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Dear Sir/ madam,

GMC response to CMA consultation: Self-funded IVF: consumer law and guidance

Thank you for the opportunity to respond to your consultation on 'Self-funded IVF: consumer law guidance'. The following is the response from the General Medical Council (GMC).

Given that the guidance and consultation questions relate to a range of very specific issues that lie outside our remit and direct experience, we are limiting our response to a partial answer of consultation question 2.8 (which asks about relevant professional laws, regulations or standards) by setting out the role and purpose of GMC guidance and by highlighting particular standards that are of relevance to the issues raised in the draft CMA guidance. More broadly, however, we welcome this work, which should help fertility patients make informed decisions about their treatment and protect them from poor practice.

The GMC's role

As you will be aware, the GMC regulates all doctors in the UK and our role is to protect patients and improve medical education and practice across the UK. As part of this role, we:

- decide which doctors are qualified to work in the UK
- oversee UK medical education and training
- set the standards doctors need to follow throughout their careers
- where necessary, take action to prevent a doctor from putting the safety of patients, or the public's confidence in doctors, at risk..

Our mandate is set out in the [Medical Act 1983](#), which covers:

- our statutory purpose
- governance of the GMC (including how our members are appointed)
- our responsibilities in relation to the medical education, registration and revalidation of doctors; and for giving guidance to doctors on matters of professional conduct, performance and ethics.

Role and purpose of GMC guidance

As part of our role, we publish guidance for doctors setting out the principles of good practice and the standards expected of them in the course of their work. Our standards define what makes a good doctor by setting out the professional values, knowledge, skills and behaviours required of all doctors in the UK. All doctors must be aware of and follow our guidance and they must demonstrate, through the revalidation process, that they work in line with the principles and values set out in our guidance.

We have a UK-wide remit and our guidance applies to all registered doctors, whether or not they hold a license to practise. It also applies regardless of their speciality, grade or area of work. It is therefore necessarily high level in order to be widely applicable and we expect doctors to use their professional judgement to apply the principles to the situations they face in practice. The core professional standards expected of all doctors are set out in *Good Medical Practice*, which covers fundamental aspects of a doctor's role, including working in partnership with patients and treating them with respect. We also provide detailed guidance on ethical principles that most doctors will use every day, such as consent and confidentiality, as well as specific guidance on a range of areas, including Financial and commercial arrangements and conflicts of interest.

Our guidance is neither legal nor clinical advice, although it is consistent with the law across all four nations of the UK. We also make clear that doctors must comply with the law and keep up to date with relevant developments and guidance from other bodies that affect their work (see paragraphs 11 and 12 of *Good medical practice*). A serious or persistent failure to follow our guidance, that poses a risk to patient safety or public trust in doctors, could put a doctor's registration at risk.

Relevant GMC guidance

You have asked in question 2.8 about any relevant regulations or standards. The parts of our guidance which would seem to be most relevant to the issues raised by the draft guidance can be found in [Good medical practice](#), [Decision making and consent](#) and [Financial and commercial arrangements and conflicts of interest](#).

These include standards relating to:

- doctors' duty to act with integrity and be honest and trustworthy with patients, including being clear about any limits of their knowledge
- offering treatments that are judged to be effective for the patient, based on the best available evidence
- the importance of shared decision making with patients, which will involve exploring and identifying what is important to patients and providing clear, accurate information about treatment options
- providing clear, factual information in any written or advertising materials, which don't exploit patients' vulnerability or lack of medical knowledge
- being open, clear and honest about fees and any financial interests

It is vital that the doctor patient relationship is one that is based on trust. Doctors must always be honest and trustworthy with patients and take reasonable steps to ensure the information they provide is accurate (see *Good medical practice*, paragraph 68). Our guidance makes clear that in providing clinical care, doctors have a duty to provide treatments that are judged to be effective and based on the best available evidence (see *Good medical practice*, paragraph 16 b).

In terms of decision making about treatment options, our guidance on *Decision making and consent* goes into considerable detail about how this should be a shared process between a doctor and their patient. By doing this well, doctors should be confident that they are sharing information the patient needs in order to make decisions that are right for them. As part of this, doctors must explore what matters to patients in order to help them give them the information they want or need to make decisions. This will include explaining the nature of each treatment option (including the option to take no action), the associated potential benefits and risks of harm and any uncertainties about the likely success for each option.

When recommending a particular option, doctors must try to be objective and explain their reasons for their recommendation, without putting pressure on patients to accept their advice. They should also not rely on assumptions about what information a patient might want or factors they may consider significant and they should inform patients if an option is an innovative treatment. If any part of this discussion is delegated to another member of the healthcare team, the treating doctor retains overall responsibility for ensuring that the patient has been given all relevant information to enable them to provide informed consent. Arrangements should also be in place to ensure that decisions are reviewed regularly, and that patients are clear that they can change their minds at any time about their treatment. (see paragraphs 10-13; 17-21; 25-26; 40; 45; 56-59).

In terms of financial dealings, doctors must ensure that when advertising their services, the information they publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge (*Good medical practice*, paragraph 70). Doctors must be honest with patients about financial or commercial dealings and must not allow any interests they have to affect the way they prescribe or treat patients (see paragraphs 77 and 78 of *Good medical practice* and paragraphs 14-15 and 17 of *Financial and commercial arrangements and conflicts*

of interest). Finally, in terms of fees, we make clear that doctors must be honest and open and must not exploit patients' vulnerability or lack of medical knowledge when charging fees for treatments and services (see paragraphs 3-5 of *Financial and commercial arrangements and conflicts of interest*)

The standards mentioned above are set out in full below:

Good medical practice

11: You must be familiar with guidelines and developments that affect your work.

12: You must keep up to date with, and follow, the law, our guidance and other regulations relevant to your work.

16 b): In providing clinical care you must:

- a. prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health and are satisfied that the drugs or treatment serve the patient's needs
- b. provide effective treatments based on the best available evidence

68: You must be honest and trustworthy in all your communication with patients and colleagues. This means you must make clear the limits of your knowledge and make reasonable checks to make sure any information you give is accurate.

70: When advertising your services, you must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.

77: You must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals.

78: You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.

Decision making and consent

10: You must give patients the information they want or need to make a decision. This will usually include:

- diagnosis and prognosis
- uncertainties about the diagnosis or prognosis, including options for further investigation

- options for treating or managing the condition, including the option to take no action
- the nature of each option, what would be involved, and the desired outcome
- the potential benefits, risks of harm, uncertainties about and likelihood of success for each option, including the option to take no action.
By 'harm' we mean any potential negative outcome, including a side effect or complication

11: You must try to make sure the information you share with patients about the options is objective. You should be aware of how your own preferences might influence the advice you give and the language you use. When recommending an option for treatment or care to a patient you must explain your reasons for doing so, and share information about reasonable alternatives, including the option to take no action. You must not put pressure on a patient to accept your advice.

12: You should not rely on assumptions about:

- the information a patient might want or need
- the factors a patient might consider significant
- the importance a patient might attach to different outcomes.

13: Other examples of information that might be relevant and, if so, should be shared with patients include:

- whether an option is an innovative treatment designed specifically for their benefit
- whether there is a time limit on making their decision and what the implications of delaying might be
- the names and roles of key people who will be involved in their care, and who they can contact (and how) if they have questions or concerns
- their right to refuse to take part in teaching or research
- their right to seek a second opinion
- any bills they will have to pay
- any conflicts of interest that you or your organisation may have
- any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer.

17: You should try to find out what matters to patients about their health – their wishes and fears, what activities are important to their quality of life, both personally and professionally – so you can support them to assess the likely impact of the potential outcomes for each option.

18: You must seek to explore your patient's needs, values and priorities that influence their decision making, their concerns and preferences about the options and their expectations about what treatment or care could achieve.

19: You should ask questions to encourage patients to express what matters to them, so you can identify what information about the options might influence their choice.

20: You should explore with patients what risks they would and wouldn't be prepared to take to achieve a desired outcome, and how the likelihood of a particular outcome might influence their choice.

21: You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action.

25: You must answer patients' questions honestly and accurately, and as fully as is practical in the circumstances. You must be clear about the limits of your knowledge and, if you can't answer a question, explain whether it is something you are uncertain of or something that is inherently uncertain.

26: If you are uncertain about the diagnosis, or the clinical effect a particular treatment might have, or if the available evidence of benefits and harms of an option is unclear, you should explain this to the patient. Some things will become clearer after treatment starts, so you should discuss in advance what the arrangements will be for monitoring the effect of the treatment and reviewing the decision to provide it. You should also explore in advance what options the patient might prefer in the future, depending on how treatment progresses, and the factors that might influence their choice

40: As decision making is a dynamic, ongoing process, a team-based approach can be helpful in fulfilling patients' information needs, which may change as their treatment or care progresses.

45: If part of the decision-making process has been delegated, you are still responsible for making sure that the patient has been given the information they need to make the decision ..., has had time and support to consider it, and has given their consent before you provide treatment or care. You should also check that the patient has a realistic expectation of the outcome.

56: Unless treatment or care begins immediately after a patient has given consent, there will be opportunity for a decision to be reviewed.

57: You should review a patient's decision immediately before providing treatment or care and, if treatment is ongoing, make sure there are clear arrangements in place to review decisions regularly, allowing patients opportunity to ask questions and discuss any concerns. You should also consider regularly reviewing a decision to take no action.

58: Reviewing a decision is particularly important:

- if you haven't personally had a discussion with the patient because they were initially seen by a colleague
- if significant time has passed since the decision was made
- if the patient's condition has changed
- if you have reason to believe the patient might have changed their mind
- if any aspect of the chosen treatment or care has changed
- if new information has become available about the potential benefits or risks of harm of any of the options that might make the patient choose differently.

59: You must make sure that patients are kept informed about the progress of their treatment, and you should let patients know that they can change their mind at any time.

Financial and commercial arrangements and conflicts of interest

3: You must be honest and open in any financial arrangements with patients.

4: If you charge fees you must:

- a. tell patients about your fees, if possible before seeking their consent to treatment
- b. tell patients if any part of the fee goes to another healthcare professional.

5: You must not exploit patients' vulnerability or lack of medical knowledge when charging fees for treatments and services

14: If you, or someone close to you, or your employer, has a financial or commercial interest in an organisation providing healthcare such as:

- a pharmaceutical or medical devices company
- a nursing or care home
- a pharmacy or dispensary

you must not allow that interest to affect the way you prescribe for, advise, treat, refer or commission services for patients. You must be open and honest with your patients about any such interests that could be seen to affect the way you prescribe for, advise, treat, refer or commission services for them.

15: You must not try to influence patients' choice of healthcare services to benefit you, someone close to you, or your employer. If your organisation dispenses medicines, you must not allow your financial or commercial interests to affect the way you prescribe.

17: If you plan to refer a patient for investigation, treatment or care at an organisation in which you have a financial or commercial interest, you must tell the patient about that interest and make a note of this in the patient's medical record.

I hope this is helpful.

Yours faithfully

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