PSNC Legislation and Regulatory Affairs Subcommittee Agenda

For the meeting to be held on 9 October 2018

At Swindon Marriott Hotel, Pipers Way, Swindon, SN3 1SH

Commencing at 15.45

Members: Ian Cubbin, Jas Heer, Has Modi, Janice Perkins, Stephen Thomas.

1. Welcome from Chair
2. Apologies for absence
3. Conflicts or declaration of interest
4. Minutes of the last meeting **(Appendix 01/10/2018)**
5. Matters Arising

Action

6. …..
7. …..
8. …..
9. …..

Report

10. EPS phase 4 Regulations **(Appendix 06/10/2018)**
11. Rebalancing Board Consultation on SP and RP **(Appendix 07/10/2018)**
12. Submission to HL Select Committee on the rural economy **(Appendix 08/10/2018)**
13. Any other business

Appendix 01/10/2018

PSNC Legislation and Regulatory Affairs Subcommittee Minutes

for the meeting held on Tuesday 10th July 2018

at Crewe Hall, Weston Road, Crewe, CW1 6UZ

As a preliminary, the subcommittee agreed that Stephen Thomas should be Vice Chair of the subcommittee.

Members: Stephen Thomas (Vice Chair), Jas Heer, Janice Perkins and Has Modi.

Together with: Mark Burdon, Peter Cattee, Marc Donovan, Jessica Ferguson, Sam Fisher, David Hamilton, Gordon Hockey, Tricia Kennerley, Sunil Kocchar, Zoe Long, Margaret MacRury, Fin McCaul, Lucy Morton – Channon, Garry Myers, Indrajit Patel, Sian Retallick, Faisal Tuddy, Gary Warner.

Apologies for absence: Ian Cubbin.

Minutes of the previous meeting and matters arising

The draft minutes for the meeting on 8th May 2018 were approved by the Subcommittee. …..

Agenda and Subcommittee Work
The Subcommittee considered the ongoing work.

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Other ongoing matters were noted.

The Subcommittee agreed the revised terms of reference, noting that the updated name of the subcommittee would need changing in the PSNC Rules at an appropriate time.

1	Consider and resolve regulatory issues associated with the current CPCF and future developments; where necessary proactively seek changes to the regulatory framework, to support contractors.

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Decision: DHSC UK-wide Consultation on Pharmacy legislation on dispensing errors and organisational governance
The Subcommittee considered the paper on the governance of pharmacies. Although this is not a funding matter, the changes could have wide repercussions for pharmacy contractors and it was agreed that PSNC should respond to the consultation. In particular, it was noted that any professional recommendations would eventually become contractual.

The Subcommittee was supportive of the paper in the agenda which it felt was balanced and was broadly supportive of the consultation proposals. It was noted that it is difficult to respond without knowing the proposals for supervision, because they are part of the governance framework, but there should still be a response. It was noted that more information may become available following the Stakeholder meeting on 24 July. There was discussion around what role a superintendent needs to have and whether they need to have an impact on financial matters or not.

Recommendation: PSNC should be broadly supportive of the proposals in the consultation.

Decision: GPhC Consultation on developing our approach to regulating registered pharmacies

The Subcommittee considered the GPhC's suggestion to allow unannounced visits to pharmacies. It was noted that in many instances currently, an exact date of inspection is not given of visits to pharmacies. However, other healthcare professions do get notice of inspections, and it was agreed that if the GPhC inspection regime is to be closer to the CQC model it should follow the same principles as CQC. Broadly these are that unannounced inspections have value and can assure public confidence in the inspection regime, but they should not be the standard approach, for reasons of patient safety. Independent contractors felt that notice was needed to enable them to plan their days and ensure they have enough cover to allow pharmacists to talk to the GPhC inspectors. It was agreed that PSNC must set out its concerns in a way that addresses patient concerns. It was also agreed that notice of a visit can encourage compliance on relatively minor issues in the time between notification and the visit.

There was also discussion on the proposed grading system and it was noted that the CQC inspection system for dentists does not use a grading system because only 10% of the practices are inspected and to do so would give an unfair advertising advantage to those inspected (and with good inspection results). This is because the practice can use an excellent or other rating in advertisements. It was agreed that this point should be raised in the consultation response.

Recommendation:

- Respond broadly as outlined in the paper;
- Highlight some of the issues with unannounced visits;
- Highlight the divergence from CQC standards and patient safety issues;
- State that we are not against unannounced inspections per se;
- Push back on grading scheme because this potential advertising must be available to all; and
- Query the terminology used for 'themed inspections'.

Decision: GPhC Discussion paper: Making sure patients and the public obtain medicines and other pharmacy services safely online

Broadly, the Subcommittee agreed with the paper and members will share any detailed views with Gordon Hockey by email.

Decision: Brexit

The Subcommittee agreed to the formation of a Brexit forum, involving the CEOs of the major representative bodies involved in community pharmacy and the medicines supply chain.

Ensure administration of the regulations is undertaken properly and effectively; advising and supporting LPCs and contractors

Decision: Post Payment Verification – provider assurance carried out by NHSBSA

The Subcommittee considered the paper in the agenda. It was noted that there is a lot of focus on the submission of information from pharmacies to BSA, but very little about the reports that come back from BSA and the timeliness of that – any specific issues experienced by contractors should be raised directly to the office. It was noted that contractor feedback about the process has been positive and that the system overall allows claims made on trust with an audit of those claims, which is advantageous to CP.

Recommendation:

Provisional acceptance of NHS England's national provider assurance carried by NHSBSA, with further consideration to follow of the main change not tested during the concept stage.

Any other business

HMRC interest in the treatment of locum staff by pharmacy businesses is increasing and everyone in the sector needs to be aware of this and work together to lobby on the matter. It was noted that the CCA is liaising with the NPA and PSNC on the issue. It was agreed this is a sector wide issue that needs a sector wide approach. The subcommittee agreed a watching brief on the issue.

It was reported that the DHSC has indicated its intention to consult on the supply of specials medicines.

(Appendix 02/10/2018)

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(Appendix 04/10/2018)

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Subject	EPS phase 4 draft Regulations
Date of meeting	9 October 2018
Committee/Subcommittee	HPR/LRA subcommittee
Status	Confidential; the Regulations are confidential until published
Overview	The regulations include the regulatory changes necessary for the implementation of EPS phase 4.
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

Introduction

1. The Regulations set out the regulatory framework for the pilot/introduction of phase 4 of the Electronic Prescription Service (EPS). The references to regulations that follow relate to the National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018, attached as **annex A**.

EPS

2. EPS phase 4 will include the introduction of an EPS token that may be used to represent an electronic prescription that may be drawn down from the spine by the dispensing contractor chosen by the patient.

3. If the patient has a nominated dispenser and wishes to use the nominated dispenser, the prescriber will not provide the patient with an EPS token.

4. The regulations change the legal instrument against which prescription charges collected by a community pharmacy contractor are deducted from reimbursement – from the dispensing token to the electronic message.

5. Real Time Exemption Checking (RTEC) is enabled in the regulations. Where RTEC is used to check an exemption and an appropriate entry made in the electronic claim from the community pharmacy, the dispensing token does not need to be sent to NHSBSA.

6. There are corresponding changes to the GMS Contract Regulations.

GDPR

7. There is provision in the Charges Regulations for the use of relevant information by NHS service providers, including contractors, and others processing data on their behalf, including PSNC. (Reg 15)

The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

8. A subgroup of the subcommittee considered the issues and priorities with the DHSC Regulations Review in the context of these proposed changes. There were additional suggestions from DHSC for inclusion in these regulations and a note of the subgroup's views is attached as **annex B**. The changes to the regulations relating to Dispensing Doctors and prescription direction were not introduced; both need further consideration.

9. The minor changes to the Regulations made in these regulations are as follows:

    - NHS England may issue a breach notice for failure to open during core hours only after having made reasonable efforts to communicate with the contractor with a view to establishing whether there was a good cause for the failure. (Reg 3)

    - NHS England may rescind a remedial notice or breach notice at any time. (Regs 2 and 5)

    - The rules on making representation at oral hearings of market entry applications are simplified, but oral representations are only permitted where the Secretary of State (the Primary Care Appeals Service) is satisfied that the person concerned made a reasonable attempt to express his or her views on the appeal in his or her written representations. Reg 6)

Conclusion

10. The changes when introduced set the framework for EPS phase 4 and start the process of regulatory changes that will be introduced following the DHSC review of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

STATUTORY INSTRUMENTS

2018 No. 000

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018

Made - - - -	*2018*
Laid before Parliament	*2018*
Coming into force - -	*26th November 2018*

CONTENTS

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 7(1C), 85(1), 89(1) and (2)(a) and (c), 94(1), 126(2) 129(6), 130(1), 132(1), 150A, 172(1), 178, 182, 184(1) and 272(7) and (8) of, and paragraph 3(1) and (3)(c) and (d) of Schedule 12 to, the National Health Service Act 2006([1]).

([1]) 2006 c.41. Section 7(1C) was inserted by Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), section 21(1) and (2). Section 89 has been amended by the 2012 Act, sections 28(1) and 202(2), and Schedule 4, paragraph 34. Section 94 has been amended by the 2012 Act, section 28(2), and Schedule 4, paragraph 38. Section 126 has been amended by the 2012 Act, sections 213(7)(k) and 220(7), and Schedule 4, paragraph 63. Section 129(6) has been amended by: the Health Act 2009 (c. 21) ("the 2009 Act"), sections 26 and 27, and Schedule 6; the 2012 Act, section 207(1) to (9), and Schedule 4, paragraph 66; the Protection of Freedoms Act 2012 (c. 9), Schedule 9, paragraph 121; and S.I. 2010/231. Section 130 has been amended by the 2012 Act, section 207(10), and by S.I. 2010/22. Section 132 of the has been amended by the 2012 Act, Schedule 4, paragraph 69, by the Protection of Freedoms Act 2012, Schedule 9, paragraph 122, and by S.I. 2007/289 and 2010/22 and 231. Section 150A was inserted by the 2009 Act, section 28, and amended by the 2012 Act, Schedule 4, paragraph 78. Paragraph 3 of Schedule 12 has been amended by the 2009 Act, section 29(13) to (15), and by the 2012 Act, Schedule 4, paragraph 93(4). *See* section 275(1) of the 2006 Act for the meanings given to "prescribed" and "regulations". By virtue of section 271(1) of the 2006 Act, the functions of the Secretary of State being exercised in the making of these Regulations are exercisable only in relation to England.

PART 1

Introductory

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services, Charges and Prescribing) (Amendment) Regulations 2018 and come into force on 26th November 2018.

(2) In these Regulations—

"the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2015([2]);

"the GMS Contracts Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2015([3]);

"the PLPS Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013([4]); and

"the PMS Agreements Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2015([5]).

PART 2

Amendments to the PLPS Regulations

Amendment of regulation 2 of the PLPS Regulations

2.—(1)Regulations([6]) (interpretation) is amended as follows.

(2) At the appropriate place in the alphabetical order insert the following definition—

""EPS token" means a form (which may be an electronic form) approved by the Secretary of State, which—

(a) is issued by a prescriber at the same time as an electronic prescription is created; and

(b) has a barcode that enables the prescription to be dispensed by a provider of pharmaceutical services that is able to use the Electronic Prescription Service for the purposes of dispensing prescriptions, in circumstances where the provider is not dispensing the prescription as a nominated dispensing contractor;".

(3) At the appropriate place in the alphabetical order insert the following definition—

""paramedic independent prescriber" means a person—

(a) who is registered in Part 8 of the register maintained under article 5 of the Health and Social Work Professions Order 2001([7]); and

(b) against whose name in that register is recorded an annotation signifying that that person is qualified to order drugs, medicines or appliances as a paramedic independent prescriber;".

(4) In sub-paragraph (c) of the definition of "electronic prescription form", after "nominated dispensing contractor" insert "or via an information hub".

(5) In sub-paragraph (b) of the definition of "electronic repeatable prescription", after "nominated dispensing contractor" insert "or via an information hub".

([2]) S.I. 2015/570.
([3]) S.I. 2015/1862.
([4]) S.I. 2013/349.
([5]) S.I. 2015/1879.
([6]) Regulation 2 has been amended by S.I. 2015/137, 570, 1862 and 1879, and 2016/696 and 1077.
([7]) S.I. 2002/254.

(6) In the definition of "prescriber", after "optometrist independent prescriber" insert ", a paramedic independent prescriber".

Amendment of regulation 69 of the PLPS Regulations

3.—(1) Regulation 69 of the PLPS Regulations (local dispute resolution before serving remedial notices or breach notices) is amended as follows.

(2) In paragraph (3)(a)(i), after "good cause" insert ", the NHSCB having made reasonable efforts to communicate with C with a view to establishing what the cause was".

Amendment of regulation 70 of the PLPS Regulations

4.—(1) Regulation 70 of the PLPS Regulations (breaches of terms of service: remedial notices) is amended as follows.

(2) After paragraph (7), insert the following paragraph—

"[OBJ]".

Amendment of regulation 71 of the PLPS Regulations

5.—(1) Regulation 71 of the PLPS Regulations (breaches of terms of service: breach notices) is amended as follows.

(2) After paragraph (4), insert the following paragraph—

"[OBJ]".

Amendment of Schedule 3 to the PLPS Regulations

6.—(1)Regulations([8]) (appeals to the Secretary of State) is amended as follows.

(2) In paragraph 8 (oral hearings), in sub-paragraph (2)(a), delete from ", which—" to "at the oral hearing".

Amendment of Schedule 4 to the PLPS Regulations

7.—(1) Schedule 4 to the PLPS Regulations (terms of service of NHS pharmacists) is amended as follows.

(2) In paragraph 5([9]) (dispensing of drugs and appliances)—

(a) in sub-paragraph (2)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "P receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents P with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iii), and

(ii) requests the provision of drugs or appliances in accordance with the related electronic prescription form,"; and

(b) in sub-paragraph (3)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "P receives" insert "as a nominated dispensing contractor"

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

([8]) There are no relevant amendments to Schedule 3.

([9]) Paragraph 5 has been amended by S.I. 2015/915.

"(c) any person—

(i) presents P with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iv), and

(ii) requests the provision of drugs or appliances in accordance with the related electronic repeatable prescription,".

(3) In paragraph 7([10]) (preliminary matters before providing ordered drugs or appliances)—

(a) in sub-paragraph (3), for "a declaration that" substitutes "or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription that";

(b) after sub-paragraph (3), insert the following sub-paragraph—

"OBJ"; and

(c) in sub-paragraph (5), for "transmit to the Electronic Prescription Service" substitute "ensure that the following information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription service (if it is not already recorded in those records)".

(4) In paragraph 9 (refusal to provide drugs or appliances ordered), after sub-paragraph (2) insert the following sub-paragraph—

"OBJ".

(5) paragraph 11(additional requirements in relation to electronic prescribing)—

(a) in sub-paragraph (2)(a), for "the dispensing contractor chosen by that person" substitute "a nominated dispensing contractor"; and

(b) after sub-paragraph (5), insert the following paragraph—

"OBJ".

Amendment of Schedule 5 to the PLPS Regulations

8.—(1) Schedule 5 to the PLPS Regulations (terms of service of NHS appliance contractors) is amended as follows.

(2) In paragraph 4 (dispensing of appliances)—

(a) in sub-paragraph (2)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "C receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents C with an EPS token that relates to an order of a kind specified in paragraph (a)(i) or (ii), and

(ii) requests the provision of an appliance in accordance with the related electronic prescription form,"; and

(b) in sub-paragraph (3)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "C receives" insert "as a nominated dispensing contractor"

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents C with an EPS token that relates to an order of a kind specified in paragraph (a)(i) or (ii), and

([10]) Paragraph 7 has been amended by S.I. 2015/570 and 2016/296.

(ii) requests the provision of appliances in accordance with the related electronic repeatable prescription,".

(3) In paragraph 6([11]) (preliminary matters before providing appliances)—

(a) in sub-paragraph (3)(a), for "a declaration that" substitutes "or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription that";

(b) after sub-paragraph (3), insert the following sub-paragraphs—

"[OBJ]"; and

(c) in sub-paragraph (3)(c), for "transmit to the Electronic Prescription Service" substitute "ensure that the following information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription service (if it is not already recorded in those records)".

(4) In paragraph 8 (refusal to provide appliances ordered), after sub-paragraph (1) insert the following sub-paragraph—

"[OBJ]".

(5) In paragraph 10 (additional requirements in relation to electronic prescribing)—

(a) in sub-paragraph (2)(a), for "the dispensing contractor chosen by that person" substitute "a nominated dispensing contractor"; and

(b) after sub-paragraph (5), insert the following paragraph—

"), (5C) or (5E) of the Charges Regulations in respect of that prescription (which may be the associated EPS token), to the NHS BSA.".

Amendment of Schedule 6 to the PLPS Regulations

9.—(1) Schedule 6 to the PLPS Regulations (terms of service of dispensing doctors) is amended as follows.

(2) In paragraph 2([12]) (dispensing of drugs and appliances ordered by another prescriber)—

(a) in sub-paragraph (2)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "D receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents D with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iii), and

(ii) requests the provision of drugs or appliances in accordance with the related electronic prescription form,"; and

(b) in sub-paragraph (3)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "D receives" insert "as a nominated dispensing contractor"

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents D with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iv), and

([11]) Paragraph 6 has been amended by S.I. 2015/570.

([12]) Paragraph 2 has been amended by S.I. 2015/915.

(ii) requests the provision of appliances in accordance with the related electronic repeatable prescription,".

(3) In paragraph 4([13]) (preliminary matters before providing drugs or appliances)—

(a) in sub-paragraph (a), for "a declaration that" substitutes "or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription that"; and

(b) in sub-paragraph (c), for "transmit to the Electronic Prescription Service" substitute "ensure that the following information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription service (if it is not already recorded in those records)".

(4) After paragraph 4, insert the following paragraph—

"Charge exemption and remission of charges declarations and checks

4A.—(1) For the purposes of paragraph 4, satisfactory evidence includes evidence derived from a real time exemption check of electronic records that are managed by the NHS BSA for the purposes (amongst other purposes) of providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under the Charges Regulations.

(2) If D dispenses an electronic prescription, D must send the form duly completed by or on behalf of the patient, if one is required under regulation 4(2)(b) or (3A) of the Charges Regulations in respect of that electronic prescription (which may be the associated EPS token), to the NHS BSA.".

(5) In paragraph 6 (refusal to provide drugs or appliances ordered), after sub-paragraph (1) insert the following sub-paragraph—

"".

Amendment of Schedule 7 to the PLPS Regulations

10.—(1) Schedule 7 to the PLPS Regulations (mandatory terms for LPS schemes) is amended as follows.

(2) In paragraph 3([14]) (dispensing)—

(a) in sub-paragraph (1)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "C receives" insert "as a nominated dispensing contractor",

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents C with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iii), and

(ii) requests the provision of an appliance in accordance with the related electronic prescription form,"; and

(b) in sub-paragraph (2)—

(i) omit "or" at the end of paragraph (a),

(ii) in paragraph (b), after "C receives" insert "as a nominated dispensing contractor"

(iii) insert "; or" at the end of paragraph (b), and

(iv) after paragraph (b), insert the following paragraph—

"(c) any person—

(i) presents C with an EPS token that relates to an order of a kind specified in paragraph (a)(i) to (iv), and

([13]) Paragraph 4 has been amended by S.I. 2015/570.

([14]) Paragraph 3 has been amended by S.I. 2015/915.

(ii) requests the provision of appliances in accordance with the related electronic repeatable prescription,".

(3) In paragraph 5([15]) (preliminary matters before providing ordered drugs or appliances)—

(a) in sub-paragraph (3), for "a declaration that" substitutes "or duly completes a declaration as or on behalf of the person named on the prescription form or repeatable prescription that";

(b) after sub-paragraph (3) insert the following sub-paragraphs—

"[OBJ]"; and

(c) in sub-paragraph (5), for "transmit to the Electronic Prescription Service" substitute "ensure that the following information is duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription service (if it is not already recorded in those records)".

(4) In paragraph 7 (refusal to provide drugs or appliances ordered), after sub-paragraph (2) insert the following sub-paragraph—

"[OBJ]".

(5) In paragraph 9 (additional requirements in relation to electronic prescribing)—

(a) in sub-paragraph (2)(a), for "the dispensing contractor chosen by that person" substitute "a nominated dispensing contractor"; and

(b) after sub-paragraph (4), insert the following paragraph—

"[OBJ]".

PART 3

Amendments to the Charges Regulations

Amendment of regulation 2 of the Charges Regulations

11.—(1)Regulations([16]) (interpretation) is amended as follows.

(2) In sub-paragraph (c) of the definition of "electronic prescription form", after "nominated dispensing contractor" insert "or via an information hub".

(3) In sub-paragraph (b) of the definition of "electronic repeatable prescription", after "nominated dispensing contractor" insert "or via an information hub".

(4) At the appropriate place in the alphabetical order insert—

""paramedic independent prescriber" means a person—

(a) who is registered in Part 8 of the register maintained under article 5 of the Health and Social Work Professions Order 2001([17]) (establishment and maintenance of register); and

(b) against whose name in that register is recorded an annotation signifying that that person is qualified to order drugs, medicines or appliances as a paramedic independent prescriber;".

(5) In the definition of "prescriber", after "optometrist independent prescriber" insert ", a paramedic independent prescriber".

(6) At the appropriate place in the alphabetical order insert—

"[OBJ]".

Amendment of regulation 3 of the Charges Regulations

12.—(1)Regulations([18]) (supply of drugs and appliances by chemists) is amended as follows.

([15]) Paragraph 5 has been amended by S.I. 2015/570 and 2016/296.
([16]) Regulation 2 has been amended by S.I. 2015/1879 and 2016/696 and 1077.
([17]) S.I. 2002/254; amended by S.I. 2009/1182.
([18]) Relevant amendments have been made to regulation 3 by S.I. 2016/1077 and 2018/201.

(2) In paragraph (3)(b), after "by a chemist" insert "or the prescriber".

(3) In paragraph (4)(b), after "by a chemist" insert "or the prescriber".

(4) In paragraph (5), omit sub-paragraphs (a) and (b).

(5) After paragraph (5), insert the following paragraphs—

"an non-electronic prescription form other than one to which paragraph (5) applies, or a non-electronic repeatable prescription, no charge is to be made and recovered under paragraph (1) or (2) where—

(a) there is an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations([19]) (entitlement to full remission and payment); and

(b) subject to regulation 10(5)(b), a declaration of entitlement to an exemption or remission is duly completed by or on behalf of the patient on the non-electronic prescription form or the batch issue.

(5B) In cases involving an electronic prescription form or an electronic repeatable prescription, no charge is to be made and recovered under paragraph (1) or (2) where—

(a) there is an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations; and

(b) subject to regulation 10(5)(a), entitlement to that exemption or remission has been declared to the chemist by or on behalf of the patient and the chemist has duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription Service a record of that entitlement (if that entitlement is not already recorded in those records).

(5C) Where a declaration is made under paragraph (5B)(b), subject to paragraph (5D), the patient or a person acting on the patient's behalf must duly complete a record of that declaration on an approved form provided by the Board for recording such declarations and issued by the chemist or the prescriber.

(5D) That record is not required where a real time exemption check by the chemist of electronic records that are managed by the NHS BSA for the purposes (amongst other purposes) of providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under these Regulations has confirmed that no charge is to be made and recovered under paragraph (1) or (2).

(5E) In cases involving a relevant emergency supply of a drug, no charge is to be made and recovered under paragraph (1) or (2) where—

(a) there is an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations; and

(b) a declaration of entitlement to an exemption or remission is duly completed by or on behalf of the patient on an approved form provided by the Board for recording patient declarations in respect of supplies in accordance with regulation 225 of the Human Medicines Regulations 2012([20]) (emergency sale etc. by a pharmacist: at patient's request) and issued by a chemist.

(5F) For the purposes of paragraph (5E), a supply of a drug is a relevant emergency supply of a drug if it is—

(a) in accordance with regulation 225 of the Human Medicines Regulations 2012, and

(b) pursuant to arrangements made in accordance with directions given by the Secretary of State under section 127 of the 2006 Act or, if the drug is supplied under arrangements for the provision of local pharmaceutical services, equivalent arrangements to arrangements made in accordance with such directions.".

([19]) S.I. 2003/2382; amended by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475, 2015/570, 993 and 1776, and 2016/1045.

([20]) S.I. 2012/1916; amended by S.I. 2014/490.

Amendment of Regulation 4 of the Charges Regulations

13.—(1)Regulations([21]) (supply of drugs and appliances by doctors) is amended as follows.

(2) In paragraph (2)(b), after "by a doctor" insert "or the prescriber".

(3) In paragraph (3), for sub-paragraphs (a) and (b) substitute—

"(a) in cases involving a non-electronic prescription form, there is—

(i) an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations([22]) (entitlement to full remission and payment), and

(ii) subject to regulation 10(5)(b), a declaration of entitlement to an exemption or remission is duly completed by or on behalf of the patient on the non-electronic prescription form;

(b) in cases involving an electronic prescription form, there is—

(i) an exemption by virtue of regulation 10(1) or entitlement to remission of the charge by virtue of regulation 5 of the Travel Expenses and Remission of Charges Regulations, and

(ii) subject to regulation 10(5)(b), entitlement to that exemption or remission has been declared to the doctor by or on behalf of the patient and the doctor has duly entered into the records managed by the Information Centre that are accessible as part of the Electronic Prescription service a record of that entitlement (if that entitlement is not already recorded in those records);".

(4) After paragraph (3) insert the following paragraphs—

"(3A) Where a declaration is made under paragraph (3)(b)(ii), subject to paragraph (3B), the patient or a person acting on the patient's behalf must duly complete a record of that declaration on an approved form provided by the Board for recording such declarations and issued by the doctor or the prescriber.

(3B) That record is not required where a real time exemption check by the doctor of electronic records that are managed by the NHS BSA for the purposes (amongst other purposes) of providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under these Regulations has confirmed that no charge is to be made and recovered under paragraph (1).".

Amendment of regulation 10 of the Charges Regulations

14.—(1) Regulation 10 of the Charges Regulations (exemptions: general) is amended as follows.

(2) In paragraph (5), for "regulations 3(5)" substitute "regulations 3(5) to (5E)".

New regulation 18A of the Charges Regulations

15. After regulation 18 of the Charges Regulations (repayment of charges), insert the following regulation—

"Sharing of prescription and charging data

18A.—(1) As regards any order for a drug or an appliance in respect of which—

(a) a charge is payable under these Regulations (whether or not it is partially remitted); or

(b) a charge would be payable under these Regulations, but for an exemption by virtue of these Regulations,

paragraph (3) applies to the data relating to that order which is described in paragraph (2), which may be electronic data.

([21]) Relevant amendments have been made to regulation 4 by S.I. 2018/201.

([22]) S.I. 2003/2382; amended by S.I. 2004/663 and 936, 2006/562, 2008/1697, 2009/411, 2013/475, 2015/570, 993 and 1776, and 2016/1045.

(2) The data relating to that order described in this paragraph is—

(a) data used for ordering the drug or appliance, which may be in the form of a prescription form, if the data, in the form in which it is used for ordering the drug or appliance, is also used for the purposes of claiming a payment by way of—

(i) reimbursement for the cost of the supply of the drug or appliance, or

(ii) remuneration for the service provided in the course of which the drug or appliance was supplied;

(b) data derived from the data used for ordering the drug or appliance (which may have been in the form of a prescription form), which is to be or has been provided to a health service body by a provider of NHS services for the purposes of claiming a payment by way of—

(i) reimbursement for the cost of the supply of the drug or appliance, or

(ii) remuneration for the service provided in the course of which the drug or appliance was supplied;

(c) data relating to whether a charge is payable by a patient under these Regulations in respect of the order.

(3) The processing of information which relates to a patient and which is or is part of data described in paragraph (2) is the exercise of a function conferred on a person by an enactment, and if the information—

(a) is personal data but not personal data concerning health, is necessary for the performance of a task carried out in the public interest for the purposes of section 8(c) of the Data Protection Act 2018([23]) (lawfulness of processing: public interest etc); or

(b) is personal data concerning health, is necessary for the management of health care systems or services, as mentioned in paragraph 2(2)(f) of Schedule 1 to the Data Protection Act 2018 (special categories of personal data and criminal convictions etc data),

in circumstances where the processing is by or on behalf of a relevant body or a provider of NHS services (including by another body on behalf of the relevant body or the provider of NHS services) and is for the purposes of performing, or doing anything which is calculated to facilitate or is conducive or incidental to performing, the functions listed in paragraph (4).

(4) Those functions are—

(a) reimbursement for the cost of the supply of that drug or appliance (taking account, as appropriate, of any charge payable under these Regulations);

(b) remuneration for providing the service in the course of which that drug or appliance was supplied (taking account, as appropriate, of any charge payable under these Regulations);

(c) ascertaining whether a charge is payable by a patient under these Regulations;

(d) providing advice, assistance and support to patients or their representatives in respect of whether a charge is payable under these Regulations;

(e) recovery of unpaid charges payable under these Regulations, and the making and recovery of penalty charges;

(f) repayment or partial repayment of amounts paid as a charge under these Regulations where no amount or only part of the amount was payable; and

(g) management functions of a relevant body relating to ensuring that the functions mentioned in sub-paragraphs (a) to (f) are performed effectively, efficiently and economically.

(5) A person who—

(a) is employed or engaged by a relevant body or provider of NHS services, or by a body processing data on their behalf as mentioned in paragraph (3); and

(b) in the course of being so being so employed or engaged, is required, for the purposes mentioned in paragraph (3), to undertake the processing of data described in paragraph (2) which is also personal data concerning health,

([23]) 2008 c. 12.

owes a duty of confidentiality in respect of that data (whether or not that person would do so but for this paragraph), but that duty is such that, if the processing is for the purposes mentioned in paragraph (3), that person is able, lawfully, to process that data by virtue of this regulation.".

PART 4

Amendments to the GMS Contracts Regulations

Amendment of regulation 3 of the GMS Contracts Regulations

16.—(1)Regulations([24]) (interpretation) is amended as follows.

(2) In paragraph (b)(ii) of the definition of "prescription form", for "nominated dispensing contractor" substitute "nominated dispenser or via an information hub".

(3) In paragraph (c)(ii) of the definition of "repeatable prescription", for "nominated dispensing contractor" substitute "nominated dispenser or via an information hub".

(4) At the appropriate place in the alphabetical order insert—

"by virtue of regulation 116(a) to (c) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (authorised persons to apply for services);".

(5) At the appropriate place in the alphabetical order insert—

"".

(6) At the appropriate place in the alphabetical order insert—

""EPS token" means a form (which may be an electronic form) approved by the Secretary of State, which—

(a) is issued by a prescriber at the same time as an electronic prescription is created; and

(b) has a barcode that enables the prescription to be dispensed by a provider of pharmaceutical services that is able to use the Electronic Prescription Service for the purposes of dispensing prescriptions, in circumstances where the provider is not dispensing the prescription as a nominated dispenser;".

Amendment of regulation 56 of the GMS Contracts Regulations

17.—(1) Regulation 56 of the GMS Contracts Regulations (orders for drugs, medicines or appliances) is amended as follows.

(2) In paragraph (1), for "paragraphs (2) and (3)" substitute "paragraphs (1A), (2) and (3)".

(3) After paragraph (1), insert the following paragraphs—

"particular occasion when a drug, medicine or appliance is needed as mentioned in paragraph (1)—

(a) the prescriber is able, without delay, to order the drug, medicine or appliance by means of an electronic prescription;

(b) the Electronic Prescription Service software that the prescriber would use for that purpose provides for the creation and transmission of electronic prescriptions without the need for a nominated dispenser; and

(c) none of the reasons for issuing a non-electronic prescription form or a non- electronic repeatable prescription given in paragraph (1B) applies,

the prescriber must create and transmit an electronic prescription for that drug, medicine or appliance.

(1B) The reasons given in this paragraph are—

(a) although the prescriber is able to use the Electronic Prescription Service, the prescriber is not satisfied that—

(i) the access that he or she has to the Electronic Prescription Service is reliable, or

([24]) Amended by S.I. 2016/696 and 1077 and 2018/844.

(ii) the Electronic Prescription Service is functioning reliably;

(b) the patient, or where appropriate the patient's authorised person, informs the prescriber that the patient wants the option of having the prescription dispensed elsewhere than in England;

(c) the patient, or where appropriate the patient's authorised person, insists on the patient being issued with a non-electronic prescription form or a non-electronic repeatable prescription for a particular prescription and in the professional judgment of the prescriber the welfare of the patient is likely to be in jeopardy unless a non-electronic prescription form or a non-electronic repeatable prescription is issued;

(d) the prescription is to be issued before the contractor's EPS phase 4 date or the contractor has no such date.".

Amendment of regulation 57 of the GMS Contracts Regulations

18.—(1) Regulation 57 of the GMS Contracts Regulations (electronic prescriptions) is amended as follows.

(2) In paragraph (1), omit sub-paragraphs (a) and (b).

(3) After paragraph (1), insert the following paragraphs—

"(1A) If a prescriber orders a drug, medicine or appliance by means of an electronic prescription, the prescriber must issue the patient with—

(a) subject to paragraph (1C), an EPS token; and

(b) if the patient or where appropriate an authorised person so requests, a written record of the prescription that has been created.

(1B) On and after the contractor's EPS phase 4 date, if the order is eligible for Electronic Prescription Service use, the prescriber must ascertain if the patient or where appropriate the patient's authorised person wants to have the electronic prescription dispensed by a nominated dispenser.

(1C) The prescriber must not issue the patient with an EPS token if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.".

(4) Omit paragraphs (3) and (4).

Amendment of regulation 58 of the GMS Contracts Regulations

19.—(1) Regulation 58 of the GMS Contracts Regulations (nomination of dispensers for the purposes of electronic prescriptions) is amended as follows.

(2) In paragraph (1)—

(a) after "its patients must" insert ", if a patient or where appropriate the patient's authorised person so requests,"; and

(b) after "chosen by the patient" insert "or where appropriate the patient's authorised person".

(3) Omit paragraph (3).

(4) In paragraph (4)—

(a) In sub-paragraph (a), after "a patient" insert "or a patient's authorised person"

(b) In sub-paragraph (b)—

(i) after "by a patient" insert "or a patient's authorised person",

(ii) after "whom the patient" insert "or the patient's authorised person", and

(iii) after "provide the patient" insert "or, as the case may be, the patient's authorised person".

PART 5

Amendments to the PMS Agreements Regulations

Amendment of regulation 3 of the PMS Agreements Regulations

20.—(1)Regulations([25]) (interpretation) is amended as follows.

(2) In paragraph (b)(ii) of the definition of "prescription form", for "nominated dispensing contractor" substitute "nominated dispenser or via an information hub".

(3) In paragraph (c)(ii) of the definition of "repeatable prescription", for "nominated dispensing contractor" substitute "nominated dispenser or via an information hub".

(4) At the appropriate place in the alphabetical order insert—

"by virtue of regulation 116(a) to (c) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (authorised persons to apply for services);".

(5) At the appropriate place in the alphabetical order insert—

"[OBJ]".

(6) At the appropriate place in the alphabetical order insert—

""EPS token" means a form (which may be an electronic form) approved by the Secretary of State, which—

(a) is issued by a prescriber at the same time as an electronic prescription is created; and

(b) has a barcode that enables the prescription to be dispensed by a provider of pharmaceutical services that is able to use the Electronic Prescription Service for the purposes of dispensing prescriptions, in circumstances where the provider is not dispensing the prescription as a nominated dispenser;".

Amendment of regulation 49 of the PMS Agreements Regulations

21.—(1) Regulation 49 of the PMS Agreements Regulations (orders for drugs, medicines or appliances) is amended as follows.

(2) In paragraph (1), for "paragraphs (2) and (3)" substitute "paragraphs (1A), (2) and (3)".

(3) After paragraph (1), insert the following paragraphs—

"particular occasion when a drug, medicine or appliance is needed as mentioned in paragraph (1)—

(a) the prescriber is able, without delay, to order the drug, medicine or appliance by means of an electronic prescription;

(b) the Electronic Prescription Service software that the prescriber would use for that purpose provides for the creation and transmission of electronic prescriptions without the need for a nominated dispenser; and

(c) none of the reasons for issuing a non-electronic prescription form or a non- electronic repeatable prescription given in paragraph (1B) applies,

the prescriber must create and transmit an electronic prescription for that drug, medicine or appliance.

(1B) The reasons given in this paragraph are—

(a) although the prescriber is able to use the Electronic Prescription Service, the prescriber is not satisfied that—

(i) the access that he or she has to the Electronic Prescription Service is reliable, or

(ii) the Electronic Prescription Service is functioning reliably;

(b) the patient, or where appropriate the patient's authorised person, informs the prescriber that the patient wants the option of having the prescription dispensed elsewhere than in England;

([25]) Amended by S.I. 2016/696 and 1077 and 2018/844.

(c) the patient, or where appropriate the patient's authorised person, insists on the patient being issued with a non-electronic prescription form or a non-electronic repeatable prescription for a particular prescription and in the professional judgment of the prescriber the welfare of the patient is likely to be in jeopardy unless a non-electronic prescription form or a non-electronic repeatable prescription is issued;

(d) the prescription is to be issued before the contractor's EPS phase 4 date or the contractor has no such date.".

Amendment of regulation 50 of the PMS Agreements Regulations

22.—(1) Regulation 50 of the PMS Agreements Regulations (electronic prescriptions) is amended as follows.

(2) In paragraph (1), omit sub-paragraphs (a) and (b).

"(1A) If a prescriber orders a drug, medicine or appliance by means of an electronic prescription, the prescriber must issue the patient with—

(a) subject to paragraph (1C), an EPS token; and

(b) if the patient or where appropriate an authorised person so requests, a written record of the prescription that has been created.

(1B) On and after the contractor's EPS phase 4 date, if the order is eligible for Electronic Prescription Service use, the prescriber must ascertain if the patient or where appropriate the patient's authorised person wants to have the electronic prescription dispensed by a nominated dispenser.

(1C) The prescriber must not issue the patient with an EPS token if the patient, or where appropriate the patient's authorised person, wants to have the electronic prescription dispensed by a nominated dispenser.".

(3) Omit paragraphs (3) and (4).

Amendment of regulation 51 of the PMS Agreements Regulations

23.—(1) Regulation 51 of the PMS Agreements Regulations (nomination of dispensers for the purposes of electronic prescriptions) is amended as follows.

(2) In paragraph (1)—

(a) after "its patients must" insert ", if a patient or where appropriate the patient's authorised person so requests,"; and

(b) after "chosen by the patient" insert "or where appropriate the patient's authorised person".

(3) Omit paragraph (3).

(4) In paragraph (4)—

(a) In sub-paragraph (a), after "a patient" insert "or a patient's authorised person"

(b) In sub-paragraph (b)—

(i) after "by a patient" insert "or a patient's authorised person",

(ii) after "whom the patient" insert "or the patient's authorised person", and

(iii) after "provide the patient" insert "or, as the case may be, the patient's authorised person".

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

Name
Parliamentary Under Secretary of State
Department of Health and Social Care

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the PLPS Regulations"), which govern the arrangements in England under Part 7 of the National Health Service Act 2006 ("the 2006 Act") for the provision of pharmaceutical services and local pharmaceutical services. These Regulations also amend the National Health Service (Charges for Drugs and Appliances) Regulations 2015 ("the Charges Regulations"), which provide for the making and recovery of charges for drugs and appliances supplied in England, most often on prescription, under the 2006 Act. These Regulations also amend the National Health Service (General Medical Services Contracts) Regulations 2015 ("the GMS Contracts Regulations") and the National Health Service (Personal Medical Services Agreements) Regulations 2015 ("the PMS Agreements Regulations"), which make provision in respect of the services provided in England under a general medical services contract and a personal medical services agreement made pursuant to Part 4 of the 2006 Act.

Part 1 contains general provisions. Part 2 contains the amendments to the PLPS Regulations – and principally these amendments relate to electronic prescribing. Prior to these Regulations, an NHS patient wishing to have an electronic prescription dispensed by a provider of pharmaceutical or local pharmaceutical services needed have a nominated dispensing contractor who was recorded as such in the Electronic Prescription Service (EPS). However, new arrangements, known as EPS phase 4, will allow for the NHS patient to have a prescription dispensed by a dispensing contractor who is not the patient's nominated dispensing contractor but to whom the patient presents an EPS token which has the appropriate barcode – as well as allowing for dispensing by a nominated dispensing contractor (regulations 2(2) and (4) to (6), 7(2) and (5)(a), 8(2) and (5)(a), 9(2) and 10(2) and (5)(a)). Not all dispensing contractors will have the facility to dispense against such a token, and these Regulations also ensure that dispensing contractors are not under an obligation to dispense if they do not have the necessary access to the EPS (regulations 7(4), 8(4), 9(5) and 10(4)). All patients who are claiming exemption from prescription charges, apart from those who are exempt by reason of their age, are obliged to make a declaration to the dispensing contractor that they are exempt, and amendments are made to dispensing contractors' terms of service both in relation to the recording of these declarations and for allowing real time exemption checks of electronic database records managed by the NHS Business Services Authority to be considered by the dispensing contractor as satisfactory evidence of exemption entitlement (regulations 7(3), 8(3), 9(3) and (4), and 10(3)). Forms recording patient declarations, where these have to be completed, have to be sent on by the dispensing contractor to the NHS Business Services Authority (regulations 7(5)(b) 8(5)(b), 9(4) and 10(5)(b)).

Some other amendments are also made to the PLPS Regulations. Provision is made so that prescriptions written by paramedic independent prescribers will be dispensed as part of pharmaceutical and local pharmaceutical services (regulation 2(2)). Providers of such services who are known as NHS chemists are subject to an enforcement scheme that provides for the service of breach and remedial notices by the NHS Commissioning Board (now known as NHS England), and amendments are made to provide for the rescission of such notices (regulations 4 and 5). Also, if NHS England are minded to serve a breach notice relating to an NHS chemist not being open for business at its notified hours without good cause, they are now required to make a reasonable effort to communicate with the NHS chemist to find out what the cause was (regulation 3). A number of decisions by NHS England under the PLPS Regulations are appealable to the NHS Litigation Authority, and there is a simplification of the arrangements under which certain third parties may attend oral hearings, removing a requirement that they need to indicate, when they make their written representations, that they also wish to make oral representations (regulation 6).

Under the Charges Regulations, entitlement to some exemptions from paying prescription charges is based on the patient both having a valid exemption certificate (recording for example a relevant medical exemption) and duly declaring the exemption. The obligations on NHS chemists and doctors in general practice to levy prescription charges are amended so that, if the prescription is an electronic prescription, the obligation not to levy a charge is predicated on the record of that declaration being duly entered into the EPS. In the case of a paper prescription, it is predicated on the paper declaration by or on behalf of the patient. In the case of an electronic prescription, the patient or someone acting on their behalf is nevertheless required to produce a separate declaration of entitlement, unless the dispensing contractor has been able to undertake a real time exemption checks of electronic database records managed by the NHS Business

Services Authority, which has confirmed the entitlement to an exemption declared by the patient (regulations 11(2) and (3) and 12 to 14).

Provision is also made in the Charges Regulations so that prescriptions charges can be levied in respect of prescriptions written by paramedic independent prescribers (regulation 11(4) and (5)), and to provide for a statutory gateway to enable information on or derived from both electronic and paper prescriptions to be used for the purposes of paying providers of NHS services (such as NHS chemists and doctors in general practice) and for matters relating to prescription charge enforcement. That statutory gateway also ensures that a duty of confidentiality is owed by the persons relying on it, whether or not they would otherwise owe such a duty (regulation 15).

The terms of service in the GMS Contracts Regulations and the PMS Agreements Regulations in respect of electronic prescribing are also amended to take account of the new EPS phase 4 arrangements, described above, under which patients will be able to have an electronic prescription dispensed by a dispensing contractor who is not the patient's nominated dispensing contractor. Prior to these Regulations, prescribers prescribing under a general medical services contract or a personal medical services agreement (most commonly doctors in general practice) had the option of issuing either a paper prescription or an electronic prescription. If the prescriber's practice is participating in EPS phase 4, the prescriber will be under an obligation issue an electronic rather than a paper prescription, subject to various exceptions. If the NHS patient has a nominated dispensing contractor, he or she will be asked if they wish to use that dispensing contractor, and if they do, the prescriber will not issue an EPS token (making the prescribing process potentially paperless) (regulation 16(2), (3), (5) and (6), 17, 18, 20(2), (3), (5) and (6), 21 and 22). In some instances, prescription items are requested on behalf rather than by patients, and arrangements for nominating dispensing contractors in the PLPS, GMS Contracts and PMS Agreements Regulations are all aligned so the same categories of authorised representatives can act on behalf of patients under all these sets of Regulations (regulation 16(4), 19, 20(4) and 23).

Annex B

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Subject	Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018
Date of meeting	9 October 2018
Committee/Subcommittee	HPR/LRA subcommittee
Status	Confidential until response is sent
Overview	A copy of the response and the subcommittee is asked to note that clarification of the proposals is sought as per the response.
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

Introduction

1. The PSNC response to the consultation is attached.

2. Particular attention is drawn to question 11 and the PSNC response which are:

> **Question 11: Do you agree that Responsible Pharmacist's duties should be clarified so that it is clear these are related to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines)?**
>
> Clarification is sought on any potential additional implications of the proposed changes to the Medicines Act, which relate to the role of the responsible pharmacist.
>
> The consultation document indicates that the proposed changes are necessary '*to clarify that the RP's duty relates to the operation of the pharmacy business 'at or from' the particular premises (e.g. including home deliveries of medicines) for which the RP is in charge*.'
>
> However, for home deliveries, the supply takes place 'at' the pharmacy premises and relevant pharmacists are professionally responsible for the sale or supply of the

medicine to the patient (including to the patient's home); and a responsible pharmacist's relevant duties or professional standards can be set by the pharmacy regulators.

Accordingly, first, the need for the statutory changes is unclear and, second, the distinction between supply 'at' a pharmacy premises and supply 'from' a pharmacy premises is unclear.

This is particularly relevant since it is proposed that pharmacy regulators will have power to set out the detail of responsible pharmacists' statutory responsibilities.

3. The concern is that the proposed change in legislation from dispensing, assembly or supply or medicines 'at' a pharmacy to the dispensing, assembly or supply of medicines 'at or from' a pharmacy may have other implications. The change is stated to be in relation to the professional role of the Responsible Pharmacist (RP) and the need to ensure professional responsibility for the medicines until they are received by the patient – with home deliveries. But, this has always been the case and, therefore, does not support the need to change the legislation as proposed.

4. The proposed legislative change may have implications for innovative supply routes 'from' a pharmacy, which may or may not be welcome to PSNC.

5. The Office will seek clarification of the possible consequences of the various legislation changes including those to Section 10 of the Medicines Act

Introduction

The Pharmaceutical Services Negotiating Committee (PSNC) welcomes the opportunity to respond to the consultation and the draft orders:

- Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018; and,

- Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

We are broadly supportive of the proposals as described in the consultation document, which we consider should assist the development and delivery of pharmacy services, to the benefit of patients and the public.

We consider that there are issues still to clarify and these include some of the issues identified at the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board Partners' Forum on 24th July 2018.

Our issues are as follows:

- Capturing the full emerging roles and responsibilities of superintendent pharmacists and responsible pharmacists and the relationship between the two roles: both dispensing and in wider service provision;

- Ensuring that the superintendent pharmacist is sufficiently senior within the retail pharmacy business to carry out the role;

- Clarifying any potential additional implications of the proposed changes to the Medicines Act, which relate to the role of the responsible pharmacist;

- Requiring pharmacy regulators to consult with interested parties before setting any professional standards relating only to responsible pharmacists and/or superintendent pharmacists;

- Ensuring patient safety is afforded the same level of consideration as minimising burdens on business, in respect of the pharmacy regulators' powers;

- The protection in place around how a future "super-regulator", that might subsume the role of the General Pharmaceutical Council, could use the new powers proposed for pharmacy regulators.

Our response to each of the questions in relation to the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018 is set out on the following pages.

Part 2 — The draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

Question 1: Do you agree that the Superintendent Pharmacist should be a senior manager of the retail pharmacy business (which may be just one part of the company for which they work) with the authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale of medicinal products and the supply of such products?

Broadly yes.

The proposal recognises the involvement of other senior managers in the management of retail pharmacy businesses, while at the same time seeking to maintain the unique statutory and professional position of the superintendent pharmacist.

The superintendent pharmacist's unique position, which underpins the governance of retail pharmacy businesses, is sought with the new proposed duty for superintendent pharmacists (the proposed new duty in section 72AA of the Medicines Act 1968, question 3 below) and the ability of the pharmacy regulators to set professional standards for superintendent pharmacists (proposed amendment of article 48 of the Pharmacy Order 2010, question 8 below).

However, while the overall structure is sound, the proposed statutory provisions no longer set out either the wide role of the superintendent pharmacist that is currently envisaged by use of the term 'management' of the business, or the detail of '..keeping [and] preparing … medicines …' The new duty provides some guidance, but the emphasis remains on the retail sale of medicines or their supply in circumstances corresponding to retail sale (dispensing against prescriptions). There is, therefore, considerable reliance on future professional standards to determine and describe in detail the duties and responsibilities of superintendent pharmacists.

Accordingly, greater clarity is sought on:

- the duties and responsibilities of the 'senior manager superintendent pharmacist', particularly alongside other senior managers who may be involved in the retail pharmacy business; and,

- the likely professional standards for superintendent pharmacists that will be issued initially by the pharmacy regulators.

Also, due to the significance of the professional standards to the proposed governance framework, we suggest that the pharmacy regulators should be under a duty to consult interested parties before setting standards that relate only to responsible pharmacists and/or superintendent pharmacists.

Question 2: Do you agree with the removal of the restriction for companies with "chemist" in their title such that the Superintendent Pharmacist no longer has to be a member of the board of the body corporate?

Membership of a company's board, even though this is only required for companies using the title 'chemist', signifies a level of seniority for the position that is not matched by the description of 'senior manager' and it will be important that the revised provisions of the Medicines Act 1968 and the associated professional standards ensure that superintendent pharmacists have sufficient authority to provide the necessary professional pharmacy oversight of the retail pharmacy business, for the benefit of patients and the public. As indicated above, greater clarity is sought on the duties and responsibilities of the 'senior manager superintendent pharmacist'.

Question 3: Do you agree with the proposed general duty for the role of the Superintendent Pharmacist?

Broadly yes, but subject to the above comments.

The proposed general duty gives the superintendent pharmacist 'the duty .. in relation to the retail pharmacy business to secure that the business is carried on in ways that ensure its safe and effective running so far as concerns the retail sale of medicinal products … and supply of such products [dispensed against prescriptions].'

The current governance structure provides that the superintendent pharmacist has an overarching responsibility for the keeping, preparing and dispensing of medicines and is assisted in that role by responsible pharmacists for each of the pharmacy premises. If a responsible pharmacist's statutory duty is not engaged when he or she is not actually designated that role, the Act might provide explicitly that the superintendent pharmacist's duty relates to the keeping and preparing of medicines as well as their sale and supply, to ensure that there are no gaps in the professional accountability for medicines kept, prepared, sold or supplied by the business.

Question 4: Do you agree that the Superintendent Pharmacist general duty should extend to all medicines – general sale list (GSL) medicines, as well as prescription only medicines (POM) and pharmacy (P) medicines?

Yes. This is long overdue.

Question 5: Do you agree that the role of the Superintendent Pharmacist should extend to other services, such as clinical and public health services?

Yes. Clinical and public health services should be part of a superintendent pharmacist's role. Such services are included within Essential, Advanced and (locally) Enhanced Pharmaceutical Services delivered by NHS community pharmacies and are part of pharmacy practice.

Question 6: Do you agree that the restriction whereby a Superintendent Pharmacist can only be a Superintendent Pharmacist for one business at any given time should be removed from primary legislation and the issue be left to the pharmacy regulators?

Yes. This proposal may assist bigger and smaller retail pharmacy businesses alike, as indicated in the consultation.

The removal of this restriction may result in the emergence of 'professional' superintendent pharmacists, who carry out the role for several retail pharmacy businesses. While such persons may have knowledge and experience of the role and responsibilities of a superintendent pharmacist, there is also a need for them to be sufficiently familiar with the relevant retail pharmacy business and to have the necessary time and resources, to be able to ensure the safe and effective running of the business. Such issues are likely to be addressed in professional standards issued by the pharmacy regulators and our previous comments on initial professional standards and appropriate consultation apply here.

Question 7: Do you agree with the proposal to retain the requirement for Superintendent Pharmacists to notify the General Pharmaceutical Council when they stop being Superintendent Pharmacist for a particular pharmacy and to extend the requirement to Northern Ireland and the Pharmaceutical Society of Northern Ireland?

Yes.

Question 8: Do you agree with the proposal to provide the pharmacy regulators with power to set professional standards for Superintendent Pharmacists and describe their role?

Yes, this is a pragmatic and sensible approach as the pharmacy regulators can respond to developments in pharmacy practice relatively quickly.

There is also a need to ensure consistency between the professional standards issued by the pharmacy regulators.

Due to the significance of the professional standards to the proposed governance framework, we suggest that the pharmacy regulators should be under a duty to consult interested parties before setting standards that relate only to responsible pharmacists and/or superintendent pharmacists.

Question 9: Do you agree that the statutory duty of the Responsible Pharmacist should be engaged only for the time when the Responsible Pharmacist is actually designated the RP role for that pharmacy, and is therefore in charge?

Broadly, yes.

Additional clarity is sought on the roles of, and relationship between, responsible pharmacists and the superintendent pharmacist.

In addition, the current governance structure provides that the superintendent pharmacist has an overarching responsibility for the keeping, preparing and dispensing of medicines and is assisted in that role by responsible pharmacists for each of the pharmacy premises. If a responsible pharmacist's statutory duty is not engaged when he or she is not actually designated that role, the Act might provide explicitly that the superintendent pharmacist's duty relates to the keeping and preparing of medicines as well as their sale and supply, to ensure that there are no gaps in the professional accountability for medicines kept, prepared, sold or supplied by the business.

Question 10: Do you agree that the trigger for when there needs to be an RP in charge of the premises is when medicines are being sold or supplied, or handled, assembled prepared or dispensed at or from the premises with a view to sale or supply?

Yes, although additional clarity is sought on the role of the responsible pharmacist and (see our answer to question 11) any potential additional implications of the proposed changes to the Medicines Act, which relate to the role of the responsible pharmacist.

Question 11: Do you agree that Responsible Pharmacist's duties should be clarified so that it is clear these are related to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines)?

Clarification is sought on any potential additional implications of the proposed changes to the Medicines Act, which relate to the role of the responsible pharmacist.

The consultation document indicates that the proposed changes are necessary '*to clarify that the RP's duty relates to the operation of the pharmacy business 'at or from' the particular premises (e.g. including home deliveries of medicines) for which the RP is in charge*.'

However, for home deliveries, the supply takes place ‘at’ the pharmacy premises and relevant pharmacists are professionally responsible for the sale or supply of the medicine to the patient (including to the patient’s home); and a responsible pharmacist’s relevant duties or professional standards can be set by the pharmacy regulators.

Accordingly, first, the need for the statutory changes is unclear and, second, the distinction between supply 'at’ a pharmacy premises and supply 'from’ a pharmacy premises is unclear.

This is particularly relevant since it is proposed that pharmacy regulators will have power to set out the detail of responsible pharmacists’ statutory responsibilities.

Question 12: Do you agree that the pharmacy regulators rather than Ministers should set out the detail of the Responsible Pharmacist’s statutory responsibilities?

Broadly, yes although it is unclear why this is necessary when pharmacy regulators can set responsible pharmacists’ professional standards.

It is suggested that the pharmacy regulators should be under a statutory duty to consult interested parties before issuing any statutory responsibilities relating to responsible pharmacists.

As discussed at the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board Partners’ Forum on 24th July 2018, there is a need to recognise protection of patient safety as well as business efficiency, on the face of the Medicines Act. This should apply to responsible pharmacists and superintendent pharmacists.

Question 13: Do you agree that the pharmacy regulators should have the power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time?

Yes, this is a pragmatic and sensible approach as the pharmacy regulators can respond to developments in pharmacy practice relatively quickly.

There is also a need to ensure consistency between the professional standards issued by the pharmacy regulators.

Question 14: Do you agree that the duty on the Responsible Pharmacist to establish, maintain and keep procedures under review is removed and instead is subsumed into the general duties of Superintendent Pharmacists?

Yes.

Question 15: Do you agree that the duties relating to record keeping should be set out by the pharmacy regulators, rather than in Ministerial legislation, and be enforced where appropriate via fitness to practice procedures?

Yes.

Question 16: Do you agree that the pharmacy regulators should be provided with a new general rule/regulation making power in respect to the Responsible Pharmacist and remove the specific Ministerial regulation making powers in respect of: (e) the qualification and

experience of Responsible Pharmacists; (f) the Responsible Pharmacist and supervision; (g) procedures; and (h) the record-keeping of the Responsible Pharmacist

Yes. As discussed at the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board Partners' Forum on 24th July 2018, there is a need to consider how any new super regulator might use powers introduced for pharmacy regulators.

We suggest that a statutory duty to consult interested parties, before setting professional standards that relate only to responsible pharmacists and/or superintendent pharmacists, would add some protection to the use of such powers by any future super regulator (as well as assisting pharmacy regulators with the use of such powers).

Question 17: Do you agree that the pharmacy regulators should be given new powers to set professional standards for Responsible Pharmacists and describe their role?

Yes, this is a pragmatic and sensible approach as the pharmacy regulators can respond to developments in pharmacy practice relatively quickly.

There is also a need to ensure consistency between the professional standards issued by the pharmacy regulators.

Due to the significance of the professional standards to the proposed governance framework, we suggest that the pharmacy regulators should be under a duty to consult interested parties before setting standards that relate only to responsible pharmacists and/or superintendent pharmacists.

Question 18: Do you agree that the Pharmacy (Northern Ireland) Order 1976 should be amended to provide for the appointment of a Deputy Registrar and to provide that the Deputy Registrar may be authorised by the Registrar to act on their behalf in any matter?

Yes.

Part 2 – Question 19: Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.

We suggest that there will be additional regulatory burden in that:

- All pharmacists and pharmacy technicians will need to familiarise themselves with the proposed changes as well as all pharmacy staff in patient facing roles, because the governance structure within retail pharmacy businesses is relevant to all those involved in the sale and supply of medicines to the public and patients.

- While welcomed, the increased workload for the pharmacy regulators is a cost to pharmacists, pharmacy technicians and retail pharmacy businesses registered with those regulators.

Part 2 – Question 20: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?

No.

Subject	Rural issues
Date of meeting	9 October 2018
Committee/Subcommittee	HPR/LRA subcommittee
Status	Open
Overview	Following a meeting of the Rural Working Party, a submission was drafted and sent in response to the House of Lords Select Committee on the rural economy – call for evidence.
Proposed action(s)	None
Author(s) of the paper	Gordon Hockey

Introduction

The Pharmaceutical Services Negotiating Committee (PSNC) promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health and Social Care as the body that represents NHS pharmacy contractors including those operating within the rural economy.

Our goal is to develop the NHS community pharmacy service, to enable community pharmacies to offer an increased range of high quality and fully funded services that meet the needs of their local communities and provide value and good health outcomes for the NHS and the public.

We are keen to respond to this consultation and consider that measures to ensure the adequate provision of community pharmacies in rural areas are vital. Are answers to the question are as follows.

General issues

1. What do you understand by the "rural economy"? How has it changed over recent years, and what has been the impact of these changes?

   No comment.

2. Could you give examples of notable success stories and good practice in the rural economy? How might rural successes be replicated and better promoted?

   The Essential Small Pharmacy Local Pharmaceutical Scheme (now closed) was a success story for the rural economy; relevant issues are discussed in our responses to later questions.

3. How do you see the future of the rural economy? Where is the greatest potential for growth, and what might be the impact of technological and other changes?

Community pharmacies embrace technology and over 60% of prescription dispensed are now electronic; however, it is important that technology is harnessed for the benefit of the patient and the patient's health and the community pharmacy network provides considerable health and social benefits. More detail is included in our responses to later questions.

Infrastructure and services

4. How can access to transport be improved in rural areas?

In some rural areas, public transport services are provided infrequently or only for part of a week. In the absence of adequate public transport, the public, particularly the elderly with mobility challenges and persons with disabilities, without access to private transport, can have difficulty accessing community pharmacy services; although many patients do benefit from home deliveries by community pharmacies.

Access to healthcare services could be improved if the health needs of the rural population were considered as part of planning relevant public transport services.

5. What barriers to growth are created by poor digital connectivity? How can connectivity be improved across the board?

The electronic prescription service (EPS) enables prescribers to send prescriptions electronically to a pharmacy of the patient's choice and currently approximately 60% of all prescriptions dispensed by community pharmacy are electronic prescriptions. This is likely to increase in the future as EPS is enhanced.

Benefits of EPS include avoiding unnecessary trips to the GP and enabling community pharmacy to manage workflow better and reduce the time patients wait for their medicine to be dispensed.

If connectivity in rural areas is poor, this is a barrier to the introduction of EPS.

6. What can be done to improve and maintain provision for essential services such as healthcare, education and banking in rural areas?

To improve and maintain provision of pharmacy services in rural areas, community pharmacies must be adequately funded. There was a scheme to support financially essential small pharmacies in rural areas, but this has been closed.

The Essential Small Pharmacies, Local Pharmaceutical Services (ESPLPS) Scheme, had for many years sustained predominantly rural pharmacies that would otherwise not be financially viable. The arrangements continued in some form until March 2017 until it was closed.

Current community pharmacy funding arrangements include the Pharmacy Access Scheme (PhAS), which protects access to community pharmacies in areas where there are fewer pharmacies and, broadly, maintains their funding at pre-December 2016 levels; subject to a 3% efficiency cut. This is funded by remuneration would otherwise fund other community pharmacies not benefitting from PhAS. However, it does not replace the additional funding that was provided to pharmacies that were in the ESPLPS scheme. Under the current scheme, some rural pharmacies although 'eligible' for PhAS ' do not receive any supporting payments, which is due to the way such payments are calculated.

In general terms, former ESPLPS pharmacies are not adequately supported under the new arrangements for supporting rural pharmacies.

It is also notable that the financial support provided by PhAS to some pharmacies is at the expense of additional funding cuts to non-PhAS community pharmacies.

To improve and maintain health services such as pharmacies in rural areas, a credible successor to the ESPLPS scheme should be introduced to safeguard patient access to smaller pharmacies in rural areas.

Community pharmacies in rural areas provide wider health and social benefits and assist other parts of the health sector, for example:

Health prevention and urgent care

An example of community pharmacy's current and future offering is highlighted for example by Public Health England's 2017 report Pharmacy: A way forward for Public Health, which include the following statements:

> *Executive summary*
>
> *Community pharmacy teams play a pivotal role as a community and health asset in communities. High quality public health and clinical interventions drive delivery that is focused on prevention, health improvement and protection of local communities. Delivered through integrated pharmacy team, working coherently in a local primary care and public health network.*
>
> *….*
>
> *Healthcare professionals, including pharmacy teams working in all sectors can play an important role in supporting people to make small and sustainable changes that improve their health. Brief and very brief interventions by healthcare professionals have Pharmacy been shown to be effective ways of supporting sustainable behaviour change and consumer research suggests that most people feel it is appropriate for healthcare professionals to ask about these behaviours and offer help.*
>
> *….*
>
> *Community pharmacies are often embedded in some of the most deprived and challenging communities, providing daily contact for individuals seeking ad hoc and unplanned health advice alongside picking up prescribed medicines or purchasing over the counter health related products. England has 1.2 million visits to a pharmacy for health related reasons every day, this presents a huge opportunity to support behaviour change through making every one of those contacts count.*
>
> *Community pharmacy teams are well placed to support patients with long term conditions to reduce their risks through healthy behaviours, as these patients will be in regular contact with community pharmacies to collect their prescribed medicines. This provides a unique opportunity for secondary prevention as well the wider opportunities for primary prevention through their daily customer base.*

And (page 33)

> ***Community pharmacy teams can help maximise the impact of contact with the general public by:***

….

- ***recognising people who are socially isolated and lonely, particularly those living in rural areas, supporting them and signposting to local services and opportunities***

The report by Public Health England's 2017 report Pharmacy: A way forward for Public Health, can be found at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/643520/Pharmacy_a_way_forward_for_public_health.pdf

Social Isolation

We echo other studies and reports on loneliness including the report by Rural England in 2016 'Older people in rural areas: Vulnerability due to loneliness and isolation paper' which include the following:

Main Findings

….

There are clear links between acute loneliness and poor health.

Social isolation is related to negative impacts on health and well-being

…..

(page 1 of the Report)

Loneliness and isolation affect the quality of life, happiness and health of many older people and those living is rural areas face particular challenges. These include: demographic change; family dispersal; mobility; access to services; and financial constraints on service providers.

(Page 1 of the Report)

There is extensive research indicating that loneliness can affect health and has cost implications for health and social care. The adverse health effects of loneliness may include:

- *increased risk of heart disease*
- *Impacts on blood pressure*

- *links to depression*
- *greater risk of blood clots*
- *increases the risk of onset of disability*
- *increased likelihood of early admission into residential or nursing care*
- *increased the risk of developing dementia*
- *exercising less and drinking more alcohol*

(Dept for Health 2102, UCL et al [ELSA],ONS2013, Scie 2012, Jopling 2015)
(Page 3 of the Report)

The services available in small rural communities are often extremely limited. The absence of shops, Post Offices and Pubs in many hamlets and small villages limits opportunities for interactions between older people within their own communities and the lack of public transport is an obstacle to them meeting elsewhere.
(Page 4 of the Report)

The report by *Rural England in 2016 'Older people in rural areas: Vulnerability due to loneliness and isolation paper'* can be found at:
https://ruralengland.org/wp-content/uploads/2016/04/Final-report-Loneliness-and-Isolation.pdf

7. What can be done to support local shops, community pubs and other rural amenities at risk of closure?

Local community pharmacies in rural areas sometimes require support to be financially viable in smaller communities.

Business, employment, skills and demography

8. How can rural businesses be helped to thrive, and how can new industries and investment be supported? How might labour and skills shortages be overcome?

No comment other than to highlight our understanding that recruitment of pharmacists in rural areas in an increasing problem.

9. How can deprivation and inequality in rural areas be tackled?

We seek to highlight that community pharmacies can play a part in tackling inequality:

a) NHS England is under a duty to have regard to have "regard to the need **to reduce inequalities** between people in England with respect to the benefits they can obtain from the health service".

b) The **inverse care law** -The Kinds Fund https://www.kingsfund.org.uk/publications/articles/inverse-care-law is described as follows:

The inverse care law was suggested thirty years ago by Julian Tudor Hart in a paper for The Lancet, to describe a perverse relationship between the need for health care and its actual utilisation. In other words, those who most need medical care are least likely to receive it. Conversely, those with least need of health care tend to use health services more (and more effectively).

Inverse laws are of course commonplace, and essentially arise because of income inequalities. In most areas of life (politics of envy aside) most of us are reasonably happy with this state of affairs. The fact that the rich have more clothes than they strictly 'need' is not too great a cause for concern. But the fact that an inverse law applies to health care offends against most people's views about fairness - a view which forms the basis for the existence of the NHS.

The concern about fairness arises from a deeper view about the distribution of health. Inequalities in health arise, not only from variations in access to health services, but also variations in the quality of health care from area to area. And of course, variations in factors outside the control of the NHS - wealth, lifestyle, genetic and environmental considerations - will all affect people's health status.

There is considerable evidence that many populations, particularly those living in areas of high socio-economic deprivation, suffer on all three counts: they use poor quality services,

to which they have relative difficulty securing access and they suffer multiple external disadvantage.

c) The important role community pharmacies play in bucking the inverse care law, particularly in rural areas. A study on 'The positive pharmacy care law: an area-level analysis of the relationship between community pharmacy distribution, urbanity and social deprivation in England' https://bmjopen.bmj.com/content/4/8/e005764 and the implications for policy makers were:

Implications for policymakers

This is the first study to systematically explore the spatial distribution of community pharmacies in England. It is also the first study that examines the relationship between accessibility of community pharmacies and social deprivation and to explore the idea of an inverse pharmacy care law. The paper shows that community pharmacies are easily accessible by the majority of the population in England, with 89% able access a community pharmacy within 20 min walk. Our study also shows that there is no inverse pharmacy law for community pharmacies in England: access to a community pharmacy is greater in areas of higher deprivation compared to more affluent areas—a positive pharmacy care law. This is a very timely finding as a recent initiative led by NHS England—the Call to Action—is seeking to develop local strategy for community pharmacy initiatives and inform strategic policy making in terms of commissioning community pharmacy services.35 Our work supports this initiative and shows that community pharmacies are uniquely placed in the community to deliver healthcare interventions. In addition, as the accessibility of community pharmacies is greatest in areas of highest deprivation, they may have an important role to play in reducing inequalities in priority public health conditions in England.

10. How can more young people be encouraged to stay in or return to rural areas and contribute to their communities?

No comment.

11. What can be done to address the challenges associated with an ageing rural population, such as social isolation and social care provision? What opportunities are there for the older retired population to help support the rural economy?

Social isolation has been addressed primarily as a health issue, as above.

In addition, it is notable that rural community pharmacies support patients with home delivery services which are not NHS services and are often provided free of charge. They are of significant benefit to housebound patients and those with disabilities who couldn't otherwise access the community pharmacy.

Rural housing and planning

12. How can the affordability of rural housing be improved? What are the other challenges associated with rural housing and how can these be addressed?

No comment.

13. How have recent planning policy reforms affected rural housing and the wider rural economy? What changes, if any, are needed to planning rules?

No comment.

Government policy, devolution and local government

14. Do the Government and other public bodies pay sufficient attention to the rural economy and if not, why not? What might be done to ensure that Government and other public bodies hear and act on rural voices?

15. What is being done in local government to support rural economies? How effectively do other public bodies such as Local Enterprise Partnerships operate in rural areas, and how might coordination between bodies be improved?

We seek to demonstrate that appropriately funded community pharmacy services contribute significantly to savings health and social care.

A PWC report on 'The Value of Community Pharmacy' in 2016 indicated that for the 12 community pharmacy services considered, **every £1 of public money spent on community pharmacy created £21 worth of value**.

The key findings from the report were:

Through the services considered in this report, in 2015 community pharmacy in England contributed a net increase of £3.0 billion in value in that year, with a further £1.9 billion expected to accrue over the next 20 years.

- *The in-year benefit in 2015 of £3.0 billion is net of the £247 million in compensation which pharmacy received through funding from national and local sources for the 12 services evaluated. Even considering just this limited list of 12 services, and applying conservative assumptions, the single year net benefit identified exceeds the total £2.8 billion community pharmacy was paid by NHSE in 2015.*
- *On top of this, we estimate that indirect health system cost savings could be worth up to a further £2.5 billion in 2015 from the knock-on effects of self-care and medicines support.*
- *Apportioning the single year net benefit evenly across all the 11,815 pharmacies which operated in England at the end of 2015 leads to a benefit of more than £250,000 per pharmacy in 2015 alone. This rises to more than £410,000 when considering the long term effects as well, and up to £625,000 per pharmacy when potential knock-on health impacts are included.*
- *Figure 1 below summarises how this value is distributed between different beneficiaries of community pharmacy activity. The NHS itself is the biggest beneficiary: community pharmacies contributed a net value of £1,352 million in the short run; this is net of the funding received by community pharmacies for the 12 services, both directly from the NHS and from local commissioners (which was £247 million – hence the gross value was £1,599 million). Of this net value to the NHS, the majority was direct NHS cash savings as a result of cost efficiencies, worth £1,111 million in 2015. In addition, the NHS saved an extra £242 million as a result of avoided treatment, and a further £172 million in avoided long term treatment costs.*

- *Further, 55% of in-year benefits and 91% of long run benefits (69% of total benefits) accrued outside the NHS. Other public sector bodies (e.g. local authorities) and wider society together received over £1 billion of benefits in 2015 as a result of the community pharmacy services covered. A further £1.7 billion is expected to accrue over the next 20 years.*
- *In addition, patients experienced around £600 million of benefits, mainly in the form of reduced travel time to alternative NHS settings to seek a similar type of services as the ones provided by community pharmacy.*

The report is at: https://psnc.org.uk/our-news/pwc-report-quantifies-value-of-community-pharmacy/

We seek to show the wider health benefits delivered by local community pharmacies including those in rural areas.

We seek adequate funding for rural community pharmacies. The former ESPLPS scheme should be re-introduced with agreed revisions, with appropriate additional funding.