

**INSURANCE  
DEPARTMENT OF BANKING AND INSURANCE  
DIVISION OF INSURANCE**

**Actuarial Services  
Benefit Standards for Infertility Coverage  
Adopted New Rules: N.J.A.C. 11:4-54**

Proposed: August 5, 2002 at 34 N.J.R. 2521(a).

Adopted: March 26, 2003 by Holly C. Bakke, Commissioner, Department of Banking and Insurance.

Filed: March 26, 2003 as R. 2003 d.160, **with substantive changes** not requiring additional public notice and opportunity for comment (see N.J.A.C. 1:30-6.3).

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

Effective Date: April 21, 2003.

Expiration Date: November 30, 2005.

**Summary** of Public Comments and Agency Responses:

The Department received comments from the following: Health Net of New Jersey, Inc.; Marsh USA, Inc. on behalf of MIIX Group of Companies; New Jersey Association of Health Plans; Robyn Nutter; Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey; Diocese of Camden; Oxford Health Plans; Flaster Greenberg on behalf of RESOLVE of New Jersey; and AmeriHealth HMO, Inc. and AmeriHealth Insurance Company, Inc.

**COMMENT:** One commenter stated that while P.L. 2001, c. 236 states that "No certificate of authority to establish and operate a health maintenance organization in this State shall be issued or continued . . . unless the health maintenance organization provides . . . for medically necessary expenses incurred in the diagnosis and treatment

of infertility[,] . . ." the Department's proposal at N.J.A.C. 11:4-54.1(b) does not include the phrase "certificate of authority." The commenter stated that the rules should clearly provide that an HMO may not operate in New Jersey unless it fully complies with the law.

**RESPONSE:** The Department agrees with the commenter. Under the Department's proposed language, out-of-State contracts issued by HMOs that are licensed in New Jersey would not have been required to comply with the law. To make the new rules consistent with the statutory mandate, the Department has revised N.J.A.C. 11:4-54.1(b) to reflect that all contracts and evidence of coverage forms issued by HMOs, other than those issued to small employers as defined at N.J.S.A. 17B:27A-17, that include pregnancy-related coverage are required to provide infertility benefits.

**COMMENT:** Two comments concerned the proposed definition of "assisted reproductive technologies" or "ART." One commenter stated that the definition should be amended to include gamete intrafallopian transfer and zygote intrafallopian tube transfer procedures because those procedures are included in the American Society for Reproductive Medicine (ASRM) definition of ART. The second commenter stated that medical advances and laboratory technologies are what are considered ART, not the act of retrieving eggs, although in most cases retrieving eggs is a critical part of a complete ART procedure. The commenter included the ASRM and the International Council on Infertility Information Dissemination (INCIID) definitions of ART. ASRM defines ART as "procedures in which pregnancy is attempted through gamete manipulation outside of the body, such as in vitro fertilization or gamete intrafallopian transfer." INCIID defines

ART as "several procedures employed to bring about conception without sexual intercourse, including IUI, IVF, GIFT and ZIFT." The commenter suggested that the phrase "whereby eggs are surgically removed from a woman's ovaries" be deleted from the definition.

**RESPONSE:** The Department is deleting the definition in its entirety because the term "assisted reproductive technology" is not used in the text of the rules.

**COMMENT:** One comment concerned the proposed definition of "assisted hatching." The commenter stated that the proposed definition describes a type of assisted hatching that most facilities no longer use, and that this procedure is not used to assist in fertilization of the egg, but is used on an already formed embryo. The commenter suggested revising the definition to state that assisted hatching means "a micromanipulation technique in which a hole is artificially created in the outer shell of any embryo to assist with the potential implantation of that embryo."

**RESPONSE:** The Department agrees, and is revising the definition as suggested by the commenter.

**COMMENT:** Three comments concerned the proposed definition of "completed egg retrieval." One commenter stated that the definition should include medications.

The second commenter stated that the proposed definition could be interpreted as only counting successful egg retrievals, which could result in numerous attempts being made and billed by providers without reaching the limit of four completed egg retrievals per lifetime. The commenter suggested that all attempted egg retrievals be counted if they are billed, whether successful or not; and if a provider decides not to

charge for a cycle in which no eggs are obtained, the unsuccessful attempt would not be counted.

The third commenter stated that the phrase "culture and fertilization of the oocyte(s)" should be deleted from the definition because the fertilization that occurs outside the body falls under the concept of ART. The commenter expressed concern that carriers may interpret the proposed definition to mean that every ART procedure requiring fertilization of an egg constitutes a "completed egg retrieval." The commenter further stated that the definition's reference to "all office visits, procedures and laboratory and radiological tests" should be included only if there are standard industry-wide billing procedures and CPT codes applicable solely to egg retrieval as opposed to similar visits, procedures and tests conducted for other reasons. The commenter stated that it appears that the law intended to limit a "completed egg retrieval" to only the actual surgical procedure and its related expenses to remove eggs from a woman's ovaries because the law lists as separate benefits all aspects of infertility treatment performed after egg retrieval. Accordingly, any other type of treatment (for example, an office visit to discuss the procedure) should not be considered a "completed egg retrieval" and counted against the lifetime maximum.

**RESPONSE:** The Department does not agree that the definition of "completed egg retrieval" should include medications because medications are a separate required benefit at N.J.A.C. 11:4-54.4(a)9.

The Department agrees with the comment that all attempted egg retrievals for which coverage is sought, whether successful or not, should be counted toward the four-per-lifetime maximum, and is revising the definition accordingly.

The Department does not believe that "culture and fertilization of the oocyte(s)" or "all office visits, procedures and laboratory and radiological tests" should be deleted from the definition. The definition of "egg retrieval" as a procedure by which eggs are collected from a woman's ovarian follicles eliminates any possible misinterpretation that each and every ART procedure, office visit or test would be considered a completed egg retrieval. Further, the Department does not believe that separate CPT codes applicable to egg retrieval for office visits, procedures or tests covered by the mandate are necessary. The law references several items that may or may not be part of a completed egg retrieval.

**COMMENT:** One commenter stated that the definition of "cryopreservation" should be amended to include female gametes (ova) because cryopreservation is a technique used to store gametes and/or embryos for future infertility procedures and the definition should not be restricted to male gametes (sperm).

**RESPONSE:** The Department's proposed definition did include embryos. However, to further clarify its text, the Department is revising the definition upon adoption to include both female and male gametes.

**COMMENT:** Two commenters stated that the Department's proposed definition of "egg transfer" should be amended to clarify that zygote transfers can be either fresh or frozen. One of the commenters stated that the term "retrieved" could suggest that

every egg transfer is part of a "completed egg retrieval" process, and counts toward the four-per-lifetime maximum.

**RESPONSE:** The Department does not believe it is necessary to amend the definition because N.J.A.C. 11:4-54.4(a)4 requires benefits to be paid for fresh and frozen embryo transfers. Also, as stated in a previous Response, the definition of "egg retrieval" eliminates any possible misinterpretation that an egg transfer alone constitutes a completed egg retrieval.

**COMMENT:** One comment concerned the proposed definition of "fertilization." The commenter suggested deleting "and the resulting combination of genetic material that develops into an embryo" because it draws a conclusion that an embryo will result.

**RESPONSE:** Although the Department's definition is technically correct, the definition is being revised as suggested by the commenter for clarification.

**COMMENT:** One comment concerned the proposed definition of "gamete intrafallopian tube transfer" or "GIFT." The commenter suggested revising the definition to read that GIFT means "the direct transfer of a sperm/egg mixture into the fallopian tube by laparoscopy" because GIFT is only performed by laparoscopy and not by an IVF procedure.

**RESPONSE:** The Department agrees, and is revising the definition accordingly.

**COMMENT:** One commenter stated that the proposed definition of "gestational carrier" should be revised to clarify that the term is used to describe a female who has contracted with a third-party for the purpose of that female becoming pregnant with an embryo or embryos that are not part of her own genetic or biologic entity.

**RESPONSE:** The Department partially agrees with the commenter, and is revising the definition to mean "a woman who has become pregnant with an embryo or embryos that are not part of her genetic or biologic entity, and who intends to give the child to the biological parents after birth." However, the Department does not agree that the definition should allude to any contractual relationship that may, or may not, exist. For example, a gestational carrier may be a family member who does not have a contract with the biological parents.

**COMMENT:** One commenter stated that the definition of "infertility" should be revised because the proposed definition, which describes infertility as "a male [who] is unable to impregnate a female," will require coverage only for heterosexual couples. According to the commenter, the definition should be gender neutral and conform to the language of the law (that is, "a person is not able to impregnate another person[.] . . ." As an example, the commenter states that a female in a homosexual relationship who is diagnosed with infertility ought to be covered under the proposed definition without regard to whether she had unprotected sexual intercourse for one or two years.

**RESPONSE:** The Department does not believe it is necessary to revise the proposed definition of "infertility." A female in a homosexual relationship would not necessarily be excluded from coverage under this definition, but to obtain coverage she would be required to establish infertility pursuant to this subchapter's definition of that term.

**COMMENT:** One commenter expressed concern with the language in the proposed definition stating that "[i]nfertility shall not mean a person who has been

voluntarily sterilized regardless of whether the person has attempted to reverse the sterilization." The commenter indicated that a person who has successfully reversed a sterilization procedure could still be infertile, and should be eligible for coverage under the law.

**RESPONSE:** The Department agrees with the commenter that a person who has successfully reversed a sterilization procedure could still be infertile. However, it would be difficult for a carrier to medically determine whether, or the extent to which, the sterilization contributed to the infertility. For that reason, these rules do not require carriers to provide infertility benefits to a person who has successfully reversed a sterilization procedure. Accordingly, the Department does not believe that any purpose would be served by revising the first sentence at N.J.A.C. 11:4-54.5(a)1 as suggested by the commenter.

**COMMENT:** Two comments concerned proposed N.J.A.C. 11:4-54.5(a)1 regarding the exclusion for reversal of voluntary sterilization, and the requirement that carriers provide coverage to partners of persons who have successfully reversed sterilization. One commenter proposed adding "unless the person has been diagnosed medically sterile or unable to carry a pregnancy to live birth" at the end of the first sentence. The commenter stated that it is unfair to deny coverage to someone who paid out of pocket for a reversal, and that both Illinois and Massachusetts only exclude coverage for the reversal while the subsequent infertility treatment is covered.

The second commenter requested that the Department clarify the term "partner," at N.J.A.C. 11:4-54.5(a)1, and suggested adding "who has independently,



objectively demonstrated infertility" so as to avoid the situation where infertility benefits are sought by the couple where the "person's" reversed sterilization simply was not successful.

**RESPONSE:** Revising the first sentence of N.J.A.C. 11:4-54.5(a)1 to read "Reversal of voluntary sterilization unless the person has been diagnosed medically sterile or unable to carry a pregnancy to live birth" would serve no purpose because the definition of "infertility" excludes persons who have been voluntarily sterilized regardless of whether the person has attempted to reverse the sterilization. Therefore, carriers would not be required to provide infertility benefits to someone who has successfully reversed a sterilization procedure even if they subsequently were diagnosed medically sterile or unable to carry a pregnancy to live birth.

The Department agrees that clarification of the term "partners" in the second sentence of N.J.A.C. 11:4-54.5(a)1 would be appropriate. Accordingly, the Department is revising the sentence to read "Coverage for infertility services provided to partners of persons who have successfully reversed sterilization may not be excluded provided that the partner is infertile as defined by P.L. 2001, c. 236 and this subchapter."

**COMMENT:** One commenter stated that the phrase "whereby eggs are removed from the ovaries" should be deleted from the proposed definition of "in vitro fertilization" or "IVF." The commenter stated that IVF is an ART procedure, and that frozen eggs can be used for IVF without the need to retrieve eggs each and every time.

**RESPONSE:** The Department does not believe it is necessary to revise the definition. Even if frozen eggs are used for an IVF procedure, at some point the egg retrieval procedure necessarily preceded the IVF.

**COMMENT:** One commenter stated that in the definition of "microsurgical sperm aspiration," "aspermia" should be spelled "azoospermia."

**RESPONSE:** The Department agrees, and is correcting the misspelling.

**COMMENT:** One commenter suggested that the Department add a definition of "surrogate" to mean "a woman who has contracted with a third party for the purpose of becoming pregnant with designated sperm. The resultant pregnancy is formed by the union of the contracted sperm contributor and the female's own egg. Surrogate also refers to a woman who has contracted with a third party to be an egg donor and has agreed to carry any resultant embryos. The surrogate is biologically related to any offspring."

**RESPONSE:** The Department agrees that it would be appropriate to include a definition of "surrogate" as follows: "A surrogate means a woman who carries an embryo that was formed from her own egg inseminated by the sperm of a designated sperm donor." As stated above in response to a comment regarding the definition of "gestational carrier," the definition of "surrogate" need not refer to any contractual arrangement that may exist between the surrogate and the infertile couple.

**COMMENT:** One commenter questioned whether proposed N.J.A.C. 11:4-54.3(a), prohibiting carriers from imposing a separate copayment, coinsurance, deductible, dollar maximum, visit maximum or procedure maximum on any infertility

treatment other than limiting coverage to four completed egg retrievals per lifetime, would permit a carrier to "register" infertility members as it currently does its pregnant population?

**RESPONSE:** The Department does not understand the commenter's use of the term "register," and therefore is unable to adequately respond to the comment.

**COMMENT:** Three comments concerned proposed N.J.A.C. 11:4-54.3(b), which prohibits carriers from imposing a separate preauthorization notice or other utilization management requirement on infertility treatment. One commenter stated that the proposed provision "states that if there is an already existing procedure for precert, then the carrier may require preauthorization."

The second commenter stated that the only preauthorization requirement should be for certain diagnostic tests or egg retrieval procedures if the procedure requires anesthesia and is considered "surgery." The commenter added that a patient should be permitted to visit obstetrician-gynecologists (OB-GYNs) who specialize in reproductive endocrinology without a referral because they should function as a type of primary care physician (PCP) since they are OB-GYNs with additional training. Only one referral from the patient's PCP or OB-GYN should be required at the beginning of treatment and not for each subsequent visit.

The third commenter stated that the proposed prohibition on separate preauthorization requirements unnecessarily goes beyond the statute, and hinders the ability of managed care plans to assist their members through case management. The commenter stated that it is appropriate to apply preauthorization requirements to

certain pregnancy-related procedures, just as it is to certain infertility procedures, and that it would be in the best interest of the member to have that determination made in advance. The commenter suggests that preauthorization be permitted, at least with respect to the more expensive in vitro fertilization procedures.

**RESPONSE:** The rules do not prohibit imposing a preauthorization requirement on specified infertility treatments such as IVF. Rather, the rules only prohibit a carrier from requiring that all or any infertility treatment be preauthorized. Thus, a carrier cannot demand preauthorization for an office visit or testing to diagnose infertility. Regarding referrals, the rules likewise require carriers to be consistent in their application of referral requirements.

**COMMENT:** Five comments concerned proposed N.J.A.C. 11:4-54.3(c), which permits carriers to limit infertility benefits to services performed at facilities that conform to standards established by the American Society for Reproductive Medicine (ASRM) or the American College of Obstetricians and Gynecologists (ACOG), and prohibits carriers from imposing any additional standards applicable to fertility services on facilities or providers. One commenter requested that the Department clarify that in-network benefits may be limited to facilities and providers in a carrier's network.

Two of the commenters suggested that the rules permit carriers to limit in vitro fertilization benefits to services performed by reproductive/endocrinology and infertility specialists (REI) only because they are trained and certified in infertility treatment. ACOG does not develop standards for ART providers, and ASRM has guidelines but does not certify or accredit.

One commenter stated that the prohibition on carriers imposing any additional standards other than ASRM or ACOG standards is inconsistent with the statutes and regulations governing HMOs, which require them to have continuous quality improvement programs.

One commenter stated that the law's requirement that services be performed at "facilities that conform to standards established by" ASRM and ACOG, as well as the Department's proposed language permitting carriers to limit benefits to services performed at facilities conforming to ASRM or ACOG standards, is ambiguous and not in accordance with current legal parameters and standards of care for physicians. The commenter states that New Jersey licensed physicians may practice in any area as long as they meet the standard of care. The commenter added that neither the ASRM nor ACOG publish "standards" per se, and suggests that the rules be revised to state that services "shall be provided by a physician who is a member of one of these two organizations."

One commenter questioned whether this proposed provision will permit carriers to drop ASRM and ACOG facilities as participating providers to avoid providing infertility benefits or to deny such facilities member status to avoid providing benefits. Also, if these facilities are not participating providers, will infertility benefits be covered at other treatment centers?

**RESPONSE:** The Department does not believe it is necessary to clarify that in-network benefits may be limited to facilities and providers in a carrier's network

because all benefits provided in an HMO contract are restricted to network providers unless it is an emergency or an urgent out-of-area situation.

The Department's rules place no restrictions on physicians. Rather, the rules merely conform to the facility restriction contained in the statute.

The requirements and prohibitions contained in the Department's rules do not in any way override an HMO's obligations with regard to quality improvement programs.

The Department disagrees that permitting carriers to limit benefits to services performed at ASRM or ACOG facilities is ambiguous, and merely repeats the statutory language. The rules place no restrictions or requirements on physicians, but only address facilities. Accordingly, the Department does not intend to revise the rules to state that services shall be provided by physicians who are members of either the ASRM or ACOG. Carriers may prefer that certain procedures be performed only by the most qualified specialists (for example, reproductive endocrinologists) rather than by OB/GYNs, and the rules place no restrictions on carriers in that regard.

If a carrier decides to drop from, or deny participating provider status to, all ASRM and ACOG facilities, it would be in violation of network adequacy requirements established by law (see N.J.A.C. 8:38-6 applicable to HMOs, and N.J.A.C. 8:38A-4 applicable to carriers offering managed care plans). It should be noted that network adequacy is determined by the Department of Health and Senior Services (DHSS).

**COMMENT:** Several comments concerned the proposed required benefits provision at N.J.A.C. 11:4-54.4. One of the commenters stated that the law defines infertility coverage as "coverage which includes, but is not limited to . . ." According to

the commenter, the legislative intent was to recognize evolving medical procedures and developing new treatment modalities, and the Department's regulations must address the issue of new medical procedures that meet the standard of care and are developed after adoption of the regulations. The commenter requested that N.J.A.C. 11:4-54.4(a) be revised to read that "Infertility coverage shall include, but not be limited to, payment of benefits for procedures recognized by the American Society for Reproductive Medicine or the American College of Obstetricians and Gynecologists as follows:[.]"

**RESPONSE:** The Department is revising proposed N.J.A.C. 11:4-54.4(a) to read "Infertility coverage shall include, but is not limited to, payment of benefits for the following services and procedures recognized by the American Society for Reproductive Medicine or the American College of Obstetricians and Gynecologists:".

**COMMENT:** One commenter stated that while "cryopreservation" is defined at N.J.A.C. 11:4-54.2, it is not included in the list of required benefits. The commenter added that cryopreservation is necessary when there are embryos not used during a fresh in vitro fertilization cycle.

**RESPONSE:** The proposed rules include a definition of "cryopreservation" because N.J.A.C. 11:4-54.5(a)3 permits the exclusion of benefits for costs associated with cryopreservation.

**COMMENT:** One commenter stated that it appears that there is no limit as to the number of embryo transfers that may take place because proposed N.J.A.C. 11:4-54.4(a)4 does not include a limitation regarding the number of cycles.

**RESPONSE:** The number of covered embryo transfers would be limited by the number of eggs retrieved in the lifetime maximum of four completed egg retrievals.

**COMMENT:** Seven commenters were concerned with proposed N.J.A.C. 11:4-54.4(a)5, which limits benefits to four completed egg retrievals per lifetime of the covered person. One commenter stated that the Department's language in Bulletin No. 02-09 -- that four completed egg retrievals shall be counted towards a covered person's lifetime maximum only if they were covered by a carrier -- was clearer than the proposed language at N.J.A.C. 11:4-54.4(a)5ii even though that provision states that uncovered egg retrievals shall not count toward the maximum.

Four commenters stated that proposed N.J.A.C. 11:4-54.4(a)5ii is inconsistent with the statute, which clearly states that the benefit offered by the plan must cover "four completed egg retrievals per lifetime of the covered person." The commenters indicated that the limit of four egg retrievals appears to have been founded on medical appropriateness rather than source of payment because the chance of conception after four retrievals diminishes greatly. The commenters further stated that other states (for example, Illinois) have interpreted the lifetime maximum to mean four per the lifetime of the member regardless of payment method. The commenters suggest deleting the language exempting retrievals not paid for by a carrier from the four-per-lifetime limit.

One commenter stated that this provision should clearly state that only the surgery and any related expenses in connection with retrieving a woman's eggs from her ovaries is considered a "completed egg retrieval" and only those procedures and related expenses will count toward the lifetime maximum. The commenter also stated



that the provision should clarify that the ART procedures used to achieve conception without sexual intercourse (GIFT, ZIFT, IVF or IUI) alone are not a "completed egg retrieval" and would not count toward the lifetime maximum when frozen eggs are being utilized for that procedure.

**RESPONSE:** The Department does not believe it is necessary to revise the proposed language regarding the four completed egg retrievals because N.J.A.C. 11:4-54.4(a)5ii clearly states that uncovered egg retrievals shall not count toward the four-per-lifetime maximum. On the issue of whether uncovered egg retrievals should be counted toward the four per lifetime limit on the offered benefit, the intent of the law was to require carriers to cover four completed egg retrievals, not to restrict a person from undergoing more than four retrievals.

Regarding the comments concerning clarification of the procedures and expenses included in completed egg retrievals, the proposed definition of "completed egg retrieval" states that it means "all office visits, procedures and laboratory and radiological tests performed in preparation for oocyte retrieval; retrieval of the oocyte(s); and, if the retrieval is successful, culture and fertilization of the oocyte(s)." Accordingly, a completed egg retrieval is not limited to only the surgery itself and any related expenses as suggested by the commenter. In reply to the comment concerning procedures on frozen eggs, the Department does not believe it is necessary to specify that ART procedures using frozen eggs would not count toward the completed egg retrieval maximum because such procedures do not involve egg retrievals.

**COMMENT:** Four commenters expressed concern with proposed N.J.A.C. 11:4-54.4(a)5i, which requires coverage of the medical costs of a live egg donor used in an egg retrieval. One of the commenters stated that proposed N.J.A.C. 11:4-54.4(a)5i should be amended to add the phrase "including office visits, medication, laboratory and radiological procedures of the donor and the recipient." The commenter added that the language in the Department's Bulletin No. 02-09 -- that "carriers are required to cover all medical expenses of egg and sperm donors to the extent that benefits remain and are available under the recipient's policy . . ." -- is broader than the proposed rule.

Two commenters requested that the Department delete this proposed provision because nothing in the statutory language requires donor costs to be covered, carriers will be required to bear the medical costs of non-covered donors, and this requirement penalizes employers and individuals for obtaining insurance coverage and will increase premiums. One commenter noted that traditionally, under infertility benefits offered by most insurance companies, the covered person would be entitled to lab services and the embryo transfer. The procurement, screening process, medication, lab work and retrieval procedure are the responsibility of the contracting parties.

One commenter questioned whether a carrier would be able to exclude coverage of members who have elected to act as egg or sperm donors, surrogates or gestational carriers. The commenter stated that such members would not meet the definition of infertility as stated in the regulation, and a carrier should be able to avoid paying for a retrieval under both the member-donor's and infertile member's policies.

**RESPONSE:** The Department does not believe it is necessary to revise the proposed language because "medical costs" as used in the proposal would include the items referred to by the commenter.

The rules' requirement that donor medical costs be covered is analogous to carriers covering the costs of organ and bone marrow donors.

These rules permit exclusion of benefits for surrogates who are not covered by the carrier's policy or contract. That exclusion, however, would have no effect on coverage by the surrogate's own policy or contract. These rules require coverage of gestational carriers and all medical costs of egg or sperm donors.

**COMMENT:** One commenter stated that proposed N.J.A.C. 11:4-54.4(a)6 contains no limit as to the number or cycles of gamete intrafallopian transfer (GIFT) and zygote intrafallopian transfer (ZIFT) that would be covered.

**RESPONSE:** The number of covered GIFT and ZIFT procedures would be limited by the maximum four-per-lifetime completed egg retrievals.

**COMMENT:** One commenter noted that proposed N.J.A.C. 11:4-54.4(a)7 contains no limit as to the number of intracytoplasmic sperm injections (ICSI) that will be covered.

**RESPONSE:** The law does not contain a limit as to the number of ICSIs.

**COMMENT:** One commenter noted that proposed N.J.A.C. 11:4-54.4(a)8 contains no limit as to the number of IVFs that will be covered. A second commenter requested specifics regarding when coverage would end for surrogates and gestational carriers who are not members. The commenter recommended that for donors,

coverage end with the day of retrieval and release from REI care. The commenter also suggested that once a chemical pregnancy (positive blood pregnancy test) has occurred, that liability end for services to surrogates or gestational carriers who are not members. Maternity coverage begins at first appointment to the OBGYN. Further care would then become obstetrical care, which is specifically excluded by the proposed rules from mandated coverage for nonmembers. The commenter also requested clarification regarding a plan's responsibility for covering complications such as hospitalization for ovarian hyperstimulation, which is pre-pregnancy and could occur with egg donors or surrogates who undergo ovulation induction with medication. The commenter also asked whether carriers must cover ectopic pregnancies or miscarriages in a surrogate or gestational carrier, which would occur following the positive pregnancy test. Finally, the commenter asked whether carriers would be required to pay for fetal reduction procedures in surrogates or gestational carriers who are not members; the commenter suggested that carriers not be required to do so since this would occur after a chemical pregnancy has been diagnosed.

**RESPONSE:** The number of covered IVFs would be limited by the maximum four-per-lifetime completed egg retrievals.

The rules do not require coverage for surrogates where the surrogate is not covered by the carrier's policy or contract, but do require coverage in cases where an embryo is transferred to a gestational carrier. Accordingly, these rules would not require complications experienced by a surrogate who is not covered by the carrier's

policy or contract to be covered, but would require coverage of complications experienced by a gestational carrier.

Regarding the comment concerning coverage of complications experienced by egg donors, the rules require coverage of egg donors to continue until the donor is released by the REI. The Department has revised N.J.A.C. 11:4-54.4(a)5i accordingly.

**COMMENT:** Two comments were received on proposed N.J.A.C. 11:4-54.4(a)9, requiring that medications be covered even if the contract or policy does not provide prescription drug benefits. One commenter was pleased that the Department is requiring that medications be covered, stating that such coverage is required by the law. The commenter noted that some insurers are asserting that they are not mandated to provide coverage for fertility medications because the insured does not also have a policy covering the costs of prescription drugs, while others have relied on the pregnancy-related procedures language to deny coverage.

A second commenter presented a series of questions and comments concerning prescription drug coverage: (1) Whether "drop-ship mail orders" can be used for members who do not have prescription drug coverage. (2) Whether members must be able to have drugs covered at a retail pharmacy at the point of sale. (3) The commenter recommended that a plan be able to require that members without prescription drug coverage notify the plan (or have their doctor notify the plan) so that the member can be identified and coverage provided at the point of sale (that is, the retail pharmacy). (4) A plan should be able to impose the standard terms and conditions of prescription drug coverage imposed on members with such coverage on

members without prescription drug coverage. (5) If a group does not have a separate drug benefit, can a plan establish a copayment for orals/injectables provided under the medical program similar to the copayment that would apply under a prescription drug program?

**RESPONSE:** Where a contract or policy does not include prescription drug coverage, N.J.A.C. 11:4-54.4(a)9 should be read as requiring that infertility drugs be covered in the same manner that carriers cover insulin for persons without prescription drug coverage.

The Department cannot adequately respond to the second commenter's series of questions. These issues can only be addressed on a case-by-case basis, and would require consideration of all the pertinent facts and circumstances, including the contract form language.

**COMMENT:** Two comments concerned the exclusion at proposed N.J.A.C. 11:4-54.5(a)2 for medical services rendered to a surrogate for purposes of childbearing where the surrogate is not covered by the carrier's policy or contract. One commenter stated that the Department's Bulletin No. 02-09 recognized that there are legitimate medical expenses that a surrogate incurs up to conception, which should be covered, and that there is a conflict between the proposed rules and the bulletin. The commenter stated that since many insurers are now covering some of the surrogate's medical costs, the proposed language should be revised by replacing "childbearing" with "pregnancy related services."

The second commenter stated that while the proposal specifically defines "gestational carrier or surrogate," the exclusion refers to surrogate only. The proposed provision should be revised to permit exclusion of benefits to gestational carriers also.

**RESPONSE:** The intent of Bulletin No. 02-09 and of the rules was to provide that surrogates would not be covered, and that only the costs of transferring an embryo to a gestational carrier would be covered.

**COMMENT:** One comment concerned proposed N.J.A.C. 11:4-54.5(a)4, permitting exclusion of benefits for nonmedical costs of an egg or sperm donor. The commenter requested clarification of carrier liability for donors, and specifically at what point benefits would end. The commenter stated that there may be times when an egg donor requires hospitalization for hyperstimulation of her ovaries, and questioned whether a carrier would be required to pay for that hospitalization for a non-member. The commenter also requested an explanation as to what "non-medical costs" would encompass.

**RESPONSE:** As stated above, the Department has added language at N.J.A.C. 11:4-54.4(a)5i, and at N.J.A.C. 11:4-54.5(a)4, clarifying that donor coverage is required only until the donor has been released by the reproductive endocrinologist. "Non-medical" costs include compensation for pain and suffering and missed work, donor search fees, etc.

**COMMENT:** One comment concerned proposed N.J.A.C. 11:4-54.5(a)5, which permits excluding coverage for infertility treatments that are experimental or investigational in nature. The commenter stated that the phrase should be amended to

state that the exclusion of a particular procedure should be "in accordance with national standards of care." The commenter noted that since the ASRM or other nationally recognized medical organizations routinely recognize the medical efficacy of new procedures, an insurer should not be permitted to consider a procedure experimental if it meets the standard of care for a new procedure which is recognized in peer review medical literature or the subject of clinical trials.

**RESPONSE:** The Department does not believe it is necessary to revise the rule language as suggested by the commenter. The phrase "experimental or investigational in nature" is the standard terminology used in all policies and contracts for all illnesses, and no purpose would be served by using different terminology regarding infertility treatments. A carrier's determination as to whether infertility treatments are considered experimental or investigational in nature would be held to the same standards and procedures for making such a determination regarding any other illness.

**COMMENT:** One comment concerned proposed N.J.A.C. 11:4-54.5(a)8, which permits group policies, contracts, riders and endorsements that provide hospital or medical benefits, other than policies or contracts that provide prescription drug benefits only, to exclude medication benefits if these benefits are provided under another group health insurance policy or contract issued to the same policyholder or contractholder. The commenter questioned whether a carrier may request that members provide information relating to drug coverage with carriers. The commenter also questioned whether an exclusion could be added stating that "Group policies, other contracts, riders and endorsements 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."

**RESPONSE:** Carriers that use the permitted exclusion may seek the necessary information from members in order to administer it. The requested exclusion language would be redundant.

**COMMENT:** One comment concerned proposed N.J.A.C. 11:4-54.5(a)7, permitting exclusion of benefits for IVF, GIFT, and ZIFT 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. The commenter asked "when does coverage end? Is the intent that there is no coverage for infertility after four (4) completed retrievals or by age -- whichever comes first. If someone has had four (4) completed egg retrievals, yet is under age 46, are they still entitled to treatment for infertility other than IVF? For example, medications, bloodwork, ultrasounds, inseminations."

**RESPONSE:** Coverage for IVF, GIFT and ZIFT may be excluded if the covered person meets any one of the three prongs (that is, coverage may be excluded if the covered person has failed to use all reasonable less expensive and medically appropriate treatments, if the covered person has reached the limit of four covered completed egg retrievals, or if the covered person is 46 years of age or older). This three-prong limit applies only to IVF, GIFT and ZIFT, and coverage for other treatment(s) would be determined by the remainder of this subchapter.

**COMMENT:** Two comments were received concerning the proposed religious employer exclusion provision at N.J.A.C. 11:4-54.6. One commenter stated its intent to exclude infertility benefits based on this exclusion. The second commenter stated that the proposal states that any infertility treatment can be excluded if it is against a religious employer's bona fide religious tenets, but the law states that certain exclusions shall be granted after a request is made by the religious employer. The commenter also expressed concern as to what type of entity is considered to be a "religious employer," and questioned whether there is a policy used by the Department on how to interpret the law's definition of a religious employer, or if the employer is permitted to make the definition.

**RESPONSE:** The commenter expressing its intent to exercise the religious employer exclusion would be required to make a request to its carrier.

The proposed rules do not state that coverage for any infertility treatment shall be excluded by a carrier under the religious employer exclusion. Rather, the proposed provision reiterates verbatim the language used in the law. Additionally, the rules define "religious employer," and carriers receiving requests for exclusions from employers on that basis would need to determine whether the employer meets that definition.

**COMMENT:** One comment related to proposed N.J.A.C. 11:4-54.7 (concerning the effect of the rules on previously filed forms). The commenter questioned whether carriers may adjust premiums midyear to cover the expense of infertility services and prescription drugs under the medical benefit.

**RESPONSE:** The deeming of previously filed forms only affects the carrier's ability to issue new contracts and renew existing contracts. Accordingly, it would not be necessary for carriers to make any midterm rate adjustments.

**COMMENT:** One commenter submitted several questions regarding implementation of the regulations: (1) Will the Department provide examples of how and when the proposed regulations should be applied? (2) If the proposed new rules are adopted into the law, will they be retroactive to the inception date of the law or will there be effective dates for this clarification of the law? (3) Will there be guidance for the insurance carriers on how they need to proceed if the proposed regulations change their current process of coverage for these benefits? (4) Will a grievance procedure be detailed in the final proposal?

**RESPONSE:** P.L. 2001, c.236, enacted August 31, 2001, became effective 90 days after enactment, and applies to all policies and contracts issued or renewed on or after the effective date. The rules at N.J.A.C. 11:4-54.7 state that previously filed or approved forms that are not in compliance with the new infertility mandate shall be deemed withdrawn and shall not be delivered, issued, executed or renewed. Following adoption of the rules, the Department is not required to provide further guidance to carriers regarding implementation of the law or the rules. However, if issues of general interest develop in the implementation of the rules, the Department would consider the issuance of bulletins and, if necessary, the adoption of amendments to the rules to address such issues. Carriers should handle grievances related to this mandate pursuant to procedures already in place for any other grievances.

**Summary** of Agency-Initiated Changes:

1. "Groups of 50 or more persons" has been replaced with "groups other than small employers as defined at N.J.S.A. 17B:27A-17" at N.J.A.C. 11:4-54.1 to clarify the Legislature's intent regarding health benefits plans that are required to provide infertility benefits.
2. The definition of "gestational carrier" at N.J.A.C. 11:4-54.2 has been revised for clarification purposes.
3. A definition of "surrogate" has been added at N.J.A.C. 11:4-54.2 because that term is used in these rules.
4. In the definition of "egg transfer" at N.J.a.C. 11:4-54.2, the spelling of "laproscopy" has been corrected.

**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.

**Full text** of the adoption follows (additions to proposal indicated in boldface with asterisks **\*thus\***; deletions from proposal indicated in brackets with asterisks **\*[thus] \***):

## SUBCHAPTER 54. BENEFIT STANDARDS FOR INFERTILITY COVERAGE

## 11:4-54.1 Purpose and scope

- (a) (No change from proposal.)
- (b) This subchapter shall apply to **\*[all]\* \*the following\*** **\***:
- \*1. all\*** policies, contracts, riders and endorsements delivered, issued, executed or renewed in this State by health service corporations, hospital service corporations, medical service corporations<sup>\*,.]\*</sup> **\*and\*** health insurance companies **\*[and health maintenance organizations]** **\*** for groups **\*[of 50 or more persons]\* \*other than small employers as defined at N.J.S.A. 17B:27A-17\*** that provide hospital or medical benefits, including pregnancy-related benefits<sup>\*,.]\*</sup> **\*.z\***
- \*2.\* All contracts and evidence of coverage forms issued by health maintenance organizations for groups other than small employers as defined at N.J.S.A. 17B:27A-17 that include pregnancy-related coverage, and** **\***
- \*[This subchapter shall also apply to]** **\* \*3.\*** 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]\* \*other than small employers as defined at N.J.S.A. 17B:27A-17\*** that provide hospital or medical benefits, including pregnancy-related benefits.
- (c) (No change from proposal.)

## 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:

\*["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] \* **hole is artificially created in the outer shell of an embryo to assist with the potential implantation of that embryo.** \*

"Completed egg retrieval" means all office visits, procedures and laboratory and radiological tests performed in preparation for oocyte retrieval; **the attempted or successful** \* retrieval of the oocyte(s); and \* **if the retrieval is successful.** \* 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] \* **female gametes (ova) and male gametes (sperm)** \*.

"Egg transfer" or "oocyte transfer" means the transfer of retrieved eggs into a woman's fallopian tubes through \*[laparoscopy] \* **laparoscopy** \* as part of gamete intrafallopian transfer (GIFT).

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

"Gamete intrafallopian tube transfer" or "GIFT" means the direct transfer of a sperm/egg mixture into the fallopian tube by \*[egg transfer] \* **laparoscopy**. 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] \* **has become pregnant with an embryo or embryos that are not part of her genetic or biologic entity, and who intends to give the child to the biological parents after birth**.\*

"Microsurgical sperm aspiration" means the techniques used to obtain sperm for use with intracytoplasmic sperm injection (ICSI) in cases of obstructive \*[aspermia] \* **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").

**\*"Surrogate" means a woman who carries an embryo that was formed from her own egg inseminated by the sperm of a designated sperm donor.\***

11:4-54.4 Required benefits

(a) Infertility coverage shall include **\*, but is not limited to,\*** payment of benefits for the following **\*services and procedures recognized by the American**

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

1. – 4. (No change from proposal.)
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 **\*until the donor is released from treatment by the reproductive endocrinologist** \*;
  - ii. (No change from proposal.)
6. – 11. (No change from proposal.)

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.

**\*i.\*** Coverage for infertility services provided to partners of persons who have successfully reversed sterilization may not be excluded **\*provided that the partner is infertile as defined by P.L. 2001, c. 236 and this subchapter** \*;

2. – 3. (No change from proposal.)

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 **\*until the donor is released from treatment by the reproductive endocrinologist \***;

5. – 8. (No change from proposal)

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