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NHS England

Standard Personal Medical Services Agreement Variation Notice

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Standard Personal Medical Services (PMS) Agreement Variation Notice

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Prepared by Hill Dickinson on behalf of NHS England.

The text of the Standard Personal Medical Services (PMS) Agreement Variation Notice July 2026 has been prepared by Hill Dickinson on behalf of NHS England.

It is prepared on the basis that the signed agreement to be varied is in the form of the NHS England Standard Personal Medical Services Agreement and is up to date with all prior variation notices (up to and including the NHS England Standard Personal Medical Services Agreement Variation Notice August 2025).

Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities."

Dear Sir/Madam

Notice of Variation to your Personal Medical Services Agreement dated [ ]

We give you notice under paragraph 52(2) of Schedule 2 to the National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/1879) that the terms of your Personal Medical Services Agreement dated [ ] are varied as set out below with effect from [*insert here date on which variations will take effect. Where reasonably practicable this should not be less than 14 days after the date on which this notice is served. This is a regulatory requirement*].

These variations are made to comply with:

- National Health Service (Pharmaceutical and Local Pharmaceutical Services) (Miscellaneous Amendments) Regulations 2025; and
- National Health Service (General Medical Services Contracts and Personal Medical Services Agreements) (Amendment) Regulations 2026;

which came into force since the last update to the Standard Personal Medical Services Agreement.

These variations are also made to that ensure your contract complies with the terms of:

- National Health Service (Charges, Primary Medical Services and Pharmaceutical and Local Pharmaceutical Services) (Coronavirus) (Further Amendments) Regulations 2021;

which came into force on 21 December 2021 but was not covered by previous variation notices.

For the avoidance of doubt nothing in this notice shall affect accrued rights or liabilities up to the date of the variation.

We request you to acknowledge receipt of this notice by signing and returning the enclosed duplicate of it.

Dated:

Signed:

on behalf of [INSERT ICB NAME]

Print name:

Wording of Variations

Part 1

1. In clause 1.1, **remove** the definitions for "Listed Medicines" and "Listed Medicines Voucher".

2. In clause 1.1, **insert** the following definitions:

"**"Listed Prescription Items"** means the prescription items mentioned in regulation 13(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (exemption from charges: risks to public health);

"Listed Prescription Items Voucher" means a form which:

(a) is provided or approved by the Commissioner for the purposes of ordering a prescription item mentioned in regulation 13(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2015; and

(b) may be an electronic form sent or to be sent via a secure service approved for this purpose by the Commissioner;".

Part 7

3. In clause 7.8.2, immediately before the words "the appropriate response", **insert** the words "Subject to sub-clause 7.8.2A,".

4. Immediately after clause 7.8.2.4.2, **insert**:

"7.8.2A The Contractor must not ask a Patient to contact the practice on another day.".

5. In clause 7.8.3, immediately before the words "the appropriate response", **insert** the words "For matters which the Contractor has identified as clinically urgent, ".

6. Immediately after clause 7.8.3.2, **insert**:

"7.8.3A For matters which the Contractor has identified as not clinically urgent, the appropriate response must be provided before the end of the next working day after contact.".

7. Immediately after clause 7.17, **insert**:

"**Co-operation with NHS England: performance management**

7.17A The Contractor must co-operate with the Commissioner, in so far as is reasonable, in relation to the performance and improvement of services provided under this Agreement, including co-operating with the provision of any support, performance review or improvement activity.".

Part 27

8. **Replace** clause 27 with:

"27 Sub-contracting of clinical matters

27.1 The Contractor must not sub-contract any of its rights or duties under this Agreement in relation to clinical matters to any person unless:

27.1.1 in all cases, including those duties relating to out of hours services to which clause 27A (sub-contracting out of hours services) applies, the Contractor has taken reasonable steps to satisfy itself that:

27.1.1.1 it is reasonable in all the circumstances to do so, and

27.1.1.2 the person to whom any of those rights or duties is sub-contracted is qualified and competent to provide the service, and

27.1.2 except in cases to which clause 27A applies, the Contractor has given notice in writing to the

Commissioner of its intention to sub-contract, as soon as reasonably practicable before the date on which the proposed sub-contract is intended to come into effect.

27.2 Sub-clause 27.1.2 does not apply to a contract for services with a health care professional for the provision by that professional personally of clinical services.

27.3 A notice given under sub-clause 27.1.2 must include:

27.3.1 the name and address of the proposed sub-contractor,

27.3.2 the duration of the proposed sub-contract,

27.3.3 the services to be covered by the proposed sub-contract, and

27.3.4 the address of any premises to be used as Practice Premises under the proposed sub-contract.

27.4 On receipt of a notice given under sub-clause 27.1.2, the Commissioner may request such further information relating to the proposed sub-contract as appears to it to be reasonable, and the Contractor must supply such information to the Commissioner promptly.

27.5 The Contractor must not proceed with a contract or, if the contract has already taken effect, the Contractor must take steps to terminate it, where:

27.5.1 before the end of the period of 28 days beginning with the date on which the Commissioner received a notice from the Contractor under sub-clause 27.1.2, the Commissioner gives notice in writing of its

objection to the contract on the grounds that the contract would:

27.5.1.1 put the safety of the Contractor's Patients at serious risk, or

27.5.1.2 put the Commissioner at risk of material financial loss, or

27.5.2 the sub-contractor would be unable to meet the Contractor's obligations under this Agreement.

27.6 A notice given by the Commissioner under sub-clause 27.5.1 must include a statement of the reasons for the Commissioner's objection.

27.7 Sub-clauses 27.1 to 27.6 also apply in relation to any renewal, or material variation, of a contract in relation to clinical matters.

27.8 Where the Commissioner does not give notice of an objection under sub-clause 27.5, the parties to this Agreement are deemed to have agreed a variation of this Agreement which has the effect of adding the address of any premises which was notified to the Commissioner under sub-clause 27.3.4 to the list of Practice Premises and, in these circumstances, clause 53.1 (variation of an agreement) does not apply.

27.9 Subject to sub-clause 27.10, a sub-contract entered into by a Contractor must prohibit the sub-contractor from sub-contracting any of the clinical services that it has agreed with the Contractor to provide under the sub-contract.

27.10 A sub-contract entered into by the Contractor may allow the sub-contractor to sub-contract clinical services the Contractor has agreed to provide under the Network Contract Directed Enhanced Service Scheme, pursuant to the Primary Medical Services

(Directed Enhanced Services) Directions [1], provided the Contractor obtains the written approval of the Commissioner prior to the sub-contractor sub-contracting those services.

27.11 The Contractor must not sub-contract any of its rights or duties under this Agreement in relation to the provision of essential services to a company or firm that is:

27.11.1 wholly or partly owned by the Contractor, or by any former or current employee of, or partner or shareholder in, the Contractor,

27.11.2 formed by or on behalf of the Contractor, or from which the Contractor derives or may derive a pecuniary benefit, or

27.11.3 formed by or on behalf of a former or current employee of, or partner or shareholder in, the Contractor, or from which such a person derives or may derive a pecuniary benefit, where sub-clause 27.12 applies to that company or firm.

27.12 This sub-clause applies to a company or firm which is or was formed wholly or partly for the purpose of avoiding the restrictions on the sale of goodwill of a medical practice in section 259 of the 2006 Act[2] (sale of medical practices), and Schedule 21 to the 2006 Act (prohibition of sale of medical practices), or any regulations made wholly or partly under those provisions of the 2006 Act.

27A **Sub-contracting out of hours services**

[1] These directions are available online at: https://www.gov.uk/government/publications/primary-medical-services-directed-enhanced-services-directions. Hard copies are available from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

[2] Section 259 was amended by paragraph 132 of Schedule 4 to the Health and Social Care Act 2012 (c. 7) and paragraph 1 of Schedule 1 to the Health and Care Act 2022 (c. 31).

27A.1 A Contractor must not sub-contract all or part of its duty to provide out of hours services under this Agreement to a person other than those specified in sub-clause 27A.2 without the prior written approval of the Commissioner.

27A.2 The persons specified in this sub-clause are:

27A.2.1 a person who holds a contract made in accordance with the General Medical Services Contracts Regulations and under such contract is required to provide the equivalent of essential services to its Patients during all or part of the out of hours period,

27A.2.2 a provider of an agreement which includes the provision of out of hours services,

27A.2.3 a health care professional, not falling within clause 27A.2.1 or 27A.2.2, who is to provide the out of hours services personally under a contract for services, or

27A.2.4 a group of medical practitioners, whether in partnership or not, who provide out of hours services for each other under informal rota agreements.

27A.3 The requirement in sub-clause 27A.1 to obtain prior written approval does not apply in any case where a Contractor sub-contracts all or part of its duty to provide out of hours services under this Agreement on a short term or occasional basis.

27A.4 An application for approval under sub-clause 27A.1 must be made by the Contractor in writing to the Commissioner and must state:

27A.4.1 the name and address of the proposed sub-contractor,

27A.4.2 the duration of the proposed sub-contract,

27A.4.3 the services to be covered by the sub-contract,

27A.4.4 the address of any premises to be used as Practice Premises under the sub-contract, and

27A.4.5 the manner in which the sub-contractor proposes to meet the Contractor's obligations under this Agreement in respect of the services to be covered by the sub-contract.

27A.5 Before the end of the period of seven days beginning with the date on which the Commissioner received the application under sub-clause 27A.4, the Commissioner may request such further information relating to arrangements under the proposed sub-contract as appears to it to be reasonable.

27A.6 Where the Commissioner receives an application which meets the requirements specified in sub-clause 27A.4, or receives any further information requested under sub-clause 27A.5 in relation to an application, the Commissioner must, before the end of the period of 28 days beginning with the date on which it received the application or that information (whichever is the latest):

27A.6.1 approve the application;

27A.6.2 approve the application subject to conditions; or

27A.6.3 refuse the application.

27A.7 The Commissioner must not refuse the application if it is satisfied that the arrangements covered by the proposed sub-contract would, in respect of the services to be provided, enable the Contractor to satisfactorily meet its obligations under this Agreement and would not:

27A.7.1 put the safety of the Contractor's Patients at serious risk, or

27A.7.2 put the Commissioner at risk of material financial loss.

27A.8 The Commissioner must give notice in writing to the Contractor of its decision on the application and, where it refuses an application, it must include in the notice a statement of the reasons for its refusal.

27A.9 Where the Commissioner approves an application under this clause, the parties to this Agreement are deemed to have agreed a variation of this Agreement which has the effect of adding to the list of Practice Premises, for the purposes of the provision of services in accordance with that application, any premises the address of which was notified to the Commissioner under sub-clause 27A.4.4 and, in these circumstances, clause 53.1 (variation of an agreement) does not apply.

27A.10 Sub-clauses 27A.1 to 27A.9 also apply in relation to any renewal or material variation of a sub-contract in relation to out of hours services.

27A.11 A sub-contract entered into by a Contractor must prohibit the sub-contractor from sub-contracting the out of hours services that it has agreed with the Contractor to provide under the sub-contract.".

Part 33ZD

9. **Replace** clause 33.ZD.2 with:

"33ZD.2 An "online consultation tool" is an online facility provided using Appropriate Software which satisfies the condition in clause 33ZD.2A and through which a Patient, or an appropriate person acting on behalf of a person to whom clause 33ZD.4 applies, may make:

33ZD.2.1 a request for advice or information related to the

Patient's health, or

33ZD.2.2 a clinical or administrative request.

33ZD.2A The condition in this clause is that the online facility does not limit the number of requests using the Online Consultation Tool that can be made during Core Hours or during any period of time within Core Hours.".

Part 38

10. **Replace** clause 38.31 with:

"38.31 **Collection of data relating to use of the Online Consultation Tool and Video Consultations**

38.31.1 The Contractor must make available to the Commissioner such information as is specified by the Commissioner that is available to the Contractor in connection with use of the Online Consultation Tool under clause 33ZD and Video Consultations under clause 33ZF.

38.31.2 The Contractor must make information available to the Commissioner under clause 38.31.1 within such reasonable time frame as may be specified by the Commissioner.".

11. Immediately after clause 38.33, **insert**:

"**NHS staff surveys**

38.34 The Contractor must make available to the Commissioner such information as specified by the Commissioner in connection with staff surveys that relate to the Contractor's staff.

38.35 The Contractor must make information available to the Commissioner under clause 38.34 within such reasonable time frame as may be specified by the Commissioner.

Information relating to the Lung Cancer Screening Programme

38.36 The Contractor must allow the extraction by NHS England, or by persons authorised by NHS England, of data reasonably required for the purpose of the Lung Cancer Screening Programme, from the record that the Contractor is required to keep under clause 29 by such means, and at such intervals, as are notified to the Contractor by NHS England.

38.37 The Contractor must co-operate, in so far as is reasonable, with NHS England, or persons authorised by NHS England, in relation to data extractions under clause 38.36.

38.38 In this regulation, "Lung Cancer Screening Programme" means the national programme arranged by NHS England of lung health checks for the purpose of detecting and diagnosing lung cancer, for persons identified by NHS England as recommended for such checks.".

Part 40

12. In clause 40.1, immediately after the words "Digital Practice Area Map", **insert** the words ", for approval by the Commissioner".

Schedule 4

13. In Schedule 4, at each place where it occurs **replace** the words "Listed Medicine" with the words "Listed Prescription Item".

14. In Schedule 4, at each place where it occurs **replace** the words "Listed Medicines" with the words "Listed Prescription Items".

15. In paragraph 1.4, immediately before the words "if one is used", **insert** the words "(with an Electronic Signature, if an electronic form is used)".

16. In paragraph 1.5, immediately before the words "if one is used", **insert** the words "(with an Electronic Signature, if an electronic form is used)".

17. In paragraph 3, **replace** the heading with "**Patient choice: pharmaceutical services**".

18. Immediately after paragraph 3.2, **insert**:

"3.2A The Contractor must, where the Patient has nominated a Dispenser, consult the Patient, or the Patient's Authorised Person, as to their choice of Dispenser in respect of each order for drugs, medicines or Appliances made by a Prescriber under paragraphs 1.2 - 1.13.3.2 of this Schedule 4.".

19. **Replace** paragraph 3.4 and sub-paragraphs with:

"3.4 A Contractor must not seek to persuade a Patient, or a Patient's Authorised Person, to nominate a Dispenser recommended by the Prescriber or the Contractor.

3.5 The Contractor must direct the Patient, or the Patient's Authorised Person, to the relevant information made available by the Commissioner about all chemists who are available in the Patient's chosen area and who are able to provide the required service where:

3.5.1 a Patient does not have a Nominated Dispenser;

3.5.2 a Patient, or a Patient's Authorised Person, asks the Contractor to recommend a chemist whom the Patient or the Patient's Authorised Person might nominate as the Patient's Dispenser; or

3.5.3 the Contractor refers a Patient to a pharmaceutical service.".

20. In paragraph 7.2.3.3.2, **replace** the word "medicine's" with the word "item's".

Schedule 5

21. Immediately after paragraph 4B.5.2, **insert**:

"4C **Referral pathways**

4C.1 The Commissioner may notify the Contractor of Referral Pathways that apply to the referral of Patients for other services under the 2006 Act.

4C.2 The Contractor must, where clinically appropriate, comply with any relevant Referral Pathways notified under paragraph 4C.1, prior to referring a Patient for services under the 2006 Act.

4C.3 In this paragraph:

"Advice and Guidance" means arrangements established by the Commissioner to enable contractors to obtain consultant-led clinical advice about the management of a Patient for the purpose of informing clinical decision making in relation to a referral;

"referral pathways" means arrangements, such as Advice and Guidance, determined by the Commissioner as applying to the referral of a Patient for a service under the 2006 Act, including any locally determined arrangements that apply in relation to the Contractor's Practice Area.

4D **Directory of Services**

4D.1 The Contractor must record in the Directory of Services an electronic mail address nominated for the purpose of communicating clinical information relating to the Contractor's Patients with health service providers.

4D.2 The Contractor must monitor the electronic mail address nominated under paragraph 4D.1 at least once per day during Core Hours.

4D.3 In paragraph 4D.1, "Directory of Services" means the national directory of services provided as part of the health service in England, managed by NHS England[3].".

[3] For further information, see: https://digital.nhs.uk/services/directory-of-services-dos

22. Immediately after paragraph 5.4.2.4, **insert**:

"5.4A Where the Contractor receives an application by the method referred to in sub-paragraph 5.3.1, they must submit the information provided in the application via the online registration service referred to in sub-paragraph 5.3.2, except where the Contractor's computerised clinical system does not facilitate interconnectivity with the online registration service supplied by the Commissioner.".

Schedule 12

23. **Replace** point 14 of information to be included in Practice Leaflets with: "The opening hours of the Practice Premises and all means of contacting the Contractor throughout the Core Hours as required by clause 7.8.".

Schedule 14

24. Immediately after paragraph 15(d)(iii), **insert**:

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

15ZA.

(1) For the purposes of clauses 27.1 to 27A.11 of this Agreement, 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 clauses in respect of sub-contracting them.

(2) For the purposes of this paragraph and paragraph 15ZB, "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) of the *Pharmaceutical Regulations*) 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 the ***dispensing doctor*** 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 the ***dispensing doctor***'s listed dispensing premises; or

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

(4) For the purposes of this paragraph and paragraphs 15ZB and 15ZC, "hub and spoke arrangements" are arrangements between the ***dispensing doctor*** and a retail pharmacy business:

(a) are for the purpose of the retail pharmacy business supporting the ***dispensing doctor*** with regard to the fulfilment of orders:

(i) submitted to the ***dispensing doctor*** on prescription forms or ***LPIV***s, or

(ii) for the provision of prescription items by the ***dispensing doctor*** in accordance with ***PTP***s or ***PTPGDs***; and

(b) provide for the assembly or part-assembly of those orders (including in accordance with an ***SSP***) at premises of the retail pharmacy business with a view to the supply of the prescription items at or from the listed dispensing premises of the ***dispensing doctor*** 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 15ZB and 15ZC, any prior notification that the ***dispensing doctor*** is required to give to NHS England or an ICB before the commencement of arrangements by virtue of which the ***dispensing doctor*** sub-contracts the core dispensing functions must include the following particulars:

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

(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 the retail pharmacy business proposes to meet the ***dispensing doctor***'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 15ZB and 15ZC, if the ***dispensing doctor*** 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 an 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 15ZB and 15ZC, 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 the ***dispensing doctor*** (and so the arrangements must not allow the retail pharmacy business 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 the retail pharmacy business to the ***dispensing doctor*** 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[4] (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 the ***dispensing doctor*** cannot only sub-contract to the retail pharmacy business 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 the retail pharmacy business to the ***dispensing doctor*** 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 the retail pharmacy business does not sub-contract any of the core dispensing functions that the retail pharmacy business performs on behalf of the ***dispensing doctor***;

(e) they must provide for the discontinuation of the arrangements, as set out in paragraph 15ZB (in addition to any patient safety or commercial grounds the

[4] Inserted by S.I. 2025/758.

dispensing doctor or the retail pharmacy business may have for discontinuing the arrangements); and

(f) they must not be or have become invalid by virtue of paragraph 15ZB.

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

(9) The ***dispensing doctor*** 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

15ZB.

(1) NHS England may at any time request from the ***dispensing doctor*** (as defined in paragraph 15ZA(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, the ***dispensing doctor*** 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 15ZA(7), including where they have had them but they have lapsed;

(b) the hub and spoke arrangements have the features required by paragraph 15ZA(7) but there has been a breach of those requirements;

(c) the hub and spoke arrangements put the safety of any persons to whom the ***dispensing doctor*** 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 the ***dispensing doctor*** repeatedly breaching the ***dispensing doctor***'s terms of service, or to the ***dispensing doctor*** breaching its terms of service in circumstances where the ***dispensing doctor*** is likely to continue to do so repeatedly;

(f) The retail pharmacy business's (as defined in paragraph 15ZA(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) The ***dispensing doctor*** 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 the ***dispensing doctor*** 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 the ***dispensing doctor*** 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 the ***dispensing doctor*** 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 the ***dispensing doctor*** and there are no new issues of substance to be resolved,

NHS England must, where requested to do so by the ***dispensing doctor***, make every reasonable effort to communicate and co-operate with the ***dispensing doctor*** 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

15ZC.

(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 15ZA(4)) which is a non-regulation-222A order (as defined in paragraph 15ZA(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[5], sub-paragraph (3) applies to the processing of any relevant data:

(a) by the ***dispensing doctor*** or the retail pharmacy business (as defined in paragraph 15ZA(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 15ZA(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 the ***dispensing doctor*** or the retail pharmacy business; 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

5 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.

law for the purposes of section 11(1)(b) of the Data Protection Act 2018[6] (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.".

25. In paragraph 25, immediately after the words "available on prescription", **insert** the words "at or".

[6] Section 11 has been amended by S.I. 2019/419

26. In paragraph 31, immediately after the words “the provision of pharmaceutical services at”, **insert** the words “or from”.

27. In paragraph 31, immediately after the words “provide pharmaceutical services at”, **insert** the words “or from”.

I/We [ ] acknowledge receipt of the notice of variation dated [ ] of which the above is a duplicate. I/We acknowledge that this notice will take effect from [ ].

Signed:

[on behalf of]:

Print name:

Date: