

**INSURANCE
DIVISION OF INSURANCE**

**Actuarial Services
Benefit Standards for Infertility Coverage**

Proposed New Rules: N.J.A.C. 11:4-54

Authorized By: Holly C. Bakke, Commissioner, Department of Banking and Insurance.

Authority: N.J.S.A. 17:1-8.1 and 15e; P.L. 2001, c. 236.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2002-260

Submit comments by October 4, 2002 to:

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The agency proposal follows:

Summary

P.L. 2001, c. 236, approved August 31, 2001 (the Act), mandates that all New Jersey health insurers insuring groups of 50 or more persons and providing hospital or medical benefits, including pregnancy-related benefits, provide coverage for medically necessary expenses incurred in the diagnosis and treatment of infertility. The Act requires that the mandated benefits be provided to the same extent as for other pregnancy-related procedures under the contract, except that infertility services are

required to be performed at facilities that conform to standards established by the American Society for Reproductive Medicine or the American College of Obstetricians and Gynecologists. The Act further provides that the same copayments, deductibles and benefit limits be applied to infertility benefits as to other medical or surgical benefits under the contract. The Act also permits religious employers to exclude certain coverage if it is contrary to the religious employer's bona fide religious tenets.

The Department of Banking and Insurance (Department) is proposing these new rules for the purpose of implementing the Act by establishing uniform definitions of terms associated with infertility coverage, and benefits that must be provided for infertility in this State.

The Department's proposed provisions include the following:

N.J.A.C. 11:4-54.1 sets forth the purpose and scope of these new rules.

N.J.A.C. 11:4-54.2 contains definitions for terms used throughout the subchapter.

N.J.A.C. 11:4-54.3 requires infertility coverage to be provided to the same extent as other pregnancy-related procedures, and prohibits carriers from imposing a separate copayment, coinsurance, deductible, dollar maximum, visit maximum or procedure maximum on any infertility treatment except for limiting infertility coverage to four completed egg retrievals per lifetime of the covered person. This section also prohibits carriers from imposing a separate preauthorization notice or other utilization management requirement on all infertility treatment. This section permits carriers to limit benefits to services performed at facilities that conform to standards established by

the American Society for Reproductive Medicine or the American College of Obstetricians and Gynecologists.

N.J.A.C. 11:4-54.4 sets forth the benefits that carriers are required to provide for infertility treatment.

N.J.A.C. 11:4-54.5 lists the permissible exclusions from fertility benefits required to be provided.

N.J.A.C. 11:4-54.6 permits religious employers to exclude coverage for certain infertility treatments and procedures only if those treatments or procedures are contrary to the employer's bona fide religious tenets, and requires insurers to provide written notice of such exclusion to all prospective insureds or covered persons.

N.J.A.C. 11:4-54.7 states that all forms previously filed or approved by the Commissioner, but fail to comply with the requirements of these proposed rules, are deemed withdrawn.

As the Department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

These proposed new rules will have a positive social impact on eligible infertile individuals who have been unable to obtain certain infertility treatment because of affordability issues. These proposed new rules will assure those individuals that such treatment will be covered by large group health plans.

Economic Impact

These proposed new rules will have a favorable impact on those individuals who are eligible to obtain mandated infertility treatment in that such treatment previously paid for out-of-pocket will now be covered by their group health insurance plan.

Health carriers will likely be unfavorably impacted by these proposed new rules because they will be required to provide benefits for all medically necessary expenses incurred in the diagnosis and treatment of infertility that they may not have been providing prior to this statutory mandate, including but not limited to diagnosis and diagnostic tests, medications, surgery, in vitro fertilization, embryo transfer, artificial insemination, gamete intra fallopian transfer, zygote intra fallopian transfer, intracytoplasmic sperm injection, and four completed egg retrievals per lifetime of the covered person.

Federal Standards Statement

A Federal standards analysis is not required because these rules mandate that certain benefits for the treatment of infertility be provided pursuant to P.L. 2001, c. 236, and are not subject to any Federal requirements or standards.

Jobs Impact

The Department does not anticipate that the proposed new rules will result in the generation or loss of jobs.

Regulatory Flexibility Analysis

The Department believes that the proposed new rules will apply to few, if any, "small businesses" as that term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. To the extent that the proposed new rules apply to small businesses, such small businesses will be health carriers authorized to transact business in this State. The rules may require such small business health carriers to incur additional costs in providing benefits for infertility treatment that may not have been provided previously. However, these proposed new rules should not independently impose any undue additional costs or burdens on any health carriers in that the rules merely implement the statutory requirements of P.L. 2001, c. 236.

The proposed new rules provide no different reporting, recordkeeping or compliance requirements based on carrier size. As indicated in the Summary above, the rules set forth which carriers will be required to provide the infertility treatment mandated by P.L. 2001, c. 236, and that legislation provides no different compliance requirements based on carrier size. Since the statutory requirements do not vary based on carrier size, and no additional adverse economic impact should be directly imposed by these rules, the Department believes that different reporting or compliance requirements based on carrier size would not be appropriate or feasible. Accordingly, the proposed new rules provide no differentiation in compliance requirements based on carrier size. The Department does not anticipate that carriers will need to hire

additional employees or obtain any other professional services to comply with the rules' requirements.

Smart Growth Impact

The proposed new rules have no impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Full text of the proposed new rules follows:

SUBCHAPTER 54. BENEFIT STANDARDS FOR INFERTILITY COVERAGE

11:4-54.1 Purpose and scope

(a) The purpose of this subchapter is to implement P.L. 2001, c. 236 by establishing uniform definitions of terms associated with infertility coverage and benefits that must be provided for infertility in this State.

(b) This subchapter shall apply to all policies, contracts, riders and endorsements delivered, issued, executed or renewed in this State by health service corporations, hospital service corporations, medical service corporations, health insurance companies and health maintenance organizations for groups of 50 or more persons that provide hospital or medical benefits, including pregnancy-related benefits. This subchapter shall also apply to all certificates_and evidence of coverage forms delivered, issued, executed or renewed in this State where the related group policy or

contract is delivered, issued, executed or renewed in this State for groups of 50 or more persons that provide hospital or medical benefits, including pregnancy-related benefits.

(c) This subchapter shall not apply to any policy or contract which, pursuant to a contract between a carrier and the New Jersey Department of Human Services, provides benefits to persons who are eligible for medical assistance under P.L. 1968, c. 413 (N.J.S.A. 30:4D-1 et seq.); the Children's Health Care Coverage program under P.L. 1997, c. 272 (N.J.S.A. 30:4I-1 et seq.); the FamilyCare Health Coverage Program under P.L. 2000, c. 71 (N.J.S.A. 30:4J-1 et seq.); or any other program administered by the Division of Medical Assistance and Health Services in the New Jersey Department of Human Services.

11:4-54.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise:

"Artificial insemination" means the introduction of sperm into a woman's vagina or uterus by noncoital methods for the purpose of conception, and includes intrauterine insemination.

"Assisted reproductive technologies" or "ART" means all treatments or procedures, including prescription drug therapy, whereby eggs are surgically removed from a woman's ovaries and combined with sperm in the laboratory, and returned to the woman's body or donated to another woman.

“Assisted hatching” means a micromanipulation technique in which a fine needle is used to drill a hole in the shell of an egg to assist the sperm in fertilizing the egg.

“Carrier” means a health service corporation, hospital service corporation, medical service corporation, insurance company and a health maintenance organization.

“Completed egg retrieval” means all office visits, procedures and laboratory and radiological tests performed in preparation for oocyte retrieval; retrieval of the oocyte(s); and culture and fertilization of the oocyte(s).

“Cryopreservation” means the freezing of embryos in liquid nitrogen until such time as required for a frozen embryo transfer. Cryopreservation also refers to the freezing of sperm.

“Egg retrieval” or “oocyte retrieval” means a procedure by which eggs are collected from a woman’s ovarian follicles.

“Egg transfer” or “oocyte transfer” means the transfer of retrieved eggs into a woman’s fallopian tubes through laparoscopy as part of gamete intrafallopian transfer (GIFT).

“Embryo” means a fertilized egg that has begun cell division and has completed the pre-embryonic stage.

“Embryo transfer” means the placement of an embryo into the uterus through the cervix or, in the case of zygote intrafallopian tube transfer (ZIFT), the placement of an embryo in the fallopian tube. Embryo transfer includes the transfer of cryopreserved embryos and donor embryos.

"Fertilization" means the penetration of the egg by the sperm and the resulting combination of genetic material that develops into an embryo.

"Gamete" means a reproductive cell. In a male, gametes are sperm; in a female, gametes are eggs or ova.

"Gamete intrafallopian tube transfer" or "GIFT" means the direct transfer of a sperm/egg mixture into the fallopian tube by egg transfer. Fertilization takes place inside the fallopian tube.

"Gestational carrier" means a woman who carries an embryo that was formed from the egg of another woman.

"Infertility" means a disease or condition that results in the abnormal function of the reproductive system such that:

- (1) A male is unable to impregnate a female;
- (2) A female under 35 years of age is unable to conceive after two years of unprotected sexual intercourse;
- (3) A female 35 years of age and over is unable to conceive after one year of unprotected sexual intercourse;
- (4) The male or female is medically sterile; or
- (5) The female is unable to carry a pregnancy to live birth.

Infertility shall not mean a person who has been voluntarily sterilized regardless of whether the person has attempted to reverse the sterilization.

"Infertility coverage" means coverage required by P.L. 2001, c. 236 for the diagnosis and treatment of infertility.

“Intracytoplasmic sperm injection” or “ICSI” means a micromanipulation procedure whereby a single sperm is injected into the center of an egg.

“Intrauterine insemination” means a medical procedure whereby sperm is placed into a woman’s uterus to facilitate fertilization.

“In vitro fertilization” or “IVF” means an ART procedure whereby eggs are removed from a woman’s ovaries and fertilized outside her body. The resulting embryo is then transferred into a woman’s uterus.

“Microsurgical sperm aspiration” means the techniques used to obtain sperm for use with intracytoplasmic sperm injection (ICSI) in cases of obstructive azoospermia. It can involve the extraction of sperm and fluid from epididymal tubules inside the epididymis (“MESA”) or the provision of testicular tissue from which viable sperm may be extracted (“TESE”).

“Oocyte” means the female egg or ovum.

“Ovulation induction” means the use of drugs (oral or injected) to stimulate the ovaries to develop follicles and eggs.

“Pregnancy-related benefits” means benefits for normal pregnancy and childbirth.

“Religious employer” means an employer that is a church, convention or association of churches, or any group or entity that is operated, supervised or controlled by or in connection with a church, convention or association of churches, as defined in 26 U.S.C. §3121(w)(3)(A) (Federal Insurance Contributions Act) and that

qualifies as a tax-exempt organization under 26 U.S.C. §501(c)(3) (Internal Revenue Code, Exempt Organizations).

“Sexual intercourse” means sexual union between a male and a female.

“Zygote” means a fertilized egg before cell division begins.

“Zygote intrafallopian tube transfer” or “ZIFT” means a procedure whereby an egg is fertilized in vitro, and the zygote is transferred to the fallopian tube at the pronuclear stage before cell division takes place.

11:4-54.3 Infertility coverage provided to the same extent as other pregnancy-related procedures

(a) A carrier shall not impose a separate copayment, coinsurance, deductible, dollar maximum, visit maximum or procedure maximum on any infertility treatment other than limiting infertility coverage to four completed egg retrievals per lifetime of the covered person.

(b) A carrier shall not impose a separate preauthorization notice or other utilization management requirement on infertility treatment. (For example, if a carrier requires all hospitalizations or all surgeries to be preauthorized, and a particular infertility treatment is to be performed during a hospitalization or is a surgical procedure, the carrier may require preauthorization of the treatment. But a carrier shall not require that all infertility treatments be preauthorized.)

(c) A carrier may limit benefits required to be provided pursuant to this subchapter to services performed at facilities that conform to standards established by

the American Society for Reproductive Medicine or the American College of Obstetricians and Gynecologists. Carriers shall not impose any additional standards in the group policy or contract and in the certificate or evidence of coverage applicable to fertility services on facilities or other providers.

11:4-54.4 Required benefits

(a) Infertility coverage shall include payment of benefits for the following:

1. Artificial insemination with no limit as to the number of cycles;
2. Assisted hatching;
3. Diagnosis and diagnostic tests;
4. Fresh and frozen embryo transfer;
5. Four completed egg retrievals per lifetime of the covered person.
 - i. Where a live donor is used in the egg retrieval, the medical costs of the donor shall be covered;
 - ii. Egg retrievals where the cost was not covered by any carrier shall not count in determining whether the four completed egg retrieval limit has been met;
6. Gamete intrafallopian transfer and zygote intrafallopian transfer;
7. Intracytoplasmic sperm injections;
8. In vitro fertilization, including in vitro fertilization using donor eggs and in vitro fertilization where the embryo is transferred to a gestational carrier or surrogate;
9. Medications, including injectible infertility medications, even if the contract or policy does not provide prescription drug benefits. Where a contract or

policy provides both prescription drug and medical and hospital benefits, infertility drugs shall be covered under the prescription drug coverage;

10. Ovulation induction; and

11. Surgery, including microsurgical sperm aspiration.

11:4-54.5 Permissible benefit exclusions

(a) Following are the only permissible exclusions from the infertility benefit requirements of this subchapter:

1. Reversal of voluntary sterilization. Coverage for infertility services provided to partners of persons who have successfully reversed sterilization may not be excluded;

2. Payment for medical services rendered to a surrogate for purposes of childbearing where the surrogate is not covered by the carrier's policy or contract;

3. Costs associated with cryopreservation and storage of sperm, eggs and embryos;

4. Nonmedical costs of an egg or sperm donor. Medical costs of donors, including office visits, medications, laboratory and radiological procedures and retrieval, shall be covered.

5. Infertility treatments that are experimental or investigational in nature;

6. Ovulation kits and sperm testing kits and supplies;

7. In vitro fertilization, gamete intrafallopian tube transfer, and zygote intrafallopian tube transfer for persons who have not used all reasonable less expensive and medically appropriate treatments for infertility, who have exceeded the limit of four covered completed egg retrievals, or who are 46 years of age or older; and

8. Group policies, contracts, riders and endorsements that provide hospital or medical benefits, other than policies or contracts that provide prescription drug benefits only, may provide that infertility medication benefits are excluded if infertility medication benefits are provided under another group health insurance policy or contract issued to the same policyholder or contractholder.

11:4-54.6 Religious employer exclusions

(a) A carrier shall exclude coverage for in vitro fertilization, embryo transfer, artificial insemination, zygote intrafallopian transfer, gamete intrafallopian transfer, and intracytoplasmic sperm injection at the request of a religious employer only if the required coverage is contrary to the religious employer's bona fide religious tenets.

(b) A carrier that issues a policy or contract containing a religious employer exclusion shall provide written notice of such exclusion to each prospective insured or covered person. Such notice shall appear in not less than 10-point type in the certificate or evidence of coverage, the covered person's application or enrollment form, and all sales and marketing materials.

11:4-54.7 Effect on previously filed forms

Forms previously filed or approved by the Commissioner pursuant to N.J.S.A. 17B:27-49 and 26:2J-43 that contain provisions not in compliance with this subchapter shall be deemed withdrawn and shall not be delivered, issued, executed or renewed.

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