STATUTORY INSTRUMENTS

# 2005 No. 641

# NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical Services) Regulations 2005

Made	10th March 2005
Laid before Parliament	11th March 2005
Coming into force	1st April 2005

## THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) REGULATIONS 2005

## PART 1

## General

- 1. Citation, commencement and extent
- 2. Interpretation
- 3. Terms of service

## PART 2

Pharmaceutical Lists and Applications for Admission to a Pharmaceutical List

- 4. Preparation of lists
- 5. Applications for inclusion in or amendment to a pharmaceutical list
- 6. Applications involving a minor relocation within a Primary Care Trust's area
- 7. Applications involving a minor relocation between neighbouring Primary Care Trusts
- 8. Applications involving a change of ownership
- 9. Applications following suspension from the list
- 10. Right of return to pharmaceutical lists
- 11. Refusal: general provisions
- 12. Necessary or desirable test
- 13. Exemption from the necessary or desirable test
- 14. Variation of directed services in respect of exempted premises
- 15. Approved retail areas
- 16. New one-stop primary care centres

- 17. Refusal: distance selling premises
- 18. Refusal: premises which are in a controlled locality but not in a reserved location
- 19. Refusal: fitness to practise grounds
- 20. Imposition of conditions
- 21. Conditional inclusion relating to fitness to practise matters
- 22. Relevant procedures for applications
- 23. Notification of applications
- 24. Determination of applications
- 25. Deferral of consideration of certain applications
- 26. Deferral of consideration of applications on fitness to practise grounds
- 27. Notification of decision
- 28. Notifications by Primary Care Trusts to other persons
- 29. Appeals
- 30. Appeals against imposition of conditions and related decisions
- 31. Determination that an area is a controlled locality
- 32. Appeals relating to rurality of an area
- 33. Notification of an application in respect of premises in a controlled locality
- 34. Decision not to consider an application in respect of premises in a controlled locality
- 35. Pharmaceutical services in reserved locations
- 36. Determination of applications in respect of controlled localities
- 37. Notification of decision in respect of applications in controlled localities
- Appeals in connection with determinations in respect of controlled localities etc
- 39. Procedure after grant of application
- 40. Preliminary consent to be included in a pharmaceutical list
- 41. Effect of preliminary consent

#### PART 3

Conditional inclusion, suspension and removal from pharmaceutical lists

- 42. Review of decision to impose conditions
- 43. Appeals following a review
- 44. Removal for breach of conditions
- 45. Removal from pharmaceutical lists
- 46. Criteria for decisions on removal
- 47. Cases where the Primary Care Trust must remove a chemist
- 48. Procedure on removal
- 49. Supplementary matters relating to removal
- 50. Procedure on suspension
- 51. Procedure on review of Primary Care Trust decision
- 52. Review periods on national disqualification
- 53. Withdrawals from the list
- 54. Temporary provision of services during a period of suspension
- 55. Notifications

## PART 4

#### Payments to chemists

- 56. Standards of, and payments for, drugs and appliances
- 57. Claims and overpayments
- 58. Payments to suspended chemists

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

59. Reward Scheme

## PART 5

## Provision of Pharmaceutical Services by Doctors

- 60. Arrangements for provision of pharmaceutical services by doctors
- 61. Outline consent and premises approval
- 62. Taking effect of outline consent and premises approval
- 63. Lapse of outline consent and premises approval
- 64. Premises approval: change of premises before outline consent takes effect
- 65. Premises approval: additional and new premises after outline consent has taken effect
- 66. Premises approval: practice amalgamations
- 67. Premises approval transitional provisions
- 68. Dispensing doctor lists
- 69. Removal of entries from dispensing doctor lists

## PART 6

## Miscellaneous

- 70. Publication of particulars
- 71. List of chemists providing an ETP service
- 72. Exercise of choice of chemist in certain cases
- 73. Transitional provisions
- 74. Transitional arrangements in respect of terms of service
- 75. Minor and consequential amendments and revocations Signature

## SCHEDULE 1 — TERMS OF SERVICE OF PHARMACISTS PART 1 — GENERAL

- 1. Incorporation of provisions
- Division of responsibilities between individuals and corporate bodies PART 2 — ESSENTIAL SERVICES
- 3. Essential services
- 4. Dispensing services
- 5. Dispensing of drugs and appliances
- 6. Urgent supply without a prescription
- 7. Preliminary matters before providing ordered drugs or appliances
- 8. Providing ordered drugs or appliances
- 9. Refusal to provide drugs or appliances ordered
- 10. Further activities to be carried out in connection with the provision of dispensing services
- 11. Additional requirements in relation to electronic prescribing
- 12. Disposal service in respect of unwanted drugs
- 13. Basic procedure in respect of unwanted drugs
- 14. Further activities to be carried out in connection with the disposal of unwanted drugs
- 15. Promotion of healthy lifestyles
- 16. Prescription linked intervention
- 17. Public health campaigns
- 18. Signposting

- 19. Service outline in respect of signposting
- 20. Support for self-care
- 21. Service outline in respect of support for self-care PART 3 — HOURS OF OPENING
- 22. Pharmacy opening hours: general
- 23. Matters to be considered when issuing directions in respect of pharmacy opening hours
- 24. Determination of pharmacy opening hours instigated by the Primary Care Trust
- Determination of pharmacy opening hours instigated by the pharmacist PART 4 — CLINICAL GOVERNANCE, FITNESS TO PRACTISE AND COMPLAINTS
- 26. Clinical governance
- 27. Professional Standards
- 28. Inducements etc.
- 29. Duty to provide information about fitness to practise matters: pharmacists on pharmaceutical lists on 1st April 2005
- 30. Duty to provide information about fitness to practise matters as they arise
- 31. Home Primary Care Trust of bodies corporate
- 32. Complaints

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PART 5 — OTHER TERMS OF SERVICE
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- 33. Directed Services
- 34. Information to be supplied
- 35. Withdrawal from pharmaceutical lists
- 36. Charges for drugs and refunds
- 37. Inspections and access to information

## SCHEDULE 2 — TERMS OF SERVICE OF DISPENSING DOCTORS

- 1. Incorporation of provisions
- 2. Persons duly authorised to dispense on behalf of dispensing doctors
- 3. Dispensing of drugs and appliances ordered by another prescriber
- 4. Dispensing of drugs and appliances ordered by the dispensing doctor
- 5. Preliminary matters before providing ordered drugs or appliances
- 6. Provision of Scheduled drugs
- 7. Refusal to provide drugs or appliances ordered
- 8. Fees and charges
- 9. Complaints procedures
- 10. Inspections and access to information

#### SCHEDULE 3 — TERMS OF SERVICE OF SUPPLIERS OF APPLIANCES

- 1. Incorporation of provisions
- 2. Division of responsibilities between individuals and corporate bodies
- 3. Dispensing services
- 4. Dispensing of appliances
- 5. Preliminary matters before providing appliances
- 6. Providing appliances
- 7. Refusal to provide appliances ordered
- 8. Further activities to be carried out in connection with the provision of dispensing services
- 9. Additional requirements in relation to electronic prescribing
- 10. Opening hours: general
- 11. Matters to be considered when issuing directions in respect of opening hours

- 12. Determination of opening hours instigated by the Primary Care Trust
- 13. Determination of opening hours instigated by the supplier of appliances
- 14. Professional Standards
- 15. Inducements etc.
- 16. Duty to provide information about fitness to practise matters: suppliers of appliances on pharmaceutical lists on 1st April 2005
- 17. Duty to provide information about fitness to practise matters as they arise
- 18. Home Primary Care Trust of bodies corporate
- 19. Complaints
- 20. Directed Services
- 21. Information to be supplied
- 22. Withdrawal from pharmaceutical lists
- 23. Charges for appliances
- 24. Inspections and access to information

SCHEDULE 4 —

- Part 1 INFORMATION TO BE INCLUDED IN AN APPLICATION FOR INCLUSION IN A PHARMACEUTICAL LIST OR INCLUSION IN A LIST IN RESPECT OF DIFFERENT SERVICES OR PREMISES
- 1. APPLICATION
- 2. DETAILS OF APPLICANT
- 3. DETAILS OF PREMISES AND OPENING HOURS
- 4. PHARMACEUTICAL SERVICES TO BE PROVIDED
- 5. NECESSARY OR DESIRABLE TEST
- 6. APPLICATIONS MADE UNDER REGULATION 5(1)(b)(ii) OR 5(1)(c)
- 7. APPLICATIONS MADE UNDER REGULATION 5(1)(b)(iii)
- 8. APPLICATIONS MADE IN ACCORDANCE WITH REGULATION 8
  - Part 2 NOTIFICATION OF COMMENCEMENT DATE
    - Part 3 INFORMATION AND UNDERTAKINGS TO BE GIVEN BY AN APPLICANT IN CONNECTION WITH AN APPLICATION FOR INCLUSION (OR TEMPORARY INCLUSION) IN A PHARMACEUTICAL LIST
- 1. An applicant (other than an applicant which is a body...
- 2. An applicant which is a body corporate shall provide the...
- 3. An applicant shall provide the following undertakings-
- 4. An applicant shall supply in writing information as to whether...
- 5. If the applicant (and where the applicant is a body...
- 6. Where the applicant (or where the applicant is a body...
- 7. Where the applicant (or where the applicant is a body...
- 8. Where the applicant is a body corporate, the name and...
- 9. The applicant shall supply the name of any Primary Care...
- 10. If the applicant is the director or superintendent of a...
- 11. If, in the case of any application, the Primary Care...
- 12. The applicant shall give a written undertaking to notify the...

## SCHEDULE 5 — MINOR AND CONSEQUENTIAL AMENDMENTS

- 1. The National Health Service (General Medical Services Contracts) (Personal Medical Services Agreements) and (Pharmaceutical Services) (Amendment) Regulations 2005
- 2. The Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004

- The Health and Social Care (Community Health and Standards) Act 2003 (Supplementary and Consequential Provision) (NHS Foundation Trusts) Order 2004
- 4. The Nurses and Midwives (Parts of and Entries in the Register) Order of Council 2004
- 5. The National Health Service (General Medical Services etc) (Patients' Forums) Amendment Regulations 2003
- 6. The National Health Service (Pharmaceutical Services) (General Medical Services) and (Charges for Drugs and Appliances) Amendment Regulations 2003
- 7. The National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc) (England) Regulations 2003
- 8. The National Health Service (Local Pharmaceutical Services Etc) Regulations 2002
- 9. The National Health Service Reform and Health Care Professions Act 2002 (Supplementary, Consequential etc Provisions) Regulations 2002
- 10. The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) (No. 2) Regulations 2002
- 11. The National Health Service (Local Pharmaceutical Services and Pharmaceutical Services) Regulations 2002
- 12. The National Health Service (Pharmaceutical Services) and (Misuse of Drugs) (Electronic Communications) Order 2001
- 13. The National Health Service (Charges for Drugs and Appliances) Regulations 2000
- 14. The National Health Service (Payments by Local Authorities to NHS Bodies) (Prescribed Functions) Regulations 2000
- The National Health Service (Pilot Schemes for Personal Dental Services: Miscellaneous Provisions and Consequential Amendments) Regulations 1998
- 16. The National Health Service (Indicative Amounts) Regulations 1997
- 17. The National Health Service (Service Committees and Tribunal) Regulations 1992
- 18. The National Health Service (General Dental Services) Regulations 1992

SCHEDULE 6 — REVOCATIONS

Explanatory Note