

2010 No. 554

FEES AND CHARGES

HEALTH AND SAFETY

**The Blood Safety and Quality (Fees Amendment) Regulations
2010**

Made - - - - *25th February 2010*
Laid before Parliament *4th March 2010*
Coming into force - - *1st April 2010*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(a) and section 56(1) and (2) of the Finance Act 1973(b).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to health protection measures regulating the use of material of human origin(c).

The Treasury has consented to the making of these Regulations as required by section 56(1) of the Finance Act 1973.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Blood Safety and Quality (Fees Amendment) Regulations 2010 and shall come into force on 1st April 2010.

(2) In these Regulations, “the principal Regulations” means the Blood Safety and Quality Regulations 2005(d).

Amendment of regulation 22 of the principal Regulations

2.—(1) Regulation 22 of the principal Regulations (fees) is amended as follows.

(2) In paragraph (2)—

- (a) in sub-paragraph (a), for “£3,044” substitute “£3,074”;
- (b) in sub-paragraph (b), for “£513” substitute “£518”; and

(a) 1972 c.68. Under section 57(1) of the Scotland Act 1998 (c.46), despite the transfer to Scottish Ministers of functions in relation to implementing obligations under European Union law in relation to devolved matters, the functions of the Secretary of State in relation to implementing these obligations continues to be exercisable by the Secretary of State as regards Scotland.

(b) 1973 c.51.

(c) S.I. 2004/3037.

(d) S.I. 2005/50, as amended by S.I. 2005/1098, 2532 and 2898, 2006/2013, 2007/604, 2008/525 and 941 and 2009/372 and 3307.

- (c) in sub-paragraph (c), for “£458” substitute “£463”.
- (3) In paragraph (2A)(b), for “£487” substitute “£492”.
- (4) In paragraph (3)—
 - (a) in sub-paragraph (a), for “£2,557” substitute “£2,583”; and
 - (b) in sub-paragraph (b), for “£1,279” substitute “£1,292”.
- (5) In paragraph (3A), for “£676” substitute “£683”.
- (6) In paragraph (3C)(c), for “£487” substitute “£492”.

- (7) In paragraph (5)—
 - (a) in sub-paragraph (a), for “£2,557” substitute “£2,583”; and
 - (b) in sub-paragraph (b), for “£1,279” substitute “£1,292”.
- (8) In paragraph (5B)—
 - (a) in sub-paragraph (a), for “£2,557” substitute “£2,583”; and
 - (b) in sub-paragraph (b), for “£1,279” substitute “£1,292”.

- (9) In paragraph (5C)—
 - (a) in sub-paragraph (a), for “£2,557” substitute “£2,583”; and
 - (b) in sub-paragraph (b), for “£1,279” substitute “£1,292”.

(10) Before paragraph (6) insert—
 “(5E) The fee payable by a blood establishment or a person who is responsible for the management of a hospital blood bank who gives a notification under regulation 12(1) of its desire to make written representations to, or appear before and be heard by, a person appointed by the Secretary of State, is £10,000.

- (5F) The Secretary of State will refund to that person—
- (a) 60% of that fee if the person withdraws the notification two weeks before the commencement of the hearing before the person appointed;
 - (b) 100% of that fee if, in respect of the hearing before a person appointed, the decision notified by the Secretary of State is—
 - (i) not to suspend or revoke, as the case may be, the authorisation pursuant to regulation 5;
 - (ii) to withdraw any notice served pursuant to regulation 4(8), 5 or 11; or
 - (iii) to overturn the refusal of authorisation or the imposition of any condition pursuant to regulation 4(5).”.

(11) After paragraph (7)(iib) insert—
 “(iic) the fee payable pursuant to paragraph (5E) shall be payable at the time the notification is given;”.

(12) In paragraph (9), for “The Secretary of State” substitute “Save in respect of the fee payable under paragraph (5E), the Secretary of State”.

Signed by authority of the Secretary of State for Health

22nd February 2010

Mike O’Brien
 Minister of State,
 Department of Health

We consent

25th February 2010

Tony Cunningham
Steve McCabe
 Two of the Lords Commissioners of Her Majesty’s Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Blood Safety and Quality Regulations 2005 (S.I. 2005/50) (“the principal Regulations”), which implement Directive 2002/98/EC of the European Parliament and of the Council setting out the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components^(a) and related Commission Directives^(b).

Regulation 2 amends regulation 22 of the principal Regulations to increase the fees payable by blood establishments and hospital blood banks or facilities in relation to authorisation, operation, and haemovigilance. The overall average fee increase is around 1%. It also introduces a new fee for applications under regulation 12(1) of the principal Regulations to make written representations to, or appear before and be heard by, a person appointed by the Secretary of State.

An impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ and copies have been placed in the libraries of both Houses of Parliament.

© Crown copyright 2010

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Carol Tullo, Controller of Her Majesty’s Stationery Office and Queen’s Printer of Acts of Parliament.

(a) OJ No. L33, 8.2.2003, p.30 to which amendments have been made by Regulation (EC) No. 596/2009 of the European Parliament and of the Council (OJ No. L188, 18.7.2009, p.14).
(b) Commission Directive 2004/33/EC (OJ No. L91, 30.3.2004, p.25), Commission Directive 2005/61/EC (OJ No. L256, 1.10.2005, p.32) and Commission Directive 2005/62/EC (OJ No. L256, 1.10.2005, p.41).

STATUTORY INSTRUMENTS

2010 No. 554

FEES AND CHARGES

HEALTH AND SAFETY

The Blood Safety and Quality (Fees Amendment) Regulations
2010

£4.00