STATUTORY INSTRUMENTS

2025 No. 989

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Miscellaneous Amendments) Regulations 2025

Made - - - -	*1st September 2025*
Laid before Parliament	*3rd September 2025*
Coming into force - -	*1st October 2025*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 7, 8, 126(2), 128A, 129, 130, 132, 136, 139, 142(b), 143, 148, 150A, 151(5) and (7), 154, 160, 162, 164, 169(3) and 272(7) and (8) of, and paragraphs 2 and 3 of Schedule 12 to, the National Health Service Act 2006(**1**).

(**1**) 2006 c. 41. Section 7 has been amended by the Health and Social Care Act (c. 7) ("the 2012 Act"), section 21. Section 8 has been amended by the 2012 Act, Schedule 4, paragraph 5(1) and (2). Section 126 has been amended by: the 2012 Act, sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63; the Children and Social Work Act 2017 (c. 16), Schedule 5, paragraphs 30 and 47; and the Health and Care Act 2022 (c. 31) ("the 2022 Act"), Schedule 1, paragraph 1. Section 128A was inserted by the Health Act 2009 (c. 21) ("the 2009 Act"), section 25. Section 129 has been amended by: the 2009 Act, section 26(3) and (7) and 27, and Schedule 6; the 2012 Act, section 207(6) and (8), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraphs 120 and 121; the 2022 Act, Schedule 1, paragraph 1; and S.I. 2010/231. Section 130 has been amended by: the 2012 Act, section 207(10)(a) and (b); the 2022 Act, Schedule 1, paragraph 1; and S.I. 2010/22. Section 132 has been amended by: the Protection of Freedoms Act 2012, Schedule 9, paragraph 122; the 2012 Act, Schedule 4, paragraph 69(4); the 2022 Act, Schedule 1, paragraph 1; and S.I. 2007/289 and 2010/22 and 231. Section 136 has been amended by the 2012 Act, section 207(11)(a) and (b), and the 2022 Act, Schedule 1, paragraph 1. Section 139 has been amended by the Crime and Courts Act 2013 (c. 22) ("the 2013 Act"), Schedule 9, paragraph 52. Section 148 has been amended by the 2022 Act, Schedule 1, paragraph 1, and S.I. 2010/22. Section 150A was inserted by the 2009 Act, section 28, and has been amended by 2022 Act, Schedule 1, paragraph 1. Section 151 has been amended by the 2022 Act, Schedule 1, paragraph 1. Section 154 has been amended by the 2022 Act, Schedule 1, paragraph 1, and S.I. 2010/22. Section 160 has been amended by the 2022 Act, Schedule 1, paragraph 1. Section 162 has been amended by the 2022 Act, Schedule 1, paragraph 1. In section 164, subsections (8A) to (8E) were inserted by the Health Service Medical Supplies (Costs) Act 2017 (c. 23), section 1, and subsections (8A) and (8D) have been amended by the 2022 Act, section 161(1)(a) to (c). Section 169 has been amended by S.I. 2010/22. Paragraph 2 of Schedule 12 has been amended by: the 2012 Act, sections 207(12)(a) and (b), and Schedule 4, paragraph 93; and the 2022 Act, Schedule 1, paragraph 1. Paragraph 3 of Schedule 12 has been amended by: the 2009 Act, section 29(13) to (15); the 2012 Act, Schedule 4, paragraph 93(4); the 2013 Act, Schedule 9, paragraph 52(1)(b) and (2); and the 2022 Act, Schedule 1, paragraph 1. *See* section 275(1) of the National Health Service Act 2006 for the meanings given to "prescribed" and "regulations" which are relevant to the powers being exercised.

PART 1

General

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Miscellaneous Amendments) Regulations 2025.

(2) These Regulations come into force on 1st October 2025.

(3) These Regulations extend to England and Wales and apply in relation to England only(**2**).

Amendments to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

2. The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013(**3**) are amended as follows.

PART 2

Amendments relating to the transfer of functions to the NHS Counter Fraud Authority

Amendment to regulation 2

3. In regulation 2 (interpretation)(**4**), in paragraph (1), at the appropriate place insert—

> ""NHS CFA" means the NHS Counter Fraud Authority, established by the NHS Counter Fraud Authority (Establishment, Constitution, and Staff and Other Transfer Provisions) Order 2017(**5**);".

Amendment to regulation 33

4. In regulation 33 (refusal of applications for inclusion in a pharmaceutical list on fitness grounds)(**6**), in paragraph (2)(c)(i), for "NHS BSA" substitute "NHS CFA".

Amendments to regulation 34

5. In regulation 34 (deferral of consideration of applications for inclusion in a pharmaceutical list on fitness grounds)(**7**), in paragraph (1)—

(a) in sub-paragraph (h), for "NHS BSA" substitute "NHS CFA"; and

(b) in sub-paragraph (i), for "NHS BSA" substitute "NHS CFA".

Amendment to regulation 88

6. In regulation 88 (wider notifications of fitness decisions)(**8**), in paragraph (2)(h), for "NHS BSA" substitute "NHS CFA".

(**2**) *See* section 271(1) of the National Health Service Act 2006, by virtue of which the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England.
(**3**) S.I. 2013/349, as amended.
(**4**) There have been amendments to regulation 2 but none are relevant.
(**5**) S.I. 2017/958, as amended.
(**6**) Regulation 33 has been amended by S.I. 2014/417, 2015/1472 and 2023/1071.
(**7**) Regulation 34 has been amended by S.I. 2014/417 and 2023/1071.
(**8**) Regulation 88 has been amended by S.I. 2023/1071.

Amendment to regulation 106

7. In regulation 106 (LPS proposals: fitness information to be supplied)(**9**), in paragraph (2)(l), for "NHS BSA" substitute "NHS CFA".

Amendments to Schedule 2

8.—(1) Schedule 2 (applications in respect of pharmaceutical lists and the procedures to be followed) is amended as follows.

(2) In Part 1 (information to be included in routine and excepted applications)—

(a) in paragraph 3 (fitness information about individuals: routine and excepted applications for inclusion in a pharmaceutical list)(**10**), in sub-paragraph (10), for "NHS BSA" substitute "NHS CFA"; and

(b) in paragraph 4 (fitness information about corporate bodies: routine and excepted applications for inclusion in a pharmaceutical list)(**11**), in sub-paragraph (7), for "NHS BSA" substitute "NHS CFA".

(3) In Part 4 (determination and deferral of applications), in paragraph 23 (additional matters for consideration in relation to applications for inclusion in a pharmaceutical list)(**12**), in sub-paragraph (1)(a), for "NHS BSA" substitute "NHS CFA".

Amendments to Schedule 4

9. In Schedule 4 (terms of service of NHS pharmacists), in Part 4 (other terms of service), in paragraph 31 (duty to provide information about fitness matters as they arise)(**13**)—

(a) in sub-paragraph (1)(k), for "NHS BSA" substitute "NHS CFA"; and

(b) in sub-paragraph (2)(f), for "NHS BSA" substitute "NHS CFA".

Amendments to Schedule 5

10. In Schedule 5 (terms of service of NHS appliance contractors), in paragraph 21 (duty to provide information about fitness matters as they arise)(**14**)—

(a) in sub-paragraph (1)(k), for "NHS BSA" substitute "NHS CFA"; and

(b) in sub-paragraph (2)(f), for "NHS BSA" substitute "NHS CFA".

Amendment to Schedule 7

11. In Schedule 7 (mandatory terms for LPS schemes), in paragraph 15 (duty to provide information about fitness to practise matters as they arise)(**15**), in sub-paragraph (1)(j), for "NHS BSA" substitute "NHS CFA".

(**9**) Regulation 106 has been amended by S.I. 2023/1071.
(**10**) Paragraph 3 has been amended by S.I. 2023/479 and 2024/894.
(**11**) Paragraph 4 has been amended by S.I. 2015/58.
(**12**) Paragraph 23 has been amended by S.I. 2023/1071 and 2024/894.
(**13**) Paragraph 31 has been amended by S.I. 2023/1071.
(**14**) Paragraph 21 has been amended by S.I. 2023/1071.
(**15**) Paragraph 15 has been amended by S.I. 2023/1071.

PART 3

Amendments relating to "hub and spoke" dispensing

Amendment to Schedule 4

12. In Schedule 4 (terms of service of NHS pharmacists), in Part 2 (essential services), after paragraph 7 (preliminary matters before providing ordered drugs or appliances)(**16**), insert—

"**Sub-contracting aspects of dispensing under "hub and spoke" arrangements**

7A.—(1) Subject to sub-paragraph (3), an NHS pharmacist (P1) must not sub-contract the performance of any of its core dispensing functions.

(2) For the purposes of this paragraph and paragraph 7B, "core dispensing functions" means the assembly or part-assembly of any prescription item (including bagging and the application of dispensing labels) with a view to the supply of that prescription item in accordance with a prescription, a SSP, a LPIV, a PTP or a PTPGD.

(3) Sub-paragraph (1) does not apply to—

(a) a contract for services between P1 and—

(i) a health care professional (for example, a locum) or a provider of locums, or

(ii) a corporate body that is—

(aa) is a subsidiary undertaking of P1, or

(bb) a subsidiary undertaking of a parent undertaking of which P1 is also a subsidiary undertaking,

for the performance by that health care professional, a locum provided by the provider of locums, or the corporate body of core dispensing functions at P1's pharmacy premises;

(b) arrangements whereby a retail pharmacy business that is not P1 is nevertheless carrying on a retail pharmacy business at P1's premises as a temporary arrangement related to the purchase of those premises; or

(c) the performance of any of P1's core dispensing functions under valid hub and spoke arrangements.

(4) For the purposes of this paragraph and paragraphs 7B and 7C, "hub and spoke arrangements" are arrangements between P1 and another retail pharmacy business (P2) which—

(a) are for the purpose of P2 supporting P1with regard to the fulfilment of orders—

(i) submitted to P1 on prescription forms or LPIVs, or

(ii) for the provision of prescription items by P1 in accordance with PTPs or PTPGDs; and

(b) provide for the assembly or part-assembly of those orders (including in accordance with a SSP) at premises of P2 with a view to the supply of the prescription items at or from the pharmacy premises of P1 to or for the use of the patients for whom they were ordered.

(5) For the hub and spoke arrangements to be valid for the purposes of this paragraph and paragraphs 7B and 7C, P1 must—

(**16**) Paragraph 7 has been amended by S.I. 2015/570, 2016/296, 2018/1114, 2019/990 and 2023/98.

(a) have given notice in writing to NHS England of P1's intention to sub-contract core dispensing functions—

(i) not less than 28 days before the date on which the proposed arrangements are intended to commence, or

(ii) by a date agreed with NHS England before which the proposed arrangements are to commence; and

(b) have taken reasonable steps, before entering into the arrangements, to satisfy itself of P2's fitness to carry out core dispensing functions on behalf of P1.

(6) A notice under sub-paragraph (5)(a) must include the particulars which have been approved by NHS England for the purposes of making such notifications.

(7) For the hub and spoke arrangements to be valid for the purposes of this paragraph and paragraphs 7B and 7C, they must have the following features—

(a) they must provide, and ensure, that any prescription item that is assembled or part-assembled under the arrangements is supplied to or for the use of the patient for whom it is dispensed at or from the pharmacy premises of P1 (and so the arrangements must not allow P2 to fulfil the order directly);

(b) in the case of an order for a medicine on a prescription form or LPIV, they must ensure that what is done, in the course of fulfilling the order, is done in a manner that ensures compliance with the requirements that are to be complied with for the supply from P2 to P1 of the medicine to be treated as, or as part of, a retail sale in accordance with regulation 222A(2)(a) of the Human Medicines Regulations 2012(**17**) (assembly or part-assembly as part of "hub and spoke" dispensing arrangements between different businesses);

(c) in the case of orders for prescription items that are not orders for medicines on a prescription form or a LPIV ("non-regulation-222A orders")—

(i) they must relate to fulfilling both orders for medicines on prescription forms and non-regulation-222A orders, and accordingly P1 cannot only sub-contract to P2 core dispensing functions in respect of non-regulation-222A orders, and

(ii) they must ensure that what is done, in the course of fulfilling the non-regulation-222A order, is done in a manner that would ensure compliance with the requirements that would need to be complied with for the supply from P2 to P1 of the prescription item, if it were instead of a medicine ordered on a prescription form or a LPIV, to be treated as, or as part of, a retail sale in accordance with regulation 222A(2)(a) of the Human Medicines Regulations 2012;

(d) they must provide, and ensure, that P2 does not sub-contract any of the core dispensing functions that P2 performs on behalf of P1;

(e) they must provide for the discontinuation of the arrangements, as set out in paragraph 7B (in addition to any patient safety or commercial grounds P1 or P2 may have for discontinuing the arrangements); and

(f) they must not be or have become invalid by virtue of paragraph 7B.

(8) If P1 has hub and spoke arrangements in place, P1 must also have in place, as part of P1's business continuity plan required by paragraph 29D, business continuity arrangements which ensure that P1 is able to meet all P1's obligations to provide dispensing services in

(**17**) Inserted by S.I. 2025/758.

the event of any temporary or permanent discontinuation or disruption of the hub and spoke arrangements.

(9) P1 must give notice in writing to NHS England of any—

(a) temporary discontinuation of hub and spoke arrangements that amounts to a suspension of those arrangements; or

(b) permanent discontinuation of hub and spoke arrangements,

either before that discontinuation occurs or as soon as is reasonably practicable after it occurs, unless it is in response to a notice of objection from NHS England.

Objection to and discontinuation of hub and spoke arrangements

7B.—(1) At any stage after receipt of a notice under paragraph 7A(5)(a), NHS England may request from P1 (as defined in paragraph 7A(1)) further information relating to the proposed or commenced hub and spoke arrangements that is relevant to one or more of the objection criteria, and if NHS England makes such a request, P1 must supply the requested information to NHS England promptly.

(2) For the purposes of this paragraph, the objection criteria are—

(a) the proposed or commenced hub and spoke arrangements do not have the features required by paragraph 7A(7), including where they have had them but they have lapsed;

(b) in the case of commenced hub and spoke arrangements, they have the features required by paragraph 7A(7) but there has been a breach of those requirements;

(c) the proposed hub and spoke arrangements would put, or the commenced hub and spoke arrangements put, the safety of any persons to whom P1 provides pharmaceutical services at serious risk;

(d) the proposed hub and spoke arrangements would put, or the commenced hub and spoke arrangements put, NHS England at risk of material financial loss;

(e) in the case of commenced hub and spoke arrangements, those arrangements have led to P1 repeatedly breaching P1's terms of service, or to P1 breaching its terms of service in circumstances where P1 is likely to continue to do so repeatedly;

(f) P2's (as defined in paragraph 7A(4)) fitness to carry out core dispensing functions is impaired; or

(g) in the opinion of NHS England, there are reasonable grounds for believing one or more of the objection criteria in paragraphs (a) to (f) are established.

(3) NHS England may, before the commencement of proposed hub and spoke arrangements, issue a notice of objection to the proposed arrangements, based on one or more of the objection criteria and if it does so—

(a) P1 must not commence the arrangements unless or until the notice of objection is withdrawn by NHS England; and

(b) any arrangements that are commenced, in breach of this sub-paragraph, are invalid.

(4) NHS England may, after the commencement of hub and spoke arrangements, issue a notice of objection to the arrangements, based on one or more of the objection criteria, and if it does so—

(a) those arrangements become invalid; and

(b) P1 must discontinue the arrangements promptly.

(5) NHS England may withdraw a notice of objection issued under sub-paragraph (4), which has the effect of the arrangements to which the notice related no longer being invalid.

(6) NHS England must, in a notice of objection, give its reasons for issuing the notice.

(7) Subject to sub-paragraph (9), before issuing a notice under sub-paragraph (4), NHS England must make every reasonable effort to communicate and co-operate with P1 with a view to resolving the matter without the notice being issued.

(8) Where P1 invites a Local Pharmaceutical Committee to participate in the attempts to resolve the matter referred to in sub-paragraph (7), NHS England must make every reasonable effort to communicate and co-operate with the Committee in its attempts to assist in resolving the matter.

(9) Sub-paragraphs (7) and (8) do not apply where NHS England is satisfied—

(a) its concerns relate to a matter that has already been the subject of dispute resolution between NHS England and P1 and there are no new issues of substance to delay issuing the notice; or

(b) that it is appropriate to proceed immediately to issuing a notice—

(i) to protect the safety of any persons to whom P1 may provide pharmaceutical services, or

(ii) to protect NHS England from material financial loss.

(10) After issuing a notice of objection under sub-paragraph (3), or issuing a notice of objection under sub-paragraph (4) which was not delayed by virtue of sub-paragraph (7) or (8), NHS England must, where requested to do so by P1, make every reasonable effort to communicate and co-operate with P1 with a view to resolving the matter in a manner that may lead to the notice of objection being withdrawn.

(11) Where P1 invites a Local Pharmaceutical Committee to participate in the attempts to resolve the matter referred to in sub-paragraph (10), NHS England must make every reasonable effort to communicate and co-operate with the Committee in its attempts to assist in resolving the matter.

(12) Sub-paragraphs (10) and (11) do not apply where NHS England is satisfied its concerns that led to the notice of objection being issued relate to a matter that has already been the subject of dispute resolution between NHS England and P1 and there are no new issues of substance to be resolved.

Hub and spoke arrangements: sharing of "relevant data" between different businesses

7C.—(1) This paragraph applies to "relevant data", which is data that relates to a patient and which is shared for the purpose of fulfilling an order under hub and spoke arrangements (as defined in paragraph 7A(4)) which is a non-regulation-222A order (as defined in paragraph 7A(7)(c)).

(2) For the purposes of section 8(c) (lawfulness of processing: public interest etc) of, and paragraph 2(2)(a), (c) and (d) of Schedule 1 (special categories of personal data etc – health or social care purpose) to, the Data Protection Act 2018(**18**), sub-paragraph (3) applies to the processing of any relevant data—

(a) by P1 or P2 (as defined in paragraph 7A(1) and (4)) which relates to a patient; and

(b) which is necessary for the purposes of—

(**18**) 2018 c. 12. Section 8 has been amended by the Data (Use and Access) Act 2025 (c. 18), section 70(7), and S.I. 2019/419. Paragraph 2 of Schedule 1 has been amended by S.I. 2019/419.

(i) fulfilling an order of a type mentioned in paragraph 7A(4)(a) under valid hub and spoke arrangements, or

(ii) discharging any related professional obligations to the patient (including obligations relating to the keeping of records).

(3) That processing is—

(a) necessary for the performance of a task carried out in the public interest; and

(b) if the data is personal data concerning health, necessary for the purposes of preventative medicine, medical diagnosis or for the provision of health care or treatment.

(4) Any person (P3) who—

(a) is employed or engaged by P1 or P2; and

(b) in the course of being so employed or engaged is required to undertake the processing of data described in sub-paragraph (2),

owes a duty of confidentiality in respect of that data (whether or not they would do so but for this sub-paragraph).

(5) The duty in paragraph (4)—

(a) is a duty of confidentiality which, if not owed by a health care professional, is owed under an enactment or rule of law for the purposes of section 11(1)(b) of the Data Protection Act 2018(**19**) (special categories of personal data etc: supplementary); and

(b) is such that, if the processing is necessary for the purposes described in sub-paragraph (2)(b), P3 is able, lawfully, to process that data by virtue of this paragraph.

(6) For the purposes of sub-paragraph (2)(b)(ii), a professional obligation to a patient is to be regarded as such notwithstanding that discharging the obligation may—

(a) also be an obligation that arises in some other way (for example, arising from a duty of care); or

(b) be done by a person who is not a health care professional.

(7) Sub-paragraphs (2) and (3) do not apply where, in reliance or purported reliance on valid hub and spoke arrangements, a person processes any data which relates to a patient but, in the course of the doing of anything that relates to the fulfilling of the order to which that data relates, there is a breach of—

(a) the requirements to be fulfilled if what is done is to be treated as part of valid hub and spoke arrangements; or

(b) a duty of confidentiality owed in respect of the data by a health care professional or under an enactment or rule of law as mentioned in sub-paragraph (5)(a).

(8) Words and expressions used in both—

(a) sub-paragraphs (1) to (7); and

(b) Parts 1 and 2 (preliminary and general processing) of, and paragraphs 2(2)(a), (c) and (d) of Schedule 1 to, the Data Protection Act 2018,

bear the meanings they bear in those provisions of the Data Protection Act 2018.”.

(**19**) Section 11 has been amended by S.I. 2019/419.

Amendment to Schedule 6

13. In Schedule 6 (terms of service of dispensing doctors), after paragraph 4 (preliminary matters before providing ordered drugs or appliances)(**20**) insert—

"**Sub-contracting aspects of dispensing under "hub and spoke" arrangements**

4ZA.—(1) For the purposes of—

(a) Part 5 of Schedule 3 to the GMS Regulations (other contractual terms – sub-contracting);

(b) Part 5 of Schedule 2 to the PMS Regulations (other required terms – subcontracting); and

(c) any contractual arrangements with an APMS practice that restrict the sub-contracting of rights or duties under the arrangements in relation to clinical matters,

core dispensing functions are clinical matters (whether or not they would be considered as such but for this sub-paragraph) and accordingly, the specific requirements in this Schedule in respect of sub-contracting those functions are in addition to the general requirements in those Schedules in respect of sub-contracting them.

(2) For the purposes of this paragraph and paragraph 4ZB, "core dispensing functions" means the assembly or part-assembly of any prescription item (including bagging and the application of dispensing labels) with a view to the supply of that prescription item in accordance with a prescription, an SSP, a LPIV, a PTP or a PTPGD.

(3) A dispensing doctor (and by extension a provider of primary medical services as mentioned in regulation 47(2)(b), referred to together for the purposes of this paragraph and paragraphs 4ZB and 4ZC as (D)) must not sub-contract the performance of any of its core dispensing functions, but this does not apply to—

(a) a contract for services between D and a health care professional (for example, a locum), or a provider of locums, for performance by that professional, or by locums provided by that provider of locums, personally of core dispensing functions at D's listed dispensing premises; or

(b) the performance of any of D's core dispensing functions under valid hub and spoke arrangements.

(4) For the purposes of this paragraph and paragraphs 4ZB and 4ZC, "hub and spoke arrangements" are arrangements between D and a retail pharmacy business (P) which—

(a) are for the purpose of P supporting D with regard to the fulfilment of orders—

(i) submitted to D on prescription forms or LPIVs, or

(ii) for the provision of prescription items by D in accordance with PTPs or PTPGDs; and

(b) provide for the assembly or part-assembly of those orders (including in accordance with an SSP) at premises of P with a view to the supply of the prescription items at or from the listed dispensing premises of D to or for the use of the patients for whom they were ordered.

(5) For the hub and spoke arrangements to be valid for the purposes of this paragraph and paragraphs 4ZB and 4ZC, any prior notification that D is required to give to NHS England or an ICB before the commencement of arrangements by virtue of which D sub-contracts the core dispensing functions must include the following particulars—

(**20**) Paragraph 4 has been amended by S.I. 2015/570, 2018/1114, 2019/990 and 2023/98.

(a) the name, pharmacy premises address and General Pharmaceutical Council premises registration number of P;

(b) the duration of the proposed arrangements;

(c) a description of the core dispensing functions to be covered by arrangements; and

(d) a description of the manner in which P proposes to meet D's obligations under the terms of service in respect of the core dispensing functions to be covered by the arrangements.

(6) For the hub and spoke arrangements to be valid for purposes of this paragraph and paragraphs 4ZB and 4ZC, if D is not otherwise (apart from by virtue of this sub-paragraph) required to give prior notification to NHS England or an ICB before the commencement of the sub-contracting of clinical services such as core dispensing functions—

(a) it must give that prior notice in the case of hub and spoke arrangements, and in a manner that puts NHS England or the ICB for its location on reasonable notice of the commencement of the arrangements; and

(b) the notification that it does give must include the particulars specified in sub-paragraph (5)((a) to (d).

(7) For the hub and spoke arrangements to be valid for the purposes of this paragraph and paragraphs 4ZB and 4ZC, they must have the following features—

(a) they must provide, and ensure, that any prescription item that is assembled or part-assembled under the arrangements is supplied to or for the use of the patient for whom it is dispensed at or from the listed dispensing premises of D (and so the arrangements must not allow P to fulfil the order directly);

(b) in the case of an order for a medicine on a prescription form or LPIV, they must ensure that what is done, in the course of fulfilling the order, is done in a manner that ensures compliance with the requirements that are to be complied with for the supply from P to D of the medicine to be treated as, or as part of, a retail sale in accordance with regulation 222A(2)(a) of the Human Medicines Regulations 2012(**21**) (assembly or part-assembly as part of "hub and spoke" dispensing arrangements between different businesses);

(c) in the case of orders for prescription items that are not orders for medicines on a prescription form or a LPIV ("non-regulation-222A orders")—

(i) they must relate to fulfilling both orders for medicines on prescription forms and non-regulation-222A orders, and accordingly D cannot only sub-contract to P core dispensing functions in respect of non-regulation-222A orders, and

(ii) they must ensure that what is done, in the course of fulfilling the non-regulation-222A order, is done in a manner that would ensure compliance with the requirements that would need to be complied with for the supply from P to D of the prescription item, if it were instead of a medicine ordered on a prescription form or a LPIV, to be treated as, or as part of, a retail sale in accordance with regulation 222A(2)(a) of the Human Medicines Regulations 2012;

(d) they must provide, and ensure, that P does not sub-contract any of the core dispensing functions that P performs on behalf of D;

(**21**) Inserted by S.I. 2025/758.

(e) they must provide for the discontinuation of the arrangements, as set out in paragraph 4ZB (in addition to any patient safety or commercial grounds D or P may have for discontinuing the arrangements); and

(f) they must not be or have become invalid by virtue of paragraph 4ZB.

(8) If D has hub and spoke arrangements in place, D must also have in place business continuity arrangements which ensure that D is able to meet all D's obligations to provide dispensing services in the event of any temporary or permanent discontinuation or disruption of the hub and spoke arrangements.

(9) D must give notice in writing to NHS England of any—

(a) temporary discontinuation of hub and spoke arrangements that amounts to a suspension of those arrangements; or

(b) permanent discontinuation of hub and spoke arrangements,

either before that discontinuation occurs or as soon as is reasonably practicable after it occurs, unless it is in response to a notice of objection from NHS England.

Objection to and termination of hub and spoke arrangements

4ZB.—(1) NHS England may at any time request from D (as defined in paragraph 4ZA(3)) information relating to hub and spoke arrangements that is relevant to the termination criteria (whether or not the arrangements have commenced), and if NHS England makes such a request, D must supply the requested information to NHS England promptly.

(2) For the purposes of this paragraph, the termination criteria are—

(a) the hub and spoke arrangements do not have the features required by paragraph 4ZA(7), including where they have had them but they have lapsed;

(b) the hub and spoke arrangements have the features required by paragraph 4ZA(7) but there has been a breach of those requirements;

(c) the hub and spoke arrangements put the safety of any persons to whom D provides pharmaceutical services at serious risk;

(d) the hub and spoke arrangements put NHS England at risk of material financial loss;

(e) the hub and spoke arrangements have led to D repeatedly breaching D's terms of service, or to D breaching its terms of service in circumstances where D is likely to continue to do so repeatedly;

(f) P's (as defined in paragraph 4ZA(4)) fitness to carry out core dispensing functions is impaired; or

(g) in the opinion of NHS England, there are reasonable grounds for believing one or more of the termination criteria in paragraphs (a) to (f) are established.

(3) NHS England may, after the commencement of hub and spoke arrangements, issue a notice of objection to the arrangements, based on one or more of the termination criteria, and if it does so—

(a) those arrangements become invalid on the termination date specified in the notice of objection; and

(b) D must discontinue the arrangements on or by the date specified in the notice for their termination.

(4) NHS England may withdraw a notice of objection issued under sub-paragraph (3), which has the effect of the arrangements to which the notice related no longer being invalid.

(5) NHS England must, in a notice of objection, give its reasons for issuing the notice.

(6) Subject to sub-paragraph (7), before issuing a notice of objection, NHS England must make every reasonable effort to communicate and co-operate with D with a view to resolving the matter without the notice being issued.

(7) Sub-paragraph (6) does not apply where NHS England is satisfied—

(a) its concerns relate to a matter that has already been the subject of dispute resolution between NHS England and D and there are no new issues of substance to delay issuing the notice; or

(b) that it is appropriate to proceed immediately to issuing a notice—

(i) to protect the safety of any persons to whom D may provide pharmaceutical services, or

(ii) to protect NHS England from material financial loss.

(8) After issuing a notice of objection, unless—

(a) it was delayed by virtue of sub-paragraph (6); or

(b) NHS England is satisfied its concerns related to a matter that has already been the subject of dispute resolution between NHS England and D and there are no new issues of substance to be resolved,

NHS England must, where requested to do so by D, make every reasonable effort to communicate and co-operate with D with a view to resolving the matter in a manner that may lead to the notice of objection being withdrawn.

Hub and spoke arrangements: sharing of "relevant data" between different businesses

4ZC.—(1) This paragraph applies to "relevant data", which is data that relates to a patient and which is shared for the purpose of fulfilling an order under hub and spoke arrangements (as defined in paragraph 4ZA(4)) which is a non-regulation-222A order (as defined in paragraph 4ZA(7)(c)).

(2) For the purposes of section 8(c) (lawfulness of processing: public interest etc) of, and paragraph 2(2)(a), (c) and (d) of Schedule 1 (special categories of personal data etc – health or social care purpose) to, the Data Protection Act 2018(**22**), sub-paragraph (3) applies to the processing of any relevant data—

(a) by D or P (as defined in paragraph 4ZA(3) and (4)) which relates to a patient; and

(b) which is necessary for the purposes of—

(i) fulfilling an order of a type mentioned in paragraph 4ZA(4)(a) under valid hub and spoke arrangements, or

(ii) discharging any related professional obligations to the patient (including obligations relating to the keeping of records).

(3) That processing is—

(a) necessary for the performance of a task carried out in the public interest; and

(b) if the data is personal data concerning health, necessary for the purposes of preventative medicine, medical diagnosis or for the provision of health care or treatment.

(4) Any person (X) who—

(**22**) 2018 c. 12. Section 8 has been amended by the Data (Use and Access) Act 2025 (c. 18), section 70(7), and S.I. 2019/419. Paragraph 2 of Schedule 1 has been amended by S.I. 2019/419.

(a) is employed or engaged by D or P; and

(b) in the course of being so employed or engaged is required to undertake the processing of data described in sub-paragraph (2),

owes a duty of confidentiality in respect of that data (whether or not they would do so but for this sub-paragraph).

(5) The duty under paragraph (4)—

(a) is a duty of confidentiality which, if not owed by a health care professional, is owed under an enactment or rule of law for the purposes of section 11(1)(b) of the Data Protection Act 2018(**23**) (special categories of personal data etc: supplementary); and

(b) is such that, if the processing is necessary for the purposes described in sub-paragraph (2)(b), X is able, lawfully, to process that data by virtue of this paragraph.

(6) For the purposes of sub-paragraph (2)(b)(ii), a professional obligation to a patient is to be regarded as such notwithstanding that discharging the obligation may—

(a) also be an obligation that arises in some other way (for example, arising from a duty of care); or

(b) be done by a person who is not a health care professional.

(7) Sub-paragraphs (2) and (3) do not apply where, in reliance or purported reliance on valid hub and spoke arrangements, a person processes any data which relates to a patient but, in the course of the doing of anything that relates to the fulfilling of the order to which that data relates, there is a breach of—

(a) the requirements to be fulfilled if what is done is to be treated as part of valid hub and spoke arrangements; or

(b) a duty of confidentiality owed in respect of the data by a health care professional or under an enactment or rule of law as mentioned in sub-paragraph (5)(a).

(8) Words and expressions used in both—

(a) sub-paragraphs (1) to (7); and

(b) Parts 1 and 2 (preliminary and general processing) of, and paragraphs 2(2)(a), (c) and (d) of Schedule 1 to, the Data Protection Act 2018,

bear the meanings they bear in those provisions of the Data Protection Act 2018.".

Amendment to Schedule 7

14. In Schedule 7 (mandatory terms for LPS schemes), after paragraph 5 (preliminary matters before providing ordered drugs or appliances)(**24**) insert—

"**Sub-contracting aspects of dispensing under "hub and spoke" arrangements**

5A.—(1) Subject to sub-paragraph (3), an LPS contractor (C) must not sub-contract the performance of any of its core dispensing functions.

(2) For the purposes of this paragraph and paragraph 5B, "core dispensing functions" means the assembly or part-assembly of any prescription item (including bagging and the application of dispensing labels) with a view to the supply of that prescription item in accordance with a prescription, a SSP, a LPIV, a PTP or a PTPGD.

(**23**) Section 11 has been amended by S.I. 2019/419.
(**24**) Paragraph 5 has been amended by S.I. 2015/570, 2016/296, 2018/1114, 2019/990 and 2023/98.

(3) Sub-paragraph (1) does not apply to—

(a) a contract for services between C and—

(i) a health care professional (for example, a locum) or a provider of locums, or

(ii) a corporate body that is—

(aa) a subsidiary undertaking of C, or

(bb) a subsidiary undertaking of a parent undertaking of which C is also a subsidiary undertaking,

for the performance by that health care professional, a locum provided by that provider of locums or the corporate body of core dispensing functions at C's pharmacy premises;

(b) arrangements whereby a retail pharmacy business that is not C is nevertheless carrying on a retail pharmacy business at C's premises as a temporary arrangement related to the purchase of those premises; or

(c) the performance of any of C's core dispensing functions under valid hub and spoke arrangements.

(4) For the purposes of this paragraph and paragraphs 5B and 5C, "hub and spoke arrangements" are arrangements between C and a retail pharmacy business (P) which—

(a) are for the purpose of P supporting C with regard to the fulfilment of orders—

(i) submitted to C on prescription forms or LPIVs, or

(ii) for the provision of prescription items by C in accordance with PTPs or PTPGDs;

(b) provide for the assembly or part-assembly of those orders (including in accordance with an SSP) at premises of P with a view to the supply of the prescription items at or from the scheme premises of C to or for the use of the patients for whom they were ordered.

(5) For the hub and spoke arrangements to be valid for the purposes of this paragraph and paragraphs 5B and 5C, C must—

(a) have given notice in writing to NHS England of C's intention to sub-contract core dispensing functions—

(i) not less than 28 days before the date on which the proposed arrangements are intended to commence, or

(ii) by a date agreed with NHS England on which the proposed arrangements are to commence; and

(b) have taken reasonable steps, before entering into the arrangements, to satisfy itself of P's fitness to carry out core dispensing functions on behalf of C.

(6) A notice under sub-paragraph (5)(a) must include the particulars which have been approved by NHS England for the purposes of making such notifications.

(7) For the hub and spoke arrangements to be valid for the purposes of this paragraph and paragraphs 5B and 5C, they must have the following features—

(a) they must provide, and ensure, that any prescription item that is assembled or part-assembled under the arrangements is supplied to or for the use of the patient for whom it is dispensed at or from the scheme premises of C (and so the arrangements must not allow P to fulfil the order directly);

(b) in the case of an order for a medicine on a prescription form or LPIV, they must ensure that what is done, in the course of fulfilling the order, is done in a

manner that ensures compliance with the requirements that are to be complied with for the supply from P to C of the medicine to be treated as, or as part of, a retail sale in accordance with regulation 222A(2)(a) of the Human Medicines Regulations 2012(**25**) (assembly or part-assembly as part of "hub and spoke" dispensing arrangements between different businesses);

(c) in the case of orders for prescription items that are not orders for medicines on a prescription form or a LPIV ("non-regulation-222A orders")—

(i) they must relate to fulfilling both orders for medicines on prescription forms and non-regulation-222A orders, and accordingly C cannot only sub-contract to P core dispensing functions in respect of non-regulation-222A orders, and

(ii) they must ensure that what is done, in the course of fulfilling the non-regulation-222A order, is done in a manner that would ensure compliance with the requirements that would need to be complied with for the supply from P to C of the prescription item, if it were instead of a medicine ordered on a prescription form or a LPIV, to be treated as, or as part of, a retail sale in accordance with regulation 222A(2)(a) of the Human Medicines Regulations 2012;

(d) they must provide, and ensure, that P does not sub-contract any of the core dispensing functions that P performs on behalf of C;

(e) they must provide for the discontinuation of the arrangements, as set out in paragraph 5B (in addition to any patient safety or commercial grounds C or P may have for discontinuing the arrangements); and

(f) they must not be or have become invalid by virtue of paragraph 5B.

(8) If C has hub and spoke arrangements in place, C must also have business continuity arrangements in place which ensure that C is able to meet all C's obligations to provide dispensing services in the event of any temporary or permanent discontinuation or disruption of the hub and spoke arrangements.

(9) C must give notice in writing to NHS England of any—

(a) temporary discontinuation of hub and spoke arrangements that amounts to a suspension of those arrangements; or

(b) permanent discontinuation of hub and spoke arrangements,

either before that discontinuation occurs or as soon as is reasonably practicable after it occurs, unless it is in response to a notice of objection from NHS England.

Objection to and discontinuation of hub and spoke arrangements

5B.—(1) At any stage after receipt of a notice under paragraph 5A(5)(a), NHS England may request from C (as defined in paragraph 5A(1)) further information relating to the proposed or commenced hub and spoke arrangements that is relevant to one or more of the objection criteria, and if NHS England makes such a request, C must supply the requested information to NHS England promptly.

(2) For the purposes of this paragraph, the objection criteria are—

(a) the proposed or commenced hub and spoke arrangements do not have the features required by paragraph 5A(7), including where they have had them but they have lapsed;

(**25**) Inserted by S.I. 2025/758.

(b) in the case of commenced hub and spoke arrangements, they have the features required by paragraph 5A(7) but there has been a breach of those requirements;

(c) the proposed hub and spoke arrangements would put, or the commenced hub and spoke arrangements put, the safety of any persons to whom C provides pharmaceutical services at serious risk;

(d) the proposed hub and spoke arrangements would put, or the commenced hub and spoke arrangements put, NHS England at risk of material financial loss;

(e) in the case of commenced hub and spoke arrangements, those arrangements have led to C repeatedly breaching C's terms of service, or to C breaching its terms of service in circumstances where C is likely to continue to do so repeatedly;

(f) P's (as defined in paragraph 5A(4)) fitness to carry out core dispensing functions is impaired; or

(g) in the opinion of NHS England, there are reasonable grounds for believing one or more of the objection criteria in paragraphs (a) to (f) are established.

(3) NHS England may, before the commencement of proposed hub and spoke arrangements, issue a notice of objection to the proposed arrangements, based on one or more of the objection criteria and if it does so—

(a) C must not commence the arrangements unless or until the notice of objection is withdrawn by NHS England; and

(b) any arrangements that are commenced, in breach of this sub-paragraph, are invalid.

(4) NHS England may, after the commencement of hub and spoke arrangements, issue a notice of objection to the arrangements, based on one or more of the objection criteria, and if it does so—

(a) those arrangements become invalid; and

(b) C must discontinue the arrangements promptly.

(5) NHS England may withdraw a notice of objection issued under sub-paragraph (4), which has the effect of the arrangements to which the notice related no longer being invalid.

(6) NHS England must, in a notice of objection, give its reasons for issuing the notice.

(7) Subject to sub-paragraph (9), before issuing a notice under sub-paragraph (4), NHS England must make every reasonable effort to communicate and co-operate with C with a view to resolving the matter without the notice being issued.

(8) Where C invites a Local Pharmaceutical Committee to participate in the attempts to resolve the matter referred to in sub-paragraph (7), NHS England must make every reasonable effort to communicate and co-operate with the Committee in its attempts to assist in resolving the matter.

(9) Sub-paragraphs (7) and (8) do not apply where NHS England is satisfied—

(a) its concerns relate to a matter that has already been the subject of dispute resolution between NHS England and C and there are no new issues of substance to delay issuing the notice; or

(b) that it is appropriate to proceed immediately to issuing a notice—

(i) to protect the safety of any persons to whom C may provide pharmaceutical services, or

(ii) to protect NHS England from material financial loss.

(10) After issuing a notice of objection under sub-paragraph (3), or issuing a notice of objection under sub-paragraph (4) which was not delayed by virtue of sub-paragraph (7) or

(8), NHS England must, where requested to do so by C, make every reasonable effort to communicate and co-operate with C with a view to resolving the matter in a manner that may lead to the notice of objection being withdrawn.

(11) Where C invites a Local Pharmaceutical Committee to participate in the attempts to resolve the matter referred to in sub-paragraph (10), NHS England must make every reasonable effort to communicate and co-operate with the Committee in its attempts to assist in resolving the matter.

(12) Sub-paragraphs (10) and (11) do not apply where NHS England is satisfied its concerns that led to the notice of objection being issued relate to a matter that has already been the subject of dispute resolution between NHS England and there are no new issues of substance to be resolved.

Hub and spoke arrangements: sharing of "relevant data" between different businesses

5C.—(1) This paragraph applies to "relevant data", which is data that relates to a patient and which is shared for the purpose of fulfilling an order under hub and spoke arrangements (as defined in paragraph 5A(4)) which is a non-regulation-222A order (as defined in paragraph 5A(7)(c)).

(2) For the purposes of section 8(c) (lawfulness of processing: public interest etc) of, and paragraph 2(2)(a), (c) and (d) of Schedule 1 (special categories of personal data etc – health or social care purpose) to, the Data Protection Act 2018(**26**), sub-paragraph (3) applies to the processing of any relevant data—

(a) by C or P (as defined in paragraph 5A(1) and (4)) which relates to a patient; and

(b) which is necessary for the purposes of—

(i) fulfilling an order of a type mentioned in paragraph 5A(4)(a) under valid hub and spoke arrangements, or

(ii) discharging any related professional obligations to the patient (including obligations relating to the keeping of records).

(3) That processing is—

(a) necessary for the performance of a task carried out in the public interest; and

(b) if the data is personal data concerning health, necessary for the purposes of preventative medicine, medical diagnosis or for the provision of health care or treatment.

(4) Any person (X) who—

(a) is employed or engaged by C or P; and

(b) in the course of being so employed or engaged is required to undertake the processing of data described in sub-paragraph (2),

owes a duty of confidentiality in respect of that data (whether or not they would do so but for this sub-paragraph).

(5) The duty under paragraph (4)—

(a) is a duty of confidentiality which, if not owed by a health care professional, is owed under an enactment or rule of law for the purposes of section 11(1)

(**26**) 2018 c. 12. Section 8 has been amended by the Data (Use and Access) Act 2025 (c. 18), section 70(7), and S.I. 2019/419. Paragraph 2 of Schedule 1 has been amended by S.I. 2019/419.

(b) of the Data Protection Act 2018(**27**) (special categories of personal data etc: supplementary); and

(b) is such that, if the processing is necessary for the purposes described in sub-paragraph (2)(b), X is able, lawfully, to process that data by virtue of this paragraph.

(6) For the purposes of sub-paragraph (2)(b)(ii), a professional obligation to a patient is to be regarded as such notwithstanding that discharging the obligation may—

(a) also be an obligation that arises in some other way (for example, arising from a duty of care); or

(b) be done by a person who is not a health care professional.

(7) Sub-paragraphs (2) and (3) do not apply where, in reliance or purported reliance on valid hub and spoke arrangements, a person processes any data which relates to a patient but, in the course of the doing of anything that relates to the fulfilling of the order to which that data relates, there is a breach of—

(a) the requirements to be fulfilled if what is done is to be treated as part of valid hub and spoke arrangements; or

(b) a duty of confidentiality owed in respect of the data by a health care professional or under an enactment or rule of law as mentioned in sub-paragraph (5)(a).

(8) Words and expressions used in both—

(a) sub-paragraphs (1) to (7); and

(b) Parts 1 and 2 (preliminary and general processing) of, and paragraphs 2(2)(a), (c) and (d) of Schedule 1 to, the Data Protection Act 2018,

bear the meanings they bear in those provisions of the Data Protection Act 2018.".

PART 4

Amendments relating to "at or from" pharmacy premises

Amendments to regulation 2

15.—(1) Regulation 2 (interpretation)(**28**), paragraph (1) is amended as follows.

(2) In the definition of "distance selling premises", after "or potential pharmacy premises, at" insert "or from".

(3) In the definition of "medical practice premises"—

(a) in sub-paragraph (a), after "as the practice premises" insert "at or"; and

(b) in sub-paragraph (b), after "practice premises" insert "at or".

Amendments to regulation 10

16.—(1) Regulation 10 (pharmaceutical lists)(**29**), is amended as follows.

(2) In paragraph (1), after "pharmaceutical services", insert "at or".

(3) In paragraph (3)—

(**27**) Section 11 has been amended by S.I. 2019/419.
(**28**) A relevant amendment has been made to regulation 2 by S.I. 2023/1071. There have been other amending instruments, but none are relevant.
(**29**) Regulation 10 has been amended by S.I. 2016/1077, 2022/930 and 2023/1071.

(a) in sub-paragraph (a), after "in the area of the HWB at" insert "or from"; and

(b) in sub-paragraph (b), after "and times at which, at" insert "or from".

(4) In paragraph (7)(a)(ii)—

(a) in sub-paragraph (aa), after "additional premises", insert "at or";

(b) in sub-paragraph (bb), after "and at", insert "or from"; and

(c) in sub-paragraph (cc), after "to provide," insert "at or".

Amendments to regulation 11

17.—(1) Regulation 11 (terms of service of NHS chemists: general)(**30**) is amended as follows.

(2) In paragraph (1)(d)(ii), for "carrying-on of activities on" substitute "carrying-on of activities at or from".

(3) In paragraph (2)(d)(ii), for "carrying-on of activities on" substitute "carrying-on of activities at or from".

Amendments to regulation 12

18. In regulation 12 (routine applications for inclusion in or amendments to a pharmaceutical list), in paragraph (b)—

(a) in sub-paragraph (i), after "additional premises", insert "at or";

(b) in sub-paragraph (ii), after "and at", insert "or from"; and

(c) in sub-paragraph (iii), after "to provide," insert "at or".

Amendments to regulation 24

19.—(1) Regulation 24 (relocations that do not result in significant change to pharmaceutical services provision)(**31**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), after "accessing pharmaceutical services at" insert "or from"; and

(b) in sub-paragraph (d)—

(i) after "provide at", insert "or from", and

(ii) after "providing at", insert "or from".

(3) In paragraph (2)—

(a) in sub-paragraph (b), after "pharmaceutical services at", insert "or from"; and

(b) in sub-paragraph (e)—

(i) after "provide at" insert "or from", and

(ii) after "providing at" insert "or from".

(4) In paragraph (3)(b)—

(a) in paragraph (ii), after "at" insert "or from"; and

(b) in paragraph (iii), after "at" insert "or from".

(**30**) Regulation 11 has been amended by S.I. 2020/351 and 2023/1071.
(**31**) Regulation 24 has been amended by S.I. 2014/417 and 2023/1071.

Amendments to regulation 26

20.—(1) Regulation 26 (change of ownership applications)(**32**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a)—

(i) after "pharmaceutical services at" insert "or from", and

(ii) in paragraph (ii), after "at" insert "or from";

(b) in sub-paragraph (b)—

(i) after "carry on at" insert "or from", and

(ii) after "providing pharmaceutical services at" insert "or from"; and

(c) in sub-paragraph (d), after "pharmaceutical services at" insert "or from".

(3) In paragraph (2)—

(a) in sub-paragraph (a)—

(i) in paragraph (i), after "providing at" insert "or from", and

(ii) in paragraph (ii)—

(aa) after "provided at" insert "or from", and

(bb) after "pharmaceutical services at" insert "or from";

(b) in sub-paragraph (b), after "pharmaceutical services at" insert "or from";

(c) in sub-paragraph (c)—

(i) after "provided at" insert "or from", and

(ii) after "but at" insert "or from"; and

(d) in sub-paragraph (e)—

(i) in paragraph (i), after "being provided at" insert "or from", and

(ii) in paragraph (ii)—

(aa) after "provided at" insert "or from", and

(bb) after "will commence at" insert "or from".

Amendments to regulation 26A

21. In regulation 26A (consolidation onto an existing site)(**33**), in paragraph (7)—

(a) in sub-paragraph (a)—

(i) after "carry on at" insert "or from", and

(ii) after "pharmaceutical services at" insert "or from"; and

(b) in sub-paragraph (c), after "pharmaceutical services at" insert "or from".

Amendments to regulation 29

22. In regulation 29 (temporary arrangements during emergencies or because of circumstances beyond the control of NHS chemists)(**34**)—

(a) in paragraph (1)(b), after "pharmaceutical services at" insert "or from"; and

(b) in paragraph (3)—

(**32**) Regulation 26 has been amended by S.I. 2014/417 and 2023/1071.
(**33**) Regulation 26A was inserted by S.I. 2016/1077 and has been amended by S.I. 2023/1071.
(**34**) Regulation 29 has been amended by S.I. 2023/1071.

(i) for "at P1 at" substitute "at or from P1 at or from", and

(ii) after "were ordinarily provided at" insert "or from".

Amendment to regulation 31

23. In regulation 31 (refusal: same or adjacent premises)(**35**), in paragraph (2)(a), after "("the existing services") insert "at or".

Amendment to regulation 40

24. In regulation 40 (applications for new pharmacy premises in controlled localities: refusals because of preliminary matters)(**36**), in paragraph (1)(b)(ii), after "additional pharmacy premises" insert "at or".

Amendments to regulation 41

25. In regulation 41(applications for new pharmacy premises in controlled localities: reserved locations)(**37**)—

(a) in paragraph (1)(b)(ii), after "additional pharmacy premises" insert "at or"; and

(b) in paragraph (3)(b), after "pharmaceutical services were provided at" insert "or from".

Amendment to regulation 42

26. In regulation 42 (second and subsequent determinations of reserved location status)(**38**), in paragraph (5)(b), after "pharmacy business at" insert "or from".

Amendment to regulation 44

27. In regulation 44 (prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location)(**39**), in paragraph (1)(b)(ii), after "additional pharmacy premises" insert "at or".

Amendments to regulation 46

28. In regulation 46 (dispensing doctor lists)(**40**), in paragraph (1)—

(a) in sub-paragraph (a), after "pharmaceutical services" insert "at or"; and

(b) in sub-paragraph (b), after "pharmaceutical services" insert "at or".

Amendment to regulation 47

29. In regulation 47 (terms of service of dispensing doctors: general)(**41**), in paragraph (1)(d)(ii), for "activities on", substitute "activities at or from".

(**35**) Regulation 31 has been amended by S.I. 2014/417, 2016/1077 and 2023/1071.
(**36**) Regulation 40 has been amended by S.I. 2014/417 and 2023/1071.
(**37**) Regulation 41 has been amended by S.I. 2023/1071.
(**38**) Regulation 42 has been amended by S.I. 2023/1071.
(**39**) Regulation 44 has been amended by S.I. 2023/1071.
(**40**) Regulation 46 has been amended by S.I. 2023/1071.
(**41**) Regulation 47 has been amended by S.I. 2023/1071.

Amendments to regulation 48

30.—(1) Regulation 48 (arrangements for the provision of pharmaceutical services by doctors: applications by patients)(**42**) is amended as follows.

(2) In paragraph (3)—

(a) in sub-paragraph (a)(ii), after "for the premises" insert "at or"; and

(b) in sub-paragraph (b)(iii), after "to the premises" insert "at or".

(3) In paragraph (5)—

(a) in sub-paragraph (a)—

(i) in paragraph (i), after "applies," insert "at or", and

(ii) in paragraph (ii), after "applies," insert "at or"; and

(b) in sub-paragraph (b)—

(i) in paragraph (i), after "applies," insert "at or", and

(ii) in paragraph (ii), after "applies," insert "at or".

Amendment to regulation 50

31. In regulation 50 (discontinuation of arrangements for the provision of pharmaceutical services by doctors)(**43**), in paragraph (7)(b), after "to obtain services", insert "at or".

Amendments to regulation 51

32.—(1) Regulation 51 (outline consent and premises approval: applications by doctors)(**44**) is amended as follows.

(2) In paragraph (1)(b), after "medical practice premises" insert "at or".

(3) In paragraph (2)—

(a) in sub-paragraph (a), after "medical practice premises" insert "at or"; and

(b) in sub-paragraph (b), after "medical practice premises" insert "at or".

Amendments to regulation 53

33.—(1) Regulation 53 (decisions on outline consent and premises approval applications and the taking effect of grants)(**45**) is amended as follows.

(2) In paragraph (7)—

(a) in sub-paragraph (a)(ii)(bb), after "additional premises" insert "at or"; and

(b) in sub-paragraph (b)(i), after "of pharmaceutical services" insert "at or".

(3) in paragraph (11), after "are provided at" insert "or from".

(4) in paragraph (13)(b)(i), after "being provided at" insert "or from".

(**42**) Regulation 48 has been amended by S.I. 2023/1071.
(**43**) Regulation 50 has been amended by S.I. 2023/1071.
(**44**) Regulation 51 has been amended by S.I. 2023/1071.
(**45**) Regulation 53 has been amended by S.I. 2023/1071.

Amendment to regulation 54

34. In regulation 54 (premises approval: relocations of practice premises which are not significant before outline consent takes effect)(**46**), in paragraph (1), after "to change the premises" insert "at or".

Amendments to regulation 55

35.—(1) Regulation 55 (premises approval: relocations of practice premises which are not significant after outline consent has taken effect)(**47**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), after "pharmaceutical services" insert "at or"; and

(b) at the end of the paragraph, after "medical practice premises" insert "at or".

(3) In paragraph (2)(a), after "pharmaceutical services at" insert "or from".

Amendment to regulation 56

36. In regulation 56 (taking effect of premises approval where there is no related application for outline consent)(**48**), in paragraph (3), after "pharmaceutical services are provided at" insert "or from".

Amendments to regulation 57

37. In regulation 57 (gradual introduction of premises approval)(**49**), in paragraph (1)—

(a) after "provides pharmaceutical services" insert "at or"; and

(b) in sub-paragraph (b), after "provide pharmaceutical services" insert "at or".

Amendments to regulation 60

38. In regulation 60 (lapse of outline consent and premises approval)(**50**), in paragraph (3)—

(a) in sub-paragraph (b), after "regulation 48 at" insert "or from"; and

(b) in sub-paragraph (c), after "authority to dispense" insert "at or".

Amendments to regulation 61

39. In regulation 61 (temporary arrangements during emergencies or circumstances beyond the control of a dispensing doctor)(**51**)—

(a) in paragraph (5), after "dispensing services at" insert "or from"; and

(b) in paragraph (6)—

(i) for "at P1 at" substitute "at or from P1 at or from", and

(ii) after "were ordinarily provided at" insert "or from".

(**46**) Regulation 54 has been amended by S.I. 2023/1071.
(**47**) Regulation 55 has been amended by S.I. 2023/1071.
(**48**) Regulation 56 has been amended by S.I. 2023/1071.
(**49**) Regulation 57 has been amended by S.I. 2023/1071.
(**50**) Regulation 60 has been amended by S.I. 2023/1071.
(**51**) Regulation 61 has been amended by S.I. 2023/1071.

Amendment to regulation 63

40. In Regulation 63 (appeals against decisions under Part 8)(**52**), in paragraph (1)(b)(ii), after "to obtain services" insert "at or".

Amendments to regulation 65

41.—(1) Regulation 65 (core opening hours conditions)(**53**) is amended as follows.

(2) In paragraph (4)—

(a) in sub-paragraph (a)—

(i) in paragraph (i), after "pharmaceutical services at" insert "or from",

(ii) in paragraph (ii), after "are to be provided at" insert "or from", and

(iii) after "pharmaceutical services at" insert "or from"; and

(b) in sub-paragraph (b)—

(i) in paragraph (i), after "provide pharmaceutical services at" insert "or from",

(ii) in paragraph (ii), after "are to be provided at" insert "or from", and

(iii) after "is to provide pharmaceutical services at" insert "or from".

(3) In paragraph (5)—

(a) in sub-paragraph (a), after "provide pharmaceutical services at" insert "or from"; and

(b) in sub-paragraph (b)(ii)—

(i) in sub-paragraph (aa), after "are to be provided at" insert "or from",

(ii) in sub-paragraph (bb), after "are to be provided at" insert "or from", and

(iii) after "provide pharmaceutical services at" insert "or from".

Amendments to regulation 65A

42.—(1) Regulation 65A (continuity in respect of opening hours directions)(**54**) is amended as follows.

(2) In paragraph (3), after "being provided, but at" insert "or from".

(3) In paragraph (4)(a), after "provide pharmaceutical services, at" insert "or from".

Amendments to regulation 66

43.—(1) Regulation 66 (conditions relating to providing directed services)(**55**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), after "those directed services at" insert "or from"; and

(b) in sub-paragraph (b), after "those directed services at" insert "or from".

(3) In paragraph (2)(b), after "the services be provided at" insert "or from".

(4) In paragraph (5), after "The condition is that, at" insert "or from".

(**52**) Regulation 63 has been amended by S.I. 2023/1071.
(**53**) Regulation 65 has been amended by S.I. 2023/479 and 1071.
(**54**) Regulation 65A was inserted by S.I. 2023/479.
(**55**) Regulation 66 has been amended by S.I. 2023/1071.

Amendment to regulation 67

44. In regulation 67 (conditions relating to voluntary closure of premises)(**56**), in paragraph (4), after "pharmaceutical services at", at each place where it occurs (three times), insert "or from".

Amendment to regulation 73

45. In regulation 73 (removal of listings: cases relating to remedial notices and breach notices)(**57**), in paragraph (5)(a), after "provide pharmaceutical services at" insert "or from".

Amendment to regulation 74

46. In regulation 74 (removal of listings: cases relating to death, incapacity or cessation of service)(**58**), in paragraph (3), after "provided pharmaceutical services at" insert "or from".

Amendment to regulation 75

47. In regulation 75 (voluntary and automatic removal of listings: change of ownership, relocation, temporary provision and voluntary closure)(**59**), in paragraph (3), after "suspended NHS chemist at" insert "or from".

Amendment to regulation 99

48. In regulation 99 (designation of areas, premises or descriptions of premises)(**60**), in paragraph (2), after "or premises or descriptions of premises at" insert "or from".

Amendments to regulation 101

49. In regulation 101 (cancellation of designations)(**61**), in paragraph (2)—

(a) in sub-paragraph (d), after "or to the premises" insert "at or"; and

(b) in sub-paragraph (e), after "provision of LP services at" insert "or from".

Amendment to regulation 109

50. In regulation 109 (LPS pilot schemes: health service body status)(**62**), in paragraph (5), after "must not be provided" insert "at or".

Amendment to regulation 114

51. In regulation 114 (lists of LPS chemists)(**63**), in paragraph (2)(b), after "times as which, at" insert "or from".

Amendment to Schedule 1

52. In Schedule 1 (information to be contained in pharmaceutical needs assessments), in paragraph 7 (map of provision), after "identifies the premises at" insert "or from".

(**56**) Regulation 67 has been amended by S.I. 2016/1077, 2023/479 and 1071.
(**57**) Regulation 73 has been amended by S.I. 2023/1071.
(**58**) Regulation 74 has been amended by S.I. 2023/1071.
(**59**) Regulation 75 has been amended by S.I. 2016/296 and 1077 and 2023/1071.
(**60**) Regulation 99 has been amended by S.I. 2023/1071.
(**61**) Regulation 101 has been amended by S.I. 2023/1071.
(**62**) Regulation 109 has been amended by S.I. 2015/58 and 2023/1071.
(**63**) Regulation 114 has been amended by S.I. 2023/1071.

Amendments to Schedule 2

53.—(1) Schedule 2 (applications in respect of pharmaceutical lists and the procedures to be followed) is amended as follows.

(2) In Part 1 (information to be included in routine and excepted applications), in paragraph 9 (Undertakings)(**64**), in sub-paragraph (1)—

(a) in paragraph (c)(ii), after "perform all the activities at" insert "or from"; and

(b) in paragraph (d)(i), after "does commission the services" insert "at or".

(3) In Part 5 (notification, taking effect of decisions and rights of appeal to the Secretary of State)—

(a) in paragraph 29 (template notice of commencement to be included with a notice of decision)(**65**)—

(i) in sub-paragraph (b), after "are to be provided" insert "at or", and

(ii) in sub-paragraph (d), after "provision of those services at" insert "or from";

(b) in paragraph 29A (template notice of consolidation)(**66**), in sub-paragraph (2)—

(i) in paragraph (b), after "of the premises at" insert "or from",

(ii) in paragraph (c), after "cease being provided at" insert "or from", and

(iii) in paragraph (d), after "address of the premises at" insert "or from";

(c) in paragraph 33 (conditional grant in cases relating to future needs or future improvements or better access)(**67**), in sub-paragraph (2)—

(i) after "pharmaceutical services are not provided at" insert "or from", and

(ii) after "the application relates (or at" insert "or from";

(d) in paragraph 34 (taking of effect of listing decisions: general)(**68**)—

(i) in sub-paragraph (1)(b)—

(aa) in sub-paragraph (i), after "additional premises" insert "at or",

(bb) in sub-paragraph (ii), after "different premises, and at" insert "or from", and

(cc) in sub-paragraph (iii), after "to provide," insert "at or", and

(ii) in sub-paragraph (2), after "was made and at" insert "or from".

Amendment to Part 2 of Schedule 4

54. In Schedule 4 (terms of service of NHS pharmacists), in Part 2 (essential services), in paragraph 11 (additional requirements in relation to electronic prescribing)(**69**), in sub-paragraph (1)(b), after "pharmacists in the area at" insert "or from".

Amendments to Part 3 of Schedule 4

55.—(1) Schedule 4 (terms of service of NHS pharmacists), Part 3 (hours of opening) is amended as follows.

(2) In paragraph 23 (pharmacy opening hours: general)(**70**)—

(**64**) Paragraph 9 has been amended by S.I. 2016/1077 and 2023/1071.
(**65**) Paragraph 29 has been amended by S.I. 2016/1077 and 2023/1071.
(**66**) Paragraph 29A was inserted by S.I. 2016/1077 and has been amended by S.I. 2023/1071.
(**67**) Paragraph 33 has been amended by S.I. 2023/1071.
(**68**) Paragraph 34 has been amended by S.I. 2016/1077, 2020/885 and 1126, and 2023/479 and 1071.
(**69**) Paragraph 11 has been amended by S.I. 2018/1114 and 2020/1126.
(**70**) Paragraph 23 has been amended by S.I. 2023/479 and 1071.

(a) in sub-paragraph (1)—

(i) after "pharmaceutical services are provided at" insert "or from",

(ii) in paragraph (c), after "are to be provided at" insert "or from",

(iii) in paragraph (d), after "are to be provided at" insert "or from",

(iv) in paragraph (e), after "are to be provided at" insert "or from";

(b) in sub-paragraph (5)—

(i) in paragraph (a), after "are provided at" insert "or from", and

(ii) in paragraph (b), after "ordinarily provides at" insert "or from";

(c) in sub-paragraph (6)(b), after "ordinarily provides at" insert "or from"; and

(d) in sub-paragraph (7)—

(i) after "are to be provided at" insert "or from",

(ii) in paragraph (a), after "are provided at" insert "or from",

(iii) in paragraph (ba), after "are to be provided at" insert "or from",

(iv) in paragraph (bc)(ii), after "are to be provided at" insert "or from", and

(v) in paragraph (bd), after "are to be provided at" insert "or from".

(3) In paragraph 23A (local hours plans)(**71**), in sub-paragraph (5)(a), after "are provided at" insert "or from".

(4) In paragraph 24 (matters to be considered when issuing directions in respect of pharmacy premises core opening hours)(**72**)—

(a) in sub-paragraph (3), after "provide pharmaceutical services at" insert "or from"; and

(b) in sub-paragraph (4), after "provide pharmaceutical services at" insert "or from".

(5) In paragraph 25 (determination of pharmacy premises core opening hours instigated by NHS England)(**73**)—

(a) in sub-paragraph (1), after "provide pharmaceutical services at" insert "or from";

(b) in sub-paragraph (3)—

(i) in paragraph (b), after "provide pharmaceutical services at" insert "or from", and

(ii) in paragraph (c)(i), after "provide pharmaceutical services at" insert "or from";

(c) in sub-paragraph (4)—

(i) in paragraph (a)(i), after "pharmaceutical services at" insert "or from", and

(ii) in paragraph (b), after "are to be provided at" insert "or from";

(d) in sub-paragraph (6), after "pharmaceutical services at" insert "or from"; and

(e) in sub-paragraph (10), after "pharmaceutical services at" insert "or from".

(6) In paragraph 26 (determination of pharmacy premises core opening hours instigated by the NHS pharmacist)(**74**)—

(a) in sub-paragraph (1)—

(i) after "core opening hours at" insert "or from", and

(ii) in paragraph (a), after "pharmaceutical services at" insert "or from";

(b) in sub-paragraph (4)—

(**71**) Paragraph 23A was inserted by S.I. 2023/479.
(**72**) Paragraph 24 has been amended by S.I. 2023/479 and 1071 and 2025/636.
(**73**) Paragraph 25 has been amended by S.I. 2023/1071.
(**74**) Paragraph 26 has been amended by S.I. 2023/479, 1071 and 2025/636.

(i) in paragraph (b), after "pharmaceutical services at" insert "or from", and

(ii) in paragraph (c)(i), after "pharmaceutical services at" insert "or from";

(c) in sub-paragraph (5)—

(i) in paragraph (a)(i), after "pharmaceutical services at" insert "or from", and

(ii) in paragraph (b), after "are to be provided at" insert "or from";

(d) in sub-paragraph (12), after "pharmaceutical services at" insert "or from"; and

(e) in paragraph 27 (temporary opening hours and closures during an emergency requiring the flexible provision of pharmaceutical services)(**75**)—

(i) in sub-paragraph (1), after "provide pharmaceutical services at" insert "or from", and

(ii) in sub-paragraph (2), after "provide pharmaceutical services at" insert "or from".

Amendment to Part 4 of Schedule 4

56. In Schedule 4 (terms of service of NHS pharmacists), in Part 4 (other terms of service), in paragraph 29D (business continuity plans to deal with temporary suspensions)(**76**), in sub-paragraph (2)(b), after "provision of pharmaceutical services at" insert "or from".

Amendments to Schedule 5

57.—(1) Schedule 5 (terms of service of NHS appliance contractors) is amended as follows.

(2) In paragraph 13 (opening hours: general)(**77**)—

(a) in sub-paragraph (1)—

(i) after "services are provided at", insert "or from",

(ii) in paragraph (c), after "are to be provided at" insert "or from",

(iii) in paragraph (d), after "are to be provided at" insert "or from", and

(iv) in paragraph (e), after "are to be provided at" insert "or from";

(b) in sub-paragraph (4)—

(i) in paragraph (a), after "pharmaceutical services are provided at" insert "or from", and

(ii) in paragraph (b), after "C ordinarily provides at" insert "or from";

(c) in sub-paragraph (5)(b), after "C is ordinarily to provide at" insert "or from"; and

(d) in sub-paragraph (6)—

(i) after "pharmaceutical services are to be provided at" insert "or from",

(ii) in paragraph (a), after "pharmaceutical services are provided at" insert "or from", and

(iii) in paragraph (b)—

(aa) in sub-paragraph (i), after "are to be provided at" insert "or from",

(bb) in sub-paragraph (iii), after "are to be provided at" insert "or from", and

(cc) in sub-paragraph (iv), after "ordinarily to provide at" insert "or from".

(3) In paragraph 14 (matters to be considered when issuing directions in respect of core opening hours)(**78**)—

(a) in sub-paragraph (3), after "may provide pharmaceutical services at" insert "or from"; and

(**75**) Paragraph 27 has been amended by S.I. 2023/1071.
(**76**) Paragraph 29D was inserted by S.I. 2023/479.
(**77**) Paragraph 13 has been amended by S.I. 2023/1071.
(**78**) Paragraph 14 has been amended by S.I. 2023/1071.

(b) in sub-paragraph (4), after "must provide pharmaceutical services at" insert "or from".

(4) In paragraph 15 (determination of core opening hours instigated by NHS England)(**79**)—

(a) in sub-paragraph (1), after "to provide pharmaceutical services at" insert "or from";

(b) in sub-paragraph (3)—

(i) in paragraph (b), after "must provide pharmaceutical services at" insert "or from", and

(ii) in paragraph (c)(i), after "must provide pharmaceutical services at" insert "or from";

(c) in sub-paragraph (4)—

(i) in paragraph (a)(i), after "must provide pharmaceutical services at" insert "or from", and

(ii) in paragraph (b), after "are to be provided at" insert "or from";

(d) in sub-paragraph (6), after "is to provide pharmaceutical services at" insert "or from"; and

(e) in sub-paragraph (10), after "is to provide pharmaceutical services at" insert "or from".

(5) In paragraph 16 (determination of core opening hours instigated by the NHS appliance contractor)(**80**)—

(a) in sub-paragraph (1), after "provide pharmaceutical services at" insert "or from";

(b) in sub-paragraph (4)—

(i) in paragraph (b), after "must provide pharmaceutical services at" insert "or from", and

(ii) in paragraph (c)(i), after "must provide pharmaceutical services at" insert "or from";

(c) in sub-paragraph (5)—

(i) in paragraph (a)(i), after "must provide pharmaceutical services at" insert "or from", and

(ii) in paragraph (b), after "pharmaceutical services are to be provided at" insert "or from"; and

(d) in sub-paragraph (12), after "is to provide pharmaceutical services at" insert "or from".

(6) In paragraph 17 (temporary open hours and closures during an emergency requiring the flexible provision of pharmaceutical services)(**81**)—

(a) in sub-paragraph (1), after "is obliged to provide pharmaceutical services at" insert "or from"; and

(b) in sub-paragraph (2), after "is obliged to provide pharmaceutical services at" insert "or from".

Amendments to Schedule 6

58.—(1) Schedule 6 (terms of service of dispensing doctors) is amended as follows.

(2) In paragraph 7 (dispensing doctors issuing prescription forms which may be presented to an NHS chemist), after "available on prescription" insert "at or".

(3) In paragraph 10 (voluntary closure of premises)(**82**), in sub-paragraph (2)—

(a) after "provision of pharmaceutical services at" insert "or from"; and

(**79**) Paragraph 15 has been amended by S.I. 2023/1071.
(**80**) Paragraph 16 has been amended by S.I. 2023/1071.
(**81**) Paragraph 17 has been amended by S.I. 2023/1071.
(**82**) Paragraph 10 has been amended by S.I. 2023/1071.

(b) after "cease to provide pharmaceutical services at" insert "or from".

Amendments to Schedule 7

59.—(1) Schedule 7 (mandatory terms for LPS schemes) is amended as follows.

(2) In paragraph 1, (general provisions)(**83**), in sub-paragraph (1)(b)(ii), for "activities on" substitute "activities at or from".

(3) In paragraph 26 (variation of LPS schemes)(**84**)—

(a) in sub-paragraph (3)(a), after "provide local pharmaceutical services at" insert "or from"; and

(b) in sub-paragraph (4), after "provide local pharmaceutical services at" insert "or from".

PART 5

Other miscellaneous amendments

Amendments to regulation 2

60. In regulation 2 (interpretation)(**85**), in paragraph (1)—

(a) omit the definition of "NHSmail"; and

(b) at the appropriate place insert—

> ""NHS.net Connect" means the secure e-mail service of that name for the sharing of patient identifiable and patient sensitive information, for which NHS England is responsible;".

Amendment to regulation 6

61. In regulation 6 (subsequent assessments and later first assessments)(**86**), after paragraph (3) insert—

> "(3ZA) Except in the circumstances provided for in paragraph (4), a supplementary statement must not provide (and if it does, it must not be read as providing) a new analysis of service provision (for example, by identifying gaps in service provision).
>
> (3ZB) Paragraph (3ZA) does not apply in the case of a routine application submitted before 1st October 2025 based on a need, an improvement or better access identified in a supplementary statement as part of the provision of a new analysis of service provision (but does apply to consideration after that date of an unforeseen benefits application submitted before that date).".

Amendment to regulation 64

62. In Regulation 64 (distance selling premises: specific conditions)(**87**), in paragraph (3)(e), omit "in X's practice leaflet,".

(**83**) Paragraph 1 has been amended by S.I. 2023/1071.
(**84**) Paragraph 26 has been amended by S.I. 2023/1071.
(**85**) Relevant amendments have been made to regulation 2 by S.I. 2020/1126 and 2023/98 and 1071.
(**86**) Regulation 6 has been amended by S.I. 2016/1077, 2020/885 and 2021/1346.
(**87**) Regulation 64 has been amended by S.I. 2014/417, 2023/1071 and 2025/636.

Amendments to regulation 91A

63.—(1) Regulation 91A (zero or nominal product reimbursement for vaccines and antivirals)(**88**) is amended as follows.

(2) In paragraph (2)—

(a) omit "or" at the end of sub-paragraph (ad); and

(b) after sub-paragraph (ad) insert—

"(ae) a drug or medicine which is used for vaccinating or immunising people against human papillomavirus, if the conditions set out in paragraph (3) are satisfied; or".

(3) In paragraph (3A), for "to (ad)" substitute "to (ae)".

Amendments to Part 4 of Schedule 4

64.—(1) Schedule 4 (terms of service of NHS pharmacists), Part 4 (other terms of service) is amended as follows.

(2) In paragraph 28 (clinical governance and the promotion of healthy living)(**89**), in sub-paragraph (2)—

(a) omit paragraph (a)(i); and

(b) in paragraph (e)(iii), omit "and references".

(3) In paragraph 29C (contact via NHSmail, pharmacy profiles and the Central Alerting System)(**90**)—

(a) in the title, for "NHS mail" substitute "NHS.net Connect";

(b) in sub-paragraph (1)—

(i) for "NHSmail" at the first place it occurs, substitute "messages via NHS.net Connect", and

(ii) for "NHSmail", at the second place it occurs, substitute "NHS.net Connect";

(c) in sub-paragraph (2), at both places that it occurs, for "NHSmail" substitute "NHS.net Connect"; and

(d) in sub-paragraph (5)—

(i) in paragraph (a), for "NHSmail" substitute "NHS.net Connect",

(ii) in paragraph (b), at both places that it occurs, for "NHSmail" substitute "NHS.net Connect", and

(iii) in paragraph (c), for "NHSmail" substitute "NHS.net Connect".

Amendments to Schedule 5

65. In Schedule 5 (terms of service of NHS appliance contractors), in paragraph 18 (clinical governance)(**91**), in sub-paragraph (2)—

(a) omit paragraph (a)(i); and

(b) in paragraph (e)(iii), omit "and references".

(**88**) Regulation 91A was inserted by S.I. 2022/930 and has been amended by S.I. 2024/838 and 894 and 2025/636.
(**89**) Paragraph 28 has been amended by S.I. 2015/58, 2016/1077, 2020/1126, 2021/1346, 2022/930 and 2023/1071.
(**90**) Paragraph 29C was inserted by S.I. 2020/1126 and has been amended by S.I. 2023/98.
(**91**) Paragraph 18 has been amended by S.I. 2023/1071.

Amendments to Schedule 7

66.—(1) Schedule 7 (mandatory terms for LPS schemes) is amended as follows.

(2) In paragraph 13C (contact via NHSmail and the Central Alerting System)(**92**)—

(a) in the title, for "NHSmail" substitute "NHS.net Connect";

(b) in sub-paragraph (1)—

(i) for "NHSmail" at the first place it occurs, substitute "messages via NHS.net Connect", and

(ii) for "NHSmail", at the second place it occurs, substitute "NHS.net Connect";

(c) in sub-paragraph (2), at both places that it occurs, for "NHSmail" substitute "NHS.net Connect"; and

(d) in sub-paragraph (3)—

(i) in paragraph (a), for "NHSmail" substitute "NHS.net Connect",

(ii) in paragraph (b), at both places that it occurs, for "NHSmail" substitute "NHS.net Connect", and

(iii) in paragraph (c), for "NHSmail" substitute "NHS.net Connect".

Signed by authority of the Secretary of State for Health and Social Care

Stephen Kinnock
Minister of State
Department of Health and Social Care

1st September 2025

(**92**) Paragraph 13C was inserted by S.I. 2020/1126.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349, as amended – "the PLPS Regulations"). The PLPS Regulations govern the arrangements in England, under Part 7 of the National Health Service Act 2006 ("the 2006 Act"), for the provision of pharmaceutical and local pharmaceutical services.

These Regulations place a restriction on community pharmacies and the GP practices that dispense medicines in some rural areas (known as "dispensing doctors") from sub-contracting any of their core dispensing functions under the PLPS Regulations, subject to exceptions. These include an exception for so-called "hub and spoke" dispensing arrangements, which are provided for in most cases by regulation 222A of the Human Medicines Regulations 2012 (S.I. 2012/1916, as amended by S.I. 2025/758) ("the 2012 Regulations"). Under "hub and spoke" arrangements, a "spoke" (either a community pharmacy or a dispensing doctor) submits the information contained in a prescription to a "hub" pharmacy, which sends the prescribed item back to the "spoke" for final supply to or for the patient. Part 3 of these Regulations sets out the NHS terms of service being inserted into the PLPS Regulations for such supply.

In the case of community pharmacies, these terms of service include the community pharmacy needing to give notice to NHS England of their intention to enter into hub and spoke arrangements and what features those arrangements must have. NHS England are also granted a power to ask for information at any time in relation to specific objection criteria. In appropriate circumstances, NHS England can issue a notice of objection to the hub and spoke arrangements and the community pharmacy must then end the arrangements, subject to dispute resolution arrangements. An information gateway is also created for products on prescription, and some pandemic supplies, that are not covered by the arrangements in regulation 222B of the 2012 Regulations, most notably prescription foods, cosmetics and medical devices such as dressings. A shortened version of the arrangements for community pharmacies – to accommodate the existing arrangements for sub-contracting under GP contracts – is applied to dispensing doctors.

Partly as a result of amendments introduced to the 2012 Regulations by S.I. 2025/758, consequential amendments are made to the PLPS Regulations so that references to "on", "at" or "from" premises are now to be read as "at or from" premises. This brings the PLPS Regulations into line with the Medicines Act 1968 and the 2012 Regulations on this issue. This clarifies that transactions starting at pharmacy premises may be completed elsewhere (Part 4).

A number of miscellaneous other amendments are also made. References to the NHS Business Services Authority that were related to fraudulent activity have been replaced by references to the NHS Counter Fraud Agency to reflect an operational reorganisation (Part 2). Vaccines for human papillovirus are added to the list of vaccines suppliable to community pharmacies as part of what are, in practice, NHS central purchasing arrangements, so are supplied at no cost to the pharmacy (regulation 63). The requirements for community pharmacies to produce practice leaflets are removed (regulations 62, 64(2)(a) and 65(a)), as are the requirements that references are necessary for all staff involved in the provision of NHS services (regulations 64(2)(b) and 65(b)). What can be included in supplementary statements for local plans for the provision of pharmaceutical services known as pharmaceutical needs assessments is clarified (regulation 60). References to "NHSmail" are replaced with "NHSnet. Connect" to reflect current practice (60, 64(3) to (5) and 66).

An assessment of the effect of this instrument was undertaken and it was deemed that a full impact assessment would not be proportionate. These Regulations are not expected to have a significant

impact on the public and voluntary sectors, and only a limited impact on the private sector, below the threshold for undertaking a full impact assessment.