Medical Innovation Bill [HL]

EXPLANATORY NOTES

Explanatory notes to the Bill, prepared by Lord Saatchi, the member in charge of the Bill, are published separately as HL Bill 61—EN.

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TO

Make provision about innovation in medical treatment.

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

1 Responsible innovation

The purposes of this Act are to—

(a) codify existing best-practice as to decisions by doctors to innovate where evidence-based treatment or management is not optimal or appropriate, because the available evidence is insufficient or uncertain,

(b) enhance certainty and clarity for doctors and others on the criteria to be applied in determining whether to innovate in those cases,

(c) encourage responsible innovation in medical treatment and management by supporting reasonable and logical clinical decisions, and

(d) deter reckless, illogical and unreasonable departure from standard practice.

2 Innovation in absence of evidence-based treatment

(1) This section applies where a doctor believes that it is not possible or appropriate to make a purely evidence-based decision in determining how to treat a patient's condition, because in the doctor's opinion—

(a) there is no research or other evidence available in relation to the condition, or

(b) the available research or other evidence is insufficient or uncertain.

(2) In determining whether to depart from what the doctor believes to be the pre-existing range of acceptable treatments for the condition, the doctor must consider—

(a) the reasons why the available research or other evidence is insufficient or unclear including, in particular, whether it is referable to the nature of the condition (as in, for example, a cancer that affects relatively few patients),

(b) the relative risks that are, or can reasonably be expected to be, associated with the treatment the doctor proposes to apply and other treatments,

(c) the relative likely success rates of the treatment the doctor proposes to apply and other treatments, in the doctor's reasonable judgment,

(d) the relative likely consequences of applying, or failing to apply, the treatment the doctor proposes to apply, and other treatments,

(e) opinions or requests expressed by or in relation to the patient, and

(f) any other matter that appears to the doctor to be reasonably necessary to be considered in order to reach a clinical judgment.

(3) The doctor must also consider what process to adopt with a view to ensuring that the decision to innovate is made accountably, transparently and with full consideration of all relevant matters; the process may include, in particular—

(a) decisions made within a multi-disciplinary team;

(b) notification in advance to the doctor's responsible officer (within the meaning of Part 5A of the Medical Act 1983);

(c) explanation to the patient of the doctor's reasons for proposing to depart from standard treatment, including discussion of any contrary opinions expressed by the doctor's colleagues.

(4) It is not in itself negligent for a doctor to depart from what the doctor believes to be the pre-existing range of acceptable treatments for a condition where the decision to innovate was taken in accordance with subsections (2) and (3).

(5) Nothing in this section permits a doctor—

(a) to provide treatment without consent that is otherwise required by law, or

(b) to administer treatment for the purposes of research or for any purpose other than the best interests of the patient.

(6) In this section—

(a) "doctor" means a person listed in the register of medical practitioners under section 2 of the Medical Act 1983, and

(b) a reference to treatment of a condition includes a reference to its management (and a reference to treatment includes a reference to inaction).

(7) The General Medical Council may issue guidance about the factors to be considered, and the processes to be followed, by doctors in applying this section; and—

(a) failure to follow the guidance shall not of itself give rise to civil or criminal liability, but

(b) a court or tribunal may have regard to the guidance and the extent to which it has been followed.

3 Statutory functions to be used to support responsible innovation

(1) This section applies to the exercise of functions under or by virtue of the National Health Service Act 2006 by—

(a) the National Health Service Commissioning Board;

(b) clinical commissioning groups;

(c) the Secretary of State; and

(d) persons responsible for the provision of services in Wales.

(2) In exercising their functions the persons to whom this section applies shall have regard to the desirability of supporting responsible innovation in cases where evidence to support particular courses of treatment or management is unavailable or uncertain.

4 Technical provision

(1) This Act comes into force on Royal Assent.

(2) This Act extends to the United Kingdom.

(3) This Act may be cited as the Medical Innovation Act 2012.

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Lord Saatchi

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