National Family Planning & Reproductive Health Association

September 2011

Women's Health Preventive Services Benefit:

Considerations for Family Planning Providers

Introduction

The Affordable Care Act (ACA) requires that all private health insurance plans beginning on or after September 23, 2010, cover preventive services recommended by the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices, and the American Academy of Pediatrics' Bright Futures report with no cost-sharing. However, a number of family planning services, including the provision of contraception and screening for sexually transmitted infections, are not included among the services recommended by these bodies.

To address the gaps in coverage for women's health, the ACA included a provision, authored by Senator Barbara Mikulski (D-MD) and commonly referred to as "the Women's Health Amendment," that requires all insurance plans to cover a broader package of preventive health services for women than those currently recommended by the aforementioned clinical advisory groups.

In 2010, the U.S. Department of Health and Human Services (HHS) tasked the Institute of Medicine (IOM) with reviewing the preventive screenings and services to be considered for the women's health preventive services benefit. The IOM convened a Committee on Preventive Services for Women ("the committee"), which included specialists in women's health issues, adolescent health issues, disease prevention, and evidence-based guidelines, to develop a set of recommendations for consideration by HHS. Issued in July 2011, the committee's final report, *Clinical Preventive Services for Women: Closing the Gaps,* includes recommendations for eight women's health-related preventive services and screenings to be covered without cost-sharing.

Although these recommendations are based partly on clinical treatment guidelines, they do *not* represent clinical guidelines themselves. The intent of the preventive services benefit is to address gaps that exist in insurance coverage for specific conditions that uniquely affect women. Because cost-sharing can impede women from receiving services that they would otherwise choose to receive, the women's health preventive services benefit is designed to eliminate the barrier that cost-sharing represents.

On August 1, 2011, HHS released an interim final rule adopting the IOM recommendations in full. HHS also amended the prevention recommendations to allow religious institutions that offer insurance to their employees to exclude coverage of contraceptive services. HHS' action means the eight preventive services detailed below must be covered by all commercial health insurance plans (except for

"grandfathered health plans"[1]), without co-pay or cost-sharing to the consumer, in plan years beginning on or after August 1, 2012. These coverage benefits will affect patients and providers in all areas of health care provision but will have particular impact on providers who specialize in women's health.

Recommendations

In order to support its recommendations, the committee performed literature reviews and examined clinical service provision guidelines and current coverage mechanisms. The committee considered existing gaps in coverage for conditions or services that affect a broad population, could have a large potential impact on health and well-being, and had high-quality supportive evidence.[2]

Recommendation 1

The committee recommends for consideration as a preventive service for women: screening for gestational diabetes in pregnant women at between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.

Gestational diabetes, or diabetes that is diagnosed or arises during pregnancy, takes place in about two to ten percent of pregnant women. Most women can recover from gestational diabetes after giving birth, but a woman with a history of gestational diabetes has an increased risk of developing type 2 diabetes in the future and her children are more likely to be overweight and to have insulin resistance during childhood. The U.S. has one of the highest rates of gestational diabetes in the world, as well as one of the highest overall diabetes rates in the world. Annually, indirect and direct costs of diabetes care total an estimated $174 billion. Although there is insufficient evidence to recommend routine screening for gestational diabetes, current clinical professional guidelines support screening for women at high risk of developing diabetes and pregnant women of later gestational age. [3]

Recommendation 2

The committee recommends for consideration as a preventive service for women: the addition of high-risk HPV DNA testing in women with normal cytology results. Screening should begin at 30 years of age and should occur no more frequently than every 3 years.

[1] *See* 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251 and 45 CFR 147.140 (75 FR 34538, June 17, 2010). A grandfathered health plan is a plan with at least one enrollee on March 23, 2010. Plans will lose their grandfathered status if, as compared to their policies in effect on March 23, 2010, they make changes including, but not limited to, significantly cutting or reducing benefits, raising co-insurance charges, significantly raising co-payments, significantly raising deductibles, or adding or tightening annual limits on what the insurer pays. The federal government estimates that between 39% and 69% of employer group plans will relinquish grandfathered status by 2013.

[2] IOM (Institute of Medicine). 2011. *Clinical Preventive Services for Women: Closing the Gaps.* Washington, DC: The National Academies Press. p. 67.

[3] *Id.* p.74-80.

In the United States, 12,200 cases of invasive cervical cancer and 4,210 related deaths occurred in 2010. Cervical cancer is directly caused by infection with at least 1 of 20 high-risk types of human papillomavirus (HPV), which is highly prevalent and usually resolves without developing into cervical cancer. Deaths from cervical cancer are almost entirely preventable, due to screening, early detection and treatment advances; over 50% of invasive cervical cancers occur among unscreened and under-screened women.

Current American Cancer Society and American College of Obstetricians and Gynecologists (ACOG) guidelines call for screening all sexually active women beginning at age 21 or within three years of the onset of sexual activity, and at least every three years thereafter.

In addition to the Pap test/cytology screening, high-risk HPV DNA testing can more finely detect HPV types most commonly associated with the development of cancer. In spite of these technological advances, women may still lack access to newer screening methods. While HPV DNA testing is becoming more prevalent—the U.S. Department of Defense recently added the high-risk HPV DNA test to its list of covered preventive services, for example—there are still significant coverage gaps for cytology and DNA testing. [4]

For many years, family planning providers have screened annually for cervical cancer in their patient populations using the traditional Pap test. In 2009, Title X sites provided over 2 million Pap tests; of these, 12% indicated a precancerous or cancerous condition. These 2 million tests represent about 42% of female patients in the Title X setting, a decrease from 52% in 2005. This change may be the result of new clinical guidelines recommending less frequent screenings, as well as technological developments in screening. [5] However a number of publicly supported family planning providers do not perform HPV DNA tests. There is some question in the clinical and provider communities about the cost-effectiveness of the co-test, and some safety-net providers report not being able to afford the HPV DNA test. Ideally the new coverage requirement would help alleviate the costs related to the service for those women who have commercial insurance coverage. However, this expanded funding source still may not cover the acquisition cost, and does not address the cost burden for non-commercially insured patients, meaning that many Title X family planning providers may still be unable to provide HPV DNA testing in their Title X centers even for patients with commercial insurance coverage.

Recommendation 3

The committee recommends for consideration as a preventive service for women: annual counseling on sexually transmitted infections for all sexually active women.

[4] IOM (Institute of Medicine). 2011. *Clinical Preventive Services for Women: Closing the Gaps.* Washington, DC: The National Academies Press. p.80-4.

[5] Fowler, CI, Gable, J, Wang, J, and Lloyd, SW. (November 2010). *Family Planning Annual Report: 2009 National Summary*. Research Triangle Park, NC: RTI International.

In 1997, the Institute of Medicine called sexually transmitted infections (STIs) "a hidden epidemic," in part because of the prevalence of STIs and in part because many are asymptomatic and therefore go undiagnosed. In women, untreated STIs can lead to pelvic inflammatory disease, ectopic pregnancy, and infertility.

Although there is insufficient evidence to suggest new recommendations for STI screening, current clinical guidelines and federal programs support covering counseling for STIs. The ACA provides for STI counseling only for adults who currently have STIs or multiple sexual partners, although the Bright Futures guidelines recommend that all sexually active adolescents receive annual screenings for gonorrhea and Chlamydia. In order to address the coverage gap, the committee recommended STI counseling for all sexually active women and included STI screening in the recommended services that comprise the annual well-woman exam (recommendation 8). [6]

In the Title X service setting, screening for Chlamydia and gonorrhea is routine. In 2009, 2.3 million female patients received screening for Chlamydia and for gonorrhea.[7] Requiring commercial insurance coverage for annual counseling on STIs could help reduce some of the costs associated with STI services that to date have been otherwise unreimbursable, leaving family planning providers to cover the costs with Title X or other grant funds. This recommendation will provide a new source of revenue for the STI counseling already being performed in the family planning setting.

Recommendation 4

The committee recommends for consideration as a preventive service for women: counseling and screening for HIV infection on an annual basis for sexually active women.

The rate of human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) in women is increasing. In 2009, women accounted for 25 percent of new AIDS cases, up from 8 percent in 1985. As with STIs, women frequently underestimate their risk of acquiring HIV, and risk-based screening has not been shown to be effective in identifying individuals with HIV. Early screening for HIV is effective and is recommended by a number of clinical professional societies and the U.S. Centers for Disease Control and Prevention (CDC). Title X service centers offer both confidential and anonymous testing for HIV. HIV diagnosis, particularly early in the course of the infection, benefits both the patient and any sexual partners, but current USPSTF recommendations are limited to only pregnant women and high-risk adolescents and adults. [8]

[6] IOM (Institute of Medicine). 2011. *Clinical Preventive Services for Women: Closing the Gaps.* Washington, DC: The National Academies Press. p.84-8*.*

[7] Fowler, CI, Gable, J, Wang, J, and Lloyd, SW. (November 2010). *Family Planning Annual Report: 2009 National Summary*. Research Triangle Park, NC: RTI International.

[8] IOM (Institute of Medicine). 2011. *Clinical Preventive Services for Women: Closing the Gaps.* Washington, DC: The National Academies Press. p.88-91.

In 2009, over 800,000 confidential HIV tests were performed on women in the Title X program, with an additional 9,058 anonymous HIV tests performed on both men and women. Of the confidential tests, approximately 1200 were positive.[9] The role of the Title X family planning program in screening for HIV has grown over the past decade as the CDC has ramped up its efforts to include all public health providers in HIV prevention and treatment efforts. Between 2005 and 2009, the number of confidential HIV tests increased 64 percent, demonstrating the commitment of the Title X program to HIV screening. As with the STI counseling recommendation, the HIV counseling and screening recommendation will help cover the cost of HIV services currently being provided in the family planning setting.

Recommendation 5

The committee recommends for consideration as a preventive service for women: the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.

Half of all pregnancies in the U.S. are unintended, a rate significantly higher than in other developed countries. Of these, 42 percent end in abortion. Children born as the result of unintended pregnancies are more likely to be born preterm and to have lower birth weights and less likely to be breastfed. Direct medical costs of unintended pregnancy are estimated at around $11 billion. The *Healthy People 2020* objectives include increasing the percentage of pregnancies that are intended from 51 to 56 percent; notably, *Healthy People 2020* also includes a goal to increase the number of insurance plans offering contraceptive services and supplies.

Family planning services, including both contraceptive methods and counseling, allow women and their families to prevent unintended pregnancy and to promote optimal birth spacing.

Many private and public insurance plans include coverage for contraception. However, when cost-sharing mechanisms are in place, patients experience barriers to accessing these services. The ACA does not explicitly require coverage for contraception or contraceptive counseling, even though a wealth of evidence exists to show that family planning is effective at reducing unintended pregnancy. [10]

In 2009, Title X service sites provided at least one contraceptive method to over 4 million women. Of the 4.8 million female patients overall, almost 50% were using a highly effective method at last visit. Highly effective methods, such as intrauterine devices and oral contraceptives, are better at preventing pregnancy but are also more expensive than methods such as condoms or other barrier methods. [11]

[9] Fowler, CI, Gable, J, Wang, J, and Lloyd, SW. (November 2010). *Family Planning Annual Report: 2009 National Summary*. Research Triangle Park, NC: RTI International.
[10] *Id.* p.91-8.
[11] Fowler, CI, Gable, J, Wang, J, and Lloyd, SW. (November 2010). *Family Planning Annual Report: 2009 National Summary*. Research Triangle Park, NC: RTI International.

Of all the IOM recommendations, the contraceptive coverage requirement will have the most significant impact on the Title X provider network. More expensive contraceptive methods such as IUDs will no longer be financially out of reach for patients with commercial coverage, and will provide a new funding source for longer-acting methods, which could help providers expand their provision of these methods. However, expanded commercial reimbursement does not address how family planning providers will afford to stock the devices.

Recommendation 6

The committee recommends for consideration as a preventive service for women: comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding. (The ACA ensures that breastfeeding counseling is covered; however, the committee recognizes that interpretation of this varies.)

Breastfeeding improves health outcomes for both mothers and infants. The key timeframe for breastfeeding is during the first six months of life; the U.S. would save 911 excess deaths and $13 billion per year if all children were exclusively breastfeed during the first six months of life. In the U.S., there is a significant gap between the number of women who intend to breastfeed and the number who in fact breastfeed. Barriers to following through on these intentions include lack of support for breastfeeding skills and lack of reimbursement for lactation support and services. However, lactation support and supplies are not currently covered through the provisions of the ACA, in spite of significant evidence supporting the effectiveness of breastfeeding and the dearth of coverage. [12]

Recommendation 7

The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information about current and past violence and abuse from women and adolescent girls in a culturally sensitive and supportive manner to address current health concerns, prevent future health problems, and provide for the woman or girl's safety.

In the U.S., an estimated 1 to 5 million women are abused, either physically, sexually or emotionally, by intimate partners. The cost to taxpayers of interpersonal violence (IPV) is as much as $5.8 million, and women experiencing intimate partner violence have medical costs 60% higher than women not experiencing abuse. The health consequences of sexual or interpersonal violence can include physical injuries and death, as well as short- and long-term psychological conditions. Clinical guidelines for

[12] *Id.* p.98-105.

women and adolescents recommend both screening and counseling for interpersonal violence. The ACA does not provide for interpersonal and domestic violence detection and counseling. [13]

Although not included in every Title X program, IPV screening and counseling form an important part of the provision of family planning services. Many Title X and family planning clinic administrators have rigorous IPV intervention programs. As the women's health preventive coverage requirements become more available to all women, it may be advantageous to routinely track the accessibility of these services in family planning health clinics. The new recommendation will provide family planning providers with a new funding source to pay for these interventions.

Recommendation 8

The committee recommends for consideration as a preventive service for women: at least one well-woman preventive care visit annually for adult women to obtain the recommended preventive services, including preconception and prenatal care. The committee also recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.

Well-woman visits offer women the opportunity to receive preventive services recommended above, as well as preconception and prenatal care. The ACA provides for preventive services with no cost-sharing, but insurance plans may charge copayments for office visits. As mentioned above, even small cost-sharing requirements can prevent women from obtaining needed medical services. In the U.S., 44 percent of women, as compared with 35 percent of men, experienced difficulty paying medical bills in 2010. Clinical professional guidelines and current state and federal policies support coverage for well-woman visits so that preventive services may be offered without cost-sharing. [14]

In the Title X setting, over 9 million family planning visits occurred in 2009. This represents an average of about two visits per patient over the course of a year.[15] The impact of this coverage requirement could be significant, helping to alleviate the difficulty family planning providers experience in obtaining financing for not only the services provided during a family planning visit but the visit itself.

Process for Updating the Recommendations

In addition to determining the services for recommendation, the committee was also tasked with giving HHS guidance on a process for updating the recommendations. Recognizing that a scientific examination of clinical services would limit opportunities for outside influence, the committee first

[13] *Id.* p.105-10.
[14] IOM (Institute of Medicine). 2011. *Clinical Preventive Services for Women: Closing the Gaps.* Washington, DC: The National Academies Press. p.110-19.
[15] Fowler, CI, Gable, J, Wang, J, and Lloyd, SW. (November 2010). *Family Planning Annual Report: 2009 National Summary*. Research Triangle Park, NC: RTI International.

made recommendations intended to protect the integrity of any process HHS designed to update the services.

Under the rubric of "guiding principles" the committee recommended that any process for updating the preventive services be "independent, free of conflict of interest, evidence-based, gender specific, life-course oriented, transparent, informed by systemic surveillance and monitoring, cognizant of the need to integrate clinical preventive services with effective interventions in public health, the community, the workplace and the environment, and appropriately resourced to meet its mandate."[16] These principles serve to insulate the current recommendations and those that may come in the future from political and ideological influence.

The committee recommends that HHS facilitate a system in which it receives coverage recommendations from an established body and checks the recommendations by available or newly established clinical review organizations. The committee suggests that three separate bodies are needed to produce coverage decisions that are both supported by evidence and informed by an examination of "medicolegal considerations, ethical considerations, patient and provider preferences, cost, and cost-effectiveness."[17]

To update the coverage work, the committee recommends that HHS establish a Preventive Services Coverage Commission ("coverage commission") that will be responsible for proposing which new services should be covered under the ACA. Moreover, the coverage commission should continue to be independent from those bodies conducting evidence reviews because, in the opinion of the committee, clinical bodies often lack the expertise or "independence" needed to make coverage recommendations.

Impact on Publicly Supported Family Planning

In the recommendations for updating the preventive services and in the final reviews of its work the committee makes astute observations about public health delivery that resonate with safety-net providers generally and family planning providers specifically.

The committee acknowledges that while its work will fill many of the gaps that currently exist in insurance coverage for women's preventive health services, the work leaves out some preventive health interventions known to be successful in women's lives. "Although the ACA preventive coverage rules are clearly directed at clinical services, the committee recognizes that in view of the importance of community-based preventive services and the public health system in achieving clinical aims, the committee encourages the Secretary to consider widening the scope of authority to include public health efforts to more comprehensively address prevention."[18] The committee's acknowledgement that *systems* currently exist to further the public health goals, particularly for women, could be tremendously helpful in helping to highlight the role the women's health safety net plays in the lives of millions of

[16] *Id.* p, 145.
[17] *Id.* p. 145.
[18] *Id* .p. 147.

people. It may also be used to emphasize the value family planning providers and other safety-net systems have in advancing the goals of the ACA.

The committee also reinforces the potential impact the ACA – particularly the preventive health services policies – will have on millions of women:

> "The ACA offers much promise in promoting prevention as an effective tool to improve health and well-being. When patients have health insurance coverage, a clear understanding of recommended services and screenings, and a usual source of care, it is the committee's belief that positive health outcomes will ensue. The ACA provides hope in efforts to eliminate health disparities and improve the health and well-being of women, children, and men across the United States." [19]

To have contraceptive methods and counseling included as a recommendation is a preventive and public health victory, and throughout the IOM review process, NFPRHA consistently urged the committee to recommend that the full range of family planning services by covered by commercial insurance plans without co-pay, including the visit, the contraceptive method and the counseling associated with the visit. The need for preventive services such as family planning, STI/HIV testing and counseling, and cervical cancer screening will continue and possibly grow as patients gain insurance coverage.

Many family planning providers have routinely struggled with the lack of reimbursement for providing a variety of services involved in a family planning visit. In Title X sites in 2009, 66% of family planning patients lacked any form of insurance and 20% received public coverage such as Medicaid. Only 8% had private insurance.[20] As commercial insurance coverage begins to expand under the ACA, some of the patients currently being seen in Title X-funded centers will gain coverage for services like contraceptive methods and contraceptive counseling through the women's preventive service benefit. This coverage will allow providers to receive reimbursement through commercial insurance plans for previously unreimbursed or grant-subsidized services they are already providing to their patients.

The coverage recommendations promise to improve women's preventive health, but there may be some real financial implications – both positive and negative – in having preventive services offered in the family planning setting covered without a patient co-pay. For example, the contraceptive coverage recommendation will mandate coverage for more expensive contraceptive methods such as IUDs. However, the loss of a commercial co-payment could have a negative impact on the reimbursement rate insurance companies are willing to pay for these devices, meaning that the rate could fall short of the cost incurred by the health center.

---

[19] *Id.* p. 154.

[20] Fowler, CI, Gable, J, Wang, J, and Lloyd, SW. (November 2010). *Family Planning Annual Report: 2009 National Summary*. Research Triangle Park, NC: RTI International.

Moving forward, it will be important for NFPRHA and publicly supported family planning providers to assess the business implications of the IOM coverage requirements. Ultimately, however, the new coverage requirements of the women's health preventive services benefit will allow patients to receive needed care, without the burden of cost-sharing, and will allow providers to provide high-quality care with new financing.