These notes refer to the Medical Innovation Bill [HL][Bill 162], as brought from the Lords on 26 January 2015.

MEDICAL INNOVATION BILL [HL]

EXPLANATORY NOTES

INTRODUCTION

1. These Explanatory Notes relate to the Medical Innovation Bill [HL] as brought from the House of Lords on 26 January 2015. They have been prepared by Michael Ellis MP in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.

2. The Notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill.

BACKGROUND AND SUMMARY

3. The Bill is designed to codify existing best practice in relation to decisions by medical practitioners to depart from standard practice and to administer innovative treatment, and to bring the test of whether innovation is negligent forward to the time of treatment in order to give clarity and certainty to patients and doctors. The existing common law test of the support of a responsible body of medical opinion is expressly preserved. The fundamental proposition of the Bill is that it is not negligent for a doctor to depart from standard practice where the decision is taken responsibly, in consultation with relevant colleagues and by applying an accountable and transparent procedure that allows full consideration of all relevant matters. The process also includes provision for the recording of the results of innovative treatment.

COMMENTARY ON CLAUSES

Clause 1 – Responsible Innovation

4. Subsection (1) sets out the purpose of the Act: to encourage responsible innovation.

5. Subsection (2) declares that it is not in itself negligent for a doctor to depart from standard practice where the decision to innovate if the decision is taken responsibly, as described in the later provisions of the Bill.

6. Subsections (3)(a) and (b) and (4) require the decision-making process to include consultation with appropriately qualified colleagues, who must have expertise and experience in dealing with patients with the relevant condition.

7. Subsection (3)(c) requires the decision-making process to include obtaining any consents required by law; the Bill does not affect legal requirements for doctors to obtain patients' informed consent to any treatment proposed.

8. Subsection (3)(d)(i) requires the decision-making process to include consideration of opinions or requests expressed by the patient or on behalf of the patient (for example, by family members in the case of a patient who is unable to communicate his or her own opinions). Opinions and requests are to be taken into consideration by the doctor in forming a professional judgment, but are not necessarily determinative.

9. Subsection (3)(d)(ii) requires the decision-making process to include a risk-benefit analysis.

10. Subsection (3)(d)(iii) requires the decision-making process to include consideration of any other matters that the doctor thinks necessary to consider in reaching a clinical judgment.

11. Subsection (3)(e) requires the doctor to comply with any professional requirements that may be in place to register the proposed innovative treatment with a data-capture scheme. The Bill does not establish a data-bank, but if one is established, and if the medical regulatory bodies require doctors to use it, then the Bill will make compliance with registration requirements compulsory for doctors relying on the provisions of the Bill in order to innovate. The provision includes reference to the registration of all data, including negative results and information about small-scale treatments and patients' experiences.

12. Subsections (3)(f) and (5) require the doctor to take any other steps necessary to ensure that decisions to innovate are accountable and transparent; that expressly includes a requirement to record in the patient's notes details of the colleagues whose views were obtained, what those views were, and other details about the innovative treatment and the decision to provide it.

13. Subsection (6) clarifies that nothing in the clause allows a doctor to administer treatment to a patient for any purpose, including research, other than the best interests of that patient.

14. Subsection (7) excludes cosmetic surgery from the provisions of the Bill.

Clause 2 – Effect on existing law

15. Clause 2 preserves the existing common law test in accordance with which the question whether a decision to innovate was negligent will be tested by the courts by reference to whether the decision would have been supported by a responsible body of medical opinion. The effect of the Bill is therefore not to replace the common law test, but to provide an alternative statutory route that in effect applies the responsible-body test at the time when the doctor decides whether to innovate.

Clause 3 – Short title, commencement and extent

16. Clause 3(2) to (4) provide for the substantive provisions of the Bill to be commenced by order of the Secretary of State.

17. Clause 3(5) provides for the Bill to be part of the law of England and Wales, and not Scotland or Northern Ireland.

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