

LEGISLATIVE COUNCIL BRIEF

Human Organ Transplant Ordinance
(Chapter 465)

HUMAN ORGAN TRANSPLANT (AMENDMENT) BILL 1999

INTRODUCTION

At the meeting of the Executive Council on 5 January 1999, the Council ADVISED and the Chief Executive ORDERED that the Human Organ Transplant (Amendment) Bill 1999, at Annex, should be introduced into the Legislative Council. The Bill sets out the circumstances under which an organ transplant involving a live donor may still be carried out in cases where the patient is incapable of understanding the explanation required to be given to him under section 5(4)(c) of the Human Organ Transplant Ordinance (the Ordinance).

BACKGROUND AND ARGUMENT

General Background

2. The Ordinance, which came into full operation on 1 April 1998, prohibits commercial dealings in human organs intended for transplant, restricts the transplant of human organs between living persons, and regulates the importing of human organs intended for transplant. While it is our policy to encourage cadaveric donation, we do not disallow organ transplant involving a live donor, which may be the only effective treatment for some patients.

Present Position

3. Under section 5(4)(c) of the Ordinance, in cases of transplants between living persons, arrangement must be made, prior to the transplant, for the donor and the patient to be given an explanation of the procedure and the risks involved, and his entitlement to withdraw consent at any time. This requirement has been imposed to ensure that both the donor and the patient realise that an organ transplant is a high risk medical procedure to both of them. It is possible that certain patients may decide to refuse donation from a live donor having regard to the risk on the part of the donor.

4. Meeting this requirement, however, poses a problem in cases where the condition of the patient has deteriorated so rapidly that it has become not possible to arrange for him to be interviewed and given the relevant explanation. The same problem occurs when the patient is a minor or a mentally disordered/handicapped person. In such cases, the transplant cannot be carried out lawfully, with subsequent adverse effect on the health of the intended patient.

The Proposal

5. To overcome this problem, we propose to add to the Ordinance a new provision that the requirement to explain to the patient under section 5(4)(c) of the Ordinance may be waived where circumstances have made compliance impossible, i.e. in cases where the patient is incapable of understanding an explanation given to him because of his illness or impaired state of consciousness, or because he is a minor or a mentally disordered/handicapped person.

6. To prevent abuse of this exemption, we propose to require a medical practitioner to certify in writing that the patient is incapable of understanding an explanation given to him and also to certify that it would not be in the best interests of the patient to wait until he is capable of understanding such an explanation. These two certificates may be provided by the same or different medical practitioners, other than the medical practitioner who will remove the organ from the donor or

transplant the donor's organ into the patient. This confirmation from a third party will help to reduce abuses.

7. In addition to the two certificates, we propose to require the medical practitioner who is to transplant the donated organ into the patient to keep a medical report in writing stating the reasons why the requirement to explain to the patient cannot be complied with. This provision will have a deterrent effect against abuses as the medical practitioner concerned will be fully aware that the content of the medical report may be subject to scrutiny.

8. Approval from the Human Organ Transplant Board (the Board), established under section 3 of the Ordinance, to carry out a transplant between living persons is required in cases where the donor and the patient are not genetically-related or are not married for not less than three years. For such cases, a copy of the two certificates and the medical report should be submitted to the Board before the transplant. In other cases where prior approval of the Board is not required, a copy of the two certificates and the medical report should be submitted to the Board not later than 30 days after the transplant or within such longer period as the Board may allow.

9. We propose also to take advantage of this amendment exercise to expand section 5 of the Ordinance to allow the Board to prescribe by regulation the means to establish a marriage relationship. As mentioned in paragraph 8 above, approval to carry out an organ transplant between living persons is required from the Board in cases where the donor and the patient are not genetically-related or are not married for not less than three years. The existing legislation provides that the Board may prescribe by regulation the means to establish a genetic relationship, but has not provided the Board with similar power in relation to a marriage relationship. This omission has posed a problem to medical practitioners, who become uncertain of what information to acquire from the donor and the patient, especially in support of the claim that the marriage has subsisted for not less than three years.

THE BILL

10. This Bill specifies -
- (a) that the marital requirement in section 5(1)(ii) of the Ordinance (that is, for organ transplant between spouses) must be established by a means prescribed by the Board by regulation [**clause 2 (a)**]; and
 - (b) the circumstances under which an organ transplant may still be made notwithstanding the fact that the patient is, for certain specified reasons, incapable of understanding the explanation required to be given to him under section 5(4)(c) of the Ordinance [**clause 2(b)**].

LEGISLATIVE TIMETABLE

11. The legislative timetable approved by the Chief Executive in Council is as follows -

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| Publication in the gazette | 8 January 1999 |
| First Reading and commencement of Second Reading Debate | 13 January 1999 |
| Resumption of Second Reading Debate, committee stage and Third Reading | To be notified |

BASIC LAW IMPLICATIONS

12. The Department of Justice advises that this Bill is consistent with those provisions of the Basic Law carrying no human rights dimensions.

HUMAN RIGHTS IMPLICATIONS

13. The Department of Justice advises that the proposed legislation is consistent with the human rights provisions of the Basic Law.

BINDING EFFECT OF THE LEGISLATION

14. The Bill does not bind the State by express provision. The provisions of the Ordinance which are amended by the Bill do not bind the State by express provision.

FINANCIAL AND STAFFING IMPLICATIONS

15. There are no financial or staffing implications.

PUBLIC CONSULTATION

16. We described an outline of this proposed amendment at a meeting of the Health Services Panel of the Legislative Council held on 23 November 1998. We have, so far, not received any adverse reaction to this proposal.

PUBLICITY

17. A press release will be issued on the day when the Bill is gazetted.

18 For enquiries in relation to this Bill, please contact the following officer -

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Health and Welfare Bureau

7 January 1999

A BILL

To

Amend the Human Organ Transplant Ordinance.

Enacted by the Legislative Council.

1. Short title and commencement

(1) This Ordinance may be cited as the Human Organ Transplant (Amendment) Ordinance 1999.

(2) Section 2(a) shall come into operation on a day to be appointed by the Secretary for Health and Welfare by notice in the Gazette.

2. Restriction on transplants between living persons

Section 5 of the Human Organ Transplant Ordinance (Cap. 465) is amended -

(a) by adding -

“(2A) Two persons shall not in any particular case be treated as spouses whose marriage has subsisted for not less than 3 years unless the fact of the relationship has been established by such means as may be prescribed by the board by regulation.”;

(b) by adding -

“(6A) Notwithstanding subsections (4)(c) and (5) (insofar as it relates to subsection (4)(c)) or, as the case may be, subsection (6) (insofar as it relates to subsection (4)(c)) in the case, but only in the case, of the recipient -

- (a) the board may give its approval under subsection (3); or
- (b) the person who will remove from a living person an organ intended to be transplanted into another person where the approval of the board is not required under subsection (3) may remove the organ,

if the board or person, as the case may require, is satisfied that -

- (i) a registered medical practitioner, who is not the medical practitioner who will remove the organ from the donor or transplant the donor’s organ into another person, has certified in writing that the recipient is incapable of

understanding any explanation as mentioned in subsection (4)(c) by reason of -

- (A) his suffering any illness;
- (B) his being a minor;
- (C) his being a patient or a mentally handicapped person, within the meaning of the Mental Health Ordinance (Cap. 136) as read with the Mental Health (Amendment) Ordinance 1997 (81 of 1997); or
- (D) his suffering an impaired state of consciousness;

- (ii) a registered medical practitioner, who is not the medical practitioner who will remove the organ from the donor or transplant the donor's organ into another person, has certified in writing that it would not be in the best interests of the recipient to wait until he is capable of

understanding such an explanation; and

(iii) the registered medical practitioner who is to transplant the organ into the recipient has kept a medical report in writing stating the reason why subsection (4)(c) cannot be complied with in respect of the recipient.

(6B) Where subsection (6A) is applicable -

(a) in the case of subsections (4)(c) and (5), the board shall not give its approval under subsection (3) (and without prejudice to the operation of subsections (4) and (5) to the extent that subsection (6A) is not applicable) unless there has been submitted to it copies of the certificates concerned required under subsection (6A)(i) and (ii) and a copy of the report concerned required under subsection (6A)(iii);

- (b) in the case of subsection (6) -
- (i) the registered medical practitioner who is to transplant the organ into the recipient concerned shall not do so until there has been submitted to him copies of the certificates required under subsection (6A)(i) and (ii) in respect of the recipient;
 - (ii) the registered medical practitioner who has transplanted the organ into the recipient shall, not later than 30 days after the transplant or within such longer period as the board, on application, may allow, submit to the board

copies of the certificates
required under subsection
(6A)(i) and (ii) and a copy
of the report required under
subsection (6A)(iii) in
respect of the recipient.”;

(c) in subsection (7), by repealing “this section” and substituting
“subsection (1)”;

(d) by adding -

“(8) Any person who in purported compliance with -

(a) regulations made for the purposes of
subsection (2A); or

(b) subsection (6A),

knowingly or recklessly supplies information, or makes a
certification, which is false or misleading in a material respect is
guilty of an offence and is liable upon conviction to a fine at
level 5 and to imprisonment for 3 months.

(9) A registered medical practitioner who, without
reasonable excuse, fails to comply with subsection (6B)(b)(i) or
(ii) shall be guilty of

an offence and is liable upon conviction to a fine at level 5.”.

Explanatory Memorandum

This Bill amends the Human Organ Transplant Ordinance (Cap. 465) to -

- (a) specify that the marital requirement in section 5(1)(ii) of the Ordinance (that is, for organ transplant between spouses) must be established by a means prescribed by the Human Organ Transplant Board by regulation (clause 2(a)); and
- (b) specify the circumstances in which an organ transplant may still be made notwithstanding the fact that the recipient is, for certain specified reasons, incapable of understanding the explanation required to be given to him under section 5(4)(c) of the Ordinance (clause 2(b)).