

---

WELSH STATUTORY INSTRUMENTS

---

**2013 No. 898 (W.102)**

**NATIONAL HEALTH SERVICE, WALES**

The National Health Service (Pharmaceutical  
Services) (Wales) Regulations 2013

<i>Made</i>	- - - -	<i>17 April 2013</i>
<i>Laid before the National Assembly for Wales</i>		<i>18 April 2013</i>
<i>Coming into force</i>		<i>10 May 2013</i>

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL  
SERVICES) (WALES) REGULATIONS 2013

PART 1

Introduction

1. Title, commencement and application
2. Interpretation

PART 2

Pharmaceutical lists and dispensing doctor lists

3. Preparation and maintenance of pharmaceutical lists
4. Preparation and maintenance of dispensing doctor lists
5. Terms of service

PART 3

Determination of controlled localities

6. Areas that are controlled localities
7. Appeals against decisions under Part 3

PART 4

Applications by NHS pharmacists and NHS appliance  
contractors for inclusion in or amendment to pharmaceutical lists

8. Applications to be included in or for amendment to a pharmaceutical list

*Status: This is the original version (as it was originally made).*

9. Determination of applications to be included in or for amendment to a pharmaceutical list
10. Determination of applications to be included in or for amendment to a pharmaceutical list: effect of earlier determinations
11. Locations in controlled localities that are reserved locations
12. Applications for preliminary consent and effect of preliminary consent
13. Applications involving minor relocation within a Local Health Board's area
14. Applications involving minor relocation between neighbouring Local Health Board areas
15. Applications involving temporary relocation
16. Applications involving a change of ownership
17. Procedure following grant of an application
18. Application to extend the relevant period
19. Appeals

#### PART 5

#### Applications by doctors for inclusion in or amendment to dispensing doctor lists

20. Arrangements for the provision of pharmaceutical services by doctors
21. Necessary services for temporary patients
22. Provision of pharmaceutical services for immediate treatment or personal administration
23. Discontinuation of arrangements for the provision of pharmaceutical services by doctors
24. Outline consent and premises approval
25. Taking effect of outline consent and premises approval
26. Lapse of outline consent and premises approval
27. Premises approval: change of premises before outline consent takes effect
28. Premises approval: additional and new premises after outline consent has taken effect
29. Premises approval: practice amalgamations
30. Appeals

#### PART 6

#### Fitness grounds and inclusion in and removal from pharmaceutical lists

31. Deferral of applications on fitness grounds
32. Refusal of applications on fitness grounds
33. Conditional inclusion relating to fitness grounds
34. Removal from a pharmaceutical list for breach of conditions on fitness grounds or imposition or variation or imposition of new conditions under section 108 of the 2006 Act
35. Removal from a pharmaceutical list for other reasons
36. Suspension from a pharmaceutical list
37. Notification of decision to impose conditions
38. Review of decision to impose a suspension under section 110 of the 2006 Act or a contingent removal under section 108 of the 2006 Act
39. Review of a decision to impose conditions
40. Appeals

## PART 7

### Payments to NHS pharmacists and NHS appliance contractors

41. The Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors
42. Local Health Boards as determining authorities
43. Overpayments
44. Reward scheme
45. Payments to suspended NHS pharmacists and NHS appliance contractors

## PART 8

### Miscellaneous

46. Home Local Health Board
  47. Publication of particulars
  48. Exercise of choice in certain cases
  49. Transitional provisions
  50. Minor and consequential amendments and revocations
- Signature

---

## SCHEDULE 1 **Information to be included in applications to provide pharmaceutical services**

### PART 1 — Application for inclusion in or for amendment to a pharmaceutical list

#### *Information required from all applicants*

1. ***Details of the application***
2. Type of consent applied for (full or preliminary).
3. Type of application (for example: new inclusion; minor relocation within...)
4. ***Details of the applicant***
5. If the applicant is an individual or a partnership carrying...
6. If the applicant is a body corporate carrying on a...
7. ***Details of the premises and opening hours***
8. Whether the applicant is currently in possession of the premises...
9. The days on which the pharmacy will be open for...
10. ***Pharmaceutical services to be provided***
11. Details of directed services that the applicant applies to provide....
12. If the application is to provide services of a different...
13. Information relating to the necessary or expedient test
14. Information relating to the prejudice test
15. Information relating to applications involving relocations
16. Where the application involves a minor relocation between neighbouring Local...
17. The applicant must provide details of whether—
18. If the application is for a temporary relocation, the applicant...
19. Information relating to applications involving a change of ownership
20. The applicant must provide details of whether—
21. Applicant's undertaking

*Status: This is the original version (as it was originally made).*

PART 2 — Information and undertakings for applications for inclusion in a pharmaceutical list

22. Applicant's details
23. Investigations, proceedings and convictions
24. If the applicant (and where the applicant is a body...
25. Pharmaceutical qualifications, referees etc.
26. Where the applicant (or where the applicant is a body...
27. Where the applicant is a body corporate, the name and...
28. The applicant must supply the name of any Local Health...
29. If the applicant is the director or superintendent of a...
30. Undertakings

PART 3 — Notification of commencement date

31. Information to be provided prior to the commencement of the provision of pharmaceutical services

PART 4 — Applications for outline consent and premises approval

32. Details of the application
33. Type of application (outline consent, premises approval or both).
34. Details of the applicant
35. The General Medical Council reference number under which the applicant...
36. Application for outline consent
37. Address of any pharmacy within the area described and delineated...
38. Application for premises approval
39. Distance between those premises and the nearest pharmacy (and the...
40. Whether the application is for premises approval, for additional premises...
41. Whether the application arises because a practice amalgamation has taken...
42. If outline consent has already been granted a description and...
43. Details of any other medical practice premises which have been...
44. Pharmaceutical services to be provided
45. Prejudice test
46. Necessary or expedient
47. Applicant's undertaking

SCHEDULE 2 Procedures to be followed by Local Health Boards to determine applications under the Regulations

PART 1 — Preliminary matters

1. General principles
2. Timetable for determining applications
3. Persons prohibited from taking part in decision-making on applications

PART 2 — Determination of controlled localities

4. Notice of proposed determination in respect of controlled localities
5. Deferral of applications
6. Imposition of conditions
7. Notification of determinations and action following determinations

PART 3 — Applications for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists

8. Notice of certain applications
9. Persons and bodies to be notified
10. Content of notifications
11. Oral hearings

12. Information to which a Local Health Board must have regard
  13. Imposition of conditions
  14. Notification of decisions: applications for inclusion in or amendment to pharmaceutical lists
  15. Notification of decisions: applications for inclusion in or amendment to dispensing doctor lists
  16. Notification of decisions: applications under regulation 18 for extension of the relevant period
  17. Notification of decisions: applications under regulation 11(2)
  18. Action following determination in respect of reserved locations
- SCHEDULE 3  
3
- PART 1 — Preliminary matters
1. General principles
  2. Oral hearings
- PART 2 — Appeals against decisions determining controlled localities
3. Right of appeal to the Welsh Ministers
  4. Notification of appeals
  5. Decision on appeals
- PART 3 — Appeals against decisions for inclusion in or amendment to pharmaceutical lists and dispensing doctor lists
6. Right of appeal to the Welsh Ministers
  7. Notification of appeals
  8. Decision on appeals
  9. Effect of decisions by the Welsh Ministers
- SCHEDULE 4  
4
- PART 1 — General
1. Interpretation
  2. Incorporation of provisions
- 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 specified appliances
  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 — Pharmacy Opening Hours

*Status: This is the original version (as it was originally made).*

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 Local Health Board
  25. Determination of pharmacy opening hours instigated by the NHS pharmacist
  26. Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services
- PART 4 — Clinical Governance and Complaints
27. Clinical governance
  28. Professional standards
  29. Inducements
  30. Duty to provide information about fitness to practise matters: NHS pharmacists on pharmaceutical lists on 10 May 2013
  31. Duty to provide information about fitness matters as they arise
  32. Home Local Health Board of bodies corporate
  33. Complaints
- PART 5 — Other terms of service
34. Directed services
  35. Information to be supplied
  36. Withdrawal from pharmaceutical lists
  37. Charges for drugs and refunds
  38. Inspections and access to information
- SCHEDULE 5
1. Terms of service for NHS appliance contractors who provide pharmaceutical services only by the provision of appliances
  1. Incorporation of provisions
  2. Division of responsibilities between individuals and corporate bodies
  3. Dispensing services
  4. Dispensing of appliances
  5. Urgent supply without a prescription
  6. Preliminary matters before providing appliances
  7. Providing appliances
  8. Refusal to provide appliances ordered
  9. Further activities to be carried out in connection with the provision of dispensing services
  10. Additional requirements in relation to specified appliances
  11. Signposting
  12. Opening hours: general
  13. Matters to be considered when issuing directions in respect of opening hours
  14. Determination of opening hours instigated by the Local Health Board
  15. Determination of opening hours instigated by the NHS appliance contractor
  16. Clinical governance
  17. Professional Standards
  18. Inducements
  19. Duty to provide information about fitness to practise matters as they arise
  20. Home Local Health Board of bodies corporate
  21. Complaints
  22. Directed Services

23. Information to be supplied
  24. Withdrawal from pharmaceutical lists
  25. Charges for appliances
  26. Inspections and access to information
- SCHEDULE 6
- Terms of service for doctors providing pharmaceutical services
  1. Interpretation
  2. Incorporation of provisions
  3. Persons duly authorised to dispense on behalf of dispensing doctors
  4. Dispensing of drugs and appliances ordered by another prescriber
  5. Dispensing of drugs and appliances ordered by the dispensing doctor
  6. Preliminary matters before providing ordered drugs or appliances
  7. Provision of Scheduled drugs
  8. Refusal to provide drugs or appliances ordered
  9. Fees and charges
  10. Complaints and concerns
  11. Inspections and access to information
- SCHEDULE 7
- Minor and consequential amendments
  1. The National Health Service (Service Committees and Tribunal) Regulations 1992
  2. The National Health Service (Indicative Amounts) Regulations 1997
  3. The National Health Service (Payments by Local Authorities to Health Authorities) (Prescribed Functions) (Wales) Regulations 2001
  4. The National Health Service (General Medical Services Contracts) (Wales) Regulations 2004
  5. The National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007
  6. The Single Use Carrier Bags Charge (Wales) Regulations 2010
- SCHEDULE 8
1. Revocations
  2. The National Health Service (Pharmaceutical Services) Amendment Regulations 1993.
  3. The National Health Service (Pharmaceutical Services and Charges for Drugs...
  4. The National Health Service (Pharmaceutical Services) Amendment Regulations 1995.
  5. The National Health Service (Pharmaceutical Services) Amendment Regulations 1996.
  6. The National Health Service (Pharmaceutical Services) Amendment Regulations 1998.
  7. The National Health Service (Pharmaceutical Services) Amendment Regulations 1999.
  8. The National Health Service (Pharmaceutical Services) and (General Medical Services)...
  9. The National Health Service (General Medical Services) and (Pharmaceutical Services)...
  10. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2003)...
  11. The National Health Service (Amendments concerning Supplementary and Independent Nurse...

**Status:** This is the original version (as it was originally made).

12. The National Health Service (Pharmaceutical Services) (Amendment) (No.2) (Wales) Regulations...
13. The National Health Service (Pharmaceutical Services etc) (Repeatable Prescriptions) (Amendment)...
14. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2004....
15. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2005....
16. Paragraph 6 of Schedule 1 to the General Dental Services...
17. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2006....
18. Paragraph 1 of Schedule 2 to the National Health Service...
19. Regulation 3 of the National Health Service (Miscellaneous Amendments Concerning...
20. Regulations 3, 4, 5, 6, 7 and 8 of the...
21. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2009....
22. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2010)....
23. Regulation 2 of the National Health Service (Miscellaneous Amendments Relating...
24. The National Health Service (Pharmaceutical Services) (Amendment) (Wales) (No.2) Regulations...
25. Paragraph 2 of Schedule 2 to the National Health Service...  
Explanatory Note