

**REPORT OF THE SPECIAL ADVISORY COMMISSION
ON MANDATED HEALTH INSURANCE BENEFITS**

**MANDATED COVERAGE FOR INFERTILITY
SENATE BILL 631**

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2009

January 12, 2009

To: The Honorable Timothy M. Kaine
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to § 2.2-2504 and § 2.2-2505 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of Senate Bill 631 regarding coverage for infertility.

Respectfully submitted,

Timothy Hugo
Chairman
Special Advisory Commission on
Mandated Health Insurance Benefits

**SPECIAL ADVISORY COMMISSION ON
MANDATED HEALTH INSURANCE BENEFITS**

Timothy Hugo, Chairman
George Barker, Vice Chairman

Clifford Athey, Jr.
Terry Kilgore
A. Donald McEachin
Donald W. Merricks
Elnora Allen
Angela Benton
Peter Bernard
Dorothy S. Brodersen

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Dr. James F. Childress
Phyllis L. Cothran
Joe Kelliher
Laura Lee Viergever
Alfred W. Gross
Karen Remley, M.D., M.B.A.

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INTRODUCTION

The 2008 Senate Committee on Commerce and Labor referred Senate Bill 631 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) to be reviewed prior to the 2009 Session of the General Assembly. Senate Bill 631 was introduced by Senator Patricia Ticer.

The Advisory Commission held a public hearing to receive comments on Senate Bill 631 on October 27, 2008 in Richmond, VA. In addition to the bill's patron, eight speakers addressed the proposal, including the main proponents, RESOLVE: The National Infertility Association (RESOLVE). The Virginia Association of Health Plans (VAHP) opposed the bill. Written comments supporting the bill were received from 17 families and RESOLVE. VAHP submitted written comments opposing the bill, as well as the Virginia Chamber of Commerce (VCC) and the National Federation of Independent Business (NFIB).

The Joint Legislative Audit and Review Commission (JLARC) staff of the Virginia General Assembly prepared an "Evaluation of the Proposed Mandated Health Insurance Benefits: Senate Bill 631, Mandated Coverage of Infertility" pursuant to §§ 2.2-2503 and 30-58.1 of the Code of Virginia. A copy of the evaluation is available on the JLARC website at <http://jlarc.state.va.us>.

SUMMARY OF PROPOSED LEGISLATION

Senate Bill 631 adds § 38.2-3418.15 to the mandated benefits article and amends §38.2-4319 to make it applicable to health maintenance organizations (HMOs).

The bill requires insurers to propose coverage for the treatment of infertility. The bill applies to insurers proposing to issue individual or group accident and sickness policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing individual or group subscription contracts; and HMOs providing health care plans to provide coverage for the treatment of infertility.

The bill defines "infertility" as the inability to conceive after one year of unprotected sexual intercourse. Infertility treatment does not include reversal of vasectomy or tubal ligation. "Treatment for infertility" includes, but is not limited to the following procedures performed on a covered individual who is less than 50 years old: in vitro fertilization (IVF), embryo transfer, artificial insemination, gamete intrafallopian tube transfer (GIFT), intracytoplasmic sperm injection, zygote intrafallopian transfer (ZIFT), and low tubal ovum transfer. Treatment must be required only if the covered individual has not undergone four complete

oocyte retrievals except that if a live birth follows a complete oocyte retrieval, then two more oocyte retrievals must be covered.

Reimbursement for treatment for infertility must be determined according to the same formula by which charges are developed for other medical and surgical procedures. The coverage must have durational limits, deductibles, and coinsurance factors that are no less favorable than for physical illness generally.

The bill applies to policies, contracts or plans delivered, issued for delivery, or extended in the Commonwealth on and after July 1, 2008, or at any time thereafter when any term of the policy, contract or plan is changed or premium adjustments are made. The bill does not apply to short-term travel, accident only, limited or specified disease, or policies or contracts designed for issuance to persons eligible for Medicare, or similar coverage under state or federal government plans, or short-term nonrenewable policies of no more than six months' duration.

PRIOR LEGISLATION

Similar legislation to mandate coverage of infertility or to mandate an offer of coverage had been reviewed by the Advisory Commission five times prior to 2008. In 1990, Delegate Jerruld Jones introduced House Bill 271. The Advisory Commission voted 6 to 5 to favorably recommend House Bill 271 with amendments to narrow the scope of coverage and language which would also limit the cost impact of the bill.

In 1992, the Advisory Commission reviewed House Bill 990, which was very similar to House Bill 271 of 1990, and reflected the amendments proposed by the Advisory Commission. The Advisory Commission voted 5 to 1 to not recommend enactment.

Infertility coverage was re-introduced in 1994 as a mandated offer of coverage as House Bill 1387. House Bill 1387 defined "infertility" and "infertile" in the same manner as House Bill 271. There were, however, changes in coverage limitations. House Bill 1387 covered embryo transfer, low tubal ovum transfer, artificial insemination, IVF, GIFT, and ZIFT. In addition to changing the mandated benefit requirement to a mandated offer requirement, other provisions in House Bill 1387 differed from House Bill 271 and 990, including provisions for a limited number of treatment attempts following less costly but unsuccessful attempts and national guideline requirements for treatment facilities. House Bill 1387 also imposed the requirement that a period of one year had passed since the covered individual was deemed to be infertile. The Advisory Commission voted unanimously against enacting the bill.

Infertility coverage was introduced again in 1999 as a mandated benefit by Delegate William Barlow as House Bill 2403. The bill defined "infertility" as "the inability to conceive after one year of unprotected sexual intercourse."

Treatment did not include the reversal of a vasectomy or a tubal ligation. This bill was not recommended for enactment by a vote of 8 to 1.

Delegate Barlow reintroduced very similar infertility legislation in 2000 as House Bill 1151. House Bill 1151 was referred to the Committee on Corporations, Insurance, and Banking and was left in committee.

In 2004, House Bill 619 was introduced by Delegate Charles W. Carrico, Sr. House Bill 619 incorporated within it very similar infertility provisions included in Senator Ticer's 2008 proposed legislation, except that it added infertility treatment to the state employee health insurance plan. On October 18, 2004, the Advisory Commission voted unanimously (9-0) to recommend against enactment of House Bill 619.

INFERTILITY

Dorland's Medical Dictionary defines infertility as the "diminished or absent capacity to produce offspring." The definition further explains that infertility does not denote the complete inability to produce offspring, which would be sterility. It also notes that infertility is also called relative sterility.¹

Medline defines infertility as the inability to achieve pregnancy despite trying for one year. A broader view of infertility includes the inability to carry a pregnancy to term and have a baby.² Resolve, the National Infertility Organization, indicates that infertility is a medically recognized disease that affects men and women equally. It is defined as a group of diseases of the reproductive system and recognized by the inability to conceive or retain a pregnancy during a one-year period (six months for a woman 35 years of age or older).³

Infertility can be attributed to any abnormality in the female or male reproductive system. In 24 percent of most infertility cases, the etiology is due to male factors. In 21% of cases, the etiology is recognized as ovarian dysfunction. In 14% of most cases, tubal factors are the underlying cause of infertility. Thirteen % of cases are attributed to endometriosis, uterine or cervical factors, or other causes. In approximately one fourth of couples (28%), the cause is uncertain and is referred to as "unexplained infertility. The etiology can be multifactorial for some couples.⁴

INFERTILITY TREATMENTS

Infertility treatments are normally called Assisted Reproductive Technology (ART). Procedures are classified according to whether the ART patient uses her own eggs or eggs donated by another woman, whether the embryos transferred were freshly fertilized or previously frozen, and whether the

embryos were transferred into a gestational surrogate or a new treatment procedure was used.⁵

Artificial insemination involves placing sperm in a woman's vagina by means other than sexual intercourse. The term "fertility drug" usually refers to products that induce, enhance, or regulate ovulation. Ovulation induction refers to the administration of medications to stimulate ovulation. Fertility drugs are usually the initial treatment for women with ovulation disorders. Some drugs are taken orally and some are injected. According to the Jones Institute, the basic facts on the drugs most commonly prescribed are listed below:⁶

- Clomid, is a commonly prescribed fertility drug that can establish normal ovulation in some women.
- Metformin is an effective fertility drug for lowering insulin levels in some women with polycystic ovary syndrome (PCOS). Normalizing insulin levels allows normal ovulation to occur.
- FSH (follicle stimulating hormone) is an injected fertility medication that stimulates and supports the development of multiple eggs. Used in IVF and stimulated IUI.
- Human chorionic gonadotropins (hCG) are an injected hormone used to induce ovulation.
- Other fertility drugs, such as progesterone are used to promote the development of the endometrium to adequately support the growing embryo.
- Corticosteroids sometimes are used to treat immune disorders that can cause the production of antisperm antibodies.
- Many other medications may be used to treat diseases that can affect fertility, such as insulin for diabetes or antibiotics to treat reproductive tract infections.

Other procedures included in the legislation include (but are not limited to):

In Vitro Fertilization (IVF): a type of ART that is used when a woman's fallopian tubes are blocked or when a man has low sperm counts. With IVF, a drug is used to stimulate the development, growth, and maturation of multiple eggs located within follicles on the ovaries. Once mature, the eggs are removed and placed in a culture dish with the man's sperm for fertilization. After approximately 40 hours, the eggs are examined to confirm if they have become fertilized by the sperm and are dividing into cells. These fertilized eggs (embryos) are then placed in the woman's uterus, thus bypassing the fallopian tubes. IVF bypasses the fallopian tubes and is sometimes considered the treatment of first choice for patients with damaged or absent fallopian tubes, endometriosis, or

moderate to severe male factor infertility, infertility of unknown origin, and other infertility disorders.⁷ More detailed procedures involved in IVF as described by the Jones Institute are described below (unless otherwise noted):

EGG RETRIEVAL

In the vast majority of artificial reproduction, egg retrieval is performed transvaginally with ultrasound guidance. This procedure usually is performed under intravenous sedation with local anesthesia, but general anesthesia may be given. The risks of egg retrieval include bleeding, which may require transfusion and a laparoscopy and/or laparotomy to correct the situation, and infection, which may require hospitalization with intravenous antibiotic therapy. Major complications are extremely rare, but do occur, as with any minor operative procedure.

The eggs are then combined with sperm in culture dishes; the resulting embryos are placed in an incubator where they are nourished until they are ready for transfer usually in 3-5 days. The IVF incubator is a highly controlled environment that maintains precise temperatures, gas concentrations, and uses highly filtered purified air.

IMMATURE EGGS

Approximately 80% of the eggs collected are mature. The remaining 20% of the eggs are immature at the time of egg retrieval. Although about 60% of the immature eggs will mature with overnight incubation of an in vitro culture, a pregnancy rarely occurs (< 2%) from the transfer of only embryos that originate from immature eggs.

EGG FREEZING

Candidates for egg freezing include women encountering declining fertility due to advancing age. Also, younger women consider egg freezing because women in their twenties or thirties have lower rates of miscarriage and of babies with birth defects compared to older women. With the advances in cryopreservation, freezing of eggs at a younger and more fertile age would potentially allow women to be their own egg donors later in life.

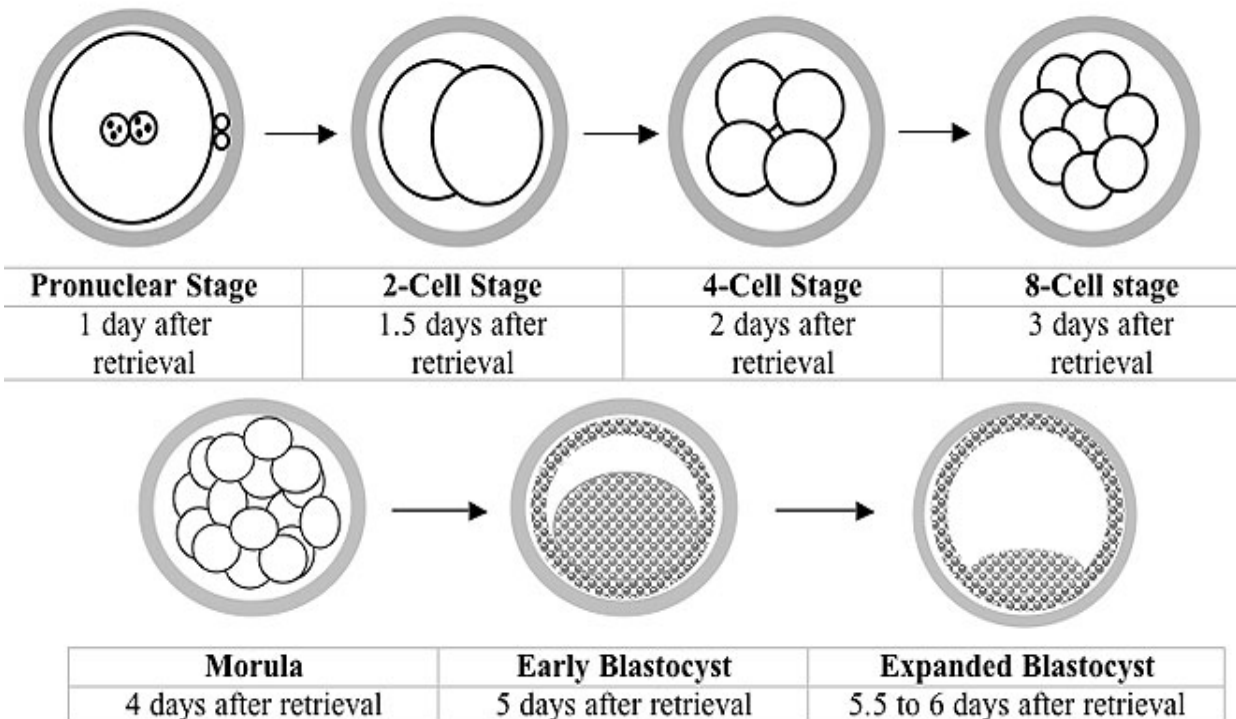
Cancer patients consider egg freezing because 8% of women diagnosed with cancer were under the age of 40. Unfortunately for these women of childbearing age, treatments such as chemotherapy and radiation have been shown to cause damage to maturing follicles in the ovaries. These treatments are used to kill rapidly dividing cells but may cause damage to the eggs stored in

the ovaries as well. In many cases, women who undergo chemotherapy or radiation will enter menopause prematurely and be unable to ever have children using their own eggs.

Women who may not have a partner with whom they want to have children or those who are too young to have a partner are also ideal candidates for egg freezing.⁸

Transcervical embryo transfer: All of the eggs are retained in the incubator for approximately five hours prior to insemination. The five hour interval between egg retrieval and insemination mimics the time required for the sperm and eggs to travel and meet in the fallopian tube following intercourse and ovulation. After the insemination, the eggs are left undisturbed in the incubator for 12 to 18 hours. During this time, approximately 65% of the eggs will fertilize.⁹

Embryo Development Prior to Transcervical Embryo Transfer (IVF-ET)



Tubal transfers, such as Gamete Intrafallopian Tube Transfer (GIFT) is similar to IVF but is used when the woman has at least one normal

fallopian tube. Three to five eggs are placed in the fallopian tube, along with the man's sperm, for fertilization inside the woman's body. ZIFT, also known as tubal embryo transfer (TET), combines IVF and GIFT. The eggs retrieved from the woman's ovaries are fertilized outside of the body and placed in the fallopian tubes rather than in the uterus. Generally, the difference between IVF and GIFT and ZIFT is that with GIFT and ZIFT, gametes or zygotes are transferred into the fallopian tubes rather than into the uterus. Procedures such as GIFT or ZIFT are rarely performed. Their costs are higher due to the need for general anesthesia and laparoscopy, and there is no increase in fertility success rates.¹⁰

Intracytoplasmic sperm injection (ICSI) is used for couples in which there are serious dysfunctions with the sperm. ICSI may also be used to assist older couples or for those with failed IVF attempts. In ICSI, a single sperm is injected into a mature egg. Then the embryo is transferred to the uterus or fallopian tube.¹¹

Intrauterine insemination (IUI) is a type of ART that utilizes the partner or donor sperm. IUI requires that the female produce and ovulate eggs that can travel unimpeded through the fallopian tubes and are capable of being fertilized by sperm.¹²

Extensive research indicates that overall, there is no increase in the rate of birth defects or other abnormalities after the ICSI procedure. However, there is some concern that ICSI could increase the incidence of male infertility in offspring, and that it could enhance the occurrence of rare sexual chromosomal abnormalities. In nature, the most viable sperm reaches and fertilizes the egg; however, in ICSI, sperm are manually selected thus bypassing this natural selection process. Clinical data are not yet available to conclusively rule out this possibility.¹³

SOCIAL IMPACT

According to National Survey of Family Growth, CDC 2002, the CDC estimates, there were 7.3 million women diagnosed with infertility in 2002. That number represents one in eight couples of childbearing years. This number shows a 20% increase since the last count of 6.1 million in 1995.¹⁴

The American Academy of Family Physicians approximates that more than 115,000 ART procedures were performed in the United States in 2002, resulting in the births of 45,751 infants. Because transfer of multiple embryos remains common, more than one half of infants born through ART are from multiple births, compared with 3% in the general population, and ART-born infants account for around 17% of all multiple births. The substantially increased risks of multiple births, such as hemorrhage and hypertension in the mother and

low birth weight, higher mortality, and long-term disability in the infants, must be taken into account when considering the use of ART treatment. In 2002, about 95% of triplets and higher multiples born through ART had a low birth weight, compared with 9% of single-birth infants; 97% of triplets and higher multiples were born preterm, compared with 15% of single-birth infants.¹⁵

Infertility treatment facilities in Virginia are geographically dispersed. There are 15 infertility clinics (three in Richmond; two in Fairfax, two in Virginia Beach, one each in Alexandria, Annandale, Arlington, Charlottesville, Norfolk, Reston, Salem and Winchester). Conventional infertility treatment is often performed by obstetricians, gynecologists, urologists, and other physicians through private practices and family planning clinics on a more widespread basis. There does not appear to be a shortage of infertility services in Virginia, although there is a higher concentration of available services in urban areas.¹⁶

Proponents of the Senate Bill 631 indicate that fertility drugs used to induce ovulation are cheaper than IVF and are still used by many women. Most often, doctors try to stimulate ovulation with a drug called clomiphene citrate, which carries approximately an 8% chance of producing twins, but a very low risk of higher-order multiples. Drugs called gonadotropins, however, are more powerful and produce a higher risk of multiple births. Because the results can be harder to control than IVF, the drugs can carry a higher risk of multiple births. The May Fertility and Sterility study estimated the percentage of multiple births due to ovulation induction drugs at 21% for twins, 37% for triplets and 62% for quadruplets. However, many medical professionals use appropriate drugs in certain circumstances and proceed to IVF only if stimulating the ovaries with medication does not produce the desired results.¹⁷

A survey was conducted by Mercer and commissioned by RESOLVE that included employers who responded to the National Survey of Employer-Sponsored Health Plans in 2005. Responses from 54% of employers with 500 or more employees stated that they cover evaluation by a reproductive endocrinologist or infertility specialist, and approximately 37% cover drug therapy. Approximately 20% cover in vivo or in vitro fertilization and 10% cover other advanced reproductive procedures (i.e. GIFT, ZIFT).¹⁸

A study was published in The New England Journal of Medicine in August 2002, using 1998 data reported to the Centers for Disease Control and Prevention (CDC) by 360 fertility clinics in the US, and 2000 US Census data. The study examined how frequently IVF treatment was utilized in each category in each state and how the medical outcomes differed in terms of singleton/twin births versus triplets or more. The study determined that clinics in states that required complete coverage performed more IVF cycles than clinics in states that required partial or no coverage (3.35 vs. 1.46 and 1.21 IVF cycles per 1,000 women of reproductive age, respectively) and more transfers of frozen embryos (0.43 vs. 0.30 and 0.20 per 1000 women of reproductive age, respectively).¹⁹

The study indicated that treatment and outcomes were more conservative in states with complete insurance coverage than in those with partial or no coverage. The results suggested doctors transferred fewer fresh embryos per cycle, the rate of live births was lower, and, importantly, the percentage of pregnancies with high-order multiples (triplets or more) was lower than in partial or no-coverage states (11.2 percent vs. 8.9 percent and 9.7 percent, respectively). In summary, the study showed that state-mandated insurance coverage for IVF services is associated with increased utilization of these services, but with decreases in the number of embryos transferred per cycle, the percentage of cycles resulting in live births, and the percentage of high-order multiple pregnancies, i.e., with three or more fetuses.²⁰

These findings suggest that without more comprehensive coverage, women living with infertility will probably choose to take the risk of undergoing additional cycles of IVF, and subsequently taking the medical risks associated with transferring multiple embryos, and perhaps the risk of life without genetically related children. These results are possible especially if women are not educated about the risks involved with multiple births.²¹

According to the Journal of Multicultural Nursing & Health, private insurance covers approximately 68-72% of the United States population (Altman, 1992). Proponents note one study determined that private insurance did not equal or match advancements in infertility treatment methods with client access to the same degree of alignment that they did for the advancements in other conditions. Proponents agree that public policy decisions that impact women seeking infertility treatment should be based on science, not on bias or prejudice (Guzick, 2002; Jenker, 1991). The social advances for women have tended to trivialize reproduction in a effort to move women closer to an equal status with men (Gilbert, 1996).²²

The manuscript, *Effects of Infertility Insurance Mandates on Fertility*, concludes that individuals who are most likely to demand services (older women who are more educated) are also more likely to be affected by mandates due to their higher probability of having private health insurance. This research finds that mandates are not associated with increases in the first birth rates of non-white women despite the fact that nonwhite women have a higher likelihood of fertility problems, which, in turn, will impact utilization. The findings are not conclusive. However, proponents believe the data is compelling as it relates to demographic changes and on-going trends.²³

Proponents stated in written comments that infertility takes an enormous toll on affected individuals and on society. Couples in their most active years are distracted by the physical, financial and emotional hardships of this disease. Research indicated that infertility impacts a person's general health, marriage, job performance and social interactions. Infertility brings a deep sense of loss,

sadness and often depression. The depression and emotional distress associated with infertility and its challenges have been clinically demonstrated to be equal to the psychological suffering of cancer patients.²⁴

In the past, opponents have argued that infertility is not an illness; that treatment for infertility is not medically necessary; and, in some cases, treatment for infertility is considered experimental. Current objections from the VAHP emphasized the Advisory Commission's recommendations against passage of similar legislation in 1995, and 2000 and 2004. The VAHP stated in written comments that in 2004, the Advisory Commission voted unanimously not to recommend enactment of a similar bill due to concerns over high cost and uncertain outcomes associated with the bill, as well as increased costs for employers offering health insurance coverage.²⁵

States with the highest number of ART procedures include California (3,635), New York (1,768), New Jersey (1,692), Texas (1,666), Illinois (1,501), and Massachusetts (1,293). Nationwide, the percentage of ART-born infants who were born in multiple-birth deliveries was 49%; the percentage of twins was 44% and that of triplets or higher-order multiples was 5%.²⁶

MEDICAL EFFICACY

One of the debates surrounding IVF is its effectiveness. Determining success rates for a particular program or technique is difficult because success rates may vary depending on the reason for the infertility, the age of the patients, and the type of procedure being used. Also, pregnancy rates may be reported differently. For example, pregnancy rates may be reported by cycle, by patient, or by the type of procedure, each of which may yield different results.²⁷

In the United States, infertility affects approximately one in eight couples of childbearing years. Infertility strikes diverse groups and affects individuals of all socioeconomic levels and backgrounds. However, research indicates that while mandates have not reduced disparities in use of infertility treatment by race and socioeconomic status, mandates are associated with an increase in reported use of infertility treatment among highly educated, older women. Also, mandates for infertility are associated with higher rates of multiple births among older mothers. Finally, there are small negative effects of newer technologies on length of gestation, birth weight and Apgar scores.²⁸

According to the Assisted Reproductive Technology Surveillance Report 2005 (ARTS 2005), which is a collection of data pertaining to ART procedures in the United States and conducted by the Department of Health and Human Services and the Centers for Disease Control (CDC), there has been a substantial increase in multiple births in the United States since the 1980s. The increase has been attributed to an increased use of ART and delayed childbearing. Although infants conceived with ART accounted for 1% of the total

births in the United States in 2005, the proportion of twins and triplets or higher-order multiples attributed to ART were 16% and 38%, respectively. In 1999, the Society for Assisted Reproductive Technology (SART) and the American Society for Reproductive Medicine (ASARM) issued voluntary guidelines on the number of embryos transferred; these guidelines were revised in 2004 and 2006.²⁹

The CDC indicates that the number of ART cycles performed in the United States has more than doubled, from 64,681 cycles in 1996 to 134,260 in 2005. The number of live-birth deliveries in 2005 (38,910) was more than two and a half times higher than in 1996 (14,507). The number of infants born who were conceived using ART also increased between 1996 and 2005. In 2005, 52,041 infants were born, which was more than double the 20,840 born in 1996. Because in some cases, more than one infant is born during a live-birth delivery (e.g., twins), the total number of infants born is greater than the number of live-birth deliveries.³⁰

The report indicates that singleton live births are an important measure of success because they have a much lower risk than multiple-infant births for adverse infant health outcomes, including prematurity, low birth weight, disability, and death. Percentages of transfers that resulted in singleton live births are presented rather than percentages of cycles that resulted in singleton live births because that is the only way to directly compare cycles using fresh embryos with those using frozen embryos. From 1996 through 2005, the percentage of transfers that resulted in singleton live births for fresh–nondonor cycles increased 35%, from 17% in 1996 to 23% in 2005. Over the same time period, the percentage of transfers resulting in singleton live births increased 79% for frozen–nondonor cycles, 36% for fresh–donor cycles, and 48% for frozen–donor cycles.³¹

The ART Surveillance Report 2002 indicated that in Virginia, 1,324 live births that were a result of assisted reproduction techniques. Of the 1,324, births 629 infants were born in multiple-birth deliveries (47.5%); 532 infants were born in twin deliveries (40.2%); and 97 infants born in triplet or higher order delivery represented 7.3%.³²

Several recent scientific papers revealed mixed results in the eight-year effort to reduce the U.S. multiple-birth rate. One report published in *Fertility and Sterility* found that although the rate of higher-order multiples (triplets or more) has declined, the rate of twin births has increased. “Higher-order multiples are not considered a success of assisted reproductive technology,” says Dr. Anne Lyerly, chairwoman of the Ethics Committee for the American College of Obstetricians and Gynecologists. Dr. Lyerly stated that “twin births, although seldom are as medically complicated as higher-order multiples, are not ideal either. Success is really defined now as a singleton gestation.”³³

There appears to be a decline in multiple births that is related to doctors limiting the number of embryos transferred during in vitro fertilization to as few as possible. However, the use of fertility drugs that induce or enhance ovulation are unpredictable with regard to the number of eggs ultimately fertilized. The article stated that “women undergoing IVF today face a much lower risk of multiple pregnancies than they once did. As IVF techniques have improved, doctors are finding they can achieve high pregnancy rates – especially in women younger than 35 while transferring only one or two embryos to the uterus. Early in the evolution of IVF, it was common for doctors to transfer six or more, hoping that one would be viable.”³⁴

The ART Report 2005 concluded that multiple-infant births are associated with greater problems for both mothers and infants, including higher rates of caesarean section, prematurity, low birth weight, and infant disability or death. For fresh-nondonor ART cycles, the percentage of multiple-infant live births decreased 17% since 1996, from 38% of all live births in 1996 to 32% in 2005. Over the same time period, the percentage of multiple-infant live births decreased 16% for frozen–nondonor cycles and 2% for fresh-donor cycles. In all years except 1997, the percentage of multiple-infant live births remained stable for frozen-donor cycles.³⁵

Proponents of Senate Bill 631 indicate that fertility drugs used to induce ovulation are cheaper than IVF and are still used by many women. Most often, doctors try to stimulate ovulation with a drug called clomiphene citrate, which carries about an 8% chance of producing twins, but a very low risk of higher-order multiples. Drugs called gonadotropins, however, are more powerful and produce a higher risk of multiple births. Because the results can be harder to control than IVF, the drugs can carry a higher risk of multiple births. The May Fertility and Sterility study estimated the percentage of multiple births due to ovulation induction drugs at 21% for twins, 37% for triplets and 62% for quadruplets. However, many medical professionals use appropriate drugs in certain circumstances and proceed to IVF only if stimulating the ovaries with medication does not produce the desired results.³⁶

Approximately 65% of ART procedures among women aged <35 years were reported as the first ART procedure for that patient. The percentage of ART procedures among women who had undergone at least one previous procedure increased with age: only 43% of procedures among women aged greater than 42 years were reported as the first procedure for that patient. The percentage of procedures performed in a woman who had had a previous birth also increased with age, from 21% in women aged less than 35 years to 37% of women in the oldest age group. The majority of ART procedures used IVF, and less than 1% used GIFT or ZIFT. Use of ICSI was common among couples with or without a diagnosis of male factor infertility, and varied by patient age. Despite variation among all age groups, the total proportion of procedures using ICSI was greater than the proportion of IVF without ICSI.³⁷ Specifically, the total number of ART-

associated live birth deliveries in Virginia in 2005 was 1,572. The number of infants in multiple birth deliveries in Virginia was 713 (45.4)³⁸

The states with the highest number of ART-associated live-birth deliveries also had the highest number of infants born in multiple-birth deliveries. Of 4,138,349 infants born in the United States in 2005, a total of 49,308 (1%) were conceived using ART.³⁹

Technical and medical advances in assisted reproductive technologies (ART) and the demands of couples who view infertility as a surmountable obstacle have led to improved and progressive techniques in the specialty area of infertility treatment and services. Research indicates that couples facing the financial pressures of infertility would rather risk multiple gestations or have expensive and low-success, but covered surgeries. According to RESOLVE, the decline in use of higher-cost procedures would generally offset the cost of including the higher-cost procedures as a benefit and provide improved health outcomes.⁴⁰

FINANCIAL IMPACT

Twenty-one companies estimated cost figures between \$.17 and \$4.44 per member per month for a standard individual policy. Three companies' responses were outliers with per month, per individual member costs ranging from \$19.00 to \$47.70. Two insurers provided cost figures of \$44.41 and \$187 for individual coverage on an optional basis. Sixteen companies provided premium cost figures between \$1.00 and \$25.00 per month for standard group coverage. One insurer represented its cost as a percentage. Fifteen companies provided premium cost figures ranging from \$2.20 to \$62.50 per month per group certificate for optional coverage.

RESOLVE, in written comments, indicated that patients select treatment based on what is covered by their insurance plan rather than what is medically the best treatment. A woman who cannot conceive because of blocked fallopian tubes may undergo tubal surgery (covered by insurance at a cost of \$8,000-\$13,000 per surgery), but forgo in-vitro fertilization (IVF) because it is not covered, although it costs about the same as tubal surgery and statistically is much more likely to result in a successful pregnancy. The same is true for a couple who chooses less costly but riskier (for high order multiples) IUI over IVF simply because it is covered by insurance.⁴¹ RESOLVE indicates that insurance companies typically reimburse physicians at rates 50% lower than market rates.⁴²

The costs for the various assisted reproductive treatments differ according to geographical area and complexity of the procedure. The American Society of Reproductive Medicine (ASRM) lists the average price of an in vitro fertilization (IVF) cycle in the U.S. to be \$12,400. (ASRM does not qualify if this includes medications.) It is not uncommon for women living with infertility to undergo

several forms of infertility treatment over time which can add to the \$8,000 to \$10,000 base cost and can lead to extreme financial strain. Approximate costs of other treatments or diagnosis are listed below:

Average cost of an IUI cycle: \$865; Median Cost: \$350

Average Cost of an IVF cycle using fresh embryos (not including medications): \$8,158; Median Cost: \$7,500

Average additional cost of ICSI procedure: \$1,544; Median Cost: \$1,500

Average additional cost of PGD procedure: \$3,550; Median Cost: \$3,200
(Note: Medications for IVF are \$3,000 - \$5,000 per fresh cycle on average.)

Other trends in clinic pricing indicate that:

In areas with few infertility clinics, prices, on average, are higher;

High cost of living does not equate to high treatment costs;

IUI prices ranged from \$275 to \$2,457—a huge differential. Some prices quoted include medications, blood work and sonograms; others do not—hence the huge price differential; and

ICSI prices across the country are within \$500 of each other—\$1,000 to \$1,500.⁴³

The VAHP emphasized that coverage for infertility is generally available in the private health insurance market. Coverage for additional procedures such as those outlined in Senate Bill 631 is not typically offered through basic insurance. These procedures are typically high in cost, have varying rates of success, and may take many attempts before pregnancy is attained, or if it even occurs. [In cases where infertility may] have other medical repercussions, treatment is typically covered through health plans without the purchase of a rider. Surgical treatment of endometriosis serves as an example. Several health plans offer the option of purchasing an additional rider to help cover conception assistance procedures. The scope of benefits provided under these riders varies depending on the procedures covered. Requiring a mandated offer could restrict options currently available in the private market.⁴⁴

Patients may sometimes delay infertility treatment because of concerns over cost, lack of insurance coverage, or feeling that assisted reproductive technologies (ART) may not be effective. According to the Jones Institute, the cost is less, and often the success rate is greater, when patients consult a physician early in the treatment process.

Proponents believe comprehensive infertility coverage may actually reduce premium expense by as much as \$1 per member per month. Mercer, et al. found that with infertility coverage, unnecessary procedures such as tubal surgery could be eliminated and quality controls improved to reduce higher order multiple births and their accompanying costs.⁴⁵

CURRENT INDUSTRY PRACTICES

The State Corporation Commission Bureau of Insurance (BOI) surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Forty-two companies responded by August 27, 2008. Seven indicated they have little or no applicable health insurance business in force in Virginia and, therefore could not provide the information requested. Of the 35 respondents that completed the survey, two indicated they currently provide the coverage required under Senate Bill 631 in their standard benefit package. Thirty-two indicated they did not provide coverage under their standard benefit package. Fourteen insurers indicated they provide coverage on an optional group basis (one limited the benefit to a \$5,000 lifetime cap; and indicated that an employer had the choice of electing or rejecting coverage at the time of contracting).

SIMILAR LEGISLATION IN OTHER STATES

According to the National Conference of State Legislatures (NCLS), 15 states require health insurers either to offer or provide coverage for the diagnosis or treatment of infertility (NCSL, 2008). However, the services and procedures those states require insurers to provide or offer varies considerably. Each state mandating infertility treatments or benefits has different cost containment variables. And, some require insurers to cover very limited levels of treatment and may be considered inadequate.⁴⁶

Arkansas mandates insurance coverage for IVF only; excludes other forms of ART; excludes HMOs; and allows a limited lifetime maximum benefit of \$15,000. Massachusetts, New Jersey and Illinois are considered to provide the most comprehensive benefit mandates by some experts. In Massachusetts, the comprehensive benefit includes most treatments except surrogacy, reversal of voluntary sterilization and cryopreservation. Others consider Rhode Island to have the broadest coverage.

The Connecticut, New Jersey, New York, and Rhode Island mandates refer to a patient's age. Specifically, New Jersey permits insurers to limit coverage for certain treatments to people age 45 or younger. New York requires coverage for certain infertility treatments for people age 21 through 44 and also permits insurers to provide coverage for people outside that age range. Rhode Island requires coverage for all infertility coverage for women between the ages of 25 and 42.

Listed below is a limited description of each mandate:

Arkansas

Mandates insurance carriers that provide maternity–related benefits to cover IVF. Allows insurers to impose a lifetime benefit cap of \$15,000. Health maintenance organizations are exempt from the law.

Hawaii

Mandates insurance carriers that provide pregnancy–related benefits to cover one cycle of IVF, only after several conditions have been met.

Illinois

Mandates insurance carriers that provide pregnancy–related benefits to cover the diagnosis and treatment of infertility, including various ART procedures, but limits first-time attempts to four complete oocyte (egg) retrievals, and second births to two complete oocyte retrievals. Insurance carriers are not required to provide this benefit to businesses (group policies) of 25 or fewer employees.

Louisiana

Mandates insurance carriers to cover the "diagnosis and treatment of correctable medical conditions." Insurers may not deny coverage for treatment of a correctable medical condition to someone solely because the condition results in infertility. Coverage is not required for fertility drugs; in vitro fertilization or any other assisted reproductive technique; or reversal of tubal ligation, a vasectomy, or any other method of sterilization.

Maryland

Mandates insurance carriers that provide pregnancy–related benefits to cover IVF after a two–year wait following most diagnoses, with no wait required for certain diagnoses. Insurance carriers are not required to provide this benefit to businesses (group policies) of 50 or fewer employees. Religious organizations can choose not to provide coverage based on their religious views. A carrier may limit IVF benefits to three attempts per live birth, not to exceed a lifetime maximum benefit of \$100,000.

Massachusetts

Mandates insurance carriers that provide pregnancy–related benefits to cover comprehensive infertility diagnosis and treatment, including ART procedures.

Montana

Mandates HMOs (but not other types of insurers) to cover infertility treatment as a basic health care service. The law does not define "infertility services", and some HMOs exclude IVF.

New Jersey

Mandates insurance carriers that provide pregnancy–related benefits to cover comprehensive diagnosis and treatment of infertility, including assisted reproductive technology procedures, but limits attempts to four complete oocyte (egg) retrievals per lifetime. Insurance carriers are not required to provide this benefit to businesses (group policies) of 50 or fewer employees.

New York

Mandates coverage for the diagnosis and treatment of correctable medical conditions. Requires coverage for the diagnosis and treatment of infertility for patients between the ages of 21 and 44, who have been covered under the policy for at least 12 months. Certain procedures are excluded, including IVF, GIFT, reversal of elective sterilization, sex change procedures, cloning, and experimental procedures. Plans that include prescription coverage must cover drugs approved by FDA for use in diagnosis and treatment of infertility (including Ovulation Induction). The law does not apply to HMOs.

Ohio

Mandates HMOs (but not other types of insurers) to cover infertility treatment as a "preventative" benefit. The treatment must be "medically necessary," and the Ohio Department of Insurance has ruled that GIFT, ZIFT and IVF are not medically necessary.

Rhode Island

Requires insurers and HMOs that provide pregnancy–related benefits to cover the cost of medically necessary expenses of diagnosis and treatment of infertility. The law defines infertility as "the condition of an otherwise healthy married individual who is unable to conceive or produce conception during a period of one

year." The patient's co-payment cannot exceed 20 percent of the charge (RIGL 27-20-20).

West Virginia

Mandates HMOs (but not other types of insurers) to cover infertility treatment as a preventative benefit. The law does not define "infertility treatment," and HMOs have interpreted the term as excluding IVF.

States with a "Mandate to Offer"

Currently, three states have mandates to offer infertility treatment. Insurers in these states must offer employers a policy that provides coverage of infertility treatment.

California

Mandates insurance carriers to offer group policyholders coverage of infertility treatment, excluding IVF but including GIFT. (Group health insurers covering hospital, medical or surgical expenses must let employers know infertility coverage is available.)

Connecticut

Mandates insurance carriers to offer coverage of comprehensive infertility diagnosis and treatment, including IVF procedures, to group policyholders.

Texas

Mandates insurance carriers that provide pregnancy-related benefits to offer coverage of infertility diagnosis and treatment, including IVF, to group policyholders.

REVIEW CRITERIA

SOCIAL IMPACT

- a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

The American Academy of Family Physicians approximates that more than 115,000 ART procedures were performed in the United States in 2002, resulting in the births of 45,751 infants. Because transfer of multiple embryos remains common, more than one-half of infants born through ART are from multiple births, compared with 3% in the general population, and ART-born

infants account for around 17% of all multiple births. The substantially increased risks of multiple births, such as hemorrhage and hypertension in the mother and low birth weight, higher mortality, and long-term disability in the infants, must be taken into account when considering the use of ART treatment. In 2002, about 95% of triplets and higher multiples born through ART had a low birth weight, compared with 9% of single-birth infants; 97% of triplets and higher multiples were born preterm, compared with 15% of single-birth infants.⁴⁷

Infertility treatment and services are generally available. There are 15 infertility clinics in Virginia (three in Richmond; two in Fairfax; two in Virginia Beach; and one each in Alexandria, Annandale, Arlington, Charlottesville, Norfolk, Reston, Salem and Winchester). Conventional infertility treatment is often performed by obstetricians, gynecologists, urologists, and other physicians through private practices and family planning clinics on a more widespread basis. Fertility Specialists are gynecologists who exclusively commit their practice to the treatment of women and men who have difficulties conceiving. There is an adequate number of infertility services in Virginia although there is a higher concentration of available services in urban areas.⁴⁸

According to testimony by RESOLVE, an estimated 176,000 couples who live in the Commonwealth of Virginia are affected by infertility, and a vast majority of them have no insurance coverage to diagnose or treat their reproductive problems.⁴⁹

b. The extent to which insurance coverage for the treatment or service is already available.

The State Corporation Commission Bureau of Insurance (BOI) surveyed 50 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission this year. Forty-two companies responded by August 27, 2008. Seven indicated they have little or no applicable health insurance business in force in Virginia and, therefore, could not provide the information requested. Of the 34 respondents that completed the survey, two indicated they currently provide the coverage required under Senate Bill 631 in their standard benefit package. Thirty-two indicated they did not provide coverage under their standard benefit package. Fourteen insurers indicated they provide coverage on an optional group basis (one limited the benefit to a \$5,000 lifetime cap and indicated that employer had the choice of electing or rejecting coverage at the time of contracting).

The VAHP emphasized that coverage for infertility is generally available in the private health insurance market. Coverage for additional procedures such as those outlined in Senate Bill 631 is not typically offered through basic insurance. These procedures are typically high in cost, have varying rates of success, and may take many attempts before pregnancy is attained, or if it even occurs. [In cases where infertility may] have other medical repercussions, treatment is

typically covered through health plans without the purchase of a rider. Surgical treatment of endometriosis serves as an example. Several health plans offer the option of purchasing an additional rider to help cover conception assistance procedures. The scope of benefits provided under these riders varies depending on the procedures covered. Requiring a mandated offer could restrict options currently available in the private market.⁵⁰

- c. *If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.*

Health care for infertility treatments is available, but proponents suggest that most insurers do not provide insurance coverage for infertility treatment, and that those without insurance coverage for infertility are left to finance the cost of treatments on their own, which can cause significant financial hardship. Those families without the necessary financial resources must go without the treatment.

At the public hearing, a private citizen testified of having to pay a \$6,000 deductible in addition to out-of-pocket expenses of approximately \$18,000 for one IVF cycle. Another private citizen told the Advisory Commission of her experience with a shared risk program. She and her husband were prepared to pay nearly \$20,000 up front for six chances at IVF. If they conceived, the cost would have been only \$20,000. If they did not conceive within the six chances, the \$20,000 would be reimbursed to them and they would have proceeded with adoption procedures. She further explained the rarity of a doctor participating in a shared risk program and her good fortune of not having to consider the alternative of paying more than \$12,000 per IVF cycle, excluding medications. The alternative to the shared risk program would have cost this couple more than \$35,000 to have a chance of starting a family. In total, eight families testified of the extent of the cost associated with treatments. The shared experiences included spending thousands of dollars in preparation to conceive, which included for some going into debt, borrowing money from family, and exhausting all financial resources.

In a survey conducted by Mercer, it was determined that when timely and appropriate treatment for infertility is accessed, 70-80% of those provided with the necessary care will achieve a successful outcome. Lack of insurance coverage and other barriers to care can considerably increase out-of-pocket costs, and those afflicted with infertility will fail to obtain the appropriate treatment.⁵¹

- d. *If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.*

Proponents testified that considerable financial hardship is placed on infertile couples who seek treatment without insurance coverage, and the hardships come in various forms and various levels. Several proponents cited out-of-pocket expenses for treatment of several IVF cycles, charging medical expenses on credit cards, taking second mortgages on their homes, and borrowing money from friends and family in addition to conventional household debt. Couples in their most active years are distracted by the physical, financial and emotional hardships of this disease. Research indicated that infertility impacts a person's general health, marriage, job performance and social interactions. Infertility brings a deep sense of loss, sadness and often depression. The depression and emotional distress associated with infertility and its challenges have been clinically demonstrated to be equal to the psychological suffering of cancer patients.⁵²

The costs for the various assisted reproductive treatments differ according to geographical area and complexity of the procedure. The American Society of Reproductive Medicine (ASRM) reports the average price of an in vitro fertilization (IVF) cycle in the U.S. is \$12,400. (ASRM does not qualify if this includes medications.) It is not uncommon for women living with infertility to undergo several forms of infertility treatment over time, which can add to the \$8,000 to \$10,000 base cost and can lead to extreme financial strain.⁵³

The Jones Institute of Reproductive Medicine reports the following cost estimates:

Average cost of an IUI cycle: \$865; Median Cost: \$350
Average Cost of an IVF cycle using fresh embryos (not including medications): \$8,158; Median Cost: \$7,500
Average additional cost of ICSI procedure: \$1,544; Median Cost: \$1,500
Average additional cost of PGD procedure: \$3,550; Median Cost: \$3,200
(Note: Medications for IVF are \$3,000 - \$5,000 per fresh cycle on average.)

Other trends in clinic pricing include:

In areas with few infertility clinics, prices, on average, are higher.
High cost of living does not equate to high treatment costs.
IUI prices ranged from \$275 to \$2,457—a huge differential. Some prices quoted include medications, blood work and sonograms; others do not—hence the huge price differential.
ICSI prices across the country are within \$500 of each other—\$1,000 to \$1,500.⁵⁴

Proponents testified that patients may sometimes delay infertility treatment because of concerns over cost, lack of insurance coverage, or feeling that assisted reproductive technologies (ART) may not be effective. According to the Jones Institute, the cost is less, and often the success rate is greater, when

patients consult a physician early in the treatment process. The medical professional is essential to addressing critical treatment time, which reduces cost and frustration, and increases the chances of pregnancy.

e. *The level of public demand for the treatment or service.*

According to *National Survey of Family Growth, CDC 2002*, the CDC estimates there were 7.3 million women diagnosed with infertility in 2002. That number represents one in eight couples of childbearing years.

There are 15 infertility clinics in Virginia (three in Richmond; two in Fairfax; two in Virginia Beach; one each in Alexandria, Annandale, Arlington, Charlottesville, Norfolk, Reston, Salem and Winchester). There is an adequate number of infertility services in Virginia although there is a higher concentration of available services in urban areas.⁵⁵

The ART Surveillance Report 2005 indicated that in Virginia, pregnancies which produced 994 live birth deliveries yielded 1,324 infants as a result of assisted reproduction techniques; 629 infants born in multiple-birth deliveries (47.5%); infants born in twin deliveries represented 40.2%; and, infants born in triplet or higher order delivery was 7.3%.⁵⁶

f. *The level of public demand and the level of demand from providers for individual and group insurance coverage of the treatment or service.*

A study was published in *The New England Journal of Medicine* in August 2002, examining how frequently IVF treatment was utilized in each category in each state and how the medical outcomes differed in terms of singleton/twin births versus triplets or more. The study determined that clinics in states that required complete insurance coverage performed more IVF cycles than clinics in states that required partial or no coverage (3.35 vs. 1.46 and 1.21 IVF cycles per 1,000 women of reproductive age, respectively) and more transfers of frozen embryos (0.43 vs. 0.30 and 0.20 per 1000 women of reproductive age, respectively).⁵⁷

The study indicated that treatment and outcomes were more conservative in states with complete insurance coverage than in those with partial or no coverage. The results suggested doctors transferred fewer fresh embryos per cycle, the rate of live births was lower, and, importantly, the percentage of pregnancies with high-order multiples (triplets or more) was lower than in partial or no-coverage states (11.25 vs. 8.9% and 9.7%, respectively). In summary, the study showed that state-mandated insurance coverage for IVF services is associated with increased utilization of these services but with decreases in the number of embryos transferred per cycle, the percentage of cycles resulting in

live births, and the percentage of high-order multiple pregnancies, i.e., with three or more fetuses.⁵⁸

- g. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.*

No information was received from collective bargaining organizations addressing potential interest in negotiating privately for inclusion of this coverage in group contracts.

- h. Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.*

The Advisory Commission has reviewed six similar mandates since 1990 to provide coverage for infertility treatment. In the 2004 session, SB 619 was introduced and was identical to SB 631 however, it included the state employee health plan. The Advisory Commission voted unanimously (9-0) to recommend against enactment of House Bill 619.

FINANCIAL IMPACT

- a. The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.*

The JLARC evaluation indicated that based on the experience of other states, “the proposed mandate would increase access to infertility treatment and likely reduce the cost of that treatment.”⁵⁹

The medical professional is key to addressing critical treatment time, which reduces cost and frustration, and increases the chances of pregnancy.⁶⁰

- b. The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

In the Mercer survey, it was determined that when timely and appropriate treatment for infertility is accessed, 70-80% of those provided with the necessary care will achieve a successful outcome. Lack of insurance coverage and other barriers to care can considerably increase out-of-pocket costs, and those afflicted with infertility will fail to obtain the appropriate treatment.⁶¹

The general consensus is that the proposed mandate would increase the utilization of infertility treatment in Virginia based on the experience of other states with infertility mandates. Several studies indicate utilization would increase if a mandate which expands access to individuals who previously could not afford treatment or if individuals who were previously receiving treatment now chose to avail themselves to higher quantities or higher level of treatment.

The CDC reports that in certain states, ART procedures are not covered by insurance carriers, and patients may feel pressured to maximize the opportunity for live-birth delivery. Particularly, if success is defined solely as total live-birth delivery, anecdotal evidence suggests that certain ART providers might feel pressure to transfer multiple embryos to maximize their publicly reported success rates. In the United States, multiple embryo transfer was still a common practice in 2005; approximately 47% of ART procedures that used fresh, nondonor eggs or embryos and progressed to the embryo-transfer stage involved the transfer of three or more embryos.⁶²

Approximately 18% of procedures involved the transfer of four or more, and 6% of procedures involved the transfer of five or more embryos. Among women aged younger than 35 years, the proportion of ART procedures that involved four or more embryos transferred was approximately 8% because women in this age category typically experience higher success rates with fewer embryos transferred. Multiple scientific reports have advocated that singleton live-birth rates be presented as a distinct indicator of ART success.⁶³

Success rates based on singleton live-birth deliveries will provide patients with a measure that more directly highlights infant outcomes with the optimal short-term and long-term prognosis. Twins, triplets or higher-order multiples have substantially increased risks for infant morbidity and mortality. The risks for low birthweight and preterm birth both exceed 57% for twins, and the risk for very low birthweight is 9%. In addition, because twins are at substantially increased risk for perinatal and infant mortality, singleton live-birth rates are a valid measure of success.⁶⁴

c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

For some couples, infertility treatment provides an alternative that allows them to reproduce biologically. Without the benefit of fertility treatments, infertile couples may be limited to adoption or remaining childless. Although adoption seems to be a viable option for some couples, adoption can be expensive. Studies indicate that the expense of adoption can equal the cost of IVF treatments.

A woman who cannot conceive because of blocked fallopian tubes may undergo tubal surgery (covered by insurance at a cost of \$8,000- \$13,000 per

surgery), but forgo in-vitro fertilization (IVF) because it is not covered, although it costs about the same as tubal surgery and statistically is much more likely to result in a successful pregnancy. The same is true for a couple who chooses less costly but riskier (for high order multiples) IUI over IVF simply because it is covered by insurance.⁶⁵

- d. *The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

RESOLVE reports that in those states that have passed infertility mandates, physicians are often reimbursed less per treatment cycle, but have experienced treating more patients. It has not been determined that if increased demand could not be absorbed by existing infertility clinics in Virginia, there could be an increase in the number of providers in the Commonwealth.

- e. *The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.*

Twenty-one companies provided premium cost estimates relating to Senate Bill 631. Respondents estimated cost figures between \$.17 and \$4.44 per member per month for a standard individual policy. One company provided the monthly cost at \$313.50 for individual major medical coverage and did not respond to questions about each bill. Fifteen companies provided premium cost figures ranging from \$2.20 to \$62.50 per month for coverage under a group certificate offered as an option. One insurer represented its cost as a percentage.

Proponents believe comprehensive infertility coverage may actually reduce premium expense by as much as \$1 per member per month. Mercer, et al. found that with infertility coverage, unnecessary procedures such as tubal surgery could be eliminated and quality controls improved to reduce higher order multiple births and their accompanying costs.⁶⁶

- f. *The impact of coverage on the total cost of health care.*

RESOLVE highlights a report indicating that states with mandated benefits for infertility have lower multiple gestation rates, which reduces the use of expensive care associated with prematurity, low birthweight and other intensive neonatal support. These findings suggest that mandated IVF benefits are likely to enhance newborn health and thus result in lower overall healthcare costs.⁶⁷

RESOLVE cites figures indicating that comprehensive infertility coverage may reduce premium expense by as much as \$1 per month per member. In a study conducted by Mercer, et al, it indicated that unnecessary procedures such

as tubal surgeries could be eliminated and quality controls improved to reduce higher order multiple births and accompanying costs.⁶⁸ Another Mercer study indicates that the decline in use of high-cost procedures would likely offset the cost to include IVF as a benefit and provide improved health outcomes.⁶⁹

The JLARC evaluation indicated that “while evidence shows that mandated health insurance coverage for infertility treatment could potentially reduce the impact of multiple births, it is difficult to determine the net cost impact of potential reductions in preterm and low birth weight babies with increased utilization of infertility treatment.”⁷⁰

MEDICAL EFFICACY

- a. *The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.*

RESOLVE cites a statistic from the American Society of Reproductive Medicine indicating that proper treatment of infertility offers one of the highest rates of success of any disease. More than 80% of couples who complete treatment will succeed in having a family.⁷¹

Determining success rates for a particular program or technique is difficult because success rates may vary depending on the reason for the infertility, the age of the patients, and the type of procedure being used. Also, pregnancy rates may be reported differently. For example, pregnancy rates may be reported by cycle, by patient, or by the type of procedure, each of which may yield different results.⁷²

Proponents cite a study conducted by Mercer, et al. indicating that with infertility coverage, unnecessary procedures such as tubal surgery could be eliminated and quality controls improved to reduce higher order multiple births and their accompanying costs.⁷³

The CDC indicates that the number of ART cycles performed in the United States has more than doubled, from 64,681 cycles in 1996 to 134,260 in 2005. The number of live-birth deliveries in 2005 (38,910) was more than two and a half times higher than in 1996 (14,507). The number of infants born who were conceived using ART also increased between 1996 and 2005. In 2005, 52,041 infants were born, which was more than double the 20,840 born in 1996. Because in some cases more than one infant is born during a live-birth delivery (e.g., twins), the total number of infants born is greater than the number of live-birth deliveries.⁷⁴

The report indicates that singleton live births are an important measure of success because they have a much lower risk than multiple-infant births for adverse infant health outcomes, including prematurity, low birth weight, disability, and death. Percentages of transfers that resulted in singleton live births are presented rather than percentages of cycles that resulted in singleton live births because that is the only way to directly compare cycles using fresh embryos with those using frozen embryos. From 1996 through 2005, the percentage of transfers that resulted in singleton live births for fresh–nondonor cycles increased 35%, from 17% in 1996 to 23% in 2005. Over the same time period, the percentage of transfers resulting in singleton live births increased 79% for frozen–nondonor cycles, 36% for fresh–donor cycles, and 48% for frozen–donor cycles.⁷⁵

Other research suggests that without more comprehensive coverage, women living with infertility will probably choose to take the risk of undergoing additional cycles of IVF, and subsequently taking the medical risks associated with transferring multiple embryos, and perhaps the risk of life without genetically related children. These results are possible especially if women are not educated about the risks involved with multiple births.⁷⁶

The American Academy of Family Physicians approximates that more than 115,000 ART procedures were performed in the United States in 2002, resulting in the births of 45,751 infants. Because transfer of multiple embryos remains common, more than one-half of infants born through ART are from multiple births, compared with 3% in the general population, and ART-born infants account for around 17% of all multiple births. The substantially increased risks of multiple births, such as hemorrhage and hypertension in the mother and low birth weight, higher mortality, and long-term disability in the infants, must be taken into account when considering the use of ART treatment. In 2002, about 95% of triplets and higher multiples born through ART had a low birth weight, compared with 9% of single-birth infants; 97% of triplets and higher multiples were born preterm, compared with 15% of single-birth infants.⁷⁷

The VAHP stated in written comments that although the bill includes seven specific assisted reproductive procedures, the bill does not limit coverage to those procedures alone, leaving the benefit open to other measures. The VAHP does not believe it is consistent with the role of health insurance to mandate services that will only affect a small portion of the residents of the Commonwealth of Virginia. The proposed mandate would affect roughly 25 percent of all Virginians.⁷⁸

b. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

1) *The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.*

Not applicable.

2) *The methods of the appropriate professional organization that assure clinical proficiency.*

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

a. *The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.*

A medical doctor in written comments in support of Senate Bill 631 indicated that fertility issues are a significant health problem and constitute a "Life Crisis." He cited a 1998 Supreme Court ruling signifying that infertility is a "major life event under the American with Disabilities Act," because it interferes with a major life function, and reproductive issues are considered a major disability.

Proponents argue that Senate Bill 631 addresses a broad medical and social need. Testimony at the public hearing held on October 27, 2008, indicated that a study conducted in 2007 by the ASRM concluded that states with mandated benefits have lower multiple gestation rates which results in reduced utilization of expensive care associated with prematurity, low birth rate and other intensive neonatal support. Subsequent to these advantages, mandating coverage for infertility treatment would also enhance newborn health and result in an overall reduction of healthcare costs.⁷⁹ According to the *March of Dimes*, direct health care costs to employers for a premature baby during the first year of life average about \$41,610, 15 times higher than \$2,830 for a full-term delivery.⁸⁰

Dorland's Medical Dictionary defines infertility as the "diminished or absent capacity to produce offspring." The definition further explains that infertility does not denote the complete inability to produce offspring, which would be sterility. It also notes that infertility is also called relative sterility.⁸¹

A broader view of infertility includes the inability to carry a pregnancy to term and have a baby.⁸² RESOLVE, the National Infertility Organization, indicates that infertility is a medically recognized disease that affects men and

women equally. It is defined as a group of diseases of the reproductive system and recognized by the inability to conceive or retain a pregnancy during a one-year period (six months for a woman 35 years of age or older).⁸³

RESOLVE indicates that the medical community recognizes infertility as a disease. As such, many infertility treatments have been tested and proven effective for several years and are effective in helping couples achieve pregnancy, and are not cosmetic treatments. Proponents state that ART treatments, if covered, will limit the number of multiples birth pregnancies, and, therefore, reduce the number of low birth-weight babies. They believe all couples should have the ability to achieve pregnancy.

Proponents agree that public policy decisions that impact women seeking infertility treatment should be based on science not on bias or prejudice (Guzick, 2002; Jenker, 1991).⁸⁴

Opponents believe that requiring a mandate for infertility coverage could restrict options currently available in the private market. In summary, infertility services, including assisted reproductive technologies, are available to and are utilized by Virginia women. There is strong disagreement on the need for this benefit.

The VAHP opposes House Bill 631 indicating in written comments that although the bill includes seven specific assisted reproductive procedures, the bill does not limit coverage to those procedures alone, leaving the benefit open to other measures. The VAHP suggests that at a time when employers, particularly small- and medium-sized businesses, are struggling to provide basic coverage, VAHP does not believe it is appropriate to mandate services that will only affect a small portion of the residents of the Commonwealth of Virginia. The proposed mandate will only pertain to roughly 25 percent of all Virginians.⁸⁵

The Virginia Chamber of Commerce (VCC) opposed recommendation of SB 631, stating in written comments that mandates minimally impact the affordability of health insurance for most individuals. The VCC cited several categories of data supported by the Council for Affordable Health Insurance and the Kaiser Family Foundation and Health Research & Education Trust as to why the cumulative impact of recommending mandates is detrimental to small business.⁸⁶

The JLARC findings pertaining to Senate Bill 631 suggest that provisions of this bill may improve access to infertility services and affordability. The assessment points out that infertility is a disease affecting one in eight couples that can be medically treated with a high rate of success. However, the most effective or appropriate treatment for this disease is not available to many people because of cost. Based on the premise that the role of health insurance is to promote public health, encourage the use of preventive care, and provide

protection from excessive financial expenses from unexpected illness, a case can be made that the proposed mandate is consistent with the role of health insurance.⁸⁷

b. The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.

Twenty-one companies provided premium cost estimates relating to Senate Bill 631. Respondents estimated cost figures between \$.17 and \$4.44 per member per month for a standard individual policy. One company provided the monthly cost at \$313.50 for individual major medical coverage and did not respond to questions about each bill. Fifteen companies provided premium cost figures ranging from \$2.20 to \$62.50 per month for coverage under a group certificate offered as an option. One insurer represented its cost as a percentage.

An ARTS report indicates that singleton live births are an important measure of success relating to infertility treatments because they have a much lower risk than multiple-infant births for adverse infant health outcomes, including prematurity, low birth weight, disability, and death. Percentages of transfers that resulted in singleton live births are presented rather than percentages of cycles that resulted in singleton live births because that is the only way to directly compare cycles using fresh embryos with those using frozen embryos. From 1996 through 2005, the percentage of transfers that resulted in singleton live births for fresh–nondonor cycles increased 35%, from 17% in 1996 to 23% in 2005. Over the same time period, the percentage of transfers resulting in singleton live births increased 79% for frozen–nondonor cycles, 36% for fresh–donor cycles, and 48% for frozen–donor cycles.⁸⁸

The ART Surveillance Report 2005 indicated that in Virginia, pregnancies which produced 994 live birth deliveries yielded 1,324 infants. The ART Report 2005 indicated that in Virginia there were 1,324 live births as a result of assisted reproduction techniques; 629 infants born in multiple-birth deliveries (47.5%); infants born in twin deliveries represented 40.2%; infants born in triplet or higher order delivery represented 7.3%.⁸⁹

The ART Report 2005 concluded that multiple-infant births are associated with greater problems for both mothers and infants, including higher rates of caesarean section, prematurity, low birth weight, and infant disability or death. For fresh-nondonor ART cycles, the percentage of multiple-infant live births decreased 17% since 1996, from 38% of all live births in 1996 to 32% in 2005. Over the same time period, the percentage of multiple-infant live births decreased 16% for frozen–nondonor cycles and 2% for fresh-donor cycles. In all years except 1997, the percentage of multiple-infant live births remained stable for frozen-donor cycles.⁹⁰

In the past, opponents have argued that infertility is not an illness; that treatment for infertility is not medically necessary; and in some cases, treatment for infertility is considered experimental. Current objections from the VAHP emphasized the Advisory Commission's recommendations against passage of similar legislation in 1995, 2000, and 2004. The VAHP stated in written comments that in 2004, the Advisory Commission voted unanimously not to recommend enactment of a similar bill due to concerns over high cost and uncertain outcomes associated with the bill, as well as increased costs for employers offering health insurance coverage.⁹¹

The VAHP emphasized that coverage for infertility is generally available in the private health insurance market, and that coverage for additional procedures such as those outlined in Senate Bill 631 is not typically offered through basic insurance. These procedures are typically high in cost, have varying rates of success, and may take many attempts before pregnancy is attained, or if it even occurs. In cases where infertility may have other medical repercussions, treatment is typically covered through health plans without the purchase of a rider. Surgical treatment of endometriosis serves as an example. Several health plans offer the option of purchasing an additional rider to help cover conception assistance procedures. The scope of benefits provided under these riders varies depending on the procedures covered. Requiring a mandated offer could restrict options currently available in the private market.⁹²

The JLARC evaluation addressed the effects of balancing a need for coverage compared to costs of mandating the benefit for policyholders in the following manner:

Whether the need for coverage of infertility treatment outweighs the cost is less clear. Some researchers and advocates have suggested that health insurance coverage of infertility treatment could reduce overall health care costs through decrease in multiple births and the costs associated with preterm births. However, it is difficult to determine the net cost impact of the potential reductions in preterm and low birthweight babies with increased utilization of infertility treatment.⁹³

- c. *The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.*

In the case of group coverage, the decision whether to select the optional coverage or not would lie with the master contract holder and not the individual insureds.

RECOMMENDATION

The Advisory Commission voted unanimously (10-0) to recommend against the enactment of Senate Bill 631 on November 19, 2008.

CONCLUSION

The Advisory Commission expressed concern for those Virginia consumers who need infertility treatments and would benefit from the provisions of Senate Bill 631. However, the Advisory Commission members had questions about the cost impact of the bill on individual and group policyholders and the resulting impact on the number of people insured.

After reviewing data from other states with mandates for infertility and reviewing other follow-up information, the Advisory Commission voted to not recommend enactment of Senate Bill 631.

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