Sunrise Review criteria (from RCW 48.47.030)

Based on the availability of relevant information, the following criteria shall be used to assess the impact of proposed mandated benefits:

1. The social impact:

(i) To what extent is the benefit generally utilized by a significant portion of the population?

Approximately 12% of U.S. women 15–44 years of age have difficulty getting or staying pregnant¹. This means about one in eight face medical challenges in having children. Infertility equally affects men and women. Overall, one-third of infertility cases are caused by male reproductive issues, one-third by female reproductive issues, and another one-third by both male and female reproductive issues or is unexplained. It is estimated that over 200,000 Washington State residents are impacted by the disease of infertility².

In addition to heterosexual couples, other populations may require medical assistance to have children, and without insurance coverage for fertility treatment, these populations face significant barriers to family building. For these populations, disparities in access to care are even greater. Persons of color particularly face considerable disparities in access to care and lack of health equity; studies show that insurance or employer mandates can improve utilization³.

Cancer Patients. In the United States, approximately 160,000 individuals between ages 0-45 are diagnosed with cancer each year⁴. As cancer treatment improves, these patients face good odds; approximately 85% of this age group will survive their disease⁵. Chemotherapy, radiation, and surgery can cause medically induced (iatrogenic) infertility through damaging gametes (eggs and sperm), reproductive organs, and/or endocrine functioning; they may also impact the ability to carry a pregnancy. Patients with certain non-cancerous medical conditions (e.g., sickle cell disease, lupus, and thalassemia, etc.) may require similar therapies as cancer patients, and are, therefore, also at risk^{6,7}. Sickle cell disease, for example, affects approximately 100,000 patients per year in the U.S⁸. Sickle cell patients are increasingly being recommended for stem cell transplants, which, while curative, are sterilizing due to their toxic effects on the ovaries and sperm-producing germ cells.

In Washington, approximately 3,800 persons of reproductive age are diagnosed annually with cancer⁹. Many of these patients would face at least some risk for infertility due to their cancer treatments and could, therefore, benefit from having the opportunity to preserve their fertility prior to treatment. Fertility preservation treatments need to be undertaken quickly, before the start of cancer treatments, which makes it very difficult for patients to afford the out-of-pocket costs. The direct costs of fertility preservation represent an additional burden to the already considerable direct and indirect costs from

the cancer itself, including lost wages during cancer treatment. Studies confirm that preservation of fertility is of high importance to patients with a new diagnosis^{10,11}. The majority (51.7%) of young women undergoing cancer treatment prioritized having children was "most important" in their life¹².

Again, cost is often cited as the most significant barrier to fertility preservation¹³. Costs can range from several hundred dollars for sperm banking, to approximately \$15,000 for egg banking, underscoring the additional costs faced by females over males¹⁴. These costs are also exacerbated by the short window of time that cancer patients have before starting potentially sterilizing treatment.

Racial and ethnic minorities. Racial disparities in both infertility incidence and utilization of infertility treatment have been well documented¹⁵. Non-Hispanic Black women are 80% more likely to report infertility than Caucasian women yet they access infertility services at a substantially lower rate³. Data show that of those using assisted reproductive technology (ART) procedures, approximately 85% are non-Hispanic Whites, with Hispanic and Blacks representing only 4.5 – 6.5% of ART patients. While the roots of these disparities are multi-faceted, race is often linked to lower socioeconomic status, which, in turn, is linked to diminished access to healthcare services. Some studies have also suggested sociocultural factors may influence Black women's reluctance to seek infertility services¹⁶. Asian women also experience declining fertility earlier than White women and also have higher rates of endometriosis and other conditions that cause infertility^{17,18}.

LGBTQ and single parents. Unmarried individuals and many in the LGBTQ community require medical assistance and encounter additional barriers to building their families. Some experience discrimination based on their sexual orientation, and some cannot meet narrow, heteronormative definitions of infertility that link coverage to attempts at pregnancy within a partnered, heterosexual relationship.

In addition, transgender individuals may need to preserve their gametes before undergoing gender-affirming treatments. Such services could be viewed as akin to those for iatrogenic infertility for other conditions and diseases (like cancer), but discrimination and cost may still present obstacles to care. Health insurers are required to cover preventative services and cannot limit sex-specific recommended preventive services based on one's sex assigned at birth, gender identity, or recorded gender. The health care law prohibits discrimination on basis of sex.

Military. More than 95% of active-duty servicewomen are in their child-bearing years, yet their access to infertility care is severely limited. In addition, both those serving as well as female veterans report higher rates of infertility than women in the general population¹⁹. IVF and egg and sperm freezing are critical options for many military members prior to deployment. Active deployment in dangerous areas can lead to injuries and trauma that can impact service members' reproductive functions. Access to reproductive care is vital to both readiness and retention of a skilled military force. However, due to a Congressional ban, the VA specifically excludes coverage for in vitro

fertilization (IVF), one of the leading ART procedures; similarly, TRICARE, which provides health benefits to active duty members, does not cover IVF. Congressional and DoD authorizations now allow for certain exceptions, but IVF is only available when the infertility is causally linked to service, and is further restricted to those who are legally married and use the gametes of their spouse, necessarily limiting coverage to only partnered heterosexuals²⁰.

While the proposed legislation cannot affect government-managed fertility benefits for Washington's sizable military population, it can create access for this deserving population by making benefits available to the partner or spouse of a service member.

Carriers of Pediatric Genetic Diseases. Health care for children and adults with genetically transmitted diseases like cystic fibrosis and sickle cell disease is a significant cost to the health care system²¹, but can be preventable with genetic carrier screening [currently referred to as preimplantation genetic testing for monogenic/single gene defects (PGT-M) or past as preimplantation genetic diagnosis (PGD)]. If couples have a child with a genetic disease or know they are at high risk of having one, their options moving forward are to have no more children, to terminate a pregnancy if it is affected, to hope that luck is on their side and they don't have a child with a serious illness, or to do IVF with special preimplantation genetic testing to select for embryos that do not carry the disease. In general, only individuals who have insurance that already covers infertility have partial or complete coverage can effectively access IVF-PGT M can prevent these serious and costly genetic diseases. A mandate to cover fertility care could prevent the often devastating emotional, financial and social burden of these diseases to affected families as well as on the health care system.

(ii) To what extent is the benefit already generally available?

In the United States, only one in four people can access the care they need to become pregnant²², disparities highlighted in the White Paper released by the American Society for Reproductive Medicine in 2015²³. The single largest barrier in access to care is due to the out-of-pocket cost¹⁵. The high cost of IVF in the United States principally reflects the overall costliness of the U.S healthcare system rather than uniquely high service costs intrinsic to IVF as a medical intervention ²⁴. For patients without insurance coverage, financial constraints add to the considerable, and often overwhelming, stress and anxiety experienced with infertility. For a vast number of Washington state residents without insurance coverage, the financial barriers make accessing infertility treatment prohibitive.

The current landscape for insurance coverage for infertility in the United States is changing. As of 2021, nineteen states have infertility insurance mandates. Five (Colorado, Delaware, New Hampshire, New York, Utah) have passed in the last three years²⁵. Eleven states have added fertility preservation coverage since 2017²⁶.

(iii) If the benefit is not generally available, to what extent has its unavailability resulted in persons not receiving needed services?

Although Washington is presently a non-mandated state, select narrow demographics in Washington state do have excellent insurance benefits for fertility needs, including comprehensive IVF and fertility preservation benefits. These demographics are primarily represented by employees in technology, such Amazon, Google, Microsoft. Most individuals (which includes school teachers, nurses, vocational workers) do not have insurance coverage for fertility care.

At the heart of the problem -- which is what this bill seeks to address -- is a lack of equitable access to fertility care in Washington state. Lower-income persons, people of color, and LGBTQ persons encounter profound disparities in access to care and lack of health equity¹⁵. These disparities have been widely established in studies and brought to the forefront by ASRM, most recently in the ASRM Diversity, Equity, and Inclusion Taskforce Report²⁷. Although barriers remain, studies confirm that insurance coverage improves utilization of treatments in these groups¹⁵³. In a study at University of Michigan, employer-sponsored IVF coverage increased utilization among all women, including a larger proportional increase among low-salary groups, Black and Asian women²⁸. Insurance mandates are necessary to achieving greater equity to address the needs of lower income persons, people of color and LGBTQ persons¹⁵, which the proposed legislation seeks to address.

(iv) If the benefit is not generally available, to what extent has its unavailability resulted in unreasonable financial hardship?

One fresh IVF cycle accounts for 52% of an individual's average disposable income in states without ART insurance mandates, compared with 13% for states with mandates²⁹. The average cost of an IVF cycle in the United States is \$15,000³⁰. A recent survey found that women (25-34 years old) accrued \$30,000 of debt on average after undergoing fertility treatment³¹. In addition to the substantial direct costs, there are significant indirect costs to patients. Patients with IVF insurance coverage are 2.5 times less likely to miss time from work due to infertility³². The LGBTQ community also faces additional financial obstacles, including when insurers define infertility based on heterosexual sexual intercourse, which would be updated in the pending legislation¹⁵.

(v) What is the level of public demand for the benefit?

One in eight struggle with infertility, yet only one in four receive the treatment needed to overcome infertility^{22,23}. The above statistics do not take fully into account the needs of the LGBTQ community and other unpartnered individuals who cannot reproduce without medical intervention. According to a 2003 Harris Interactive Poll, 80% of the general population believes infertility treatment should be covered by insurance and a subsequent poll in 2019 found that most Americans (84%) think treatments should be affordable for anyone who needs it^{33,34}. The majority of IVF physicians support insurance coverage for infertility³⁵.

According to the 2021 Mercer Survey on Fertility Benefits, a survey of over 450 employers, more employers are responding to the requests of their employees and adding fertility benefits as part of a comprehensive program that seeks to support all aspects of employee health and well-being³⁶. At the top of the list of achievements resulting from providing coverage was "ensuring access to quality, cost-effective care" – 71% report that their infertility benefits have achieved this outcome to a significant or moderate extent. Second was "satisfying employee requests," cited by 64% of respondents. Additional reasons cited by employers for covering infertility treatment were to "stay competitive to recruit and retain top talent" (51%) and to "be recognized as a "family friendly employer" (50%). Additionally, respondents that have added coverage within the last two years are more likely to have done so in support of Diversity, Equity, and Inclusion: 61% of respondents cited it as a primary objective.

(vi) What is the level of interest of collective bargaining agents in negotiating privately for inclusion of this benefit in group contracts?

There has been interest by collective bargaining agents in other states and locally with respect to inclusion of infertility coverage in health plans.

2. The financial impact:

(i) To what extent will the benefit increase or decrease the cost of treatment of service?

A Milliman actuarial report was provided to the Arizona legislature in 2018 for a bill (SB 1149) requiring coverage for infertility health benefits for insurance plans. According to the report, "We have no reason to believe that covering infertility benefits in an insurance plan will change the fees charged for infertility services"³⁷. In Massachusetts, which has had a mandate since 1987, mandated infertility coverage was associated with increased use of IVF in the population³⁸. This increased utilization, however, was not associated with excessive increases in consumer cost for infertility insurance coverage. Health care expenditures for IVF increased only at a rate comparable or slower than inflation³⁸.

An IVF cycle is a complex service, requiring multiple injectable medications, blood draws, ultrasounds, a surgery that requires anesthesia sedation and, arguably, the most complex laboratory and sophisticated procedures in all medical care. In most fertility centers, the charges to a patient for an IVF cycle are very close to the real costs of providing the care to keep prices low to make services as accessible as possible to cash-paying patients. It is possible that higher volumes of IVF resulting from expanded insurance coverage could introduce some efficiencies that could lower cost to an extent. We expect cost to remain relatively stable except for CPI adjustments.

(ii) To what extent will the coverage increase the appropriate use of the benefit?

According to the Arizona Milliman Report, "Including infertility treatment in health insurance coverage removes a large portion of the financial burden for paying for these services, and thus can provide freedom to the insured individual and her doctor to choose the most clinically appropriate course of treatment"³⁷. A national study found that IVF availability and utilization were significantly higher in states with mandated IVF coverage³⁹. A study in Massachusetts, which provides unlimited IVF coverage, found IVF utilization increased after implementation of their IVF mandate, but overutilization by patients with a low chance of pregnancy success was not observed³⁸.

(iii) To what extent will the benefit be a substitute for a more expensive benefit?

According to the Milliman Report, "The mandated treatment or service will not be a substitute for a more expensive treatment or service"³⁷. State-mandated insurance coverage of IVF has been associated with lowering multiple births, which will make pregnancy care not only safer for patients but less expensive for insurance companies and for the government⁴⁰. Studies have demonstrated patients are more likely to transfer a single embryo with IVF when insurance covers their treatment. In addition, they are less likely to pursue less expensive treatments like gonadotropin therapy coupled to intrauterine insemination that can be associated with higher-order twin and triplet pregnancies⁴¹. Any reduction in multiple births significantly reduces health care costs and saves insurance companies money. Pregnancies with the delivery of twins cost approximately five times as much on average when compared with singleton pregnancies, and pregnancies with the delivery of triplets or more increase cost nearly twenty-fold⁴². These numbers do not include the long-term health care and societal costs of prematurity associated with multiple births, which can include medical care for chronic lung disease, special education for development and learning delays, and financial and emotional impact on families.

(iv) To what extent will the benefit increase or decrease the administrative expenses of health carriers and the premium and administrative expenses of policyholders?

We expect that the coverage will have a minimal effect on the administrative expenses of insurers³⁷ and that insurers could save significant money in the long run⁴³. A 2011 study showed that patients in states with IVF insurance mandates report lower multiple gestation rates due to transferring significantly fewer embryos per cycle than states without insurance coverage for IVF⁴⁴. The health care costs of twin and triplet pregnancies, deliveries and neonatal care are considerable⁴³. Patients with insurance coverage are free to make more appropriate decisions with their physicians based on medical necessity rather than financial considerations that often result in multiple births, which are more costly in the long run, as detailed in above section.

Inclusion of coverage for fertility treatment minimally impacts premiums^{38,45}. A 2016 study of the Massachusetts mandate, which is one of the most comprehensive state laws in the country in respect to extent of covered infertility benefits, estimated that the law increases premiums by as little as 0.12 percent to 0.96 percent⁴⁶. Colorado, which

passed a comprehensive infertility insurance law in 2020, estimated \$4,951 in costs to the Division of Insurance in FY 2020-21 and \$8,906 in FY 2021-22 and future years for plan review in the Department of Regulatory Agencies⁴⁷.

(v) What will be the impact of this benefit on the total cost of healthcare services and on premiums for health coverage?

A New England Journal of Medicine study found that states with IVF insurance have lower rates of multiple births than states without IVF coverage⁴⁸. National savings from fewer multiple births have been estimated to be over \$6 billion a year, making it likely that insurers could potentially save tens, if not hundreds, of millions of dollars a year by providing IVF coverage since patients will no longer be forced to use medical options that are more risky⁴³. Clinical practices in states without IVF insurance coverage have the highest number of embryos transferred per cycle and the highest rate of live births of multiple infants, especially three or more^{44,48}. Multiple pregnancies cost about \$4.2 billion more than singleton pregnancies in pre-term care⁴⁹. As noted earlier, pregnancies with the delivery of twins cost approximately five times as much than a single child and pregnancies with triplets or more cost nearly twenty times as much⁴². These costs do not include the considerable long-term care costs that can sometimes result from multiple pregnancies and premature births.

The proposed legislation requires coverage in accordance with the guidelines of the American Society for Reproductive Medicine (ASRM), using single embryo transfer when medically appropriate to avoid multiple pregnancies. It is also well documented that requiring infertility insurance minimally impacts insurance premiums. Comprehensive reviews from Connecticut, Maryland, Massachusetts, and Rhode Island, which have mandated infertility benefits since the 1980s, show that the cost of infertility coverage is less than 1% of the total premium cost^{46,50,51}. In many states, this translates to about a dollar or less per member per month. In 2019, New York updated its insurance laws to cover IVF and fertility preservation, effective January 1, 2020. The New York State Department of Financial Services estimated that premiums would increase 0.5% to 1.1% due to mandating IVF coverage, and 0.02% for mandating fertility preservation for iatrogenic (medically-induced) infertility⁵².

The goal of the proposed legislation is to reduce the financial strain on families while only minimally impacting insurance premiums, if at all, while at the same time generating significant savings (and healthier outcomes) from a reduction in multiple births. As noted earlier, a 2014 study estimated that the national savings from fewer multiple births would be over \$6 billion a year, making it likely that insurers could potentially save tens, if not hundreds, of millions of dollars a year by providing IVF coverage since patients will no longer be forced to use medical options that are more risky⁴³.

It is also noteworthy that a 2021 Mercer survey of over 450 employers nationwide found that 97% of employers offering infertility treatment, even those that include IVF, have not experienced increases in their medical costs³⁶.

(vi) What will be the impact of this benefit on costs for state-purchased healthcare? State employment?

Several states provide infertility insurance coverage for state employees. Maryland, which was the first state to pass an infertility insurance mandate in 1985, provides the same coverage to state employees. New York covered IVF for its state employees before extending it to more New Yorkers in 2020. New Jersey added coverage for state and school employees in 2017.

At the county level, in Washington state, King County has provided its employees infertility insurance coverage, including for IVF, for over two decades and has maintained coverage over that interval.

(vii) What will be the impact of this benefit on affordability and access to coverage?

The average cost of an IVF cycle in the United States is approximately \$15,000³⁰. A recent survey found that women (25-34 years old) accrued \$30,000 of debt on average after undergoing fertility treatment³¹. As a result, only Washington state residents who have the financial means to pay out of pocket or who work for employers like Google, Microsoft, Nordstrom, and Starbucks that provide coverage are able to afford the medically necessary treatment to build their families.

One fresh IVF cycle accounts for 52% of an individual's average disposable income in states without ART insurance mandates, compared with 13% for states with mandates²⁹. Insurance coverage improves utilization of treatments among previously underserved communities and does not lead to overutilization; a study in Massachusetts, which provides unlimited IVF coverage, found IVF utilization increased after implementation of their IVF mandate, but as cited earlier, overutilization by patients with a low chance of pregnancy success was not found. Insurance coverage also encourages safer, more medically effective treatment protocols. When patients do not have coverage for IVF and must pay out of pocket, they are more likely to transfer multiple embryos. Studies show patients in mandated states are more likely to have elective single embryo transfer.

By requiring insurance coverage for infertility and defining infertility in an inclusive manner, the proposed legislation will help Washingtonians in the individual, small and large group markets gain access to the treatments they need to build their families.

3. Evidence of healthcare service efficacy:

(i) If a mandatory benefit of a specific service is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the

health consequences of that service compared to no service or an alternative service?

IVF has been long established to be the most effective treatment for infertility; its versatility extends past infertility and includes fertility preservation for cancer patients, preimplantation genetic testing of embryos in parents who are carriers for life-altering genetic diseases, and partner IVF for lesbian couples. In 2018, the most recent year for which IVF outcomes are currently available, of the 50,651 IVF cycles performed in the United States in patients under the age of 35, the live birth rate was 52.0%⁵³. This rate is substantially higher than the live birth rate associated with alternative fertility treatments, specifically gonadotropin IUI (15-20% per cycle) and clomiphene or letrozole IUI (8-12% per cycle). In addition, alternative treatment or no treatment for patients with bilateral tubal obstruction or with severe male factor may correspond to a 0% success rate, meaning there are patients for whom no alternative fertility treatment to make possible biological parenting.

The consequences of no fertility care can be profound. Potential fertility loss due to cancer treatment is associated with emotional distress, fear, anxiety, and moderate or severe depression^{54,55}. Some patients with cancer even select less effective cancer treatment options due to the risk of infertility^{56,57}. Less effective cancer treatment is associated with unnecessary increased morbidity and mortality which carries additional preventable costs.

An actuarial report prepared by Wakely Consulting, Inc., for the Department of Financial Services in New York cited studies showing that the prevalence of major depression in infertile couples can range anywhere from 15% up to 54%, and the prevalence of clinically significant anxiety can range anywhere from 8% to 28%⁵². A study in Journal of Clinical Psychiatry estimates that the economic burden of depression is approximately \$210.5 billion per year, with about half of that cost being associated with loss of productivity in the workplace, and the other half being the true medical costs⁵⁸. When applying that to the population of couples struggling with both infertility and depression, Wakely estimated that the cost of depression related to infertility ranges from \$3 billion to \$10 billion a year in the U.S. Offering fertility benefits that cover effective therapeutic treatments for infertile couples may reduce associated mental health costs, and, at the very least, reduce the additional financial stress that exacerbates the psychosocial burden of infertility. Lower dropout rates and shorter return to treatment have been observed in patients having insurance coverage for IVF⁵⁹.

(ii) If a mandated benefit of a category of healthcare provider is sought, to what extent has there been conducted professionally accepted controlled trials demonstrating the health consequences achieved by the mandated benefit of this category of healthcare provider?

In the United States, fertility treatments via assisted reproductive technologies are provided by board-certified/board-eligible subspecialists in Reproductive Endocrinology & Infertility. According to the Fertility Clinic Success Rate and Certification Act of 1992,

all cycles performed in the United States fertility clinics are reported to the Centers for Disease Control and Prevention (CDC). In addition, there is additional voluntary oversight of all reported cycles by the Society for Assisted Reproductive Technology (SART) for which most IVF clinics maintain membership.

(iii) To what extent will the mandated benefit enhance the general health status of the state residents? The department may supplement these criteria to reflect new relevant information or additional significant issues.

Studies show states that cover IVF – now considered the standard of care for many infertility cases – have better outcomes for both mother and child and achieve long-term health care savings through the reduction of multiple births^{48,49}. Similarly, fertility preservation is widely accepted as the standard of care for patients diagnosed with cancer during their reproductive years^{60,61}. Patients unable to afford fertility preservation sometimes choose less effective medical treatments, which can lead to worse, and more costly, results if their cancer is not cured or treated properly⁶².

For a vast number of patients without insurance coverage, the financial barriers make accessing their treatment limiting or, in too many cases, simply prohibitive. At best, financial constraints add to the considerable, and often overwhelming, stress and anxiety experienced with infertility. At worst, patients give up their hopes of becoming parents or choose more aggressive treatments that lead to multiple births with costlier and worse outcomes for mothers and babies. Lack of insurance coverage implies that infertility is a condition undeserving of financial assistance and minimizes both its impact and importance to patients⁶³.

Importantly, mandating infertility insurance coverage will also improve access to care and outcomes for currently underserved communities, including racial and ethnic minorities and lower-income populations. The more inclusive definition of infertility proposed in the legislation (and passed elsewhere) will also remove the financial obstacles to care for the LGBTQ community and unpartnered individuals.

Carriers of pediatric genetic diseases, such as cystic fibrosis and sickle cell disease, will be able to access IVF to prevent the passing on of these diseases to their offspring, not only enhancing the health status of their children but relieving the health care system of considerable costs.

The World Health Organization (WHO), American Medical Association (AMA) and the American Congress of Obstetricians and Gynecologists (ACOG) all recognize infertility as a disease. As such, infertility should be covered by health insurance like other diseases to improve the health of the more than 200,000 Washingtonians living with this disease and other residents who face barriers building their families in the Evergreen State.

Washington should join the growing number of states with an infertility insurance law (19 to date), particularly since Oregon and California have already introduced legislation to address this lack of health equity.

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