STATUTORY INSTRUMENTS

1997 No. 694

FEES AND CHARGES

The Medical Devices Fees (Amendment) Regulations 1997

Made - - - -	*10th March 1997*
Laid before Parliament	*10th March 1997*
Coming into force - -	*1st April 1997*

The Secretary of State, with the consent of the Treasury, in exercise of the powers conferred on him by section 56(1) and (2) of the Finance Act 1973(**1**) and of all other powers enabling him in that behalf, hereby makes the following Regulations:—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medical Devices Fees (Amendment) Regulations 1997 and shall come into force on 1st April 1997.

(2) In these Regulations, "the principal Regulations" means the Medical Devices Fees Regulations 1995(**2**).

(3) In these Regulations, a reference to a numbered column is a reference to the column bearing that number in the Table set out in the Schedule to the principal Regulations, a reference to a fee number is a reference to the entry bearing that number in column 1 of that Table and a reference to a fee for a specified amount is a reference to the entry for that amount in column 3 of that Table.

Amendment of the Schedule to the principal Regulations

2. In column 3 there shall be substituted for the fee—

(a) "£900" where it appears against fee number 1(a), the fee "£2,200";

(b) "£650" where it appears against fee number 1(b), the fee "£1,600";

(c) "£1,300" where it appears against fee number 2(a), the fee "£2,600";

(d) "£400" where it appears against fee number 2(b), the fee "£650";

(e) "£2,700" where it appears against fee number 2(e), the fee "£3,200";

(f) "£1,600" where it appears against fee number 2(e), the fee "£2,600";

(g) "£1,600" where it appears against fee number 2(f), the fee "£2,600"; and

(**1**) 1973 c. 51.
(**2**) S.I. 1995/2487.

(h) "£160" where it appears against fee numbers 2(e) and 2(f), the fee "£185".

Amendment of regulation 6 of the principal Regulations

3. In regulation 6(1)(a) of the principal Regulations (withdrawals), there shall be substituted for the words "5 days", the words "7 days".

Signed by authority of the Secretary of State for Health

John Horam
Parliamentary Under-Secretary of State,
5th March 1997 Department of Health

We consent to the making of these Regulations.

Patrick McLoughlin
Richard Ottaway
Two of the Lords Commissioners of Her
10th March 1997 Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Fees Regulations 1995 ("the principal Regulations"). The principal Regulations prescribe the fees payable in connection with the services provided by the Department of Health pursuant to the Secretary of State's functions under Council Directives 90/385/EEC on the approximation of the laws of member States relating to active implantable medical devices (O.J. No. L189, 20.7.90, p. 17) ("the 1990 Directive") and 93/42/EEC concerning medical devices (O.J. No. L169, 12.7.93, p. 1) ("the 1993 Directive").

Regulation 2, by amending the Table of Fees set out in the Schedule to the principal Regulations, varies the fees payable for clinical investigations and applications from notified bodies. The fee for a notification of clinical investigation of a Group A (low risk) device is increased from £900 to £2,200 whilst the fee for a Group A re-notification is increased from £650 to £1,600. The fee for an application for designation as a notified body is increased from £1,300 to £2,600. The fee for a second or subsequent designation application made only to address the grounds for rejection of a previous application is increased from £400 to £650. The basic fee for an inspection of premises for the purpose of deciding whether or not the conditions specified in Annex 8 of the 1990 Directive or Annex XI of the 1993 Directive are fulfilled is increased from £2,700 to £3,200, whilst that for ensuring that the conditions continue to be fulfilled is increased from £1,600 to £2,600. The fee for the inspection of a manufacturer's premises where the notified body is undertaking any task in relation to that manufacturer is increased from £1,600 to £2,600. The half day rate for inspections is increased from £160 to £185.

Regulation 3 increases from 5 days to 7 days the period (beginning with receipt of the notice) during which a person who withdraws his notice of intended clinical investigation is only required to pay fifty per cent of the fee otherwise payable.

A compliance cost assessment is available, copies of which have been placed in the libraries of both Houses of Parliament. Copies of the assessment are also available from the Medical Devices Agency, Hannibal House, Elephant and Castle, London SE1 6TQ.