

## How we deal with complaints about licensed centres

### 1. About this document

- 1.1 This document sets out the procedure that the Human Fertilisation and Embryology Authority (“the Authority”, “we”) will use, and the principles we will take into account, when considering complaints from patients about the treatment that they have received at a centre that is licensed by the Authority.
- 1.2 In establishing our Complaints Policy, we have had regard to the Statutory Code of Practice for Regulators issued on 17 December 2007.

### 2. What is a complaint?

- 2.1 A complaint is an expression of dissatisfaction with the treatment or service you received from a licensed centre, which actively seeks a remedy.

### 3. What is the role of the Authority in dealing with complaints against licensed centres?

- 3.1 Under the Human Fertilisation and Embryology Act 1990 (the Act), we have a number of statutory duties. These include a duty to:
  - (a) license and inspect centres carrying out in vitro fertilisation and donor insemination;
  - (b) regulate the storage of eggs, sperm and embryos;
  - (d) produce a code of practice;
  - (e) maintain a register of information about donors, treatments and children born as a result of those treatments;
  - (f) provide relevant advice and information to patients, donors and clinics;
  - (g) review information about the provision of treatment services and activities governed by the Act;
  - (h) give advice to the Secretary of State for Health if requested to do so;
  - (i) investigate serious adverse incidents and serious adverse reactions.
- 3.2 As from October 2009, we will also have additional duties to:-
  - (j) maintain a statement of the general principles which we consider that centres licensed by us should follow when carrying out their activities governed by the Act; and
  - (k) promote compliance with the requirements of the Act and our Code of Practice.

- 3.3 The Authority undertakes periodic routine inspections of all licensed centres. We inspect centres to ensure that they are complying with the:-
- a) statutory requirements under the Act;
  - b) conditions of their licence;
  - c) any relevant directions issued by the Authority; and
  - d) guidance set out in the Code of Practice that we issue to centres.
- 3.4 Unlike some other healthcare bodies, the Authority does **not** have a specific statutory duty to investigate patient complaints. However, complaints made by patients about the treatment or service that they have received at a centre licensed by the Authority, may impact on our duty to provide advice and information to patients. Depending on the matters raised, complaints may also give rise to a duty to investigate serious adverse events and serious adverse reactions.
- 3.5 It is important for patients to understand that the Authority's power to intervene in complaints against licensed centres is limited. The Authority is not able to adjudicate on patient complaints or require centres to apologise or to pay compensation or refunds to patients. Neither is the Authority able to act as a mediator between the patient and the centre.

#### **4. What complaints about licensed centres can the Authority consider?**

- 4.1 The Authority can only consider a complaint made by a patient, where that complaint indicates a potential breach of the Act, licence conditions, directions issued by the Authority or the guidance set out in our Code of Practice.
- 4.2 If the complaint indicates that a potential serious adverse event or serious adverse reaction may have occurred, we shall consider the matter in accordance with our policy for investigating serious adverse events and adverse reactions.

#### **5. What complaints about licensed centres is the Authority not able to consider?**

- 5.1 The Authority is not able to consider general complaints about the statutory framework governing fertility treatment and research, or matters which are the responsibility of other regulatory bodies.
- 5.2 If we think that your complaint reveals concerns about a health care professional's fitness to practise, we may refer your complaint to a professional body such as the General Medical Council, the Nursing and Midwifery Council or the Health Professions Council. If we do so, we will advise you of the referral and provide you with the contact details of the relevant professional body.
- 5.3 The Authority is not able to consider complaints which relate to contractual issues between a patient and a licensed centre, or matters such as the cost of fertility treatment generally.

## 6. **How to make a complaint about a licensed centre**

- 6.1 In the Code of Practice that we issue, we require all centres to maintain a quality assurance system, and to have in place a system for dealing and responding to complaints.
- 6.3 If you are dissatisfied with the treatment or service that you have received at a centre licensed by the Authority, we would normally expect you to complain to that centre directly in the first instance, and to have followed their complaints procedure first.
- 6.4 If having complained to the centre, you remain dissatisfied with the response you received from them and then wish to bring the matter to the attention of the Authority, please do so in writing, and address your complaint to the Complaints Inspector and send it to us at one of the addresses below:
- By post: HFEA, 21 Bloomsbury Street, London. WC1B 3HF.
- By email: [admin@hfea.gov.uk](mailto:admin@hfea.gov.uk)
- 6.5 When making a complaint, please provide your full name and postal address. In order to investigate a complaint, we will need to obtain your consent to obtain copies of your medical records. We are therefore not able to consider anonymous complaints.
- 6.6 To assist you in making a complaint, we have provided a complaints form which is annexed to this document, and which can be downloaded from our website. You can also obtain a copy by ringing the Complaints Inspector on 0207 291 8245.
- 6.7 We would prefer you to use this form when making your complaint. It will help us, and you, if you do. This is because the form sets out the information that we need in order to consider your complaint properly. It is important that you set out clearly what the grounds of your complaint are, what outcome you would like to achieve, who was involved in the subject matter of your complaint(if known), and that you provide any relevant supporting evidence. Use of the form will enable your complaint to be dealt with more quickly and will reduce the need to seek further information.
- 6.8 If you would like assistance in completing the complaints form, please contact the Complaints Inspector on 0207 291 8245.

## 7. **Time Limit for making a complaint about a licensed centre**

- 7.1 If you wish to make a complaint about the treatment or service that you have received at a licensed centre, please do so as soon as possible after the matter that you wish to complain about has occurred.

7.2 Please note that we will not normally consider complaints if they are made **more than 6 months** after you became aware of the matters that gave rise to the complaint or after the conclusion of the centre's complaint process.

## 8. What principles will we apply when dealing with a complaint about a licensed centre?

8.1 The Authority will:

- (a) acknowledge all complaints that we receive within 5 working days;
- (b) keep you informed of the progress of your complaint;
- (c) endeavour to ensure that complaints are handled fairly and as promptly as possible;
- (d) provide persons who are the subject of a complaint with a reasonable opportunity to respond;
- (e) inform you, the licensed centre and persons who are the subject of a complaint of the outcome of any investigation that we undertake;
- (f) where appropriate, identify actions to secure any necessary improvements;
- (g) where appropriate, share any learning points.

## 9. Acknowledgement of complaints about licensed centres

9.1 We aim to acknowledge all complaints **within five working days** of receipt.

9.2 The acknowledgment will give you the name and contact details of the person who will be responsible for responding to you.

9.3 All complaints about licensed centres that are received by the Authority are logged and the Head of Clinical Governance will be notified of the existence of the complaint.

## 10. How will the Authority deal with a complaint about a licensed centre?

10.1 When we receive a complaint about a licensed centre, we will first check whether the complaint concerns matters that we are able to deal with, and if so, whether the patient has first tried to resolve the matter with the licensed centre directly.

10.2 If the patient has not tried to resolve the matter directly with the licensed centre, we will usually ask the patient to use the centre's own complaints procedure before we take the matter further.

10.2.1 However, if the complaint indicates that a serious incident or serious adverse reaction may have taken place, we will consider the matter in accordance with our policy for investigating serious incidents and adverse reactions.

10.3 Where we are able to consider the complaint, we may contact you to obtain further details and may ask for your written consent to obtain records relating to your treatment at the licensed centre.

- 10.4 A copy of your complaint, and any additional information or material that you provide will be shown to the Person Responsible at the licensed centre, and any other person who is the subject of your complaint, for comment.
- 10.5 We will ask your permission before we share your complaint and the information you have provided, with the licensed centre. Depending on the issues raised in your complaint, and the timing of the next scheduled inspection of the licensed centre, we may decide to discuss your complaint with the Person Responsible as part of the inspection process.

## **11. What might be the potential outcomes of my complaint?**

- 11.1 Any learning points may be shared with the licensed centre, and other stakeholders in the fertility and healthcare sectors in order to enable them to improve their quality assurance systems.
- 11.2 Where the complaint reveals evidence of non compliance by a licenced centre with its statutory requirements, licence conditions, directions issued by the Authority or the Code of Practice, the matter may be brought to the attention of the Authority's Licence Committee in accordance with our Compliance and Enforcement Policy.
- 11.3 Where your complaint reveals general learning points which we consider should be shared more widely, we may issue an alert to all licensed centres, or modify the guidance set out in our Code of Practice. If we do so, we will endeavour to ensure that the details set out in our alert or guidance do not identify you.

## **12. Who will investigate my complaint?**

- 12.1 Complaints notified to the Authority will be considered by the Complaints Investigator. The Inspector assigned to the licensed centre may also be asked to assist in the consideration of your complaint.

## **13. What if I am not satisfied with the response?**

- 13.1 If you are not satisfied with the outcome of the initial consideration of your complaint, you can ask for a review to be conducted by the Head of Clinical Governance. If you wish a review to be conducted, you must write to the Head of Clinical Governance asking for the review within **10 working days** of receipt of our letter informing you of the outcome of our consideration of your complaint. If you do not follow this time limit, we may decide not to conduct the review.
- 13.2 You should set out in your letter the specific reason(s) for your dissatisfaction with the outcome of the original consideration, what aspects of the original complaint and response you believe require further investigation and the reasons for this.

- 13.3 A review will only take place if you produce new or additional information which was not, for a valid reason, available at the time of the original consideration and which might have influenced the outcome.
- 13.4 We will write to you within five working days of receipt of your request, to inform you whether or not a review is to be held. If a review is to be held, the person conducting that review will inform you of the likely timescales for completion of the review. If a review is not to be held, you will be informed of the reason for this decision.
- 13.5 We aim to complete any review within 28 working days. When the review is complete, the person conducting the review will confirm the outcome in writing to you.
- 13.6 The decision of the person conducting the review will be final. Once the decision has been communicated to you, we will not usually enter into any further correspondence with you about your complaint.

#### **14. Vexatious and Persistent Complaints**

- 14.1 Whilst we recognise that most complainants will exercise their rights to complain sensibly and responsibly, some individuals or organisations may attempt to abuse their rights with requests which are vexatious, persistent or are an abuse of process.
- 14.2 A complaint will be considered to be vexatious and/or persistent and/or an abuse of process if:
- (a) it makes demands for action or information that would impact substantially and unreasonably on our work;
  - (b) it is persistently pursued when our complaints procedure has been fully and properly exhausted;
  - (c) the substance of the complaint is continually changed with new issues and concerns being raised whilst the complaint is being addressed or following conclusion of the review/investigation under our complaints procedure;
  - (d) the complainant refuses to identify precisely the issues that they wish to be investigated despite reasonable efforts by staff to help them identify their concerns;
  - (e) it is designed to cause disruption, annoyance or expense or has the effect of harassing the Authority including where the complaint is identical or substantially similar to a previous complaint made by or on behalf of the complainant;
  - (f) it can be fairly characterised as obsessive or manifestly unreasonable; and

- (g) The subject matter of the complaint is, or has been the subject of legal proceedings.
- 14.3 We reserve the right to deal with vexatious or persistent complaints or complaints that are considered to be an abuse of process by:
- (a) limiting communication with the complainant to just one form and to one point of contact;
  - (b) confirming to the complainant in writing that the investigation/review is complete and that continued correspondence will serve no purpose;
  - (c) informing persistent complainants in writing that if they continue to complain unnecessarily, we reserve the right to take no further action in response to their complaints; or
  - (d) suspending any investigation/review pending the conclusion of any legal proceedings in an appropriate case

## **15. Monitoring and recording**

- 15.1 All complaints will be recorded on a central complaints database and monitored regularly by us. The Authority will consider and an annual report on complaints notified to it, and a copy of this report will be placed on the Authority's website. The report will focus on learning points for the fertility sector and will preserve patient confidentiality.

## **16 Data Protection and Freedom of Information**

- 16.1 By using our complaints procedures, you consent to us processing your personal data for purposes related to your complaint.
- 16.2 We may disclose your data to other individuals or bodies if we are legally required or permitted to do so under the Data Protection Act 1998 or the Freedom of Information Act 2000.