DS 21/75

Department of Health and Social Security
Hannibal House Elephant and Castle London SE1 6TE

DHSS Telephone: 01-703 6380 ext 320

To
Regional Health Authorities
Area Health Authorities
Boards of Governors

Your reference

Our reference
G/P25/66B
Date
21 January 1975

Dear Sir

PRESCRIPTION CHARGES FOR DRUGS GIVEN TO OUTPATIENTS IN CLINICAL TRIALS

1. A number of representations have been received over a period of time from administrators, consultants and pharmacists in hospitals about the payment of prescription charges for drugs used in clinical trials. The subject has also been raised by the Standing Pharmaceutical Advisory Committee. The matter has now been reviewed in the light of representations received.

2. Regulation 5(1) of the NHS (Charges for Drugs and Appliances) Regulations 1974 provides that any outpatient who for the purposes of his treatment is supplied at a hospital with drugs (otherwise than for administration in the hospital) shall, unless entitled to exemption, be liable to pay a prescription charge.

3. Broadly speaking, clinical trials of drugs are of two kinds:-

(a) trials in which some of the participants are given a drug and the others are given an inert substance and the question to be answered is whether or not the drug (or drugs) under investigation has any beneficial effect, ie whether it is in fact a "treatment" at all; and

(b) trials in which no inert substance is used but in which two treatments are being compared and the issue to be settled is which treatment is the better.

4. In the case of trials falling in category (b) above, both the drugs which are being compared are supplied for the purposes of treatment and prescription charges are therefore payable by outpatients under the regulations. This applies even if all or some of the drugs are supplied free of charge by the manufacturers; the source of supply of a drug does not affect a patient's liability to pay prescription charges, which bear no relationship to the cost of any particular drug supplied. The Department recognises that patient should not be expected to pay an abnormally high number of prescription charges in circumstances where, for trial purposes, a greater number of drugs than would normally be the case are used simultaneously and in small quantities. If this were so, and if the drugs were supplied

by the hospital pharmacy, the Department would be prepared to advise that for the purposes of payment of prescription charges such a batch of trial drugs or ointments could be regarded as one item.

5. In the case of trials falling in category (a), on the other hand, neither the drug(s) nor the inert substance can be said to be supplied for the purposes of the patient's treatment. It is therefore considered that there is no statutory authority for requiring the payment of prescription charges by outpatients participating in this type of trial, and it has been decided that charges should not be levied in such cases.

6. Health authorities are asked to ensure that the question of liability to prescription charges for drugs used in clinical trials is determined in accordance with the above distinction (in the event of any trial not falling readily within either of the categories described in paragraph 3, the criterion is whether or not the drugs in question are supplied for the purposes of the patient's treatment). They are also asked to bear in mind the importance of ensuring that all drugs used in clinical trials of either category in hospitals should be kept under the control of the hospital pharmacist.

7. Six copies of this letter are enclosed. Regional/Area Administrators are asked to pass copies to the other members of the Regional/Area Team of Officers and to the Regional/Area Pharmaceutical Officer, and Secretaries of Boards of Governors are asked to pass copies of the other officers of the Board concerned.

Yours faithfully

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