NEW YORK STATE DEPARTMENT OF FINANCIAL SERVICES PROPOSED FIFTY-FOURTH AMENDMENT TO 11 NYCRR 52 (INSURANCE REGULATION 62)

MINIMUM STANDARDS FOR FORM, CONTENT AND SALE OF HEALTH INSURANCE, INCLUDING STANDARDS OF FULL AND FAIR DISCLOSURE

I, Maria T. Vullo, Superintendent of Financial Services, pursuant to the authority granted by Sections 202 and 302 of the Financial Services Law, Sections 301, 3216(i)(17), 3217, 3217-a, 3221(l)(8) and (16), 4303(j) and (cc), and 4324 of the Insurance Law, and Section 4408 of the Public Health Law, do hereby promulgate the Fifty-Fourth Amendment to Part 52 of Title 11 of the Official Compilation of Codes, Rules and Regulations of the State of New York (Insurance Regulation 62), to take effect immediately upon publication of the Notice of Adoption in the State Register and to apply to all policies and contracts issued, renewed, modified or amended after that date, to read as follows:

(DELETED MATTER IN BRACKETS; NEW MATTER UNDERSCORED)

Section 52.1(r) is added as follows:

(r)(1) It is the policy of the State of New York to protect women's access to comprehensive and affordable contraception. One of the greatest impediments to gender equality is the inability to make justified reproductive health decisions or decide when and if to become a parent. Contraception has been a critical tool for women to gain economic and social independence. The use, accessibility and availability of contraception also reduces the rate of unintended pregnancy and abortion. Irrespective of whether the federal government rolls back access to reproductive health care, the State of New York will protect women's unassailable rights to their reproductive freedom.

(2) Currently, the insurance coverage mandates for contraception are in federal statutes, federal regulations, state statutes, and state regulations. Section 52.17(a)(36) and (37) and Section 52.18(a)(11) and (12) of this Part provide a comprehensive list of these coverage mandates for individual, small group and large group comprehensive health insurance coverage that include:

(i) an insurer shall cover contraceptive drugs, devices or other products for women approved by the Federal Food and Drug Administration ("FDA") and voluntary sterilization procedures for women;

(ii) an insurer shall cover the initial dispensing of the entire prescribed supply, up to 12 months, of a prescription contraceptive,

(iii) an insurer shall cover at least one form of contraception within each of the methods of contraception that the FDA has identified for women without annual deductibles or coinsurance, including co-payments (collectively "cost-sharing");

(iv) where a form of contraception is covered without cost-sharing, an insurer shall cover services for insertion or implantation and services related to follow-up and management of side effects, counseling

for continued adherence, and device removal, without annual deductibles or coinsurance, including copayments;

(v) If a woman's attending health care provider recommends a particular contraceptive item or service approved by the FDA, based on a determination of medical necessity, that is subject to cost-sharing, then the insurer shall cover that item or service without annual deductibles or coinsurance, including co-payments. An insurer shall defer to the attending health care provider's determination of medical necessity. The superintendent may develop a standard exception form with instructions that an attending health care provider may use to prescribe a particular FDA-approved contraceptive item or service based on a determination of medical necessity for an insured. The insurer shall accept the standard exception form submitted by the insured's attending health care provider;

(vi) An insurer shall provide coverage for emergency contraception without cost sharing when provided pursuant to an ordinary prescription, a non-patient specific regimen order, or when lawfully provided other than through a prescription or order;

(vii) An insurer shall not impose cost-sharing on in-network voluntary sterilization procedures for women;

(viii) An insurer shall not impose any restrictions or delays, including quantity limits, on any mandatory contraception coverage; and

(ix) An insurer shall publish an up-to-date, accurate, and complete list of all covered contraceptive drugs, devices and other products on its formulary drug list in an easily accessible manner.

Sections 52.17(a)(36) and (37) are amended as follows:

(36) <u>The Insurance Law mandates coverage for various contraceptive items and services</u>. For coverage of contraceptive items or services provided pursuant to Insurance Law section 3216(i)(17), 4303(j) or 4303(cc), an insurer shall allow coverage for the dispensing of [an initial three-month supply of a contraceptive to an insured. For subsequent dispensing of the same contraceptive covered under the same policy or renewal thereof, an insurer shall allow coverage for the dispensing of] the entire prescribed supply, up to 12 months, of the contraceptive to the insured at the same time.

(37)(i) For coverage of [in-network] contraceptive items or services provided pursuant to Insurance Law section 3216(i)(17) [or], 4303(j) or 4303(cc), an insurer shall cover <u>contraceptive drugs</u>, <u>devices or other</u> products for women approved by the Federal Food and Drug Administration or generic equivalents approved as substitutes by the Federal Food and Drug Administration, including (1) over-the-counter contraceptive drugs, (2) over-the-counter contraceptive devices or other products for women, under the prescription or order of a health care provider, and (3) voluntary sterilization procedures for women.

(*a*) An insurer shall provide in-network coverage for at least one form of contraception within each of the methods of contraception that the Federal Food and Drug Administration has identified for women without annual deductibles or coinsurance, including co-payments. Additionally, where a form of contraception is covered pursuant to this paragraph without annual deductibles or coinsurance, including co-payments, an insurer

shall cover services for insertion or implantation and services related to follow-up and management of side effects, counseling for continued adherence, and device removal, without annual deductibles or coinsurance, including co-payments. If a woman's attending health care provider recommends a particular contraceptive item or service approved by the Federal Food and Drug Administration, based on a determination of medical necessity, that is subject to [cost-sharing] <u>annual deductibles or coinsurance, including co-payments</u>, then the insurer shall cover that item or service without annual deductibles or coinsurance, including co-payments. The insurer shall defer to the attending health care provider's determination of medical necessity. <u>The superintendent may develop a standard exception form with instructions that an attending health care provider may use to prescribe a particular Federal Food and Drug Administration-approved contraceptive item or service based on a determination of medical necessity for an insured. The insurer shall accept the standard exception form submitted by the insured's attending health care provider.</u>

(b) An insurer shall provide coverage for emergency contraception, without annual deductibles or coinsurance, including co-payments when provided pursuant to an ordinary prescription, a non-patient specific regimen order, over-the-counter, or when otherwise lawfully provided.

(c) An insurer shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on in-network voluntary sterilization procedures for women required to be covered pursuant to this subparagraph.

(ii) Except as otherwise authorized under this paragraph or paragraph (36) of this subdivision, a policy shall not impose any restrictions or delays, including quantity limits, on the coverage required under this paragraph.

(iii) An insurer shall publish an up-to-date, accurate, and complete list of all covered contraceptive drugs, devices and other products on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug may be obtained, in a manner that is easily accessible to insureds and prospective insureds. The formulary drug list shall clearly identify the contraceptive drugs, devices and other products that are available without annual deductibles or coinsurance, including co-payments, in compliance with subparagraph (i)(a) of this paragraph.

Sections 52.18(a)(11) and (12) are amended as follows:

(11) <u>The Insurance Law mandates coverage for coverage of contraceptive items or services</u>. For coverage of contraceptive items or services provided pursuant to Insurance Law section 3221(l)(8), 3221(l)(16), 4303(j) or 4303(cc), an insurer shall allow coverage for the dispensing of [an initial three-month supply of a contraceptive to an insured. For subsequent dispensing of the same contraceptive covered under the same policy or renewal thereof, an insurer shall allow coverage for the dispensing of] the entire prescribed supply, up to 12 months, of the contraceptive to the insured at the same time.

(12)(i) For coverage of [in-network] contraceptive items or services provided pursuant to Insurance Law section 3221(1)(8) [or], 3221(1)(16), 4303(j) or 4303(cc), an insurer shall cover contraceptive drugs, devices or other products for women approved by the Federal Food and Drug Administration or generic equivalents approved as substitutes by the Federal Food and Drug Administration, including (1) over-the-counter contraceptive drugs, (2) over-the-counter contraceptive devices or other products for women under the prescription or order of a health care provider, and (3) voluntary sterilization procedures for women.

(a) An insurer shall provide in-network coverage for at least one form of contraception within each of the methods of contraception that the Federal Food and Drug Administration has identified for women without annual deductibles or coinsurance, including co-payments. Additionally, where a form of contraception is covered pursuant to this paragraph without annual deductibles or coinsurance, including co-payments, an insurer shall cover services for insertion or implantation and services related to follow-up and management of side effects, counseling for continued adherence, and device removal, without annual deductibles or coinsurance, including co-payments. If a woman's attending health care provider recommends a particular contraceptive item or service approved by the Federal Food and Drug Administration, based on a determination of medical necessity, that is subject to annual deductibles or coinsurance, including co-payments [cost-sharing], then the insurer shall cover that item or service without annual deductibles or coinsurance, including co-payments. The insurer shall defer to the attending health care provider's determination of medical necessity. The superintendent may develop a standard exception form with instructions that an attending health care provider may use to prescribe a particular Federal Food and Drug Administration-approved contraceptive item or service based on a determination of medical necessity for an insured. The insurer shall accept the standard exception form submitted by the insured's attending health care provider.

(b) An insurer shall provide coverage for emergency contraception, without annual deductibles or coinsurance, including co-payments when provided pursuant to an ordinary prescription, a non-patient specific regimen order, over-the-counter, or when otherwise lawfully provided.

(c) An insurer shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on in-network voluntary sterilization procedures for women required to be covered pursuant to this subparagraph.

(ii) Except as otherwise authorized under this paragraph or paragraph (11) of this subdivision, a policy shall not impose any restrictions or delays, including quantity limits, on the coverage required under this paragraph.

(iii) An insurer shall publish an up-to-date, accurate, and complete list of all covered contraceptive drugs, devices and other products on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug may be obtained, in a manner that is easily accessible to insureds and prospective insureds. The formulary drug list shall clearly identify the contraceptive drugs, devices and other products that are available without annual deductibles or coinsurance, including co-payments, in compliance with subparagraph (i)(a) of this paragraph.

Pursuant to the authority vested in the Commissioner of Health by section 365-a of the Social Services Law and section 201(1)(v) of the Public Health Law, Part 505 of Title 18 (Social Services) of the Official Compilation of Codes, Rules, and Regulations of the State of New York is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (d) of Section 505.3 is amended to read as follows:

(d) Prescription refills.

(1) A written order may not be refilled unless the practitioner has indicated the number of allowable refillings on the order.

(2) No written order for drugs may be refilled more than six months after the date of issuance, nor more than five times within a six month period, with the exception of prescription contraceptives for family planning purposes, which may be filled twelve times within one year after the date of issuance.

(3) Refills must bear the prescription number of the original written order.

Subparagraph (ii) of paragraph (2) of subdivision (e) of Section 505.3 is amended to read as follows:

(e) Prescribed quantities.

(1) Drugs must be ordered in a quantity consistent with the health needs of the patient and sound medical practice.

(2) Dispensing limits for drugs.

(i) Except as provided in subparagraph (ii) of this paragraph, the maximum quantity of

drugs dispensed is limited to the larger of:

(a) a 30 day supply; or

(b) 100 doses. One hundred doses is 100 units of a solid formulation.

(ii) The dispensing limit does not apply to long-term maintenance drugs. Long-term maintenance drugs are:

(a) drugs ordered or prescribed with one or more refills in quantities of a 30day supply or greater. The quantity ordered or prescribed must be based on generally accepted medical practice. The ordering practitioner must be contacted if dispensing the supply specified in the prescription would result in the medical assistance recipient receiving a quantity of drugs which exceeds the manufacturer's labeling indications; or

(b) drugs ordered or prescribed without refills in quantities of a 60-day supply or greater. The quantity ordered or prescribed must be based on generally accepted medical practice. The ordering practitioner must be contacted if dispensing the supply specified in the prescription would result in the medical assistance recipient receiving a quantity of drugs which exceeds the manufacturer's labeling indications; or

(c) drugs ordered or prescribed for family planning purposes. The quantity ordered or prescribed must be based on generally accepted medical practice.
Prescription contraceptives for family planning purposes may be dispensed in a twelve-month supply at one time; or

(d) prescriptions written and dispensed on the official New York StatePrescription Form for up to a three-month supply when written in conformity withthe Controlled Substance Act (Title IV of Article 33 of the Public Health Law).