RCPAQAP
The Royal College of Pathologists of Australasia
Quality Assurance Programs

By email: health@parliament.qld.gov.au

The Secretary
Health, Communities, Disability Services and Domestic and Family Violence Prevention Committee
Parliament House
George Street
Brisbane QLD 4000

Dear Mr Hansen,

RE: Health and Other Legislation Amendment Bill 2018

This submission relates to proposed amendments to the *Transplantation and Anatomy Act 1979* (Qld) (**Act**) incorporated in the above Bill.

Specifically this submission relates to the proposed amendment to Section 42AA (the **Section**) of the Act.

RCPA Quality Assurance Programs Pty Ltd (**RCPAQAP**) provides quality assurance programs to pathology labs across Australia. It is a company established and controlled by the Royal College of Pathologists of Australasia. We are world leaders in the provision of external quality assurance (EQA) for pathology laboratories. We offer a comprehensive range of EQA for all disciplines of pathology. Our programs are offered in Australia and internationally in over 60 countries. RCPA QAP presently holds a Ministerial permit allowing sale of this tissue.

RCPA QAP is strongly in favour of the objective of the intended amendments to the Act in relation to Section 42AA. The current Ministerial permit system is, in our view, unwieldy and inefficient in practice, given the reasonable requirements of the Minister and the Department when assessing applications.

However, we are concerned that the objective of the amendment to the Section will not be fully achieved because we would consider that it is difficult to characterise much of the tissue that we provide as having been the subject of "processing or treatment". Indeed it is quite important that many of the tissue samples we source and provide are in fact in their native state, and are unprocessed.

The requirement for the tissue having been subjected to processing or treatment to fall within the exception is one of the four pre-conditions to the application of the exception created by the Section (specifically Section 42AA(1)(a)).

This pre-condition is retained in the amendments provided by the Bill. As we understand it, the proposed amendments are intended to enable quality assurance materials, reagents, reference and control materials to be exempt from the prohibition on trade in tissue, which is currently set out in Part 7 of the Act.

However, if the pre-condition of "processing or treatment" is retained for this category of what is proposed to be termed "exempt material", what we understand to be a key objective of the amendment will not be fully achieved, and RCPA QAP will for some categories of tissue still be required to utilise the Ministerial permit system.

Royal College of Pathologists of Australasia
Quality Assurance Programs
ABN 32 003 520 072
Suite 201, Level 2, 8 Herbert Street
St Leonards NSW 2065
t 1300 78 29 20 f 02 9356 2003
E rcpaqap@rcpaqap.com.au
rcpaqap.com.au

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The tissue used in our quality assurance programs is donated by various pathology laboratories for nil consideration. The tissue is essentially 'left-over' after the necessary pathology evaluation has been completed in the clinical context. It is then re-distributed to other pathology laboratories as part of the EQA program.

We also are concerned about the language proposed to be inserted as sub-paragraph (iii) in Section 42AA(1)(c) of the Act. It refers to exempt material being "derived wholly or in part from tissue". Our concern again is that what we provide is actually tissue, it is not in the usual sense of the word "derived" from tissue. Again this is partly reflective of the reality that there often isn't any processing or treatment of the relevant samples.

We drawn the Committee's attention to the relevant exemption contained in the NSW *Human Tissue Act* (**NSW Act**). Specifically section 34(1)(b3)(i) of the NSW Act, which provides that the following is permissible, or put another way, exempt from the relevant prohibitions in the NSW Act:

> "*the use of small samples of any tissue that is lawfully removed from the body of a person (whether living or deceased) for the purpose of carrying out analyses or tests that are part of a program (including any quality assurance program, quality control program, audit or evaluation) to ensure, or improve, the quality of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution or a supplier of blood or blood products*"

The virtue of this approach is that it is appropriately concise and standalone. While the wording would need adjustment to fit within the approach taken in the Act, the drafting of the NSW Act appropriately balances the State's interest in preventing trade in human tissue, with the benefits of allowing use of tissue in quality assurance programs which are designed to help maintain and enhance the quality of the services provided by the participating pathology laboratories, which is clearly the underlying intent of the proposed amendments to the Section.

Addressing our concerns as stated above in the context of the current structure of the Section with its four compounding conditions is quite difficult, and might reasonably be approached by splitting the exemption into two parts, which would require more extensive re-drafting.

Alternatively, it might be considered that paragraph (a) of Section 42AA(1) - (the requirement for the tissue having been subjected to processing or treatment) is superfluous and could be deleted. This would certainly address our first concern. As to our second concern this could be addressed by inserting the words "being or" before "derived" in the proposed sub-paragraph (iii) of Section 42AA(1)(c), so that sub-paragraph (iii) would read:

> (iii) any exempt material being or derived wholly or in part from tissue; and"

We would be happy to work with the Committee to assist with a suggested reformulation of the proposed amendments to address our concerns as stated above.

Finally, we would like to recognise the assistance and co-operation we have had to date from the Department of Health in assisting in the operation of the EQA program.

Yours faithfully

Tony Badrick
Chief Executive Officer
RCPA Quality Assurance Programs Pty Ltd