CMA
Competition & Markets Authority

Draft guidance for fertility clinics on consumer law

Consultation Document

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CMA128

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1. About the consultation

Introduction

1.1 The Competition and Markets Authority (CMA) is consulting on draft consumer law guidance for fertility clinics.[1] [2] The purpose of this guidance is to help providers of fertility treatment to patients in the UK understand and comply with their existing obligations under consumer law.

1.2 Compliance with consumer law is important not only for protecting patients but also in maintaining the reputation of the fertility sector and supporting open and fair competition amongst clinics, which itself protects patients' interests. It also helps to reduce the number of complaints made by consumers and avoid disputes between clinics and patients.

1.3 Fertility clinics provide an extremely important service for those struggling to have a baby and many patients have positive experiences of the clinics where they have treatment.

1.4 The CMA has produced this draft guidance following concerns identified in the media, Advertising Standards Authority's (ASA) reviews of clinics' advertising, CMA reviews of clinic websites and existing research and discussions with the sector regulator, the Human Fertilisation and Embryology Authority (HFEA), that indicated that certain clinic practices may be preventing or inhibiting patients from making informed choices.

1.5 The CMA's discussions with the HFEA and stakeholders, including clinics, the professional bodies and patient representative groups, highlighted a general lack of awareness about how consumer law applies in the sector and that guidance on consumer law would be helpful for fertility clinics and patients.

1.6 The decision to publish guidance was taken before the Coronavirus (COVID-19) hit the UK in the Spring of 2020. The CMA recognises the challenges that the fertility sector - along with many others in the UK - have been facing as a result of the pandemic. Many clinics will already be reviewing their practices and terms in light of the changing circumstances so this guidance is now even more timely.

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[1] Draft guidance

[2] Although the CMA is not under a statutory duty to consult on the guidance, it has decided it would be helpful to do so in this case.

1.7 In addition to the consultation, the CMA is publishing the findings report from the qualitative research it commissioned of patients' experiences of self-funded fertility treatment.[3] The findings from this research have helped inform the draft guidance.

1.8 The HFEA fully supports the CMA's work in developing this guidance and the CMA has worked closely with the sector regulator throughout the process. The British Fertility Society and Association of Reproductive and Clinical Scientists are also supportive of the CMA's work in the sector. Patient groups, such as the charity Fertility Network, have also said that they welcome the production of consumer law guidance by the CMA.

1.9 When the final guidance on complying with consumer law is published, the CMA will also publish some short accessible advice for patients to help them understand their rights under consumer law. The CMA expects to publish the final guidance and patient advice in March 2021.

1.10 The CMA intends to undertake a follow-up compliance review across the fertility sector approximately six months after publication of its final guidance to assess what progress has been made. It will work closely with the HFEA, the ASA and other compliance partners such as local authority Trading Standards Services in holding fertility clinics to account.

Scope of the consultation

1.11 The draft guidance is primarily aimed at providers of fertility treatment to patients in the UK, except for the NHS when it directly provides free treatment in accordance with its statutory duties. Such providers therefore include:

- private fertility clinics, irrespective of how the treatment is funded;
- NHS fertility clinics, if and when they provide treatment which a patient pays for;
- clinicians acting in a self-employed capacity;
- clinicians where they are acting on behalf of, or in the name of, a private IVF clinic.

[3] Consumer research report

1.12 The draft guidance (and UK consumer law more generally) will be relevant to both (i) UK-based fertility clinics and (ii) fertility clinics based outside the UK in so far as they are conducting activities in the UK.

1.13 Although the focus of the draft guidance is on those providers of fertility treatment described above, UK consumer law also protects patients in their dealings with other businesses active in the fertility sector such as sperm banks, businesses selling complementary fertility treatments, and businesses supplying finance for fertility treatment.

1.14 The draft guidance will also be of interest to potential and existing patients, their partners and representatives, fellow enforcers of consumer law, namely local authority Trading Standards Services (TSS), professional bodies, and the HFEA.

1.15 The draft guidance sets out the CMA's views on how consumer law applies to clinics in the fertility sector. It does not provide advice on other laws or rules enforced by the sector regulator, the HFEA, or on medical regulation or other guidelines relevant to the sector.

1.16 The draft guidance focusses on the following key areas:

(a) **Information provision** – what information fertility clinics should provide to prospective patients and existing patients and when.

(b) **Treating patients fairly** - what fertility clinics should do to ensure that their practices, terms and complaints handling processes are fair.

1.17 The draft guidance focusses on the following aspects of consumer law:

(a) **the Consumer Protection from Unfair Trading Regulations 2008** (CPRs), particularly in relation to the provision of material information and ensuring compliance with the requirements of professional diligence.

(b) **the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013** (CCRs) in relation to the provision of pre-contractual information.

(c) **the Consumer Rights Act 2015** (CRA) in relation to unfair contract terms.

1.18 Consumer law sets minimum standards that apply to various aspects of clinics' dealings with potential and existing patients. It sits alongside other sector-specific regulatory obligations and guidelines, for example in relation to information provision and complaints handling.

1.19 Although this guidance is concerned with the application of consumer law, failing to comply with sector-specific rules, guidance and/or codes of conduct or any relevant rules, guidance and/or codes of conduct applicable to the medical profession, may be relevant to a finding that consumer law has been infringed, and vice versa.

1.20 The draft guidance is not a substitute for the law itself, and does not replace the role of the courts, which is to provide the definitive interpretation of consumer law based on the facts of each case. Ultimately, a fertility clinic is responsible for ensuring that it is complying with the law. If in doubt, a fertility clinic should seek its own independent legal advice on the interpretation and application of the law.

About the CMA

1.21 The CMA is the UK's primary competition and consumer authority.[4] Its objective is to make markets work well for consumers, businesses and the broader economy.

1.22 The CMA has a range of consumer powers to tackle practices and market conditions that present challenges for consumers and hinder their decision making. This includes powers to protect consumers from unfair business practices and unfair contract terms (for which it has the lead role).

1.23 The CMA shares these enforcement powers with other bodies, such as TSS. The CMA also shares certain consumer functions with other agencies, such as the ASA.

1.24 As part of its role, the CMA produces guidance for businesses to clarify their legal obligations and promote compliance. In recent years the CMA has produced guidance on the applicability of consumer law in a range of sectors. This includes for the higher education and care home sectors, which, like the fertility sector, are not 'typical' consumer markets.

[4] It was established in April 2014 and took over many of the functions previously performed by the Office of Fair Trading (OFT) and the Competition Commission.

2. Questions for consideration

In responding to these questions, please give your reasons and any relevant supporting information or evidence.

Scope

2.1 Does the draft guidance cover all of the important issues around the consumer law practices, policies and terms used by fertility clinics in their dealings with patients? If not, what else should this guidance include and why?

2.2 Paragraph 2.18 of the draft guidance explains that the guidance is aimed at all providers of fertility treatment to patients in the UK, except for the NHS when it directly provides free treatment in accordance with its statutory duties. The CMA considers that this will include clinicians acting in a self-employed capacity. However, in order to make the guidance as useful as we can, we would find it helpful to hear more about the extent to which, and the circumstances in which, patients contract directly with an individual clinician rather than the clinic.

2.3 Would it be helpful if the guidance said more on fertility clinics' relationships with third parties, for example partner clinics abroad, third party finance providers, or sperm banks etc. If so, what issues would it be helpful for the guidance to consider?

Ensuring that potential patients and existing patients get the information they need to make informed decisions (chapter 3)

The CPRs

2.4 The draft guidance – see Chapter 3 – sets out the CMA's views on what is likely to constitute 'material information' under the CPRs, by which we mean the information that potential and existing patients need, at certain stages, in order to make informed choices about matters such as which fertility clinic to choose, and what treatments to buy. The information that must be provided according to the CPRs is the information that is necessary for the average patient to make an informed transactional decision, which is distinct from information that is only useful or may be helpful.

(a) Do you agree with our assessment of the information likely to constitute 'material information' under the CPRs? (see paragraph 3.32 of the draft guidance): in particular:

(i) Is there any information currently included that you do not think constitutes 'material information' and if so why?

(i) Is there any other information you think ought to be included as constituting 'material information' and if so why?

2.5 Are there any important elements of a patient's journey with clinics that we have missed and what do you think the implications of this may be?

2.6 The draft guidance – see Chapter 3 (paragraphs 3.33 to 3.36) - sets out the CMA's views on the types of business practices that may constitute misleading omissions or misleading actions under the CPRs. Are there any additional examples that would be useful in the guidance?

The CCRs

2.7 Chapter 3 of the draft guidance sets out the CMA's views on the application of the CCRs including the information that fertility clinics are required to provide to patients before they enter into a contract with the clinic. The 'pre-contract' information clinics need to provide and how clinics need to provide it will depend on how the contract is entered into with the patient.

(a) Do you agree with our assessment that a patient may enter into more than one contract with a fertility clinic for services (treatment)? (see paragraph 3.39 of the guidance)

(b) Do you agree with our assessment that:

(i) a contract for the initial consultation, scans and tests is likely to a 'distance contract'?

(ii) a contract for the fertility treatment is likely to be an on-premises contract (unless there is no in person face-to face contact)?

Treating patients fairly

Professional Diligence

2.8 In paragraph 4.5 we refer to the existence of sector-specific or relevant medical professional laws, regulations and standards, which are likely to

inform the standard of professional diligence in the fertility sector. Please provide views on:

(a) which laws, regulations and standards are especially important and explain your reasons;

(b) the existing sector specific regulations and standards which shouldn't be considered relevant and explain your reasons.

2.9 In paragraph 4.7 we provide examples of clinics' commercial practices which may fail to comply with the requirements of professional diligence.

(a) Do you agree that the practices highlighted should be included in the list of examples?

(b) Are there further commercial practices which you think we should add to this list?

Terms

2.10 The draft guidance – see Chapter 4 (paragraphs 4.26 to 4.57) – sets out the CMA's view on the examples of contract terms that could be open to legal challenge for potential unfairness under the CRA including terms:

- allowing a wide discretion to vary the service being provided;
- allowing a wide discretion to vary the agreed price (in circumstances where the agreed treatment plan has not changed);
- giving you a wide discretion to end the contract;
- allowing unbalanced rights to cancellation and refunds;
- transferring inappropriate risks to patients;
- assigning the contract;
- excluding or restricting your liability to your patients.

(a) Do you agree with the CMA's views on the potential unfairness of the terms listed?

(b) Are there any additional types of fair terms, which should be highlighted in the guidance?

Complaints handling

2.11 Do you agree with the CMA's views on how consumer law applies to a fertility clinic's complaint handling processes and practices? (paragraphs 4.58 to 4.66 refer)

General/ additional

2.12 What, if any, aspects of the draft guidance do you consider need further clarification or explanation, and why? In responding, please specify which Chapter and section of the draft advice (and, where appropriate, the issue) each of your comments relate to.

2.13 Overall, is the draft guidance sufficiently clear and helpful for the intended audience?

2.14 Are there any other comments that you wish to make on the draft guidance?

3. Consultation process

3.1 We are publishing this consultation on the CMA's webpages and sending it to a range of interested parties to seek views on the questions set out in section 2 of this document.

3.2 We are also planning to hold stakeholder roundtable events during the consultation period (during December 2020). These will be held virtually. To ensure we can accommodate all stakeholders that wish to attend, place numbers will be limited to one per clinic / organisation. If you are interested in attending one of the roundtables please email: ConsumerLawIVFTeam@cma.gov.uk

Duration

3.3 The consultation will run for a period of 9 weeks from 3 November 2020 to 5 January 2021. Responses should be submitted by email to ConsumerLawIVFTeam@cma.gov.uk by no later than 5pm on Tuesday 5 January 2021.

3.4 Please note that due to the ongoing Covid-19 situation, the CMA is unable to accept delivery of any correspondence or documents by post or courier to any of our offices.

How to respond

3.5 Please respond to as many of the questions as you can and support your answers with any evidence or examples you may have.

3.6 When responding to this consultation, please state whether you are responding as an individual or are representing the views of a group or organisation (including those representing consumer or business interests). If the latter, please make clear who you are representing and their role. The data use statement below sets out how the CMA may use information provided to it as part of this consultation.

Use of information provided to the CMA

3.7 This section sets out how the CMA may use the information provided to it during the course of this consultation.

3.8 The information you provide will help to inform the CMA's final guidance for fertility clinics on consumer law.

3.9 We may wish to refer to comments received in response to this consultation in future publications. Where appropriate, we may also use the information you provide in the carrying out of the CMA's other functions, for example, in enforcement action using our consumer powers or we may share information with another regulator or public authority (such as local authority Trading Standards Services, the Human Fertilisation and Embryology Authority or the Advertising Standards Authority).

3.10 However, we may only publish or share information in specific and limited circumstances set out in legislation (principally, Part 9 of the Enterprise Act 2002). In particular, prior to any publication or any such disclosure, we must have regard to (among other considerations) the need for excluding, so far as is practicable:

(a) Any information relating to the private affairs of an individual which might, in our opinion, significantly harm the individual's interests. The CMA considers this could include information relating to a patient's health and medical treatment; or

(a) Any commercial information relating to a business which, if published or shared, might, in our opinion, significantly harm the legitimate business interests of that business.

3.11 If you consider that your response contains such information, that information should be marked 'confidential information' and an explanation given as to why you consider it is confidential.

3.12 Any personal data you provide to us in responding to this consultation will be processed by the CMA, as controller, in line with data protection legislation. This legislation is the General Data Protection Regulation 2016 (GDPR) and the Data Protection Act 2018.

3.13 'Personal data' is information which relates to a living individual who may be identifiable from it.

3.14 Any personal data you provide to us will be handled in accordance with our obligations under the Data Protection Act 2018 and the General Data Protection Regulation. For more information about how the CMA processes personal data, your rights in relation to that personal data (including how to complain), how to contact us, details of the CMA's Data Protection Officer, and how long we retain personal data, see the "key information on data protection" section of our case page.

3.15 The CMA is also bound by the Freedom of Information Act 2000 (the FoIA). Under the FoIA, where a person makes a request in accordance with the

requirements of the FoIA, the CMA may have to disclose whether it holds the information sought and may be under a duty to disclose it, unless an exemption applies. If you consider that any information you provide may be exempt from such disclosure you should say so and explain why.

3.16 When replying by email, this statement overrides any standard confidentiality disclaimer that may be generated by your organisation's IT system

3.17 Further details of the CMA's approach can be found in the Transparency and Disclosure: Statement of the CMA's Policy and Approach (CMA6).[5]

Compliance with the Cabinet Office Consultation Principles

3.18 This consultation is compliant with the latest Cabinet Office Consultation Principles. The Cabinet Office Consultation Principles criteria can be found at www.gov.uk/government/publications/consultation-principles-guidance.

After the consultation

3.19 We will collate responses to the consultation and publish an anonymised summary of the responses received that fall within the scope of the consultation together with a list of all respondees (save for individuals).

3.20 We aim to publish the final version of the compliance guidance for fertility clinics during March 2021. These documents will be available on our webpages at www.gov.uk/cma and respondents will be notified when they are available.

3.21 Please note that while we are interested in hearing about patients experiences of self-funded IVF, we are unable to provide patients with advice on individual complaints.

[5] https://www.gov.uk/government/publications/transparency-and-disclosure-statement-of-the-cmas-policy-and-approach