PSNC Health Policy and Regulations Subcommittee Minutes

for the meeting held on Tuesday 10th October 2017

at PSNC Office 14 Hosier Lane, London, EC1A 9LQ

Members: Ian Cubbin (Chair), David Evans, Janice Perkins, Prakash Patel and Stephen Thomas.

Together with: David Broome, Mark Burden, Will Goh, Gordon Hockey, Andrew Lane and Bharat Patel.

Apologies for absence

There were no apologies.

Minutes of the previous meeting and matters arising

The draft minutes for May were approved by the subcommittee.

Agenda and Subcommittee Work

All ongoing matters were noted.

1	Considering and where necessary, proactively seeking, potential changes in the regulatory framework that could support contractors and robustly responding to any Government proposals, including on remote dispensing and supervision

ETP claims – Switching

This item concerns financial losses suffered by community pharmacy relating to the introduction of the Electronic Transmission of Prescriptions (ETP).

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Review of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

The Department of Health (DH) is undertaking the first 5-yearly statutory review of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 which must be published by 31 March 2018. The scope of the review is set out in regulation 121.

Confidential until the response is sent to DH [sent on 13 October 2017]

The subcommittee noted the reports of Regulations Review Working Group; PSNC Rural Group and the PSNC and DH bilateral meeting and decided that the response to the review should reflect the issues raised in the meetings, in particular:

- Broadly, the regulations work as intended and achieve the original policy objectives - [*to ensure a proportionate regulatory regime which encourages the supply of NHS pharmaceutical services without excessive provision in areas already meeting demand; to ensure benefits of new entry outweigh costs; and to align provision more transparently with local needs*] – and the regulations remain appropriate and proportionate.
- A needs-based assessment for new NHS contracts remains appropriate.

- An unintended consequence of the regulations is the use of Distance Selling Premises (DSPs) to be used to establish local pharmacies without the need to meet any needs-based test (for current needs, future needs or unforeseen benefits).
- There should be better enforcement of the regulations with regard to prescription direction.
- While the performance and market exit provisions are reasonable, they should be applied properly and in accordance with the regulations.
- The inducement provisions, which are clearly intended to prevent medical doctors benefiting from prescription direction, do not appear to stop to be effective where the doctor owns the pharmacy business; and this should be addressed.

The subcommittee also noted the various technical issues identified and the PSNC offer to assist DH with aspects of the review.

The subcommittee also asked that the response include:

- DH should establish with PSNC, NHS England and other appropriate stakeholders a group to monitor issues arising on an ongoing, so that if possible, they could be resolved long before the next review.
- The current understanding or accord with the Dispensing Doctors Association has brought relative harmony to relations between dispensing doctors and rural pharmacy contractors and that it would be better to maintain this than seek certain changes to part 7 (controlled localities etc.) and part 8 (dispensing doctors) of the regulations.
- A recent FHSAU appeal decision suggesting that two locums should be engaged to ensure that at least one attends was unacceptable and should be addressed in the review.
- DSPs should be given requirements to ensure they provide a national service (as already required by the regulations) and any DSPs acting as local pharmacies should be investigated and there be a robust process for dealing with this abuse of the regulations.

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General Pharmaceutical Council (GPhC) consultation on guidance to ensure a safe and effective pharmacy team.

The GPhC is consulting on new guidance for pharmacy owners which outlines what they are expected to do to ensure everyone in the pharmacy team can provide safe and effective services to patients and the public.

The subcommittee considered the GPhC consultation and was concerned by a number of issues:

- No explanation was given for the proposed changes other than the GPhC desire to stop accrediting courses; what is the problem that GPhC is seeking to solve?
- While giving responsibility to pharmacy contractors – employers – GPhC was being very prescriptive, which was inconsistent and unnecessary.
- The guidance was more onerous than the Standards and inappropriately written in virtually mandatory terms (should).
- An ‘equivalent’ course or module to a ‘level 2 NVQ’ course or module must be permitted to avoid excessive costs to contractors.
- The proposal did not accommodate increasingly diverse roles in the supply of medicines, some of which are not patient facing.

The broad principles of the guidance were accepted by the subcommittee as was a modular approach to training courses.

Review of the Safe Custody Regulations 1973

The Home Office is reviewing the safe custody regulations and held a series of stakeholder meetings in August, which were attended by Will Goh, Regulations Officer.

The subcommittee noted that the intention of the review is to (1) widen the scope of those subject to the regulations and (2) allow controlled drugs to be stored with greater security than permitted by the very prescriptive 1973 Regulations.

The subcommittee endorsed the office view that since there is no evidence that the existing requirements are insufficient, any improvements or future-proofing of the regulations should carry no additional cost or regulatory burden to community pharmacy; i.e. that contractors should be able to retain their existing cabinets under any new regulations.

2 Ensuring administration of the regulations is undertaken properly and effectively, advising and supporting LPCs and contractors where necessary

General Data Protection Regulation (GDPR)

The Director of Operations and Support reported that steps were being taken to produce a code/guidance on the GDPR for community pharmacy with RPS and the NPA. Also, that NHS Digital has indicated that the IG Toolkit will be updated this year to include the GDPR requirements, although formally they will not be part of the self-assessment for 2017/18.

The subcommittee endorsed this approach, noting that the office would issue preliminary advice on the GDPR next month and fuller guidance in the New Year.

Primary Care Support England (PCSE)

Stakeholder meetings

The subcommittee noted that in July 2017, the Director of Operations and Support and the Regulations Officer visited PCSE/Capita in Leeds to discuss various issues; the dedication of the Capita team and their wiliness to learn and resolve problems was reported and that key points made by PSNC, which were:

Notifications for routine and excepted applications:

- At least one LPC is always notified.
- The 2km is guidance for contractor notifications and discretion is necessary.
- If all those notified are cc'd into the letters any problems should become apparent sooner.
- LPCs through NHS England can feedback any problems they see with notifications if they know who has and who hasn't been notified.

IT issues with the controlled stationary portal:

- Lots of frustration from contractors.

- Security necessary but to level commensurate with activity and not above general NHS England requirements for its staff (your client's own security level).
- Longer duration of password - e.g. a year.
- Ability to reuse an old password (but not the one you're changing from).
- Immediate return email if new password required/requested (work around useful too).

Transformation - online portal for market entry applications

The subcommittee also noted that there is ongoing development of an online portal for market entry related applications and shortly a wider group of community pharmacy stakeholders will be engaged to review the developing system, which is due to be trialled in February 2018.

Equality Act 2010 and MDS

In August 2017, the office published PSNC Briefing 60/17: Equality Act 2010 – a quick reference guide to help contractors understand:

1. Their obligation to make "reasonable adjustments" under the Equality Act.
2. When medicines must be dispensed in MDSs or another reasonable adjustment should be made.
3. Whether there is a duty to provide free home delivery (under the Equality Act).

The Director of Operations and Support indicated that steps were being taken to seek an updated assessment toolkit (The current version is on the Primary Care Commissioning website) The subcommittee considered that the current assessment toolkit was sufficiently out of date that it should be removed from that website.

It was also reported that one LPC had agreed with its local Social Services that MDS trays are chargeable and it was agreed this example should be made available to other LPCs through PSNC.

Freedom to Speak Up Guardians and whistleblowing

In September 2017, the office updated guidance on whistleblowing issued earlier this year.

It was noted that some LPCs had decided that a member or officer of the LPC will be the *Freedom to Speak Up Guardian* for their (usually independent) contractors; and other have decided not to undertake the role due to the potential conflicts of interest associated with the role. There was discussion about the narrower NHS England role (advised to LPCs) and the wider role envisaged by the Francis Report.

The Director of Operations and Support agreed to review the PSNC insurance provisions for LPCs to ensure any LPC member or officer undertaking the role would be covered by the insurance.

Rural Working Group (RWG)

The subcommittee noted the recent meeting of the Rural Working Group and that the two main recommendations from the meeting were:

- The group's comments to be taken into account in the PSNC response to the Regulations Review.
- Renew efforts to seek to ensure rural GP practices are EPS 2 enabled.

Health Service Safety Investigations Bill Advanced Services

The subcommittee noted the draft bill, which proposes setting up the Health Service Safety Investigations Body (HSSIB), which will conduct investigations and seek to learn from patient safety incidents in the NHS, to reduce health care harm and improve patient care.

Provider Assurance/Post Payment Verification (PPV) for Advanced Services

The subcommittee noted that in August, the Committee approved proposals from NHS England and NHS BSA for a pilot of PPV of payment claims for the Medicines Use Review (MUR) service. The proposals had been developed by a working group, which included PSNC within its membership. The subcommittee also noted that if the pilot is successful, it is expected that other Advanced services will then be included within the NHS BSA activity.

The subcommittee considered that in future, discussion of relevant issues would be helpful at the appropriate subcommittee; and that this would ensure that as the PPV activity increases, the workload for contractors remains manageable. It was suggested that a small group of committee members might be available over the summer break to ensure such decisions had some additional oversight when the subcommittees and committee are not meeting.

It was also commented that generally submissions to NHSBSA should not include confidential patient information.

Updating the Approved Particulars

The subcommittee noted that NHS England is updating the approved particulars and PSNC will reach agreement on an implementation date that gives contractors time to update their practice leaflets.

Out Of Pocket (OOP) claims

The subcommittee noted that there have been a number of recent FHSAU appeal cases involving Out-of-pocket (OOP) expense claims and messages/confirmation from the decisions include:

- There are three requirements for an OOP claim:
  - claims are made only 'in exceptional circumstances',
  - claims are made only where the drug is 'not required to be frequently supplied by the contractor'; and
  - the contractor has 'taken all reasonable steps to avoid claiming'.
- The issue is whether the pharmacy claiming OOP expenses is entitled to claim them, not whether other pharmacies did or didn't claim. *(REF: SHA/18657-18666)*
- The onus is on the contractor appealing to the FHSAU to demonstrate that it is unreasonable to order (Denosumab) direct from the manufacturer because there may be a delay; [in effect, the contractor must be able to show why the claim was exceptional and all reasonable steps had been taken to avoid claiming]. *(REF: SHA/18657-18666)*
- OOP expenses will not be paid if a contractor obtains medicines from a supplier with which the contractor has a connection, and which appears to charge carriage and handling fees which can be claimed as OOP expenses, in preference to using alternative suppliers which do not charge such fees. (*REF: SHA/18651*)

It is suggested that these messages are consistent with the OOP expenses provisions in the Drug Tariff.

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Any other business

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