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BILL ANALYSIS

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Senate Bill 647 (Substitute S-4 as passed by the Senate)
Senate Bill 648 (Substitute S-2 as passed by the Senate)
Senate Bill 649 (Substitute S-3 as passed by the Senate)
Senate Bill 650 (Substitute S-2 as passed by the Senate)
Senate Bills 651 and 652 (as passed by the Senate)
Sponsor: Senator Tom George, M.D. (S.B. 647)
Senator Mark C. Jansen (S.B. 648)
Senator Roger Kahn, M.D. (S.B. 649)
Senator Dennis Olshove (S.B. 650)
Senator Jud Gilbert, II (S.B. 651)
Senator Jim Barcia (S.B. 652)
Committee: Health Policy

Date Completed: 5-20-10

RATIONALE

Embryonic stem cells are unspecialized cells characterized by their ability to renew themselves for long periods of time through cell division, and their capacity to differentiate into specialized cell types, such as blood, muscle, and nerve cells. Embryonic stem cell lines used in research are derived from embryos created through in vitro fertilization (IVF), an increasingly common treatment for infertility. (Typically, excess embryos not implanted are discarded.) The stem cells generally are harvested when the embryo is four to five days old, at which time it is a ball of cells called a blastocyst. The cells are placed in laboratory culture dishes, where they proliferate, yielding millions of stem cells that make up an embryonic stem cell line.

Under certain conditions, the stem cells begin to differentiate. Scientists are working to understand how the differentiation can be directed in order to generate cultures of specific cell types so that, in the future, they can use the resulting cells to treat various conditions and diseases, such as Parkinson's disease, diabetes, spinal cord injury, muscular dystrophy, heart disease, strokes, burns, and vision and hearing loss. In addition, embryonic stem cells have applications in pharmaceutical testing and human growth and development research. Embryonic stem cell research, however, has been controversial because it results in the destruction of the blastocyst, which some consider the termination of human life.

In November 2008, Michigan voters approved Proposal 08-2, which added Article I, Section 27 to the State Constitution to address human embryo and human embryonic stem cell research. The constitutional amendment authorizes the use of human embryos for any research permitted under Federal law, subject to certain conditions; prohibits stem cells from being harvested more than 14 days after cell division begins; prohibits any person from selling or purchasing human embryos for stem cell research; and prohibits State and local laws that prevent, restrict, or discourage stem cell research, future therapies, and cures. (Article I, Section 27 is described below, under **BACKGROUND**.) It has been suggested that implementing legislation is necessary to provide greater specificity regarding the regulations established by the constitutional amendment, including the definition of relevant terms and measures for oversight and enforcement.

CONTENT

Senate Bill 647 (S-4) would amend the Public Health Code to do the following:

- **Allow a person to conduct research that jeopardized the life or health of a donated human embryo that was created for IVF purposes but was not needed or suitable for implantation, if the research involved only the extraction or use of embryonic stem cells and other conditions were met.**
- **Require a person who conducted such research to establish an oversight committee to ensure that the research met the Code's standards.**
- **Require a person who conducted such research to file an annual report with the Department of Community Health (DCH) using a unique identifier provided by the Department.**
- **Require the DCH to compile an aggregate statistical report without identifying specific researchers.**
- **Require the DCH to destroy an annual report from a researcher after five years.**
- **Limit the use of data from individual reports.**
- **Prescribe penalties for the disclosure of confidential identifying information and failure to file a required report.**
- **Prohibit a person from purchasing or selling a human embryo or oocyte for stem cell research or therapies and cures.**
- **Prohibit a person from creating or attempting to create a human embryo for the purpose of conducting nontherapeutic research or a human-animal chimeric embryo, and designate a violation a felony.**

Senate Bill 648 (S-2) would amend the Code of Criminal Procedure to add the following to the sentencing guidelines:

- **The transfer, distribution, or donation of an embryo, fetus, or neonate for wrongful use.**
- **The purchase of a human embryo or oocyte for a stem cell procedure.**
- **The creation of a human embryo for nontherapeutic research purposes or an animal chimeric embryo.**
- **The disclosure of confidential identifying information or a violation of a related Federal law by a person conducting research using live human embryos.**

Senate Bill 649 (S-3) would amend the Public Health Code to do all of the following:

- **Prohibit a physician or health facility or agency that provided IVF services from delivering, transmitting, or otherwise conveying oocytes or embryos to a researcher without obtaining the written, informed consent of the individual who obtained the services.**
- **Prescribe a civil fine for a person who violated the prohibition.**
- **Require a physician or health facility or agency that provided IVF services to submit to the DCH a report regarding those services using a unique identifier provided by the Department.**
- **Prescribe a civil fine for failure to file a required report.**
- **Require the DCH to make available an annual aggregate statistical report summarizing the information from the reports without identifying specific providers.**
- **Prohibit the report data from being used or maintained in a manner that made it possible to identify a person who had obtained IVF services.**
- **Prescribe a felony penalty for a violation of the reporting requirements.**

Senate Bill 650 (S-2) would amend the Code of Criminal Procedure to add to the sentencing guidelines an IVF services reporting violation.

Senate Bills 651 and 652 would amend the Michigan Penal Code and the Code of Criminal Procedure, respectively, to make it a felony to transport into the State a human embryo created through human cloning.

Senate Bills 647 (S-4) and 649 (S-3) are tie-barred to each other. Senate Bill 648 (S-2) is tie-barred to Senate Bill 647. Senate Bill

650 (S-2) is tie-barred to Senate Bill 649. Senate Bill 652 is tie-barred to Senate Bill 651.

Senate Bill 647 (S-4)

Human Embryo Research

The Public Health Code prohibits a person from using a live human embryo, fetus, or neonate for nontherapeutic research if, in the best judgment of the person conducting the research, based upon the available knowledge or information at the approximate time of the research, the research substantially jeopardizes the life or health of the embryo, fetus, or neonate. The bill would create an exception to this prohibition. Under the bill, pursuant to Article I, Section 27 of the State Constitution, a person could not conduct research that substantially jeopardized the life or health of a human embryo unless all of the following requirements were met:

-- The research was permissible under Federal law and conducted pursuant to the requirements of Federal law.
-- The embryo was created for IVF purposes.
-- The embryo was in excess of the clinical need of or was not suitable for implantation in the individual seeking the IVF services and would otherwise be discarded.
-- The embryo had not been allowed to develop more than 14 days after cell division began, not including any time during which the embryo was frozen.
-- The research involved only the extraction or use of embryonic stem cells from the embryo.
-- The embryo was donated for research with the voluntary and written informed consent by the individual seeking the IVF services.

The person conducting the research would have to do either of the following:

-- Obtain a copy of the written informed consent given under Section 2694 (which Senate Bill 649 (S-3) would add) from the physician or health facility or agency that provided the IVF services.
-- Obtain written informed consent that met the requirements of Section 2694 from the individual who obtained the IVF services and was donating the embryo for research.

(Under the bill, "human embryo" would mean an organism consisting entirely of biological components of the species Homo sapiens capable of differentiation and maturation, regardless of the means of creation, including fertilization and somatic cell nuclear transfer, beginning from the single cell stage through the seventh week of development. "Created for in vitro fertilization purposes" would mean created for implantation and gestation in a woman's uterus by either IVF or the intentional division of a human embryo created by IVF. "Not suitable for implantation" would mean the human embryo exhibits genetic or morphological characteristics that, in the attending physician's best judgment, negatively affect the potential for successful implantation, gestation, or healthy development of the embryo; or lead to a disease likely to be fatal to the embryo or any human derived from it. The term would not include identified genetic characteristics that do not affect the health of the embryo or any human derived from it, including gender or physical appearance.

Under the Code, "nontherapeutic research" means scientific or laboratory research, or other kind of experimentation or investigation not designed to improve the health of the research subject.)

A person who conducted research using live human embryos would have to establish a stem cell research oversight committee substantially in accordance with the guidelines for human embryonic stem cell research issued by the National Research Council and the Institute of Medicine of the National Academies in 2005. At least once per year, the committee would have to conduct continuing review of the research to ensure that it continued to meet the standards of Part 26 (Data, Information, and Research) of the Public Health Code. Pursuant to its review, a stem cell research oversight committee could revoke its previous approval and require modifications to the plan or design of a continuing research project before permitting the research to continue. A committee could provide scientific and ethical review of research consistent with Part 26.

Sale of Embryos

The bill would prohibit a person from purchasing or selling, or offering or attempting to purchase or sell, for valuable consideration a human embryo or oocyte for stem cell research or therapies and cures as allowed under Article I, Section 27 of the State Constitution, or for any other purpose. ("Valuable consideration" would mean the payment or provision of anything of value, including cash, gifts, reduced or waived fees for services rendered, medical treatment, or payment for expenses or accommodations. The term would not include medical treatment or services provided at no cost as part of a clinical trial or experimental therapy related to the treatment of infertility if the trial or experiment were not conducted by a person involved directly in research authorized by the bill.)

The Code prohibits a person from knowingly selling, transferring, distributing, or giving away an embryo, fetus, or neonate for a use that violates Sections 2685 to 2689. The bill would eliminate the reference to selling, and would refer to donating instead of giving away.

A violation of the current prohibition is a felony punishable by up to five years' imprisonment. Under the bill, the penalty also could include a maximum fine of $5,000. This penalty also would apply to a violation of the proposed prohibition.

(Sections 2685 to 2689 do the following:

-- Prohibit a person from using a live human embryo, fetus, or neonate for nontherapeutic research if it substantially jeopardizes the life or health of the embryo, fetus, or neonate.
-- Prohibit the performance of nontherapeutic research on an embryo or fetus known by the researcher to be the subject of a planned abortion performed for any purpose other than to protect the life of the mother.
-- Provide that an embryo, fetus, or neonate is considered live if it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted embryo or fetus at approximately the same age of gestational development.
-- Prohibit research from being performed knowingly upon a dead embryo, fetus, or neonate unless the mother's written consent has been obtained first.
-- Require research performed upon a dead embryo, fetus, or neonate to be conducted in accordance with the standards applicable to research conducted under Part 101 of the Code (the Revised Uniform Anatomical Gift Law).
-- Prohibit a person from performing or offering to perform an abortion if any of the consideration is that the embryo or fetus, whether alive or dead, may be used for research or study.)

Creation of Embryos; Penalties

The bill would prohibit a person from creating or attempting to create a human embryo for the purpose of conducting nontherapeutic research upon it. In addition, the bill would prohibit a person from creating or attempting to create a human-animal chimeric embryo consisting of biological components from the species Homo sapiens and at least one other species where the embryo was capable of differentiating and maturing in a manner substantially similar to the embryonic maturation process of any of the species constituting the chimeric embryo. A person who violated either of these provisions would be guilty of a felony punishable by imprisonment for up to five years and/or a maximum fine of $5,000.

Annual Report; Penalties

Under the bill, except as otherwise provided, a person who conducted permitted research using live human embryos annually would have to submit to the DCH a report on forms prescribed and provided by the Department, using a unique identifier provided by the Department, and at the time and in the manner prescribed by the Department. If Federal law, rule, regulation, or guideline applicable to research using live human embryos required the person to file a report that contained all of the information required to be reported under the bill, the person could file that report to comply with the bill. A person would not have to file the required report until the DCH developed the reporting form and made it available. A person who conducted research using living human

embryos would have to collect and report only the following information to the DCH:

-- The name of the company, corporation, academic institution, or other person managing or overseeing the research.
-- The name and address of the physician's office or health facility or agency where embryos were donated and the number of embryos acquired from each office or facility or agency.
-- The number of embryos thawed for use in research.
-- The number of embryos being discarded without being used for research.
-- The number of embryos held in storage at the beginning and end of the reporting year.

A person who conducted research using live human embryos would have to report its research, oversight, and review policies and procedures with regard to the research conducted. The person would have to certify that its research, oversight, and review policies and procedures were in compliance with Federal law, rules, regulations, and guidelines applicable to that research. A violation of a Federal law, rule, regulation, or guideline applicable to research using live human embryos would be a violation of the bill's reporting requirements.

The DCH would have to do all of the following:

-- Within one year after the bill's effective date, develop and make available in print and electronic format a form for people to use in filing the required report.
-- Make available annually in aggregate a statistical report summarizing the information submitted in each individual report.
-- Destroy each report and each copy of it after retaining the report for five years after it was received.
-- Establish a program that would issue to each person required to report to the DCH a unique identifier under which to submit the report.

In the aggregate statistical report, the DCH could not identify the person who conducted research using live human embryos to whom any specific information applied.

A person submitting a report could not include the name, common identifiers such as Social Security number or driver license number, or other information or identifiers that would make it possible to identify in any manner or under any circumstances an individual who had obtained IVF services and who subsequently donated human embryos for research purposes. A State agency could not compare data in an electronic or other information system file with data in any other electronic or other information system that would result in identifying in any manner or under any circumstances an individual who donated human embryos for research. A person could not maintain statistical information that could reveal the identity of an individual who had donated human embryos for research.

Except as otherwise provided, a person could not disclose confidential identifying information about an individual who obtained IVF services. The required reports would be statistical reports to be used only for medical and health purposes and could not be incorporated into the permanent official records of the system of vital statistics. Except for the DCH's aggregate statistical reports, information submitted to the Department by a researcher would be confidential and would not be subject to the disclosure requirements of the Freedom of Information Act. That information could be disclosed, however, in any of the following circumstances:

-- With the written consent of the person who conducted research using live embryos.
-- Pursuant to a court proceeding.
-- To a DCH agent or employee.
-- To an agent or employee of a state or the Federal government authorized by law to see or review the information.

A person who disclosed confidential identifying information or violated a Federal law, rule, regulation, or guideline would be guilty of a felony punishable by imprisonment for up to one year and/or a maximum fine of $5,000. A person who failed to file a required report would be responsible for a State civil infraction and could be ordered to pay a civil fine of at least $5,000 per violation.

Senate Bill 648 (S-2)

Under the Code of Criminal Procedure, the use of a live human embryo or fetus for nontherapeutic research is a Class E felony against a person with a statutory maximum of five years' imprisonment. The bill would refer to "improper" use of an embryo or fetus for nontherapeutic research.

The sale or delivery of a fetus or embryo also is designated a Class E felony against a person with a statutory maximum of five years' imprisonment. The bill would delete this violation, and instead refer to the purchase or sale, or offered or attempted purchase or sale, of a human embryo or oocyte for a stem cell procedure. In addition, the bill would add the transfer, distribution, or donation of an embryo, fetus, or neonate for wrongful use. Both of these offenses would be Class E felonies against the public trust with a statutory maximum of five years' imprisonment.

Under the bill, the creation or attempted creation of a human embryo for nontherapeutic research purposes or the creation or attempted creation of an animal chimeric embryo would be a Class E felony against the public trust with a statutory maximum of five years' imprisonment. An embryonic research reporting violation, including the disclosure of personal identifying information or a violation of a related Federal law, would be a Class G felony against the public trust with a statutory maximum of one year's imprisonment.

Senate Bill 649 (S-3)

IVF Services: Informed Consent

The bill would prohibit a physician or health facility or agency that provided IVF services from delivering, transmitting, or otherwise conveying oocytes or embryos to any person who conducted research as permitted under Section 2685 of the Public Health Code (pursuant to Senate Bill 647 (S-4)) without first obtaining the voluntary and written informed consent of the individual who obtained the services. In a manner that complied with the Federal Health Insurance Portability and Accountability Act, a physician or health facility or agency would have to transmit a copy of the consent when it delivered, transmitted, or otherwise conveyed oocytes or embryos to the person who conducted the research. In addition to any information required to be provided by the accepted standard of care, the documented informed consent would have to include the following information, as applicable:

-- The oocytes and embryos were in excess of the individual's clinical need and would otherwise be discarded.
-- The oocytes and embryos were not suitable for implantation and would otherwise be discarded.
-- An individual who consented to the donation of oocytes or embryos could withdraw that consent at any time until they were used in research.

A physician or health facility or agency that provided IVF services in Michigan could not do so without first informing the individual seeking them of all of the following:

-- That Michigan law permits research using live human embryos and that, subject to certain requirements, excess human embryos could be donated for this research.
-- The legal prohibitions on people offering or providing any valuable consideration in exchange for providing excess oocytes or embryos to any other person.
-- Options available to create, use, or store oocytes or embryos in a quantity most acceptable to the individual seeking the services and the potential or expected annual financial obligations if the individual chose to cryopreserve and store excess oocytes or embryos.

A person who violated these provisions would be responsible for a State civil infraction and could be ordered to pay a civil fine of at least $5,000 per violation.

IVF Services Annual Report

Under the bill, except as otherwise provided, a physician or health facility or agency that provided human IVF services annually would have to submit to the DCH a report on forms prescribed and provided by the Department, using a unique identifier provided by the Department, and at the time and in the manner prescribed by the Department. If Federal law, rule, regulation, or guideline applicable to research using live human embryos required the physician or health

facility or agency to file a report that contained all of the information required to be reported under the bill, the person could file the Federal report to comply with the bill. A physician or health facility or agency would not have to file the required report until the DCH developed the reporting form and made it available. The physician or health facility or agency would have to collect and report to the DCH the number of the following:

-- Patients on whom oocyte extractions were attempted.
-- Patients from whom oocytes were extracted successfully.
-- Oocytes extracted from all patients.
-- Complications experienced by patients undergoing oocyte extraction.
-- Oocytes retained in storage.
-- Oocytes discarded before fertilization attempts.
-- Oocytes exposed to sperm for fertilization.
-- Embryos successfully created.
-- Embryos undergoing genetic screening.
-- Embryos discarded before implantation attempts.
-- Embryos terminated intentionally in utero after pregnancy was established.
-- Infants with disabilities or deformities detectable at birth.
-- Embryos thawed for implantation or donation.
-- Embryos viable after the thawing process.
-- Embryos donated for implantation.
-- Embryos donated for research.
-- Embryos discarded after storage at the direction of the individual seeking IVF services.
-- Embryos held in storage at the beginning and end of the reporting year.

Reported information also would include the health facility or agency, academic institution, or other person to which embryos were donated for research.

The bill would require the DCH to do all of the following:

-- Within one year after the bill's effective date, develop and make available in print and electronic format a form for physicians and health facilities and agencies to use in filing the required report.
-- Make available annually in aggregate a statistical report summarizing the information submitted in each individual report.
-- Destroy each individual report and each copy after retaining the report for five years after it was received.
-- Establish a program that would issue to each person required to report to the DCH a unique identifier under which the person was to submit the report.

In its annual aggregate report, the DCH could not identify the physician or health facility or agency to whom the specific information applied.

A person who submitted a report could not include the name, common identifiers such as Social Security number or driver license number, or other information or identifiers that would make it possible to identify in any manner or under any circumstances an individual who had obtained IVF services. A State agency could not compare data in an electronic or other information system file with data in any other electronic or other information system that would result in identifying in any manner or under any circumstances an individual who had obtained IVF services. A person could not maintain statistical information that could reveal the identity of an individual who had obtained IVF services.

Except as otherwise provided, a person could not disclose confidential identifying information about an individual who obtained IVF services. The required reports would be statistical reports to be used only for medical and health purposes and could not be incorporated into the permanent official records of the system of vital statistics. Except for the DCH's annual statistical report, information submitted to the Department by a physician or health facility or agency would be confidential and would not be subject to the disclosure requirements of the Freedom of Information Act. That information could be disclosed, however, in any of the following circumstances:

-- With the written consent of the physician or health facility or agency.
-- Pursuant to a court proceeding.
-- To a DCH agent or employee.

-- To an agent or employee of a state or the Federal government authorized by law to see or review the information.

A person who disclosed confidential identifying information would be guilty of a felony punishable by imprisonment for up to one year and/or a fine of up to $5,000. A person who failed to file a required report would be responsible for a State civil infraction and could be ordered to pay a civil fine of at least $5,000 per violation.

Senate Bill 650 (S-2)

The bill would add to the sentencing guidelines the disclosure of confidential identifying information with regard to an IVF reporting requirement. The offense would be a Class G felony against the public trust with a statutory maximum of one year's imprisonment.

Senate Bill 651

The bill would prohibit a person from intentionally transporting, attempting to transport, or causing to be transported into the State a human embryo created through human cloning. A person who violated the prohibition would be guilty of a felony punishable by imprisonment for up to 10 years and/or a maximum fine of $10,000 (the current penalty for intentionally engaging in human cloning).

Senate Bill 652

The bill would add to the sentencing guidelines the transport of a human embryo created through human cloning. The offense would be a Class D felony against a person with a statutory maximum of 10 years.

MCL 333.2685 et al. (S.B. 647)
777.13k (S.B. 648)
Proposed MCL 333.2694 & 333.2695 (S.B. 649)
MCL 777.13k (S.B. 650)
750.430a (S.B. 651)
777.16v (S.B. 652)

BACKGROUND

Article I, Section 27 of the State Constitution states that, to ensure that Michigan citizens have access to stem cell therapies and cures, and to ensure that physicians and researchers can conduct the most promising forms of medical research in Michigan, and that all such research is conducted safely and ethically, any research permitted under Federal law is permitted in Michigan, subject to the requirements of Federal law and only the following additional limitations and requirements:

-- No stem cells may be taken from a human embryo more than 14 days after cell division begins, excluding any time during which an embryo is frozen.
-- The embryos were created for the purpose of fertility treatment and, with voluntary and informed consent, the person seeking fertility treatment chose to donate the embryos for research; and the embryos were in excess of the person's clinical need, or were not suitable for implantation, and would otherwise be discarded.
-- No person may purchase or sell for valuable consideration human embryos for stem cell research or stem cell therapies and cures.

In addition, all stem cell research, therapies, and cures must be conducted and provided in accordance with State and local laws of general applicability, including laws concerning scientific and medical practices and patient safety and privacy, to the extent that any such laws do not prevent, restrict, obstruct, or discourage any permitted stem cell research, therapies, and cures; or create disincentives for anyone to engage in or otherwise associate with such research, therapies, or cures.

Article I, Section 27 provides that nothing in it alters Michigan's prohibition on human cloning.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Constitutional amendments frequently provide a general regulatory framework, and require further legislative action to flesh out relevant concepts and ensure that the will of the people is carried out. Such is the case with regard to Proposal 08-2, which allows embryonic stem cell research to be conducted in Michigan. Important terms, such as "valuable consideration" and "not suitable for implantation" should be defined,

and informed consent provisions and privacy protections should be enacted, along with oversight and enforcement measures.

Opposing Argument

Michigan voters approved Proposal 08-2 to allow research involving human embryos, subject to Federal law and *only* the restrictions listed in the Constitution. The regulation proposed by the bills would go beyond what voters approved, require researchers and IVF providers to file burdensome paperwork, and create an impression that Michigan is inhospitable to the biomedical field and its associated economic activity.

Embryonic stem cell research already is a highly regulated field. It is subject to multiple layers of oversight to ensure that the research is conducted in an ethical and transparent manner. The National Institutes of Health (NIH) regulates stem cell research in compliance with Federal policy, and recently issued final guidelines governing the use of human embryonic stem cells. These guidelines apply to federally funded research; all public and private institutions, however, require compliance with NIH guidelines. In addition, the U.S. Food and Drug Administration has jurisdiction over research intended to lead to medical products, and could block the sale of any product resulting from stem cell lines that were not created ethically.

The National Academy of Sciences (NAS) and the International Society for Stem Cell Research, two nongovernmental entities, have developed guidelines regarding the ethical procurement of gametes, derivation of cell lines, and informed consent. Also, the NAS guidelines provide for local Embryonic Stem Cell Research Oversight committees. Moreover, several additional layers of local oversight exist, including institutional review boards, animal care and use committees, and institutional biosafety committees. These existing regulations, guidelines, and policies are sufficient for the implementation of Proposal 08-2.

Since the passage of Proposal 08-2, millions of dollars have been invested or proposed for investment in expanding Michigan's stem cell research opportunities. The State's research universities have received Federal grants, begun planning new initiatives and collaborative projects, and hired new staff. The World Stem Cell Summit has been scheduled to be held in Detroit in response to passage of Proposal 08-2. The ballot proposal has positioned Michigan to be a leader in stem cell research and to reap the associated economic benefits. The proposed legislation, however, could create uncertainty among businesses that conduct the research and those who provide funding for it in public institutions, threatening potentially life-saving advances as well as the economic activity. The requirements proposed by the bills would be unnecessarily duplicative and could hamper promising stem cell research.

Response: While multiple layers of oversight regarding embryonic stem cell research already exist, many of the practices used in the industry are in accordance with voluntary guidelines, which do not have the force of law. In another vein, if human embryo research already is regulated adequately, enacting similar practices in State statute should not be problematic. It is important to codify best practices and eliminate ambiguity in order to create parity among all research entities, whether public or private, ensure that embryo donors are well informed and their privacy protected, and give the State the appropriate tools to penalize bad actors. There are penalties in place for human and animal research performed outside legal boundaries; it would be proper to enact similar penalties for those who did not hew to the restrictions established for embryonic stem cell research.

The bills' reporting requirements would constitute only a minor administrative increase over the paperwork health care providers and researchers already are required to submit for various purposes, such as Medicaid compliance. A one-page report once each year should not be overly burdensome. In addition, it would not obstruct any research because the information would be compiled after the cells were harvested and used. The reporting requirements actually would be less onerous than regulations in some other states that allow embryonic stem cell research, such as California and Massachusetts, where researchers must register with the state and get prior authorization for their work.

The potential for economic benefit as a result of embryonic stem cell research is questionable. Given the nature of scientific

research, it could be several decades before any significant advances occur and reach commercialization. In any case, ethical concerns with regard to stem cell research should not be abandoned merely because this field could stimulate economic growth. Furthermore, the bills simply would implement in statute the constitutional amendment already approved by voters, so concerns about unfavorable perceptions of Michigan are unfounded.

Opposing Argument

The legislation would go beyond the regulation of stem cell research and hinder the practice of IVF in several ways. Senate Bill 647 (S-4) would prohibit a person from selling or purchasing an oocyte (i.e., an egg cell) for stem cell research, therapies, and cures, or *for any other purpose*. Infertile people who undergo IVF, however, often purchase oocytes from donors. The bill would preclude people from employing this method in expanding their families.

Furthermore, the particular informed consent requirements for IVF patients under Senate Bill 649 (S-3) would be impractical. While informed consent is a critical element of any medical procedure, including assisted reproduction, the information covered in the process can change frequently as technology and treatment advance, and should be specific to the individual patient's situation and treatment plan. Prescribing in statute the exact information to be covered under informed consent, combined with the intrusive reporting requirements, would limit infertile people's ability to use IVF without significantly enhancing patient care. Ultimately, the bill's requirements could add to the cost of IVF, which often is not covered by insurance and thus already presents a significant financial burden to patients.

Response: Other states that allow embryonic stem cell research also ban the sale and purchase of eggs for several reasons, such as preventing the exploitation of poor women. The prohibition would be reasonable and would put Michigan in line with these other states.

The required reports would be based on aggregate data and would not identify individual patients. The reporting requirements would be no more intrusive than others already existing in Michigan law, such as the requirement that hospitals report to the State the number of autopsies they conduct every year.

Legislative Analyst: Julie Cassidy

FISCAL IMPACT

The bills would have an indeterminate fiscal impact on State and local government.

There are no data to indicate how many offenders would be convicted of the proposed offenses. Table 1 below shows the proposed sentencing classification and minimum and maximum ranges under the sentencing guidelines for each of the proposed offenses. Local governments would incur the costs of incarceration in local facilities, which vary by county. The State would incur the cost of felony probation at an annual average cost of $2,000, as well as the cost of incarceration in a State facility at an average annual cost of $33,000.

Individuals convicted of a felony under Senate Bill 647 (S-4) or 649 (S-3) also could be subject to penal fines, not to exceed $5,000. Individuals convicted of the felony proposed by Senate Bill 650 could be fined up to $10,000. Any additional penal fine revenue would benefit public libraries.

In addition, Senate Bill 647 (S-4) would establish a minimum civil infraction fine of $5,000 for failure to file a required report, and Senate Bill 649 (S-3) would establish a minimum civil infraction fine of $5,000 for failure to obtain informed consent from patients or failure to file a required report. Civil fine revenue would benefit the General Fund.

Under Senate Bill 647 (S-4), the Department of Community Health would see a marginal indeterminate increase in costs due to the requirement to collect and aggregate the reports on research using live human embryos.

Table 1

Offense	Class	Sentence Range Minimum	Sentence Range Maximum	Statutory Maximum
Transfer of embryo for wrongful use [a)]	E-Public Trust	0-3 mo.	24-38 mo.	5 yrs
Purchase or sale of human embryo for stem cell procedure [a)]	E-Public Trust	0-3 mo.	24-38 mo.	5 yrs
Creation of human embryo for nontherapeutic purpose or creation of animal chimeric embryo[a)]	E-Public Trust	0-3 mo.	24-38 mo.	5 yrs
Embryonic research reporting violation[a)]	G-Public Trust	0-3 mo.	7-12 mo.	1 yr
Disclosure of confidential info[b)]	G-Public Trust	0-3 mo.	7-12 mo.	1 yr
Transporting cloned human embryo[c)]	D-Person	0-6 mo.	43-76 mo.	10 yrs

[a)]Under Senate Bills 647 (S-4) and 648 (S-2)
[b)]Under Senate Bills 649 (S-3) and 650 (S-2)
[c)]Under Senate Bills 651 and 652

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