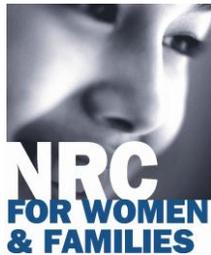


**JACOBS INSTITUTE
OF WOMEN'S HEALTH**



September 24, 2012

Ms. Danielle Holahan
New York State Health Benefit Exchange
New York State Department of Health

(Submitted electronically to Exchange@health.state.ny.us)

RE: Benchmark Options for Essential Health Benefits

Dear Ms. Holahan:

We write on behalf of three nonprofit women's organizations, the Jacobs Institute of Women's Health, the National Research Center for Women & Families, and Our Bodies Ourselves. Our national organizations are working collaboratively in key states to ensure that they provide appropriate, medically necessary healthcare coverage for women and families that is consistent with the guidelines and goals of the Affordable Care Act. We are dedicated to improving the health of women in New York State and across the country.

We would like to take this opportunity to comment on New York's selection on an Essential Health Benefits benchmark plan. We know how challenging it is to find a benchmark plan that protects and promotes the health of women and families, while striking a good balance that is affordable and fiscally responsible.

One issue of great concern to our organizations is insurance coverage for the medically necessary, timely removal of an implanted device when it fails or deteriorates in the body. Lack of insurance coverage for this care can lead to delays in removal which can have terrible repercussions for the health of the patient and enormous medical costs as well. The need for coverage for care of this kind rarely gets much attention, but it holds the potential to contribute to the health of millions of New York State adults and children who are living with implanted devices of many types.

Our organizations are particularly concerned with, and supportive of, coverage for the removal of breast implants when such removal is medically necessary because of leakage or other serious health problems. The Food and Drug Administration (FDA), which

regulates these products, clearly states that leaking implants should be removed as soon as possible.¹

Current federal law requires Medicare and virtually all types of insurance policies to cover the cost of reconstruction with breast implants after mastectomy.² This coverage includes the implantation of a device on the opposite side as well, to provide symmetry. If those implants leak and need to be removed, the law also helps women with the expenses associated with that surgery. All plans under consideration in New York State provide for this mandated coverage.

However, the Empire Plan explicitly excludes coverage of cosmetic or reproductive surgery or treatment that is primarily to change appearance. It is not clear whether that would exclude transgender individuals. The Empire plan is silent on whether it provides coverage for anyone who suffers from leaking breast implants that were initially implanted for cosmetic or transgender purposes. Regardless of the reason for the initial implant (breast reconstruction following mastectomy for breast cancer or implants for cosmetic or sex reassignment surgery), a woman suffering from a leaking breast implant experiences the same potentially serious complications.

Only about 25 percent of women with breast implants are mastectomy patients,³ leaving 75 percent of individuals with implants without the protection of federal law requiring coverage when their implants leak and require removal. Many individuals with implants are working class women who can't afford to fix implant problems if insurance doesn't cover it. This is particularly an issue for young women, transgender individuals, and those in the entertainment industry who get implants for job-related reasons.

Breast implants do not last a lifetime, and research shows that most women will have at least one broken implant within fifteen (15) years.⁴ Timely removal of these broken implants reduces problems caused by implant leakage, such as granulomas that can be mistaken for tumors, leaking silicone gel that can occur when a woman with broken implants undergoes mammography, or hardening/scarring of breast tissue (called capsular contracture) that can cause chronic breast pain.

It is vital that New York State's Essential Health Benefits include coverage for the more than 100,000 state residents with breast implants. The OXFORD HMO small group plan is the most generous plan in this regard. The Oxford HMO plan covers the removal of a ruptured silicone breast implant regardless of the indication for the initial implant placement. The Oxford HMO plan also provides coverage for the medically necessary

¹ U.S. Food and Drug Administration, Risks of Breast Implants. 6 June 2011. Accessed at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/Breastimplant/ucm064106.htm> on September 1, 2012.

² Women's Health and Cancer Rights Act of 1998 (P.L. 105-277) 29 U.S.C. Section 1185(b)

³ U.S. Food and Drug Administration. FDA Update on the Safety of Silicone-Gel Filled Breast Implants. Accessed at <http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM260139.pdf> on September 1, 2012.

⁴ See footnote 3.

removal of symptomatic breast implants for the most severe types of capsular contracture and for women who suffer with moderate or severe pain or debilitating limits to arm movement.

In our experience, failing to provide such coverage is penny wise and pound foolish, because medically-necessary and timely removal of broken breast implants reduces problems caused by leaking implants, such as silicone leakage into the lymph nodes, and from there to the lungs or liver, or debilitating breast pain that can result in unemployment and disability. In addition to the higher cost of treating such complications instead of preventing them, excluding coverage of medically necessary removal is very harmful to women's health. (Please note that we are discussing medically necessary removal only, we are not discussing replacement of broken implants.)

We are also concerned, however, about the Oxford plans exclusion of surgeries, drugs, and supplies "related to sex transformation," when such treatment is medically necessary. We believe that such exclusionary language is discriminatory and therefore contrary to New York State law. However, it seems that under the Empire plan, a person who had breast implants surgery as part of a "sex transformation" procedure might have no coverage to have the implants removed even if they were causing very serious health complications.

Although we prefer the Oxford HMO small group plan because it specifies coverage for the medically necessary and timely removal of broken breast implants, we also support the Empire Plan because of its more comprehensive coverage generally, and specifically its coverage of infertility treatment and transgender care.

Sincerely,

Susan F. Wood, Ph.D., Executive Director, Jacobs Institute of Women's Health
Diana Zuckerman, Ph.D., President, National Research Center for Women & Families
Judy Norsigian, Executive Director, Our Bodies, Ourselves

Founded in 1990, the Jacobs Institute of Women's Health works to improve health care for women through research, dialogue and information dissemination. Our mission is to identify and study women's health care issues involving the interaction of medical and social systems; to facilitate informed dialogue and foster awareness among consumers and providers alike; and promote problem resolution, interdisciplinary coordination and information dissemination at the regional, national and international levels. JIWH publishes the peer-reviewed multidisciplinary journal Women's Health Issues and is a program within the George Washington University School of Public Health and Health Services.

The National Research Center for Women & Families is dedicated to improving the health of adults and children by using research-based information to encourage new, more effective programs, policies and medical treatments. Founded in 1999, they work at the national, state and local level, assisting individuals, policymakers, agencies and other

organizations in order to ensure the best possible health care and reduce dangerous exposures in our homes and communities. Their primary program is their Cancer Prevention and Treatment Fund, although they work on an inclusive range of health and health policy issues.

Our Bodies Ourselves (OBOS) is a nonprofit, public interest women's health education, advocacy, and consulting organization operating for more than 40 years. Best known for the classic text, Our Bodies, Ourselves, we provide evidence-based information about health, sexuality and reproduction to improve decision-making at both the personal and policy levels.