STATUTORY INSTRUMENTS

1996 No. 698

NATIONAL HEALTH SERVICE, ENGLAND AND WALES

The National Health Service (Pharmaceutical Services) Amendment Regulations 1996

Made - - - - 11th March 1996
Laid before Parliament 11th March 1996
Coming into force - - 1st April 1996

The Secretary of State for Health, in exercise of powers conferred on him by sections 41, 42, 43, 49E and 126(4) of the National Health Service Act 1977(1) and of all other powers enabling him in that behalf, hereby makes the following Regulations:—

PART I

GENERAL

Citation, commencement and interpretation

- 1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) Amendment Regulations 1996 and shall come into force on 1st April 1996.
- (2) In these Regulations, "the 1992 Regulations" means the National Health Service (Pharmaceutical Services) Regulations 1992(2).

^{(1) 1977} c. 49; see section 128(1), as amended by the National Health Service and Community Care Act 1990 (c. 19) (the "the 1990 Act"), section 26(2)(g) and (i), for the definitions of "prescribed" and "regulations". Section 41 was amended by the Health Services Act 1980 (c. 53)("the 1980 Act"), sections 1 and 20(1) and Schedule 1, paragraph 53 and Schedule 7; by S.I. 1985/39, article 7(13); by the 1990 Act, Schedule 9, paragraph 18(1) and Schedule 10; by the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), section 2; and (from 1st April 1996) by the Health Authorities Act 1995 (c. 17)("the 1995 Act"), Schedule 1, paragraph 29. Section 42 was substituted by the National Health Service (Amendment) Act 1986 (c. 66), section 3(1); extended by the Health and Medicines Act 1988 (c. 49), section 17; and amended by S.I. 1987/2202, article 4, by the 1990 Act, section 12(3), and (from 1st April 1996) by the 1995 Act, Schedule 1, paragraph 30. Section 43 was amended by the 1980 Act, sections 1 and 21(2) and Schedule 1, paragraph 55; by S.I. 1985/39, article 7(15); by the 1990 Act, Schedule 9, paragraph 18(2); and (from 1st April 1996) by the 1995 Act, Schedule 1, paragraph 31. Section 49E was inserted by the National Health Service (Amendment) Act 1995 (c. 31), section 2(1). Section 126(4) was amended by the 1990 Act, section 65(2).

⁽²⁾ S.I. 1992/662, amended by S.I. 1993/2451, 1994/2402 and 1995/644.

PART II

SUSPENSION BY THE NHS TRIBUNAL

Amendment of regulation 2 of the 1992 Regulations

2. In regulation 2 of the 1992 Regulations (interpretation), in paragraph (1), after the definition of "Scheduled drug" insert—

""suspended by direction of the Tribunal" means suspended as respects the provision of pharmaceutical services by a direction of the Tribunal made pursuant to section 49A(2) or section 49B(1) of the Act(3) or to any provisions in force in Scotland or Northern Ireland corresponding to those provisions".

Amendment of regulation 17 of the 1992 Regulations

- **3.** In regulation 17 of the 1992 Regulations (removal from pharmaceutical lists), after paragraph (3) insert—
 - "(3A) A period during which the chemist was suspended by direction of the Tribunal does not count towards the period of six months referred to in paragraph (3)".

Payments to suspended chemists

4. After regulation 18 of the 1992 Regulations insert—

"Payments to suspended chemists

- **18A.**—(1) The Health Authority shall make payments to any chemist who is suspended by direction of the Tribunal in accordance with the Secretary of State's determination in relation to such payments.
- (2) The Secretary of State shall make the determination in accordance with paragraph (3) after consultation with such organisations as he may recognise as representing chemists with whom arrangements for the provision of pharmaceutical services exist, and it shall be published with the Drug Tariff.
- (3) The determination may be amended from time to time by the Secretary of State after consultation with the organisations referred to in paragraph (2), and any amendments shall also be published with the Drug Tariff.
- (4) Subject to paragraphs (5) and (6), the Secretary of State's determination shall be such as to secure that, as far as reasonably practicable, and after making adjustments for any reduction in expenses, the suspended chemist receives payments at a rate corresponding to his remuneration under the Drug Tariff (but excluding any payments made by virtue of regulation 18(1)(f) and (i)) during the 12 months ending with the direction for suspension by the Tribunal.
- (5) The Secretary of State's determination may include provision that payments in accordance with the determination are not to exceed a specified amount in any specified period.
- (6) In a case to which section 49B(3) of the Act applies, the determination shall provide for the payments to be reduced to take account of any payments which the suspended chemist receives for providing pharmaceutical services other than as a principal".

Prevention of employment of disqualified or suspended pharmacists

- **5.**—(1) Paragraph 5 of Schedule 2 to the 1992 Regulations (which says that drugs must be provided either by or under the direct supervision of a pharmacist) is amended as follows.
 - (2) In sub-paragraph (1), omit the words from "who" to the end.
 - (3) After sub-paragraph (1) insert—
 - "(1A) Where the pharmacist referred to in sub-paragraph (1) is employed by a chemist, the pharmacist must not be one—
 - (a) who, having been disqualified under section 46(2)(b) of the Act (or under any corresponding provision in force in Scotland or Northern Ireland) from inclusion in the pharmaceutical list of a Health Authority (or, in Scotland, of a Health Board or, in Northern Ireland, of a Health and Social Services Board), is also the subject of a declaration under section 46(2)(c) of the Act (or any corresponding provision in force in Scotland or Northern Ireland) that he is not fit to be engaged in any capacity in the provision of pharmaceutical services; or
 - (b) who is suspended by direction of the Tribunal, other than in a case falling within section 49B(3) of the Act.".

PART III

COMPLAINTS

Complaints against chemists

6. In Schedule 2 to the 1992 Regulations (terms of service), after paragraph 10 insert—

"Complaints

10A.—(1) Subject to sub-paragraph (2), a chemist shall establish, and operate in accordance with this paragraph, a procedure (in this paragraph and in paragraph 10B referred to as a "complaints procedure") to deal with any complaints made by or on behalf of any person to whom he has provided pharmaceutical services.

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- (2) The complaints procedure to be established by a chemist may be such that it also deals with complaints made in relation to one or more other chemists.
- (3) The complaints procedure to be established by a chemist who provides pharmaceutical services from more than one set of premises may be such that it relates to all those premises together.
- (4) A complaints procedure shall apply to complaints made in relation to any matter reasonably connected with the chemist's provision of pharmaceutical services and within the responsibility or control of—
 - (a) the chemist;
 - (b) where the chemist is a body corporate, any of its directors or former directors;
 - (c) a former partner of the chemist;
 - (d) any pharmacist employed by the chemist;
 - (e) any employee of the chemist other than one falling within sub-paragraph (d),

and in this paragraph and paragraph 10B, references to complaints are to complaints falling within this sub-paragraph.

- (5) A complaint may be made on behalf of any person with his consent, or—
 - (a) where he is under 16 years of age—
 - (i) by either parent, or in the absence of both parents, the guardian or other adult person who has care of the child, or
 - (ii) where he is in the care of an authority to whose care he has been committed under the provisions of the Children Act 1989(4) or in the care of a voluntary organisation, by that authority or voluntary organisation; or
 - (b) where he is incapable of making a complaint, by a relative or other adult person who has an interest in his welfare.
- (6) A complaint may be made as respects a person who has died by a relative or other adult person who had an interest in his welfare, or where he was as described in paragraph (a)(ii) of sub-paragraph (5), by the authority or voluntary organisation.
 - (7) A complaints procedure shall comply with the following requirements—
 - (a) the chemist must specify a person (who need not be connected with the chemist and who, in the case of an individual, may be specified by his job title) to be responsible for receiving and investigating all complaints.
 - (b) all complaints must be—
 - (i) recorded in writing.
 - (ii) acknowledged, either orally or in writing, within the period of three days (excluding Saturdays, Sundays, Christmas Day, Good Friday and bank holidays) beginning with the day on which the complaint was received by the person specified under paragraph (a), or where that is not possible as soon as reasonably practicable, and
 - (iii) properly investigated;
 - (c) within the period of 10 days (excluding Saturdays, Sundays, Christmas Day, Good Friday and bank holidays) beginning with the day on which the complaint was received by the person specified under paragraph (a) or, where that is not possible as soon as reasonably practicable, the complainant must be given a written summary of the investigation and its conclusions;
 - (d) where the investigation of the complaint requires consideration of any records relating to the person as respects whom the complaint is made, the person specified under paragraph (a) must inform him or the person acting on his behalf if the investigation will involve disclosure of information contained in those records to a person other than the chemist or a director, partner or employee of the chemist; and
 - (e) the chemist must keep a record of all complaints and copies of all correspondence relating to complaints, but such records must be kept separate from any records relating to the person by whom the complaint was made.
- (8) At each of the premises at which the chemist provides pharmaceutical services he must provide information about the complaints procedure and give the name (or title) and address of the person specified under paragraph (7)(a); and where he provides supplemental services he must provide the same information to the person referred to in regulation 16(2)(a).
- **10B.**—(1) A chemist must cooperate with any investigation of a complaint by the Health Authority in accordance with the procedures which it operates in accordance with directions

given under section 17 of the Act(5), whether the investigation follows one under the chemist's complaints procedure or not.

- (2) The cooperation required by sub-paragraph (1) includes—
 - (a) answering questions reasonably put to the chemist by the Health Authority;
 - (b) providing any information relating to the complaint reasonably required by the Health Authority; and
 - (c) attending any meeting to consider the complaint (if held at a reasonably accessible place and at a reasonable hour, and due notice has been given), if the chemist's presence at the meeting is reasonably required by the Health Authority.".

Complaints against dispensing doctors

- 7. In Schedule 2 to the 1992 Regulations (terms of service), after paragraph 13 insert—
- "14.—(1) A doctor who is authorised or required by a Health Authority under regulation 20 to provide drugs or appliances to a patient, or who otherwise provides pharmaceutical services, shall secure that the practice based complaints procedure he has established and operates in accordance with paragraph 47A of the doctors' terms of service(6) applies in relation to any matter reasonably connected with his provision of pharmaceutical services as it applies as respects his provision of general medical services.
- (2) Accordingly, paragraph 47B of those terms of service also applies in relation to complaints about such matters".

PART IV

MISCELLANEOUS

Nurse prescribing

8. In regulation 2(1A) of the 1992 Regulations(7) (which describes nurse prescribers who may issue prescription forms), in each of sub-paragraphs (a)(iii) and (b)(ii), for the words from "a fund-holding practice" to "effect" substitute "a medical practitioner whose name is included in a medical list".

Supplemental services and additional professional services

- **9.**—(1) In regulation 16 of the 1992 Regulations (supplemental services), omit paragraphs (2)(b) and (3)(b), and the word "and" and immediately preceding the latter.
- (2) In regulation 16A of the 1992 Regulations (additional professional services)(8), after sub-paragraph (b) of paragraph (2) insert—
 - "(c) keeping records in connection with drugs supplied to any person—
 - (i) who claims exemption under regulation 6(1)(c) of the National Health Service (Charges for Drugs and Appliances) Regulations 1989(9) (which provides that those aged 60 or over are exempt from prescription charges), or

⁽⁵⁾ Section 17 substituted from 1st April, 1996 by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 8.

⁽⁶⁾ Contained in Schedule 2 to S.I. 1992/635; paragraphs 47A and 47B were inserted by S.I. 1996/703.

⁽⁷⁾ Paragraph (1A) of regulation 2 was inserted by S.I. 1994/2402.

⁽⁸⁾ Regulation 16A was inserted by S.I. 1993/2451 and amended by S.I. 1995/644.

⁽⁹⁾ S.I. 1989/419; the relevant amending instrument is S.I. 1995/2737.

(ii) who, in the opinion of the pharmacist providing the drug, is likely to have difficulty understanding the nature and dosage of the drug provided and the times at which it is to be taken,

in circumstances where the nature of the drug is such that, in the opinion of the pharmacist providing it, the same or a similar drug is likely to be prescribed for that person regularly on future occasions.

- (3) In paragraph (2)(c) above, "records" includes a record of—
 - (a) the name and address of the person to whom the drug is supplied;
 - (b) the name, quantity and dosage of the drug provided; and
 - (c) the date on which it is provided.".
- (3) In Schedule 2 (terms of service), in paragraph 8 (remuneration of chemists)—
 - (a) omit sub-paragraph (1); and

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- (b) in sub-paragraph (1A)(c), after "on request", insert—
 - "(a) make available to the Health Authority all records kept in accordance with regulation 16A(2)(c); and

(b)".

Changes to discipline arrangements for pharmacists

- **10.**—(1) The 1992 Regulations are amended as follows.
- (2) In regulation 2 (interpretation), in paragraph (1)—
 - (a) for the definition of "joint services committee" substitute—
 - ""joint discipline committee" shall have the same meaning as in the National Health Service (Service Committees and Tribunal) Regulations 1992(10);"
 - (b) after the definition of "patient" insert—
 - ""pharmaceutical discipline committee" shall have the same meaning as in the National Health Service (Service Committees and Tribunal) Regulations 1992(11);" and
 - (c) omit the definition of "pharmaceutical services committee".
- (3) In regulation 24 (claims and overpayments), in paragraph (2)(b), for "regulation 7(1)" substitute "regulation 5(1)"; and for "regulation 10(1)(c)" substitute "regulation 9(1)(c)".(12)
- (4) In Schedule 2 (terms of service), in paragraph 2 (incorporation of provisions), in sub-paragraph (c)(i), for "the pharmaceutical service committee and the joint services committee" substitute "the pharmaceutical discipline committee and the joint discipline committee".

Other amendments to Terms of Service

- 11.—(1) Schedule 2 to the 1992 Regulations (terms of service for chemists) is amended as follows.
 - (2) In paragraph 3 (provision of pharmaceutical services), after sub-paragraph (1) insert—

⁽¹⁰⁾ S.I. 1992/664; the relevant amending instrument is S.I. 1996/703.

⁽¹¹⁾ S.I. 1992/664; the relevant amending instrument is S.I. 1996/703.

⁽¹²⁾ These changes are made necessary by the amendments to S.I. 1992/664 made by S.I. 1996/703.

- "(1A) If the person presenting the prescription form asks the chemist to do so—
 - (a) he shall give an estimate of the time when the drugs, medicines or appliances will be ready; and
 - (b) if they are not ready by then, he shall give a revised estimate of the time when they will be ready (and so on)."
- (3) In paragraph 4 (premises and hours), in sub-paragraph (3)(13), after "Christmas Day" insert ", 28th December if 26th December is a Saturday,".
 - (4) After paragraph 8 insert—

"Professional Standards

- **8A.**—(1) A pharmacist whose name is on the pharmaceutical list shall provide pharmaceutical services and exercise any professional judgment in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession.
- (2) A chemist who employs a pharmacist in connection with the provision of pharmaceutical services shall secure that the pharmacist complies with the requirements set out in sub-paragraph (1).".

Signed by authority of the Secretary of State for Health

Gerald Malone
Minister of State (Department of Health)

11th March 1996

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the National Health Service (Pharmaceutical Services) Regulations 1992, which govern the arrangements to be made by Health Authorities for the provision in their area of pharmaceutical services under the National Health Service Act 1977.

Part II amends the 1992 Regulations to reflect the power of the NHS Tribunal to suspend a chemist or to declare a chemist not fit to be engaged in any capacity in the provision of pharmaceutical services. The Terms of Service for chemists are amended to prevent the employment of pharmacists in relation to whom such a declaration is in force. The amendments also provide for payments to suspend chemists.

Part III requires chemists to set up and operate (in accordance with the Regulations) a complaints procedure and to cooperate with any investigation of a complaint by a Health Authority in accordance with its procedures.

Part IV conatins a number of unrelated amendments to the 1992 Regulations.

Regulation 8 provides for all nurses employed by GPs (and not just those employed in GP fund-holding practices) to write prescriptions.

Regulation 9 alters that status of the keeping of records by a chemist in connection with the supply of drugs from that of a supplemental service to that of an additional professional service.

Regulation 10 amends regulations 2 and 24 and paragraph 2 of Schedule 2 to reflect amendments made to the National Health Service (Service Committees and Tribunal) Regulations 1992 (S.I. 1992/664) by the National Health Service (Service Committees and Tribunal) Amendment Regulations 1996 (S.I. 1996/703).

Regulation 11 amends the Terms of Service for pharmacists by requiring a chemist to give, on request, an estimate of the time when any drugs, medicines or appliances prescribed will be ready; by altering the definition of "working day" to exclude 28th December if Boxing Day is a Saturday; and to require pharmacists to provide pharmaceutical services and exercise their professional judgement to a standard generally accepted in the pharmaceutical profession.

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The Drug Tariff, referred to in the insertion made by regulation 4, is available to chemists and Health Authorities from the Prescription Pricing Authority, Bridge House, 152 Pilgrim Street, Newcastle-upon-Tyne, NE1 6SN.