with other Federal agencies and offices to address HIV/AIDS prevention, care, and treatment, including for women. With the release of the *National*

HIV/AIDS Strategy (NHAS) on July 13, 2010, OHAP was tasked with the development of an Operational Plan to guide the U.S. Department of Health and Human Services (HHS) through its implementation. To develop the HHS Operational Plan, OHAP worked in collaboration with other Federal agencies and offices, and the Office of the Assistant Secretary for Health convened meetings with HHS agency leads and HIV/AIDS leads from other Federal departments to solicit input from within and outside the Department.⁵² The *HHS Operational Plan: Achieving the Vision of the National HIV/AIDS Strategy* was released in February 2011.

As outlined in the HHS Operational Plan, the first phase of the implementation of the *National HIV/AIDS Strategy* will include a demonstration project in the twelve Metropolitan Statistical Areas with the highest HIV/AIDS prevalence. These cities include: Atlanta, Baltimore, Chicago, Dallas, Houston, Los Angeles, Miami, New York City, Philadelphia, San Francisco, San Juan and Washington, DC. The “HHS 12 Cities Project” will provide an opportunity to escalate and integrate HIV/AIDS services. The goal of this demonstration project is to “concentrate resources and actions across categorical program lines, and scale up effective HIV prevention and treatment strategies.”⁵³ Much of the programming will be targeted to the populations most severely affected by the HIV/AIDS epidemic including African American and Latina women, and women who use injection drugs.

While the implementation of the *National HIV/AIDS Strategy* is still in development, OHAP expects that it will lead to advancements in the field of HIV/AIDS. The goals of the *National HIV/AIDS Strategy* are to reduce new infections, improve access to care, improve health outcomes for people living with HIV/AIDS, and reduce health disparities. The efforts towards achieving these goals will improve the lives of women and the entire population.

A representative of the Office of HIV/AIDS Policy (OHAP) served as an active member on CCWH during the reporting period.

Office of Minority Health (OMH)

The Office of Minority Health (OMH) within the U.S. Department of Health and Human Services (HHS) was created in 1986 and is one of the most significant outcomes of the 1985 *Secretary's Task Force Report on Black and Minority Health*.⁵⁴ The Office is dedicated to improving the health of racial and ethnic minority populations in the U.S. through the development of health policies and programs that will help eliminate health disparities.

OMH programs address disease prevention, health promotion, risk reduction, healthier lifestyle choices, use of health care services, and barriers to health care for racial and ethnic minority populations in the U.S.⁵⁵ During the reporting period, OMH identified women’s health-related projects and administered the following programs that address women’s health:

- OMH’s *A Healthy Baby Begins with You* campaign, which includes preconception health peer education and infant mortality prevention programs. Trainings for more than 400 *Healthy Baby* preconception health peer educators were held in at least 8 states in communities across the U.S. The Campaign’s “Crisis in the Crib” video was accepted by

the American Public Health Association Film Festival and received an award from the Congressional Black Caucus. A new effort was launched with the Seattle Indian Health Board to develop a *Native American Healthy Baby* campaign for American Indians residing in urban areas.

- OMH's American Indian and Alaska Native (AI/AN) Partnership Program, which provides support to Tribal epidemiology centers to work with their respective Tribal leaders to: better access data, engage in data development activities, and use a broad array of data to facilitate evidence-based health care decision-making and address health disparities planning; develop non-traditional alliances and partnerships to improve coordination and alignment of health and human services and access to quality care for their communities; and improve the diversity of the Tribal health care, public health, and research workforce. In FY 2010 more than 1,200 individuals received services and/or training from the AI/AN Partnership Program grantees and their partner organizations. Of the total FY 2010 participants in this program 51%, were female (N=599,088).

- OMH's Community Partnership to Eliminate Health Disparities Demonstration Grant Program (CPEHD) (which ended August 31, 2010 and has been replaced by the Partnerships Active in Communities to Achieve Health Equity Program), designed to support activities that address racial and ethnic health disparities through community-level activities that promote health, reduce risks, and increase access and use of preventive health care and treatment services. During FY 2010, 64% of the participants in this program were female. Grantees under the CPEHD program interacted with more than 19,000 individuals during health promotion and education activities, health screenings and health fairs; disseminated health materials to more than 800,000 individuals; served more than 16,000 individuals by project partners, primarily through referrals for follow-up health care; and provided services to nearly 200,000 individuals directly from grantee organizations.

- OMH's Youth Empowerment Program (YEP), designed to address unhealthy behaviors in at-risk minority youth, provide them opportunities to develop more positive life styles, and enhance their capacity to make healthier life choices. The 17 YEP grantees are institutions of higher education who partner with primary and secondary schools, sports organizations, youth clubs, other related community organizations and institutions, and the community at-large on reducing risky behaviors among targeted minority youth 10-18 years of age. Activities conducted by grantees during the first six months of FY 2010 reached nearly 24,000 individuals including the youth cohorts, their families, and the communities at-large. Of the 2,940 youth cohort participants in FY 2010, 54% were female.

The Deputy Director of OMH served as an active member on the HHS Coordinating Committee on Women's Health (CCWH) during the reporting period.

Office of Population Affairs (OPA)

The Office of Population Affairs (OPA), located in the Office of the Assistant Secretary for Health within HHS, operates under the direction of the Deputy Assistant Secretary for Population Affairs whose responsibilities include implementation of the mandated provisions of the Title X Family Planning Program (“Population Research and Voluntary Family Planning Programs” [P.L. 91-572]), enacted in 1970 as Title X of the Public Health Service Act (PSHA).⁵⁶

The mission of the Title X Family Planning Program is to assist individuals in determining the number and spacing of their children. Title X is the only Federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. The Title X Family Planning Program is designed to provide access to contraceptive services, supplies, and information to all who want and need them. By law, priority is given to persons from low-income families.

In fiscal year 2010, Congress appropriated approximately \$317.5 million for family planning activities supported under Title X. At least 90% of the appropriation is used for clinical family planning services as described in the statute and regulations [45 CFR Part 59].

In calendar year 2009 (the year of most current national data), 89 Title X grantees provided family planning services to 4,811,691 women through a network of more than 4,500 community-based clinics, which included State and local health departments, Tribal organizations, hospitals, university health centers, independent clinics, community health centers, faith-based organizations, and other public and private nonprofit agencies. Of the women served, 19% identified themselves as African American; 28% as Hispanic; and 90% of those served had incomes at or below 200% of the Federal Poverty Level.

In accordance with Section 3509, OPA identified women’s health-related projects and supported the following services to women in the most recent reporting period:

- *Contraceptive Care:* Title X family planning clinics offer a broad range of FDA-approved methods of contraception. In 2009, 4,155,112 women were provided with contraceptive methods. Each year, approximately 1 million unintended pregnancies are averted, including more than 233,000 among teens.
- *Cervical Cancer Screenings:* In 2009, 2,035,017 female clients received 2,190,127 screenings for cervical cancer. It is estimated that these screenings contributed to preventing approximately 670 cases of invasive cervical cancer.
- *Sexually Transmitted Infection Screening and Treatment:* In 2009, 2,342,220 women were tested for Chlamydia, 2,589,430 were tested for Gonorrhea, and 633,777 were tested for syphilis.
- *HIV Testing:* In 2009, 844,888 tests were conducted to screen for HIV in women.

Title X-supported clinics play a critical role in ensuring access to confidential, voluntary family planning information and services for women. Title X grantees must also comply with State laws requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape or incest. None of the funds appropriated may be used in programs where abortion is a method of family planning.

During the reporting period, the Deputy Assistant Secretary for the Office of Population Affairs (OPA) served as an active member on CCWH.

President's Council on Fitness, Sports and Nutrition (PCFSN)

The President's Council on Fitness, Sports and Nutrition (PCFSN) was founded in 1956 as the President's Council on Youth Fitness by President Dwight D. Eisenhower. The Council is a Federal advisory committee of volunteer citizens who advise the President through the Secretary of the U.S. Department of Health and Human Services (HHS) about physical activity, fitness, sports and nutrition in the United States. Through its programs and partnerships, including with public, private, and non-profit sectors, the Council serves as a catalyst to promote health, physical activity, fitness, and enjoyment for people of all ages, backgrounds, and abilities through participation in physical activity and sports.⁵⁷

During the reporting period, PCFSN reported on the current level of PCFSN activities regarding women's health to the HHS Coordinating Committee on Women's Health (CCWH). The Council also looked for opportunities to partner with the Office on Women's Health (OWH) to help elevate and disseminate messages regarding health and fitness to women and young girls.

The Council coordinated with the HHS Office on Women's Health on activities for issues of particular concern to women including OWH's *Best Bones Forever!* Atlanta Dance Contest on October 29, 2010. The *Best Bones Forever!* campaign encourages young women to be active and to consume more vitamin D and calcium-rich foods to build stronger bones.⁵⁸ A Council member participated in the event in an effort to promote physical activity and good nutrition among the event participants and spectators.

Since November 2010, the Office on Women's Health has been promoting the use of the PCFSN's signature program, the President's Challenge, as a way to encourage girls ages 6-17 and women 18 and older to engage in regular physical activity. The President's Challenge helps people of all ages, backgrounds, and abilities increase their physical activity through research-based information, easy-to-use tools and resources, and friendly motivation.⁵⁹ The Council plans to continue to identify projects in women's health that should be conducted or supported when they fall within the mission of the PCFSN.

During this reporting period, a representative from the Council served as an active member on the HHS Coordinating Committee on Women's Health (CCWH).

V. CONCLUSION

Section 3509 of the Affordable Care Act directs U.S. Department of Health and Human Services (HHS) agencies and offices to make women's health a priority. Section 3509 calls for greater authorization and prioritization of women's health issues within HHS agencies and offices, and greater coordination across HHS agencies and offices, including through the mandated HHS Coordinating Committee on Women's Health (CCWH). The law also recommends greater access to women's health information for women and health professionals, including in disease prevention, health promotion, service delivery, and research, such as through the mandated National Women's Health Information Center (NWHIC). Section 3509 outlines the steps and activities needed within various HHS Federal agencies and offices to address the gaps and disparities in women's health, and to support innovative and evidence-based programs.

Overall, the Affordable Care Act is expected to improve women's health through increased access to health care and health information for women, and through more programs and services tailored to women's unique health needs. In addition to the requirements under Section 3509, the Affordable Care Act includes other provisions specific to women's health, including but not limited to: a prohibition on gender rating in new health insurance plans starting in 2014; a Pregnancy Assistance Fund to assist pregnant and parenting teens and women; and early childhood home visitation programs to promote improvements in maternal and prenatal health.

The HHS Office on Women's Health (OWH), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA) have all made significant progress on the requirements outlined in Section 3509 of the Affordable Care Act. Additionally, various other HHS Federal agencies and offices have contributed to and participated in such efforts, including through the HHS Coordinating Committee on Women's Health (CCWH). Further progress is expected on the requirements of Section 3509 as well as with the requirements of the other sections of the Affordable Care Act.

The Secretary, through the HHS Office on Women's Health, will submit the next report to Congress no later than March 23, 2013.⁶⁰ Future reports will also describe the activities carried out under Section 3509, using this report for baseline comparison.

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APPENDICES

Appendix I. CCWH Membership

The U.S. Department of Health and Human Services Coordinating Committee on Women's Health (CCWH) is chaired by the Deputy Assistant Secretary for Health (Women's Health) and is comprised of senior-level representatives from each of the following Federal agencies and offices within the Department.

Table 3. HHS Coordinating Committee on Women's Health Membership	
Agency or Office	Website
<i>Office of the Assistant Secretary for Health (ASH) Offices</i>	
Office of Adolescent Health (OAH)	http://www.hhs.gov/ash/oah
Office of Disease Prevention and Health Promotion (ODPHP)	http://odphp.osophs.dhhs.gov
Office of HIV/AIDS Policy (OHAP)	http://www.hhs.gov/ash/ohap
Office of Intergovernmental Affairs (OIA)	http://www.hhs.gov/intergovernmental
Office of Minority Health (OMH)	http://minorityhealth.hhs.gov
Office of Population Affairs (OPA)	http://www.hhs.gov/opa
Office on Women's Health (OWH)	http://www.womenshealth.gov/about-us
President's Council on Fitness, Sports, and Nutrition (PCFSN)	http://www.fitness.gov
Regional Women's Health Office	http://www.womenshealth.gov/about-us
<i>Staff Divisions</i>	
Office of the Assistant Secretary for Financial Resources (ASFR)	http://dhhs.gov/asfr
Office of the Assistant Secretary for Planning and Evaluation (ASPE)	http://aspe.hhs.gov
Office on Disability (OD)	http://www.hhs.gov/od
Office of Global Health Affairs (OGHA)	http://www.globalhealth.gov

<i>Operating Divisions</i>	
Administration on Aging (AoA)	http://www.aoa.gov
Administration for Children and Families (ACF)	http://www.acf.hhs.gov
Agency for Healthcare Research and Quality (AHRQ)	http://www.ahrq.gov
Centers for Disease Control and Prevention (CDC)	http://www.cdc.gov
Centers for Medicare & Medicaid Services (CMS)	http://www.cms.hhs.gov
Food and Drug Administration (FDA)	http://www.fda.gov
Health Resources and Services Administration (HRSA)	http://www.hrsa.gov
Indian Health Service (IHS)	http://www.ihs.gov
National Institutes of Health (NIH)	http://www.nih.gov
Substance Abuse and Mental Health Services Administration (SAMHSA)	http://www.samhsa.gov

Appendix II. Acronyms

The following acronyms were used in this report, including some acronyms for programs and initiatives for specific HHS agencies and offices.

AACP	American Association of Colleges of Pharmacy
AAWS	Associate Administrator for Women’s Services (SAMHSA)
ACF	Administration for Children and Families
ACRWH	Advisory Committee for Research on Women’s Health (NIH)
ACWS	Advisory Committee for Women’s Services (SAMHSA)
AHRQ	Agency for Health Care Research and Quality
AI/AN	American Indian, Alaska Native
ANSWHR	Advancing Novel Science in Women’s Health Research (NIH)
AoA	Administration on Aging
ASFR	Office of the Assistant Secretary for Financial Resources
ASH	Office of the Assistant Secretary for Health
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ATSDR	Agency for Toxic Substances and Disease Registry
BIRCWH	Building Interdisciplinary Research Careers in Women’s Health (NIH)
CCWH	HHS Coordinating Committee on Women’s Health
CCRWH	Coordinating Committee on Research on Women’s Health (NIH)
CDC	Centers for Disease Control and Prevention
CMHS	Center for Mental Health Services
CMS	Centers for Medicare & Medicaid Services
CSAP	Center for Substance Abuse Prevention (SAMHSA)
CSAT	Center for Substance Abuse Treatment (SAMHSA)
DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives (NIH)
FCA	Family Caregiver Alliance
FDA	Food and Drug Administration
FYSB	Family and Youth Services Bureau (ACF)
GDM	Gestational Diabetes Mellitus
GHI	Global Health Initiative
HHS	U.S. Department of Health and Human Services
HIV/AIDS	Human Immunodeficiency Virus, Acquired Immunodeficiency Syndrome
HRSA	Health Resources and Services Administration
IC	Institutes and Centers (NIH)
IHS	Indian Health Service
IOM	Institute of Medicine
LGBT	Lesbian, Gay, Bisexual or Transgender
MCHB	Maternal and Child Health Bureau (HRSA)
MCH	Maternal and Child Health (OGHA)
MDGs	Millennium Development Goals
MHA	Mental Health America
NASADAD	National Association of State Alcohol and Drug Abuse Directors
NCOA	National Council on Aging

NCST	National Center on Senior Transportation
NCTR	National Center for Toxicological Research (FDA)
NHAS	National HIV/AIDS Strategy
NHQR	National Healthcare Quality Report
NICHD	National Institute of Child Health and Human Development
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NLM	National Library of Medicine
NWHIC	National Women's Health Information Center
OA	Office of the Administrator
OAA	Older Americans Act
OAH	Office of Adolescent Health
ODPHP	Office of Disease Prevention and Health Promotion
OGC	Office of the General Counsel
OGHA	Office of Global Health Affairs
OHAP	Office of HIV/AIDS Policy
OMH	Office of Minority Health
OPA	Office of Population Affairs
ORWH	Office of Research on Women's Health (NIH)
OS	Office of the Secretary
OWH	Office on Women's Health (HHS) or Office of Women's Health
PAHO	Pan American Health Organization
PCFSN	President's Council on Fitness, Sports and Nutrition
PHSA	Public Health Service Act
PSPC	Patient Safety and Clinical Pharmacy Services Collaborative (HRSA)
SAMHSA	Substance Abuse and Mental Health Services Administration
SCOR	Specialized Centers of Research (NIH)
SMP	Senior Medicare Patrol (AoA)
SUAs	State Units on Aging
SWCC	SAMHSA Women's Coordinating Committee (SAMHSA)
TPP	Teen Pregnancy Prevention
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government
VAW	Violence Against Women
WHO	World Health Organization
WISER	Women's Institute for a Secure Retirement
WSN	Women's Services Network
YEP	Youth Empowerment Program (OMH)
QPR	Quarterly Progress Report

Appendix III. Affordable Care Act (Section 3509)

Section 3509 of the Affordable Care Act is taken directly from the “Compilation of Patient Protection and Affordable Care Act”, which includes the “Patient Protection and Affordable Care Act” (P.L. 111–148) and the amendments made by Title X of the Act and the “Health Care and Reconciliation Act of 2010” (P.L. 111-152).⁶¹ Section 3509 is under Title III “Improving the Quality and Efficiency of Health Care,” and Subtitle F “Health Care Quality Improvements”.

SEC. 3509. IMPROVING WOMEN’S HEALTH.

(a) HEALTH AND HUMAN SERVICES OFFICE ON WOMEN’S HEALTH.—

(1) ESTABLISHMENT.—Part A of title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

“SEC. 229 [42 U.S.C. 237a]. HEALTH AND HUMAN SERVICES OFFICE ON WOMEN’S HEALTH.

“(a) ESTABLISHMENT OF OFFICE.—There is established within the Office of the Secretary, an Office on Women’s Health (referred to in this section as the ‘Office’). The Office shall be headed by a Deputy Assistant Secretary for Women’s Health who may report to the Secretary.

“(b) DUTIES.—The Secretary, acting through the Office, with respect to the health concerns of women, shall—

“(1) establish short-range and long-range goals and objectives within the Department of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their life-span;

“(2) provide expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues relating to women’s health;

“(3) monitor the Department of Health and Human Services’ offices, agencies, and regional activities regarding women’s health and identify needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities;

“(4) establish a Department of Health and Human Services Coordinating Committee on Women’s Health, which shall be chaired by the Deputy Assistant Secretary for Women’s Health and composed of senior level representatives from each of the agencies and offices of the Department of Health and Human Services;

“(5) establish a National Women’s Health Information Center to—

“(A) facilitate the exchange of information regarding matters relating to health information, health promotion, preventive health services, research advances, and education in the appropriate use of health care;

“(B) facilitate access to such information;

“(C) assist in the analysis of issues and problems relating to the matters described in this paragraph; and

“(D) provide technical assistance with respect to the exchange of information (including facilitating the development of materials for such technical assistance);

“(6) coordinate efforts to promote women’s health programs and policies with the private sector; and

“(7) through publications and any other means appropriate, provide for the exchange of information between the Office and recipients of grants, contracts, and agreements under subsection (c), and between the Office and health professionals and the general public.

“(c) GRANTS AND CONTRACTS REGARDING DUTIES.—

“(1) AUTHORITY.—In carrying out subsection (b), the Secretary may make grants to, and enter into cooperative agreements, contracts, and interagency agreements with, public and private entities, agencies, and organizations.

“(2) EVALUATION AND DISSEMINATION.—The Secretary shall directly or through contracts with public and private entities, agencies, and organizations, provide for evaluations of projects carried out with financial assistance provided under paragraph (1) and for the dissemination of information developed as a result of such projects.

“(d) REPORTS.—Not later than 1 year after the date of enactment of this section, and every second year thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the period for which the report is being prepared.

“(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.”.

(2) TRANSFER OF FUNCTIONS.—There are transferred to the Office on Women’s Health (established under section 229 of the Public Health Service Act, as added by this section), all functions exercised by the Office on Women’s Health of the Public Health Service prior to the date of enactment of this section, including all personnel and compensation authority, all delegation and assignment authority, and all remaining appropriations. All orders, determinations, rules, regulations, permits, agreements, grants, contracts, certificates, licenses, registrations, privileges, and other administrative actions that—

(A) have been issued, made, granted, or allowed to become effective by the President, any Federal agency or official thereof, or by a court of competent jurisdiction, in the performance of functions transferred under this paragraph; and

(B) are in effect at the time this section takes effect, or were final before the date of enactment of this section and are to become effective on or after such date, shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Secretary, or other authorized official, a court of competent jurisdiction, or by operation of law.

(b) CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE

OF WOMEN'S HEALTH.—Part A of title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

“SEC. 310A [42 U.S.C. 242s]. CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH.

“(a) ESTABLISHMENT.—There is established within the Office of the Director of the Centers for Disease Control and Prevention, an office to be known as the Office of Women's Health (referred to in this section as the ‘Office’). The Office shall be headed by a director who shall be appointed by the Director of such Centers.

“(b) PURPOSE.—The Director of the Office shall—

“(1) report to the Director of the Centers for Disease Control and Prevention on the current level of the Centers' activity regarding women's health conditions across, where appropriate, age, biological, and sociocultural contexts, in all aspects of the Centers' work, including prevention programs, public and professional education, services, and treatment;

“(2) establish short-range and long-range goals and objectives within the Centers for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Centers that relate to prevention, research, education and training, service delivery, and policy development, for issues of particular concern to women;

“(3) identify projects in women's health that should be conducted or supported by the Centers;

“(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

“(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

“(c) DEFINITION.—As used in this section, the term ‘women's health conditions’, with respect to women of all age, ethnic, and racial groups, means diseases, disorders, and conditions—

“(1) unique to, significantly more serious for, or significantly more prevalent in women; and

“(2) for which the factors of medical risk or type of medical intervention are different for women, or for which there is reasonable evidence that indicates that such factors or types may be different for women.

“(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.’’.

(c) OFFICE OF WOMEN'S HEALTH RESEARCH.—Section 486(a) of the Public Health Service Act (42 U.S.C. 287d(a)) is amended by inserting ‘‘and who shall report directly to the Director’’ before the period at the end thereof.

(d) SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.—Section 501(f) of the Public Health Service Act (42 U.S.C. 290aa(f)) is amended—

(1) in paragraph (1), by inserting ‘‘who shall report directly to the Administrator’’ before the period;

(2) by redesignating paragraph (4) as paragraph (5); and

(3) by inserting after paragraph (3), the following:

“(4) OFFICE.—Nothing in this subsection shall be construed to preclude the Secretary from establishing within the Substance Abuse and Mental Health Administration an Office of Women’s Health.”

(e) AGENCY FOR HEALTHCARE RESEARCH AND QUALITY ACTIVITIES REGARDING WOMEN’S HEALTH.—Part C of title IX of the Public Health Service Act (42 U.S.C. 299c et seq.) is amended—

(1) by redesignating sections 925 and 926 as sections 926 and 927, respectively; and

(2) by inserting after section 924 the following:

“SEC. 925 [42 U.S.C. 299b–24a]. ACTIVITIES REGARDING WOMEN’S HEALTH.

“(a) ESTABLISHMENT.—There is established within the Office of the Director, an Office of Women’s Health and Gender-Based Research (referred to in this section as the ‘Office’). The Office shall be headed by a director who shall be appointed by the Director of Healthcare and Research Quality.

“(b) PURPOSE.—The official designated under subsection (a) shall—

“(1) report to the Director on the current Agency level of activity regarding women’s health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work, including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

“(2) establish short-range and long-range goals and objectives within the Agency for research important to women’s health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

“(3) identify projects in women’s health that should be conducted or supported by the Agency;

“(4) consult with health professionals, nongovernmental organizations, consumer organizations, women’s health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

“(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women’s Health (established under section 229(b)(4)).”

“(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.”

(f) HEALTH RESOURCES AND SERVICES ADMINISTRATION OFFICE OF WOMEN’S HEALTH.—Title VII of the Social Security Act (42 U.S.C. 901 et seq.) is amended by adding at the end the following:

“SEC. 713 [42 U.S.C. 914]. OFFICE OF WOMEN’S HEALTH.

“(a) ESTABLISHMENT.—The Secretary shall establish within the Office of the Administrator of the Health Resources and Services Administration, an office to be known as the Office of Women’s Health. The Office shall be headed by a director who shall be ap-

pointed by the Administrator.

“(b) PURPOSE.—The Director of the Office shall—

“(1) report to the Administrator on the current Administration level of activity regarding women’s health across, where appropriate, age, biological, and sociocultural contexts;

“(2) establish short-range and long-range goals and objectives within the Health Resources and Services Administration for women’s health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Administration that relate to health care provider training, health service delivery, research, and demonstration projects, for issues of particular concern to women;

“(3) identify projects in women’s health that should be conducted or supported by the bureaus of the Administration;

“(4) consult with health professionals, nongovernmental organizations, consumer organizations, women’s health professionals, and other individuals and groups, as appropriate, on Administration policy with regard to women; and

“(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women’s Health (established under section 229(b)(4) of the Public Health Service Act).

“(c) CONTINUED ADMINISTRATION OF EXISTING PROGRAMS.—The Director of the Office shall assume the authority for the development, implementation, administration, and evaluation of any projects carried out through the Health Resources and Services Administration relating to women’s health on the date of enactment of this section.

“(d) DEFINITIONS.—For purposes of this section:

“(1) ADMINISTRATION.—The term ‘Administration’ means the Health Resources and Services Administration.

“(2) ADMINISTRATOR.—The term ‘Administrator’ means the Administrator of the Health Resources and Services Administration.

“(3) OFFICE.—The term ‘Office’ means the Office of Women’s Health established under this section in the Administration.

“(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.”.

(g) FOOD AND DRUG ADMINISTRATION OFFICE OF WOMEN’S HEALTH.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

“SEC. 1011 [21 U.S.C. 399b]. OFFICE OF WOMEN’S HEALTH.

“(a) ESTABLISHMENT.—There is established within the Office of the Commissioner, an office to be known as the Office of Women’s Health (referred to in this section as the ‘Office’). The Office shall be headed by a director who shall be appointed by the Commissioner of Food and Drugs.

“(b) PURPOSE.—The Director of the Office shall—

“(1) report to the Commissioner of Food and Drugs on current Food and Drug Administration (referred to in this section as the ‘Administration’) levels of activity regarding women’s

participation in clinical trials and the analysis of data by sex in the testing of drugs, medical devices, and biological products across, where appropriate, age, biological, and sociocultural contexts;

“(2) establish short-range and long-range goals and objectives within the Administration for issues of particular concern to women’s health within the jurisdiction of the Administration, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in Administration protocols and policies;

“(3) provide information to women and health care providers on those areas in which differences between men and women exist;

“(4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women’s issues, consumer organizations, and women’s health professionals on Administration policy with regard to women;

“(5) make annual estimates of funds needed to monitor clinical trials and analysis of data by sex in accordance with needs that are identified; and

“(6) serve as a member of the Department of Health and Human Services Coordinating Committee on Women’s Health (established under section 229(b)(4) of the Public Health Service Act).

“(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.”.

(h) NO NEW REGULATORY AUTHORITY.—Nothing in this section and the amendments made by this section may be construed as establishing regulatory authority or modifying any existing regulatory authority.

(i) LIMITATION ON TERMINATION.—Notwithstanding any other provision of law, a Federal office of women’s health (including the Office of Research on Women’s Health of the National Institutes of Health) or Federal appointive position with primary responsibility over women’s health issues (including the Associate Administrator for Women’s Services under the Substance Abuse and Mental Health Services Administration) that is in existence on the date of enactment of this section shall not be terminated, reorganized, or have any of its powers or duties transferred unless such termination, reorganization, or transfer is approved by Congress through the adoption of a concurrent resolution of approval.

(j) RULE OF CONSTRUCTION.—Nothing in this section (or the amendments made by this section) shall be construed to limit the authority of the Secretary of Health and Human Services with respect to women’s health, or with respect to activities carried out through the Department of Health and Human Services on the date of enactment of this section.