

# Regulation of Laser Eye Surgery Bill

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**B I L L**

TO

Regulate laser eye surgery.

**B**E 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:—

*Registration requirements*

**1 Application of registration requirements of the 2000 Act to laser eye surgery**

- (1) Part 1 of the 2000 Act (introductory provisions) is amended as follows.
- (2) In section 2 (independent hospitals, etc.), in subsection (7) (meaning of “listed services”), after paragraph (e), insert— 5
- “(ea) laser eye surgery (within the meaning given by section 17 of the Regulation of Laser Eye Surgery Act 2005);”.

**2 Registration of relevant establishments and ophthalmologists**

- (1) Part 2 of the 2000 Act (establishments and agencies) is amended as follows.
- (2) In section 11 (requirement to register)— 10
- (a) after subsection (1), insert—
- “(1A) Any person who carries on activities as an ophthalmologist in a relevant establishment without being registered under this Part in respect of those activities shall be guilty of an offence.”; and
- (b) after subsection (6), insert— 15
- “(7) In this Part ‘relevant establishment’ has the meaning given by section 17 of the Regulation of Laser Eye Surgery Act 2005.”
- (3) In section 12 (applications for registration), in subsection (2), after paragraph (a), insert—
- “(aa) in relation to a relevant establishment, must— 20
- (i) state the period to which the application relates, and

- (ii) give such information as the registration authority requires for the purposes of the Regulation of Laser Eye Surgery Act 2005;
- (ab) in relation to a person seeking to carry on activities as an ophthalmologist in a relevant establishment, must— 5
- (i) state the period to which the application relates, and
- (ii) confirm that the person is a medical practitioner whose name is included in—
- (a) the register of specialists kept by the General Medical Council under article 13 of the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 (S.I. 2003/1250) and in respect of whom the register indicates his speciality to be ophthalmology, or 10
- (b) the register established and maintained by the Royal College of Ophthalmologists in accordance with the provisions of section 5 of the Regulation of Laser Eye Surgery Act 2005; and”. 15
- (4) In section 13 (grant or refusal of registration) —
- (a) in subsection (1), for the words “or agency”, substitute the words “, agency or person”; 20
- (b) in subsection (2), for the word “and” after paragraph (a), substitute—
- “(aa) in relation to a relevant establishment, the requirements of sections 7 to 12 and 15 of the Regulation of Laser Eye Surgery Act 2005; 25
- (ab) in relation to a person seeking to carry on activities as an ophthalmologist in a relevant establishment, the requirement set out in subsection (2A); and”;
- (c) in that subsection, for the words “or agency”, substitute the words “, agency or person”; 30
- (d) after subsection (2), insert—
- “(2A) The requirement set out in this subsection is the requirement for the person seeking to carry on activities as an ophthalmologist in a relevant establishment to be a medical practitioner whose name is included in— 35
- (a) the register of specialists kept by the General Medical Council under article 13 of the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2003 (S.I. 2003/1250) and in respect of whom the register indicates his speciality to be ophthalmology, or 40
- (b) the register established and maintained by the Royal College of Ophthalmologists in accordance with the provisions of section 5 of the Regulation of Laser Eye Surgery Act 2005.” 45
- (e) after subsection (3), insert—
- “(3A) Any application that is granted under subsection (3) in relation to a relevant establishment or a person seeking to carry on activities as an ophthalmologist in a relevant establishment may only be granted for a period not exceeding twelve months.”; 50
- and

- (f) in subsection (4), at the end, insert the words “which, in the case of a relevant establishment or a person seeking to carry on activities as an ophthalmologist in a relevant establishment, shall state the period for which the application is granted”.
- (5) In section 14 (cancellation of registration) – 5
- (a) in subsection (1), after the first occurrence of the words “establishment or agency”, insert the words “or as a person seeking to carry on activities as an ophthalmologist in a relevant establishment”;
- (b) in that subsection, after paragraph (c), insert – 10
- “(ca) on the ground that a person seeking to carry on activities as an ophthalmologist in a relevant establishment is carrying on, or has at any time after the commencement of section 13(2)(ab) carried on, activities in breach of the requirement in section 13(2A);” and
- (c) in subsection (3), for the word “and” after paragraph (a), substitute – 15
- “(aa) in relation to a relevant establishment, the requirements of sections 7 to 12 and 15 of the Regulation of Laser Eye Surgery Act 2005; and”.
- (6) In section 16 (regulations about registration), in subsection (1), after the word “agencies”, insert the words “or as persons seeking to carry on activities as an ophthalmologist in a relevant establishment”. 20
- (7) In section 17 (notice of proposals) –
- (a) in subsection (1), at the end, insert the words “or as a person seeking to carry on activities as an ophthalmologist in a relevant establishment”; and 25
- (b) in subsection (4), after the word “agency”, insert the words “or as a person seeking to carry on activities as an ophthalmologist in a relevant establishment”.
- (8) In section 19 (notice of decisions), in subsection (1), after the word “agency”, insert the words “or as a person seeking to carry on activities as an ophthalmologist in a relevant establishment”. 30
- (9) In section 20 (urgent procedure for cancellation, etc.) –
- (a) in subsection (1)(a)(i), at the end, insert the words “or as a person seeking to carry on activities as an ophthalmologist in a relevant establishment”; 35
- (b) in subsection (3), after the word “section”, insert the words “in respect of an establishment or agency”; and
- (c) in subsection (5), after the word “agency”, insert the words “or as a person seeking to carry on activities as an ophthalmologist in a relevant establishment”. 40
- (10) In section 24 (failure to comply with conditions), at the end, insert –
- “(2) If a person registered as a person seeking to carry on activities as an ophthalmologist in a relevant establishment fails, without reasonable excuse, to comply with any condition for the time being in force by virtue of this Part in respect of the carrying on of those activities, he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 4 on the standard scale.” 45

*Regulatory arrangements*

### 3 Duties and functions of registration authorities

- (1) It shall be the general duty of the registration authority under this Act—
- (a) to promote and secure the maintenance of high standards in the carrying out of laser eye surgery in relevant establishments, and 5
  - (b) to protect the interests of patients undergoing laser eye surgery in relevant establishments.
- (2) In pursuance of its general duty under subsection (1), the registration authority shall, in particular—
- (a) exercise its functions under sections 13 to 20 of the 2000 Act (registration) in relation to relevant establishments and persons seeking to carry on activities as an ophthalmologist in a relevant establishment having due regard to— 10
    - (i) information available to the registration authority as a result of the provisions of sections 11 and 14 of this Act, 15
    - (ii) matters that have come to the attention of the registration authority in the exercise of powers under sections 31 and 32 of the 2000 Act (inspections);
  - (b) ensure that its powers under sections 31 and 32 of the 2000 Act (inspections) are appropriately exercised in relation to relevant establishments, 20
  - (c) exercise its functions under section 5 of this Act relating to the register of ophthalmologists carrying on activities in relevant establishments,
  - (d) exercise the function of monitoring and securing compliance with the requirements of sections 7 to 12, 25
  - (e) establish and maintain a protection fund in accordance with the provisions of section 15, and
  - (f) secure that persons acting on its behalf in exercising functions and powers under paragraphs (a) to (e) of this subsection are suitably trained for the exercise of those functions and powers. 30

### 4 Duties and functions of the Royal College of Ophthalmologists

- (1) It shall be the general duty of the Royal College of Ophthalmologists under this Act—
- (a) to promote the maintenance of high standards in the carrying out of laser eye surgery in relevant establishments, and 35
  - (b) in particular, to promote the maintenance of high standards in the carrying on by ophthalmologists of activities relating to laser eye surgery in relevant establishments.
- (2) In pursuance of its general duty under subsection (1), the Royal College of Ophthalmologists shall, in particular— 40
- (a) prepare guidance for potential patients in relevant establishments about the matters specified in subsection (3),
  - (b) prepare guidance for optometrists and general practitioners about the matters specified in subsections (3) and (4),
  - (c) under take functions relating to the provision of training for ophthalmologists in accordance with the provisions of subsection (5); 45

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- (d) undertake functions under section 5 in connection with the register of ophthalmologists; and
- (e) prepare guidance for relevant establishments about –
- (i) information to be included in the statement of purpose of a relevant establishment, 5
  - (ii) information to be included in the patients' guide of a relevant establishment,
  - (iii) the contractual requirements for laser eye surgery in relevant establishments specified in section 9,
  - (iv) the procedures to be followed for determining the suitability of patients for the purposes of section 10(2), 10
  - (v) the content of consent forms and other arrangements about consent for the purposes of section 10,
  - (vi) the procedures to be followed in undertaking post-surgery assessments of patients, 15
  - (vii) information to be included in annual returns under section 11, and
  - (viii) the advertising requirements under section 12.
- (3) The matters specified in this subsection are –
- (a) the different methods of laser eye surgery that are available, 20
  - (b) the benefits and risks associated with each of the methods of laser eye surgery referred to in paragraph (a), and
  - (c) the particular benefits and risks associated with undergoing surgery on both eyes at the same time.
- (4) The matters specified in this subsection are –
- (a) such information as the Royal College of Ophthalmologists considers it appropriate to make available about the outcome of surgery generally and in particular relevant establishments, and
  - (b) such information as the Royal College of Ophthalmologists considers it appropriate to make available about the qualifications and experience of ophthalmologists in particular relevant establishments. 30
- (5) It shall be the duty of the Royal College of Ophthalmologists to promote training arrangements in relation to laser eye surgery, including, in particular –
- (a) training in the use of particular systems, 35
  - (b) training provided in relevant establishments, and
  - (c) arrangements for the approval and certification of training provision.
- (6) The Royal College of Ophthalmologists may from time to time revise guidance prepared under subsection (2).
- (7) Guidance prepared under subsection (2) or revised under subsection (6) shall be published in such form as the Royal College of Ophthalmologists considers appropriate. 40
- (8) Before publishing guidance under this section, the Royal College of Ophthalmologists shall consult –
- (a) the registration authorities, 45
  - (b) the National Institute for Clinical Excellence,
  - (c) the General Medical Council,
  - (d) the General Optical Council,

- (e) the British College of Optometrists, and
- (f) such other persons as the Royal College of Ophthalmologists considers appropriate.

## 5 Register of ophthalmologists

- (1) The Royal College of Ophthalmologists shall establish and maintain a register of the names of ophthalmologists carrying on, or seeking to carry on, laser eye surgery in relevant establishments. 5
- (2) The Royal College of Ophthalmologists shall prepare, and may from time to time revise, guidance on—
  - (a) the training and qualifications necessary for a person to have his name entered on the register, 10
  - (b) other criteria that will be used by the Royal College of Ophthalmologists in reaching its decisions on whether the name of a person should be entered on the register,
  - (c) matters relating to administrative arrangements for the register, including arrangements for the voluntary withdrawal of names from the register. 15
- (3) Guidance prepared or revised under subsection (2) shall be published in such form as the Royal College of Ophthalmologists considers appropriate.
- (4) Before publishing guidance under subsection (2), the Royal College of Ophthalmologists shall consult—
  - (a) the registration authorities,
  - (b) the National Institute for Clinical Excellence,
  - (c) the General Medical Council,
  - (d) the General Optical Council, 20
  - (e) the British College of Optometrists, and
  - (f) such other persons as the Royal College of Ophthalmologists considers appropriate. 25
- (5) The Royal College of Ophthalmologists shall make arrangements for the register maintained under this section to be available for public inspection. 30
- (6) The registration authority may, if it thinks that a person whose name is entered on the register is not a fit and proper person to be so entered, decide to exclude that person from the register.
- (7) Where the registration authority reaches a decision under subsection (6), it shall—
  - (a) serve a notice on the person to whom the decision relates, and
  - (b) inform the Royal College of Ophthalmologists of the decision. 35
- (8) A notice served under subsection (7)(a) shall inform the person to whom the decision relates of his right of appeal under section 6.
- (9) Where—
  - (a) the Royal College of Ophthalmologists has been informed under subsection (7)(b) of a decision by the registration authority and the period specified in section 6(2) has elapsed without an appeal being made, or 40

(b) the Royal College of Ophthalmologists has been informed under section 6(4)(c) of a decision by the Tribunal to confirm a decision of the registration authority,  
the Royal College of Ophthalmologists shall remove the name of the person to whom the decision relates from the register.

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## 6 Appeals to the Tribunal

(1) A person to whom a decision under section 5(6) relates may appeal against that decision to the Tribunal.

(2) No appeal against a decision may be brought by a person to whom a decision under section 5(6) relates more than 28 days after service on him of the notice of the decision.

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(3) On an appeal against a decision of the registration authority, the Tribunal may confirm the decision or direct that it shall not have effect.

(4) When the Tribunal has come to a decision under subsection (3), it shall inform –

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(a) the person to whom the decision relates,

(b) the registration authority, and

(c) the Royal College of Ophthalmologists, of that decision.

(5) Section 9 of the Protection of Children Act 1999 (c. 14) (the Tribunal) is amended as set out in subsection (6).

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(6) In subsection (2) of that section, omit the word “or” after paragraph (e) and, after paragraph (f), insert “or

(g) on an appeal under section 6 of the Regulation of Laser Eye Surgery Act 2005.”

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### *Additional regulatory requirements*

## 7 Requirement for certain activities to be carried on by or under supervision of an ophthalmologist

The registered person in relation to a relevant establishment shall ensure that prescribed activities relating to laser eye surgery are only carried on in that establishment by or under the supervision of an ophthalmologist who is registered in accordance with the provisions of Part 2 of the 2000 Act.

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## 8 Patient information

(1) The registered person in relation to a relevant establishment shall ensure that the statement of purpose in respect of that establishment –

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(a) states the qualifications of persons carrying on laser eye surgery and activities relating to laser eye surgery in the establishment;

(b) states in particular whether an ophthalmologist carrying on laser eye surgery in the establishment is a person whose name appears in the register of specialists kept by the General Medical Council under article 13 of the General and Specialist Medical Practice (Education, Training

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- and Qualifications) Order 2003 (S.I. 2003/1250) and in respect of whom the register indicates his speciality to be ophthalmology; and
- (c) provides such other information as may be specified in guidance under section 4(2)(e)(i).
- (2) The registered person in relation to a relevant establishment shall ensure that the patients' guide in respect of that establishment –
- (a) states the types of laser eye surgery provided in the establishment;
  - (b) provides information about the qualifications and experience of persons carrying on laser eye surgery and activities relating to laser eye surgery in the establishment;
  - (c) summarises the contractual requirements specified in section 9;
  - (d) summarises the consent requirements specified in section 10;
  - (e) provides a summary of information contained in annual returns for the establishment prepared under section 11 for the prescribed period;
  - (f) refers to the availability of the guidance prepared by the Royal College of Ophthalmologists under section 4(2)(a) for the time being in force; and
  - (g) provides such other information as may be specified in guidance under section 4(2)(e)(ii).
- (3) The registered person in relation to a relevant establishment shall ensure that a copy of the guidance prepared by the Royal College of Ophthalmologists under section 4(2)(a) for the time being in force is available to patients upon request.
- (4) The registered person in relation to a relevant establishment shall send a copy of –
- (a) the statement of purpose, and
  - (b) the patients' guide,
- in relation to the establishment to the Royal College of Ophthalmologists.

## 9 Contractual requirements

- (1) The registered person in relation to a relevant establishment shall ensure that no laser eye surgery is provided within the establishment otherwise than under a contract with a patient or a person authorised to act on the patient's behalf that complies with the requirements set out in subsections (2) and (3).
- (2) The requirement set out in this subsection is that the contract does not offer the patient or other person entering into a contract a financial incentive to enter into the contract at a particular time or within a particular period.
- (3) The requirements set out in this subsection are that the contract specifies –
- (a) all direct costs expected to be incurred in relation to the laser eye surgery, and
  - (b) any other costs expected to be incurred in relation to the provision of follow-up services by optometrists or medical practitioners.
- (4) The registered person in relation to a relevant establishment shall ensure that no staff of the establishment receive an undue financial incentive to encourage potential patients or persons authorised to act on behalf of potential patients to enter into a contract for the provision of laser eye surgery.

## 10 Consent requirements

- (1) The registered person in relation to a relevant establishment shall ensure that no laser eye surgery is provided except where properly informed consent has been given by a patient or a person authorised to act on the patient's behalf in a manner that complies with the requirements set out in subsections (2) to (5). 5
- (2) The requirement set out in this subsection is that consent is not sought by the relevant establishment for laser eye surgery on a patient when that relevant establishment has determined in accordance with guidance under section 4(2)(e)(iv) that the patient is unsuitable
- (3) The requirement set out in this subsection is that the person giving consent has been provided with a consent form that complies with the requirements of guidance under section 4(2)(e)(v). 10
- (4) The requirement set out in this subsection is that appropriate counselling has been made available to the person giving consent at least three days before the day on which consent is to be given. 15
- (5) The requirement set out in this subsection is that consent has been given at least seven days before the day on which laser eye surgery is to be provided.

## 11 Annual returns

- (1) The registered person in relation to a relevant establishment shall ensure that an annual return is submitted to the registration authority within the prescribed period containing— 20
  - (a) information of a prescribed kind about surgical outcomes and complication rates,
  - (b) information arising from post-surgery assessments of patients undertaken in accordance with guidance under section 4(2)(e)(vi), 25
  - (c) such information as may be required to be included in the annual return in accordance with guidance under section 4(2)(e)(vii), and
  - (d) such other information as may be prescribed.
- (2) In this section “complication rates” and “surgical outcomes” have the prescribed meaning. 30

## 12 Advertising

- (1) This section applies to advertisements for the provision of laser eye surgery by relevant establishments— 35
  - (a) within the relevant establishment,
  - (b) on the premises of any optometrist,
  - (c) in any electronic media, or
  - (d) that are otherwise paid for.
- (2) Advertisements to which this section applies shall comply with the requirements specified in regulations by the appropriate authority.
- (3) Regulations under subsection (2) shall, in particular, specify the form of a warning about the risks associated with laser eye surgery to be contained in any advertisement to which this section applies. 40

- (4) Before making regulations under subsection (2), the appropriate authority shall consult –
- (a) the Royal College of Ophthalmologists, and
  - (b) the registration authority.
- (5) For the purposes of subsection (1)(c), “electronic media” includes – 5
- (a) radio and televisions services that are subject to the standards code of the Office of Communications under section 319 of the Communications Act 2003 (c. 21) (OFCOM’s standards code), and
  - (b) the Internet.

*Enforcement, etc.* 10

### 13 Additional powers of inspection

- (1) Section 31 of the 2000 Act (inspections by persons authorised by registration authority) is amended as follows.
- (2) After subsection (1) insert –
- “(1ZA) The registration authority may at any time require a person who carries on or manages a relevant establishment to provide it with any information relating to the establishment which the registration authority considers necessary or expedient for the purposes of its functions under the Regulation of Laser Eye Surgery Act 2005.” 15
- (3) In subsection (1A), after the words “under subsection (1)”, insert the words “or under subsection (1ZA)”. 20
- (4) In subsection (3), after paragraph (b), insert –
- “(ba) in relation to a relevant establishment, make any examination to establish that equipment used in laser eye surgery is – 25
- (i) suitable for the purpose for which it is to be used,
  - (ii) properly maintained and, where appropriate, calibrated, and
  - (iii) in good working order.”

### 14 Reporting duty of National Health Service bodies

- (1) This section applies where a National Health Service body provides treatment to a person which, in the opinion of a medical practitioner, arises in whole or in part from laser eye surgery which that person has undergone as a patient in a relevant establishment. 30
- (2) When this section applies, it shall be the duty of the National Health Service body concerned to provide the prescribed information to the registration authority within such period as may be prescribed. 35

### 15 Protection fund

- (1) It shall be the duty of the registration authority to establish and maintain a protection fund in accordance with the provisions of this section.

- (2) *The registration authority may require a relevant establishment that is registered under Part 2 of the 2000 Act to pay into the protection fund in respect of each financial year such amount as the authority may determine.*
- (3) Where the registration authority is satisfied on the basis of information available to it arising from –
- (a) the exercise of powers under sections 31 and 32 of the 2000 Act (inspections) in relation to relevant establishments,
  - (b) the making of returns by relevant establishments under section 11 of this Act, and
  - (c) the provision of information about relevant establishments by National Health Service bodies under section 14,
- that the provision of laser eye surgery in the relevant establishment in a financial year has not given rise to additional costs to the National Health Service, the registration authority may take the step set out in subsection (4).
- (4) The step set out in this subsection is to make a payment to a relevant establishment from the protection fund which is equal to or less than the payment made into the protection fund by that establishment in respect of that financial year in accordance with subsection (2).
- (5) The registration authority shall prepare accounts for the protection fund for each financial year in accordance with any directions given by the appropriate authority.
- (6) Accounts prepared under subsection (5) shall in particular specify –
- (a) the total amount paid into the protection fund in respect of that financial year in accordance with the provisions of subsection (2),
  - (b) the total amount paid out of the protection fund in respect of that financial year in accordance with the provisions of subsection (4), and
  - (c) the difference between the amount specified in paragraph (a) and the amount specified in paragraph (b).
- (7) *The amount specified in subsection (6)(c) and any interest earned on the protection fund shall be paid into the Consolidated Fund.*
- (8) In this section “financial year” means –
- (a) the period beginning with the date on which this section comes into force and ending with the next 31st March, and
  - (b) each subsequent period of twelve months ending with 31st March.
- 16 Offences**
- (1) If a person registered in respect of a relevant establishment or as a person seeking to carry on activities as an ophthalmologist in a relevant establishment under Part 2 of the 2000 Act fails, without reasonable excuse, to comply with any requirement for the time being in force under sections 7 to 12, he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 4 on the standard scale.
- (2) The provisions of sections 29 and 30 (proceedings for offences and offences by bodies corporate) of the 2000 Act apply to an offence under this section as they apply to an offence under Part 2 of that Act or regulations made under it.

*Miscellaneous and final provisions***17 Interpretation**

In this Act –

- “the 2000 Act” means the Care Standards Act 2000 (c. 14);
- “the appropriate authority” means – 5
- (a) in relation to England, the Secretary of State, and
- (b) in relation to Wales, the Assembly;
- “the Assembly” means the National Assembly for Wales;
- “the British College of Optometrists” means the unincorporated body of that name; 10
- “the Commission for Healthcare Audit and Inspection” means the body established under section 41 of the Health and Social Care (Community Health and Standards) Act 2003 (c. 43);
- “establishment” has the meaning given by regulation 2(1) of the relevant regulations; 15
- “the General Medical Council” has the meaning given by section 1(1) of the Medical Act 1983 (c. 54);
- “the General Optical Council” has the meaning given by section 1(1) of the Opticians Act 1989 (c. 44);
- “general practitioner” means a medical practitioner who – 20
- (a) performs primary medical services pursuant to Part 1 of the National Health Service Act 1977 (c. 49), or
- (b) performs services which correspond to primary medical services provided under Part 1 of that Act, otherwise than in pursuance of that Act; 25
- “laser eye surgery” means a surgical procedure using a laser that is intended permanently to alter the focusing of the eye;
- “medical practitioner” means a registered medical practitioner;
- “National Health Service body” means a National Health Service trust, an NHS foundation trust, a Special Health Authority or a Primary Care Trust; 30
- “the National Institute for Clinical Excellence” means the Special Health Authority of that name established under the National Institute for Clinical Excellence (Establishment and Constitution) Order 1999 (S.I. 1999/220); 35
- “optometrist” means a person whose name is included in one of the registers maintained by the General Optical Council under section 7 of the Opticians Act 1989;
- “patient”, in relation to an establishment, means a person for whom treatment is provided in or for the purposes of the establishment; 40
- “the patients’ guide” has the meaning given –
- (a) in relation to England, by regulation 7 of the relevant regulations, and
- (b) in relation to Wales, by regulation 6 of the relevant regulations;
- “prescribed” means prescribed by regulations made by the appropriate authority; 45
- “protection fund” means the fund established and maintained in accordance with the provisions of section 15;

- “registered manager”, in relation to an establishment, means a person who is registered under Part 2 of the 2000 Act as the manager of the establishment;
- “the register of ophthalmologists” means the register established and maintained under section 5; 5
- “registered person”, in relation to an establishment, means any person who is the registered provider or the registered manager of the establishment;
- “registered provider”, in relation to an establishment, means a person who is registered under Part 2 of the 2000 Act as the person carrying on the establishment; 10
- “registration authority” means –
- (a) in relation to England, the Commission for Healthcare Audit and Inspection, and
  - (b) in relation to Wales, the Assembly; 15
- “relevant establishment” means an independent hospital or an independent clinic in which laser eye surgery is provided;
- “the relevant regulations” means –
- (a) in relation to England, the Private and Voluntary Health Care (England) Regulations 2001 (S.I. 2001/3968), and 20
  - (b) in relation to Wales, the Private and Voluntary Health Care (Wales) Regulations 2002 (S.I. 2002/325);
- “the Royal College of Ophthalmologists” means the body of that name incorporated by Royal Charter dated 14 April 1988;
- “statement of purpose” has the meaning given – 25
- (a) in relation to England, by regulation 6 of the relevant regulations, and
  - (b) in relation to Wales, by regulation 5 of the relevant regulations;
- “the Tribunal” means the Tribunal established by section 9 of the Protection of Children Act 1999 (c. 14). 30

## 18 Orders and regulations

- (1) The power to make regulations or an order under this Act is exercisable by statutory instrument.
- (2) A statutory instrument containing regulations or an order made by the Secretary of State under this Act (other than under sections 7 and 20) is – 35
  - (a) to be laid before Parliament after being made, and
  - (b) subject to annulment in pursuance of a resolution of either House of Parliament.
- (3) No regulations under section 7 may be made by the Secretary of State unless a draft of the regulations has been laid before Parliament, and approved by a resolution of each House. 40
- (4) The power conferred under this Act to make regulations or an order includes power –
  - (a) to make different provision for different cases (including different provision in respect of different areas); 45
  - (b) to make provision subject to such exemptions and exceptions as the appropriate authority thinks fit; and

- (c) to make such incidental, supplemental, consequential and transitional provision as the appropriate authority thinks fit.

## 19 Expenses

*There shall be paid out of money provided by Parliament –*

- (a) *any expenditure incurred by the Secretary of State by virtue of this Act; and* 5  
 (b) *any increase attributable to this Act in the sums payable out of money so provided under any other enactment.*

## 20 Short title, commencement and extent

- (1) This Act may be cited as the Regulation of Laser Eye Surgery Act 2005.
- (2) Section 1 shall come into force on such date as the Secretary of State may by order determine, but the date so determined shall be a date before the end of a period that ends twelve months after the day on which this Act receives Royal Assent. 10
- (3) The following sections shall come into force on such date as the Secretary of State may by order determine – 15  
 (a) sections 2 to 6,  
 (b) section 13, and  
 (c) section 16.
- (4) The Secretary of State shall consult the Assembly before making an order under subsection (2) or (3). 20
- (5) The following sections shall come into force on such date as the appropriate authority may by order determine –  
 (a) sections 7 to 12, and  
 (b) sections 14 and 15.
- (6) This Act extends to England and Wales only. 25

## SCHEDULES



# Regulation of Laser Eye Surgery Bill

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## B I L L

To regulate laser eye surgery.

*Ordered to be brought in by  
Mrs Gwyneth Dunwoody, Frank Cook,  
Dr Ian Gibson, Dr Richard Taylor,  
Dr Jenny Tonge, Dr Andrew Murrison  
and Peter Bottomley.*

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*Ordered, by The House of Commons,  
to be printed, 22nd February 2005.*

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Bill 63

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