Regulatory Policy Committee

HFEA Code of Practice Update July 2016

Human Fertilisation and Embryology Authority (HFEA)

RPC rating: validated

Description of proposal

The HFEA's code of practice is reviewed twice a year, to ensure that it is still relevant to the fertility sector. The assessment covers revisions from July 2016, affecting guidance on preimplantation genetic screening (PGS) and embryo testing.

The revisions affect sections of the code and associated guidance that are relevant to clinics licensed to carry out fertility treatments. There are 123 such clinics, of which 66 carry out private treatments and HFEA assumes that these will incur familiarisation costs. In practice, the guidance will only affect the 23 clinics that perform pre-implantation genetic testing; the HFEA assumes that the proportion carrying out private treatments is similar to the proportion for clinics licensed to carry out fertility treatments, and on this basis assumes 14 clinics that carry out private treatments are affected in practice.

Impacts of proposal

HFEA uses a standard cost model to estimate the costs of familiarisation and reviewing documentation to clinics. It has tested this model with a group of representatives of licensed clinics, who confirmed that it was broadly correct. It estimates that minor changes to guidance, where there are not any changes to practice, will cost 1 staff day per clinic. Moderate changes to guidance, which require some small alterations to practice, are assumed to cost between 2 to 10 staff days.

In this case, HFEA argues that the familiarisation costs are at the low end of moderate (2 days per clinic) for clinics that carry out pre-implantation genetic testing, and are small (1 day per clinic) for other clinics licensed to carry out fertility treatments. The regulator has carried out sensitivity analysis around this assumption, and shows that the EANDCB and BIT score round to zero in each of the three scenarios it has tested.

The RPC verifies the estimated equivalent annual net direct cost to business (EANDCB) of £0.0 million. This will be a qualifying regulatory provision.

Quality of submission

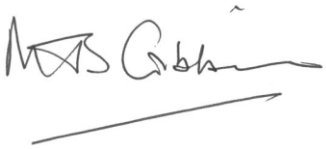
The submission is clear and provides enough information to support the estimate of the cost to business. It provides some limited discussion of indirect costs as well as calculations of the BIT score.

Departmental assessment

Classification	Qualifying regulatory provision
Equivalent annual net cost to business (EANDCB)	£0.0 million
Business net present value	£0.0 million
Societal net present value	£0.0 million

RPC assessment

Classification	Qualifying regulatory provision
EANDCB – RPC validated[1]	£0.0 million
Business Impact Target (BIT) Score[1]	£0.0 million
Small and micro business assessment	Not required



Michael Gibbons CBE, Chairman

[1] For reporting purposes, the RPC validates EANDCB and BIT score figures to the nearest £100,000.