Argraffwyd yr Offeryn Statudol hwn yn lle'r OS sy'n dwyn yr un rhif ac fe'i dyroddir yn rhad ac am ddim i bawb y gwyddys iddynt gael yr Offeryn Statudol hwnnw.

OFFERYNNAU STATUDOL CYMRU

2009 Rhif 1491 (Cy.144)

Y GWASANAETH IECHYD GWLADOL, CYMRU

Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2009

Gwnaed - - - -	*15 Mehefin 2009*
Gosodwyd gerbron Cynulliad Cenedlaethol Cymru - -	*17 Mehefin 2009*
Yn dod i rym - -	*17 Gorffennaf 2009*

Mae Gweinidogion Cymru, drwy arfer y pwerau a roddwyd iddynt gan adrannau 80, 83, 84, 86 a 203 (9) a (10) o Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru)(**1**), drwy hyn yn gwneud y Rheoliadau canlynol:

Enwi, cychwyn a chymhwyso a dehongli

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) (Diwygio) (Cymru) 2009 ac y maent yn dod i rym ar 17 Gorffennaf 2009.

(2) Mae'r Rheoliadau hyn yn gymwys o ran Cymru.

(3) Yn y Rheoliadau hyn, ystyr "y prif Reoliadau") ("*the principal Regulations*") yw Rheoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992(**2**).

Diwygio rheoliad 2 o'r prif Reoliadau

2.—(1) Diwygir rheoliad 2 o'r prif Reoliadau (dehongli) fel a ganlyn.

(2) Hepgorer y diffiniadau o—

"personal medical services;"

"pilot scheme;"

"pilot scheme provider;".

(3) Yn y man priodol yn nhrefn yr wyddor, mewnosoder y diffiniadau canlynol—

""APMS" means primary medical services provided in accordance with an APMS contract;

(**1**) 2006 p.42.
(**2**) O.S. 1992/662.

"APMS contract" means an arrangement to provide primary medical services made under section 41(2)(b) of the 2006 Act;

"APMS contractor" means a party to an APMS contract other than a Local Health Board;

"bank holiday" means any day that is specified or proclaimed as bank holiday in Wales pursuant to section 1 of the Banking and Financial Dealings Act 1971(**3**);

"director" means—

(a) a director of a body corporate; or

(b) a member of the body of persons controlling a body corporate (whether or not a limited liability partnership);

"dispensing doctor" means a doctor who provides pharmaceutical services under arrangements with a Local Health Board under Part III;

"dispensing doctor list" is to be construed in accordance with regulation 21G;

"Health and Social Services Board" means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972(**4**);

"Health Board" means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978(**5**);

"LHBMS" means primary medical services provided by a Local Health Board under section 41(2)(a) of the 2006 Act;

"LHBMS practice" means a practice established by a Local Health Board to provide LHBMS;

"listed premises" means premises in relation to which premises approval has been granted and has effect from which a doctor is able to dispense, being premises specified in relation to the doctor in the dispensing doctors' list pursuant to regulation 21G(4);

"notice" means a notice in writing and "notify" is to be construed accordingly;

"outstanding application" except where the context otherwise requires has the meaning given to it in regulation 21A(5);

"patient list" means a list of patients kept by a Local Health Board—

(a) in respect of a GMS contractor, in accordance with paragraph 14 (list of patients) of Schedule 6 to the GMS Regulations; or

(b) in respect of an APMS contractor or an LHBMS practice, in accordance with directions given by the Welsh Ministers under section 12(3) of the 2006 Act in respect of an APMS contract or an LHBMS practice;

"practice amalgamation" has the meaning given to it in regulation 21E(1);

"practice premises", in relation to a provider of primary medical services, means the address specified in the contract (in the case of a GMS or APMS contractor) or practice statement (in the case of an LHBMS practice) as one at which services are to be provided under the contract or practice statement;

"premises approval" has the meaning given to it in regulation 21(1)(b) and includes temporary premises approval granted under regulation 21D(9) or 21E(4) and residual premises approval under regulation 21E(9);

"provider of primary medical services" means a GMS contractor, APMS contractor, or an LHBMS practice;

"provisional date" is to be interpreted in accordance with regulation 21A(6) to (8);

(**3**) 1971 p.80.
(**4**) O.S. 1972/1265 (N.I. 14).
(**5**) 1978 p.29.

"relevant APMS contractor", in relation to any doctor, means the APMS contractor, where the doctor is an APMS contractor, or where he or she is not, the APMS contractor by whom the doctor is employed or engaged;

"relevant GMS contractor", in relation to any doctor, means the GMS contractor, where the doctor is a GMS contractor or, where he or she is not, the GMS contractor by whom the doctor is employed or engaged;

"relevant LHBMS practice", in relation to any doctor, means the LHBMS practice within which the doctor provides primary medical services;

"relevant local authority", in relation to a Primary Care Trust, means a local authority whose area falls, wholly or partly, within the area of the Primary Care Trust;

"relevant local involvement network" means a person who in pursuance of arrangements made by a relevant local authority under section 221(1) of the Local Government and Public Involvement in Health Act 2007(**6**) is to carry on activities specified in section 221(2) of that Act;

"relevant patient list" means, in relation to a doctor who is (or is a legal and beneficial shareholder in a company which is) a GMS contractor or APMS contractor, the patient list for that contractor or, where the doctor is not a contractor, means the patient list for the GMS contractor or APMS contractor by whom the doctor is employed or engaged or for the LHBMS practice within which the doctor provides primary medical services;

"reserved location" has the meaning given to it in regulation 11ZA;

"superintendent" has the same meaning as in section 71 (bodies corporate) of the Medicines Act 1968(**7**).".

(4) Yn lle'r diffiniad o "prescriber" rhodder—

""prescriber" means a doctor, dentist, pharmacist independent prescriber, independent nurse prescriber, nurse independent prescriber or a supplementary prescriber;".

(5) Yn lle'r diffiniad o "prescription form" rhodder—

""prescription form" means a form provided by a Health Board, a Health and Social Services Board, a Local Health Board, a Primary Care Trust, an NHS Trust, or NHS Foundation Trust and issued by a prescriber to enable a person to obtain pharmaceutical services and does not include a repeatable prescription;".

(6) Yn lle'r diffiniad o "Remission of Charges Regulations" rhodder—

""Remission of Charges Regulations" means the National Health Service (Travelling Expenses and Remission of Charges) (Wales) Regulations 2007(**8**);".

(7) Yn lle'r diffiniad o "repeatable prescriber" rhodder—

""repeatable prescriber means a prescriber who is—

(a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which gives effect to paragraph 40 of Schedule 6 to the GMS Regulations;

(b) an APMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to APMS contracts;

(c) employed or engaged by —

(i) a GMS contractor who provides repeatable prescribing services under the terms of a contract which gives effect to paragraph 40 of Schedule 6 to the GMS Regulations,

(**6**) 2007 p.28.
(**7**) 1968 p.67.
(**8**) O.S. 2007/1104 (Cy.116).

(ii) an APMS contractor who provides repeatable prescribing services under the terms of an agreement which gives effect to a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to APMS contractors, or

(iii) a Local Health Board for the purposes of providing primary medical services within an LHBMS practice which provides repeatable prescribing services in accordance with a provision in directions made by the Welsh Ministers under section 12(3) of the 2006 Act in relation to LHBMS;".

Diwygio rheoliad 4 o'r prif Reoliadau

3. Ym mharagraff (8) o reoliad 4 o'r prif Reoliadau (rhestrau fferyllol), yn lle'r ymadrodd "rheoliad 12(16)" rhodder "regulation 12(18)".

Diwygio rheoliad 5 o'r prif Reoliadau

4.—(1) Diwygir rheoliad 5 o'r prif Reoliadau (hysbysu ynghylch ceisiadau) fel a ganlyn—

(2) Ar ôl paragraff (1)(e), mewnosoder y canlynol—

"(f) any other patient, consumer or community groups in the area of the Local Health Board that the Local Health Board considers has an interest in the provision of pharmaceutical services in the area,".

(3) Ar ôl paragraff (2)(c), mewnosoder—

"and

(d) any relevant local involvement network;

(e) any other patient, consumer of community groups in the area of the Local Health Board or the Primary Care Trust that that Local Health Board or Primary Care Trust considers has an interest in the provision of pharmaceutical services in the area,".

Diwygio rheoliad 6 o'r prif Reoliadau

5. Yn lle paragraff (6) o reoliad 6 o'r prif Reoliadau (penderfynu ceisiadau), mewnosoder y paragraff canlynol—

"(6) No person—

(a) who provides or assists in providing pharmaceutical services under Part 7 of the 2006 Act;

(b) who is a GMS contractor, or is a legal and beneficial shareholder, director or company secretary of a company which is a GMS contractor, or is employed or engaged by a GMS contractor;

(c) who is an APMS contractor, or is an officer, trustee or other person concerned with the management of a company, society or voluntary organisation or other body which is an APMS contractor, or is employed or engaged by an APMS contractor;

(d) who is employed or engaged by a Local Heath Board for the purposes of providing primary medical services within an LHBMS practice,

may take part in any decision under this regulation.".

Diwygio rheoliad 7 o'r prif Reoliadau

6.—(1) Diwygir rheoliad 7 o'r prif Reoliadau (hysbysiad o benderfyniadau) fel a ganlyn.

(2) Ar ôl paragraff (1)(a)(vi), mewnosoder y canlynol—

"(vii) any other patient, consumer or community groups in the area of the Local Health Board that the Local Health Board considers has an interest in the provision of pharmaceutical services in the area; and".

(3) Ar ôl paragraff (2)(c), mewnosoder y canlynol—

"and

(d) any relevant local involvement network;

(e) any other patient, consumer of community groups in the area of the Local Health Board or the Primary Care Trust that that Local Health Board or Primary Care Trust considers has an interest in the provision of pharmaceutical services in the area,".

Diwygio rheoliad 9 o'r prif Reoliadau

7.—(1) Diwygir rheoliad 9 o'r prif Reoliadau (penderfynu ynghylch ardal reoledig) fel a ganlyn.

(2) Ym mharagraff (6) yn lle'r geiriau "by any doctor, GMS contractor" rhodder "by any provider of such services (except itself)".

(3) yn lle paragraff (7) rhodder y paragraff canlynol—

"(7) Where the Local Health Board considers that the provision of primary medical services by any provider of such services (except itself) or pharmaceutical services by any chemist is likely to be adversely affected in consequence of a determination under paragraph (4), it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (or equivalent provision under the GMS Regulations) for the provision by a doctor or GMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.".

(4) Ym mharagraff (10)—

(i) yn is-baragraff (b), yn lle "20(6)" rhodder "20(7)",

(ii) ar ôl is-baragraff (b), hepgorer y gair "or;", a

(iii) yn lle is-baragraff (c), rhodder y canlynol—

"(c) give notice to a GMS contractor pursuant to an equivalent provision to regulation 20(7); or

(d) determine an application under regulation 12,".

(5) Ym mharagraph (13) yn lle'r geiriau o "the Local Medical Committee" i'r diwedd, rhodder "those persons that they may appeal to the Welsh Ministers in accordance with regulation 10.".

Diwygio rheoliad 10 o'r prif Reoliadau

8.—(1) Diwygir rheoliad 10 o'r prif Reoliadau (apelau mewn cysylltiad â natur wledig ardal) fel a ganlyn.

(2) Yn lle geiriau terfynol paragraff (1) rhodder—

"the Local Medical Committee, Local Pharmaceutical Committee, a provider of primary medical services (except the Local Health Board) or a chemist who is required to be given notice by the Local Health Board under regulation 9(5) may appeal to the Welsh Ministers against any such determination, or as the case may be, refusal, by giving notice of appeal in accordance with paragraph (2).".

(3) Ym mharagraff (2) yn lle'r geiriau "Local Medical Committee or the Local Pharmaceutical Committee", rhodder "person making the appeal".

(4) Yn lle is-baragraff (b) o baragraff (10) rhodder yr is-baragraff canlynol—

"(b) may, in case where the Local Health Board, on determining the application, considered the question whether to postpone the making or termination of arrangements under regulation 20 (or equivalent provision under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients, themselves postpone, for such a period a they think fit, the making or termination of such arrangements;".

Mewnosod rheoliad 11ZA o'r prif Reoliadau

9. Yn union ar ôl rheoliad 10 o'r prif Reoliadau, mewnosoder y rheoliad canlynol—

"**Applications for inclusion in pharmaceutical lists in reserved locations**

11ZA.—(1) Subject to paragraphs (19) and (20) of regulation 12, the Local Health Board must, when the period for making representations has expired in accordance with paragraphs (4) and (5) of that regulation, determine whether the premises, or relevant location, from which the applicant wishes to provide pharmaceutical services in accordance with an application under regulation 4 or 14, are, at the date of the receipt of the application by the Local Health Board, in a reserved location.

(2) In this regulation—

(a) subject to paragraph (3), a "reserved location" means a location in respect of which the number of individuals on all of the patient lists for the area which is within 1.6 kilometres of the premises, or from the relevant location, as the case may be, is less than 2750; and

(b) the "relevant location" means, where the location of the premises from which the pharmaceutical services are to be provided, is specified in writing by the applicant before the Local Health Board makes its determination, that location, and where that location is not so specified, the best estimate the Local Health Board is able to make of where those premises may be.

(3) Premises, or a relevant location, are not in a reserved location where the Local Health Board considers that there are circumstances, including but not limited to the age or degree of infirmity of the individuals referred to in paragraph (2), why the extent of use of pharmaceutical services if a pharmacy were to operate from the premises or from the relevant location would be similar to or greater than might be expected if the number of individuals mentioned in paragraph (2)(a) were 2750 or more.

(4) Before reaching any decision under paragraph (3) the Local Health Board must invite and consider representations as to whether paragraph (3) may apply from those persons mentioned in regulation 12(2).

(5) Subject to regulation 12(19), where it has been determined by the Local Health Board or on appeal the Welsh Ministers, in relation to premises or a relevant location, from which pharmaceutical services are to be, or are being, provided, that those premises are in a reserved location, the chemist in relation to those premises, or that relevant location, may make an application in writing for the Local Health Board to make a further determination as to whether, on the date the request is made, that is, the date stated on it, those premises are, or that relevant location is, in a reserved location.

(6) Where, in making a further determination applied for in accordance with paragraph (5) the Local Health Board determines that those premises are, or that relevant location is, not in a reserved location, or there is an appeal against a determination by the Local Health Board and it is determined on appeal that premises are not, or that relevant location is not, in a reserved location—

(a) the Local Health Board may determine that the premises are, or the relevant location is, to be treated for the purposes of these Regulations as if they were in a reserved location, where it is of the opinion that not to do so would prejudice the proper provision of primary medical services (other than those provided by the Local Health Board itself), dispensing services or pharmaceutical services in any locality; or

(b) if the Local Health Board considers that the provision of primary medical services by a provider of primary medical services (other than one employed by the Local Health Board), or pharmaceutical services by any chemist, is likely to be adversely affected by a determination that the premises are not in a reserved location, it may make such a determination but may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (or equivalent under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients.

(7) Any determination required by paragraph (1) or paragraph (5) is to be made in accordance with this regulation and with regulation 12, save that where premises or a relevant location have been determined to be in a reserved location paragraph (14) of regulation 12 will not apply.

(8) Where—

(a) there is an appeal against a determination made by the Local Health Board that premises are, or a relevant location is, in a reserved location; and

(b) it is determined by the appeal that the premises are not, or a relevant location is not, in a reserved location,

the Local Health Board must redetermine the application.

(9) The Local Health Board must delineate precisely the boundaries of any reserved location it has determined under paragraph (1) or (5) on a map, and it must publish the map.".

Amnewid rheoliad 11 o'r prif Reoliadau

10. Yn lle rheoliad 11 o'r prif Reoliadau (ceisiadau am gynnwys mangreoedd mewn rhestrau fferyllol ar gyfer ardaloedd rheoledig), rhodder y rheoliad canlynol—

"**Applications for inclusion in a pharmaceutical list in respect of controlled localities**

11.—(1) Subject to paragraph 4, where the premises specified in an application under regulation 4 or 14 are in a controlled locality but are not in a reserved location, that application must be determined in accordance with regulation 12 unless—

(a) the applicant is seeking only to change within that controlled locality the premises at which he or she provides pharmaceutical services; and

(b) the granting of the application would not, in the view of the Local Health Board, result in a significant change in the arrangements for the provision of pharmaceutical services or dispensing services in any part of a controlled locality.

(2) Subject to paragraph (4), where—

(a) the premises specified in an application under regulation 4 or 14 (not being in a controlled locality) are within 1.6 kilometres of any part of a controlled locality in which reside patients for whom a doctor provides pharmaceutical services or for whom a GMS contractor provides dispensing services; and

(b) the granting of the application would, in the view of the Local Health Board, result in a significant change in the arrangements for the provision of pharmaceutical services or dispensing services in any part of a controlled locality,

the Local Health Board must, where it grants the application consider the conditions (if any) which are to be imposed in relation to that grant under regulation 12(17) and, pending the final determination of such conditions, may not in consequence of the grant give notice to any doctor to discontinue the provision of pharmaceutical services or dispensing services to any patient.

(3) Where the premises specified in an application under regulation 4 or 14 are within 1.6 kilometres of the locality of another Local Health Board, the Local Health Board to which the application has been submitted must make enquiries as to controlled localities in the area of that other Local Health Board in order to determine—

(a) whether the application is of the description specified in paragraph (2); and

(b) which controlled localities are to be considered for the purposes of paragraph (1)(b) or (2)(b),

and where it is satisfied that there is a relevant controlled locality in that area, it must consult with that other Local Health Board before forming a view for the purposes of paragraph (1)(b) or (2)(b).

(4) An application will not be determined under regulation 12 where—

(a) the application is made under regulation 4(2)(b)(iii), except where the additional services which the applicant wishes to be able to provide include the provision of drugs;

(b) regulation 15 applies; or

(c) the applicant intends to provide pharmaceutical services in the place of, and at the same location as, another person who provides pharmaceutical services.".

Amnewid rheoliad 12 o'r prif Reoliadau

11. Yn lle rheoliad 12 o'r prif Reoliadau (penderfynu ceisiadau ynglŷn ag ardaloedd rheoledig), rhodder y rheoliad canlynol—

"**Determination of applications in respect of controlled localities**

12.—(1) Where a Local Health Board receives an application which it is required, by virtue of regulation—

(a) 11ZA;

(b) 11;

(c) 14(3);

(d) 21;

(e) 21D; and

(f) 21E,

to determine in accordance with the provisions of this regulation, it must send a notice of the application and a copy of the application to any person specified in paragraph (2).

(2) The Local Health Board must send a notice of the application and a copy of the application referred to in paragraph (1) to—

(a) the Local Pharmaceutical Committee;

(b) the Local Medical Committee;

(c) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Local Health Board, be significantly affected if the application were granted;

(d) any person (except itself) who is a provider of primary medical services within the area of the Local Health Board or whose name is included in the dispensing doctor list of the Local Health Board, who might, in the opinion of the Local Health Board, be significantly affected if the application were granted;

(e) any Local Health Board or Primary Care Trust any part of whose area is within 2 kilometres of the premises;

(f) any Community Health Council serving the area of the Local Health Board or of any Local Health Board notified under sub—paragraph (e);

(g) any other patient, consumer or community groups in the area of the Local Health Board that the Local Health Board considers has an interest in the provision of pharmaceutical services in the area;

(h) any other Local Health Board part of whose area is or might form part of a reserved location; and

(i) where the determination is required to be made by regulation 21, any other Local Health Board part of whose area is within 1.6 kilometres of the premises from which the doctor wishes to dispense.

(3) Where a Local Health Board or Primary Care Trust is sent a copy of an application under paragraph (2)(e) it must, as soon as practicable, send a copy to—

(a) the Local Pharmaceutical Committee for its area;

(b) the Local Medical Committee for its area;

(c) any person whose name is included in the pharmaceutical list, and whose interests might, in the opinion of that Local Health Board or Primary Care Trust, be significantly affected if the application were granted;

(d) any person (except itself) who is a provider of primary medical services or whose name is included in the dispensing doctor list who might, in the opinion of that Local Health Board or Primary Care Trust, be significantly affected if the application were granted;

(e) any Community Health Council serving its area;

(f) any relevant local involvement network; and

(g) any other patient, consumer or community groups in the area of the Local Health Board or the Primary Care Trust that that Local Health Board or Primary Care Trust considers has an interest in the provision of pharmaceutical services in the area.

(4) Any person to whom a Local Health Board or Primary Care Trust has sent a copy of the application may, within 45 days of the date on which that copy was sent to him or her, make representations in writing to the Local Health Board to which the application was made.

(5) Any person who considers that he or she might be affected by the decision may, within such reasonable time as the Local Health Board to whom the application was made may allow, make representations in writing to it.

(6) Subject to regulation 11, when determining any application to which regulation 4(4) applies, a Local Health Board must have regard in particular to—

(a) whether or not any pharmaceutical services specified in the application are already provided in the neighbourhood by persons included in a pharmaceutical list; and

(b) any information available to the Local Health Board which, in its opinion, is relevant to the consideration of the application; and

(c) any representations received by the Local Health Board from—

(i) any person specified in paragraph (2)(a), (b) or (f) or paragraph (3)(a) or (b),

(ii) a chemist who was notified of the application pursuant to paragraph (2)(c) or (3)(c), or

(iii) any other Local Health Board or Primary Care Trust which was notified of the application pursuant to paragraph (2)(e).

(7) Subject to paragraph (14) and to regulation 11 and 21D(4), the Local Health Board may determine an application in such manner as it thinks fit and may, if it considers that oral representations are unnecessary, determine the application without hearing any oral representations.

(8) In any case where the Local Health Board decides to hear oral representations, it must give the applicant and any person from whom it has received representations under paragraph (4) or (5) not less than 14 days notice of the time and place at which the representations are to be heard.

(9) The Local Health Board may invite any other person to give oral evidence as it thinks fit.

(10) The applicant and any person mentioned in paragraph (8) may be assisted at any such hearing in the presentation of his or her representations by some other person, but no person is entitled to be heard in the capacity of counsel or solicitor.

(11) The procedure by which representations are heard will be such as the Local Health Board may determine;

(12) No person—

(a) who provides or assists in providing pharmaceutical services under Part 7 of the 2006 Act;

(b) who is a GMS contractor, or is a legal and beneficial shareholder, director or company secretary of a company which is a GMS contractor, or is employed or engaged by a GMS contractor;

(c) who is an APMS contractor, or is an officer, trustee or other person concerned with the management of a company, society, or voluntary organisation or any other body which is an APMS contractor, or is employed or engaged by an APMS contractor;

(d) who is employed or engaged by a Local Health Board for the purposes of providing primary medical services within an LHBMS practice,

is able to take part in any decision under this regulation.

(13) The Local Health Board may, where it thinks fit, consider two or more applications together in relation to each other, and, where it proposes to do so, it must inform the applicants and the persons to whom copies of the applications were sent under this regulation.

(14) The Local Health Board —

(a) must refuse an application to the extent that it is of the opinion that to grant it would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in any locality;

(b) must refuse an application under regulation 21 in relation to any part of the area specified in the application—

(i) which is not in a controlled locality, or

(ii) which is within 1.6 kilometres of any pharmacy;

(c) must refuse an application under regulation 21 in relation to any premises from which the doctor wishes to be authorised to dispense and which are within 1.6 kilometres of any pharmacy; and

(d) may refuse an application to which paragraph (13) applies (notwithstanding that it would, if determining that application in isolation, grant it) where the number of applications is such that to grant all of them or more than one of them would prejudice the proper provision of primary medical services, dispensing services or pharmaceutical services in any locality,

and any refusal of such an application may relate to all or any part of the area within the controlled locality, or as the case may be, all or some of the premises for which approval is sought.

(15) The determination of an application by the Local Health Board under this regulation is subject to paragraph (14) and to regulation 4(4) and 21D(4).

(16) When an application is granted by the Local Health Board it must consider whether the provision of primary medical services by any provider of such services (except itself) or pharmaceutical services by any chemist is likely to be adversely affected in consequence of that grant.

(17) Where the Local Health Board considers that the provision of primary medical services by a provider of such services (except itself) or pharmaceutical services by any chemist is likely to be adversely affected in consequence of the grant of an application under this regulation, it may determine to impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 (or equivalent provision under the GMS Regulations) for the provision by a doctor or a GMS contractor of pharmaceutical services or dispensing services to patients on the relevant patient list.

(18) Save where regulation 21A(4) applies, an application granted in accordance with the provisions of this regulation will not be treated as finally granted for the purpose of these Regulations until the end of the period for bringing an appeal under regulation 13 or until the determination of any such appeal, whichever is the later, and "final grant" is to be construed accordingly.

(19) Subject to paragraph (20), a Local Health Board must not consider under this regulation—

(a) any application for outline consent under regulation 21 where, during the relevant period, an application made under that regulation (or any corresponding provision or directions relating to dispensing services) in respect of the same area has been finally refused;

(b) any application to which regulation 11 or 14 applies where the location of the premises at which the pharmacist intends to provide pharmaceutical services is in a controlled locality and—

(i) is in an area in respect of which an application under regulation 21 (or any corresponding provision of directions relating to dispensing services) was finally granted during the relevant period, or

(ii) is within 1.6 kilometres of the location of premises in respect of which an application to which regulation 11 or 14 applies was finally refused during the relevant period;

(c) any request by a chemist under regulation 11ZA(5) for a determination as to whether premises are in a reserved location, where the application in relation to

the premises was refused by operation of regulation 12(14) during the relevant period; or

(d) any application by a doctor for outline consent or premises approval for premises in respect of which outline consent has been refused by operation of regulation 12(14) during the relevant period.

(20) A Local Health Board may at any time consider an application to which paragraph (19) applies where it is satisfied that, since the date of the refusal or, as the case may be, grant referred to in paragraph (19)(a) or (b), or, where there has been more than one such refusal or grant during the relevant period, the last such refusal or grant, there has been a substantial change of circumstances affecting the controlled locality.

(21) In this regulation "relevant period" means the period of 5 years immediately preceding the making of the application.

(22) The Local Health Board must, as soon as practicable after making the determination and in any event within four months beginning with the date of receipt of the application unless the Local Health Board has good cause to require a longer period, give notice in writing—

(a) of its decision and the reasons for that decision to—

(i) the applicant,

(ii) the Local Pharmaceutical Committee,

(iii) the Local Medical Committee,

(iv) any person who is included in a pharmaceutical list and whose interests might, in the opinion of the Local Health Board, be significantly affected if the application were granted,

(v) any person (except itself) who is a provider of primary medical services within the area of the Local Health Board or whose name is included in the dispensing doctor list of the Local Health Board whose interests might, in the opinion of the Local Health Board, be significantly affected if the application were granted,

(vi) any other Local Health Board or Primary Care Trust to which notice was sent pursuant to paragraph (2)(e), (h) or (i), and

(vii) any other person who has made representations under the provisions of paragraph (4) or (5); and

(b) the rights of appeal under regulation 13 to—

(i) the applicant, and

(ii) any person who gave evidence under the provisions of paragraph (4).

(23) Any Local Health Board or Primary Care Trust which is notified under paragraph (22)(a)(vi) must, as soon as practicable, give notice in writing of the decision and reasons for it to—

(a) the Local Pharmaceutical Committee for its area;

(b) the Local Medical Committee for its area;

(c) any person whose name is included in the pharmaceutical list, and whose interests might, in the opinion of the Local Health Board or Primary Care Trust, be significantly affected if the application were granted;

(d) any person (except itself) who is a provider of primary medical services or whose name is included in the dispensing doctor list who might, in the opinion of

the Local Health Board or Primary Care Trust, be significantly affected if the application were granted.".

Amnewid rheoliad 13 o'r prif Reoliadau

12. Yn lle rheoliad 13 o'r prif Reoliadau (apelau mewn cysylltiad â phenderfyniadau o dan reoliad 12) rhodder y rheoliad canlynol—

"**Appeals in connection with determinations under regulation 12**

13.—(1) Save where paragraph (3)(a) applies, where a Local Health Board has determined an application to which regulation 12 applied and regulation 4(2) also applied to that application, the persons who may appeal to the Welsh Ministers are—

(a) the applicant; and

(b) any person who—

(i) was given notice of the application under paragraph (2)(c) or (3)(c) of regulation 12, and

(ii) made representations to the Local Health Board in accordance with regulation 12(4).

(2) Save where paragraph (3)(a) applies, where a Local Health Board has determined an application to which regulation 12 applied and regulation 4(2) also applied to that application, or the Local Health Board has made a decision under regulation 4(10) in relation to that application, the persons who may appeal to the Welsh Ministers are—

(a) the applicant; and

(b) any person who was given notice of the decision in accordance with paragraphs (22)(a)(iv) or (23)(c) of regulation 12.

(3) Where a Local Health Board—

(a) has determined an application mentioned in paragraph (1) or (2) on the grounds mentioned in regulation 12(14)(a);

(b) has refused to consider an application under regulation 12 on the ground that it is not satisfied as mentioned in paragraph (20) of that regulation;

(c) has determined that it should, or should not postpone the making or termination of arrangements under regulation 20, as mentioned in regulation 10(10)(b), 12(17) or 11ZA(6)(b);

(d) has determined that—

(i) the provisional date will be extended under regulation 21A(8),

(ii) the application for outline consent is refused under paragraph (13)(a) of that regulation, or

(iii) outline consent will lapse under paragraph (13)(b) of that regulation.

(e) has determined an application for premises approval for new premises under regulation 21C(1);

(f) has determined an application for premises approval for additional or new premises under regulation 21D(1) or (3);

(g) has determined an application for premises approval in relation to a practice amalgamation under regulation 21E(3);

(h) has refused to grant temporary premises approval under regulation 21D(9) or 21E(4);

(i) has determined whether or not to grant premises approval to relevant premises under regulation 21F,

an appeal to the Welsh Ministers may be made, in accordance with paragraph (5) against that determination, or as the case may be, against that refusal, by any person specified in paragraph (4).

(4) The persons who may make an appeal under paragraph (3) are—

(a) in the case of an appeal mentioned in paragraph 3(a), (c), (f), (g) and (i)—

(i) the applicant,

(ii) any person who—

(aa) provides primary medical services within the area of the Local Health Board (except itself), or any Local Health Board or Primary Care Trust to which a copy of the application was sent in accordance with regulation 12(2)(e), (h) or (i), or

(bb) whose name is included in the pharmaceutical list or dispensing doctor list of the Local Health Board, or any other Local Health Board or Primary Care Trust to which a copy of the application was sent in accordance with regulation 12(2)(e), (h) or (i),

but in the case of a person specified in paragraph (ii), that person may make an appeal only if he or she has made representations pursuant to regulation 12(4) in connection with the application; and

(b) in the case of an appeal mentioned in paragraph (3)(b), (d), (e) and (h), the applicant.

(5) Where in determining any application, a Local Health Board has, pursuant to regulation 12(13), considered that application together with one or more other applications, any of the applicants and any of the persons mentioned, where relevant, in paragraph (1)(b), (2)(b) or (4)(a)(ii), may appeal against the determination of any of the applications, and where the Welsh Ministers receive appeals against two or more of the determinations, those appeals must be considered together.

(6) An appeal must be made in writing within 30 days from the date on which notice of the decision was sent to the appellant and must contain a concise statement of the grounds of appeal upon which the appellant intends to rely.

(7) If the Welsh Ministers, after considering the notice of appeal, are of the opinion that it discloses no reasonable grounds of appeal, or that the appeal is otherwise vexatious or frivolous, they may determine the appeal by dismissing it.

(8) Unless paragraph (7) applies, the Welsh Ministers will send a copy of the notice of appeal to—

(a) the Local Health Board whose determination is appealed against;

(b) the applicant;

(c) those persons mentioned, where relevant, in paragraph (1)(b), (2)(b) or (4)(a)(ii); and

(d) to any Local Medical Committee or Pharmaceutical Committee to which a copy of the application was required to be sent under regulation 12(2) or (3).

(9) Any person to whom a copy of the notice of appeal is sent pursuant to paragraph (8) may, within 30 days from the date the copy was sent to that person, make representations in writing to the Welsh Ministers.

(10) The Welsh Ministers may require an oral hearing of an appeal before they determine it.

(11) The Welsh Ministers will, where they require an oral hearing, appoint one or more persons to hear the appeal who will report to them on it with recommendations as to the relevant findings of fact and their conclusions.

(12) The procedure at any oral hearing will be determined by the person or persons hearing the appeal.

(13) The oral hearing will take place at such time and place as the Welsh Ministers may direct, and notice of the hearing will be sent, not less than 14 days before the date fixed for the hearing to—

(a) the appellant;

(b) the Local Health Board;

(c) the Local Medical Committee;

(d) the Local Pharmaceutical Committee; and

(e) any other person who made representations to the Local Health Board in connection with the application.

(14) The appellant and any of the persons to whom notice of the hearing is required to be sent under paragraph (13) may attend and be heard in person or by counsel, solicitor or other representative, and the Local Health Board may be represented at the hearing by any duly authorised officer or member, or by counsel or solicitor.

(15) On appeal under this regulation, the Welsh Ministers—

(a) may allow the appeal;

(b) may, in a case where the Local Health Board, on determining the application, considered the question whether to impose the making or termination of arrangements under regulation 20 (or equivalent provision under the GMS Regulations) for the provision by a doctor or GMS contractor of pharmaceutical services or dispensing service to patients on the relevant patient list, themselves impose conditions to postpone for such period as they think ft, the making or termination of such arrangements;

(c) must, in a case where that question was not considered by the Local Health Board when it determined the application, remit the question to the Local Health Board for determination;

(d) must, where they allow an appeal against a refusal of the Local Health Board as mentioned in paragraph (3)(b), remit the application to the Local Health Board and direct that regulation 12(19) does not apply; or

(e) may dismiss the appeal.

(16) The decision of the Welsh Ministers will be in writing and will—

(a) include a statement of their reasons for the decision and of their findings of fact; and

(b) as soon as practicable be sent to the persons mentioned in paragraph (13).".

Amnewid rheoliad 20 o'r prif Reoliadau

13.—(1) Yn lle rheoliad 20 o'r prif Reoliadau (trefniadau ar gyfer darparu gwasanaethau fferyllol gan feddygon) rhodder y rheoliad canlynol—

"**Arrangements for the provision of pharmaceutical services by doctors**

20.—(1) Where a patient—

(a) satisfies a Local Health Board that he or she would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy by reason of distance or inadequacy of means of communication; or

(b) is resident in a controlled locality, at a distance of more than 1.6 kilometres from any pharmacy, and one of the conditions specified in paragraph (3) is satisfied in the patient's case;

(c) is resident in a controlled locality and any pharmacy within a distance of 1.6 kilometres from where the patient lives has been determined to be in a reserved location, and that determination has not been altered on appeal or by way of a further determination, and one of the conditions specified in paragraph (3) is satisfied in the patient's case; or

(d) is one to whom sub-paragraph (a) or (b) applies and at the time of the request the patient is living as a member of the household, other than as a temporary resident, of another person in respect of whom a doctor has residual premises approval, and for this purpose "residual premises approval" has the same meaning as in regulation 21E(9) and a person is a "temporary resident" if he or she intends to stay in the household for more than 24 hours but not longer than three months,

that patient may at any time request in writing a doctor who falls within paragraph (2) to provide him or her with pharmaceutical services.

(2) A doctor falls within this paragraph if he or she is—

(a) the GMS contractor or the APMS contractor;

(b) engaged or employed by the GMS contractor or the APMS contractor; or

(c) engaged by a Local Health Board for the purposes of providing primary medical services within an LHBMS practice,

on whose list the patient making the request is included.

(3) The conditions referred to in paragraph (1)(b) and (c) are—

(a) that—

(i) there is in effect an outline consent granted to—

(aa) that doctor;

(bb) another doctor who is a party to the GMS contract or the APMS contract concerned;

(cc) another doctor who is engaged or employed by the GMS contractor or the APMS contractor concerned; or

(dd) another doctor who is providing medical services within the same LHBMS practice,

(ii) there is in effect premises approval in relation to the premise from which the doctor will dispense to that patient, and

(iii) any conditions imposed under regulation 10(10)(b), 11ZA(6)(b), 12(17) or 13(15)(b) in connection with that grant are such as to permit arrangements to be made under this regulation for the provision of pharmaceutical services by that doctor to the patient; or

(b) that—

(i) immediately before the coming into force of these Regulations, arrangements or requirements were in effect for —

(aa) that doctor;

(bb) another doctor who is party to the GMS contract concerned;

(cc) another doctor who was a party to the GMS contract, or who was engaged or employed by the GMS contractor concerned; or

(dd) any previous doctor who was a party to the GMS contract concerned, or who was engaged or employed by the GMS contractor concerned,

to provide drugs or appliances to patients,

(ii) the patient—

(aa) has not previously been included in a

patient list;

(bb) has changed his or her address from that last notified to the Local Health Board, or

(cc) has not changed his or her address but, immediately before his or her acceptance as a patient by that doctor, was being provided with pharmaceutical services by a doctor pursuant to an arrangement or requirement under these Regulations, and

(iii) there is in effect premises approval in relation to the premises from which the doctor will dispense to that patient.

(4) If a doctor so requested by a patient under paragraph (1)—

(a) applies to provide pharmaceutical services to the patient, and sends with his or her application the patient's request in writing, the Local Health Board will make arrangements with the doctor for the provision at listed premises in the case of a patient falling within paragraph (1)(b) or (c) or practice premises in the case of a patient falling within paragraph (1)(a) of such services by him or her; or

(b) does not so apply within 30 days, the Local Health Board may, subject to paragraph (6), require the doctor to undertake such provision at listed premises in the case of a patient falling within paragraph (1)(b) or

(c) or practice premises in the case of a patient falling within paragraph (1)(a) and must give the doctor notice to that effect.

(5) Subject to regulation 21E, an arrangement made by a Local Health Board under paragraph (4)(a) will—

(a) have effect from the date of the patient's request in writing; and

(b) enable—

(i) that doctor,

(ii) any other doctor who is party to the same GMS contract or APMS contract as that doctor,

(iii) any other doctor who is employed or engaged by the same GMS or APMS contractor, or

(iv) any doctor who provides primary medical services within the same LHBMS practice, to provide pharmaceutical services at listed premises for the patient so long as the arrangement remains in effect.

(6) A Local Health Board will not under paragraph (4)(b) require a doctor to provide pharmaceutical services at listed premises or practice premises to a person on the relevant

patient list for that doctor if that doctor satisfies the Local Health Board, or on appeal, the Welsh Ministers that—

(a) he or she does not normally provide pharmaceutical services under this regulation; or

(b) in the case of a person to whom paragraph (1)(b), (c) or (d) applies, the person would not have serious difficulty, by reason of distance or inadequacy of means of communication, in obtaining drugs and appliances from a pharmacy.

(7) A Local Health Board must give a doctor reasonable notice—

(a) that it requires him or her to provide pharmaceutical services to any person; or

(b) subject to paragraph (8), that where a person no longer satisfies the provisions of paragraph (1), the doctor must discontinue the provision of pharmaceutical services to that person.

(8) A notice under paragraph (7)(b)—

(a) is subject to any postponement or termination of arrangements for the provision of pharmaceutical services to that person by that doctor made under regulation (10)(10)(b), 11ZA(6)(b), 12(17) or 13(15); and

(b) must not be given—

(i) pending any appeal against a decision by the Local Health Board to postpone the making or termination of such arrangements, or

(ii) where regulation 9(10) so requires.

(9) Notwithstanding paragraph (4), where a drug or appliance is one for which a doctor is entitled to an additional payment if he or she provides it, the doctor may, with the consent of the patient, instead of providing it himself or herself, order it by issuing a prescription to the patient in accordance with paragraph 39 of Schedule 6 to the GMS Regulations (or equivalent provision applying in relation to an APMS contractor or an LHBMS practice).

(10) Where an arrangement or requirement for a doctor to provide drugs or appliances to a patient was in effect immediately before 1 April 1992, that arrangement will have effect as though made under this regulation notwithstanding that neither of the conditions specified in paragraph (3) is satisfied.

(11) A doctor who provides pharmaceutical services to some or all of the patients on the relevant patients list in accordance with this regulation may provide any necessary pharmaceutical services to a person whom the relevant GMS or APMS contractor or LHBMS practice has accepted as a temporary resident under paragraph 16 of Schedule 6 to the GMS Regulations or any equivalent provision applying to APMS contractor or LHBMS practices.

(12) An appeal under paragraph (6) must be made in writing within 30 days beginning on the date on which notice of the decision was sent to the doctor and must contain a concise statement of the grounds of appeal.

(13) The Welsh Ministers will, on receipt of any notice of appeal under this regulation, send a copy of that notice to the Local Health Board and the relevant GMS contractor or APMS contractor, and the Local Health Board and relevant GMS contractor or APMS contractor may, within 30 days from the date on which the Welsh Ministers sent a copy of the notice of appeal, make representations in writing to the Welsh Ministers.

(14) The Welsh Ministers may determine an appeal pursuant to paragraph (6) in such manner as they think fit.

(15) The Welsh Ministers will, upon determination by them of any appeal under this regulation, give notice of their decision in writing, together with the reasons for it, to the appellant, to the Local Health Board, and to the relevant GMS contractor or APMS contractor.".

Amnewid rheoliad 21 o'r prif Reoliadau

14. Yn lle rheoliad 21 o'r prif Reoliadau (caniatâd amlinellol) rhodder y rheoliad canlynol—

"**Outline consent and premises approval**

21.—(1) A doctor wishing to be granted the right to provide pharmaceutical services under regulation 20(1)(b) or (c) by arrangement with a Local Health Board to patients residing in an area, may apply to the Local Health Board in writing for—

(a) consent (in these Regulations referred to as "outline consent") specifying the area in relation to which he or she wishes the outline consent to be granted; and

(b) approval of any premises from which he or she wishes to dispense ("premises approval"), specifying—

(i) the premises for which the doctor wishes to be granted premises approval and whether those premises are listed premises in relation to a different area, and

(ii) whether the application arises because a practice amalgamation has taken place or will be taking place and, if so, the names of the doctors or contractors participating in the amalgamation.

(2) An application under paragraph (1) will be determined in accordance with regulation 12 and 21A.".

Amnewid rheoliad 21A o'r prif Reoliadau

15. Yn lle rheoliad 21A o'r prif Reoliadau (meddygon a oedd gynt yn cyflawni gwasanaethau meddygol personol) rhodder y rheoliad canlynol—

"**Taking effect of outline consent and premises approval**

21A.—(1) When granting outline consent, the Local Health Board must determine in accordance with paragraph (2) when the outline consent is to take effect.

(2) The outline consent will take effect—

(a) in relation to premises to which paragraph (3) applies, on the date on which outline consent is finally granted; and

(b) in relation to premises to which paragraph (4) applies, in accordance with paragraphs (11) to (13).

(3) This paragraph applies to premises for which outline consent is sought and—

(a) which were, on the date of receipt of the application by the Local Health Board—

(i) practice premises, or

(ii) in a reserved location; or

(b) in relation to which, on the day before the date on which the application for outline consent is granted, there are no outstanding applications.

(4) This paragraph applies where, on the day before the date on which the application for outline consent is granted, there are outstanding applications.

(5) For the purpose of paragraphs (3) and (4), and regulation 21C and 21D an "outstanding application" means an application under regulation 4 or 14 which—

(a) is in relation to premises which are within 1.6 kilometres of the premises for which premises approval has been sought; and

(b) which—

(i) has been made but not determined (including on appeal), or

(ii) has been granted but the provision of pharmaceutical services from those premises has not been commenced.

(6) Where paragraph (2)(b) applies, notification of the determination of the application for outline consent by the Local Health Board or, on appeal, by the Welsh Ministers, must give details of—

(a) outstanding applications; and

(b) the earliest date on which, subject to paragraph (7), an application can be made under paragraph (11) to the Local Health Board for a determination that the outline consent should come into effect ("provisional date").

(7) The provisional date is the day after the end of a period of one year beginning with the date of—

(a) the determination of the application for outline consent; or

(b) where that determination is the subject of an appeal, the determination of that appeal.

(8) The Local Health Board may, at any time before the provisional date, for good cause determine that the provisional date is to be extended for a period not exceeding three months beginning with the date specified in paragraph (7)(a) or (b), and any reference in this regulation or in regulation 21C to the provisional date includes a reference to the provisional date extended under this paragraph.

(9) The Local Health Board must—

(a) ensure that any notifications required to be given by the Local Health Board or the Welsh Ministers in relation to any outstanding applications are also given to the doctor who made the application under regulation 21; and

(b) notify that doctor if any outstanding application is withdrawn; and

(c) where it extends the provisional date under paragraph (8), notify that doctor of the new provisional date.

(10) The outline consent will lapse if, before the provisional date, pharmaceutical services are provided from premises which were the subject of an outstanding application which has been granted.

(11) On, or as soon as reasonably practicable after, the provisional date, the Local Health Board must notify the doctor who made the application under regulation 21 and—

(a) he or she may within three months of the provisional date request the Local Health Board in writing to determine whether the outline consent should come into effect; and

(b) the Local Health Board must determine the request as soon as practicable and in accordance with paragraphs (12) and (13).

(12) Where on the date of the determination under paragraph (11), the premises are practice premises, the Local Health Board must determine that the outline consent and premises approval in respect of those premises will come into effect on that date.

(13) Where on the date of the determination under paragraph (11), the premises are not practice premises—

(a) the application for outline consent will be refused as regards premises approval for those premises; or

(b) where none of the premises for which premises approval has been granted are practice premises, the outline consent will lapse.

(14) The Local Health Board must notify its determination under paragraph (11) to the applicant and those persons to whom notice of the application under regulation 21 was required to be given under regulation 12(2) and (3).

(15) Where the Local Health Board has determined that—

(a) the provisional date is to be extended under paragraph (8);

(b) the application for outline consent is to be refused under paragraph (13)(a); or

(c) outline consent is to lapse under paragraph (13)(b),

the applicant may appeal under regulation 13 to the Welsh Ministers against any such determination by giving notice of appeal in accordance with regulation 13(6).

(16) Premises approval will take effect when the related outline consent takes effect.".

Amnewid rheoliad 21B o'r prif Reoliadau

16. Yn lle rheoliad 21B o'r prif Reoliadau (rhestrau meddygon fferyllol) rhodder y rheoliad canlynol—

"**Lapse of outline consent and premises approval**

21B.—(1) An outline consent will cease to have effect—

(a) where no arrangement under regulation 20 has been made pursuant to it within 12 months from its taking effect;

(b) where more than twelve months have elapsed since the last provision of drugs and appliances under an arrangement made pursuant to regulation 20;

(c) in accordance with regulation 21A(10) or (13); or

(d) where there is a practice amalgamation and following the amalgamation there are no practice premises which have premises approval.

(2) Premises approval will cease to have effect in relation to—

(a) listed premises which have permanently ceased to be practice premises;

(b) listed premises which have not been used for dispensing by any doctor authorised to dispense from those premises for six months or such longer period as the Local Health Board may for good cause allow;

(c) listed premises where a doctor who has outline consent to dispense from those premises has notified the Local Health Board that all the doctors who have authority to dispense from those premises have ceased to do so;

(d) listed premises where there is no doctor with premises approval in respect of them remaining on the dispensing doctor list; or

(e) listed premises which were granted premises approval under regulation 21E(3), where no practice amalgamation takes place within the period specified in regulation 21E(7).

(3) Premises approval will cease to have effect where the related outline consent ceases to have effect.".

Amnewid rheoliad 21C o'r prif Reoliadau

17. Yn lle rheoliad 21C o'r prif Reoliadau rhodder y rheoliad canlynol—

"**Premises approval: change of premises before outline consent takes effect**

21C.—(1) Where—

(a) outline consent has been granted but has not yet taken effect under regulation 21A; and

(b) before the provisional date the doctor who made the application under regulation 21 intends to change the premises from which he or she wishes to dispense,

he or she may apply to the Local Health Board in writing for the Local Health Board to determine whether premises approval should be given in relation to the new premises, and the Local Health Board must make the determination in accordance with paragraph (2).

(2) If the Local Health Board is satisfied that the change of premises is a minor relocation it may grant the premises approval for those premises, but if it is not so satisfied the application for premises approval to be given in relation to the new premises will be refused.

(3) The Local Health Board must notify those persons to whom notice of the application under regulation 21 was required to be given in accordance with regulation 12(2) and (3) and applicants in relation to the outstanding applications, of its determination under paragraph (2).

(4) The determination by the Local Health Board under paragraph (2) may be appealed to the Welsh Ministers under regulation 13 by the applicant.".

Mewnosod rheoliadau newydd yn y prif Reoliadau

18. Ar ôl rheoliad 21C yn y prif Reoliadau mewnosoder y rheoliadau canlynol—

"**Premises approval: additional and new premises after outline consent has taken effect**

21D.—(1) A doctor who—

(a) has been granted outline consent which has taken effect; or

(b) provides pharmaceutical services in reliance on regulation 20(3)(b),

and who wishes to be granted premises approval in relation to premises in addition to those in respect of which premises approval has been given ("additional premises") may apply to all the appropriate Local Health Boards and—

(i) the application will be determined by the relevant Local Health Board, and

(ii) regulations 12 and 21 apply to such an application as they apply to an application for outline consent under regulation 21.

(2) For the purposes of this regulation—

(a) the "appropriate Local Health Boards" are those who hold dispensing doctor lists on which the doctor making the application is included; and

(b) the "relevant Local Health Board" is the Local Health Board in whose area the additional premises are situated.

(3) A doctor wishing to be granted premises approval in relation to premises ("new premises") where he or she wishes to dispense instead of listed premises may apply to all the appropriate Local Health Boards and the application will be determined by the relevant Local Health Board in accordance with paragraph (4).

(4) The relevant Local Health Board must—

(a) grant the application made in accordance with paragraph (3) where—

(i) the new premises are less than 500 metres by the most practicable route on foot from the listed premises which they are to replace, or

(ii) the Local Health Board is otherwise satisfied that granting the application would not result in a significant change in the arrangements for the provision of pharmaceutical or dispensing services to any part of a controlled locality, provided that no further applications will be granted under this sub-paragraph for a period of twelve months beginning with the date on which the doctor commenced providing services from the new premises unless the Local Health Board for good cause allows; or

(b) in any other case determine the application in accordance with paragraph (1) as if the references to additional premises were to new premises.

(5) The relevant Local Health Board must notify its determination under paragraph (4)(a) to the persons to whom the notice is required to be given under regulation 12(2) and (3) and to the appropriate Local Health Boards.

(6) A determination by the relevant Local Health Board may be appealed to the Welsh Ministers under regulation 13 by the applicant and any of the persons notified under paragraph (5) apart from any Local Pharmaceutical Committee or any Local Medical Committee.

(7) Subject to paragraph (8), when granted in relation to new or additional premises, the premises approval will take effect from the date of notification of the grant and for this purpose the date of the notification of a grant of any application is to be—

(a) where no appeal is made under paragraph (6) against the decision of the relevant Local Health Board, the date after the expiry of 30 days beginning with the date on which notice of that decision is given under paragraph (5); or

(b) where such an appeal is made, the date on which the Welsh Ministers give notice of their decision under regulation 13.

(8) Where—

(a) the premises approval is granted in relation to additional premises; and

(b) in relation to the premises for which the approval is granted there were, at the date of the grant, outstanding applications,

the premises approval will take effect on the date which is the day after the end of a period of one year, or such longer period (not exceeding three months) as the relevant Local Health Board may for good cause allow before the expiration of that year, from the final resolution of any outstanding application.

(9) The relevant Local Health Board may grant temporary premises approval to a doctor who has outline consent and premises approval in relation to additional or new premises where it considers it desirable to do so to secure the adequate provision of pharmaceutical services in the area served by the additional or new premises, and renew any such temporary approval granted, to secure such adequate provision, and where it does so it must—

(a) notify those persons to whom notice of the application under regulation 21 was required to be given under regulation 12(2) and (3) and applicants in relation to outstanding applications;

(b) state the period during which the temporary premises approval is to apply; and

(c) include those premises in the dispensing doctor list in relation to that doctor.

(10) Temporary premises approval may be granted for a period not exceeding twelve months, and may be renewed for a further period not exceeding three months.

Premises approval: practice amalgamations

21E.—(1) For the purposes of these Regulations, "a practice amalgamation" occurs where either—

(a) two or more providers of primary medical services merge; or

(b) a GMS contractor, an APMS contractor or a doctor who provides primary medical services for an LHBMS practice is employed or engaged by another GMS contractor or APMS contractor or by a Local Health Board to provide services within another LHBMS practice,

as a result of which two or more patient lists are combined.

(2) If, following a practice amalgamation, all the practice premises of the new practice are premises in respect of which premises approval was in effect immediately prior to the practice amalgamation, then outline consent and premises approval will continue to have effect.

(3) Where there is, or will be, a practice amalgamation and none or not all of the practice premises of the new amalgamating practice had been premises in respect of which premises approval was in effect immediately prior to the practice amalgamation, a doctor who is party to the practice amalgamation and who has been granted outline consent and premises approval which is in effect either immediately before the practice amalgamation or the date of the application under this paragraph, may make an application for premises approval, and such an application will be determined as provided in regulation 21D as if it were an application from a doctor with premises approval to have the right to dispense from—

(a) additional premises where the premise approval is required for additional premises as defined in regulation 21D(1); or

(b) new premises where the premises approval is required for new premises as defined in regulation 21D(3),

and the Local Health Board may grant temporary premises approval under regulation 21D(9).

(4) An application mentioned in paragraph (3) may be made before or after the practice amalgamation takes place, and where the practice amalgamation takes effect before the application has been finally determined—

(a) any premises approval in effect at the date of the practice amalgamation will have effect from the date of the amalgamation as if it were a temporary premises approval under regulation 21D(9) for a period stated by the Local Health Board not exceeding one year; and

(b) the new practice will have temporary premises approval from the date of the practice amalgamation to dispense from any premises mentioned in the application for a period stated by the Local Health Board not exceeding one year.

(5) When the practice amalgamation takes effect the doctors must notify all Local Health Boards in whose area the amalgamated practice is situated that the practice amalgamation has taken place.

(6) Subject to paragraph (7), where an application made under paragraph (3) was granted before the practice amalgamation takes place, premises approval will take effect from the date of the practice amalgamation.

(7) Where an application was made under paragraph (3) before the practice amalgamation takes place and the practice amalgamation has not taken place before the end of a period of one year beginning with the date that premises approval was granted under that paragraph, that grant will lapse.

(8) Where an application under paragraph (3) for premises approval is refused either for all or any of the premises specified in the application, whether before or after the practice amalgamation takes place, the doctors who had premises approval prior to making the application, and any other doctor in the new practice after that date will have residual premises approval.

(9) For the purposes of this regulation "residual premises approval" means premises approval to dispense—

(a) from premises in respect of which the doctor or another doctor in his or her practice had premises approval at the time of the application in relation to the practice amalgamation; and

(b) to—

(i) a patient for whom the doctor making the application is authorised to provide pharmaceutical services on the date the application was refused, but excluding any such patient who ceases to be a patient mentioned in regulation 20(1)(b) or (c); or

(ii) a patient who is not mentioned in paragraph (i) but who is mentioned in regulation 20(1)(a) or (d) and for whom the doctor making the application is authorised to provide pharmaceutical services on the date the application was refused.

(10) For the purposes of paragraph (9), regulation 20(1)(b) or (c) is to be read as if the words "and one of the conditions specified in paragraph (3) is satisfied in his or her case" were omitted.

Premises Approval: transitional provisions

21F.—(1) This regulation applies to a doctor who, before the coming into force of these Regulations—

(a) has been finally granted outline consent; or

(b) for whom arrangements were in effect,

to provide drugs and appliances to patients and that consent is, or those arrangements or requirements are, in effect on the date these Regulations come into force.

(2) For the purposes of this regulation "relevant premises" means—

(a) premises from which, at the date of notification under paragraph (5), the doctor is providing primary medical services; or

(b) premises in addition to or in place of the premises specified in paragraph (a) where, immediately before the coming into force of these Regulations, the doctor intended to dispense.

(3) The Local Health Board must determine whether or not to grant premises approval to relevant premises in accordance with paragraphs (4) to (6).

(4) Before the end of the period of 30 days beginning with the date these Regulations come into force, the Local Health Board must notify each doctor on its dispensing doctors list that—

(a) the Local Health Board is required to make a determination under paragraph (3) as to whether or not to grant premises approval in respect of the relevant premises; and

(b) the doctor may make written representations to the Local Health Board in relation to such a determination within the period of 30 days beginning with the date of

the Local Health Board's notification or such longer period as the Local Health Board may for good cause allow.

(5) The Local Health Board must—

(a) also notify the Local Medical Committee and the Local Pharmaceutical Committee, to which it is required to send a copy of the application under regulations 12(2) and (3), and inform them that they may make written representations within the period of 30 days beginning with the date of the Local Health Board's notification;

(b) consider any representations received from the Committees mentioned in sub-paragraph (a) and the doctor;

(c) determine whether the doctor has premises approval for premises which are, or are part of, relevant premises; and

(d) notify its decision to—

(i) the doctor,

(ii) the Committees mentioned in sub-paragraph (a),

(iii) any person providing pharmaceutical services or dispensing services in the Local Health Board's area whose interests might, in the opinion of the Local Health Board, be affected, and

(iv) all Community Health Councils in that area.

(6) The Local Health Board will grant premises approval under paragraph (3) where—

(a) it is satisfied that the relevant premises were, prior to the coming into force of these Regulations, being routinely used to provide dispensing services; or

(b) outline consent had been granted in respect of relevant premises after 16 July 2008.

(7) The Local Health Board must not refuse to grant premises approval under paragraph (3) by reason of the relevant premises being within 1.6 kilometres of any pharmacy.

(8) The Local Health Board's decision under paragraph (5)(c) may be appealed to the Welsh Ministers by a person notified of the determination under paragraph (5)(d) except the Committees mentioned in paragraph (5)(a), and regulations 13(6) to (16) apply to such appeals except that, for this purpose, regulation 13 is to be read as if—

(a) in paragraph (8) of that regulation the reference to "those persons mentioned, where relevant in paragraph (1)(b), (2)(b) or (4)(a)" were a reference to those persons notified under paragraph (5)(d);

(b) in paragraph (13) of that regulation the list of persons to whom notice of the hearing should be sent were a reference to the persons notified under paragraph (5)(d); and

(c) in paragraph (15) of that regulation sub-paragraphs (b), (c) and (d) were omitted.

(9) Until—

(a) the date of the determination of the Local Health Board under paragraph (3); or

(b) the date that any appeal under paragraph (8) is decided,

whichever is the later, a doctor will be deemed to have been granted premises approval for the relevant premises, but he or she may not make any application under regulation 21C or 21D by virtue of this paragraph.

Dispensing doctor lists

21G.—(1) The Local Health Board must prepare, maintain and publish a list, to be called the dispensing doctor list, of the names of those doctors authorised or required by the Local Health Board under regulation 20 to provide pharmaceutical services to their patients and who are actually doing so.

(2) The dispensing doctor list must indicate the name and address of the relevant GMS contractor or APMS contractor from whose premises any doctor whose name is included in that list performs primary medical services.

(3) Where the doctor whose name is included in the dispensing doctor list provides primary medical services with an LHBMS practice, the list must give the name and address of the Local Health Board.

(4) The dispensing doctor list must, in addition to the information required under paragraphs (2) and (3)—

(a) include the premises in relation to which the doctor has premises approval;

(b) state in relation to each premises included—

(i) if premises approval is deemed, temporary or residual, that this is the case,

(ii) the date on which premises approval took effect or where it has not taken effect the date that it was finally granted,

(c) state the area in relation to which there is outline consent and premises approval; and

(d) include and identify separately, any premises in relation to which the doctor has outstanding applications for premises approval.

Removal of entries from dispensing doctor lists

21H. A Local Health Board must remove the name of a doctor from its dispensing doctor list where the Local Health Board determines that—

(a) the doctor has died;

(b) the doctor is no longer performing primary medical services within the area of the Local Health Board;

(c) more than 12 months have elapsed since the doctor last provided drugs or appliances under an arrangement made with the Local Health Board pursuant to regulation 20; or

(d) the doctor has been removed from the medical performers list.".

Amnewid Rhan 6 o Atodlen 2 i'r prif Reoliadau

19.—(1) Yn lle Rhan 6 o Atodlen 2 i'r prif Reoliadau (telerau gwasanaethu ar gyfer meddygon sy'n darparu gwasanethau fferyllol) rhodder y Rhan ganlynol—

"PART 6

Terms of service for doctors who provide pharmaceutical services

Persons duly authorised to dispense on behalf of dispensing doctors

34. Where this Schedule imposes a requirement on a dispensing doctor in respect of an activity which he or she has duly authorised another person to undertake, if that other person undertakes that activity instead of the dispensing doctor—

(a) that other person must comply with that requirement; and

(b) that dispensing doctor must secure compliance with that requirement by that other person,

and references in this Schedule to a dispensing doctor are to be construed accordingly.

Dispensing of drugs and appliances ordered by another prescriber

35.—(1) Subject to the following provisions of this Schedule, where—

(a) any person presents to a dispensing doctor a prescription form which contains—

(i) an order for drugs, not being Scheduled drugs, or for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor,

(ii) an order for drugs specified in Schedule 2 to the Prescription of Drugs Regulations, signed by a prescriber other than the dispensing doctor, and including the reference "SLS", or

(iii) an order for restricted availability appliances, signed by a prescriber other than the dispensing doctor and including the reference "SLS",

and the dispensing doctor is authorised or required by virtue of regulation 20 of these Regulations to provide the drugs or appliances so ordered, he or she will, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he or she supplies in the normal course of his or her practice or business.

(2) Subject to the following provisions of this Part, where any person presents to a dispensing doctor a repeatable prescription which contains—

(a) an order for drugs, not being Scheduled drugs or controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drugs which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber,

(b) an order for a drugs specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber and including the reference "SLS",

(c) an order for appliances, not being restricted availability appliances, signed by a prescriber other than the dispensing doctor who is a repeatable prescriber, and including the reference "SLS",

and also presents an associated batch issue and the dispensing doctor is authorised or required by regulation 20 to provide the drugs or appliances so ordered, the dispensing

doctor must, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he or she supplies in the normal course of his or her practice or business.

(3) For the purposes of this paragraph, a repeatable prescription for drugs or appliances will be taken to be presented even if the person who wishes to obtain the drugs or appliances does not present that prescription, where—

(a) the dispensing doctor has that prescription in his or her possession; and

(b) that person presents, or the dispensing doctor has in his or her possession, an associated batch issue.

(4) Drugs and listed appliances provided under this paragraph must be provided in a suitable container.

Dispensing of drugs and appliances ordered by the dispensing doctor

36. In circumstances where paragraph 34 does not apply and subject to the following provisions of this Schedule, where a dispensing doctor is authorised or required by virtue of regulation 20 of these Regulations to provide drugs or appliances to a person, the dispensing doctor must—

(a) record an order for the provision of any drugs or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with the term of a contract which gives effect to paragraph 39(3) of Schedule 6 to the GMS Regulations or an equivalent provision applying in relation to that contract;

(b) provide those drugs or appliances in a suitable container;

(c) provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied; and

(d) provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.

Preliminary matters before providing ordered drugs or appliances

37. Before providing drugs or listed appliances recorded on a prescription form in accordance with paragraph 35, or in the circumstances set out in paragraph 36—

(a) the dispensing doctor must ask any person who makes a declaration that the patient does not have to pay the charges specified in regulation 4(1) of the Charges Regulations by virtue of either—

(i) entitlement to an exemption under regulation 8(1) of the Charges Regulations, or

(ii) entitlement to remission of charges under regulation 5 of the Remission of Charges Regulations,

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of regulation 8 of the Charges Regulations or in respect of remission by virtue of regulation 5(1)(e) or 5(2)(e) or (f) of the Remission of Charges Regulations, and at the time of the declaration the dispensing doctor already has such evidence available to him or her; and

(b) if no satisfactory evidence, as required by sub-paragraph (a) is produced to the dispensing doctor, the dispensing doctor must endorse the form on which the declaration is made to that effect.

Provision of Scheduled drugs

38.—(1) Subject to sub-paragraph (2), a dispensing doctor must not provide for a patient any Scheduled drug, except that, where the dispensing doctor or an independent prescriber has ordered a drug which has an appropriate non-proprietary name either by the name or by its formula, he or she may provide a drug which has the same specification notwithstanding that it is a Scheduled drug (but, in the case of a drug which combines more than one drug, only if the combination has an appropriate non-proprietary name).

(2) Nothing in this Part prevents a dispensing doctor providing, otherwise than under pharmaceutical services, a Scheduled drug or a restricted availability appliance for a patient.

Refusal to provide drugs or appliances ordered

39.—(1) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription where—

(a) the dispensing doctor reasonably believes that it is not a genuine order for the person named on the prescription form or the repeatable prescription (for example, because the dispensing doctor reasonably believes that it has been stolen or forged); or

(b) it appears to the dispensing doctor that there is an error on the prescription form or on the repeatable prescription or its associated batch issue (including a clinical error made by the prescriber), or that, in the circumstances, providing the drugs or appliances would be contrary to the dispensing doctor's clinical judgement.

(2) A dispensing doctor may refuse to provide the drugs or appliances ordered on a prescription form or repeatable prescription, or which he or she is otherwise authorised or required to provide by virtue of regulation 20 of these Regulations, where—

(a) the dispensing doctor or other persons on the premises are subjected to or threatened with violence by the person presenting the prescription or repeatable prescription, or by any person accompanying that person; or

(b) the person presenting the prescription form or repeatable prescription, or any other person accompanying that person, commits or threatens to commit a criminal offence.

(3) A dispensing doctor must refuse to provide drugs or appliances ordered on a repeatable prescription where—

(a) the dispensing doctor has no record of that prescription;

(b) it is not signed by a repeatable prescriber;

(c) to do so would not be in accordance with any intervals specified in the prescription;

(d) it would be the first time a drug or appliance had been provided pursuant to the prescription and the prescription was signed more than six months previously;

(e) if the repeatable prescription was signed more than one year previously;

(f) the expiry date on the repeatable prescription has passed; or

(g) where the dispensing doctor has been informed by the repeatable prescriber that the prescription is no longer required.

(4) Where the patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), a dispensing doctor may only provide the drugs or appliances ordered if he or she is satisfied—

(a) that the patient to whom the prescription relates—

(i) is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and

(ii) is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;

(b) that the medication regimen of the patient to whom the prescription relates has not altered in a way that indicates the need or desirability of reviewing the patient's treatment; and

(c) that there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Fees and charges

40.—(1) The terms of a GMS contract giving effect to regulation 24 of, and Schedule 5 to, the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a dispensing doctor as they apply in relation to prescriptions for drugs and appliances.

(2) Where a dispensing doctor provides a drug or appliance under pharmaceutical services or provides any additional service associated with the dispensing of such drugs and appliances in accordance with an agreement with the Local Health Board—

(a) in accordance with this Part or an agreement with the Local Health Board; and

(b) had the drug, appliance or additional service been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled by, by virtue of directions given by the Welsh Ministers under section 45 of the 2006 Act, to a payment—

(i) in respect of the drug or appliance; or

(ii) in respect of the additional service provision,

the Local Health Board will credit him or her with the payment.

Complaints procedures

41.—(1) Where a dispensing doctor—

(a) is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which give effect to paragraph 90 of Schedule 6 to the GMS Regulations;

(b) is an APMS contractor, or is engaged or employed by an APMS contractor, the complaints procedure established by the relevant APMS contract to deal with complaints in relation to the provision of primary medical services;

(c) is employed or engaged by a Local Health Board for the purposes of providing services within an LHBMS practice, the complaints procedure established by that LHBMS practice to deal with complaints in relation to the provision of primary medical services,

applies in relation to any matter reasonably connected with the provision of pharmaceutical services as it applies as respects to services provided under that contract or agreement, or within that practice.

(2) Accordingly, the term of any GMS contract which gives effect to paragraph 95 of Schedule 6 to the GMS Regulations also applies in relation to complaints about such matters.

Inspections and access to information

42.—(1) A dispensing doctor must allow persons authorised by the Local Health Board to enter and inspect any premises that he or she uses for the provision of pharmaceutical services at any reasonable time, for the purposes of—

(a) ascertaining whether or not the dispensing doctor is complying with the requirements of this Part;

(b) auditing, monitoring and analysing—

(i) the provision made by the dispensing doctor, in the course of providing pharmaceutical services, for patient care and treatment, and

(ii) the management by the dispensing doctor of the pharmaceutical services he or she provides,

where the conditions in sub-paragraph (2) are satisfied.

(2) The conditions are that—

(a) reasonable notice of the intended entry has been given;

(b) the Local Medical Committee for the area in which the premises are situated has been invited to be present at the inspection, where this is requested by the dispensing doctor;

(c) the person authorised in writing carries written evidence of his or her authorisation, which must be produced on request; and

(d) he or she does not enter any part of the premises used solely as residential accommodation without the consent of the resident.

(3) A dispensing doctor must, at the request of the Local Health Board or of a person authorised in writing mentioned in sub-paragraph (1), allow it or that person access to any information which it or that person reasonably requires—

(a) for the purposes mentioned in sub-paragraph (1); or

(b) in the case of the Local Health Board, in connection with its functions that relate to pharmaceutical services.".

Edwina Hart
Y Gweinidog dros Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru

15 Mehefin 2009

EXPLANATORY NOTE

(nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

Mae'r Rheoliadau hyn yn diwygio ymhellach Reoliadau'r Gwasanaeth Iechyd Gwladol (Gwasanaethau Fferyllol) 1992 ("y prif Reoliadau").

Mae'r prif Reoliadau yn llywodraethu trefniadau ar gyfer darparu gwasanaethau fferyllol o dan Ddeddf y Gwasanaeth Iechyd Gwladol (Cymru) 2006.

Mae'r diwygiadau yn y prif Reoliadau, a wneir gan y Rheoliadau hyn, yn gwneud newidiadau yn y modd y darperir gwasanaethau fferyllol mewn ardaloedd a bennwyd yn ardaloedd o gymeriad gwledig, hynny yw, yn "rheoledig" at ddibenion y prif Reoliadau. Mae'r Rheoliadau hyn yn gwneud diwygiadau canlyniadol yn ogystal.

Mae'r newidiadau a gyflwynir gan y Rheoliadau hyn yn cynnwys:

1. Darpariaeth sy'n rhwystro cymeradwyo ceisiadau newydd gan feddygon am yr hawl i ddarparu gwasanaethau fferyllol i gleifion, os oes fferyllfa o fewn 1.6 cilometr i'r fangre y mae'r meddyg yn dymuno darparu gwasanaethau o'r fath ohoni. Nid effeithir ar hawliau'r practisiau meddygol fferyllol presennol.

2. Bydd yn ofynnol i Fyrddau Iechyd Lleol, o fewn eu priod ardaloedd, sefydlu rhestr o'r mangreoedd y mae meddygon yn darparu gwasanaethau fferyllol ohonynt. Bydd yn ofynnol hefyd i'r Bwrdd Iechyd Lleol gymeradwyo addasrwydd pob mangre o'r fath i'w defnyddio fel mangre fferyllol ("cymeradwyaeth mangre").

3. Ar gyfer mangreoedd y mae meddygon yn darparu gwasanaethau fferyllol ohonynt ar y dyddiad y daw'r Rheoliadau hyn i rym, neu fangreoedd y rhoddwyd caniatâd amlinellol iddynt eisoes, bydd yn ofynnol sicrhau cymeradwyaeth mangre gan y Bwrdd Iechyd Lleol o fewn tri mis wedi i'r Rheoliadau hyn ddod i rym.

4. Gwneir darpariaethau newydd sy'n caniatáu i feddyg fferyllol wneud cais i adleoli mangre fferyllol heb gorfod ailymgeisio am ganiatâd amlinellol a chymeradwyaeth mangre, ar yr amod bod y Bwrdd Iechyd Lleol wedi ei fodloni bod y symudiad yn "adleoliad bach"

5. Cyflwynir darpariaethau newydd a fydd yn galluogi meddygon fferyllol i adleoli eu mangreoedd neu agor mangreoedd newydd. Ni roddir cymeradwyaeth ar gyfer hynny oni fydd y pellter rhwng y fangre ac unrhyw fferyllfa yn fwy nag 1.6 cilometr, ac ni ddaw'r gymeradwyaeth yn effeithiol cyn pen 12 mis ar ôl caniatáu'r cais (i roi cyfle i unrhyw fferyllfa yr effeithir arni gan yr adleoliad i wneud cais i adleoli).

6. Gwneir darpariaeth i bennu'r weithdrefn sydd i'w dilyn pan fo practis meddygol fferyllol yn uno â practis arall, nad yw'n bractis fferyllol.

7. Gwneir darpariaeth i gynnwys "lleoliadau neilltuedig" o fewn ardaloedd a bennwyd yn ardaloedd rheoledig at ddibenion y prif Reoliadau. Lleoliad neilltuedig yw un lle mae'r boblogaeth o gleifion (ar yr holl restrau cleifion) sydd o fewn 1.6 cilometr i leoliad amcanedig neu wirioneddol mangre'r fferyllfa arfaethedig yn llai na 2,750. Os bodlonir y Bwrdd Iechyd Lleol bod ardal benodol yn lleoliad neilltuedig, ni fydd cais am gynnwys mangre yn y rhestr fferyllol yn unol â rheoliad 4(2) o'r prif Reoliadau yn ddarostyngedig i'r prawf "niweidio". Ni fydd y cleifion sy'n byw o fewn 1.6 cilometr i'r fferyllfa newydd ac yn cael gwasanaethau fferyllol gan bractis meddygol fferyllol, yn colli eu hawl i gael gwasanaethau o'r fath, a chânt ddewis naill ai derbyn gwasanaethau fferyllol gan eu meddyg neu o'r fferyllfa.

8. Caiff Byrddau Iechyd Lleol ddiddymu (neu wrthod priodoli) statws lleoliad neilltuedig mewn dau fath o amgylchiad:

- os yw'r boblogaeth cleifion yn mynd dros 2,750, ac
- os yw'r boblogaeth cleifion islaw 2,750, ond y Bwrdd Iechyd Lleol o'r farn bod anghenion y boblogaeth o gleifion yn y lleoliad dan sylw yn debyg i'r anghenion yn yr ardaloedd hynny sydd â phoblogaeth fwy.

Mewn amgylchiadau o'r fath bydd cais a wneir o dan adran 4(2) o'r prif Reoliadau yn ddarostyngedig i'r prawf "niweidio".

9. Gwneir diwygiadau i alluogi meddygon a fferyllwyr sy'n darparu gwasanaethau mewn ardaloedd a reolir i apelio i Weinidogion Cymru pan wneir penderfyniad gan Fwrdd Iechyd lleol ynghylch natur wledig ardal benodol. Cyn hyn, Pwyllgorau Fferyllol Lleol a Phwyllgorau Meddygol Lleol yn unig oedd â hawl i apelio yn erbyn penderfyniad o'r fath.

10. Estynnir y gofynion hysbysu, gan ei gwneud yn ofynnol i Fwrdd Iechyd Lleol roi hysbysiadau o rai mathau o geisiadau a wneir o dan reoliad 4(2) o'r prif Reoliadau, i unrhyw glaf, defnyddiwr neu grŵp cymunedol yr ystyria'r Bwrdd bod buddiant ganddo yn y ddarpariaeth o wasanaethau fferyllol o fewn yr ardal.

11. Gwneir diwygiad i ddileu anghysondeb a oedd wedi golygu nad oedd yn ofynnol cymhwyso'r prawf "niweidio" i bob cais a wnaed o dan reoliad 4(2) o'r prif Reoliadau, os oedd y fangre arfaethedig wedi ei lleoli mewn ardal reoledig

12. Amnewidir y telerau gwasanaethu ar gyfer meddygon sy'n darparu gwasanaethau fferyllol o dan y prif Reoliadau. Un gofyniad newydd yn y telerau gwasanaethu yw y bydd pob mangre a ddefnyddir gan feddygon ar gyfer gwaith fferyllol yn agored i'w harolygu gan y Bwrdd Iechyd Lleol (mae darpariaeth gyffelyb eisoes yn gymwys yn achos fferyllfeydd cymunedol).