NEW YORK STATE
DEPARTMENT of
FINANCIAL SERVICES

Andrew M. Cuomo
Governor

Maria T. Vullo
Superintendent

Insurance Circular Letter No. 2 (2016)
July 8, 2016

TO: **All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, Health Maintenance Organizations ("HMOs"), Student Health Plans Certified Pursuant to Insurance Law § 1124, and Municipal Cooperative Health Benefit Plans (collectively, "issuers")**

RE: **Health Insurance Coverage for the Prevention and Treatment of Breast Cancer**

STATUTORY AND REGULATORY REFERENCES: 42 U.S.C. § 300gg-13; 42 U.S.C. § 300gg-27; N.Y. Ins. Law §§ 3216, 3221, and 4303; and §§ 52.6 and 52.7 of 11 NYCRR 52 (Insurance Regulation 62)

I. Introduction

The purpose of this circular letter is to provide guidance on and remind insurers authorized to write accident and health insurance in this state, article 43 corporations, health maintenance organizations, student health plans certified pursuant to Insurance Law § 1124, and municipal cooperative health benefit plans (collectively, "issuers") of the state and federal requirements regarding health insurance coverage of preventive care and treatment for breast cancer – including prophylactic mastectomies – and new requirements contained in Chapter 74 of the Laws of 2016 with respect to all policies and contracts issued, renewed, modified or amended on or after January 1, 2017.

II. Discussion

A. Mammography Screenings

Insurance Law §§ 3216(i)(11)(A), 3221(l)(11)(A) and 4303(p)(1) require a policy or contract that provides coverage for hospital, surgical or medical care to provide coverage for mammograms at any age for a covered person that has a prior history of breast cancer or a first degree relative with a prior history of breast cancer when a physician recommends the mammogram. These sections also require a policy or contract to cover a single baseline mammogram for covered persons age 35 through 39, and an annual mammogram for persons age 40 and older. Chapter 74 of the Laws of 2016 amended Insurance Law §§ 3216(i)(11)(B), 3221(l)(11)(B), and 4303(p)(1)(D) to require that issuers cover all these mammography screenings without annual deductibles or coinsurance for policies and contracts issued, renewed, modified, or amended on or after January 1, 2017 with respect to participating providers in the issuer's network, or with respect to non-participating providers, if the issuer does not have a

participating provider in the in-network benefits portion of its network with the appropriate training and experience to meet the particular health care needs of the insured pursuant to Insurance Law § 3217-d(d) or 4306-c(d), or as applicable, Public Health Law § 4403(6)(a).

Currently, Insurance Law §§ 3216(i)(11)(D), 3221(1)(11)(D) and 4303(p)(3) only require a policy or contract that provides non-grandfathered coverage for hospital, surgical or medical care to provide coverage for evidenced-based items or services for mammography that have in effect a rating of "A" or "B"[1] in the current recommendations of the United States Preventive Services Task Force ("USPSTF") without annual deductibles or coinsurance, which is consistent with 42 U.S.C. § 300gg-13.[2] The USPSTF "B" rating list for breast cancer screening recommends screening mammography, with or without clinical breast examination, every one to two years for women age 40 and older. The USPSTF "B" recommended breast cancer screenings are less frequent than those screenings required under Insurance Law §§ 3216(i)(11)(A), 3221(l)(11)(A), and 4303(p)(1).

Chapter 74 of the Laws of 2016, as of January 1, 2017, has removed the financial barriers for all insureds with respect to the additional mammography screenings under Insurance Law §§ 3216(i)(11)(A), 3221(l)(11)(A) and 4303(p)(1) and also for insureds under "grandfathered health plans"[3], which means that all insureds will now be able to obtain mammography screenings at the frequency identified in Insurance Law §§ 3216(i)(11)(A), 3221(l)(11)(A) and 4303(p)(1) at no cost-sharing.

B. Screening and Diagnostic Imaging

Chapter 74 of the Laws of 2016 added new Insurance Law §§ 3216(i)(11)(F), 3221(l)(11)(F), and 4303(p)(5) to require that screening and diagnostic imaging for the detection of breast cancer, including diagnostic mammograms, breast ultrasounds, or magnetic resonance imaging, covered under the policy or contract, not be subject to annual deductibles or coinsurance, effective for policies or contracts that are issued, renewed, modified, or amended on or after January 1, 2017. This new law allows insureds who need additional screening or diagnostic imaging to detect breast cancer beyond a screening mammogram to receive these services without cost-sharing when the services are otherwise covered under the policy or contract. Chapter 74 of the Laws of 2016 amended the Insurance Law to remove financial barriers for insureds that need screening or diagnostic imaging services beyond a screening mammogram in order to promote early detection of breast cancer.

C. Genetic Screening and Medications

[1] The United States Preventive Services Task Force assigns one of five letter grades (A, B, C, D, or I) to services and treatments. Under federal law, only the A + B recommendations are required to be covered and carry no cost-sharing (*see*, 42 U.S.C. § 300gg-13).

[2] 42 U.S.C. § 300gg-13 is the federal law requiring certain preventive services be covered with no cost-sharing.

[3] A grandfathered health plan means coverage provided by an issuer in which an individual was enrolled on March 23, 2010, for as long as the coverage maintains grandfathered status in accordance with § 1251(e) of the Affordable Care Act, 42 U.S.C § 18011(e).

Insurance Law §§ 3216(i)(17)(E)(i), 3221(l)(8)(E)(i) and 4303(j)(3)(A) require a policy or contract that provides non-grandfathered coverage for hospital, surgical, or medical care to provide coverage for evidence-based items or services for preventive care and screenings that have in effect a rating of "A" or "B" in the current recommendations of the USPSTF. The Legislature added Insurance Law §§ 3216(i)(17)(E)(i), 3221(l)(8)(E)(i), and 4303(j)(3)(A) for consistency with 42 U.S.C. § 300gg-13.

The USPSTF "B" rating list recommends that primary care providers screen women who have family members with breast, ovarian, tubal, or peritoneal cancer with one of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (BRCA1 or BRCA2). The USPSTF "B" rating list further recommends that women with positive screening results should receive genetic counseling and, if indicated after counseling, BRCA testing.

The USPSTF "B" rating list recommends that clinicians engage in shared, informed decision making with women who are at increased risk for breast cancer about medications to reduce their risk. The USPSTF B rating list further recommends that for women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene.

Accordingly, based on the above state and federal laws, an issuer must provide coverage, with no cost-sharing requirements:

- for primary care providers to screen women who have family members with breast, ovarian, tubal, or peritoneal cancer with one of several screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (BRCA1 or BRCA2);

- to women who have positive screening results pursuant to the above-described screening for genetic counseling and, if indicated after counseling, BRCA testing; and

- for breast cancer risk reducing medications prescribed by a clinician to women who are at increased risk of breast cancer and at low risk for adverse medication effects.

D. Breast Cancer Treatment and Breast Reconstruction

Sections 52.6(a) and 52.7(c) of 11 NYCRR 52 (Insurance Regulation 62) define "basic medical insurance" and "major medical insurance", respectively, to include surgical services, consisting of operating and cutting procedures for the treatment of sickness or injury, and endoscopic procedures, including any pre-operative and post-operative care usually rendered in connection with such operation or procedure.

Insurance Law §§ 3216(i)(18)(A), 3221(k)(8)(A), and 4303(v)(1) require a policy or contract that provides coverage for inpatient hospital care to provide coverage for such period as is determined by the attending physician, in consultation with the patient, to be medically appropriate for the patient undergoing a lymph node dissection or a lumpectomy for the treatment of breast cancer or a mastectomy covered by the policy or contract.

Insurance Law §§ 3216(i)(20)(A), 3221(k)(10)(A), and 4303(x)(1) require a policy or contract that provide coverage for surgical or medical care to provide coverage for breast reconstruction surgery after a mastectomy or partial mastectomy, including all stages of reconstruction of the breast on which the mastectomy or partial mastectomy has been performed and surgery and reconstruction of the other breast to produce a symmetrical appearance, in the manner determined by the attending physician and patient to be appropriate.

The Employee Retirement Income Security Act, 29 U.S.C. § 1185b(a), made applicable by 42 U.S.C. § 300gg-27 to group health plans and issuers offering group or individual coverage, requires that issuers that provide medical and surgical benefits with respect to a mastectomy must provide coverage for all stages of reconstruction of the breast on which the mastectomy has been performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, and prostheses and physical complications of all stages of the mastectomy, including lymphedemas, in a manner determined in consultation with the attending physician and patient.

Accordingly, based on the above state and federal laws and regulations, an issuer must provide coverage:

- for medically necessary surgeries, including mastectomies and prophylactic mastectomies, in policies or contracts that provide basic medical insurance and major medical insurance. A prophylactic mastectomy is surgery to remove one or both breasts to reduce the risk of developing breast cancer. According to the National Institute of Health's National Cancer Institute, prophylactic mastectomies have been shown to reduce the risk of breast cancer by at least 95 percent in women who have a deleterious (disease-causing) mutation in the BRCA1 gene or the BRCA2 gene and by up to 90 percent in women who have a strong family history of breast cancer. See http://www.cancer.gov/types/breast/risk-reducing-surgery-fact-sheet. While an issuer may perform a medical necessity review of surgeries, the issuer should use appropriate written clinical criteria and the most recent medical literature to determine medical necessity;

- for inpatient care following a lymph node dissection or a lumpectomy for the treatment of breast cancer or a mastectomy covered by the policy or contract for as long as is medically appropriate as determined by the attending physician, in consultation with the patient. Pursuant to Insurance Law §§ 3216(i)(18)(A), 3221(k)(8)(A), and 4303(v)(1), the issuer may not conduct a medical necessity review of the services because the law requires coverage for as long as is medically appropriate as determined by the attending physician, in consultation with the patient;

- following a mastectomy or partial mastectomy, including a prophylactic mastectomy, for all stages of reconstruction of the breast on which the mastectomy or partial mastectomy has been performed, and surgery and reconstruction of the other breast to produce a symmetrical appearance, in the manner determined by the attending physician and patient to be appropriate. Pursuant to Insurance Law §§ 3216(i)(20)(A), 3221(k)(10)(A), and 4303(x)(1), the issuer may not conduct a medical necessity review of the services because the law requires coverage for reconstruction "in the manner determined by the attending

physician and the patient to be appropriate." See OGC Opinion No. 08-07-18 (July 22, 2008); and

- for prostheses, and physical complications of all stages of the mastectomy, including lymphedemas, in a manner determined in consultation with the attending physician and patient. While an issuer may perform a medical necessity review of these items or services, the issuer should use appropriate written clinical criteria and the most recent medical literature to determine medical necessity.

III. Conclusion

In accordance with state and federal laws and regulations, an issuer must provide coverage with no cost-sharing for breast cancer screenings, breast cancer risk assessments, genetic testing, and medications to reduce the risk of breast cancer. In addition, for policies or contracts issued, renewed, modified or amended on or after January 1, 2017, coverage for certain additional breast cancer screening and diagnostic imaging, including diagnostic mammograms, breast ultrasounds, or magnetic resonance imaging, must be provided without cost-sharing. An issuer must also provide coverage for mastectomies (including prophylactic mastectomies), partial mastectomies, lymph node dissections and lumpectomies, all stages of breast reconstruction surgery on the breast or breasts that were removed, and with respect to a single mastectomy, reconstruction of the other breast to produce a symmetrical appearance, prostheses, and physical complications of all stages of the mastectomy, including lymphedemas.

Please direct any questions regarding this circular letter to Thomas Fusco, Supervising Insurance Attorney, Health Bureau, New York State Department of Financial Services, Walter J. Mahoney Office Building, 65 Court Street, Room 7, Buffalo, New York 14202 or by e-mail at Thomas.Fusco@dfs.ny.gov.

Very truly yours,

Lisette Johnson
Bureau Chief, Health Bureau