Canadian Standards Association  
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Toronto, ON  
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September 15, 2015

Dear Canadian Standards Association:

Thank you for the opportunity to comment on the Draft amendment to CSA Z900.2.1-12, \textit{Tissues for assisted reproduction}. I am pleased with the desire for clarity regarding the reimbursement of expenditures for assisted reproduction in Canada, and in particular the implicit articulation of guidelines on expenditures from Health Canada.

I have a number of important concerns about the draft amendment, including a significant concern about the role of the CSA, rather than Health Canada, in providing clarity on this issue. Further, I am particularly worried that the CSA provides information here about what might be a reimbursable expense, but does not make clear who can provide such reimbursements, how the reimbursements will occur, and the role of voluntary guidelines in this important legal and regulatory matter. Please see the attached document for these concerns and proposed revisions.

Finally, I would like to note that I do not cede copyright for these comments to the CSA. I am concerned that CSA has required the ceding of copyright in order for individuals to participate in the consultation process without clarity about how the comments might be used, or how attribution of relevant comments will occur. As a young scholar and expert in the field, I am uneasy about being required to cede copyright in order to provide input particularly when the issue at hand is of public, national concern and will have significant implications for women’s bodies and lives.

I thank the CSA for the opportunity to comment on the draft amendment.

Sincerely,

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Comments on Draft Amendment to CSA Z900.2.1-12

The Annex to CAN/CSA-.2.1-12 Tissues for assisted reproduction is important in its attempt to clarify an area of great uncertainty in the governance of assisted human reproduction in Canada by providing direction as to what might be considered receiptable expenses in the reimbursement of surrogates and gamete and embryo donors in Canada. It remains unclear to me why the CSA would undertake this process however, given that it is the jurisdiction of Health Canada, and further, given that it remains illegal to provide reimbursements to surrogates and gamete donors (in the absence of regulations) under the Assisted Human Reproduction Act. However, given that it is possible to imagine a situation in which the proposed amendments to the CSA are embedded in legislation, I would like to raise a number of concerns with the CSA’s Annex.

As stated in the attached cover letter, I do not cede copyright or ownership of my comments to the CSA. Again, I do not cede copyright of my comments to the CSA.

Scope and Intent

While clarity in the governance of assisted reproduction in Canada, including in the reimbursement of expenditures is a desirable outcome, it is unclear that the content of this Annex is within the scope of the original standard, except as related to record-keeping and the distribution of reproductive materials. The scope of the original standard is largely the health and safety of those using assisted reproduction. Although the Annex suggests that it intends to aid the “health and safety of the donor, surrogate, fetus, and existing children,” it is unclear how providing reimbursements serves this purpose. A clear, well-substantiated, and valid rationale is needed for the role of clinics in the reimbursement of expenditures for donors and surrogates.

As to the notes provided on the Annex, I have some concerns about Note 3 (i.e. “The AHR Act contains reimbursement prohibitions, however without regulations in place it is a matter for statutory interpretation regarding whether or not a particular reimbursement is permitted. In the absence of an authoritative interpretation, this Annex errs on the side of protecting and promoting the health and safety of donors and surrogates). While the CSA acknowledges that jurisdiction over the reimbursement prohibitions belongs to the federal parliament (suggesting that the nature of the reimbursements should be subject to statutory interpretation), it is clear from the parliamentary debates leading to its passage that the intent of the AHR Act’s provisions on reimbursements of expenditures were not to include a wide range of reimbursements. In fact, on my reading of the AHR Act and the debates leading to its passage, the prohibitions on payment to donors and surrogates were made because it was perceived
that payment would threaten the health and safety of donors. There was extensive opposition to reimbursing women for time off from work, or tuition. The wide range of reimbursements incorporated into this Annex stand in direct opposition of the legislative intent of the Act.

Further, the CSA Standards focus largely on who may be reimbursed for what. Little attention, however, is paid to how and when these reimbursements should occur, and by whom the reimbursements can be made. A detailed description of the administrative structures governing the how and when of reimbursement is needed to ensure ethical, legal, transparent, and accountable reimbursements of expenditures to donors and surrogates. As demonstrated in *R v. Picard*, there are opportunities for ethically and legally problematic reimbursements, even where receipts exist.

For example, the CSA standards must be amended to address the following questions:

- Who should be eligible to reimburse a donor or surrogate? For example, is this meant to be a person-to-person transaction, or is it imagined that clinics, lawyers, and brokerage firms will be intermediaries? What is the likely/probable role of clinics, lawyers, and brokerage firms in these reimbursements.
- Is there a maximum administrative fee that clinics, lawyers, and brokerage firms can charge?
- Who is to determine which receipts are eligible expenditures? This is of particular concern with respect to such expenses as “dependent care not included in (g),” “household maintenance,” which are to be determined as “demonstrably new and increased costs.”
- Who is to keep the receipts? For how long? Are they to be submitted to some authority for verification? Should the answers to these questions be informed by the norms of clinical practice in health care, health privacy law, or the norms of taxation? This will be particularly important for instances such as the “reimbursement for net income lost” for surrogates.
Section A.0

Principle 2(a) of the AHR Act states that “the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use.” Note that the people born through AHR are not named in the introduction (i.e. “The health and safety of the donor, surrogate, fetus, and existing children is paramount), other than as surrogates and fetuses. This section should be amended to incorporate consideration of people born of reproductive technologies. Moreover, as stated above, it is unclear how “the health and safety of the donor, surrogate, fetus, and existing children” is threatened by a failure to reimburse expenditures. Clarity with respect to how reimbursement promotes health and well-being to instantiate this claim.

Section A.1

The inclusion of “donor(s) of in vitro embryos” as potential recipients of reimbursements is problematic. While gamete donation typically involves the production/extraction of gametes for the reproductive purposes, embryo donation typically occurs after embryos have already been created for the reproductive purposes of the donor(s). The CSA would do well to identify these significant differences in donation practices insofar as the reimbursement of expenses to gamete donors will likely occur often, while the reimbursement of the expenditures of embryo donors should occur less frequently.

Furthermore, it is unclear how reimbursement can occur in contexts where donors are promised anonymity. This list of potential recipients of reimbursements is comprehensive except for the inclusion of “donor(s) of in vitro embryos” and insofar as there are no provisions for dealing with reimbursement related to anonymous donation.

Section A.2.1

It is unclear how reimbursement for a number of “eligible reimbursements” such as “remediation of compromises to academic progress” (A.3.5.1.) and “net income lost” (A.3.5.2) are receiptable. Further, a constraint is needed on this standard (i.e. directly related to the donation) given the broad scope of eligible expenditures (i.e. household maintenance).
Section A.2.2.1

There is a logical difference between “receiptable reimbursements of expenditures” and “receipted reimbursements of expenditures.” The CSA Standards recognize this given their reference to “other forms of evidence confirming expenditure.” Given the very broad scope of what is eligible for reimbursement and the lack of oversight (this being a possible private transaction between two people) it is critical that there be actual receipts to protect the interests of both parties. In fact, the language of “expenditures” was used in part to make clear that it was only things that could be purchased, rather than where money or income might be lost. Receipts should be available for all reasonable expenditures under A.3.2.1 (a-j), A.3.5.1 (a-k). And where receipts are not available, expenditures should not be reimbursed. Therefore, the words “or other form of evidence confirming expenditure” should be removed from A.2.2.1(a).

Further, Section A.2.2.1 suggests that the documentation “shall be submitted to the person issuing the reimbursement,” however, it is unclear who is an appropriate party to issue a reimbursement as well as what verification criteria, record-keeping, etc. is necessary. As previously noted, the CSA must make clear what processes and mechanisms will be in place to ensure that reimbursements occur in an ethical manner, and how such reimbursements can/should take place.

Section A.2.2.2

At present, Section A.2.2.2 calls for a declaration signed by “the person who is claiming reimbursement” that will “confirm that the expenditures have not been and will not be otherwise reimbursed.” There are two key concerns with this section as written. First, as noted previously, there are no mechanisms for verification or for record-keeping detailed by the CSA. It is unclear when this should be signed, and what legal status it is intended to have. Second, given that some expenditures may occur many months apart, (i.e. expenditures for surrogates may include, at present, vitamins and supplements, as well as clothing required during the post-birth recovery), it is unclear how many times reimbursement can occur, and in what circumstances, and if a declaration should be signed each time. Ongoing expenses (i.e. potential counselling) may complicate this further.
Section A.3.1

The note in section A.3.1 is of particular concern (i.e., “The eligible expenditures might be further limited by the legal contract in place”). As there is no province in which it is clear that egg donation contracts are enforceable by law, the “legal contract” referred to here is problematic. The CSA should make clear to what legal contract the Annex refers.

Section A.3.2.1

All of the eligible expenses from 3.2.1 (a-j) should be receiptable and clearly defined. No “other form” of evidence should be required. Further, it is unclear what should comprise alternative or complementary health care services, and supplemental insurance. Section 9(k) is particularly problematic, as it is not clear how “demonstrably new or increased costs will be assessed and by whom, particularly as regards “household maintenance,” “home care,” “remediation of compromises to academic progress,” and “other exceptional expenditures.” These should not be included in the reimbursement provisions given that related expenses are not directly incurred in relation to the donation of ova (i.e. unclear how home maintenance is directly related to ova donation).

Section A.3.2.2

Section A.3.2.2 raises a number of important concerns. First, insofar as the donation of ova is a potentially risky intervention, the process of informed consent should include disclosure about the potential of lost income. Reimbursing people for engaging in medical interventions because of the time spent is a problematic practice that does not occur in other areas of medical care. Further, the reimbursement of “net income lost” related to ova donation is contrary to the intent of the AHR Act, and income does not constitute an “expenditure,” and the Act did not include provisions to address lost wages of ova donors (despite including such provisions for surrogates). There is a move in this section, through the reference to “independent evidence,” to stretch what the law was to address from receipted expenditures, to “receiptable” expenditures, to something else, particularly insofar as “independent evidence,” and who might assess or validate that “evidence” is not defined.
Section A.3.3

Section 3.3 on the donation of sperm seems like a replication error, using boilerplate language taken from the section on donation of ova. It is unclear why sperm donors might need alternative or complementary medical services, for example, or supplemental insurance. Further consideration should be given to reasonable expenditures for sperm donation that reflect the nature of the process.

Section 3.4

Section 3.4 on the donation of embryo donation is entirely problematic. As donated embryos are typically already cryopreserved and in storage, it is not clear what costs donors might incur. Also, the inclusion of section (b) (i.e. reimbursement for storage fees) is particularly problematic as this will encourage a market in embryos. Storage fees are typically not incurred as part of the donation process, but rather as part of the use of the clinic services by the donor for their own family-building project. At most, donors could be reimbursed for the storage fees from the time that they decide to donate their embryos.

Further, the inclusion of (e) (i.e. administration fees) and (a) (i.e. costs of medical testing) are too open ended. I do not understand what administration fees or medical testing fees would be incurred by someone donating their embryos. The administration and other fees incurred at the clinic should be more clearly articulated here, and these costs should be oriented toward those acquiring (not donating) embryos.

Section 3.5.1

Section 3.5.1. on the reimbursement of expenditures for reimbursement to surrogates requires significant amendment. For example, as noted above for gamete and embryo donors, there is no time limit on counselling. It is conceivable that a surrogate may have a desire or need for counselling long after her surrogacy. It is impossible to anticipate the full cost of counselling given that some women may want ongoing counselling. What are the obligations for reimbursement in this case? Similarly, there are no time limits for (j) (i.e. clothing allowances, as the limit is “post-birth recovery”), or on any of the provisions in (l). There is a need for greater clarity about the maximum time limits and, perhaps more helpfully, maximum funds that might be provided for reimbursement.
Section 3.5.2

As with ova donation, the reimbursement of “net income lost” for surrogacy is contrary to the intent of the AHR Act, especially insofar as income does not constitute an “expenditure.” Further, it is noteworthy that this section includes a time limit for the provision of net income lost, though there are no time limits on reimbursement in 3.5.2.

Section A.4

Regarding record-keeping and collection, there should be additional clarity about which parties are responsible for keeping the records (i.e. who should be providing reimbursements, and more clearly, who should not). Further, as it may be individuals that are reimbursing individuals, there are additional concerns about the collection, handling, and storage of the relevant records as those providing the reimbursements may not have the expertise to ensure that privacy is protected in accordance with the authority (i.e. the province) in question.