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WELSH STATUTORY INSTRUMENTS

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**2020 No. 1073 (W. 241)**

**NATIONAL HEALTH SERVICE, WALES**

**The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020**

*Made - - - - 29 September 2020*  
*Coming into force in accordance with*  
*regulation 1(2) and (3)*

**THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) (WALES) REGULATIONS 2020**

PART 1

Introductory

1. Title, commencement and application
2. Interpretation

PART 2

Pharmaceutical needs assessments

3. Pharmaceutical needs assessments
4. Information to be contained in pharmaceutical needs assessments
5. Date by which the first pharmaceutical needs assessment is to be published
6. Subsequent assessments
7. Consultation on pharmaceutical needs assessments
8. Matters for consideration when making assessments
9. Publication of pharmaceutical needs assessments

PART 3

Pharmaceutical lists and dispensing doctor lists

10. Preparation and maintenance of pharmaceutical lists
11. Preparation and maintenance of dispensing doctor lists
12. Terms of service

**Status:** Point in time view as at 01/10/2021.

**Changes to legislation:** There are currently no known outstanding effects for the The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020. (See end of Document for details)

#### PART 4

##### Determination of controlled localities

13. Areas that are controlled localities
14. Appeals against decisions under Part 4

#### PART 5

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

15. Applications to be included in or make amendment to a pharmaceutical list
16. Determination of applications to be included in or to make amendment to a pharmaceutical list
17. Locations in controlled localities that are reserved locations
18. Applications for preliminary consent and effect of preliminary consent
19. Applications involving relocation within a Local Health Board's area
20. Applications involving relocation between neighbouring Local Health Board areas
21. Applications involving temporary relocation
22. Applications involving a change of ownership
23. Procedure following grant of an application
24. Application to extend the relevant period
25. Appeals

#### PART 6

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

26. Arrangements for the provision of pharmaceutical services by doctors
27. Necessary services for temporary patients
28. Provision of pharmaceutical services for immediate treatment or personal administration
29. Discontinuation of arrangements for the provision of pharmaceutical services by doctors
30. Outline consent and premises approval
31. Taking effect of outline consent and premises approval
32. Lapse of outline consent and premises approval
33. Premises approval: change of premises before outline consent takes effect
34. Premises approval: additional and new premises after outline consent has taken effect
35. Premises approval: practice amalgamations

#### PART 7

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

36. Deferral of applications on fitness grounds
37. Refusal of applications on fitness grounds
38. Conditional inclusion on fitness grounds

39. 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
40. Removal from a pharmaceutical list for other reasons
41. Suspension from a pharmaceutical list
42. Notification of a decision to impose conditions
43. 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
44. Review of a decision to impose conditions
45. Appeals

#### PART 8

Conditional inclusion in pharmaceutical lists: certain specific conditions that do not relate to fitness or performance

46. Core opening hours conditions
47. Conditions relating to providing directed services
48. Conditions relating to local resolution of disputes over terms of service

#### PART 9

Performance related sanctions and Market Exit

49. Local dispute resolution before serving remedial notices or breach notices
50. Breaches of terms of service: remedial notices
51. Breaches of terms of service: breach notices
52. Payment withholdings: supplementary matters
53. Removal of listings: cases relating to remedial notices and breach notices
54. Appeals against decisions under Part 9

#### PART 10

Payments to NHS pharmacists and NHS appliance contractors

55. The Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors
56. Local Health Boards as determining authorities
57. Overpayments
58. Reward scheme
59. Payments to suspended NHS pharmacists and NHS appliance contractors

#### PART 11

Miscellaneous

60. Home Local Health Board
61. Publication of particulars
62. Exercise of choice in certain cases
63. Transitional provisions
64. Minor and consequential amendments
65. Revocation  
Signature

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- SCHEDULE 1 Information to be contained in pharmaceutical needs assessments
1. Current provision of pharmaceutical services
  2. Other NHS services
  3. Gaps in provision of pharmaceutical services
  4. How the assessment was carried out
  5. Map of provision
- SCHEDULE 2 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; relocation within a...)
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 pharmaceutical services of a...

*Information relating to applications to be included in, or amend, a pharmaceutical list*

13. Where regulation 16 applies to the determination of an application,...

*Information relating to the prejudice test*

14. Where the prejudice test in regulation 16 applies to the...

*Information relating to applications involving relocations*

15. Where the applicant applies to relocate (whether within the Local...
16. Where the application involves a relocation between neighbouring Local Health...
17. The applicant must provide details of whether—
18. If the application is for a temporary relocation, the applicant...

*Information relating to applications involving a change of ownership*

19. Name of the person included in the pharmaceutical list currently...
20. The applicant must provide details of whether—

*Applicant's undertaking*

21. The applicant must give an undertaking that if the application...
 

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

22. Applicant's details
23. Investigation, 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. Meeting identified needs
47. Applicant's undertaking
- SCHEDULE 3 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 determination and action following determination
- 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 notification
11. Oral hearings
12. Information to which a Local Health Board must have regard
13. Imposition of conditions

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14. Notification of decisions: applications for inclusion in or to make an amendment to a pharmaceutical list
  15. Notification of decisions: applications for inclusion in or amendment to dispensing doctor lists
  16. Notification of decisions: applications under regulation 24 for extension of the relevant period
  17. Notification of decisions: applications under regulation 17(2)
  18. Action following determination in respect of reserved locations
- SCHEDULE 4 Appeals to the Welsh Ministers
- 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 5 Terms of service for NHS pharmacists who provide pharmaceutical services in particular by the provisions of drugs
- 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. Supply in accordance with a SSP
    7. Urgent supply without a prescription
    8. Preliminary matters before providing ordered drugs or appliances
    9. Providing ordered drugs or appliances
    10. Refusal to provide drugs or appliances ordered
    11. Further activities to be carried out in connection with the provision of dispensing services
    12. Additional requirements in relation to specified appliances
    13. Disposal service in respect of unwanted drugs
    14. Basic procedure in respect of unwanted drugs
    15. Further activities to be carried out in connection with the disposal of unwanted drugs
    16. Promotion of healthy lifestyles
    17. Prescription linked intervention
    18. Public health campaigns
    19. Signposting
    20. Service outline in respect of signposting
    21. Support for self-care
    22. Service outline in respect of support for self-care
  - PART 3 — Pharmacy opening hours
    23. Pharmacy opening hours: general

24. Matters to be considered when issuing directions in respect of pharmacy opening hours
25. Determination of pharmacy opening hours instigated by the Local Health Board
26. Determination of pharmacy opening hours instigated by the NHS pharmacist
27. Temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services
- PART 4 — Clinical governance and complaints
28. Clinical governance
29. Professional standards
30. Inducements
31. Duty to provide information about fitness to practice 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
39. Welsh language
- SCHEDULE 6 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. Supply in accordance with a SSP
6. Urgent supply without a prescription
7. Preliminary matters before providing appliances
8. Providing appliances
9. Refusal to provide 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. Signposting
13. Opening hours: general
14. Matters to be considered when issuing directions in respect of opening hours
15. Determination of opening hours instigated by the Local Health Board
16. Determination of opening hours instigated by the NHS appliance contractor
17. Clinical governance
18. Professional standards
19. Inducements
20. Duty to provide information about fitness to practise matters as they arise
21. Home Local Health Board of bodies corporate
22. Complaints
23. Directed services

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- 24. Information to be supplied
  - 25. Withdrawal from pharmaceutical services
  - 26. Charges for appliances
  - 27. Inspections and access to information
  - 28. Welsh language
  - SCHEDULE 7 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
  - 12. Welsh language
  - SCHEDULE 8 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
- Explanatory Note

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