

Draft Guidance for Fertility Clinics on Consumer Law:

Helping fertility clinics comply with their consumer law obligations

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Contents

1.	Summary	5
	Who is the CMA and why is it producing this guidance?	5
	Why is guidance for the fertility sector important?	5
	Who is this guidance for?	7
	What does consumer law require clinics to do?	8
	What does this guidance cover?	9
	What do clinics need to do?	9
	What happens if clinics do not comply with consumer law?	10
2.	Introduction	11
	The CMA's mission and powers	11
	Why produce guidance for fertility clinics?	11
	Patient vulnerability	13
	What does this guidance cover?	14
	Who is this guidance for?	15
	Relationship with sector-specific regulation	16
	Clinics, and all businesses in the fertility sector, are responsible for ensuring their own compliance with consumer law	17
	What happens if clinics do not comply with consumer law?	17
3.	Ensuring that potential and existing patients get the information they need to make info	
	Introduction	19
	Responsibility for what your staff say and do when presenting and providing information	20 ו
	Sector-specific regulation	21
	The CPRs requirements	21
	Material information under the CPRs	22
	Stages of the patient journey	22
	Stage 1 – Research	24

	Stage 2: Pre-fertility treatment	26
	Stage 3: Fertility Treatment	27
	The material information you should provide at Stage 1, Stage 2 and/or Stage 3	28
	Table 1 – Material Information at Stages 1, 2 and 3	28
	Misleading Omissions	33
	Misleading Actions	35
	The CCRs requirements	37
	Making changes to the pre-contract information	40
4.	Treating Patients Fairly	42
	A. Ensuring that commercial practices are fair	42
	B. Ensuring that terms and conditions between clinics and patients are fair	43
	Ensuring that your terms are user-friendly, clear and unambiguous	45
	Binding patients to hidden terms	47
	What is an unfair term?	49
	Terms that allow a wide discretion to vary the service being provided	50
	Terms that allow a wide discretion to vary the agreed price (in circumstances where the agreed treatment plan has not changed)	51
	Ending the contract	53
	Cancellation and Refunds	54
	Transferring inappropriate risks to patients	57
	Assigning the contract	57
	Excluding or restricting your liability to your patients	58
	C. Ensuring that complaint handling processes are accessible, clear and fair	60
A	nnex A - Overview of legislation	63
	Consumer Protection from Unfair Trading Regulations 2008 (CPRs)	63
	The scope of the CPRs – practices affecting the decisions of the 'average consumer'	64
	When will your practices be unfair under the CPRs?	64
	The 'general prohibition' on unfairness: (Regulation 3(3), CPRs)	64
	Misleading actions and misleading omissions (Regulations 5 and 6, CPRs)	65

Misleading actions	65
Misleading omissions	65
Aggressive practices and practices considered to be unfair in all circumstances	66
Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 20	1367
The Consumer Rights Act 2015 (CRA)	68
Part 1, CRA	68
Part 2, CRA	68

1. Summary

Who is the CMA and why is it producing this guidance?

- 1.1 The Competition and Markets Authority (CMA) is the UK's primary competition and consumer authority and has powers to tackle practices and market conditions that disadvantage consumers and hinder their decision making.
- 1.2 As part of its role, the CMA produces guidance for businesses to clarify their consumer law obligations and promote compliance.
- 1.3 The purpose of this guidance is to help fertility clinics understand and comply with their existing obligations under consumer law.

Why is guidance for the fertility sector important?

- 1.4 Every year around 70,000 cycles of IVF treatment take place in the UK.¹ The UK fertility market is worth around £320 million annually,² and has enjoyed steady growth over recent years. 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.
- 1.5 However, media coverage of the sector, CMA reviews of clinic websites and published research, and discussions with the Human Fertilisation and Embryology Authority (HFEA), the Advertising Standards Authority and patient groups, all indicate that certain clinic practices may be preventing or inhibiting patients from making informed choices.
- 1.6 Consumer law gives important protections to fertility patients. The CMA's discussions with the HFEA, and other organisations and people with knowledge of the sector, have highlighted a general lack of awareness about how consumer

¹ For example in 2018, 68,724 fresh and frozen IVF cycles took place in licensed fertility clinics, along with a further 5,651 donor insemination cycles. HFEA, *Fertility trends 2018: trends and figures*, 30 June 2020. www.hfea.gov.uk/about-us/publications/research-and-data/fertility-treatment-2018-trends-and-figures/

² The IVF component of this accounted for £298.5 million and the remaining £19.3 million is spent on Intrauterine Insemination. Laingbuisson *In Vitro Fertilisation: UK Market Report*, May 2018 www.laingbuisson.com/blog/ivf-adynamic-innovative-and-growing-market-in-the-uk May 2018

law applies in the sector. These discussions have also made clear that guidance on consumer law would be helpful for fertility clinics and patients. Increased compliance with consumer law should help address some of the concerns identified in the sector, such as:

- Patients being unable to make meaningful comparisons between clinics' prices because of the way some clinics present misleadingly low headline prices, which do not include essential elements of treatment.
- Patients being faced with unexpected additional costs during treatment.
- Clinics providing partial or misleading information on their success rates.
- Patients not being properly informed by clinics of the limited evidence base for add-on treatments increasing the chances of a live birth, or the risk associated with certain add-on treatments.
- 1.7 The CMA understands that consumer law obligations and rights may not always be at the forefront of clinics' and patients' thinking. Nevertheless, consumer law protects these transactions and understanding consumer law is an important consideration when providing fertility treatment.
- 1.8 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 patients and avoid disputes between clinics and patients.
- 1.9 This guidance is particularly important at a time when an increasing proportion of patients pay for treatment themselves. In particular, the share of IVF cycles funded by the NHS has declined across most English regions over recent years, with 65% of cycles in England now self-funded.³

³ HFEA, *Fertility trends 2018: trends and figures*, 30 June 2020.

- 1.10 A single cycle of IVF can cost patients around £5000,⁴ and at some clinics upwards of £20,000. As most cycles sadly are not successful, for many patients this is not a one-off purchase,⁵ and they can spend many thousands of pounds over the months and years they undergo treatment.
- 1.11 The CMA's decision to publish guidance was taken before the coronavirus (COVID-19) pandemic 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.
- 1.12 The HFEA fully supports the CMA's work to develop this guidance and the CMA has worked closely with the sector regulator throughout the process. This guidance sits alongside other sector-specific regulation.

Who is this guidance for?

- 1.13 This 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.
- 1.14 The guidance specifically considers the law as it applies to fertility clinics. However, consumer law also protects patients in their interactions with other businesses active in the fertility sector, such as sperm banks, businesses selling complementary fertility treatments and businesses supplying finance for fertility treatment. The CMA advises that these businesses also read this guidance and consider how it, and the relevant consumer law principles, apply to them.
- 1.15 Alongside this guidance for clinics, the CMA is also publishing a shorter document for patients, which sets out their rights under consumer law.

⁴ HFEA webpage: https://www.hfea.gov.uk/treatments/explore-all-treatments/in-vitro-fertilisation-ivf/

⁵ On average a patient has 2.5 cycles of treatment, data provided by HFEA.

What does consumer law require clinics to do?

- 1.16 Consumer law sets minimum standards that apply to various aspects of clinics' dealings with patients. In particular, consumer law requires that:
 - Clinics do not mislead patients (including by omission) or otherwise act unfairly towards them. This obligation applies before as well as after a patient has entered into a contract with a clinic. It also applies in circumstances where a potential patient does not enter into a contract with a clinic at all. It means that clinics must do certain things, such as provide key information upfront, so potential and existing patients can make informed decisions.
 - Clinics must ensure that their contracts with patients are fair. Clinics must not put patients at an unfair disadvantage, by tilting the rights and responsibilities under the contract too much in their own favour.
- 1.17 The law also requires that clinics consider the difficult circumstances in which people find themselves when they are making decisions about fertility treatment. For those buying fertility treatment, there are few, if any, purchases that are more important. Discussions with patient groups, and the research the CMA commissioned with patients⁶, have highlighted a range of factors that can make people vulnerable when they are buying fertility treatment. For example:
 - This is a complex purchase, involving estimations of risk and probability, where outcomes are inevitably uncertain.
 - By the time people arrive at a fertility clinic many will have been trying unsuccessfully to have a baby for many months or years. The emotional impact of this can be significant.
 - Patients often want to do all they can to increase the chances of having a baby.
 - Most patients in the UK are not used to buying healthcare, particularly

⁶ CMA research report

directly from a provider.⁷ The information asymmetries between those providing the fertility treatment and those buying the treatment are generally significant, and patients place a great deal of faith in what they are told by clinics.

What does this guidance cover?

- 1.18 Chapter 2 explains why the CMA has produced this guidance and sets out its scope.
- 1.19 Chapter 3 sets out what information clinics need to provide to prospective and existing patients and when they need to provide it. It explains that to comply with consumer law, clinics must not provide misleading information to patients, or fail to provide all the relevant 'material' information they need to make informed decisions. It also provides examples of conduct which is likely to constitute a 'misleading act' or 'misleading omission'.
- 1.20 Chapter 4 focuses on what clinics should do to ensure that their practices and contractual terms are fair. It discusses different types of terms, such as variation terms and refund and cancellation terms, and the ways in which they may be unfair to patients. It also explains the importance of ensuring that terms are transparent, as well as substantively fair. The chapter concludes by setting out what clinics should do to ensure that their complaints handling processes are fair.
- 1.21 The annex provides an overview of the relevant legislation.

What do clinics need to do?

- 1.22 As a fertility clinic you need to:
 - (a) Read this guidance and ensure that you are complying with consumer law in your dealings with prospective patients and patients.
 - (b) Consider carefully how this guidance applies to you and whether you need to make changes to your practices, such as the information you provide to

⁷ In the fertility sector insurance companies rarely act as intermediaries between patients and healthcare providers.

prospective patients and existing patients before and during treatment, and your policies and terms to make sure you are complying with the law.

- (c) Make any changes to your practices, policies and terms that are necessary to ensure that your clinic complies with the law.
- (d) Consider a wider review of your internal procedures and processes in order to support your compliance with consumer law - for example, to make sure that important information is clearly, accurately and prominently provided to prospective patients (including on websites, in written marketing materials such as brochures and in response to telephone enquiries).
- (e) Make sure that all patient-facing staff, including clinical staff and all staff involved in producing patient-facing materials, understand these requirements and comply with them. You are legally responsible for the actions of your staff, who are acting in your name, or on your behalf, in their dealings with patients.
- 1.23 If a fertility clinic, or any other business operating in the sector, is unsure of its legal obligations, it should seek independent legal advice.

What happens if clinics do not comply with consumer law?

1.24 If a fertility clinic, or any other business active in the sector, does not comply with consumer law, the CMA and other bodies, such as local authority Trading Standards Services, can bring court proceedings to stop infringements and seek compensation on behalf of patients. The Advertising Standards Authority can also take action against misleading advertisements that contravene its Advertising Codes. Moreover, clinics may face legal action from patients, who may bring legal proceedings for a clinic's breach of contract or seek redress in the courts for certain breaches of consumer law.

2. Introduction

The CMA's mission and powers

- 2.1 The Competition and Markets Authority (CMA) is the UK's primary competition and consumer authority.⁸ Its objective is to make markets work well for consumers, businesses and the broader economy.
- 2.2 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).
- 2.3 The CMA shares these enforcement powers with other bodies, such as local authority Trading Standards Services (TSS). The CMA also shares certain consumer functions with other agencies. In particular, the Advertising Standards Authority ('ASA'), which is the lead authority for ensuring compliance with specified consumer law⁹ in non-broadcast advertising (for example print, posters, direct marketing and online, such as a clinic's website) under the British Code of Advertising, Sales Promotion and Direct Marketing (the CAP Code).¹⁰ This means that if the CMA were to identify a consumer law issue relating to non-broadcast advertising it would usually refer this to the ASA to consider.¹¹
- 2.4 As part of its role, the CMA produces guidance for businesses to clarify their legal obligations and promote compliance. In recent years the CMA (and its predecessor the OFT) 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.

Why produce guidance for fertility clinics?

2.5 The CMA's engagement with the HFEA and stakeholders, including clinics, the professional bodies and patient representative groups, highlighted a general lack

⁸ 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.

⁹ Namely, the Consumer Protection from Unfair Trading Regulations 2008 (CPRs)

¹⁰ See: www.cap.org.uk/cap/codes

¹¹ See: www.gov.uk/cma-and-asa-memorandum-of-understanding-on-consumer-protection-issues

of awareness about how consumer law applies in the sector and that guidance on consumer law would be helpful for fertility clinics and patients. Ensuring compliance with consumer law should help address some of the concerns in the sector which the CMA has identified during its research and discussions with stakeholders. These concerns include:

- Patients being unable to meaningfully compare clinics' prices because of the way that information is presented with some clinics advertising misleadingly low headline prices, which do not include essential elements of a treatment cycle;
- Patients being faced with unexpected additional costs during treatment;
- Clinics providing partial or misleading information on their success rates; and
- Patients not being properly informed by clinics of the limited evidence base for add-on treatments increasing the chances of a live birth, or the risk associated with certain add-on treatments.
- 2.6 Between 2013 and 2018, the proportion of cycles that were NHS-funded decreased across many regions in England.¹² ¹³ This trend is likely to continue over coming years. As a result, adherence to consumer law is likely to be increasingly important to patients.
- 2.7 The CMA understands that consumer law obligations and rights may not always be at the forefront of clinics' and patients' thinking. Patients in particular may focus their attention on what treatment involves, rather than a clinic's terms. Nevertheless, consumer law protects these transactions and understanding consumer law is an important consideration when providing fertility treatment.
- 2.8 Compliance with consumer law is important not only in protecting patients but also in maintaining the reputation of the fertility sector and supporting open and

¹² In 2018, 59,153 of the 68,724 IVF cycles that took place in the UK as a whole were in England. HFEA, *Fertility trends 2018: trends and figures*, 30 June 2020.

¹³ The level of NHS funding for fertility treatment varies across the UK. In 2018 in Scotland, 60% of treatment was NHS-funded, compared to 45% in Northern Ireland, 41% in Wales and 35% in England. It also varies across England, for example, in 2018, it ranged from 60% in the North East, to 26% in both the East of England and Yorkshire and the Humber regions. HFEA, *Fertility trends 2018: trends and figures*, 30 June 2020.

fair competition amongst clinics. It also helps to reduce the number of complaints made by consumers and avoid disputes between clinics and patients.

2.9 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.

Patient vulnerability

- 2.10 Consumer law requires that traders take any vulnerability on the part of consumers into account in their dealings with them.
- 2.11 In certain market contexts, all consumers can experience vulnerability, albeit sometimes to differing degrees. Vulnerability can mean that consumers are especially susceptible to detriment in a market.
- 2.12 Deciding to purchase fertility treatment is a significant decision, both financially and emotionally, and for many people it will be a stressful purchase. It is the CMA's view that most, if not all fertility patients will be vulnerable to some degree. The vulnerable circumstances in which patients find themselves are an important consideration in deciding how consumer law applies in this sector. The CMA notes, for example:
 - *(a)* This is a complex purchase, involving estimations of risk and probability, where outcomes are inevitably uncertain. These are challenging concepts for many consumers in any market.¹⁴
 - (b) By the time people arrive at a fertility clinic many will have been trying unsuccessfully to have a baby for many months or years. The emotional impact of this on the patient and their partner can be significant.
 - *(c)* As the CMA's commissioned research with patients¹⁵ and conversations with patient representative groups have highlighted, patients often want

¹⁴ See for example https://www.fca.org.uk/publication/occasional-papers/occasional-paper-8.pdf

¹⁵ refer to consumer research report published alongside draft guidance

to do all they can to increase the chances of having a baby, particularly where they have had previous unsuccessful treatment or think their chances of success are low.

- (d) In addition, most patients in the UK are not used to buying healthcare, particularly directly from a provider.¹⁶ The information asymmetries between those providing the fertility treatment and those buying the treatment are generally significant, and patients place a great deal of faith in what they are told by clinics.
- *(e)* Some patients have a deference to medical professionals and would not question, or may feel uncomfortable, questioning what they are told.
- (f) There is generally a power imbalance in the relationship between medical professionals and patients, including for the reasons listed at (a) to (d) above.
- (g) The CMA knows from its research with patients and discussions with patient representative groups, that cost is an important factor for many patients, but some patients feel reluctant to raise issues of cost with a clinic, fearing it may look like they do not want a baby 'enough' or that they cannot afford treatment.
- (h) Furthermore, the nature of treatment means that once a cycle is underway and they are taking medication, it is unlikely that a patient, even if unhappy with the clinic, will walk away or be able to change clinic.

What does this guidance cover?

- 2.13 This 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.
- 2.14 This guidance covers:

¹⁶ In the fertility sector insurance companies rarely act as intermediaries between patients and healthcare providers.

- The relevant consumer protection legislation Consumer Protection from Unfair Trading Regulations 2008 ('CPRs'); Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 ('CCRs'); and Parts I and II Consumer Rights Act 2015 ('CRA') (see annex A).
- Information provision what information you should provide to prospective patients and existing patients and when (chapter 3).
- Treating patients fairly what you should do to ensure that your practices, terms and complaints handling processes are fair (chapter 4).
- 2.15 The examples of possible breaches of consumer law provided in this guidance are based on issues that the CMA considers are likely to be most relevant to the sector based on the consumer research it has commissioned, HFEA published reports and research,¹⁷ and information provided by stakeholders.
- 2.16 The guidance is not intended to be exhaustive and does not cover every situation in which an infringement may occur.

Who is this guidance for?

- 2.17 This 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.¹⁸ Such providers therefore include:
 - private fertility clinics, irrespective of how the treatment is funded;^{19 20}
 - NHS fertility clinics, if and when they provide treatment which a patient pays for;

¹⁷ HFEA *Fertility treatment 2018: trends and figures,* June 2020; HFEA, *Pilot national fertility patient survey,* 2018; HFEA, *State of the Fertility Sector 2018-19.*

¹⁸ Consumer law protects consumers in their dealings with traders. The CMA would not expect the NHS to be acting as a trader where it is providing NHS-funded treatment directly to patients in accordance with its statutory duties. ¹⁹ In other words, the CMA considers all patients receiving treatment at a private clinic are protected by consumer law, including those that are wholly self-funded and pay all treatment costs themselves; partly funded by a third party like the NHS and partly self-funded; and those that are entirely NHS funded.

²⁰ In the UK in 2018, 30% of all NHS-funded cycles (26186) took place in private clinics (7966). In England alone, 38% of all NHS-funded cycles (20804) took place in private clinics (7946). Figures provided by HFEA.

- clinicians acting in a self-employed capacity;
- clinicians where they acting on behalf of, or in the name of, a private fertility clinic.
- 2.18 References in this guidance to fertility clinics shall include reference to clinicians acting in a self-employed capacity.
- 2.19 In this guidance 'you' refers to fertility clinics. This includes those individuals who either own or have individual or collective responsibility for managing a clinic.
- 2.20 This 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. So, for example, a foreign clinic marketing its services to consumers in the UK (such as through participating in a trade show) will need to ensure that its marketing complies with UK consumer law, even if the treatment itself takes place outside the UK.
- 2.21 The focus of this guidance is on those providers of fertility treatment described in paragraph 2.18 above. However, 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.
- 2.22 Although this guidance is principally for fertility clinics, it 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, professional bodies, and the HFEA.
- 2.23 Alongside this guidance the CMA will be producing a short document for patients to help them understand their rights and how consumer law applies in the sector.

Relationship with sector-specific regulation

2.24 Consumer law sets minimum standards that apply to various aspects of clinics' dealings with patients. It sits alongside other sector-specific regulatory obligations and guidelines, for example in relation to information provision and complaints handling. This guidance does not provide advice on other laws or rules enforced

by the sector regulator, the HFEA, or the General Medical Council or the Health and Care Professions Council.

2.25 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.

Clinics, and all businesses in the fertility sector, are responsible for ensuring their own compliance with consumer law

- 2.26 This guidance sets out the CMA's views on when clinics' practices and terms are likely to comply with, or infringe, consumer law. It 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 consumer law. You may also wish to speak to your local trading standards service for advice, for example as part of a primary authority relationship.²¹
- 2.27 As set out above, this guidance has specifically considered the law as it applies to fertility clinics. However, consumer law also protects patients in their interactions with other businesses active in the fertility sector. The CMA advises that these businesses also read this guidance and consider how it, and the relevant consumer law principles, applies to them.

What happens if clinics do not comply with consumer law?

2.28 If a clinic, or any business active in the fertility sector, infringes consumer law, it may face action by:

²¹ Primary Authority is a means for businesses to form a legal partnership with a local authority, which then provides assured and tailored advice on complying with trading standards law (including consumer law). For more information, see https://www.gov.uk/guidance/local-regulation-primary-authority#what-is-primary-authority.

- (a) The CMA or other bodies that enforce general consumer law (such as local authority Trading Standards Services or DETI in Northern Ireland). These bodies can act to stop you infringing the law by bringing civil proceedings for a court injunction²² (and, where appropriate, seek compensation for affected patients) or - in relation to certain breaches - criminal prosecutions.²³
- (b) Patients themselves, who may bring legal proceedings for a clinic's breach of contract or seek redress in the courts for certain breaches of consumer law. Patients may also use consumer law to defend any action brought by you, for example where you are seeking to recover debts allegedly owed. In particular, a patient may be able to rely on unfair terms legislation, which provides that an unfair term cannot be relied on by you.
- (c) The HFEA, the sector regulator, where the conduct of concern falls below the acceptable standards, as set out in the relevant licensing conditions and Code of Practice.
- (d) The Advertising Standards Authority, which can take action against misleading advertisements that contravene its Advertising Codes. Its Codes cover advertising and marketing communications, which are likely to include clinics' information, websites, leaflets and posters directed at prospective patients.

²² Or an interdict, in Scotland

²³ In Scotland, criminal proceedings are brought via the Crown Office and Procurator Fiscal Service (COPFS)

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

Introduction

- 3.1 It is important that you provide potential and existing patients (and, where relevant, their partners) with the information they need, at the time that they need it, and in a format that is clear and easy to understand. This is so that the significant decisions they are going to make about matters such as which fertility clinic to choose, and what treatments to have, are properly informed. This is particularly important in this sector given the significant financial and emotional commitment that patients are investing in those decisions. Patients may be unable or extremely reluctant to abandon a cycle of treatment once they have started taking their medication, even if they are unhappy. This places a premium on ensuring that patients' decisions are properly informed.
- 3.2 This section sets out the CMA's views on your consumer law obligations, as set out in the CPRs and CCRs (see paragraphs 3.9 to 3.36 and 3.37 to 3.43 respectively), relating to what, when and how information should be provided to potential and existing patients. Those obligations cover information that is provided by you verbally, visually and in writing, for example, at trade shows²⁴, events and clinic open days, information in brochures, on your website generally and specifically in patient portals, during consultations and in consultation letters and costed treatment plans. The guidance also sets out some examples that may, in the CMA's view, breach consumer law.²⁵
- 3.3 Information should be clear, accurate, and easy to find. It should be provided in a way, and at a time, that ensures potential and existing patients can understand and engage with it before making any decisions about whether to have fertility treatment and, if so, which fertility clinic and treatments to choose.
- 3.4 The information provided should enable potential and existing patients to make

²⁴ UK consumer law, and this guidance, is also relevant to fertility clinics located overseas in so far as they are conducting activities in the UK. So, for example, a foreign clinic marketing its services to consumers in the UK (such as through participating in a trade show) will need to ensure that its marketing complies with UK consumer law, even if the treatment itself takes place outside the UK.

²⁵ The guidance does not state the law, only the CMA's views as to how the law is intended to operate.

properly informed decisions, at the right stage of their patient journey (see paragraphs 3.12 to 3.13). It is therefore important for you to understand what information you need to provide and when, to help ensure you are complying with consumer law. In particular, you should:

- (a) Provide the 'material information' that potential and existing patients need at each stage of your dealings with them (see paragraph 3.32);
- (b) Provide potential patients with the necessary 'pre-contract information' required under the CCRs before a contract is entered into (see paragraph 3.40). The CMA notes that the patient journey may include more than one contract (see paragraph 3.39);
- *(c)* Ensure the pre-contract information remains accurate and up to date, as any changes to it require the express consent of the patient (see paragraph 3.41); and
- (d) Specifically bring to the patient's attention any important terms and conditions so that patients can genuinely understand their rights and obligations before agreeing to treatment. For example, a term that allows you to refer patients for treatment to another clinic at a different location or a term that restricts the time period in which treatment must be taken (see paragraph 4.18 of chapter 4).

Responsibility for what your staff say and do when presenting and providing information

3.5 You should ensure that all staff in contact, indirectly or directly, with potential and existing patients understand what they need to do to comply with consumer law. You are responsible for the information provided and presented by your staff, including how and when it is provided and presented. You are also responsible if they fail to provide it. Such information may be provided, for example, through your advertising, in brochures, on your website, or through the conversations your staff may have by telephone, at clinic open days and during consultations.

Sector-specific regulation

- 3.6 Alongside your consumer law obligations, there are also sector-specific regulatory requirements relating to information provision that you will need to comply with (see paragraphs 2.25 to 2.26). In particular, there are the requirements, set out in the HFEA Code of Practice²⁶. For example, for information to be provided about the potential immediate and longer-term risks of the treatment and any treatment add-ons used, and for a costed treatment plan ('CTP') to be provided to patients before treatment starts (HFEA Code of Practice requirements 4.6 and 4.9 respectively refer).
- 3.7 Although there is overlap between consumer law and the HFEA's regulatory requirements they are not the same and compliance with one does not guarantee compliance with the other. Clinics should pay close attention to both consumer law and the sector-specific regulatory requirements. The HFEA provide guidance to clinics on how to meet their legal requirements in their Code of Practice.²⁷
- 3.8 Going forward, as the HFEA Code of Practice is updated, the CMA would expect, clinics to comply with all new additions and/or revisions made to it. Failing to comply with the regulatory requirements may also mean you breach the requirement of professional diligence under the CPRs. Further information about professional diligence is provided in paragraphs 4.2 to 4.7 of Chapter 4 (Treating Patients Fairly) and paragraphs 1.8 to 1.10 of Annex A (Overview of Legislation).

The CPRs requirements

3.9 The CPRs require that you provide material information that is truthful, clear, intelligible, unambiguous and timely at all stages of the patient journey, as set out in paragraphs 3.12 to 3.13. It is unlawful, under the CPRs, for example, to not provide material information, not provide material information at the right time, to provide false information and/or present information in a way that is likely to deceive your patients, even if the information is factually correct. Material information has to be provided irrespective of whether a patient requests it.

²⁶ hfea.gov.uk/code-of-practice-9th-edition-december-2019

²⁷ Complying with the standards set out in the HFEA's s code and guidance may not be sufficient of itself for a clinic to be complying with the requirements of professional diligence under the CPRs.

Material information under the CPRs

- 3.10 Under the CPRs, you are required to provide 'material information'²⁸, at the time patients need it, so that they can make informed decisions about matters such as whether to have fertility treatment and, if so, which fertility clinic and treatments to choose. Material information does not necessarily include all the information that might be of interest, or that is important to particular patients, but it is the information patients need to make informed decisions.
- 3.11 What constitutes material information is dependent on the stage in the patient journey (see paragraphs 3.12 to 3.13), and is also likely to vary depending on different patients' medical circumstances and the treatments being offered to them. As a general rule of thumb, aspects of the information you should provide will become more tailored as patients progress through the stages of a patient journey. For example, the information you provide about your clinic's success rates to all prospective patients, such as on your website and in brochures, will be more general in nature, than that which you should provide later on in the patient journey, such as in consultation letters and face to face appointments, as the latter should take into account the particular medical circumstances of the patient, including their diagnostic test results.

Stages of the patient journey

3.12 When potential and existing patients are considering undertaking and paying for fertility treatment, there are likely to be three main stages in the patient journey. Consumer law applies at each stage. Examples of the information to be provided at each stage are illustrated below, with further detail at paragraphs 3.14 to 3.32.

²⁸ 'Material information' is information that the average consumer needs, according to the context, to take an informed transactional decision. It includes any information requirement which applies in relation to a commercial communication as a result of a European Community obligation (Regulation 6). A 'transactional decision' is any decision taken by a consumer whether it is to act or refrain from acting concerning – (*a*) whether, how and on what terms to purchase, make payment in whole or in part for, retain or dispose of a product, or (*b*) whether, how and on what terms to exercise a contractual right in relation to a product. See Annex A.



- 3.13 Not all patients will need or want to go through all the above three stages for information provision. For example, some potential and existing patients:
 - (a) May choose not to consider and shortlist clinics at Stage 1 because they have already decided to go to a particular clinic, for example, based on a recommendation of a friend or a desire to stay with a clinic that provided their NHS funded treatment. Such potential patients would still need to be provided with relevant material information though, for example, about the costs of any pre-treatment consultation, tests and scans;
 - (b) Who are remaining with the clinic that provided their funded NHS fertility treatment or, who are agreeing to a further cycle of treatment at a clinic where they have previously paid for treatment, may not need, or may not need the full range of, the diagnostic services carried out at Stage 2 if the earlier results are still valid (i.e not time expired); and
 - (c) May choose not to proceed to Stage 2 or to Stage 3 after completing Stages 1 or 2 respectively.

Stage 1 – Research

The material information that you need to provide to potential patients at this stage is the information they need to make informed decisions about matters such as whether to continue researching fertility treatment, which clinics to shortlist and which clinic to choose for the pre-fertility treatment activities (consultation, tests and scans) at Stage 2

- 3.14 Potential patients may initially look for information about clinics in a number of places. They may be drawn to your clinic at this point through, for example, the use of a search engine or a third party website you are listed on, or through your general advertising, marketing and promotional activities.
- 3.15 The information you provide, verbally and in writing, for example in advertisements, at trade shows and events, at clinic open days/evenings, in response to telephone and online contact, in information packs, brochures and on your website plays a crucial role in enabling patients to decide whether to have treatment and, if so, to compare clinics and what they offer.
- 3.16 The information should be provided in a clear and simple manner that potential patients can understand and process, without being overwhelmed with unnecessary information at this stage. Material information should be prominently highlighted and should not omit key information, for example any information on your website about the benefits of add-on treatments, should not omit information about the clinical evidence and, if relevant, the risks associated with such treatments.
- 3.17 There will be some patients who may initially choose not to research their clinic options, as they already have a preferred clinic (see paragraph 3.13). However, you still need to provide all patients with the material information they need to make an informed decision about, for example, whether to proceed with their preferred clinic. This material information is set out in detail in Table 1 on pages 28 to 33 of this Chapter. This is likely to include information on websites about what is included in any headline price and/or a set price for a cycle of IVF, IUI, ICSI, donor egg IVF, a multi-cycle package etc, and all aspects of treatment patients may need to pay for on top of this, for example medication. It could be that when such patients see this information, they then decide to see if other clinics are more affordable for them.

- 3.18 After initially researching treatments and clinics, if patients decide to proceed, then this is likely to result in one or more clinics being shortlisted for further research, which may involve visits to those clinics, for example during open days. This may result in patients then going to one of their shortlisted clinics for a consultation, including scans and tests, to determine their own treatment options. Such consultations are likely to require payment.²⁹
- 3.19 It is important that patients are provided with the material information they need to make an informed decision regarding whether to proceed with a consultation. In addition to information regarding the general treatment costs, the CMA would normally expect such information to include, for example:
 - (a) Details about what the consultation process consists of;
 - (b) The cost of the consultation and any diagnostic tests and scans;
 - (c) The possibility that additional diagnostic tests, and costs, may be necessary once the results of the first tests are known;
 - (*d*) Details of any cancellation charges if they fail to attend the appointment; and
 - *(e)* Whether you will accept the results of any tests and scans already undertaken.
- 3.20 The above information should be provided before any appointment is made and could be provided, for example, on your website. You should confirm this information by telephone or online when patients contact you to book an appointment. If a contract is entered into at this point for a pre-fertility treatment consultation then the CCRs will apply (see paragraphs 3.37 to 3.40).
- 3.21 Providing such information will help potential patients compare the process and costs involved at the clinics they may have shortlisted. It will also stop them being surprised by the costs if they would otherwise only learn about these, for example, when they turn up for the appointment, or after the consultation and tests have taken place, when they are presented with a bill.

²⁹ Some patients may choose to pay and have consultations, tests and scans at more than one clinic.

3.22 For more detail on the CMA's views about the material information that should be provided at Stage 1, see Table 1 on pages 28 to 30 and 33.

Stage 2: Pre-fertility treatment

The material information that you need to provide to patients at this stage is the information they need to make informed decisions regarding whether to proceed and, if so, how best to proceed with Stage 3 fertility treatment

- 3.23 At Stage 2, for patients to be able to make informed decisions about whether and how to proceed with Stage 3 fertility treatment, the information that will be material is likely to be more tailored to the individual patient, than that provided at Stage 1. For example, information about a patient's likely success rates and the treatment options available to them, should be based on the individual patient's medical history and the results of their pre-diagnostic tests and scans. This will enable you to discuss with them their treatment options as well as their own likely chances of success.
- 3.24 Patients may have already formed a view about their chances of success, based on the generic success rate information you have provided, as relevant to them, at Stage 1. At Stage 2, it is important for them to know if and why, their test results suggest their own likely chances of success have now changed, which could be for the better or worse.
- 3.25 After discussing the treatment options, for those patients who wish to proceed with treatment³⁰, you should provide, amongst other things, a full and clear costed treatment plan. This should include information about the circumstances in which any changes may become necessary to the plan, and the cost implications of this³¹. This information should be provided in writing before the patient decides to proceed with treatment, so it can be properly considered.
- 3.26 At Stage 3, patients are very vulnerable in situations where changes are made after treatment is underway. This is because it is highly unlikely that at this stage they will be willing and able to change clinic and continue their treatment

³⁰ Other patients may decide to not proceed immediately, for example due to financial pressures, or proceed to Stage 3 but at a different clinic or decide not to have further treatment at all. If they decide to change clinic, then they may need to repeat some of the earlier stages of the patient journey.

³¹ It is a requirement of the HFEA Code of Practice (paragraph 4.9) that a costed treatment plan be provided before treatment starts. This should detail the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications.

elsewhere. They may struggle to meet surprising additional costs and feel awkward questioning such costs or not feel up to doing so whilst undergoing treatment. This is why it is so important to provide comprehensive information about the possibility and circumstances under which treatment and costs may need to change before patients agree to treatment.

3.27 For full details about the material information to be provided at Stage 2, see Table 1 on pages 28 to 33.

Stage 3: Fertility Treatment

Once patients are in treatment you should continue to provide them with the material information they need to make informed decisions about changes to their agreed treatment plan, or if treatment is unsuccessful, about their future options

- 3.28 Prior to treatment at Stage 3 commencing, the CMA would expect you to have a written contract in place setting out the agreed treatment plan (see chapter 4).
- 3.29 During Stage 3, some patients may need to make decisions about changes to their agreed treatment plan. The CMA understands that changes may be necessary for genuine medical reasons once treatment is underway. For example, it may emerge on the day of egg retrieval that ICSI is needed, or that medication dosages need to change depending on how patients respond to stimulation. Such changes should not come as a surprise, since you should already have alerted patients, at Stage 2, to the possibility that changes may become necessary. The CMA also understands that sometimes for medical reasons, it may be necessary to make decisions about changing the treatment plan at short notice and some clinics may already have sought consent to certain, less rare, changes in advance.
- 3.30 Whilst changes may become advisable or necessary medically, patients should still be given material information about those changes, for example, why the changes are necessary and whether there are any cost implications before deciding whether to proceed. In the CMA's view, the material information that you should provide during Stage 3, is likely to include the information as listed in Table 1 on pages 32 to 33.

3.31 In addition to changes in treatment, some patients, if treatment has been unsuccessful, may have a post treatment consultation with you at the end of Stage 3. If so, they may wish to discuss their treatment options going forward, in which case the material information provided at Stage 2 will normally be required. This is because the patient is considering entering into a new contract for further treatment.

The material information you should provide at Stage 1, Stage 2 and/or Stage 3

3.32 In the CMA's view, in order to allow patients to make informed decisions, the material information that you should provide at the different stages of a patient journey, is likely to include the following:

Material Information	Stage 1	Stage 2	Stage 3
	(Research)	(pre- fertility treatment)	(Fertility treatment)
1. The clinic location where treatment will take place	*	✓	
2. What a standard cycle of IVF typically costs, along with a realistic indicative cost range for medication	~		
 What tests, treatments, medication or other services are included in any headline price and/or a set cycle price, for example, for a cycle of IVF, IUI, ICSI, donor egg IVF or a multi- cycle package. In addition you should set out: 			
<i>(a)</i> any additional tests, treatments, medication or other services that			

Table 1 – Material Information at Stages 1, 2 and 3

Material Information	Stage 1	Stage 2	Stage 3
	(Research)	(pre- fertility treatment)	(Fertility treatment)
 may become neccesary, such as pregnancy scans/blood tests, pregnancy medication, embryo freezing and storage, and any additional fees a clinic passes to patients for the cost of regulation or counselling. (b) the cost or an indicative cost range for such additional tests, treatments, medication or other services. (c) the circumstances in which such 			
additional tests, treatment, medication or other services may be needed. (<i>d</i>) any significant associated risks.			
4. If offered , the costs of any add on treatments, along with the risks, benefits and the nature of the clinical evidence base for having these treatments (with signposting to the HFEA website).	✓	✓	
5. If applicable (i.e. not already included in any all-inclusive price), whether the patient can purchase their medication from elsewhere with a prescription provided by the clinic		✓	

Material Information	Stage 1	Stage 2	Stage 3
	(Research)	(pre- fertility treatment)	(Fertility treatment)
and any other important details relevant to medication (e.g. the need to sometimes obtain additional medication at very short notice).			
 6. The generic success rates of the clinic (taking into account the HFEA's Code of Conduct, for example according to age groups) 	×		
 7. The diagnostic tests and scans that will be undertaken, with explanations as to what they are for at Stage 2 as well as the following: (a) The costs of the consultation at Stage 2 together with the costs of the diagnostic tests and scans. (b) Whether you will accept the results of any previous diagnostic tests and scans, for example carried out by the NHS or paid for at another clinic and if so under what circumstances. (c) The possibility that more diagnostic tests and scans may be necessary, based on the results of the routine diagnostic tests and scans. 			

Material Information	Stage 1	Stage 2	Stage 3
	(Research)	(pre- fertility treatment)	(Fertility treatment)
 The results of the patient's own diagnostic scans and tests which you undertook at the beginning of Stage 2. 		~	
 If applicable, any further diagnostic scans and tests that may be necessary, along with the costs, once the results of the initial scans and tests undertaken (No 8 above refers) are known. 		~	
10. The patient's own chances of success, based on their consultation with you and tests undertaken at Stage 2.		✓	
 11. The treatment options and costs based on the patient's results³². This should set out what would be included in these options, i.e. treatments and services, and why, along with any risks that may be associated with certain treatments. 		~	
 12. The agreed treatment plan should: (a) Set out what treatments and services patients will be having along with the costs; 		✓	

³² Information about treatment options will vary for patients and be based on their own test and scan results as well as their medical condition and any wishes they may have for particular treatments.

Material Information	Stage 1	Stage 2	Stage 3
	(Research)	(pre- fertility treatment)	(Fertility treatment)
(b) If applicable, set out all aspects of treatment the patient may need to pay for on top of this and in what circumstances. For example, medication (and associated delivery charges), counselling, pregnancy scan/blood tests, pregnancy medication, embryo freezing and storage, any fees a clinic passes to patients for the cost of regulation. You should set out an indicative price range where costs may depend on individual circumstances and are not known in advance (e.g. some medication costs).			
13. Any proposed changes to the agreed treatment plan, to cover:(a) Why the agreed treatment plan needs to change.			~
<i>(b)</i> Details about the revised treatment options.			
<i>(c)</i> Cost implications of any agreed changes to the treatment plan (for example, extra costs or refunds).			
<i>(d)</i> If applicable, details of any treatment risks.			

Material Information	Stage 1 (Research)	Stage 2 (pre- fertility treatment)	Stage 3 (Fertility treatment)
<i>(e)</i> If applicable, any costs going forward, for example, embryo storage and a frozen embryo transfer if embryo freezing is being recommended.			
14. Whether any aspects of the service will, or could be, carried out by a different clinic in the same group or another clinic and if so, by who, where and in what circumstances.	✓	✓	
15. Up to date waiting time for treatment (if applicable).		~	

Misleading Omissions

- 3.33 The information you provide should not omit or hide material information. Nor should you provide material information in a manner which is unclear, unintelligible, ambiguous or untimely.
- 3.34 Where you do so, this may constitute a misleading omission under the CPRs.³³ Examples of possible misleading omissions could include where a clinic:

(a) Omits or hides information, or only provides partial information, about treatment and costs on its website and instead directs potential patients to contact them for such information, or further information, by phone or e-mail.

³³ A 'misleading omission' may occur if you omit material information that the average consumer needs, according to the context, to make an informed transactional decision, or if you hide or provide material information in an unclear, unintelligible, or ambiguous way (Regulation 6 of the CPRs).

- (b) Omits to publish the clinic's most recent HFEA verified data on success rates.
- (c) Offers, recommends or provides information about optional add-on treatments but omits information about:
 - i. clinical evidence for such treatments, particularly where none exists or is limited in nature
 - ii. the risks associated with these add-on treatments
 - iii. the HFEA's information and traffic light system for add-on treatments.³⁴
- (d) Omits to explain why certain treatments are necessary or being recommended – for example when ICSI is being recommended and there is no known male factor problem.
- (e) Advertising donor egg treatment, but omitting the fact that most of the donor egg treatment takes place in partnership with a clinic abroad, under a different regulatory framework, or using imported eggs and/or sperm for example.
- (f) Omits to declare a conflict of interest or personal financial interest (such as commission) that a clinician may have with respect to a treatment, product or service they are offering at the clinic or where they are recommending the services of other businesses, for example businesses that offer complementary therapies, such as acupuncture therapy.³⁵
- (g) Advertises unrealistically low headline prices in order to appear very attractive to potential patients – with essential elements of treatment and costs only revealed later in the process.
- (h) On egg freezing fails to explain the effect of age on the likely outcome or the limited nature of the evidence base for the success rates for live births resulting from frozen eggs.

³⁴ www.hfea.gov.uk/treatments/treatment-add-ons

³⁵ As required by the GMC in their good medical practice document: www.gmc-uk.org/good medical practice

- (i) On donor sperm fails to explain that ICSI may be needed and why, and the additional cost involved.
- (j) Fails to provide patients with their own likely success rates **<u>after</u>** they have had the results of their diagnostic tests and scans.
- (k) Fails to provide a costed treatment plan, providing instead, for example, a generic price list.
- (I) On multi-cycle packages fails to provide full information about:
 - i. what's included and excluded from the multi-cycle package
 - ii. likely additional costs over and above the fee for the multi-cycle package
 - iii. the eligibility criteria for being accepted onto a multi-cycle package
 - iv. any time limits for completing all cycles
 - v. the clinics where treatment can take place, and the criteria for choosing these particular clinics.
- (m) Makes material information difficult to find or it is unclear, unintelligible, ambiguous or untimely through, for example, putting it on a website that is hard to navigate, providing it in a number of different places, providing links which do not navigate the user to the correct place or burying it in small print.

Misleading Actions

- 3.35 The information you provide should not contain false information. Nor should it, or its overall presentation, in any way deceive, or be likely to deceive, potential or current patients, even if the information is factually correct. You should be very conscious when describing treatments of how patients are likely to interpret what you say to avoid misleading them.
- 3.36 Providing misleading information may constitute a misleading action under the CPRs.³⁶ Examples of possible misleading actions could include where a clinic:

³⁶Regulation 5 of the CPRs. In addition to engaging in a misleading commercial practice under the CPRs, you may also infringe the Advertising Standards Authority's self-regulatory 'UK Code of Non-broadcast Advertising and Direct
- (a) Makes unsubstantiated claims that compare a clinic favourably to others, for example, 'best centre in London' or 'best success rates'.
- *(b)* Advertises and sells IVF treatment as 'natural IVF', 'mild IVF', 'IVF light' or similar, when it involves the same medical procedures as standard IVF.
- (c) On success rates:
 - i. Claims that success rates are better than they are by, for example,
 - relying on more favourable but out of date results
 - promoting the results of a subset of patients, whose results are more favourable, in a way that suggest such rates are more broadly applicable to a wider range of patients
 - when part of a group, only giving prominence to the more favourable results of a clinic within that group
 - ii. Giving prominence to clinical pregnancy rates rather than live births rates.
- (*d*) Advertises unrealistically low headline prices in order to appear very attractive to potential patients with essential elements of treatment and costs only revealed later in the process.
- (e) Makes false or unsubstantiated claims about the success or effectiveness of treatments, such as egg freezing and/or optional add-on treatments.
- (*f*) When advertising favourable comparisons with the costs of other clinics, fails to indicate the likely total cost for a typical cycle based on up to date information relating to the costs of the most recent patients.
- (g) Presents a treatment or test as standard in the sector or medically necessary when this is not the case. For example, ICSI, which treats male infertility, is not a routine treatment needed by all patients and pre-

and Promotional Marketing' (CAP Code). Adherence to the CAP Code is required in the HFEA Code (paragraph 4.8).

implementation genetic testing and sperm DNA fragmentation testing are optional add-on tests and are also not routine in the sector.

- (*h*) Misrepresents an add-on treatment as new or innovative, when in fact it has been around for a number of years.
- (i) Makes false claims about the availability of donor eggs, sperm and/or embryos and where these have been obtained (UK or abroad). This includes where claims are made about having gametes available from particular ethnic groups.
- (j) Misrepresents the quality of donor sperm being sold.
- (*k*) Promotes donors' characteristics, which could be attractive to potential recipients whilst omitting other, potentially less attractive characteristics.
- (*I*) On multi-cycle packages misrepresents the benefits of the packages³⁷, for example, by:
 - i. Advertising cost savings but not comparing prices on a like for like basis.
 - ii. Implying that all patients may benefit from the advertised claims of 100% refunds where this may not be the case, for example **bold** claims of 100% refund when small print says "up to" 100%.

The CCRs requirements

3.37 In addition to the information requirements set out above, consumer law also requires that you provide certain information to patients³⁸ before they are bound by a contract with you.³⁹ Although there is some overlap between the information requirements under the CPRs and the CCRs they are not the same, and compliance with one does not ensure compliance with the other.

³⁷ This includes claims made on your website which relate to services offered by third party providers.

³⁸ The CCR pre-contract information requirements do not apply to contracts for the supply of medicinal products, e.g. drugs.

³⁹ A contract for these purposes is between a trader and a consumer. The CMA does not consider this would include where the treatment is being provided to a patient for free by the NHS.

- 3.38 The 'pre-contract information' that you need to provide and how you need to provide it will depend on how the contract is entered into with the patient. For the purposes of the CCRs, a patient's contract is likely to be a distance contact (where for example it is entered into over the phone or by email) or an on-premises contract (where it is entered into in person at your clinic or following a face to face meeting with a patient at your clinic).
- 3.39 There may be more than one contract that you enter into with patients during the patient journey. For example, the CMA would generally expect there to be a contract for the initial consultation, scans and tests (which is likely to be a 'distance contract') ⁴⁰, and then a separate contract, if the patient decides to proceed, for the fertility treatment itself, (which is likely to be an on-premises contract, unless there is no in person face-to face contact). But there could be other contracts, for example, if, after the initial consultation and diagnostic scans and tests, the patient agrees to pay for additional investigations that are deemed medically necessary based on their earlier results.
- 3.40 The pre-contract information, which you need to give or make available⁴¹ to potential patients in a clear and comprehensive manner before they are bound by your contract⁴² is the following:

Table 2 – Pre-contract Information

Pre-contract Information

(Points 1 to 5 are relevant for on-premises contracts. Points 1 to 6 are relevant for distance contracts)

 ⁴⁰ A contract will exist even if a document is not provided that looks like a contract. Contracts can be made orally, partly in writing and partly orally. A contract can also be implied from the conduct of both clinic and patient.
 ⁴¹ One way of achieving this is to provide the contract and relevant pre-contract information in writing to patients to read (and take away if desired) before they agree to be bound by it. For the purposes of the CCRs, pre-contract information is only 'made available' if the patient can reasonably be expected to know how to access it.
 ⁴² For on-premises contracts, the full list of information to provide is contained in Schedule 1 CCRs. For distance contracts, the full list of information to provide is contained in Schedule 1 CCRs sets out the information to provide for distance contracts where the means of distance communication limits space or time.

- 1. The identity of the clinic (such as the clinic's trading name), the geographical address at which the clinic is established and the clinic's telephone number.
- 2. The main characteristics of the service you will provide.⁴³ You must give as much information as the means of communication allows.
- 3. The total price of the service, inclusive of taxes, or where the nature of the service is such that the price cannot reasonably be calculated in advance, the manner in which the price is to be calculated.
- 4. Where applicable, the arrangements for payment by the patient, delivery, performance, and the time by which the clinic undertakes to deliver the service, i.e. the initial consultation and diagnostic scans and tests or the fertility treatment.
- 5. Where applicable, the clinic's complaint handling policy.
- 6. For distance contracts only:⁴⁴
- (a) In addition to the identity and contact information outlined in 1 above and, where available, the clinic's fax number and e-mail address, to enable the patient to contact the trader quickly and communicate efficiently.
- *(b)* That the patient has a right to cancel⁴⁵ the contract within the cancellation period without giving any reason;⁴⁶ how they can exercise their right to

⁴³The CMA considers this should include you providing the names of the treatments and what they involve.
⁴⁴Where you agree a distance contract with a patient, the CCRs require that you provide a confirmation of the distance contract to the patient in a durable medium. An example would be an email with documents attached that a patient can later refer to. A website link would not be a durable medium as websites may be changed and so would not be a permanent record of what the patient had been given.

⁴⁵A patient will have a statutory right to cancel a distance contract except in limited circumstances. There is no statutory right to cancel a contract to the extent it is for the supply of prescribed medicine.

⁴⁶ The normal cancellation period ends at the end of the 14 days after the day on which the contract is entered into. If the patient is not informed of their right to cancel, the cancellation period will be extended.

cancel; the circumstances in which their right to cancel is lost;⁴⁷ and the consequences of exercising their right to cancel where they have expressly requested the service starts during the cancellation period, namely that the patient is required to pay the clinic reasonable costs for services already supplied.

- (c) Where applicable, the existence and the conditions of deposits or other financial guarantees to be paid or provided by the patient at the request of the clinic.
- (*d*) Where the clinic is acting on behalf of another clinic, the geographical address and identity of that other clinic.
- (e) If different from the address provided in relation to point (d) above, the geographical address of the place of business of the clinic, and, where the clinic acts on behalf of another clinic, the geographical address of the place of business of that other clinic, where the patient can address any complaints.

Making changes to the pre-contract information

3.41 Consumer law provides that the pre-contract information you provide to a potential patient is to be treated as a term of the contract that you subsequently enter into with them.⁴⁸ It is therefore important for you to ensure that the pre-contract information is accurate and up to date, because otherwise you may breach the terms of your contract with your patient. This may be particularly relevant where you are relying on pre-contract information that is provided on your website⁴⁹ or in pre-printed leaflets and marketing materials.

⁴⁷ A patient loses their right to cancel where: (a) they expressly request the treatment is provided before expiry of the 14 day cancellation period; (b) they acknowledge they will lose their cancellation rights if the treatment is fully provided; and (c) a clinic fully provides the treatment.

⁴⁸ Contract law governs when a contract is concluded (i.e. entered into). The most obvious example is where a clinic provides a patient with written contractual terms and the patient then signs such terms to confirm their agreement. Contracts can also be made orally, partly in writing and partly orally and implied from the conduct of both clinic and patient.

⁴⁹ For example, in relation to the steps to be followed as part of any complaints handling process.

- 3.42 Consumer law provides that you cannot rely on any change to the pre-contract information provided to a patient (whether such a change takes place before or after the contract is entered into) unless that change has been expressly agreed between you and your patient. In practical terms, this means you will need to highlight changes to pre-contract information promptly and obtain the patient's consent before proceeding on the basis of the change. This may be particularly important, for example, if you are updating a standard price list that has previously been provided to the patient.
- 3.43 Where a change to pre-contractual information is made after a contract has been entered into, there may be certain circumstances in which you can rely on a variation clause to agree such changes with a patient. However, any such clause must be fair in accordance with unfair terms legislation. This is discussed further at paragraphs 4.26 to 4.36 in the next chapter, Treating Patients Fairly.

4. Treating Patients Fairly

4.1 This section sets out the CMA's views on the steps clinics should take to ensure their business practices, terms and complaint handling processes are fair and comply with consumer law obligations.

A. Ensuring that commercial practices are fair

- 4.2 As set out at Annex A, the CPRs prohibit clinics from engaging in commercial practices which are unfair. This includes prohibitions against commercial practices which amount to misleading actions and/or misleading omissions. The CPRs also prohibit commercial practices which contravene the requirements of 'professional diligence' and which are likely to appreciably impair the average patients' ability to make an informed decision, and are likely to cause them to take a different decision as a result.
- 4.3 As explained at paragraph 1.9 of Annex A, 'professional diligence' is an objective standard of special skill and care which a clinic may reasonably be expected to exercise towards patients, and which is commensurate with either honest market practice or the general principle of good faith in the fertility sector. It is intended to reflect what patients would reasonably expect of a clinic.
- 4.4 To the extent there is poor current practice across the fertility sector, this will not amount to the objective standard of professional diligence, as this is not what a reasonable patient would expect of a clinic that is acting in accordance with honest market practice or good faith.
- 4.5 As set out at paragraphs 2.25 to 2.26, there are a number of sector-specific or relevant medical professional laws, regulations and standards applicable in the fertility sector which are likely to inform the standard of professional diligence that you are expected to meet. These include those published by the HFEA, the General Medical Council and the Health and Care Professions Council. Consequently, if your commercial practices breach these standards⁵⁰, you may well also breach the requirements of professional diligence under the CPRs.

⁵⁰ Complying with the standards set out in these codes and guidance may not be sufficient of itself in order for a clinic to be acting in accordance with the requirements of professional diligence.

- 4.6 Furthermore, where you breach other provisions of the CPRs, for example the prohibitions against misleading actions or omissions, this may also demonstrate your failure to comply with the requirements of professional diligence.
- 4.7 As a result, you will need to consider how the consumer law obligations relating to professional diligence impact the wide ranging aspects of the services you provide. Below are some indicative examples of where clinics' commercial practices may fail to comply with the requirements of professional diligence:
 - The routine use of ICSI, either for all patients, or for all patients using donor sperm, regardless of the sperm's quality once it has been thawed;
 - The routine over-testing of patients where there is no robust evidence to suggest such tests are beneficial to the patients' individual circumstances and their chances of having a successful live birth. This may involve carrying out, and charging for, tests with unnecessary frequency;⁵¹
 - Referring patients to a nutritionist, or recommending the purchase of supplements where there is no evidence to suggest that either course of action is warranted;
 - Proactively offering to sell add-on treatments after the treatment plan has been agreed in circumstances where there is no evidence to demonstrate a material change in the patient's circumstances.

B. Ensuring that terms and conditions between clinics and patients are fair

4.8 Where a consumer is paying for goods or services there will be a contract between the parties which covers the terms of the service or nature of the goods

⁵¹ For example, this may include pre-implantation genetic testing, sperm DNA fragmentation testing and Natural Killer cell testing.

to be supplied.⁵² This is the case, even when that service is a medical one and the consumer is also a patient.

4.9 Where 'terms' are referred to in this section, this includes all wording which gives rise to an obligation or right between the clinic and the patient. This wording may be contained in contracts, agreements, conditions, policies, notices⁵³ and regulations.⁵⁴ Unfair terms legislation (Part 2 of the CRA 2015) will apply to all your terms and as such all terms are potentially subject to a test of fairness under the legislation.

Examples of the key pieces of information that the CMA would normally expect to be included within the terms are set out below:¹

- (a) An explanation of the services (and the price) that are to be provided to patients under the contract;
- (b) Any important conditions attached to the service being offered for example if there is a time limit on completing the treatment or if patients are required to purchase medication directly from the clinic or a chosen supplier;
- *(c)* Information about why and how the treatment (and who provides the treatment) may vary;
- (d) Information about why and how the agreed price may vary in the future (in circumstances where no changes are made to the agreed treatment plan). For example, for contracts for egg or embryo storage, which may last a number of years;
- *(e)* The name and location(s) of the clinic(s) where treatment will be carried out, including, where applicable, whether a partner or third-party business will be carrying out any aspects of the service;

⁵² This guidance should be read in conjunction with the CMA's Unfair Terms Guidance - see CMA 37.

⁵³ It is important to note that a term in a notice need not technically have contractual effect for it to be challenged as unfair.

⁵⁴ Depending on the circumstances, it may also be contained in your correspondence with patients, brochures, information packs, on your website, on a poster in your clinic, or even word of mouth such as what a staff member might say to prospective patients at an open evening or during a consultation before an agreement has been reached to proceed with treatment.

- (f) How and when payments are to be made and to whom (where third parties will be providing some services);
- (g) Cancellations and refund policies;
- (h) Complaints-handling policy.
- 4.10 You should ensure you do not use terms that are unfair. As described at paragraph 2.13, patients are likely to be in a vulnerable position compared to you. The vulnerable circumstances of patients, at the time the contract is agreed, and when any term is being enforced subsequently, will be important considerations for a court when assessing the fairness of your terms.
- 4.11 If a term is found by a court to be unfair, it will not be binding on patients and cannot be enforced. Patients may also be able to rely upon the unfair terms legislation in any legal proceedings they bring themselves against a clinic or in defence of a claim where a clinic tries to enforce an unfair term.

Ensuring that your terms are user-friendly, clear and unambiguous

4.12 Terms and conditions should be easily located by and accessible to prospective patients. They should also be brought to prospective patients' attention in a timely manner before they agree to any treatment (for example, when arranging an initial consultation and / or undergoing tests or scans and / or when agreeing a costed treatment plan).⁵⁵ Patients should always have an appropriate opportunity to read and understand terms before they accept them. This is particularly important in this sector as the personal and complex nature of the purchase means patients are already having to process a significant amount of information and their contractual rights are unlikely to be at the forefront of their thinking.

⁵⁵ In order to comply with information requirements under the CPRs (see paragraph 3.10 and 3.11), the CMA would also expect patients to be clearly signposted to important information, for example via your website, in brochures and during visits to a clinic.

- 4.13 Furthermore, where treatment involves a number of stages, the CMA would expect clinics to direct patients to the terms and conditions that are directly relevant to that particular stage of treatment.
- 4.14 Unfair terms legislation requires that your written terms are transparent, i.e. written in plain and intelligible language and are legible⁵⁶ the wording used in your terms should be simple, clear and informative, so that patients can genuinely understand their rights and obligations before agreeing to them.⁵⁷

Terms are more likely to be clear and unambiguous where you:

- (a) Set out all the rights and obligations arising under the contract. Where you fail to do this, terms may not be incorporated into the contract and may be unenforceable against patients;
- *(b)* Include upfront 'key facts' sections or executive summaries, highlighting particularly surprising or important terms at the beginning;
- (c) Are written in plain and simple language that an ordinary person would understand, avoiding legal jargon and where necessary explaining any medical terms;
- (d) Are clear about their meaning, to avoid any ambiguity or confusion;
- (e) Use meaningful headings to make your terms easy to navigate.
- 4.15 As well as helping you to comply with your obligations under consumer law, setting out your terms clearly will save you time in answering questions and reduce the likelihood of disputes.

⁵⁶ Sections 68(1) and (2) CRA 2015.

⁵⁷ The Court of Justice of the European Union has explained that terms should not only make grammatical sense but must put the consumer into the position of being able 'to evaluate, on the basis of clear, intelligible criteria, the economic consequences for him which derive from it [the term]' (see Case C-26/13 Árpád Kásler and Hajnalka Káslerné Rábai v OTP Jelzálogbank Zrt., at paragraph 75).

Binding patients to hidden terms

- 4.16 As set out in paragraph 4.12 above, you should ensure that your standard terms and conditions are brought to the attention of prospective patients in good time. This is so that they have a real opportunity to read and understand their rights and obligations under the contract, before being bound by them.
- 4.17 A provision that purports to bind patients to terms that they have not had the chance to become familiar with or understand, may be unfair under consumer law. In the CMA's view, this may occur where, for example:
 - (a) Terms are deemed to have been accepted by patients by signing a document, such as a costed treatment plan, in circumstances where different terms are provided in a variety of locations, making them difficult to find and review. The CMA has been made aware of examples where terms are provided on different pages of a clinic's website, in separate documents provided to patients, and some provided verbally during face to face meetings;
 - (b) Terms are only provided after patients have entered into a contract (whether in writing or not) for example for tests, procedures or consultations. In these circumstances, patients will not be aware of key terms of the contract nor had the opportunity to consider these and other applicable terms;
 - (c) Terms are written in language that is difficult to understand (for example, using jargon or unfamiliar medical terms without explanation).
- 4.18 You should also ensure that any terms that may be particularly surprising or important, and especially those whose significance may be missed, are specifically brought to the patient's attention.⁵⁸ Non-exhaustive examples of such terms could include:
 - (a) Terms restricting the time period during which treatment must be completed, for example when purchasing a multi-cycle package. A term which sets a deadline for completing treatment which may be

⁵⁸ The CMA notes, however, that terms will still need to be fair even if they are brought to the attention of patients. What is a fair term is discussed further in paragraphs 4.20-4.25.

unachievable for some patients may be unfair (see also paragraphs 4.50-4.52). It is important that patients are made aware of factors which may affect their ability to complete treatment within a set time period;

- (b) A term that requires patients to purchase medication from the clinic or from a supplier chosen by the clinic, especially where this may result in higher medication charges than if purchased independently from a pharmacy of the patient's choice.⁵⁹ The CMA recognises that in some scenarios patients may benefit from purchasing their medication via the clinic or their chosen supplier. For example, where the bargaining power of the clinic means they can offer the product at a lower price than competing providers or where there is a need to provide medication at short notice. However, the CMA is also aware of instances where patients would have been able to purchase medication from an independent supplier at a significantly reduced price;
- (c) A term that allows the clinic to refer patients to an alternative clinic for treatment or parts of treatment. When choosing a clinic, patients are likely to have factored in information which is directly relevant to their chosen clinic, for example the success rates for the clinic they understood would be providing the treatment. If any part of their treatment may be carried out by another clinic, the contract must set out clearly the circumstances in which this may happen and this must be brought to the patient's attention before patients commit to treatment;
- (d) Terms that provide the clinic with an unduly wide discretion to substitute clinicians, with or without notice, particularly where the continuous care by the same clinician is likely to be important to the patient.
- 4.19 Complying with the information requirements set out in chapter 3 and ensuring that your terms are user-friendly and transparent will help them to be fair.However, your terms also need to be substantively fair (see below).

⁵⁹ The CMA considers that even where such a clause is drawn to the attention of consumers, it may still be unfair. This will depend on all of the circumstances but one important factor will be the extent of any potential price differential.

What is an unfair term?

- 4.20 A term will be unfair if 'contrary to the requirement of good faith, it causes a significant imbalance⁶⁰ in the parties' rights and obligations under the contract to the detriment of the patient'.⁶¹
- 4.21 As the significant imbalance is concerned with the parties' rights and obligations under the contract, the focus of the fairness assessment is on potential, rather than actual, outcomes for patients as a result of the contractual term.
- 4.22 The concept of 'good faith' is intended to have a broad application and to ensure that the fairness assessment includes '*an overall evaluation of the different interests involved*'. The requirement of good faith embodies a general principle of 'fair and open dealing'. It looks to good standards of commercial morality and practice.
- 4.23 In terms of fair dealing, this requires that clinics should not, whether deliberately or unconsciously, take advantage of the patient's circumstances to their detriment. When determining the patient's circumstances⁶² clinics should factor in the typical characteristics of patients in this sector, such as a lack of experience or unfamiliarity with medical procedures and their willingness to do all they can to increase their chances of having a baby. Clinics also need to actively take the legitimate interests of their patients into account when setting their terms. They should consider whether it is reasonable to assume that patients would agree to such terms if the respective negotiating positions of the clinic and patient were equal.⁶³

⁶⁰ In assessing whether the 'significant imbalance' test is met, it is necessary to consider whether the wording used tilts the rights and responsibilities between the patient and clinic too much in favour of the clinic. For instance, by granting the clinic a beneficial option or discretion or power, or by imposing on the consumer a disadvantageous burden or risk or duty, whether financial or non-financial.

⁶¹ Section 62(4) CRA 2015. The assessment of fairness is carried out having regard to the nature of the goods or services supplied, all the circumstances attending the conclusion of the contract and the contract as a whole. (Section 62(5) CRA 2015)

⁶² Section 62(5) CRA 2015 – "In assessing fairness, a court will: (a) take into account the nature of the subject matter of the contract; and (b) refer to all the circumstances existing when the term was agreed and to all of the other terms of the contract or of any other contract on which it depends".

⁶³ See CJEU case C-415/11 Aziz v Caixa D'Estalvis de Catalunya, Tarragona i Manresa, at paragraphs 44, 45 and 69.

- 4.24 In terms of open dealing, terms should be '*expressed fully, clearly and legibly, containing no concealed pitfalls or traps. Appropriate prominence should be given to terms which might operate disadvantageously*⁷⁶⁴ to patients. You should not assume that patients can identify terms which are important or which may operate to their disadvantage.⁶⁵
- 4.25 The following sections provide examples of the types of terms that could be open to challenge for being unfair. You should note that a term that is unfair is not legally binding on patients.

Terms that allow a wide discretion to vary the service being provided

- 4.26 For your contracts to be considered fairly balanced, patients should be entitled to receive the service they expect based on the pre-contract information and the agreed terms, and not something that is, in any significant respect, different.
- 4.27 The CMA recognises that sometimes it may be necessary for you to make adjustments to the treatment being offered.
- 4.28 Consumer law requires that you specify, at the outset, the circumstances in which you may need to make changes, so that patients can foresee, when deciding whether to proceed with treatment, the circumstances in which changes may occur and understand how they may be affected. It is particularly important that this information is provided in a clear and transparent manner. However, given the nature of your contracts, in the CMA's view it is also important the potential for changes (both in terms of when changes may occur, and what the change may be) is narrow. This is because, for example, patients will often be unable or reluctant to stop treatment or switch to another clinic if they are unhappy with the change, because of the cost, stress and inconvenience involved and the potential negative impact on their health.
- 4.29 Any need for variation must be balanced against the overarching requirement that patients should be treated fairly. For example, terms that unilaterally give you a wide discretion to change the treatment you provide (including where treatments that have been agreed at the outset are later withdrawn), or allow

 ⁶⁴ Director General of Fair Trading V First National Bank, Lord Bingham of Cornhill, [2001] UKHL 52, paragraph 17
 ⁶⁵ See for example, The Office of Fair Trading v Foxtons Ltd [2009] EWHC 1681 (Ch), and Spreadex Ltd v Cochrane [2012] EWHC 1290 (Comm), at paragraph 21.

you to do so without good reasons that are specified in the contract, are likely to be unfair under consumer law. This is because clinics could seek to use them, for example, to require patients to accept unanticipated costs or reduced treatment benefits.

4.30 However, the CMA appreciates that there may be genuine reasons why treatment needs to be varied. For example, the CMA would be unlikely to object to variation on medical grounds,⁶⁶ such as where ICSI is required as the sperm sample taken on the day of egg retrieval is of poor quality but previous tests had had not shown there to be a male infertility issue. Neither would the CMA be likely to object to a variation in service where patients request and receive additional treatment(s).⁶⁷

Terms that allow a wide discretion to vary the agreed price (in circumstances where the agreed treatment plan has not changed)

4.31 Balanced contracts require that patients receive the treatment they expect, in exchange for paying a price they expect. For example, terms which give you, in effect, an unilateral, unlimited right to increase the price of your treatment after it has been agreed are likely to be unfair under consumer law. Concerns are also likely to arise where a term allows the clinic significant discretion in deciding when and by how much the price may change or where a term allows for a change to the price when the contract covers a relatively short period of time (for example, the time between agreeing a treatment plan and completing that cycle of treatment). This is especially the case where patients would have little or no practical choice but to pay the higher price or cancel their treatment (which they may be unable or extremely reluctant to do).

Examples of potentially unfair price variation terms include:

(a) 'Prices are correct as of DD/MM/YYYY but are subject to variation and review without notice'

(b) 'Prices may be subject to change'

⁶⁶ Provided that the potential for this to happen, and when and how this might affect them, is made clear to patients before agreeing to treatment, as set out at paragraphs 3.26-3.31 on information provision.

⁶⁷ Provided that the benefits and risks of any additional treatments are clearly explained to patients in a timely manner and when they are in a position to consent – see paragraphs 3.25-3.31 on information provision

- 4.32 Price increase terms need to be treated with great care, in particular so that they do not allow you to increase your prices arbitrarily. It is the CMA's view that the use of price variation terms is more likely to be appropriate where the contract covers a long period of time, such as is the case with egg or embryo storage, as it may be difficult to accurately predict how costs may fluctuate, especially where some of those costs may be outside the clinic's control.
- 4.33 As with variation terms on the service to be provided (see paragraph 4.28 above), transparency is critical, so that prospective patients can foresee changes and understand the practical implications for them.
- 4.34 Where a genuine reason for a price variation term exists, to ensure compliance with consumer law, your price variation terms must set out clearly the circumstances in which the agreed price may change and the method of calculating the change. This should enable patients to foresee, on the basis of clear, objective and intelligible criteria, the changes that may be made and evaluate the practical implications for them, before entering the contract.
- 4.35 Simply stating that your fees may go up as a result of 'increased lab costs' or 'the wider national economic picture' or merely stating that any increases will be 'cost reflective' or 'reasonable' will not make your terms fair, as patients will be unable to foresee what sort of changes such wording allows, and in what circumstances. Such vague wording also provides significant scope to make unexpected changes, to the detriment of patients and fails to recognise that, generally speaking, you are likely to be much better able to anticipate changes in your costs than patients are. For example, where you contract with patients to store their frozen embryos or eggs, a term that fails to set out in an appropriately clear and specific way the circumstances and reasons for a future price increase for storage services, along with an indication of the level of increase (e.g. RPI), is likely to be unfair.
- 4.36 You must also ensure that you provide patients with advance written notice of the change in their fees, before it takes effect, so that they may take steps to avoid the price increase, for example moving their eggs or embryos to an alternative location and / or obtaining a refund of any prepaid fees.

Ending the contract

4.37 Where your terms give you a wide discretion to end the contract,⁶⁸ whether for no reason at all or for vaguely defined reasons, such terms are likely to be unfair. This is likely to be the case even where you provide patients with advance notice and a refund of prepayments, because of the significant imbalance in rights and obligations arising under the contract.

Example of a potentially unfair term:

- (a) We may terminate the contract at any time and at our sole discretion, including for any of the following reasons
- (b) You do not comply with these terms or do not agree to any change in our terms.
- 4.38 However, you are not obliged to provide services unconditionally. In this context, fairness is more likely to be achieved where your terms allow you to end the contract only if patients are in serious breach of their obligations under the contract, where there is a genuine medical reason for not proceeding with treatment, or where it is genuinely impossible for you to continue providing treatment for reasons beyond your control (i.e. exceptional reasons).
- 4.39 The CMA considers that legitimate reasons for ending a contract could include:
 - It is the clinician's professional opinion that continuing the treatment would not be suitable based on the patient's circumstances.
 - The decision to end the contract reflects changes in the relevant laws and regulatory requirements;
 - The patient fails to provide the required consent to allow treatment to continue, or make payments in accordance with the terms of the contract without good reason.

⁶⁸ Whether by suspension or termination.

4.40 Where it is necessary to end the contract (either by the patient or the clinic) patients may be due a refund of payments made in advance or a reduction in outstanding fees. This is covered in the following section.

Cancellation and Refunds

- 4.41 Where clinics fail to provide any of the services set out in the contract, the CMA considers that consumer law will generally allow patients to obtain a refund for any prepayments, or avoid future payments where treatment is paid for in arrears. In particular, where none of the contracted services are provided, the CMA would expect a patient to be offered a full refund or to not be required to make payments that would have been due had the services been provided. Examples are where:
 - *(a)* A clinic has cancelled a contract without providing any of the agreed services;
 - (b) Patients have paid a deposit for donor egg treatment, but the clinic is unable to provide the service within the timescale set out in the contract;
 - *(c)* None of the agreed service is provided as a result of Government public health measures;
 - *(d)* The patient cancels, or is prevented from receiving any services, because Government public health measures mean they are not allowed to use the services.
- 4.42 In some instances, clinics will have provided some services but may not be able to provide all of the agreed services. For example, where:
 - (a) Patients are unable to complete their treatment for medical reasons for example where insufficient follicles are developing, no eggs are collected at retrieval, no embryo is available to transfer or as a result of ovarian hyperstimulation syndrome;
 - *(b)* Procedures that have been charged for are cancelled for non-medical reasons for example where patients chose to pay for a treatment but

the equipment or clinic staff are not available when required.

- 4.43 In the above scenarios patients will already have received some of the services they have paid for in advance, or are contracted to pay for following treatment. In those cases, the CMA considers that patients would normally be expected to pay for the services that they have received, but be entitled to a refund for the services that are not provided. Where the patient is not at fault or in breach of their obligations (as in the examples above), the CMA would normally expect a patient to obtain a refund reflecting the price of the services not provided by the clinic. For example, if no eggs are collected, this would be the cost to the patient of the embryology services following egg collection and the embryo transfer. Sometimes the price for the services not provided will be expressly stated in the information provided to patients (for example, specified in the costed treatment plan). However, in other cases the patient will have paid (or agreed to pay) a single price for a number of different services. In such a case, the CMA would expect the refund provided to patients to reflect a fair proportion of the total price paid.⁶⁹
- 4.44 Where payment was not obtained in advance, rather than providing a refund, the CMA would expect clinics to reduce the amount owed by an equivalent amount.
- 4.45 In the CMA's view, the above rights to a refund will usually apply even where patients have paid what the clinic describes as a non-refundable deposit or payment.
- 4.46 The CMA also considers that clinics should not charge an admin fee (or equivalent) for processing refunds in the above circumstances.

Examples of potentially unfair terms include:

(a) If there are no eggs or fertilisation fails, or no embryo transfer takes place, no refund will be issued.

⁶⁹ The CMA would typically expect a fair proportion of the price to reflect the costs associated with the services not provided. So, for example, if the services not provided account for 10% of the total costs associated with providing the whole bundle of services, the CMA would normally expect the refund to consumers to be 10% of the total price paid by the consumer.

(b) There is no refund offered if no eggs are collected, or that eggs are collected but are immature or do not achieve fertilisation

- (c) All services will be cancelled if you develop Covid-19 or you place yourself at risk of Covid-19 infection. You will be liable for the treatment.
- 4.47 The right to a refund (or a reduction to the amount owed by the patient) should not be diluted through terms which create disproportionate financial sanctions for patients where they cancel the contract (for example, where they change their minds about some or all of the treatment). Such sanctions may take the form of inflated termination charges or requirements to pay compensation over and above a clinic's genuine pre-estimate of loss. Consumer law considers the effects of contractual terms. Consequently, it will continue to protect patients even where a financial sanction is not framed as such.
- 4.48 Consequently, terms which set out your cancellation charges in the event of cancellation by your patients are likely to be unfair where they allow for:
 - (a) Non-refundable advance payments and cancellation charges that are calculated to cover all of the clinic's costs and loss of profit from the provision of all the services under the contract.
 - *(b)* Sliding scales of cancellation charges which allow the clinic to recover more from patients than the losses it is likely to suffer if the patient cancels.

Terms which set out your cancellation charges when consumers cancel are more likely to be fair where:

- (a) Non-refundable advance payments and cancellation charges reflect the clinic's net costs or net loss of profit resulting directly from the cancellation – for example, the clinic's actual costs minus the amount it has saved from not providing the services;
- (b) Sliding scales representing the amount to be refunded are dependent on the stage at which treatment ends, and reflect the clinic's genuine pre-estimate of loss resulting directly from the cancellation. They also help provide certainty to patients.

4.49 Regardless of whether patients or a clinic cancels the contract, where patients have a right to a refund or a reduction in price, you should not mislead or pressure them into accepting a credit note to be used against future treatment in lieu of a refund or reduction in price. Furthermore, a refund or a reduction in price should still be clearly and easily available to patients. Any restrictions that apply to a credit note (or similar), such as the period in which credits must be used or services re-booked, must also be fair and made clear to patients.

Transferring inappropriate risks to patients

- 4.50 A contractual term may be unfair if it imposes on patients a risk that the clinic should properly bear. A risk lies more appropriately with the clinic if, for instance, it is a risk patients cannot be expected to know about or the clinic can mitigate the risk more effectively than the patient.
- 4.51 For example, multi-cycle IVF or egg freezing packages which require patients to complete their treatment within an unreasonable timeframe are examples which may give rise to fairness concerns. Patients may not be in a position to know if the timescale is feasible and even if the timeframe may be feasible, patients may nonetheless be unable to meet it through no fault of their own. On the other hand, a clinic is likely to be better placed to assess a feasible timeframe, have some degree of influence over aspects of the timeframe, and is likely to be better placed than the patient to mitigate the potential consequences (e.g. financial) of failing to meet an agreed timeframe.
- 4.52 It is important to consider whether a fully informed consumer with equal bargaining strength could be expected to agree to the term. As part of the fairness assessment the CMA will also consider whether a potentially onerous term is clearly expressed and brought to the patients' attention before they enter into the contract.⁷⁰

Assigning the contract

4.53 If you transfer patients' rights under a contract to a different clinic, this is called an 'assignment' (or, in Scotland, an 'assignation').⁷¹ As a result, patients may find

⁷⁰ It's important to note that on its own, this isn't sufficient to render an otherwise unfair term fair.

⁷¹ This may arise where a clinic is purchased by a new owner.

themselves dealing with a different clinic. Where ownership of a clinic changes hands, the rights and obligations under patients' contracts are likely to transfer with it. To ensure compliance with consumer law, the patients' legal position should be unaffected by the transfer.

- 4.54 As a general rule, contracts may not be unilaterally varied in these circumstances and may only be terminated in accordance with their terms. Therefore, once the new owner is in place, the CMA would expect them to abide by the terms of the patient's contract, including the provisions on variation. If, as is typical, the seller requires a promise from the buyer in respect of any failure on the buyer's part to continue to perform ongoing business contracts, this too will be a restriction on the buyer's ability to renegotiate contracts.
- 4.55 Where terms give a clinic the right to 'assign' or 'transfer' its rights and obligations⁷² to a different clinic and where this may significantly prejudice the patient's rights, this is likely to infringe consumer law. A term is unlikely to be fair if it allows for the 'transfer' of rights and obligations that could result in, for example, existing patients having to deal with a clinic which offers an inferior service. To help you to comply with your consumer law obligations, you should ensure that you consult with patients before 'transferring' rights and obligations so that they understand the implications. You must obtain their consent to any transfer or change that may adversely affect them, and do so before it takes place.

Excluding or restricting your liability to your patients

4.56 A contractual term may be considered unfair where it unduly excludes or restricts a clinic's liability towards patients. There are examples of such terms on both the 'grey list'⁷³ and the list of terms 'blacklisted' under the CRA 2015, i.e. prohibited or deemed not to be binding.

⁷² Generally, only the benefits under the contract can be 'assigned' and not the obligations/burdens under the contract, for instance the provision of services by the trader to the consumer. In practice, parties often behave as though the burden of the contract can also be assigned. It is the CMA's view that such a course of dealing may be classified in legal terms as a novation (that is the old contract is replaced with a new contract between the consumer and the new trader on the same terms as the last) or as an assignment of the benefit of the contract coupled with the subcontracting of the obligations to the new business. What is said in this section is considered to apply whether assignment or novation is involved.

⁷³ This lists terms which may be regarded as unfair. The 'grey list' is contained in section 63(1) together with Schedule 2, Part I CRA 2015.

Examples of terms likely to be considered unfair or which are blacklisted are those which seek to:⁷⁴

- (a) Exclude or limit the clinic's liability if it fails to provide the service (i.e. treatments) which it has agreed to provide, or it fails to provide them to the required standard;
- (b) Exclude or limit patients' rights to take legal action or exercise any other legal remedy;
- (c) Exclude or limit patients' statutory rights and remedies under the CRA;⁷⁵
- (d) Exclude or limit the clinic's liability in the event of death or personal injury to patients resulting from negligence on the part of the clinic.⁷⁶
- (e) Exclude or limit the clinic's liability if it fails to provide the service (i.e. treatments) which it has agreed to provide, or it fails to provide them to the required standard;
- *(f)* Exclude or limit patients' rights to take legal action or exercise any other legal remedy;
- (g) Exclude or limit patients' statutory rights and remedies under the CRA;⁷⁷
- (*h*) Exclude or limit the clinic's liability in the event of death or personal injury to patients resulting from negligence on the part of the clinic.⁷⁸
- 4.57 In order to improve the likelihood that your contractual terms are fair, you should avoid unnecessary 'legal jargon' or vague or uncertain wording (for example, '*we*

⁷⁴ Further advice on exclusion and limitation clauses is available in CMA 37. Annex A of CMA 37 contains examples of terms which may be unfair.

⁷⁵ Blacklisted pursuant to section 57 CRA 2015.

⁷⁶ Blacklisted pursuant to section 65(1) CRA 2015.

⁷⁷ Blacklisted pursuant to section 57 CRA 2015.

⁷⁸ Blacklisted pursuant to section 65(1) CRA 2015.

may exclude or limit our liability so far as the law permits'), since the practical effect is unclear for patients.

C. Ensuring that complaint handling processes are accessible, clear and fair

- 4.58 There may be times when patients are dissatisfied with their experience at a clinic or have problems that they want investigating. It is important that you encourage and respond to feedback and demonstrate that you are committed to resolving any complaints quickly, fairly and effectively. This will help you to address the needs and expectations of patients and maintain a high standard of care and quality service.
- 4.59 Consumer law requires you to give or make available to prospective patients information about your complaint handling policy before they become bound by any contract with you.
- 4.60 To help you to comply with your consumer law obligations, you should ensure that you have a written complaint handling procedure which is:
 - Easy to find;
 - Easy to understand and use;
 - Written and followed in such a way that complaints are dealt with fairly and effectively, with due regard to the upset and worry that they could cause to patients undergoing treatment or contemplating further treatment (as well as clinic staff);
 - Applied consistently across your clinics, where you have more than one.
- 4.61 You risk infringing consumer law if your policies, practices or terms have the effect of discouraging someone from making a complaint or from escalating it if they are unhappy with how it has been dealt with.
- 4.62 Alongside your consumer law obligations, there are statutory sector-specific regulations and guidance on handling complaints that you must also follow, for example the HFEA's code of practice,⁷⁹ and the requirements of these often

⁷⁹ Section 28 of the HFEA's code of practice, www.hfea.gov.uk/code-of-practice-9th-edition-december-2019

overlap. The sector rules and guidance are relevant to assessing the standards you should follow to comply with your obligations under consumer law.



- *(e)* You acknowledge complaints quickly and ensure that complainants are kept informed at all times of the next steps in the complaints handling procedure;
- (f) You set out clear and reasonable timescales within which complainants can expect to hear back about their complaint;

- (g) You ensure that any investigation of a complaint is carried out by someone who is independent of (and not the direct subject of) the concerns raised, so as to avoid conflicts of interest;
- (*h*) You clearly explain your decision in writing (so there is a record), giving details of the outcome of the complaint and any action taken.
- 4.63 If the complainant is not satisfied with how you have handled their complaint, you should tell them about the further forms of action that are available to them under your internal complaints handling procedure (as well as explaining how they can escalate the complaint to relevant independent external bodies).
- 4.64 You should make clear in your written complaints handling procedure and decision letter that if a complainant remains dissatisfied with how you have dealt with their complaint or your decision, they have the right to escalate the complaint externally, and make them aware of how and to whom they can escalate their complaint with the relevant contact details.
- 4.65 Failing adequately to follow your own complaints handling procedure in practice or similar complaint procedures under relevant sector rules or other guidelines (for example, by failing adequately to respond to complaints or not properly investigating them) may mean that you fall below the standards of 'professional diligence' required under consumer law.
- 4.66 Under consumer law you are responsible for the actions of anyone acting in your name or on your behalf. It is not enough to have an accessible and fair complaints handling procedure; it must also be followed in practice. You should therefore ensure that your staff are trained in and have a good understanding of your complaints handling procedure, how it works, their role and responsibility in reporting and resolving complaints raised with them, and their role in supporting people if they want to make a complaint.

Annex A - Overview of legislation

- 1.1 This section gives a high-level overview of your main obligations to patients under relevant consumer protection legislation, namely:
 - The Consumer Protection from Unfair Trading Regulations 2008 (CPRs).
 - The Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 (CCRs).
 - The Consumer Rights Act 2015 (CRA).

Consumer Protection from Unfair Trading Regulations 2008 (CPRs)

- 1.2 The CPRs prohibit traders, including in this sector, fertility clinics, from using unfair commercial practices towards consumers. The term 'commercial practice' is broad in scope and time, and includes anything done in connection with the promotion, sale or supply of goods or services to consumers.
- 1.3 The CPRs set out broad rules outlining when commercial practices are unfair. Broadly speaking, the CPRs prohibit clinics from engaging in unfair practices in their dealings with patients. They prohibit misleading actions, misleading omissions and aggressive practices where they are likely to have an impact on patients' decisions. Part of the aim of these prohibitions is to ensure that patients get the information they need to make informed decisions in relation to any products and services offered by the clinic.
- 1.4 The CPRs can apply at any stage of a clinic's interaction with prospective patients and existing patients, including before they have chosen which clinic to use, when deciding whether to proceed with treatment or agreeing a treatment plan, and any time after treatment has commenced. Examples of commercial practices include the publication of promotional material in brochures and on your website, through to how you enforce your contract terms. It is important to note that you do not need to have entered a contract with a prospective patient for the CPRs to apply.
- 1.5 The CMA's general guidance on the CPRs can be found on the CMA's website.

The scope of the CPRs – practices affecting the decisions of the 'average consumer'

- 1.6 For there to be a breach of the CPRs, practices must normally have⁸⁰, or be likely to have, an effect on the 'transactional decisions'⁸¹ of the 'average consumer'.⁸² This is not confined to decisions by a patient about whether or not to sign a contract, but can include a wide range of decisions, for example whether or not to:
 - Browse your website
 - Make initial enquiries of or visit your clinic (even if they eventually choose a different clinic)
 - Pay for a consultation and/ or diagnostic tests
 - Pay for treatments, including any optional add-ons
 - Raise or pursue a complaint or concern
 - Seek a refund
 - Cancel or delay treatment

When will your practices be unfair under the CPRs?

1.7 The CPRs prohibit you from engaging in the following types of unfair practices.⁸³

The 'general prohibition' on unfairness: (Regulation 3(3), CPRs)

1.8 Regulation 3(3) of the CPRs contains the general prohibition of unfair commercial practices. A commercial practice is unfair if, amongst other things, it fails to meet the requirements of professional diligence and it appreciably impairs (or is likely to appreciably impair) an average consumer's ability to make an informed decision, causing them to take a different decision as a result.

⁸⁰ The CPRs also list 31 specific practices which will be unfair in all circumstances (Schedule 1 - the 'banned practices').

⁸¹ A 'transactional decision' is any decision taken by a consumer whether it is to act or refrain from acting concerning -(a) whether, how and on what terms to purchase, make payment in whole or in part for, retain or dispose of a

product, or (b) whether, how and on what terms to exercise a contractual right in relation to a product. ⁸² Under the CPRs, you will need to consider the needs of the average patient, taking into account

the typical characteristics of a patient in this sector, such as a lack of experience or unfamiliarity with medical procedures and their willingness to do all they can to increase their chances of having a baby.

⁸³ General guidance on the CPRs can be found on the CMA's website. This includes guidance on aggressive practices (regulation 7, CPRs) which restrict people's decision-making ability through intimidation or exploitation and the 31 specific practices that are banned in all circumstances.

- 1.9 'Professional diligence' is an objective standard of special skill and care which a clinic may reasonably be expected to exercise towards patients and which is commensurate with honest market practice or the general principle of good faith in the fertility sector. It is intended to reflect what patients would reasonably expect of a clinic.
- 1.10 There are a number of sector specific laws, regulations and standards applicable in the fertility sector. Further information on the general prohibition and examples of practices that may contravene the requirements of professional diligence are set out at paragraphs 4.2-4.7 of chapter 4 (Treating Patients Fairly).

Misleading actions and misleading omissions (Regulations 5 and 6, CPRs)

1.11 Regulations 5 and 6 of the CPRs prohibit commercial practices that are misleading (whether by action or omission), and that cause or are likely to cause the average consumer to take a transactional decision they would not otherwise have taken.

Misleading actions

1.12 You must not give patients false information about a wide range of matters listed in the CPRs⁸⁴, or present information in a deceptive way (even if it is factually correct). This includes information about the main characteristics⁸⁵ of the treatment, the price of treatment or the manner in which the price is calculated (such as what is included in any headline price and details of treatment that patients may need to pay for on top of this, for example for medication). Examples of misleading actions can be found in paragraph 3.36 of Chapter 3.

Misleading omissions

1.13 You must not mislead patients by failing to give them the information they need to make informed decisions about your services ('material information'). This includes where you omit information, or provide it in an unclear, unintelligible,

⁸⁴ The full list is at Section 5(4) of the CPRs.

⁸⁵ The main characteristics are defined at section 5(5) of the CPRs.

ambiguous or untimely manner, and it causes or is likely to cause patients to take a different decision as a result.

- 1.14 Furthermore, where you provide prospective patients with information about the characteristics and costs of fertility treatment (an 'invitation to purchase'⁸⁶), you must ensure that you provide them with the total price of your service, including any mandatory extras and, where there are additional charges that cannot reasonably be calculated in advance, the fact that such charges will or could be payable and how they will be calculated.
- 1.15 Chapter 3, *Information Provision,* sets out more detailed advice on the types of information that patients will need to make informed decisions and at what stage of the patient journey this information needs to be provided. Examples of misleading omissions can be found in paragraph 3.34.

Aggressive practices and practices considered to be unfair in all circumstances

- 1.16 The CPRs prohibit practices which are likely to significantly impair a patient's freedom of choice or conduct through the use of harassment, coercion or undue influence, and which cause or are likely to cause them to take a different decision as a result.
- 1.17 There are also 31 specific practices listed in Schedule 1 CPRs, which will be unfair in all circumstances. They include 'bait advertising' i.e. making an invitation to purchase at a specified price without disclosing the existence of reasonable grounds a clinic may have for believing it will not be able to provide treatment at that price. They also include claims that a particular treatment or product (such as complimentary medicines) can cure a particular diagnosis.

⁸⁶ The CPRs make special provision for commercial practices which amount to an 'invitation to purchase', i.e. a commercial communication which describes the characteristics of fertility treatment and the price to be paid and which thereby enables a prospective patient to decide whether to proceed with such treatment. For such communications, the CPRs specify information that is automatically to be regarded as material such that its omission is therefore a breach of the prohibition against misleading omissions.

Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013

- 1.18 Under the CCRs, clinics are required to give or make available⁸⁷ certain precontractual information to potential patients, and to do so 'in a clear and comprehensible manner'⁸⁸ before they are bound by a contract. This is set out in more detail in paragraphs 3.37 – 3.40 of Chapter 3. The CCRs also provide patients with additional cancellation rights in certain circumstances for contracts made at a distance or away from business premises. This statutory precontractual information is to be treated as legally binding on the clinic in the same way as what is said in the contract itself.
- 1.19 The CCRs apply to contracts that are 'on premises', to 'distance' contracts and to contracts made away from business premises.⁸⁹
- 1.20 A 'distance contract' is defined in the CCRs as '...a contract concluded between a trader and a consumer under an organised distance sales or service-provision scheme without the simultaneous physical presence of the trader and the consumer, with the exclusive use of one or more means of distance communication up to and including the time at which the contract is concluded.' This would include, for example, where the contract to have pre-fertility treatment diagnostic tests, scans and a consultation is agreed over the phone or online.⁹⁰
- 1.21 Contracts for fertility treatment are likely to be 'on premises' contracts⁹¹ where a patient enters into a contract with a clinic either on the clinic's premises or following an appointment on the clinic's premises. In circumstances where the patient does not visit the clinic before entering into a contract for treatment, for example if the initial consultation happens by telephone and the clinic accepts

⁸⁷ Something is made available to a patient only if that patient can reasonably be expected to know how to access it. For contracts entered into away from business premises, the required pre-contract information must be given to the patient.

⁸⁸ Unless the required information is already apparent from the context (e.g. the postal address where the patient is meeting you at that same address).

⁸⁹ For more advice see:https://www.businesscompanion.info/en/quick-guides/on-premises-sales/consumer-contractson-premises-sales

⁹⁰ Under the CCRs, where clinics agree a distance contract with a patient confirmation of the distance contract must be provided on a 'durable medium' within a reasonable time after the contract is entered into, and before treatment commences. An example of a durable medium would be an email with documents attached, which the patient can retain and use to access the documents at a later date. A website link would not be a durable medium as websites may be changed and so would not be a permanent record of what the patient had been given.

⁹¹ The CCRs define an 'on-premises contract' as "a contract which is neither off-premises nor a distance contract".

results from previous tests and scans, then the contract for the fertility treatment will be a 'distance contract' and the patient will have additional cancellation rights.

1.22 Further information about patients' cancellations rights can be found in Table 2 at paragraph 3.40 of Chapter 3. General guidance on the CCRs can be found on the Charterted Trading Standards Institute's website here.

The Consumer Rights Act 2015 (CRA)

1.23 The CRA sets out various rights and remedies for consumers (i.e. patients) in relation to your contracts for goods and services with them (Part 1). The CRA also protects them against contract terms (and notices) that could be used to give you an unfair advantage over them (Part 2).

Part 1, CRA

- 1.24 Part 1 of the CRA introduces a term in your contracts with patients that you will perform your service with reasonable care and skill. Where you fail to meet this standard, you will be in breach of contract and the CRA provides a patient with remedies over and above those available for breach of contract.⁹²
- 1.25 The CRA also 'blacklists' terms which seek to relieve you of statutory obligations you owe to patients (blacklisted terms are automatically unenforceable against patients)⁹³. This guidance covers this in more detail at paragraphs 4.56 - 4.57 of Chapter 4 (Treating Patients Fairly).

Part 2, CRA

1.26 Part 2 of the CRA aims to protect consumers against unfair contract terms and notices⁹⁴. To comply with Part 2 of the CRA you must ensure that your contract

⁹² They include the right to repeat performance / a price reduction (section 54(1) CRA 2015).

⁹³ As per section 57 CRA 2015.

⁹⁴ A consumer notice is wording that may not form part of a contract, but which relates to the rights or obligations between a clinic and patient. This could include statements made in writing or orally in your other communications – for example, brochures, welcome packs, on your website, on a poster in your clinic, or what a staff member might say to a prospective patient before they agree to IVF treatment. These statements are treated in the same way as if they were a term in your contract with residents.

terms and notices are fair. A term is unfair 'if, contrary to the requirement of good faith, it causes a significant imbalance in the parties' rights and obligations arising under the contract, to the detriment of the consumer'⁹⁵. The requirement of 'good faith' embodies a general 'principle of fair and open dealing'⁹⁶. If a term is not fair, it will not be legally binding on a patient.

- 1.27 Generally speaking, your contract terms will be unfair if they put patients at an unfair disadvantage. The law applies a 'fairness test' that starts by asking whether the wording used tilts the rights and responsibilities between the patient and clinic too much in favour of the clinic (for example, where your terms give you the right to make significant changes to the contract without the patient's consent).
- 1.28 The CRA illustrates what 'unfairness' means by listing some types of terms that are likely to be unfair. For example, your terms may be unfair if they cause or allow any of the following:
 - patients being denied full compensation when things go wrong.
 - patients losing prepayments or being denied refunds when services are not performed as agreed.
 - patients being subject to disproportionate financial sanctions or charges when they breach a term of the contract.
 - changes to the terms of the contract or service provided after the contract has been agreed, without a valid reason specified in the contract.
- 1.29 Your terms must also be transparent. This means that they should be expressed in plain and intelligible language and, when in writing, be legible. Critically, they should be easy to understand and put patients in a position where they can make informed choices about what they are signing up to.
- 1.30 Your terms should not contain concealed pitfalls or 'traps'. You should take extra steps to prominently highlight surprising or important terms and bring them to the patients' attention at the earliest opportunity, so that they understand and appreciate all the essential features of the contract before agreeing to it. In addition, your terms should not, whether deliberately or unconsciously, take advantage of the patients' circumstances to their detriment. Before setting its

⁹⁵ There are certain exemptions from the fairness test. The main exemption is commonly called 'the core exemption' and relates to terms that specify the main subject matter of the contract or set the price – provided they are transparent and prominent.

⁹⁶ Please see paragraph 4.22 for further information.

terms, a clinic should consider whether it is reasonable to assume that patients would agree to such terms if the respective negotiating positions of the clinic and patient were equal.

1.31 Further information on the steps you need to take to ensure your terms meet the fairness test and are user-friendly, clear and unambiguous is at paragraphs 4.8 – 4.25 of chapter 4 (Treating Patients Fairly). The CMA has also produced general guidance on the unfair terms provisions in Part 2 of the CRA. This guidance (and a shorter overview guide for businesses) can be found on the CMA's webpages at CMA 37.