
STATUTORY INSTRUMENTS

1992 No. 635

**The National Health Service (General
Medical Services) Regulations 1992**

PART VII

MISCELLANEOUS

Determination of question whether a substance is a drug, and recovery of cost

36.—(1) Any question whether a substance ordered by a doctor for provision by a chemist was a drug the provision of which formed part of pharmaceutical services provided under the Act shall be determined under the provisions of this regulation.

(2) Where it appears to the FHSA that a question arises under sub-paragraph (1), the FHSA shall—

- (a) notify the doctor who supplied or ordered the substance of the nature of the question arising; and
- (b) invite him to state in writing, within 30 days from the date on which the notice was sent to him, whether he wishes the question to be referred to the Local Medical Committee for its opinion.

(3) The FHSA—

- (a) shall, where the doctor states that he wishes the question to be referred to the Local Medical Committee for its opinion, refer the question accordingly;
- (b) in any other case, may refer the question to the Local Medical Committee for its opinion; and
- (c) may, in any event, seek such medical or pharmaceutical advice as it thinks fit, otherwise than from the Local Medical Committee.

(4) Where the question is referred to the Local Medical Committee under the provisions of paragraph (3), that Committee shall—

- (a) furnish the doctor concerned with a statement indicating the nature of the question referred to it by the FHSA; and
- (b) give the doctor concerned a reasonable opportunity to—
 - (i) submit to it any statement in writing, and
 - (ii) appear before it and be heard by it, in connection with the question so referred.

(5) The Local Medical Committee shall—

- (a) in forming its opinion under this regulation, have regard to any information or evidence provided by the FHSA in connection with the question referred to it; and
- (b) inform the doctor and the FHSA, in writing, of its opinion, its findings of fact and its reasons for its opinion.

(6) The FHSA shall—

- (a) send notice of the question, in writing, to—
 - (i) the doctor who ordered the substance,
 - (ii) the person to whom the order was given, and
 - (iii) any other person who, in the opinion of the FHSA, has an interest in the determination of the question; and
 - (b) invite any such person to submit to the FHSA his comments in writing on that question within 30 days or within such further period as the FHSA may for reasonable cause allow.
- (7) The FHSA shall, in determining the question, have regard to any opinion obtained by it under any of the provisions of paragraphs (3) to (5), and shall—
- (a) send notice of its decision in writing to—
 - (i) the doctor concerned,
 - (ii) the Local Medical Committee, and
 - (iii) any person who submitted comments under paragraph (6); and
 - (b) where it determines that the substance in question is not a drug the provision of which formed part of pharmaceutical services, inform the doctor of his right of appeal under paragraph (8).
- (8) Where the FHSA has determined that the substance in question is not a drug the provision of which formed part of pharmaceutical services, the doctor may appeal to the Secretary of State by giving notice of appeal, within 30 days from the date on which the notice of the decision was sent to him or within such longer period as the Secretary of State may, for reasonable cause, allow.
- (9) Any notice of appeal given under this regulation shall be given in writing and shall contain a concise statement of the grounds of appeal.
- (10) The Secretary of State shall send a copy of the notice of appeal to the FHSA whose determination is appealed against and to any person who submitted comments to the FHSA under paragraph (6).
- (11) Any person to whom a copy of the notice of appeal is sent pursuant to paragraph (10) may, within 30 days from the date on which the notice was sent to him, make representations in writing to the Secretary of State on the appeal.
- (12) The Secretary of State shall require an oral hearing of the appeal before he determines it.
- (13) An oral hearing shall take place at such time and place as the Secretary of State may direct, and notice of the hearing shall be sent, not less than 14 days before the date fixed for the hearing, to the appellant and to any person who received a copy of the notice of appeal under paragraph (10).
- (14) The appellant and any person mentioned in paragraph (10) may attend and be heard in person or by Counsel, solicitor or other representative and the FHSA may be represented at the hearing by any duly authorised officer or member, or by Counsel or solicitor.
- (15) The Secretary of State shall determine the procedure at the oral hearing as he sees fit and, on determining the appeal, shall either—
- (a) allow the appeal; or
 - (b) confirm the decision of the FHSA.
- (16) The Secretary of State shall, as soon as practicable, send to the appellant and to any person mentioned in paragraph (10) notice in writing of his decision on the appeal and shall include in the notice a statement of his reasons for the decision and of his findings of fact.
- (17) Where an FHSA or, on appeal, the Secretary of State has determined that a substance was not a drug the provision of which formed part of pharmaceutical services provided under the Act,

the FHSA shall recover from the doctor who supplied or ordered the substance, by deduction from his remuneration or otherwise, an amount calculated in accordance with paragraph (19).

(18) Any amount determined as being recoverable under this regulation shall be a debt owing by the doctor to the FHSA by which it is recoverable.

(19) For the purposes of paragraph (18), the amount to be recovered in respect of the supply of any substance shall be the cost of that substance to the FHSA, including the dispensing fee payable in respect of the supply of the preparation, and where the substance was an ingredient in a preparation of which other ingredients were drugs, the amount to be recovered shall be the cost of that substance to the FHSA together with one-half of the amount of the dispensing fee payable in respect of the supply of the preparation.