



Department
of Health &
Social Care

NICE's technology appraisal and highly specialised technology work programmes – Charging and Appeal Panels

Consultation on charging for technology appraisal
and highly specialised technology recommendations
and miscellaneous amendments to NICE legislation

August 2018

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Author: Medicines and Pharmacy Directorate/Medicines Regulation and Prescribing Branch/NICE sponsor team/17080

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Target audience:

- Life science companies
- Representative bodies
- NHS England
- Public Health England
- Clinical Commissioning Groups
- Devolved Administrations
- Local authorities
- Patient Associations
- Members of the public

Contact details:

e-mail : mbnicechargesconsultation@dh.gsi.gov.uk

NICE sponsor team

Medicines & Pharmacy Directorate

Department of Health & Social Care

Room 2S07

Quarry House

Quarry Hill

Leeds LS2 7UE

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Executive summary

The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 ("the Regulations") provide for NICE to make technology appraisal (TA) and highly specialised technology (HST) recommendations on topics referred to it by the Secretary of State. NICE proposes to charge industry for making technology appraisal and highly specialised technology recommendations which will require amendments to the Regulations. This consultation seeks views on the proposed charging policy and procedures as outlined in Chapter 2. The intention is for NICE to be able to introduce such charges with effect from 1 April 2019.

In addition, views are also sought on a proposal to amend the Regulations to enable NICE to recruit Appeal Panel members engaged in the provision of health care in the health services across the UK; currently it can only recruit members from England.

This consultation document therefore describes:

- the background to what the Government is proposing to do and why
- how NICE proposes the new charges will operate in practice, and
- how the provisions in the draft National Institute for Health and Care Excellence (Miscellaneous Amendments) Regulations 2018 ("the amending Regulations") will work.

Consultees are invited to respond to seven questions, set out in chapter 5 below.

Charges

NICE's technology appraisal and highly specialised technology programmes, together with the associated requirement for NHS commissioners and local authorities as appropriate to fund recommended treatments, play a vital role in ensuring access for NHS patients to new and cost-effective treatments. As such, it is important that NICE's technology appraisal and highly specialised technology programmes operate in a sustainable and efficient way and in a way that allows it be more responsive to developments in the life sciences sector. The [Triennial Review](#) of NICE, published in 2015, recognised this and recommended that consideration should be given to the introduction of charges for technology appraisal and highly specialised technology recommendations as one of a set of possible measures to enable NICE to operate more efficiently.

In parallel, in recent years, there has been an increase in demand for NICE's technology appraisal and highly specialised technology guidance, at the same time as its taxpayers' funded budget, like that of other public bodies, is decreasing. In 2013/14, NICE received £66.4m from Government funding; in 2018/19 this has been reduced to £51.2 m.

NICE has therefore been considering the options set out below for the introduction of charges. Following its 2016 engagement with industry and amendments to the options considered, NICE now wishes to pursue option three – charging for technology appraisals

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but with flexibility for small businesses – and DHSC is therefore seeking views on this proposal.

Charging options:

- Option 1 – Do nothing: NICE’s technology appraisal and highly specialised technology programmes would continue to be funded by Government. Given the requirement for NICE to reduce its reliance on grant-in-aid funding, NICE’s technology appraisal or highly specialised technology programmes, or its other work, would have to be stopped or scaled back.
- Option 2 – transfer the cost of making a technology appraisal or highly specialised technology recommendation to the private life sciences sector: amend the Regulations to allow NICE to impose an upfront charge on an individual life science company calculated to recover the cost of making the recommendation for their product.
- Option 3 – as per Option 2 but with more flexibility for small companies: amend the Regulations as for Option 2 but allow NICE to impose a charge on a small company calculated on an appropriate commercial basis (i.e. at a reduced rate) and to agree that a small company may pay in instalments.

Charging will provide a more sustainable model that enables NICE to continue to flex its capacity in response to the pipeline of technologies that require assessment by NICE, to adapt its methods and processes to different types of technology, and allows it to be more responsive to developments in the life sciences sector. DHSC is considering the potential for broadening the scope of referrals to NICE which, if agreed between DHSC, NHS England, NICE and industry, could result in up to 20 additional technology appraisals per year¹.

Charging will also enable NICE to continue the full breadth of its important work, while at the same time reducing its reliance on central Government funding.

Appeal panel membership

We are proposing to amend the Regulations to enable NICE to recruit to the Appeal Panel established to hear appeals against TA and HST recommendations members who are engaged in the provision of health care in the health services across the UK rather than being limited to the health service in England. The role of an Appeal Panel member is very specialised and it is important that NICE is able to recruit from a wide enough pool of people to ensure that it is able to appoint members of a high calibre to ensure sufficient challenge to its decision making processes. This change would also be more consistent with membership of other NICE committees, such as the committees responsible for developing TA and HST recommendations, to which NICE is able to appoint members from across the UK.

¹ Please note that as these proposals are still under development, they are outside the scope of the current Impact Assessment, which has been conducted on the current number of technology assessments

1. Introduction

Technology appraisal and highly specialised technology recommendations

- 1.1 NICE is the independent, expert body that develops authoritative, evidence-based guidance on the prevention and treatment of ill-health and the promotion of good health and social care. NICE produces a range of guidance products, including technology appraisals, highly specialised technology evaluations, health and care guidelines and quality standards. NICE's guidance is based on a thorough assessment of the available evidence and is developed through wide consultation with stakeholders.
- 1.2 NICE operates two separate programmes through which it makes recommendations that require relevant health bodies (NHS England, CCGs, local authorities) to provide funding to ensure the recommended medicines and other treatments are made available to treat patients:
 - Technology Appraisals (TA) - a thorough analysis of the available evidence on clinical and cost effectiveness. Most new medicines and significant licence extensions for existing medicines are appraised by NICE.
 - Highly Specialised Technology (HST) evaluations - a thorough analysis of the costs and benefits of a technology for rare or very rare conditions. A small number of very high cost medicines for very small patient populations are evaluated through the highly specialised technology programme.
- 1.3 The funding requirement that applies to NICE's technology appraisal and highly specialised technology recommendations is reflected in the NHS Constitution as a right to NICE approved treatments: "You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are appropriate for you."
- 1.4 The processes and methods for producing NICE's recommendations are thorough and have been developed through periodic review since NICE was first established in 1999. The review process includes extensive engagement with the life sciences industry and other interested parties and public consultation. An update to the ['Guide to the processes of Technology Appraisal'](#) was published in April 2018. NICE now operates several different processes for the development of technology appraisals:
 - Single Technology Appraisal (STA): a thorough analysis of the clinical and cost effectiveness of a technology.
 - Fast Track Appraisal (FTA): the fast track process provides an equally robust but less resource-intensive appraisal process than the standard appraisal process. It is an option for technologies with an incremental cost-effectiveness ratio of less than £10,000 per Quality Adjusted Life Year (QALY) or those where a cost comparison case can be made that shows a technology is likely to provide similar or greater health benefit at similar or lower cost than technologies already recommended in technology appraisal guidance for the same indication. FTAs were introduced in April 2017 and

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the process was developed to introduce a more streamlined process for technologies that demonstrate clear cost-effectiveness.

- Rapid Review (RR): Undertaken on technologies for which a NICE recommendation already exists and which need updating due to the introduction of a Patient Access Scheme.
- Multiple Technology Appraisal (MTA): a thorough analysis of the clinical and cost effectiveness of more than one technology for the same indication. A standard MTA covers up to 3 technologies and a more complex MTA more than 3.

1.5 The number and types of appraisals may change from year to year depending on the pipeline of medicines coming to market. There has been a steady increase in the volume of technology appraisal and highly specialised technology guidance published each year, as shown by the table below.

Type of appraisal/evaluation	2013/14	2014/15	2015/16	2016/17	2017/18	(Forecast) 2018/19	(Forecast) 2019/20
STA	26	26	43	48	56	61	61
FTA/Rapid Review	2	-	1	2	7	8	8
HST	0	1	1	2	3	3	3
MTA – standard	1	3	1	1	3	4	4
MTA – complex	3	2	3	2	1	2	2
Total	32	32	49	55	70	78	78

Current NICE funding

1.6 NICE's technology appraisal and highly specialised technology programmes play a vital role in ensuring access for NHS patients to new and cost-effective treatments. It is therefore essential that these programmes operate in a sustainable and efficient way. The Triennial Review of NICE, published in 2015, recognised this and recommended that consideration be given to the introduction of charges for both programmes in order to enable NICE to operate more efficiently.

1.7 As set out in the executive summary, NICE is currently largely funded by taxpayers' money through the Department of Health & Social Care (DHSC). NICE's Government funded budget, like that of other public bodies, is decreasing. In 2013/14, NICE received £66.4m from Government funding; however in 2018/19 this has been reduced to £51.2m.

1.8 Charging will provide a more sustainable model that enables NICE to flex its capacity in response to the pipeline of technologies that require assessment by NICE, adapt its

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methods and processes to different types of technology, and allows it to be more responsive to developments in the life sciences sector. The Department of Health & Social Care (DHSC) is considering the potential for broadening the scope of referrals to NICE which, if agreed between DHSC, NHS England, NICE and industry, could result in up to 20 additional technology appraisals per year.

1.9 Charging will also enable NICE to continue the full breadth of its important work, while at the same time reducing its reliance on central Government funding.

Charging for technology appraisal and highly specialised technology recommendations

1.10 With DHSC support, NICE has been considering whether it should introduce charges for its technology appraisal and highly specialised technology programmes and, if so, what charging model would be appropriate. NICE engaged with industry on a proposed charging model in 2016 and held a number of meetings with industry representative bodies in autumn 2016. Following comments received from industry representatives, the developing charging model was changed to reduce the impact on small businesses and to include explicit provision that requires NICE to keep its charging policy and procedures (including the level of charges) under review. NICE therefore wishes to proceed with option three – charging for technology appraisals but with flexibility for small companies – and DHSC is therefore seeking views on this proposal.

1.11 Charging options:

- Option 1 – Do nothing: NICE's technology appraisal and highly specialised technology programmes would continue to be funded by Government. Given the requirement for NICE to reduce its reliance on grant-in-aid funding, NICE's technology appraisal or highly specialised technology programmes, or its other work, would have to be stopped or scaled back.
- Option 2 – transfer the cost of making a technology appraisal or highly specialised technology recommendation to the private life sciences sector: amend the Regulations to allow NICE to impose an upfront charge on an individual life science company calculated to recover the cost of making the recommendation for their product.
- Option 3 – as per Option 2 but with more flexibility for small companies: amend the Regulations as for Option 2 but allow NICE to impose a charge on a small company calculated on an appropriate commercial basis (i.e. at a reduced rate) and to agree that a small company may pay in instalments.

NICE Appeal Panels

1.12 The Regulations currently require NICE to have processes in place to hear appeals against its technology appraisal and highly specialised technology recommendations. Appeals against NICE's recommendations are heard by appeal panels that must include

- a member who has experience in the life sciences industry;

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- a member who is a patient or carer or member of an organisation that represents patients or carers; and
- a member who is engaged in the provision of health care in the health services.

1.13 The appeal process is an important part of the assessment process and can lead to topics being returned to NICE's independent Appraisal Committees for further consideration. It is therefore important that NICE is able to recruit appeal panel members of a high enough calibre to provide sufficient challenge to its decision-making.

1.14 In order to ensure that NICE has access to the fullest possible range of expertise for its appeal panels, a change in the eligibility requirements is proposed. The Regulations currently restrict the pool of potential candidates able to be members of the Appeal Panel to those who are "engaged in the provision of health care in the health services". The current definition of "[health services](#)" means that only those engaged in the provision of health care in services which must or may be provided as part of the health service in England can be members of the panel. To widen the pool of people eligible to be Appeal Panel Members we are proposing to amend the Regulations to enable people engaged in the provision of health care across the UK health services to apply.

2. Charging policies and procedures

2.1 In line with Treasury’s guidance, Managing Public Money (MPM), NICE is proposing to cover the cost of making technology appraisal and highly specialised technology recommendations on drugs, medical devices and diagnostics through charges to the companies which make or sponsor them. The table below details the proposed charges, differentiated by type of product and smaller and larger companies.

Product	Larger companies proposed 2018/19 charges (ex VAT) £000s	Small companies proposed 2018/19 charges (ex VAT) £000s
Single Technology Appraisals (STA)	126	94.5
Highly Specialised Technology (HST) evaluations	126	94.5
Fast Track Appraisals (FTA) / Rapid Reviews (RR)	88	66
Multiple Technology Appraisals (MTA) – standard	188	141
Multiple Technology Appraisals (MTA) – complex	251	188

2.2 Under these cost recovery proposals, NICE expects to generate approximately £10.5m per annum net of the 25% discount for small companies (approximately £0.3m per annum), on the assumption that there is no change in the volume or mix of recommendations developed through the different technology appraisal and highly specialised technology processes. The accompanying Impact Assessment provides more detail.

Small companies

2.3 NICE’s original proposal did not include a reduction in charges and ability to pay by instalments for small companies. A clear concern for most respondents to NICE’s engagement exercise was that the introduction of charges on a full cost recovery basis could stifle innovation by small companies, or even wipe out the anticipated profit from the technology in the case of products for small patient populations (larger companies would be able to offset this loss against other products).

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2.4 Therefore, NICE's revised proposal introduces two measures to reduce the burden on small companies and to reduce the risk of lower levels of activity:

- To provide a subsidy of 25% to small companies, in effect by funding 25% of the cost of making technology appraisal and highly specialised technology recommendations for small companies from NICE's Government funds. The effect of these proposals will be to leave approximately £0.3m of costs per annum to continue to be funded by grant-in-aid. We believe that a 25% discount represents the right level to ensure that small companies are not dissuaded from participating in the process, while being manageable for NICE within its resource envelope.
- To allow small companies to pay by instalments. Under NICE's proposed charging policy, small companies will be required to pay 40% of the charge at the outset, 50% when NICE first meets to consider the recommendation (normally around half way through the process) and 10% immediately prior to publication of the recommendation.

2.5 A lower fee for small enterprises would also complement the ask from the life sciences industry; the [life sciences industrial strategy](#) published in August 2017 said:

“NICE's funding model for technology evaluation should be set up in a way that does not stifle SME engagement” and “NICE are currently creating a new funding model for technology evaluation. When creating this funding model, NICE should consider how ... SMEs should be given a special fee structure (as in the FDA and EMA), to facilitate uptake of their products.”

2.6 The number of appraisals carried out by NICE on small company products amounts to around 10% of its total technology appraisal and highly specialised technology activity. Whilst there is a potential for the proportion to vary over time, the pharmaceutical market is dominated by large companies which reduces the risk of reduced income caused by a potential significant increase in appraisals undertaken for small companies.

2.7 We continue to believe a PAYG model is the right approach to cost recovery for NICE technology appraisal and highly specialised technology recommendations. However, should companies wish to pool their resources and pay via an intermediary, NICE would be open to such arrangements provided that it continued to allow costs to be recovered on a PAYG basis and did not increase financial risks.

2.8 Industry also asked that, should the charges be introduced, they should be reviewed after one year. The Government and NICE agree that it will be important to periodically review NICE's charging policies and procedures to ensure that they are fit for purpose and do not result in any unintended consequences. The first full year will not give a full picture so the Government's intention is to monitor the impact of the charges in the first year and review them after the second year. NICE will be required to carry out a consultation before revising its charging policies and procedures. The Department of Health & Social Care and NICE intend to include discussion on charges in the annual business planning cycle.

3. Changes to be made by the amending Regulations

3.1 The draft National Institute for Health and Care Excellence (Miscellaneous Amendments) Regulations 2018 would allow NICE to impose charges for, or in connection with, the making of a technology appraisal or highly specialised technology recommendation. They would also amend the eligibility criteria for members of the appeal panel established to hear any appeals against TA or HST recommendations.

3.2 The key provisions are as follows:

- The changes would come into force on 1st April 2019.

Regulation 8A:

- A charge for, or in connection with, the making of a technology appraisal or highly specialised technology recommendation may be imposed on anyone other than the Secretary of State or a person who the Secretary of State has directed does not have to pay the charge in relation to a recommendation or type of recommendation (regulation 8A(1)-(2)).
- The charges must be calculated on a cost recovery basis except where the payee is a small company (regulation 8A (3)-(4)).
- NICE may calculate charges for small companies as it considers to be the appropriate commercial basis (regulation 8A(5)). In practice, as described in Chapter 2, NICE is proposing to charge small companies 25% less than other companies.
- A small company is defined in accordance with the conditions specified in section 382 of the Companies Act 2006 (c.46) (regulation 8A(6)-(7))².
- NICE may refuse to make the recommendation if the payee has not paid the charge (regulation 8A(8)).
- The payee will be the person identified by NICE as requesting the recommendation (e.g. the manufacturer or sponsor of the product being appraised) (regulation 8A(9)).
- Financial year is defined in accordance with the conditions specified in section 390 of the Companies Act 2006 (regulation 8A(10) – (11)).

Regulation 8B:

- Charges must be paid at the time at which NICE requests payment, with separate provision for payment where the payee is a small company (regulation 8B(1)).

² In the relevant financial year (regulation 8A(10)), a payee is a small company if at least 2 of the following conditions are met: total value of products sold or supplied is not more than £10.2 million; the company's balance sheet is not more than £5.1 million; average number of persons employed is not more than 50.

Changes to be made by the amending Regulations

- Small companies may request in writing for charges to be paid in instalments (regulation 8(B)(2)). As described in Chapter 2, NICE is proposing to allow small companies to pay 40% of the charge at the outset, 50% when NICE first meets to consider the recommendation (normally around half way through the process) and 10% immediately prior to publication of the recommendation.

Regulation 8C:

- NICE must publish its charging policies and procedures and keep them under review. It must consult the Secretary of State and such other persons as it considers appropriate before revising them.

Regulation 8D

- NICE must refund a company any charge imposed in any case where it is unable to proceed with the making of the recommendation (except where it has incurred costs in dealing with the proposed recommendation in which case those costs may be deducted from the refund) (regulation 8D(1)-(2)). For example, a refund may be required where a drug does not receive a marketing authorisation; the company does not make an evidence submission or where NICE considers it appropriate to use the cheaper, fast track appraisal process.

Regulations 6(5) and 8E:

- Any charges imposed by NICE, including for making technology appraisal and highly specialised technology recommendations, are recoverable as a civil debt.

Regulations 6(6) and 8F:

- The Secretary of State is proposing to give NICE a direction to retain the income from its charges to cover its costs.

Regulation 10

- Appeal panels must include a member who is engaged in the provision of health care in the UK health services.

4. Statutory requirements

Statutory duties under the NHS Act 2006, the Public Sector Equality Duty and the Family Test

- 4.1 In considering the proposed changes, Ministers must comply with the Public Sector Equality Duty (PSED) and consider the Family Test. Ministers must also comply with their general duties under the National Health Service Act 2006 (NHS Act 2006), where applicable. Some further information about these duties is given below.
- 4.2 The need to comply with the PSED and consider, and where sensible and proportionate, apply the Family Test arises on each occasion that Ministers perform their public functions. The general duties in the NHS Act 2006 require the Secretary of State to have regard to certain things (such as the need to reduce health inequalities) or to act with a view to certain things (such as improving the quality of health services) whenever he is exercising functions “in relation to the health service” in England.
- 4.3 Our analysis of these duties with respect to the proposals set out in this consultation document is summarised below.

Public Sector Equality Duty (Section 149 Equality Act 2010)

- 4.4 This duty comprises three equality objectives, each of which needs to be considered separately. Ministers must have due regard to the need to:
- Eliminate unlawful discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010;
 - Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
 - Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.
- 4.5 The protected characteristics covered by this duty are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.
- 4.6 We considered the implications for each of the three equality objectives in relation to the proposals for amending the Regulations to allow NICE to charge companies for making technology appraisal and highly specialised technology recommendations in relation to their products and for extending the eligibility criteria for appeal panel members:
- Eliminate discrimination - we do not consider that the proposals negatively impact on this aspect.
 - Advance equality of opportunity - NICE's work helps to ensure that patients, including those with a protected characteristic, benefit from consistent access to the same level of treatment across the country. The proposals will allow NICE to continue the full breadth of its work at a lower cost to the taxpayer and in so doing should help achieve greater equality of opportunity. It will also give NICE greater access to potential appeal panel members thereby facilitating its work.

Statutory requirements

- Foster good relations - we do not consider that the proposals will have any negative impact on good relations between those with a protected characteristic and those without.

To promote a comprehensive health service (section 1 NHS Act 2006)

4.7 The Secretary of State is required to continue the promotion in England of a comprehensive health service designed to secure improvement:

- in the physical and mental health of the people of England; and
- the prevention, diagnosis and treatment of physical and mental illness.

4.8 The proposed measures will allow NICE to continue to make the full breadth of evidence-based recommendations that result in the funding of clinically and cost effective medicines and other treatments in England and contribute to the continued promotion of a comprehensive health service designed to secure health improvements.

To act with a view to securing continuous improvement in the quality of services (section 1A NHS Act 2006)

4.9 The Secretary of State is required to exercise his NHS functions with a view to securing continuous improvement in the quality of services provided to individuals in connection with the prevention, diagnosis or treatment of illness, or public health.

4.10 NICE plays an important role in providing authoritative, evidence-based guidance for the health and care system that is intended to drive quality improvement. The introduction of charges for making technology appraisal and highly specialised technology recommendations will enable NICE to continue the full breadth of its important work.

4.11 In addition, enabling NICE wider access to potential appeal panel members will further facilitate NICE to continue with the full breadth of its work.

4.12 We therefore believe the introduction of these charges and extended appeal panel membership will further enable NICE to contribute to Secretary of State meeting his duties to secure continuous improvement in the quality of services.

To have regard to the NHS Constitution (section 1B NHS Act 2006)

4.13 The Secretary of State must have regard to the values, principles, pledges and rights in the NHS Constitution.

4.14 The NHS Constitution reflects the right to drugs and treatments that have been recommended by NICE. The proposals, including the measures for small companies, are not expected to result in a decline in the number of products assessed or recommended by NICE.

4.15 The changes to appeal panel membership, will not impact on NHS Constitution rights.

To have regard to the need to reduce health inequalities (section 1C NHS Act 2006)

- 4.16 When exercising his functions in relation to the NHS, the Secretary of State must have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the NHS.
- 4.17 It is important to emphasise that this duty is separate from the PSED. Other socio-economic impacts need therefore to be considered such as income, social deprivation and rural isolation.
- 4.18 NICE's recommendations will continue to result in the funding of clinically and cost effective medicines and other treatments and consistent access to those treatments in England irrespective of income, social deprivation and rural isolation.

To promote autonomy (section 1D NHS Act 2006)

- 4.19 The Secretary of State must have regard to securing, so far as is consistent with the interests of the NHS:
- That any other person exercising NHS functions or providing services for its purposes is free to exercise those functions or provide those services in the manner that it considers most appropriate; and
 - That unnecessary burden is not imposed on any such person.
- 4.20 The proposed changes do not impact on NICE's freedom to provide NHS services as they see fit. It will be the responsibility of NICE to ensure that the charges are calculated to enable NICE to recover the cost of making recommendations (with an appropriate subsidy for small companies), and to keep the policy, level of charges and associated guidance under review. It will also give NICE greater access to potential appeal panel members thereby facilitating its work.

To promote research (section 1E NHS Act 2006)

- 4.21 In exercising his functions in relation to the NHS, the Secretary of State must promote:
- Research on matters relevant to the NHS; and
 - The use in the NHS of evidence obtained from research.
- 4.22 In addition, the Secretary of State is also required, under the NHS Act 2006, s266 (4) (b), to bear in mind the costs of research and development.
- 4.23 We do not consider that the proposed changes will have any bearing on NICE's use of research or evidence obtained from research.

To secure education and training (section 1F NHS Act 2006)

- 4.24 The Secretary of State must exercise his NHS (and other) functions so as to ensure that there is an effective system for the planning and delivery of education and training for the persons employed, or considering becoming employed, in the NHS or connected activities.
- 4.25 We have considered this duty in relation to the measures and none of the measures impact on the Secretary of State's functions to secure education and training.

To review treatment of providers (section 1G of the NHS Act 2006)

- 4.26 The Secretary of State is required to keep under review any matter, including taxation, which might affect the ability of health care providers to provide NHS services or the reward available to them for doing so.
- 4.27 We have considered this duty in relation to the changes being proposed and do not consider that the proposed changes will have any bearing on the ability of providers to provide NHS services.

The Family Test

- 4.28 The Secretary of State must consider and, where sensible and proportionate, apply the Family Test when making policy. The five family test questions are:
- What kinds of impact might the policy have on family formation?
 - What kind of impact will the policy have on families going through key transitions such as becoming parent, getting married, fostering or adopting, bereavement, redundancy, new caring responsibilities or the onset of a long-term health condition?
 - What impacts will the policy have on all family members' ability to play a full role in family life, including with respect to parenting and other caring responsibilities?
 - How does the policy impact families before, during and after couple separation?
 - How does the policy impact on those families most at risk of deterioration of relationship quality and breakdown?
- 4.29 We have considered the Family Test and concluded that it is not applicable to the proposed changes to the Regulations.

5. Consultation Proposals and Questions

- 5.1 The Department of Health & Social Care is consulting on amendments to the Regulations to allow NICE to charge companies for making technology appraisal and highly specialised technology recommendations relating to their products. The intention would be for NICE to introduce charges with effect from 1 April 2019.
- 5.2 The changes to the Regulations are intended to place NICE's technology appraisal and highly specialised technology evaluation programmes on a more sustainable footing that better enables NICE to respond to the wider policy landscape, while operating as efficiently as possible in the context of a smaller resource envelope. NICE is expected to generate approximately £10m per annum net of the 25% discount for small companies (approximately £0.3m per annum).
- 5.3 The Department is also consulting on amendments to the Regulations to allow NICE to appoint panel members to its appeal panels who are engaged in the provision of health services across the UK, rather than just those engaged in provision in England. The changes to the Regulations will allow NICE to be able to recruit from a wider pool of people to ensure that it is able to appoint members of a high calibre to ensure sufficient challenge to its decision making processes.
- 5.4 The previous sections explained the background and rationale for the amendments. We would welcome your views in response to the following seven questions:

Question one:

Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term, given the wider policy landscape, budgetary pressures and the need to be responsive to developments in the life sciences industry? Please explain your response, including any alternative proposals if you disagree.

Question two:

Do you agree or disagree that such charges should be calculated on a cost recovery basis? Please explain your response, including any alternative proposals if you disagree.

Question three:

Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies? Please explain your response, including any alternative proposals if you disagree.

Consultation Proposals and Questions

Question four:

Do you agree or disagree that small companies should be able to pay in instalments as proposed in paragraph 2.4 bullet 2? Please explain your response, including any alternative proposals if you disagree.

Question five:

Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging? Please explain your response, including any alternative data or assumptions if you disagree.

Question six:

Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England? Please explain your response.

Question seven:

Do you have any further comments on the proposals in this consultation document?

6. How to Respond to the Consultation

Responding to the consultation

The Department welcomes responses to all of the questions above. Please submit your responses to the questions by midnight on Friday 14th September 2018.

The preferred method of receiving your response is via the on-line consultation questionnaire, which can be found alongside this consultation document on the Department's website:

<https://www.gov.uk/government/organisations/department-of-health>

Alternatively, you may wish to e-mail your responses to the questions to:

mbnicechargesconsultation@dh.gsi.gov.uk

If you do not have internet or e-mail access, then please write to:

The NICE sponsor team
Department of Health & Social Care
Room 2S07
Quarry House
Quarry Hill
Leeds
LS2 7UE

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health & Social Care's Information Charter.

Any information received, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004.

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information you have provided we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding by the Department.

Consultation Proposals and Questions

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

Next Steps

The Department will collate and consider all responses to this consultation and publish the Minister of Health & Social Care's response in late 2018, to ensure that there is sufficient time to comply with parliamentary procedures for making legislation. The intention would be for the amending Regulations to come into force on 1 April 2019 so that NICE can introduce the new charging regime at the start of the 2019/20 financial year.