September 15, 2015

Debbie Kolozsvari
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CSA Group

RE: Annex A (informative) reimbursement of expenditures for donors and surrogates

Dear Canadian Standards Association:

Attached are my comments on the draft Annex A on Reimbursement of expenditures for embryo and gamete providers and surrogates. The comments are provided under four discrete headings: (1) general overview, (2) scope, (3) process and (4) content.

I am not using the electronic submission form for several reasons. One reason is that the format limits comments to content. A second reason is that I object to the following statement:

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I do not assign the entire copyright in my comments to the CSA.

Please acknowledge receipt of this letter and the attached comments, and confirm that the CSA understands that I have not assigned copyright. If the CSA considers my comments an infringement of their Legal Notice, please advise and discard this letter and the attached document with my comments.

Sincerely,

[Signature]

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Professor and Canada Research Chair in Bioethics and Philosophy
Comments on Proposed Amendment (Annex A) to CAN/CSA Z900.2.1-12

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1. GENERAL OVERVIEW

The Assisted Human Reproduction Act 2004 (AHR Act) prohibits payment for surrogacy (s. 6), as well as the purchase of gametes (s. 7).

In principle, the AHR Act allows for reimbursement of receipted expenditures for surrogacy services and donated gametes, in accordance with the regulations, as the prohibitions under s.6 and s.7 are subject to s.12 on reimbursement of expenditures. As well, s. 12 permits, in accordance with the regulations, reimbursement for receipted expenditures incurred in the maintenance and transport of in vitro embryos.

In practice, there is considerable uncertainty as regards which receipted expenditures are eligible for reimbursement. This uncertainty is because Health Canada has not yet drafted the regulations referenced in s. 12, despite having had more than 11 years to determine the content of such regulations (the AHR Act received Royal Assent in 2004), despite having initiated plans to draft such regulations more than eight years ago (letter from Health Canada dated August 2007),¹ and despite having been the subject of several peer reviewed publications calling for legal clarity during the past four years.²,³,⁴,⁵

The proposed Annex A to the CAN/CSA Z900.2.1-12 Tissues for assisted reproduction seeks to address this lacunae by developing standards that IVF clinicians (and brokers) can use in guessing which receipted expenditures for (a) gamete donation, (b) maintenance and transport of in vitro embryos, and (c) surrogacy services may be legally reimbursable (i.e., eventually “in accordance with the regulations”).

In my view, reimbursement of “expenditures incurred in the maintenance and transport of an in vitro embryo” (s.12(1)(b)) is arguably within the scope of the CSA Standard on Tissues for assisted reproduction insofar as IVF clinics responsible for ensuring the safety of these tissues will incur costs for maintenance and transport. In sharp contrast, reimbursement for receipted expenditures for “gamete donation” (s.12(1)(a)) and “surrogacy services” (s.12(1)(c)) are arguably outside the general scope of the CSA standard. More generally, it is unclear why the CSA is stepping outside its mandate to do work that should be done by Health Canada – namely drafting the regulations for s.12.

A clear, well-substantiated, and valid rationale for why the CSA – rather than Health Canada “in consultation with Canadians” – is best suited to determine which receipted expenditures should be eligible for reimbursement for gamete providers and surrogates is needed. The notion that “something is better than nothing” is an insufficient rationale. In contemporary bioethics there is emerging concern about what has been termed “emotional blackmail” as a strategy to secure regulatory approval for drugs that are known to be minimally effective and potentially harmful. The regulator and the general public are told that “something is better than nothing”. It is worrisome, indeed, if “something is better than nothing” is the sole rationale for the CSA stepping outside its bailiwick. Arguably a more appropriate strategy would be for the CSA to join the chorus of those calling on Health Canada to do its job and draft the regulations for s.12.

The comments attached to this letter are provided under protest, in recognition of the fact that the CSA is unlikely to be persuaded by this first and foremost objection. Namely, that Health Canada should be drafting the regulations for s. 12. The CSA should not be developing voluntary standards as a second best option because “something is better than nothing”.
SCOPE

The original standard on tissues for reproduction addresses issues related to safety. It is not clear how the proposed Annex A on reimbursement for receipted expenditures promotes safety. Consider, for example, reimbursement of travel and accommodation, long distance charges, household maintenance, and tuition costs. While it is possible to argue that such expenditures should be reimbursed as a matter of fairness, it is hardly the case that such reimbursements promote safety.

The proposed Annex A seeks to enlarge the scope of the original standard beyond safety to include health. If this is a legitimate move, then presumably the original standard will need to be amended for reasons of consistency (and to ensure that the Annex does not extend beyond the original standard). In any case, the concern noted above would still apply. Many of the expenditures identified as eligible for reimbursement have nothing to do with promoting health, just as they have nothing to do with promoting safety.

There are matters within the scope of the original standard that are not addressed in the proposed Annex A. These are matters concerning: recordkeeping for receipts (1.2(d)); the distribution of embryos and reproductive materials (1.2(e)); and importation or exportation of embryos and reproductive materials (1.2(f)).

For illustrative purposes, below are questions about recordkeeping for receipts where there are potential safety concerns having to do with the risk of prosecution.

- Are receipts to be submitted to some authority for assessment (re: eligibility) and verification (re: totals) prior to reimbursement? This is of particular concern with respect to “dependent care not included in (g),” and “household maintenance,” which are to be determined as “demonstrably new and increased costs.” Demonstrated to whom? For example, can an ova provider, under the category “household maintenance”, claim the cost of a cleaning service? And, ultimately who makes this determination? Her fertility doctor? The clinic receptionist? The clinic lawyer? A clinic based ethics committee?
- If there is “reimbursement for net income lost” for surrogates, how is this to be calculated (and by whom)? Are company or government payments for sick leave, maternity leave, and personal days to be included or excluded from payments?
- What if the embryo or gamete provider wants anonymity? Can the recipient pay the clinic who in turn pays the provider? Does the clinic then keep the receipts on the basis of which the total reimbursement was determined or transfer them to the recipient? Can the clinic add an administration fee for this service?
• Can a sperm recipient who collects receipts when reimbursing a sperm provider have the lawyer who is dealing with parentage issue handle this exchange (thereby potentially absolving herself of responsibility for verifying and keeping receipts and other documentation)?
• Is there a maximum administrative fee that clinics, lawyers, and brokerage firms can charge?
PROCESS

Legal Notice of Draft Standards

“This process brings together volunteers representing varied viewpoints and interests to achieve consensus and develop a standard.”

- Failure to include persons with experiential knowledge among the volunteers (e.g., gamete providers and surrogates) is a mistake. These individuals could have made useful contributions (different from those made by expert committee members).
- Failure to initiate a public consultation is problematic insofar as Health Canada created the expectation of public consultation in a number of documents including a 2007 letter to stakeholders which includes a statement confirming that the regulations for s.12 are “currently being developed, and consultation with Canadians is a key element of this process.”

“Although CSA administers the process and establishes rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of standards.”

- The absence of independent (disinterested) review of the proposed Annex to ensure that the interests of those engaged in, or affected by, surrogacy and third-party reproduction are protected is troubling.

Disclaimer and exclusion of liability

“CSA is a private not-for-profit company that publishes voluntary standards and related documents. CSA has no power, nor does it undertake, to enforce compliance with the contents of the standards or other documents it publishes.”

- Canada needs regulations, not voluntary standards that may or may not be followed at the whim of individuals.
- Canada needs regulations that are enforceable, not voluntary standards that no organization or institution will enforce.
- Canada needs regulations that are publically available, free of charge, not CSA standards (with or without an Annex) that must be purchased.

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- I do not assign the entire copyright in my comments to the CSA.
CONTENT

Section A.0

The proposed Annex stipulates that “The health and safety of the donor, surrogate, fetus, and existing children is considered paramount.” Meanwhile, 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.” As well, the original CSA standard makes reference to “children born as a result of an assisted reproduction procedure.” Children born through assisted human reproduction are not named in the introduction, other than as fetuses.

This section should be amended to include “children born as a result of an assisted reproduction procedure.”

Section A.1 Reimbursement recipients

Clinics are not listed among the reimbursement recipients and yet it is clinics that will incur the maintenance and transportation costs for donated frozen embryos and frozen gametes originally created for own use.

This section should be amended to include clinics among reimbursement recipients.

Re reimbursement for clinics, there should be set limits re fees that can be reimbursed for maintenance and transportation. Otherwise there is an incentive to inflate these costs to whatever the market will bear (and more).

Who should reimburse the clinic for the maintenance and transportation costs incurred? Should this be (i) the individuals seeking fertility treatment who are the recipients of the materials, or (ii) the fertility clinic receiving the gametes and embryos into storage who will then pass these costs on to the recipients of the gametes and embryos, or (iii) the research facility who will then pass this cost on to the researcher who will include this in her research budget? Does this “brokering” become another transaction cost to be charged to someone? Will there be any oversight of these transfer payments?

While reimbursement recipients are listed under A.1, there is no listing for persons issuing reimbursement (i.e., reimbursement providers). Clarity on this point is essential as there are record-keeping (and so possibly legal) responsibilities for reimbursement providers who are accepting receipts.
Provide a list of reimbursement providers to include: (a) ova recipient for own use; (b) sperm recipient for own use; (c) in vitro embryo recipient for own use; (d) commissioning parent(s); (e) fertility clinic or other intermediary for use by other; (f) researcher; or (g) research facility.

If there are reimbursement providers who are not obtaining gametes or embryos for their own use, what measures should be in place to make sure that this does not become a profit-making venture contrary to s. 2(f) of the AHR Act “trade in the reproductive capabilities of women and men and the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition”?

Section A.2.1 General (Reimbursements)

A further constraint is needed on this standard given the broad scope of eligible expenditures (e.g., household maintenance).

At a minimum, it will be important to add the word “directly” as in “directly related to the donation”.

Section A.2.2.1 (Documentation)

There is a logical difference between “receiptable reimbursements of expenditures” and “receipted reimbursements of expenditures.” The proposed Annex A seeks to legitimize “receiptable expenditures” with the reference to “other form of evidence confirming expenditure.” Reimbursement based on “other form of evidence confirming expenditure” is contrary to the AHR Act S. 12 includes provisions for reimbursement solely on the basis of receipts. Given the very broad scope of what is eligible for reimbursement in the proposed Annex and the lack of oversight it is critical that there be actual receipts to protect the interests of both parties. Receipts should be available for all reasonable expenditures. Where receipts are not available, expenditures should not be reimbursed.

According to the AHR Act s.12(2) No person shall reimburse an expenditure ... unless a receipt is provided to that person for the expenditure.” Consistent with the Act, section A.2.2.2 should be deleted.

Section A.2.2.2 (Documentation)

There are no mechanisms for verification or for record-keeping. Further, the legal status of the proposed declaration is unclear.

Clarify that the declaration is to accompany receipts submitted for reimbursement. This is not a declaration about the “receiptability” of the expenses, but about the fact that the expenditures will not otherwise be reimbursed.
Section A.3.1 General (Eligible Expenditures)

This section includes the Note: The eligible expenditures might be further limited by the legal contract in place.

What is the intent of this Note? Is the CSA explicitly recognizing that private contracts will supersede its voluntary guidelines and anyone with a contract can contract for anything?

Clarify

Section A.3.2.1 Donation of Ova (Eligible Expenditures)

Concerns about the expansive nature of the list of eligible expenditures:

The expansive list of expenditures eligible for reimbursement potentially contravenes s. 2(f) “trade in the reproductive capabilities of women and men and the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition.”

In an effort to be comprehensive (and list and all possible expenditures no matter how trivial), the nature of the exchange has been transformed from an altruistic exchange to a mercantile exchange. A gift is given, but the gift box, the wrapping paper, the tape, the card, the bus fare to deliver the present, the muffin eaten along the way, the phone call to announce that one will be late for the party are all expenditures to be reimbursed. There is something very disconcerting about this scenario... Hardly seems to have anything to do with gifting...

It is clear from the parliamentary debates leading to the passage of the AHR Act that the intent of the provisions on reimbursements of expenditures was not to include a wide range of reimbursements because of the perceived risk that payments would threaten the health and safety of providers. The wide range of reimbursements incorporated into this proposed Annex A stands in direct opposition of the legislative intent of the Act. It is also somewhat ironic that what Parliament perceived as a potential threat to health and safety (e.g., encouraging women to consent to activities they would not otherwise consent to through such incentives as reimbursement of ova providers for time off from work, and tuition) is characterized in the proposed Annex as promoting health and safety.

The list of eligible expenditures should be scaled back (see detailed comments below). Moreover, the CSA would do well to think carefully about the precedent being set for other bodily tissues that are gifted (e.g., blood and solid organs).

Concerns about the conflation of two different populations of ova providers
Ova providers who consent to the production/extraction of ova solely for third-party reproduction or research, and ova providers who donate ova they originally stored for their own reproductive use incur different expenses with respect to donation. In the latter case, ova providers should only be eligible to submit receipts for (c) legal advice and (d) counselling. Past expenditures in the other categories (including years of storage fees) would have been incurred in pursuit of personal goals not as a cost of donation. If personal expenditures are to be reimbursed as part of the cost of donation, then reimbursements might become incentives used to encourage ova donation and thereby undermine voluntariness.

The Tri-Council Policy Statement (TCPS2) draws clear distinctions between reimbursements and incentives and notes that incentives “may amount to undue inducement and thus negate voluntariness.” In assessing the range of eligible expenditures, it appears that the line between reimbursements and incentives has been crossed.

*Introduce clear distinctions between ova providers who consent to the production/extraction of ova solely for third-party reproduction or research, and ova providers who donate ova they originally stored for their own reproduction and accordingly revise the list of eligible expenditures.*

**Specific expenditures**

For ova providers who consent to the production/extraction of ova solely for third-party reproduction or research:

All of the expenditures eligible for reimbursement from 3.2.1 (a-j) should be receipted. No “other form of evidence confirming expenditure” (as per A.2.2.1) should be allowed. Also, each category should be clearly defined (and in some cases there should be descriptive or numerical limits)

3.2.1 (b) Does anything and everything potentially qualify as alternative or complementary health care services? Does this include physiotherapy, a consultation with a nutritionist? What exactly is imagined as a necessary alternative or complementary health care service?

3.2.1 (c) (d) and (e) Is there a maximum amount that can be reimbursed?

3.2.1 (d) There is no time limit on counselling. Can an ova provider, five years after donation seek counselling about her decision to donate and expect to be reimbursed for this? What

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about ten, fifteen, twenty years post donation? It is difficult to anticipate regret that might require counselling.

3.2.1. (e) Is supplemental insurance limited to health insurance? Or, can this include life insurance? Or, something else?

3.2.1. (g) Is dependent care limited to child care and elder care? If so, this should be specific. Otherwise, a person might think that pet care was included (e.g., dog walking). While this may seem like an odd comment, this is prompted by the apparent all-encompassing nature of the list of expenditures eligible for reimbursement which is over-inclusive. Perhaps one strategy to improve clarity would be to provide a list of ineligible expenditures.

3.2.1 (h) The transaction costs for this category are such that there is reason to eliminate this from the list of eligible expenditures. In brief, the cost of producing and verifying receipts in this category is likely to far exceed the truly eligible expenditure (directly relevant to the donation). Who is the ova provider calling long distance? How many times? At what cost (depending on her cell phone plan)? There is no principled reason not to see “communication” as a legitimate expenditure and to reimburse it, but inclusion of this expenditure in the list seems to be the result of an effort to ensure that not a penny associated with what might otherwise be seen as an act of altruism should go unnoticed and not be reimbursed.

When tracking an expense is onerous, there is an incentive to have flat rates. Consider, for example, per diems for meals (note 3.2.1 (i) food consumed on any day during which the donor attends an appointment). The creation of multiple “legitimate” categories (with complicated record keeping for trivial amounts) risks the introduction of flat rates for reimbursement and this would further move away from the legislated requirement that there be receipts.

3.2.1 (j) The cost of obtaining medical or other records is not an expenditure of ova donation. At most this is a cost of ova acquisition. While the recipient might want access to information in these records, this is not an out-of-pocket expense for which the ova provider is to be reimbursed.

3.2.1 (k) is excessive in scope and there is no precedent for this in any other area of health care. To be specific, there is no other context in which people are protected from ALL the vagaries of life with a safety net for anything and everything that might go wrong. How are these “demonstrably new or increased costs” to be assessed and by whom, particularly as regards “household maintenance,” “home care,” “remediation of compromises to academic progress,” and “other exceptional expenditures.” How is one to avoid idiosyncratic interpretations (overly restrictive, overly generous)? It is unclear, for example, how home maintenance might be directly related to ova donation. Much on this list seems like an invitation to “find costs” to
claim. Or alternatively, to create a false sense of security – nothing bad will happen and don’t worry if it does there is money to pay for that.”

Section A.3.2.2 Donation of Ova (Eligible Expenditures)

Reimbursement of “net income lost” related to ova donation is contrary to the AHR Act. The Act included provisions for “loss of work-related income incurred during pregnancy” for surrogates 12(3)(a) and (b). There is no equivalent provision for ova providers.

Reimbursing people engaging in altruistic medical interventions for “net income lost” is inconsistent with other practices in Canada. For example, we do not reimburse blood or solid organ donors for loss of income

“Lost income” is not an “expenditure”. Because it is not an expenditure, there can be no receipts. Because there can be no receipts, the Draft Annex makes reference to “independent evidence.” This wordsmithing alone should be sufficient to indicate that there is a problem with this clause. What counts as independent evidence? If the provider is employed, does she require a letter from her employer? Addressed to whom? What if the provider wants the fact of donation to remain confidential? What if the provider is unemployed? Is independent evidence to be provided by her accountant? Her minister? Her doctor? Moreover, what is the mechanism for assessing or validating any such “evidence”?

Informed consent to ova donation should include disclosure about potential harms that could result in health consequences requiring sick leave (and thus potential loss of income). Prospective providers who do not have access to sick leave in the event of untoward consequences might want to reconsider donation.

Section A.3.3 Donation of Sperm

Concerns about the conflation of two different populations of sperm providers

It is important to distinguish between sperm providers who consent to donation for third-party reproduction or research, and sperm providers who donate sperm they originally stored for their own reproductive use. In the latter case, sperm providers should only be eligible to submit receipts for (c) legal advice and (d) counselling. Past expenditures in the other categories (including years of storage fees) would not have been incurred as a cost of donation, but rather in pursuit of personal goals.

Introduce clear distinctions between sperm providers who consent to the production/extraction of sperm solely for third-party reproduction or research, and sperm providers who donate sperm they originally stored for their own reproduction and accordingly revise the list of eligible expenditures.
For sperm providers who consent to donation solely for third-party reproduction or research, many of the expenditures listed should not be eligible for reimbursement. The use of boiler-plate language from the section of ova donation suggests a lack of care and attention to the content for this section thereby creating the false impression that the potential expenditures for sperm donation are analogous to those for ova donation. To make the point: A.3.3 (a) and (b): What medication, medical supplies, medical services, alternative or complementary health care services are required for masturbation? A.3.3 (e) what supplemental insurance is needed for masturbation? This section should refer to reasonable expenditures for sperm donation that reflect the nature of the process.

Section 3.4 Donation of in vitro embryos

Donated embryos will be cryopreserved embryos originally created for own use. It follows that any expenditures incurred in producing and storing these embryos will have been incurred in pursuit of one’s own family-making project. These expenditures will not have been incurred as a cost of donation and should not be eligible for reimbursement. On this view, (b) is not an eligible expenditure for embryo providers. Including embryo storage fees as a reimbursable expenditure for embryo providers is an example of where reimbursement crosses the line to incentive. The cost of embryo storage can be significant. If it is possible to have this cost reimbursed, individuals and couples will be incentivized to donate their embryos.

The only expenditures associated with embryo donation that should be an eligible for reimbursement to the embryo provider are: (a) legal advice and (d) counselling.

(b) storage fees from the date of embryo donation to the date of transfer to another clinic, (c) transportation costs, and (e) administration costs are costs incurred by the fertility clinic. Fertility clinics should be identified as reimbursement recipients. They should be reimbursed directly for eligible expenditures. As noted above, this would require a change to A.1 on Reimbursement recipients.

(g) the cost of medical testing is not a cost of embryo donation. At most it is a cost of embryo acquisition should the embryo recipients want to have the embryo tested. This should not be a reimbursable expenditure for either the embryo provider or the fertility clinic. This is a cost incurred by the embryo recipient

Section 3.5.1 (Surrogacy)
3.5.1 (b) Does anything and everything potentially qualify as alternative or complementary health care services? Does this include physiotherapy, a consultation with a nutritionist? What exactly is imagined as a necessary alternative or complementary health care service?

3.5.1 (c) Is legal advice limited to advice about contractual terms? What if the surrogate wants to contest some of the terms in the surrogacy arrangement she signed? Is she able to submit these legal fees for reimbursement?

3.5.1 (c) (d) and (e) Is there a maximum amount that can be reimbursed?

3.5.1 (d) 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 to deal with anguish and regret at having “given away her child”. 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?

3.5.1. (e) Is supplemental insurance limited to health insurance? Or, can this include life insurance? Or, something else?

3.5.1. (f) travel to where? Accommodation for what? What are the imagined receipted expenditures? Presumably the travel is for something other than “travel to and attending related appointments” as this is clearly specified re ova and sperm provider travel and is not so specified here. As well, such travel would not typically require accommodations. So what exactly is an imagined receipted travel expenditure that is directly related to surrogacy? Travel to visit commissioning parent(s)? Why wouldn’t the commissioning parents travel to the surrogate?

3.5.1. (g) Is dependent care limited to child care and elder care? If so, this should be specific. Otherwise, a person might think that pet care was included (e.g., dog walking). While this make seem like an odd comment, this is prompted by the apparent all-encompassing nature of the list of expenditures eligible for reimbursement which, to our mind, is already overly (and inappropriately) inclusive. Perhaps one strategy to improve clarity would be to provide a list of ineligible expenditures.

3.5.1 (h) The transaction costs for this category are such that there is reason to eliminate this from the list of eligible expenditures. In brief, the cost of producing and verifying receipts in this category is likely to far exceed expenditures directly relevant to the surrogacy services.

3.5.1 (j) Can this legitimately include two full new wardrobes? One for the pregnancy and one post-recovery? Again, this might be a category where clarity could be improved by providing a
list of ineligible expenditures, or setting a dollar value limit. The problem with setting a limit is that this incentivizes people to spend to the limit.

3.5.1 (k) The cost of obtaining medical or other records is not an expenditure of surrogacy to be borne by the surrogate. If the commissioning parent(s) wants access to information in these records (and should have to pay for this), they should pay the cost directly. It is wrong to create the fiction that this is a cost incurred by the surrogate for which she ought to be reimbursed.

3.5.1 (l) is excessive in scope and there are no equivalent precedents. Volunteer firefighters, for example, act altruistically and potentially put themselves at risk in so doing without any commitment for this expansive list of financial benefits.

Section 3.5.2 (Surrogacy)

This section includes a time limit for the provision of net income lost. There are no time limits on other eligible reimbursement in 3.5.2. Perhaps there should be.

Is reimbursement for net income lost in addition to, or in lieu of, sick leave or maternity leave benefits provided by her company (if she is employed and the company has such benefits) or the government? What oversight is needed, anticipated?

Section A.4 (Records management)

The requirement that records be kept for a minimum of two years seems rather short. Why two years? This does not seem consistent with the norms of clinical practice, criminal law, health privacy law, or tax law.

Of particular concern here is the criminal law. There is a prohibition on payment and the penalties for violating the prohibition include prison. There may be criminal matters associated with reimbursement activities should there ever be an allegation that “reimbursement” was in fact payment. If so, presumably records should be available to assist with any investigation. It would be in the interest of all parties (those paying and those receiving reimbursement) to have properly collected, handled, and stored receipts. What is the statute of limitations for such an allegation to be made? All documentation concerning reimbursement should be kept for no less time.

Privacy is an important matter and it is not clear that individual recipients who may be reimbursing individual providers, will have the requisite knowledge and expertise to ensure that privacy is protected in accordance with the authority (i.e. the province) in question.