

**JOINT LEGISLATIVE AUDIT AND REVIEW COMMISSION
OF THE VIRGINIA GENERAL ASSEMBLY**

**EVALUATION OF PROPOSED
MANDATED HEALTH INSURANCE BENEFITS**

**Evaluation of Senate Bill 631:
Mandated Coverage of
Treatment for Infertility**

October 2008

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JLARC provides evaluations of proposed health insurance mandates in accordance with Sections 2.2-2503 and 30-58.1 of the *Code of Virginia*.

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Evaluation of SB 631: Mandated Coverage of Treatment for Infertility

JLARC SUMMARY

Senate Bill 631 would require health insurance coverage for the treatment of infertility for individuals less than 50 years old. Treatment includes, but is not limited to, artificial insemination and assisted reproductive technology techniques, such as in vitro fertilization (IVF). Coverage is only required if an individual has not undergone four complete oocyte (or egg) retrievals, except that if a live birth follows a complete oocyte retrieval, then two more oocyte retrievals shall be covered. SB 631 would not cover the reversal of a vasectomy or a tubal ligation.

MEDICAL EFFICACY AND EFFECTIVENESS

According to the U.S. Department of Health and Human Services, about two-thirds of couples who are treated for infertility are able to have a baby with treatment. The efficacy and effectiveness of specific infertility treatments varies by the type of treatment and factors that are specific to the couple, in particular the age of the woman and the cause of the couple's infertility. In general, IVF procedures have the highest success rates of all infertility procedures, with live birth rates of more than 50 percent in some situations. However, many couples pursue other infertility treatments first, and frequently experience success, before turning to IVF.

In This Evaluation

Background	1
Medical Efficacy and Effectiveness	6
Social Impact	8
Financial Impact	16
Balancing Medical, Social, and Financial Considerations	22
Acknowledgments	24

Appendixes

A. Statutory Authority for JLARC Evaluation	25
B. Proposed Mandated Benefit	27
C. Evaluation Topic Areas and Criteria	31
D. Bibliography	33

SOCIAL IMPACT

Approximately 12 percent of U.S. women of childbearing age have used some type of infertility service. Few insurance companies appear to provide comprehensive coverage of infertility treatment as part of their standard benefit, but one-third of plans indicated they offer such coverage as an option to group policyholders. Some oral medications to stimulate ovulation are low cost and generally available without insurance coverage. However, costs for IVF (which is used by a minority of women) could range to more than a third of median annual household income per treatment cycle. Pregnancies achieved through infertility treatment have led to increasing numbers of multiple-birth pregnancies, which adversely impacts public health. Minimizing the use of procedures with a high risk for multiple births would help mitigate this negative public health effect, but individuals may be unwilling to do this if financial constraints limit their options for achieving a live birth.

FINANCIAL IMPACT

The proposed mandate would likely increase access to infertility treatment and reduce the cost of that treatment. However, a Bureau of Insurance survey of insurance companies indicates that SB 631 could also increase insurance premiums. Median estimates based on all insurers responding to the survey indicate that the premium impact of SB 631 would be greater than that of any existing Virginia mandates. However, median estimates reported by those companies already providing infertility coverage are substantially lower, as are the premium impacts reported from other sources. Options to reduce the premium impact of SB 631 include lowering the age limit in the bill, reducing the number of covered treatment cycles, and capping coverage amounts.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

The need for mandated coverage of infertility treatment may be a policy decision. Many couples would benefit from increased access to infertility treatment and, depending how a benefit is structured, there could be positive impacts on public health through reduced multiple births. However, to the extent that increased premiums could affect some individuals' and employers' ability to purchase health insurance, it is important to recognize that treatment of infertility is not life sustaining nor is it required for individuals to undertake normal activities of daily living (though many medical experts point out that reproduction is a normal life activity.) While this is true for many other covered treatments, it is an important consideration when determining whether to require insurance coverage of a benefit.



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BACKGROUND

There are a variety of causes of infertility, which include both female and male factors, and a range of treatment options. Treatment options can include medications to promote ovulation in the woman, intrauterine insemination, and assisted reproductive technologies, such as in vitro fertilization. Since 1990, there have been six previously proposed health insurance mandates covering infertility treatments in Virginia, though none have been adopted by the General Assembly to date.

a. Description of Medical Condition and Proposed Treatment

Infertility is a disease or condition of the reproductive system typically diagnosed after a couple has one year of unprotected, well-timed intercourse that does not result in a pregnancy or if the woman experiences multiple (two or more) miscarriages. In some cases, a diagnosis is made sooner if the particular cause of infertility is known or can be found. About 12 percent of women (7.3 million) in the United States aged 15-44 had difficulty getting pregnant or carrying a baby to term in 2002, according to the Centers for Disease Control and Prevention.

Infertility can be male- or female-related and affects individuals from all socioeconomic levels. Approximately 35 percent of infertility cases are due to a female factor, 35 percent to a male factor, 20 percent to combined male and female factors, and approximately 10 percent are unexplained. Table 1 lists some of the diagnosed

conditions that are related to infertility. Major causes of female infertility include ovulatory and tubal disorders, and endometriosis. Poor semen quality is the major cause of male infertility. Various factors can increase an individual’s risk of infertility including being over- or underweight, age, sexually transmitted diseases, tubal disease, smoking, and alcohol use. Some couples are diagnosed with unexplained infertility if no cause for infertility can be identified. Some are also diagnosed with secondary infertility, which is the inability to become pregnant or carry a pregnancy to term following the birth of one or more children.

Table 1: Medical Conditions Related to Infertility

Medical Condition	Description of Condition
Endometriosis	Disorder in which endometrial tissue (which normally lines the uterus) is found outside the uterine cavity.
Implantation Issues	Disorder in which the embryo fails to successfully attach to the uterine lining.
Luteal Phase Defect	Disorder in which the endometrium is inadequately prepared to support the embryo.
Male Factor Infertility	Includes structural abnormalities, sperm production disorders, ejaculatory disturbances, poor semen quality, and immunologic disorders.
Multiple Miscarriage	Multiple miscarriage is considered after 2 or more miscarriages
Ovulatory Disorders	Include irregular ovulation and the absence of ovulation. Ovulation may occur with or without a menstrual period.
Polycystic Ovarian Syndrome	A hormonal disorder in women which may include irregular or absent periods and absence of ovulation.
Poor Responder	Used to define women who require large doses of ovulatory stimulation medications and make less than an optimal number of eggs.
Premature Ovarian Failure	The cessation of menstrual periods before the age of 40.
Uterine Factors	Can include uterine fibroids, congenital structural abnormalities, and intrauterine adhesions.

Source: RESOLVE, the National Infertility Association.

Once diagnosed with a condition related to infertility, many women and couples seek the services of a reproductive endocrinologist or infertility specialist. Reproductive endocrinologists and infertility specialists employ a variety of approaches to treating infertility, as listed in Table 2. Infertility can be treated with medication, intrauterine insemination (IUI), and assisted reproductive technology (ART). In many cases, several of these procedures are used in conjunction with each other. Some medical conditions related to infertility, such as uterine fibroids or endometriosis, are also treated with surgery. For many of the treatments listed on Table 2, there is an increased risk of multiple births.

A first line approach to treating infertility often involves medication to stimulate ovulation in the woman, particularly if there is a

Table 2: Types of Infertility Treatment

Treatment Type	Description of Treatment
Medications Used to Stimulate Ovulation	
--Clomiphene citrate (Clomid)	Causes ovulation by acting on the pituitary gland, and taken by mouth
--Human menopausal gonadotropin (hMG)	Used for women who do not ovulate due to problems with their pituitary gland. Is injected and acts directly on the ovaries to stimulate ovulation
--Follicle-stimulating hormone (FSH)	Works much like hMG. Is injected and causes the ovaries to begin the process of ovulation.
--Gonadotropin-releasing hormone (Gn-RH) analog	Used for women who do not ovulate regularly each month or who ovulate before the egg is ready. Acts on the pituitary gland to change when the body ovulates, and is usually injected or given with a nasal spray.
--Metformin	Used for women who have insulin resistance and/or polycystic ovarian syndrome. Helps lower high levels of male hormones in women with these conditions, which helps the body to ovulate. Usually taken by mouth, and sometimes combined with Clomid or FSH.
--Bromocriptine	Used for women with ovulation problems due to high levels of prolactin.
Intrauterine insemination (IUI)	Also known as artificial insemination, specially prepared sperm are injected into the woman's uterus. Sometimes the woman is also treated with medications that stimulate ovulation before IUI.
Assisted Reproductive Technology (ART)	
--In vitro fertilization (IVF)	Involves extracting a woman's eggs, fertilizing the eggs in the laboratory, and then transferring the resulting embryos into the woman's uterus through the cervix.
--Intracytoplasmic sperm injection (ICSI)	Involves injecting a single sperm directly into the woman's egg. ICSI must be used in conjunction with another ART procedure to place the embryos into the woman's body.
--Gamete intrafallopian transfer (GIFT)	Involves using a fiberoptic instrument to guide the transfer of unfertilized eggs and sperm into the woman's fallopian tubes through small incisions in her abdomen so fertilization occurs in the woman's body. Rarely used.
--Zygote intrafallopian transfer (ZIFT)	Similar to IVF, involves fertilizing a woman's eggs in the laboratory and then guiding the fertilized eggs into her fallopian tubes. Rarely used.
Low Tubal Ovum Transfer	Used in cases where the fallopian tubes are blocked. An egg is surgically transferred past the point of obstruction into the uterine cavity. Rarely used, typically only for religious reasons.

Source: U.S. Department of Health and Human Services: The National Women's Health Information Center and 2005 Assisted Reproductive Technology Success Rates, Centers for Disease Control and Prevention.

known ovulatory disorder. Clomiphene citrate, or Clomid, is often the first treatment prescribed when a couple is diagnosed with infertility. Clomid is a pill taken by mouth and causes ovulation by acting on the pituitary gland. While some women successfully ovulate using Clomid, other women do not. In these cases, more powerful medications, such as gonadotropins, may be prescribed to stimulate ovulation, some of which must be injected.

If pregnancy is not achieved with ovulation stimulation drugs or if there is a known problem with the male's sperm, artificial insemination may be used. Artificial insemination involves the placement of specially prepared sperm in the female genital tract. The most

common type of artificial insemination is intrauterine insemination (IUI), in which the sperm is injected into the uterus. IUI may use the male partner's sperm or donor sperm, and is often used to treat mild male factor infertility, women who have problems with their cervical mucus (which can impede the ability of the sperm to move through the genital tract), and couples with unexplained infertility. IUI is often used in conjunction with ovulation stimulation drugs.

Assisted Reproductive Technology (ART) is another category of infertility treatment that many couples turn to if other treatments have been unsuccessful or if a couple has certain factors that make ART their best option, such as advanced maternal age or poor sperm quality. As will be discussed later, ART is significantly more expensive than other types of infertility treatment, which is why couples often seek other treatment options first. ART procedures involve handling both the egg and sperm outside of the woman's body. In vitro fertilization (IVF) is the most effective, and by far the most common, ART procedure. (Over 99 percent of ART procedures are IVF.) IVF involves extracting the woman's eggs from her ovaries, fertilizing the eggs in the laboratory, and then transferring the resulting embryos into the woman's uterus.

Oocyte retrieval is the portion of the IVF process that involves extracting the woman's eggs. After the eggs are extracted, they are put in a lab dish along with the man's sperm for fertilization. In some cases, intracytoplasmic sperm injection (ICSI) is used. ICSI involves injecting a single sperm directly into the woman's egg. ICSI is often used for couples in which there are serious problems with the man's sperm.

Embryo transfer is the step in the IVF process where one or more embryos are placed into the female uterus. Embryo transfer can involve either fresh or frozen embryos. Fresh embryo transfer uses eggs that are fertilized during the same IVF cycle in which the eggs are extracted. (IVF cycles follow the woman's menstrual cycle.) The embryo(s) are typically transferred three to five days after fertilization. Frozen embryo transfer involves the transfer of embryos that were created from previous IVF cycles and then cryopreserved. With a frozen embryo transfer, the embryos are thawed just prior to the transfer.

Low tubal ovum transfer is a rarely used treatment that is utilized in some cases if blockages in the fallopian tubes cannot be corrected. The woman's egg is surgically transferred past the point of obstruction into the uterine cavity after normal intercourse. Success rates for low tubal ovum transfer are low, but the procedure is accepted by some religions that oppose other forms of infertility treatment.

b. History of Proposed Mandate

Since 1990, six mandates have been proposed in the Virginia General Assembly similar to SB 631 to provide coverage for the treatment of infertility. The most recent proposal was HB 619 of the 2004 Session; this bill was identical in coverage to SB 631 except that it also included the State employee health plan. The infertility mandates proposed in sessions prior to 2004 are as follows: HB 271 (1990 Session), HB 990 (1992 Session), HB 1387 (1994 Session), HB 2403 (1999 Session), and HB 1151 (2000 Session). The Special Advisory Commission voted against enacting the previously proposed mandates with the exception of HB 271 from the 1990 Session. The commission voted to recommend HB 271 to the General Assembly, with amendments to narrow the scope of coverage and to include language which would limit the cost impact of the bill.

According to the National Conference of State Legislatures (NCSL), as of June 2008, 14 states had mandates covering infertility treatment. The coverage in different state mandates varies. Some mandates cover infertility services generally, while others specifically list IVF as a covered service. Many state mandates include caps or limits on coverage for infertility services, such as maximum benefit levels, limited numbers of treatments, and age limits. Also, two states have a mandated offer for infertility (in which insurers are required to make the coverage available for purchase for an additional fee) rather than a mandated benefit, and two states specifically exclude IVF in their coverage. In addition to the 14 states cited by NCSL, Louisiana has a mandate indicating insurers may not deny coverage for a medical condition solely because the condition results in infertility. However, the mandate does not require coverage of typical infertility treatments.

c. Proponents and Opponents of Proposed Mandate

Proponents and opponents of SB 631 will have the opportunity to express their views at the Special Advisory Commission on Mandated Health Insurance Benefits public hearing on October 27, 2008. Proponents of the proposed mandate are largely individuals and couples who have had difficulty becoming pregnant and/or sustaining pregnancies, and some infertility specialists that believe access to infertility treatment should be expanded beyond those who can afford to pay out of pocket. RESOLVE, the national infertility association, also supports mandated coverage of treatment for infertility, including SB 631. The primary opposition to SB 631 comes from the insurance industry due to the potential impact on premiums such a mandate may have. Industry representatives also indicate that treatment for infertility can be purchased as a rider through many plans.

MEDICAL EFFICACY AND EFFECTIVENESS

According to the U.S. Department of Health and Human Services, about two-thirds of couples who are treated for infertility are able to have a baby with treatment. Advocates of coverage for infertility treatments and the American Society for Reproductive Medicine cite even higher success rates of closer to 80 percent. The efficacy and effectiveness of specific infertility treatments vary by the type of treatment and factors that are specific to the couple, in particular the age of the woman and the cause of the couple's infertility. In general, IVF procedures have the highest success rates of all infertility procedures. For example, women using fresh, nondonor eggs have an 11 to 37 percent chance of experiencing a live birth in any given cycle depending on their age. Women of all ages have a greater than 50 percent chance of experiencing a live birth per cycle when using fresh embryos from donor eggs. The success rates of other types of infertility treatments are significantly lower than for IVF. However, as discussed previously, many couples pursue other infertility treatments first, and frequently experience success, before turning to IVF.

a. Medical Efficacy of Benefit

Medical experts indicate that the efficacy of different infertility treatments varies greatly depending on multiple factors, such as the age of the woman, the cause of infertility, and the types of treatment used. Pregnancy rates of various treatments should be considered against the natural pregnancy rate of 20 percent. Healthy couples normally have a one in five chance of getting pregnant with well-timed intercourse and using no contraception.

Medical Efficacy

Assessments of medical efficacy are typically based on clinical research, particularly randomized clinical trials, demonstrating the efficacy of a particular treatment compared to alternative treatments or no treatment.

With regard to ovarian stimulation medications, several studies have reported pregnancy success rates ranging from nine percent to 15 percent per cycle for clomiphene citrate. For instance, a 1997 meta-analysis across 22 different trials found a pregnancy rate of nine percent per cycle for clomiphene citrate. A 2005 study comparing the efficacy of clomiphene citrate in women with polycystic ovarian syndrome and a 2006 study assessing the efficacy of clomiphene citrate in couples with ovulatory females and with borderline male factor infertility, early stage endometriosis, and unexplained infertility found slightly higher pregnancy success rates of 15.1 percent and 12 percent per cycle, respectively. Other drugs to stimulate ovulation are often used in conjunction with IUI or ART procedures, so it appears their efficacy has not been studied as extensively when used alone. However, the 1997 meta-analysis reported a seven percent pregnancy rate per cycle for follicle-stimulating hormones.

Pregnancy rates for IUI vary based on a number of factors, most notably whether ovarian stimulation drugs are used. The 1997 meta-analysis and a 1999 study found that when no ovarian stimulation drugs are used, the pregnancy rates per cycle for IUI are around five or six percent. However, when combined with ovarian stimulation medications, these studies reported pregnancy rates ranging from seven to 15 percent per cycle. The 1999 study also found that, after four cycles, 33 percent of couples achieved pregnancy when combining IUI with follicle-stimulating hormones and gonadotropins.

Studies have also shown that several factors can improve pregnancy rates. Two recent studies found that the pregnancy rate increased based on the number of preovulatory follicles (which will be released as eggs by the woman's ovaries) and the concentration and quality of sperm. Greater numbers of follicles and better sperm resulted in improved pregnancy rates. One of these studies also found that a duration of infertility of less than three years resulted in better pregnancy success rates. Another recent study found that withholding IUI until the follicle(s) have ruptured, as detected through ultrasound, may yield pregnancy rates that are closer to the natural rate of 20 percent per cycle.

Other studies have found certain factors to be negatively correlated with IUI pregnancy rates. These include increasing maternal age and increasing numbers of IUI cycles. For example, most pregnancies occurred within the first two treatment cycles in one of the aforementioned studies.

While medical efficacy rates have been studied for ART, U.S. pregnancy and live birth rates resulting from ART are tracked in detail by the Centers for Disease Control and Prevention (CDC). These pregnancy and live birth rates are discussed below.

b. Medical Effectiveness of Benefit

Since 1992, the CDC has been required by law to publish success rates for ART procedures performed at fertility clinics in the United States. Because ART success rates are affected by multiple patient and treatment factors, the CDC indicates that using a single measure of success is not sufficient to evaluate the effectiveness of ART procedures. Table 3 shows national pregnancy and live birth rates for IVF treatments using both fresh and frozen nondonor eggs, as well as donor eggs. For women using their own eggs, the percentage of pregnancies and live births drops significantly as the woman ages. Also, fresh embryos have a slightly higher live birth success rate than frozen embryo transfers. (Pregnancy rates are not provided by the CDC for frozen embryo transfers or IVF cycles conducted with donor eggs.)

Medical Effectiveness

Medical effectiveness refers to the effectiveness of a particular treatment in a normal clinical setting as opposed to ideal or laboratory conditions.

While the age of the woman is a determining factor when using nondonor eggs, it does not affect success rates using donor eggs. Therefore, the CDC reports success rates for procedures using donor eggs for all ages combined. Fresh embryos using donor eggs results in a live birth rate of more than 50 percent, while frozen embryos from donor eggs resulted in a live birth rate of approximately 31 percent.

Table 3: National Pregnancy and Live Birth Rates for In Vitro Fertilization, 2005

Type of Cycle	Age of Woman			
	<35	35-37	38-40	41-42
Fresh Embryos from Nondonor Eggs				
Percent of cycles resulting in pregnancies	43.1%	35.7%	26.8%	17.6%
Percent of transfers resulting in live births	37.3	29.5	19.7	10.6
Frozen Embryos from Nondonor Eggs				
Percent of transfers resulting in live births	31.7	27.7	23.3	15.9
All Ages Combined				
Donor Eggs	Fresh Embryos		Frozen Embryos	
Percent of transfers resulting in live births	52.3%		30.9%	

Source: 2005 Assisted Reproductive Technology Success Rates, Center for Disease Control and Prevention

SOCIAL IMPACT

In the United States, an estimated one in eight couples is infertile, and approximately 12 percent of women of childbearing age have used an infertility service of some type. Women pursue a wide range of treatments for infertility, but a minority end up utilizing IVF. Very few insurance companies (two responding to a Bureau of Insurance survey) appear to provide comprehensive coverage of infertility treatment as would be required by SB 631 as part of their standard benefit, but one-third of plans indicated they offer such coverage as an option to group policyholders. The availability of infertility treatment without health insurance coverage varies. Some oral medications to stimulate ovulation are low cost and generally available. However, the cost of IVF could range to more than one-third of median annual household income per cycle and is, therefore, unavailable for many couples without coverage.

Pregnancies achieved through infertility treatment have led to increasing numbers of multiple-birth pregnancies, which adversely impacts public health through increased numbers of preterm and low birthweight babies. Minimizing the use of procedures that have a high risk for multiple births and reducing the number of

embryos transferred during IVF would help mitigate this negative effect. However, individuals may be unwilling to do this if they are financially constrained in their options for achieving a live birth.

a. Utilization of Treatment

The CDC estimates that about 12 percent of women of childbearing age in the United States have used an infertility service (including counseling, diagnosis, and treatment) during their lifetime. Of those seeking medical assistance, about 74 percent of women received counseling, 59 percent underwent some testing, 46 percent received drug treatment, 13 percent underwent intrauterine insemination, 8 percent underwent surgery for blocked tubes, and 3 percent used ART. Using the CDC's estimate of 12 percent women nationally using an infertility service and based on the population in Virginia of women aged 18 to 44 (estimated to be the population of childbearing age), approximately 176,000 Virginia women have used an infertility service of some kind.

Some infertility treatments—for example, counseling or some drugs to stimulate ovulation—may not be provided through an infertility specialist. However, more complex infertility treatments are typically provided by reproductive endocrinologists or infertility experts. Two reproductive endocrinologists consulted for this review provided rough estimates of the utilization rates of different treatments at their clinics. Based on information provided by these experts, it appears a minority of infertility patients pursue ART even at infertility clinics. One medical expert with a clinic in Atlanta estimated that approximately 30 percent of his patients start with ovulation stimulation drugs and then combine the drugs with IUI if they are not successful with the drugs alone. This expert estimated that about 20 percent of his patients eventually use ART. Another expert in the central Virginia region estimated that approximately 25 percent of his patients use IUI, with about 25 to 40 percent utilizing ART.

For those women using ART, nearly all use IVF because it is the safest and most effective ART procedure (Table 3). Sixty percent of couples also combine ICSI with IVF to increase their chances of having a live birth. Only a very small number of couples use other ART procedures, such as GIFT and ZIFT, and likely only under very unique circumstances. In fact, some infertility practices no longer offer non-IVF procedures as a treatment option.

An important consideration regarding utilization of different types of infertility treatment is that utilization rates across different treatments are not mutually exclusive. Many couples start with one treatment, and if they do not find success, move on to another. Also, as indicated previously, the type of treatment used is largely

dictated by the cause of infertility, if known, and other factors, such as the woman’s age. For example, a woman who is 40 or older may be directed to IVF as her first mode of treatment.

Table 3: U.S. Utilization of Assisted Reproductive Technology Procedures, 2005

Procedure	Percent of Procedures
IVF	>99%
<i>IVF with ICSI</i>	60%
<i>IVF without ICSI</i>	40%
GIFT	<1%
ZIFT	<1%
Combination	<1%

Source: 2005 Assisted Reproductive Technology Report: National Summary, Centers for Disease Control and Prevention

b. Availability of Coverage

Based on a Bureau of Insurance (BOI) survey of the top 50 health insurance providers in Virginia, only two of 42 companies responding to the survey provide coverage for infertility treatment as part of their standard benefit at the level that would be required by SB 631. A third of the companies (14 companies) indicated that they provide the coverage in SB 631 on an optional basis but only for group policyholders, although one plan indicated that there is a \$5,000 lifetime limit on its coverage. (Some plans do not market individual policies.) Eighteen companies responded that they do not provide the coverage in SB 631. However, two of these companies indicated that they provide some coverage for infertility treatment. One company responded that it covers artificial insemination as part of its standard coverage. Another company indicated that its base plan includes coverage for the diagnosis and treatment of involuntary infertility and for artificial insemination subject to a 50 percent coinsurance factor. This company also indicated that an enhanced benefit can be purchased by group plans to cover IVF at a 50 percent coinsurance factor. The remaining eight plans responding to the survey indicated that they do not market plans in Virginia to which health insurance mandates apply.

Representatives of the insurance industry indicated that, in general, many insurance plans will cover treatment for conditions that may result in infertility, such as endometriosis. However, most plans will not cover actual infertility treatment.

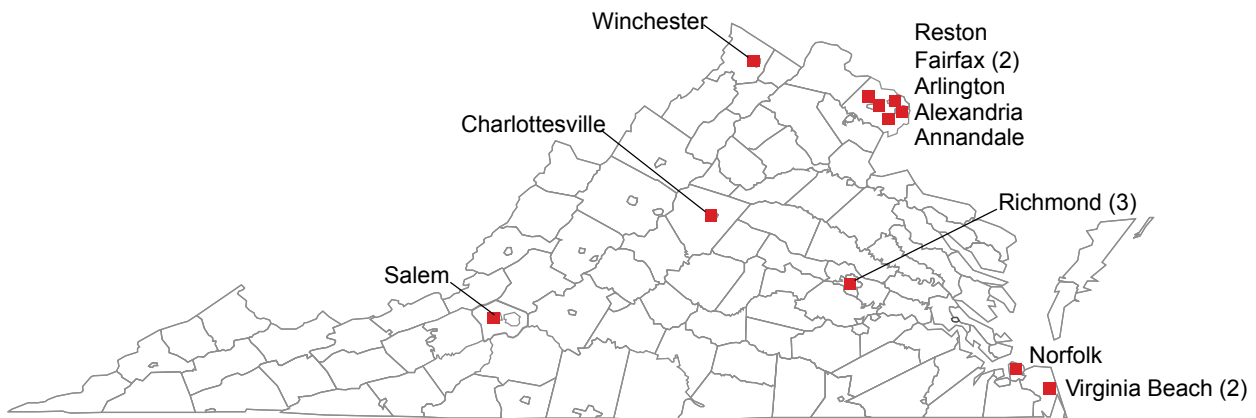
c. Availability of Treatment/ Benefit

Treatment for infertility appears to be generally available in most parts of Virginia, though a review of the locations of Virginia’s in-

fertility clinics indicates that there may be somewhat less access to more sophisticated procedures, such as IVF, in rural and south-west parts of the state. Some medications to stimulate ovulation, such as clomiphene citrate, can be prescribed by an OB/GYN and purchased at most pharmacies. Likewise, in some cases IUI is performed by an OB/GYN, which can increase its accessibility.

IVF procedures are performed and monitored by reproductive endocrinologists and infertility specialists at infertility clinics. According to the CDC, in 2005 there were 15 infertility clinics across Virginia. As shown in Figure 1, infertility clinics were more heavily concentrated in northern Virginia, central Virginia, and the Tidewater area. However, there are a number of clinics outside of these regions. According to RESOLVE, the National Infertility Association, the availability of infertility treatment in Virginia is reasonably good compared to many other states.

Figure 1: Infertility Clinics in Virginia Providing Assisted Reproductive Technology, 2005



Source: Centers for Disease Control and Prevention.

d. Availability of Treatment Without Coverage

If patients do not have insurance coverage for infertility treatment, their only option is to pay out of pocket for the treatment. As discussed in the next section, there is a wide range in the costs of different infertility treatments. Costs for some treatment, such as oral medications to stimulate ovulation, may be as low as \$10 per month and therefore would be largely available to most couples. However, costs for more sophisticated procedures, such as IVF, can range from \$10,000 to \$20,000 for one cycle and are likely unavailable to many patients without insurance coverage due to the cost.

e. Financial Hardship

The cost of infertility treatment varies significantly depending on the type of treatment used, but costs could quickly cause financial hardship for many couples. Medical experts and RESOLVE indicate that the cost of treatment varies regionally, and to some extent, is based on what the market will bear. Table 3 provides estimated costs for the most frequently utilized types of infertility treatment. As shown in Table 3, costs range from as low as \$10 per cycle for medications to stimulate ovulation to up to \$20,000 for one cycle of IVF.

Table 3: Estimated Costs of Infertility Treatment

Treatment	Estimated Cost for One Cycle
Medications to stimulate ovulation (includes oral and injectible medications)	\$10-\$5,000
IUI (includes IUI with and without medications to stimulate ovulation)	\$300-\$3,500
IVF (includes cost of medications to stimulate ovulation & ICSI) ^a	\$10,000-\$20,000
Frozen Embryo Transfer	\$2,700-\$3,000

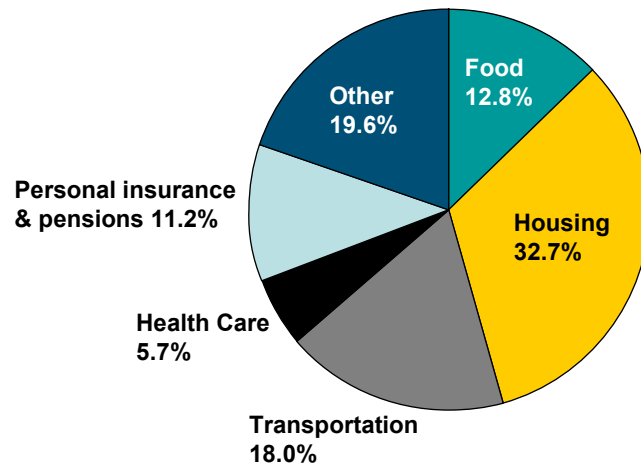
^a Some clinics offer package deals that include an agreed-upon number of IVF cycles for a set price. If pregnancy is not achieved during the agreed-upon number of cycles, the patient receives her money back (excluding money paid for medications and lab work). Such packages are typically only available to relatively young women.

Source: Central Virginia infertility clinic and RESOLVE, the National Infertility Association

The costs of several of the treatments in Table 3 could lead to financial hardship for some couples after even one treatment cycle. Based on data from the U.S. Census Bureau that has been adjusted for inflation, the median household income in Virginia in 2008 is \$58,607. Therefore, the costs for one cycle of infertility treatment could range from less than one percent of median household for some ovulation stimulation medications to more than a third of household income for IVF. As shown in Figure 2, this is significantly more than the amount households typically allocate to health care costs, which is estimated to be 5.7 percent of annual household expenditures.

Further exacerbating couples’ financial hardship is the fact that many women go through multiple treatment cycles before achieving a live birth. The type of treatment used and the number of times it is used depends on a variety of factors, including the cause of infertility and the woman’s age. However, experts indicate that in general, there are diminishing returns after three unsuccessful cycles of the same treatment. At that point, a decision will typically be made as to whether another treatment option, often more expensive and aggressive, is possible.

Figure 2: Distribution of Total Annual Household Expenditures by Major Category, 2005



Source: Bureau of Labor Statistics, Consumer Expenditure Survey

f. Prevalence/ Incidence of Condition

Prevalence

Prevalence is defined as the total number of cases of the condition in the population at a specific time.

Based on data collected by the CDC, approximately one in eight couples of childbearing years in the United States is infertile. The prevalence of infertility increases as couples age. For example, about one third of couples in which the woman is over 35 have infertility problems. Infertility occurs in men and women equally. Approximately 35 percent of infertility is due to a male factor, approximately 35 percent is due to a female factor, in 20 percent of cases there are both male and female factors contributing to infertility, and in the remaining ten percent of cases the infertility is unexplained.

g. Demand for Proposed Coverage

As indicated previously, the CDC estimates that 12 percent of women of childbearing age in the United States have used an infertility service. (These include services to diagnose and treat infertility, and services other than routine prenatal care to prevent miscarriages.) Applying Virginia's population to the CDC estimate, approximately 176,000 Virginia women have used an infertility service. It is likely that many of these women and their partners would support insurance coverage of the treatment of infertility. However, because some couples may not be able to afford infertility treatment, the estimate of 176,000 may understate the number of couples who desire and would support coverage for infertility treatment. For example, a public health expert affiliated with RESOLVE indicated that only ten percent of people who need IVF

have access to the treatment, though many of these individuals may have utilized cheaper infertility treatments. Another consideration is that health insurance mandates only affect an estimated one-quarter to one-third of the health insurance market. Therefore, the proportion of couples that would be affected by the proposed mandate could also be substantially less than 176,000.

h. Labor Union Coverage

Unions do not appear to have advocated specifically for the inclusion of infertility services in their health benefit packages. Typically, unions advocate for broader benefits, rather than benefits as specific as coverage for infertility treatment.

i. State Agency Findings

As mentioned previously, the Special Advisory Commission has reviewed six other proposed mandates since 1990 to provide coverage for infertility treatment. The most recent proposal was HB 619 of the 2004 Session, which was identical in coverage to SB 631 except that it also included the State employee health plan. Reports of the Special Advisory Commission documenting the research and testimony provided to the Commission, as well as the recommendation of the Commission, are available for each of the proposed mandates.

j. Public Payer Coverage

Infertility treatment is not covered by Medicaid.

k. Public Health Impact

There are a number of concerns surrounding the public health impact of infertility treatment. A primary concern is that women who undergo fertility-assisted pregnancies are more likely to deliver multiple-birth infants than women who conceive naturally. Multiple-infant births are associated with greater health problems for both mothers and infants, including maternal complications such as hemorrhage and hypertension, higher rates of cesarean deliveries, prematurity, low birthweight, and infant death and disability.

Medical experts indicate that the greatest risks for high-order multiple births are associated with procedures that combine ovarian stimulation medications with IUI. The risk of multiple births varies depending on the type of ovarian stimulation used. However, when IUI is combined with the more powerful medications that are injected to stimulate ovulation, the risk of multiple births is from 20 to 25 percent. Because physicians are unable to control

Public Health

The role of public health is to protect and improve the health of a community through preventive medicine, health education, and control of communicable diseases.

the number of eggs that may be released from the woman's ovaries and become fertilized, most very high-order births, such as quintuplets, are a result of ovarian stimulation medications combined with IUI.

ART procedures, which allow control of the number of embryos, are also statistically linked to greater numbers of multiple births. The CDC closely tracks the birth outcomes of babies born using ART procedures. Of the 52,041 infants born through ART in the United States in 2005, 49 percent were born in multiple-birth deliveries compared with 3 percent in the general U.S. population. (Of the 1,572 infants born through ART in Virginia, 45 percent were born in multiple-birth deliveries.) The twin rate was 44 percent compared with 3 percent in the general U.S. population, and the rate of triplets and higher-order multiples was 5 percent, approximately 25 times higher than the general U.S. population rate (0.2 percent). Although only approximately one percent of U.S. infants born in 2005 were conceived through ART, these infants accounted for 17 percent of multiple births nationwide (16 percent of twins and 38 percent of higher-order multiples). While a number of factors affected the multiple-birth risk, the number of embryos transferred was a key risk factor for multiple-birth ART deliveries.

In large part due to the multiple birth factor, babies conceived through ART are more likely to be preterm and low birthweight. The CDC reports that 42 percent of ART infants born in 2005 were preterm compared with approximately 13 percent of preterm births in the general U.S. population. With regard to multiples in particular, the CDC reports that 66 percent of ART twins and 97 percent of higher-order multiples were born preterm. Preterm infants have increased risk of death and have more health and developmental problems than full-term infants. They are also much more costly. Approximately 57 percent of ART twins and 95 percent of ART higher-order multiples were also low birthweight. However, multiple birth ART infants were not the only ones to be affected by prematurity and low birthweight. Infants conceived through ART in single birth pregnancies were also slightly more likely to be preterm and low birth rate than babies born in single births in the general U.S. population.

Proponents of health insurance mandates for infertility indicate that many of the negative public health impacts related to infertility treatment result because individuals feel they have limited opportunities to achieve pregnancy due to financial constraints. According to RESOLVE, if people are limited to what they can afford to pay for out of pocket, they will be willing to take more risks in hopes of realizing a live birth. For example, they may be more likely to choose IUI combined with ovarian stimulation than IVF because it is cheaper, or they may choose to have more embryos

transferred during an IVF cycle. The CDC also indicates that in states where ART procedures are not covered by insurance carriers, patients might feel pressured to maximize the opportunity for live-birth delivery through the transfer of multiple embryos. (The CDC also indicates that, if success is defined solely as total live-birth delivery, certain ART providers might feel pressure to transfer multiple embryos to maximize their publicly reported success rates.) Further, there is some research showing that in states with mandated insurance coverage for IVF, there are decreased numbers of embryos transferred per cycle.

Reducing the number of transferred embryos would help to minimize the risk of adverse ART outcomes. According to the CDC, approximately 47 percent of ART procedures that used fresh, nondonor eggs or embryos involved the transfer of three or more embryos. However, recent research has found that for infertile women who have a high expected probability of success with ART, single embryo transfer (SET) may be an effective strategy. Clinical trials have shown that a protocol consisting of a SET cycle followed by a second SET cycle if the first fails is associated with a cumulative probability of success that is similar to that of a single ART cycle in which two embryos are transferred simultaneously, but with a much lower risk of multiple delivery. To minimize the negative impact of multiple births associated with ART, medical experts suggest adhering to the *Guidelines on Number of Embryos Transferred* of the American Society for Reproductive Medicine (ASRM). The ASRM guidelines are tiered based on patient age and other circumstances. However, for patients under the age of 35 who have a favorable prognosis, the guidelines indicate that consideration should be given to transferring only a single embryo.

FINANCIAL IMPACT

Based on the experience of other states, the proposed mandate would increase access to infertility treatment and likely reduce the cost of that treatment. However, a BOI survey of insurance companies indicates that mandated coverage of infertility treatment would also increase insurance premiums. Median premium estimates based on the responses of all insurance companies indicate the premium impact of SB 631 would be greater than existing mandates in Virginia. However, median estimates reported by those companies already providing infertility coverage were substantially lower, as are the premium estimates based on the experience in other states. Some researchers have suggested that health insurance coverage of infertility treatment could reduce overall health care costs, through decreases in multiple births. However, it is difficult to ascertain whether this would be the case. To the extent that a mandate could increase insurance costs, it is important to consider that while infertility is a disease, the treat-

ment is not life sustaining or required for individuals to undertake normal activities of daily living, though medical experts point out that reproduction is a normal life activity.

a. Effect on Cost of Treatment

Mandated coverage of infertility treatment would likely decrease the cost of treatment. According to RESOLVE, this has been the case in other states that have passed such mandates. Although specific cost data was not provided, RESOLVE indicates that in order to maintain profit margins at the lower cost per treatment, infertility specialists have had to see more patients. For this reason, some physicians have not supported health insurance mandates for infertility. However, RESOLVE indicates that there is widespread support for a mandate among the infertility medical community in Virginia.

b. Change in Utilization

The proposed mandate would likely increase the utilization of infertility treatment in Virginia based on the experience of other states with infertility mandates. Several studies have found increased utilization of ART in those states with health insurance mandates. CDC data also seems to indicate that utilization would increase. The CDC reports that the ratio of the number of ART procedures per million population was 453 nationally in 2005. However, among those states with mandates covering ART, the average ratio was 633 procedures per million population. The ratio of ART procedures was not higher than the national number for every state with a mandate requiring coverage of ART, reflecting the notion that other factors, such as availability of services, likely affect utilization. For example, even though Arkansas has a mandate requiring coverage of ART, the utilization of ART procedures is lower in the state (173.8) than the national ratio, likely in part because no medical centers in the state offer the procedures. Also, because health insurance mandates only affect an estimated one-quarter to one-third of the market, other factors likely affect utilization. For example, even though Virginia does not have a mandate covering infertility services, the average ratio of the number of ART procedures was 559.2 in the Commonwealth, which is substantially higher than the national ratio.

Medical experts suggested several modifications to SB 631 that would help curb the ineffective utilization of infertility treatment and ensure that coverage is targeted at those who could most benefit from the treatment. First, SB 631 would require coverage of individuals who are less than 50 years old. However, one medical expert indicated that restricting coverage to individuals aged 44 or

younger might be appropriate because success rates drop drastically after that point. Also, three medical experts indicated that the bill's coverage of four complete oocyte retrievals appears generous. Reducing coverage to three oocyte retrievals would probably be adequate for most couples and reduce utilization, particularly for those situations where there is a low probability of success.

c. Serves as an Alternative

A U.S. Supreme Court opinion agreed that reproduction is a major life activity and confirmed that conditions that interfere with reproduction should be regarded as disabilities, as defined in the Americans with Disabilities Act. For many couples, infertility treatment provides an alternative that allows them to reproduce biologically. In the absence of infertility treatment, their choices are typically adoption or living childless. While adoption may be a theoretical alternative to infertility treatment for starting a family, it can be very expensive and the outcome unknown. In many cases, the cost of adoption approximates the cost of IVF. Therefore, to the extent that infertility treatment may be unaffordable, so likely is adoption for many couples. According to the CDC, the risks, benefits, and costs of alternatives such as adoption and living without children are not immediately clear, and decision-making involves serious emotional responses.

Even though medical experts agree that infertility is a medical disease that usually occurs through no fault of the individual, it is also the case that it is a disease that does not require treatment for individuals to live a normal, healthy life, from the perspective of individual biological health. Unlike some other medical conditions, such as cancer or heart disease, treatment for infertility is not life sustaining for the individual receiving treatment, the disease will not progress if left untreated, and treatment is not required for individuals to undertake normal activities of daily living (although many experts point out that reproduction is considered a normal life activity and socially desirable.) While these factors are true of many other medical conditions that are commonly treated and for which health insurance often provides coverage, it is important to consider this point in the context of requiring coverage for infertility treatment and the potential tradeoffs it may entail for individuals, families, and society.

d. Effect on Providers

The proposed mandate would likely affect providers of infertility treatment. As mentioned previously, RESOLVE indicates that in those states that have passed infertility mandates, physicians have often been reimbursed less per treatment cycle, but have seen

more patients. If increased demand could not be absorbed by the existing infertility clinics in Virginia, then there could be an increase in the number of providers attracted to the Commonwealth.

e. Administrative and Premium Costs

The proposed mandate is expected to result in increased administrative costs for insurance companies as a result of having to establish provider networks and negotiate reimbursement rates with providers that they potentially do not have in their networks. The median monthly premium estimates reported by insurance companies for standard coverage are \$19.00 and \$17.17 for individual and group plans respectively, with estimates for optional coverage being higher. These estimates appear higher than the cost of existing Virginia mandates. However, the median amounts reported by those companies already providing infertility coverage, whether as a standard benefit or a group, were substantially lower and likely within in the range of existing Virginia mandates, as were the premium impacts reported in other states.

Administrative Expenses of Insurance Companies

In its survey of insurance providers, BOI does not ask companies to provide estimates of their administrative expenses associated with the proposed mandate. However, administrative expenses related to SB 631 could be initially higher than other mandates to the extent that insurers would need to establish provider networks and negotiate reimbursement rates with providers for newly covered infertility services.

Premium and Administrative Expenses of Policyholders

BOI annually surveys the top 50 Virginia health insurers (based on premium volume) about the impact of proposed health insurance mandates. While an overall response rate to the survey of 84 percent (42 companies) was achieved, only a subset provided an estimate of the monthly premium cost for SB 631. Five companies provided an estimate for individual policy holders (Table 4), and 18 companies provided an estimate for group certificate holders. (Eight additional companies responded that they did not conduct any business in Virginia that is impacted by mandates.)

Among those companies providing individual coverage, the median monthly premium estimate for providing the proposed coverage as a standard benefit is \$19.00 per month, with estimates ranging from \$0.17 to \$47.70. The median monthly estimate for providing the proposed coverage as an option is \$490.30, with estimates ranging from \$44.41 to \$793.60. Due to the low number of insurance companies providing estimates for individual coverage, the reliability of the estimates for individual coverage is questionable, in particular those for individual optional coverage.

Average Individual Insurance Premiums

In October 2007, the Virginia Bureau of Insurance reported an average annual health insurance premium (with current mandated benefits) for an individual contract, single coverage, of \$2,929.58, or approximately \$244 per month.

Table 4: Estimated Monthly Premium Impact for SB 631

	# of Responses	Median Estimate	Highest Estimate	Lowest Estimate
Individual (Standard)	5	\$19.00	\$47.70	\$0.17
Individual (Optional)	4	\$490.30	\$793.60	\$44.41
Group (Standard)	17	\$17.17	\$59.60	\$1.00
Group (Optional)	18	\$34.81	\$992.00	\$2.20

Source: Bureau of Insurance survey of insurance providers, 2008.

Impact of Premiums on Employers' Decisions to Offer Health Insurance

"Elasticity of offer" indicates how sensitive employers are to changes in premiums in their decisions to offer health insurance. The Congressional Budget Office and others have reported an elasticity of offer of approximately -0.25 across all employers, meaning that a ten percent increase in the average premium is predicted to decrease the likelihood of an employer offering health insurance by about 2.5 percent. Small employers are more sensitive to price and have a higher elasticity of offer. In addition to premiums, other factors affect employer decisions to offer health insurance including the availability of public coverage, such as Medicaid, non-group coverage alternatives for employees, the type of industry, and the employer's location.

A premium increase of \$19.00 for individual standard coverage would result in a monthly premium increase of almost eight percent based on the estimated average monthly premium cost for a single coverage, individual contract, as defined in BOI's 2007 report on the financial impact of mandated health insurance benefits. This would be more expensive than any existing Virginia mandates. According to the BOI report, the greatest impact of any existing mandates is estimated to be 5.3 percent of the overall premium, which is the mandate requiring coverage for newborn children.

Among those companies providing group coverage, the median monthly premium estimate for providing the proposed coverage as a standard benefit is \$17.17, with estimates ranging from \$1.00 to \$59.60. The median estimate for providing the proposed coverage as an option is \$34.81, with estimates ranging from \$2.20 to \$992.00. Data is not available on the monthly premium estimate for group plans, so it is not possible to calculate the percent increase in premium costs resulting from the mandate. However, the cost should be less than for individual plans given the larger insurance pool that allows for spreading costs among a larger number of plan members.

The premium estimates provided in response to the BOI survey appear higher than what have been reported by other sources. For example, a 2006 study conducted by Mercer Health and Benefits reported that 91 percent of employers surveyed nationally indicated that infertility treatment coverage did not result in a significant increase in their health plan cost. The National Conference of State Legislatures reports that cost estimates for insurance coverage of infertility treatments range from an additional \$0.20 to \$2.00 per member per month. Also, testimony provided for the last infertility mandate proposed in Virginia indicated that the premium impact of the Massachusetts mandate was less than one percent five years after the mandate had become effective. Fur-

ther, the premium impacts provided on Table 4 are for all those plans responding to the BOI survey. The premium impacts reported by those plans that already provide coverage for infertility treatment in Virginia, either as a standard benefit or an option, were less. Among those plans, the median monthly estimate for providing group coverage as a standard benefit was \$5.20, and the median estimate for providing group coverage as an option was \$6.83. These estimates are likely within the range of existing Virginia mandates.

There are a number of ways to mitigate the premium impact of the proposed mandate, such as placing a cap on coverage amounts. Also, costs would be reduced by requiring a higher level of cost sharing than is typical, or requiring patients to pay out of pocket for certain portions of their care, such as the lab costs. Several Virginia insurers that provide coverage for infertility already report doing this. Three plans provide optional coverage choices based on the coinsurance factors ranging from 20 to 80 percent, and one plan reported providing coverage with a 50 percent coinsurance factor.

f. Total Cost of Health Care

The CDC indicates that there is inadequate data both regarding the financial impact of infertility and its consequences, as well as the costs and benefits of infertility treatment. Health risks associated with preterm births, however, have contributed to increasing health care costs. According to the CDC, the economic burden associated with preterm births in the U.S. in 2005 has been estimated to be \$26 billion (\$51,600 per infant born preterm). ART infants born preterm accounted for approximately four percent of all preterm births in the U.S. in 2005, for a total economic burden estimated at \$1 billion.

Some researchers have suggested that coverage for infertility treatment would reduce overall health care costs by reducing multiple births and the associated costs that follow. Advocates have also suggested that because insurance already bears the cost of these multiple births, more conservative use of infertility treatment that could result if insurance coverage were provided may actually reduce costs to insurers.

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 birthweight babies with increased utilization of infertility treatment. One medical expert indicated that, even though there may be positive public health impacts as a result of increased use of ART, overall health care

costs would likely increase as a result of increased utilization of the treatment.

Also, while increased health insurance coverage could theoretically reduce overall health care costs and the costs for health insurers, it seems insurers would have considered these calculations. In general, if insurers could offer a richer benefit (for example, by including coverage for infertility treatment) at the same or less cost to consumers, presumably they would do that to be more competitive. However, a public health expert consulted for this review indicated that product enhancement is rarely used by insurance companies to gain a competitive advantage. Rather, insurers typically compete on the price (or premium cost) of their products.

BALANCING MEDICAL, SOCIAL, AND FINANCIAL CONSIDERATIONS

Whether mandated coverage of infertility treatment is needed or advisable may come down to a policy decision. There are clearly many couples who would benefit from increased access to infertility treatment and, depending on how a benefit is structured, there could be positive impacts on public health through decreased incidences of multiple births. However, mandating coverage is estimated to have an impact on health insurance premiums. To the extent that increased premiums could affect the ability of some individuals and employers to purchase health insurance, it is important to recognize that the treatment of infertility is not life sustaining or required for individuals to undertake normal activities of daily living. While this is true for many other treatments, it is an important consideration when determining whether to require insurance coverage as a benefit.

a. Social Need/ Consistent With Role of Insurance

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 unavailable 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. This is further supported by the fact that, based on a BOI survey, an estimated one-third of health plans in Virginia offer infertility coverage as an option for group policyholders. Also, numerous other states have adopted health insurance mandates for the treatment of infertility.

In addition to improving couples' access to services, coverage of infertility treatment could have a positive impact on public health. Many of the public health concerns surrounding infertility treatment stem from the increased incidence of multiple births. However, there is some evidence that when individuals have health insurance coverage, they are willing to undergo more conservative procedures, for example, having fewer embryos transferred during an IVF cycle. To help minimize the negative impacts of multiple births associated with infertility treatment, it may be desirable for a mandate to require providers to adhere to ASRM *Guidelines on the Number of Embryos Transferred*.

b. Need Versus Cost

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 decreases 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.

A BOI survey of Virginia health insurers suggests that the proposed mandate would likely increase health insurance premiums, although the estimated increases based on this survey appear high. However, to the extent that increased premiums could affect the ability of some individuals and employers to purchase insurance, it is important to consider that treatment of infertility is not life sustaining or required for individuals to undertake normal activities of daily living, though many experts indicate that reproduction is a normal life activity. While this is true of many other medical conditions and treatments that are already covered by health insurance, it is an important consideration when deciding whether to require health insurers to provide a particular benefit. The premium costs of the proposed mandated could be mitigated by reducing the age of individuals covered, reducing the number of covered oocyte retrieval cycles, capping coverage amounts, or requiring greater cost sharing among benefit holders.

Mandated Offer

A mandated offer requires health insurers to offer for purchase the coverage described in the mandate for an additional fee.

c. Mandated Offer

A mandated offer could be appropriate for the treatment of infertility because many individuals and employers could make an informed decision as to whether it is a benefit that they may potentially use and want to purchase. Also, as indicated previously, a third of health insurers responding to a BOI survey already offer infertility coverage as an option to group policy holders. However,

due to adverse selection, the estimated premium impact of a mandated offer would be substantially higher. Also, RESOLVE reports that the take-up rate of infertility coverage in the two states that have mandated offers is relatively low, likely due to the cost.

ACKNOWLEDGMENTS

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Statutory Authority for JLARC Evaluation of Proposed Mandated Health Insurance Benefits

§ [2.2-2503](#). Special Advisory Commission on Mandated Health Insurance Benefits; membership; terms; meetings; compensation and expenses; staff; chairman's executive summary.

A. The Special Advisory Commission on Mandated Health Insurance Benefits (the Commission) is established as an advisory commission within the meaning of § [2.2-2100](#), in the executive branch of state government. The purpose of the Commission shall be to advise the Governor and the General Assembly on the social and financial impact of current and proposed mandated benefits and providers, in the manner set forth in this article.

B. The Commission shall consist of 18 members that include six legislative members, 10 nonlegislative citizen members, and two ex officio members as follows: one member of the Senate Committee on Education and Health and one member of the Senate Committee on Commerce and Labor appointed by the Senate Committee on Rules; two members of the House Committee on Health, Welfare and Institutions and two members of the House Committee on Commerce and Labor appointed by the Speaker of the House of Delegates in accordance with the principles of proportional representation contained in the Rules of the House of Delegates; 10 nonlegislative citizen members appointed by the Governor that include one physician, one chief executive officer of a general acute care hospital, one allied health professional, one representative of small business, one representative of a major industry, one expert in the field of medical ethics, two representatives of the accident and health insurance industry, and two nonlegislative citizen members; and the State Commissioner of Health and the State Commissioner of Insurance, or their designees, who shall serve as ex officio nonvoting members.

C. All nonlegislative citizen members shall be appointed for terms of four years. Legislative and ex officio members shall serve terms coincident with their terms of office. All members may be reappointed. However, no House member shall serve more than four consecutive two-year terms, no Senate member shall serve more than two consecutive four-year terms, and no nonlegislative citizen member shall serve more than two consecutive four-year terms. Vacancies occurring other than by expiration of a term shall be filled for the unexpired term. Vacancies shall be filled in the manner as the original appointments. The remainder of any term to which a member is appointed to fill a vacancy shall not constitute a term in determining the member's eligibility for reappointment.

D. The Commission shall meet at the request of the chairman, the majority of the voting members or the Governor. The Commission shall elect a chairman and a vice-chairman, as determined by the membership. A majority of the members of the Commission shall constitute a quorum.

E. Legislative members of the Commission shall receive such compensation as provided in § [30-19.12](#), and nonlegislative citizen members shall receive such compensation for the performance of their duties as provided in § [2.2-2813](#). All members shall be reimbursed for all reasonable and

necessary expenses incurred in the performance of their duties as provided in §§ [2.2-2813](#) and [2.2-2825](#). Funding for the compensation and costs of expenses of the members shall be provided by the State Corporation Commission.

F. The Bureau of Insurance, the State Health Department, and the Joint Legislative Audit and Review Commission and such other state agencies as may be considered appropriate by the Commission shall provide staff assistance to the Commission. The Joint Legislative Audit and Review Commission shall conduct assessments, analyses, and evaluations of proposed mandated health insurance benefits and mandated providers as provided in subsection D of § [30-58.1](#), and report its findings with respect to the proposed mandates to the Commission.

G. The chairman of the Commission shall submit to the Governor and the General Assembly an annual executive summary of the interim activity and work of the Commission no later than the first day of each regular session of the General Assembly. The executive summary shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

§ [30-58.1](#). Powers and duties of Commission.

The Commission shall have the following powers and duties:

A. Make performance reviews of operations of state agencies to ascertain that sums appropriated have been, or are being expended for the purposes for which such appropriations were made and to evaluate the effectiveness of programs in accomplishing legislative intent;

B. Study on a continuing basis the operations, practices and duties of state agencies, as they relate to efficiency in the utilization of space, personnel, equipment and facilities;

C. Make such special studies and reports of the operations and functions of state agencies as it deems appropriate and as may be requested by the General Assembly;

D. Assess, analyze, and evaluate the social and economic costs and benefits of any proposed mandated health insurance benefit or mandated provider, including, but not limited to, the mandate's predicted effect on health care coverage premiums and related costs, net costs or savings to the health care system, and other relevant issues, and report its findings with respect to the proposed mandate to the Special Advisory Commission on Mandated Health Insurance Benefits; and

E. Make such reports on its findings and recommendations at such time and in such manner as the Commission deems proper submitting same to the agencies concerned, to the Governor and to the General Assembly. Such reports as are submitted shall relate to the following matters:

1. Ways in which the agencies may operate more economically and efficiently;

2. Ways in which agencies can provide better services to the Commonwealth and to the people; and

3. Areas in which functions of state agencies are duplicative, overlapping, or failing to accomplish legislative objectives or for any other reason should be redefined or redistributed.

Proposed Mandated Benefit Requiring Coverage of Treatment for Infertility

SENATE BILL NO. 631

Offered January 9, 2008

Prefiled January 9, 2008

A BILL to amend and reenact § [38.2-4319](#) of the Code of Virginia and to amend the Code of Virginia by adding a section numbered [38.2-3418.15](#), relating to health insurance coverage for infertility.

Patron-- Ticer

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That § [38.2-4319](#) of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered [38.2-3418.15](#) as follows:

§ [38.2-3418.15](#). *Coverage for infertility treatment.*

A. Notwithstanding the provisions of § [38.2-3419](#), each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall provide coverage for the treatment of infertility under any such policy, contract, or plan.

B. For purposes of this section, "infertility" means the inability to conceive after one year of unprotected sexual intercourse. "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, embryo transfer, artificial insemination, gamete intrafallopian tube transfer, intracytoplasmic sperm injection, zygote intrafallopian transfer, and low tubal ovum transfer. Such treatment shall 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 shall be covered. "Treatment for infertility" does not include the reversal of a vasectomy or a tubal ligation.

C. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, 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 any premium adjustment is made.

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

E. This section shall not apply to short-term travel, accident-only, limited, or specified disease policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or governmental plans or to short-term nonrenewable policies of not more than six months' duration.

§ [38.2-4319](#). Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ [38.2-100](#), [38.2-136](#), [38.2-200](#), [38.2-203](#), [38.2-209](#) through [38.2-213](#), [38.2-216](#), [38.2-218](#) through [38.2-225](#), [38.2-229](#), [38.2-232](#), [38.2-305](#), [38.2-316](#), [38.2-322](#), [38.2-400](#), [38.2-402](#) through [38.2-413](#), [38.2-500](#) through [38.2-515](#), [38.2-600](#) through [38.2-620](#), Chapter 9 (§ [38.2-900](#) et seq.), §§ [38.2-1017](#) through [38.2-1023](#), [38.2-1057](#), Article 2 (§ [38.2-1306.2](#) et seq.), § [38.2-1315.1](#), Articles 3.1 (§ [38.2-1316.1](#) et seq.), 4 (§ [38.2-1317](#) et seq.) and 5 (§ [38.2-1322](#) et seq.) of Chapter 13, Articles 1 (§ [38.2-1400](#) et seq.) and 2 (§ [38.2-1412](#) et seq.) of Chapter 14, §§ [38.2-1800](#) through [38.2-1836](#), [38.2-3401](#), [38.2-3405](#), [38.2-3405.1](#), [38.2-3407.2](#) through [38.2-3407.6:1](#), [38.2-3407.9](#) through [38.2-3407.16](#), [38.2-3411.2](#), [38.2-3411.3](#), [38.2-3411.4](#), [38.2-3412.1:01](#), [38.2-3414.1](#), [38.2-3418.1](#) through ~~[38.2-3418.14](#)~~ [38.2-3418.15](#), [38.2-3419.1](#), [38.2-3430.1](#) through [38.2-3437](#), [38.2-3500](#), subdivision 13 of § [38.2-3503](#), subdivision 8 of § [38.2-3504](#), §§ [38.2-3514.1](#), [38.2-3514.2](#), [38.2-3522.1](#) through [38.2-3523.4](#), [38.2-3525](#), [38.2-3540.1](#), [38.2-3542](#), [38.2-3543.2](#), Article 5 (§ [38.2-3551](#) et seq.) of Chapter 35, Chapter 52 (§ [38.2-5200](#) et seq.), Chapter 55 (§ [38.2-5500](#) et seq.), Chapter 58 (§ [38.2-5800](#) et seq.) and § [38.2-5903](#) of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ [38.2-4200](#) et seq.) of this title except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ [38.2-100](#), [38.2-136](#), [38.2-200](#), [38.2-203](#), [38.2-209](#) through [38.2-213](#), [38.2-216](#), [38.2-218](#) through [38.2-225](#), [38.2-229](#), [38.2-232](#), [38.2-322](#), [38.2-400](#), [38.2-402](#) through [38.2-413](#), [38.2-500](#) through [38.2-515](#), [38.2-600](#) through [38.2-620](#), Chapter 9 (§ [38.2-900](#) et seq.), §§ [38.2-1017](#) through [38.2-1023](#), [38.2-1057](#), Article 2 (§ [38.2-1306.2](#) et seq.), § [38.2-1315.1](#), Articles 3.1 (§ [38.2-1316.1](#) et seq.), 4 (§ [38.2-1317](#) et seq.) and 5 (§ [38.2-1322](#) et seq.) of Chapter 13, Articles 1 (§ [38.2-1400](#) et seq.) and 2 (§ [38.2-1412](#) et seq.) of Chapter 14, §§ [38.2-3401](#), [38.2-3405](#), [38.2-3407.2](#) through [38.2-3407.5](#), [38.2-3407.6](#) through [38.2-3407.6:1](#), [38.2-3407.9](#) through [38.2-3407.09:02](#), subdivisions 1, 2, and 3 of subsection F of § [38.2-3407.10](#), [38.2-3407.11](#), [38.2-3407.11:3](#), [38.2-3407.13](#) through [38.2-3407.14](#), [38.2-3411.2](#), [38.2-3418.1](#), [38.2-3418.2](#), [38.2-3419.1](#), [38.2-3430.1](#) through [38.2-3437](#), [38.2-3500](#), subdivision 13 of § [38.2-3503](#), subdivision 8 of § [38.2-3504](#), §§ [38.2-3514.1](#), [38.2-3514.2](#), [38.2-3522.1](#) through [38.2-3523.4](#), [38.2-3525](#), [38.2-3540.1](#), [38.2-3542](#), [38.2-](#)

[3543.2](#), Chapter 52 (§ [38.2-5200](#) et seq.), Chapter 55 (§ [38.2-5500](#) et seq.), Chapter 58 (§ [38.2-5800](#) et seq.) and § [38.2-5903](#) shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ [38.2-4200](#) et seq.) of this title except with respect to the activities of its health maintenance organization.

C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

E. Notwithstanding the definition of an eligible employee as set forth in § [38.2-3431](#), a health maintenance organization providing health care plans pursuant to § [38.2-3431](#) shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B of this section shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

Evaluation Topic Areas and Criteria for Assessing Proposed Mandated Health Insurance Benefits

Topic Area	Criteria
1. Medical Efficacy	
a. Medical Efficacy of Benefit	The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any clinical research, especially randomized clinical trials, demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.
b. Medical Effectiveness of Benefit <i>JLARC Criteria*</i>	The contribution of the benefit to patient health based on how well the intervention works under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather a more flexible intervention that is often used in broader populations.
c. Medical Efficacy of Provider	If the legislation seeks to mandate coverage of an additional class of practitioners: <ol style="list-style-type: none"> 1) The results of any professionally acceptable research, especially randomized clinical trials, demonstrating the medical results achieved by the additional class of practitioners relative to those already covered. 2) The methods of the appropriate professional organization to assure clinical proficiency.
d. Medical Effectiveness of Provider <i>JLARC Criteria*</i>	The contribution of the practitioner to patient health based on how well the practitioner's interventions work under the usual conditions of clinical practice. Medical effectiveness is not based on testing in a rigid, optimal protocol, but rather more flexible interventions that are often used in broader populations.
2. Social Impact	
a. Utilization of Treatment	The extent to which the treatment or service is generally utilized by a significant portion of the population.
b. Availability of Coverage	The extent to which insurance coverage for the treatment or service is already generally available.
c. Availability of Treatment <i>JLARC Criteria*</i>	The extent to which the treatment or service is generally available to residents throughout the state.
d. Availability of Treatment Without Coverage	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.
e. Financial Hardship	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.
f. Prevalence/Incidence of Condition	The level of public demand for the treatment or service.
g. Demand for Coverage	The level of public demand and the level of demand from providers for individual or group insurance coverage of the treatment or service.

h. Labor Union Coverage	The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.
i. State Agency Findings	Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.
j. Public Payer Coverage <i>JLARC Criteria*</i>	The extent to which the benefit is covered by public payers, in particular Medicaid and Medicare.
k. Public Health Impact <i>JLARC Criteria*</i>	Potential public health impacts of mandating the benefit.
3. Financial Impact	
a. Effect on Cost of Treatment	The extent to which the proposed insurance coverage would increase or decrease the cost or treatment of service over the next five years.
b. Change in Utilization	The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.
c. Serves as an Alternative	The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.
d. Impact on Providers	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.
e. Administrative and Premium Costs	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.
f. Total Cost of Health Care	The impact of coverage on the total cost of health care.
4. Effects of Balancing Medical, Social, and Financial Considerations	
a. Social Need/Consistent with Role of Insurance	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.
b. Need Versus Cost	The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.
c. Mandated Option	The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policy holders.

*Denotes additional criteria added by JLARC staff to criteria adopted by the Special Advisory Commission on Mandated Health Insurance Benefits.

Source: Special Advisory Commission on Mandated Health Insurance Benefits and JLARC staff analysis.

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