

2018 No. 1322

NATIONAL HEALTH SERVICE, ENGLAND

**The National Institute for Health and Care Excellence
(Miscellaneous Amendments) Regulations 2018**

<i>Made</i>	- - - -	<i>6th December 2018</i>
<i>Laid before Parliament</i>		<i>12th December 2018</i>
<i>Coming into force</i>	- -	<i>1st April 2019</i>

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 237(1) to (3), (5)(c) and (6) and 304(9) and (10) of the Health and Social Care Act 2012(a).

Citation and commencement

1. These Regulations may be cited as the National Institute for Health and Care Excellence (Miscellaneous Amendments) Regulations 2018 and come into force on 1st April 2019.

Amendment of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013

2.—(1) The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013(b) are amended as follows.

(2) In regulation 5 (advice, guidance, information and recommendations), in paragraph (11), omit “appraisal” in the second place where it occurs.

(3) In regulation 6 (charges for NICE advice, guidance, information or recommendations), after paragraph (4) insert—

“(5) Charges imposed by NICE under paragraph (1) are recoverable as a civil debt.

(6) NICE must pay monies received by it by virtue of paragraph (1) to the Secretary of State except to the extent that the Secretary of State directs in writing that it may retain those monies.”.

(4) After regulation 8 insert—

“Charges relating to technology appraisal recommendations and highly specialised technology recommendations

8A.—(1) NICE may impose a charge for or in connection with the making of a technology appraisal recommendation or a highly specialised technology recommendation on persons other than—

- (a) the Secretary of State;
- (b) a person identified in a direction to NICE given by the Secretary of State under paragraph (2).

(2) The Secretary of State may direct NICE in writing not to impose a charge under paragraph (1) in relation to—

- (a) a recommendation specified in the direction; or
- (b) a recommendation of a description specified in the direction.

(3) A charge imposed under paragraph (1) must be calculated to enable NICE to recover the cost of making the recommendation from the payee except—

- (a) where paragraph (4) applies; or
- (b) in any other case or classes of case in respect of which the Secretary of State directs in writing that the charge be calculated on the basis NICE considers to be the appropriate commercial basis.

(4) This paragraph applies where the charge under paragraph (1) is imposed on a payee which is a small company.

(5) Where paragraph (4) applies, a charge imposed under paragraph (1) may be calculated on the basis NICE considers to be the appropriate commercial basis.

(6) For the purposes of paragraph (4), a payee is a small company if, for the relevant financial year, at least two of the conditions in paragraph (7) are met.

(7) Those conditions are—

- (a) the turnover of the company in the relevant financial year is not more than the amount for the time being specified in item 1 in section 382(3) (qualification of company as small) of the Companies Act 2006(a);
- (b) the company’s balance sheet total (as defined in section 382(5) of that Act) in the relevant financial year is not more than the amount for the time being specified in item 2 in section 382(3) of that Act;
- (c) the average number of persons employed by the company in the relevant financial year (determined in accordance with section 382(6) of that Act) does not exceed the number for the time being specified in item 3 in section 382(3) of that Act.

(8) If the payee has not paid a charge imposed by virtue of paragraph (1), NICE may refuse to make the recommendation.

(9) The person referred to in this regulation and regulations 8B and 8D as “the payee” is the person identified by NICE as the person who, for the purposes of section 237(5)(a) of the Act, is the person requesting the recommendation (for example, the manufacturer or sponsor of a product being appraised).

(10) In paragraphs (6) and (7), “relevant financial year” means—

- (a) if the charge is imposed in the company’s first financial year, that financial year; or
- (b) in any other case, the financial year for the company before that in which the charge is imposed.

(11) In this regulation, “financial year”, in relation to a company, means the company’s financial year as determined in accordance with section 390 of the Companies Act 2006 (company’s financial year).

(a) 2006 c.46. Section 382(3) is amended by S.I. 2015/980.

Time for payment

8B.—(1) Subject to paragraph (2), a charge imposed under regulation 8A(1) must be paid at the time NICE requests payment of the charge.

(2) Where the payee is a small company for the purposes of regulation 8A(6), the payee may request in writing for that charge to be paid in instalments.

Policies and procedures relating to charges

8C.—(1) NICE must establish policies and procedures relating to the imposition of charges under regulation 8A(1).

(2) NICE must keep the policies and procedures referred to in paragraph (1) under review and may revise them as it considers appropriate.

(3) Before revising the policies and procedures by virtue of paragraph (2), NICE must consult the Secretary of State and such other persons as it considers appropriate.

Refunds

8D.—(1) NICE must, subject to paragraph (2), refund to the payee any charge imposed under regulation 8A(1) in any case where NICE is unable to proceed with the making of the recommendation.

(2) The amount to be refunded under paragraph (1) may be reduced to take account of NICE's costs incurred in dealing with the proposed recommendation.

Recovery

8E. Charges imposed by NICE under regulation 8A(1) are recoverable as a civil debt.

Payment of monies received

8F. NICE must pay monies received by it by virtue of regulation 8A(1) to the Secretary of State except to the extent that the Secretary of State directs in writing that it may retain those monies.”.

(5) In regulation 10 (NICE recommendations: appeal panel)—

(a) in paragraph (1)(c)(iii) for “health services” substitute “UK health services”;

(b) after paragraph (2) insert—

“(3) In this regulation, “UK health services” means services which must or may be provided as part of—

(a) the health service continued under section 1(1) of the National Health Service Act 2006(a);

(b) the health care provided by virtue of Health and Social Care (Reform) Act (Northern Ireland) (2009)(b);

(c) the health service within the meaning of the National Health Service (Scotland) Act 1978(c); or

(d) the health service continued under section 1(1) of the National Health Service (Wales) Act 2006(d).”.

Signed by authority of the Secretary of State for Health and Social Care.

(a) 2006 c.41.
(b) 2009 c.1 (N.I).
(c) 1978 c.29.
(d) 2006 c.42.

6th December 2018

O'Shaughnessy
Parliamentary Under-Secretary of State,
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (S.I.2013/259) (“the 2013 Regulations”).

In particular, the amendments in regulation 2(4) provide that the National Institute for Health and Care Excellence (NICE) may impose charges for, or in connection with, the making by them of technology appraisal recommendations and highly specialised technology recommendations under regulations 7 and 8 of the 2013 Regulations.

These Regulations provide that the payee of such a charge is the person identified by NICE as the person requesting the recommendation (for example the manufacturer or sponsor of a product being appraised) and further provide that NICE may refuse to make the recommendation if the payee has not paid the charge.

These Regulations also provide that those charges are to be imposed by NICE on a full cost recovery basis except in two cases. The first is where the payee is a small company within criteria specified in section 382 of the Companies Act 2006 (c.46) in which case the charges are to be imposed on the appropriate commercial basis. The second is in other cases where the Secretary of State directs that the charge may be calculated on the basis NICE considers to be the appropriate commercial basis. They also prescribe that charges payable by small companies may be paid by instalments.

These Regulations also provide that NICE must establish policies and procedures relating to the imposition of charges for such recommendations, keep them under review and consult the Secretary of State and such other persons as it considers appropriate before revising them. They also allow for refunds to be made where NICE is unable to proceed with the making of a recommendation and provide that NICE must pay monies it receives under the new provisions to the Secretary of State except to the extent that the Secretary of State directs that it may retain those monies.

Regulation 2(2) corrects a typographical error in the 2013 Regulations. Regulation 2(3) makes similar provision in the existing charging provisions in those Regulations in relation to recovery and retention of charges as will apply in relation to the new charging provisions.

These Regulations also amend regulation 10 of the 2013 Regulations so that the members of the panel that hears an appeal brought under regulation 9 of those Regulations can include a member who is engaged in the provision of health care in the health services in Wales, Scotland or Northern Ireland as well as England.

An impact assessment of the effect that this instrument will have on the costs of the private, public and voluntary sectors is available from the NICE Sponsor Team, Department of Health and Social Care, Room 2E14, Quarry House, Quarry Hill, Leeds, LS2 7UE and is annexed to the Explanatory Memorandum that is available alongside the instrument at <http://www.gov.uk/government/uploads/> []. A copy of the assessment has been placed in the library of each House of Parliament.

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