All PSNC members can attend this meeting and may speak with the permission of the Chairman.

PSNC Health Policy and Regulations Subcommittee Agenda

Meeting to be held on Tuesday 14th March 2017, 1.45 - 3.15pm

In the 'Pudding' meeting room, Radisson Blu Hotel, Leeds

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

Apologies for absence

Prakash Patel has given his apologies.

Minutes of the previous meeting and matters arising

The minutes of the last subcommittee meeting held on 10 January 2017 are set out in **Appendix HPR 01/03/17 (pages 7-9)**.

Agenda and Subcommittee Work

Agenda items are set out under the strategic aims of the year, first matters for decision, second, matters of report.

All ongoing matters are set out in **Appendix HPR 02/03/17 (pages 10-11).**

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

Matters for Decision

a) ETP claims - Switching

NHS England has no formal process for making discretionary payments and a number of contractors are seeking such payments, particularly in relation to issues associated with the submission and payment of electronic prescriptions.

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Next steps:

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Matters for REPORT

b) Judicial Review

By way of information:

In January 2017, the High Court granted the Secretary of State's application to vary the judicial review proceedings timetable. The date for the final hearing is now 21 March 2017, with a time estimate of three

days. The NPA's application/hearing for judicial review, which has a different focus to PSNC's case, will be heard at the same time.

Following the meeting in January, an update on the progress of the judicial review was sent to LPCs.

Next steps:

The judicial review hearing commencing on 21 March 2017.

c) Pharmacy Access Scheme – PhAS

As part of the two-year final funding package imposed upon community pharmacies in England, DH introduced the Pharmacy Access Scheme (PhAS), with the stated aim of ensuring that a baseline level of patient access to NHS community pharmacy services is protected.

PSNC published a PhAS Briefing to support contractors and to act as a reminder that the deadline for reviews of 28 February was fast approaching. This can be found at http://psnc.org.uk/contract-it/pharmacy-access-scheme-phas/.

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The position for LPS contractors remains unchanged. LPS pharmacies returning to the pharmaceutical list are not eligible for PhAS payments, because they were not on the pharmaceutical list on 1 September 2016; and, applications for review are not available to them due to the terms of permitted reviews and because the closing date (28 February 2017) for most applications has passed.

The Department of Health has included reference an appeals procedure in the Drug Tariff (page 734). The procedure for appealing unsuccessful reviews is not clear or whether the appeal will be considered by a different decision-maker. The current procedure for reviews is at https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/11/phas-operational-policy.pdf .

Next steps:

Monitor the situation with PhAS generally, the calculations and LPS pharmacies.

d) Market Entry

On 5 December 2016, amendments to the 2013 Regulations came into force which facilitate pharmacy business consolidations, from two or more sites on to a single existing site. PSNC has published initial information about the changes. NHS England has published an update to the Pharmacy Manual and PSNC will publish a briefing as soon as practicable.

Next steps:

PSNC to publish an appropriate briefing note.

e) Conflicts of interests

On 7 February 2017, NHS England issued updated guidance on the management of conflicts of interests. This can be found at https://www.england.nhs.uk/wp-content/uploads/2017/02/guidance-managing-conflicts-of-interest-nhs.pdf .

During its development, it was proposed that the guidance would apply to community pharmacies (and other primary care contractors). The Director of Operations & Supports made representations (with other primary care contractors) that it would confuse rather than clarify conflict of interests duties for pharmacy contractors (and others) who are under professional obligations and regulated by terms of service or the equivalent. These representations were accepted by NHS England and the guidance states:

> 'This guidance does not apply to bodies not listed above (i.e. independent and private sector organisations, general practices*, social enterprises, community pharmacies, community dental practices, optical providers, local authorities – who are subject to different legislative and governance requirements). However, the boards/governing bodies of these organisations are invited to consider implementing the guidance as a means to effectively manage conflicts of interest and provide safeguards for their staff. The requirements of GC27.2 of the generic NHS Standard Contract (2017/18 and 2018/19 edition) should be interpreted in that light.'

The NHS standard contract 2017/18 and 2018/19 general conditions 27.2 state:

> The Provider must and must ensure that, in delivering the Services, all Staff comply with Law, with Managing Conflicts of Interest in the NHS and other Guidance, and with Good Practice, in relation to gifts, hospitality and other inducements and actual or potential conflicts of interest.

Next steps:

None.

f) The Health Service Medical Supplies (Costs) Bill - Specials

A proposed amendment to the bill on 'specials' medicines can be found at: https://www.publications.parliament.uk/pa/bills/cbill/2016-2017/0146/17146.pdf (page 1). The amendment would allow the DH to consult on different methods of supplying specials.

Next steps:

None.

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

MATTERS FOR DECISION

a. General Data Protection Regulations (GDPR)

A subcommittee member has asked for an initial discussion about the above regulations and a short note is attached as **Appendix HPR 05/03/17 (pages 36-38).**

Next steps:

It is suggested that PSNC await clarification by NHS England.

MATTERS FOR REPORT

b. Primary Care Support England (PCSE)

PCSE (formerly Primary Care Support Service – PCSS) provides administrative and payment services to community pharmacies amongst others. On 1 September 2015, Capita assumed responsibility for the delivery of most of NHS England's primary care support services.

During the summer of 2016, the Director of Operations and Support wrote to NHS England about poor delivery of controlled stationery, poor market entry management and poor customer service and received a response from NHS England director Karen Wheeler. Subsequently, a review of PCSE service delivery was announced; there were changes in the senior management at PCSE/Capita and NHS England staff were drafted in to help address operational issues.

However, some problems have continued with market entry and customer service and, in addition, the office has received increasing numbers of reports of problems with pre-registration payments. Problems have also continued for other primary care contractors.

In January 2017, after reports that GPs might be getting compensation, the Director of Operations and Support reiterated PSNC's request for a compensation scheme for pharmacy contractors and there was a preliminary discussion with a representative of NHS England. Following the announcement that a compensation for GP practices has been agreed, an update has been requested from NHS England.

Next steps:

Await a response from NHS England.

c. Annual completion of the IG Toolkit and the recent actions of the NHS England West Midlands team.

On 20 December 2016, the Director of Operations and Support wrote to Alison Tonge, Director of Commissioning Operations for the West Midland, about the West Midlands office's actions against pharmacy contractors. On 3 February a reminder letter was sent. Alison Tonge's reply was received on 28 February 2017. It has not answered/addressed any of the questions/issues raised and, in conjunction with the relevant LPCs, the Director of Operations and Support will take further steps to seek answers.

Next steps:

To pursue the questions/issues with NHS England.

d. Equality Act and its applicability to the provision of MDS trays

Legal advice was obtained from external counsel, to clarify and confirm the requirements of the Equality Act generally and specifically in relation to the provision of MDS trays and home delivery services. The relevant briefing will be updated as soon as practicable.

Next steps:

Update the January 2016 PSNC briefing on the Equality Act.

e. Accessible Information Standard (AIS)

NHS England has launched a post-implementation review of the Standard. The purpose of the review is to assess the impact of the Standard and ensure that it is, and continues to be, 'fit for purpose'.

Following the review, all of the feedback will be analysed and a report will be produced. Depending on the findings, revised versions of the Specification and / or Implementation Guidance for the Standard might be issued. However, there will be no substantive change to the overall scope of the Standard.

PSNC has submitted a response.

Next steps:

Await the outcome of NHS England's review.

f. **Pharmaceutical Needs Assessment (PNA)**

Health and Wellbeing Boards (HWBs) are due to publish revised PNAs by April 2018 and some have started engaging stakeholders, including LPCs. The office has revised and made available the PNA questionnaire for LPCs to use, to assist theirs and the HWB's assessment of pharmaceutical needs in the area.

Next steps:

None.

g. Publication of the Government's response 'Making a fair contribution – A consultation on the extension of charging overseas visitors and migrants using the NHS in England'

Attached is a copy of the Government's response as above, as **Appendix HPR 06/03/17 (pages 39-40).** It is not yet clear what this will mean for contractors, but this should become clearer as the work progresses.

Next steps:

Keep under review.

h. **GPhC consultation on religion, personal values and beliefs in pharmacy practice**

The Director of Operations and Support provided a PSNC response to the consultation, which included:

10. if a pharmacist who is contractor with the NHS cannot comply with GPhC guidance on professional standards, this could mean that he or she cannot comply with his or her 'terms of service' with the NHS (the terms of service require pharmacists to comply with professional standards); ultimately, if the business cannot support locum pharmacists (who could comply with the relevant professional standard), this could affect not only the contractor practicing his or her profession, but also his or her ability to contract with the NHS, and thus his or her right to peaceful enjoyment of his or her possessions, under Article 1 of the European Convention of Human Rights (also included in the Human Rights Act 1998). This should be considered.

In conclusion, it is suggested that pharmacists should have freedom of thought, conscience and religion and this should be made clear in GPhC standards and guidance.

The extent to which this freedom is limited, if at all, should be evidence and risk-based, and also in accordance with the Human Rights Act 1998, other relevant legislation and existing case-law and be consistent with the standards of other healthcare professions.

Next steps:

None.

Any other business.

GAH March 2017

Appendix HPR 01/03/17

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Appendix HPR 02/03/17

Report on progress on matters previously discussed by the subcommittee (March 2017 Agenda)

Matters worked on between March 2016 to present (starting with most recent open workstream items and descending to closed workstream items)			
Item/description of workstream	**Most recent action/s**	**Current status**	**Date of last subcommittee meeting**
Visitor and Migrant cost recovery	Agenda item.	Open	01/17
Pharmacy numbers – planned reduction	Now part of the judicial review. Agenda item.	Open	01/17
Planned protection for patient access – Phas	Matter of report. Agenda item.	Open	01/17
Market entry	Matter of report. Agenda item.	Open	01/17
Discretionary payments and "switching" etc.	Agenda item.	Open	01/17
Direction of Prescriptions	How to address the issues will be considered in 2017/18	Open	10/16
ToS for DSPs	On 20 October 2016, as part of the Government funding imposition, DH confirmed that it is their intention to explore new terms of service for distance-selling pharmacies in recognition of their different service offering. This will be the subject of further consultation with PSNC.	Open	10/16
Hub & spoke	Matter of report. No further substantive update has been provided by DH since their decision on 7 June 2016 to postpone plans on hub and spoke dispensing and the 6 September meeting	Open	09/16
Accessible Information Standard	NHS England currently reviewing the Information Standard and have requested responses by 10 March 2017	Open	07/16

Rebalancing	Director of Operations & Support has followed up previous requests to DH to be part of the working group on supervision, but without success.	Open	07/16
FMD	Delegated Acts issued. Department of Health currently holding meetings with stakeholders regarding implementation. Following a PSNC response to the proposed UK MVO, it is likely that PSNC, CPW, CPS and CPNI, with other community pharmacy representatives will be directly involved with the formation of the UK MVO. Issues now with the professional development team at PSNC.	Open	07/16

Text in yellow highlight is confidential

Confidential Appendix HPR 03/03/17

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Confidential Appendix HPR 04/03/17

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Appendix HPR 05/03/17

General Data Protection Regulations (GDPR)

Introduction

A subcommittee member has asked for an initial discussion about the above regulations.

An overview of which is on the website of the Information Commissioner's Office (ICO) at https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/

PSNC has issued initial guidance at https://psnc.org.uk/contract-it/pharmacy-it/information-governance/the-general-data-protection-regulation-gdpr/

Consent

The ICO is currently undertaking a consultation on its draft consent guidance which can be found at: https://ico.org.uk/about-the-ico/consultations/gdpr-consent-guidance/

Article 4 (11) of the GDRP adds states that the meaning of consent is as follows:

> *GDPR definition: "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her, such as by a written statement, including by electronic means, or an oral statement…"*

The Data Protection directive currently states consent is:

> *"any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed"*

The Data Protection Act 1998 provides that for the processing of sensitive personal data, which includes a person's physical or mental health or condition, there should be '*explicit consent*' (Schedule 3 of the 1998 Act), which is arguably similar to the enhanced meaning of consent in the GDPR.

Although the GDPR enhances the meaning of consent, it also retains provision for sensitive personal data for which explicit consent is required. It is not clear exactly what the difference is between *a clear statement or affirmative action* and *explicit consent*.

The GDRP also provides alternatives for implied consent, for example:

- A contract with the individual: for example, to supply goods or services they have requested, or to fulfil your obligations under an employment contract. This also includes steps taken at their request before entering into a contract;
- Vital interests: you can process personal data if it's necessary to protect someone's life. This could be the life of the data subject or someone else; and,
- Legitimate interests: if you are a private-sector organisation, you can process personal data without consent if you have a genuine and legitimate reason (including commercial benefit), unless this is outweighed by harm to the individual's rights and interests.

This is summarized by the NHS European Office briefing on the GDPR in May 2016, which is at http://www.nhsconfed.org/resources/2016/05/protecting-and-managing-personal-data and includes the following:

> *Where consent is used as a legal basis, the conditions around consent have been enhanced. Consent needs to be given through a clear, affirmative action, establishing a freely given, specific, informed and unambiguous indication of agreement. Silence, preticked boxes or inactivity does not constitute consent. For processing special categories of data (ie health data), the data subject must give explicit consent – so the bar is raised. Where consent is used as the legal basis, it is important to note that the 'dual consent' mechanism remains consistent with the 1995 Directive. So unambiguous consent is required for processing of personal data, and explicit consent will be required for processing of special forms of data (ie health data and genetic data). However, in both cases, alternatives to consent are available. For the health sector, the most important exemptions from the prohibition on processing of special forms of personal data are as follows:*
>
> > • *explicit consent*
> > • *protecting vital interests (life or death scenarios)*
> > • *substantial public interest*
> > • *preventative occupational medicine, medical diagnosis, provision of health and social care or treatment or management of health or social care systems (it is the first time social care has been added and this could facilitate integrated models of care) – based on national law or EU law*
> > • *public interest in the area of public health – this is specifically mentioned in the Regulation – based on national or EU law (not in the Directive)*
> > • *archiving purposes in the public interest, scientific and historical research, statistical purposes (subject to Article 89 and national or EU law).*
>
> *Importantly, Article 9(3) of the Regulation will allow for broadening of the scope of professionals allowed to access data to accommodate new ways of working and new models of care being employed across Europe. Currently health data can only be processed by "a health professional subject under national law, or rules established by national competent authorities, to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy". However the new Regulation extends the scope to include a broader spectrum of individuals who could be allowed to process health data. More precisely, the text says that health data and other sensitive categories of data may be processed for preventative occupational medicine, medical diagnosis, provision of health and social care, or treatment or management of health or social care systems when those data are processed "by or under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies, or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies".*
>
> *One note of caution is that there is a provision in the Regulation (Article 9(4)) for each country to "maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or health data".*
>
> > *Recommendations to EU and Member State implementers*
> >
> > • *Member States should ensure that national rules and laws are fit for purpose to enable appropriate sharing of data across the health and social care workforce, where necessary, for the purposes outlined in the Regulation.*

> • *Encourage Member States to discuss with hospitals and other health and care organisations before introducing any further conditions or limitations with regard to the processing of genetic data, biometric data or health data.*

Conclusion

NHS England's Information Governance Operating Model 2016/2017 (at https://www.england.nhs.uk/wp-content/uploads/2016/12/ig-operating-model-v0-23.pdf), which provides the overarching IG framework, resources and roles within NHS England (page 4) states that the Corporate IG Team objectives for 2016-17 include (page 66):

> *GDPR AB Dec 2016 Review impact of new DPA EU directive. To review and report on the differences in GDPR and current DPA in current NHS England BAU functions. To scope how the differences will impact on the operational behaviour of NHS England's current functions. Carry out relevant engagement with teams/functions that will be affected by the GDPR and report on 'gap' in current working practice to GDPR compliant working practice, and how best to change current processes. To scope and report how future projects/ procurements will need to be GDPR. compliant compared to current project/ procurements implementation workings. To produce relevant internal guidance documents on GDPR for NHS England staff use.*

It is not clear if this work has been completed.

GAH March 2017

Visitor & Migrant NHS Cost Recovery
Programme
Richmond House
79 Whitehall
London
SW1A 2NS

By email

6 February 2017

Dear Colleague,

Publication of the Government's response 'Making a fair contribution – A consultation on the extension of charging overseas visitors and migrants using the NHS in England'

As Chair of the Visitor and Migrant NHS Cost Recovery Programme's Delivery Reference Group, I am writing to members to announce that the Government has today published the response to the consultation *Making a fair contribution – A consultation on the extension of charging overseas visitors and migrants using the NHS in England* which can be found here: www.gov.uk/dh/nhscostrecovery

The consultation response summarises respondents' views and sets out what the Government now intends to do to extend charging so that a consistent approach to charging overseas visitors and migrants for their healthcare is applied across the NHS, including from April 2017:

- Non-exempt overseas visitors will become chargeable for NHS secondary and community care services provided outside hospitals, and NHS-funded secondary care delivered by non-NHS bodies, where these are funded in their entirety by NHS commissioners unless the service provided is one that will remain free to all, eg the diagnosis and treatment of specified infectious diseases
- Visitors and migrants who are entitled to an exemption from charge for NHS services under Immigration Health Surcharge arrangements will no longer be able to receive free NHS-funded assisted reproduction services (such as IVF) as part of their exemption
- New statutory requirements on all providers of NHS-funded services to charge overseas visitors upfront and in full for any care not deemed by a clinician to be "immediately necessary" or "urgent" and/or cease providing such non-urgent care where payment is not received in advance of treatment beginning
- New statutory requirements on NHS organisations to identify and flag an overseas visitor's chargeable status, starting with NHS trusts

The most vulnerable people from overseas, including refugees, will remain exempt from charging. Furthermore, the NHS will not deny urgent and immediately necessary healthcare to those in need. Exemptions from charging will also remain in place for the diagnosis and treatment of specified infectious diseases in order to protect the public.

I want to take this opportunity to say thank you for your ongoing contribution to the discussions at the Delivery Reference Group (DRG) meetings, and hope that we can continue to build on the work delivered so far on improving cost recovery in the NHS, and take forward the next phase of work for the programme. We will be in touch shortly to set up meeting dates for 2017.

No doubt, there is much to consider in terms of the practicalities for implementing the new arrangements. To that end, DH officials or I would be happy to meet with you and your organisation separately in the meantime if you would find it useful. Please contact the team at nhscostrecovery@dh.gsi.gov.uk and we will make the necessary arrangements.

Yours faithfully,

Sir Keith Pearson
Independent NHS Advisor to the Visitor and Migrant NHS Cost Recovery Programme and Chair, NHS Delivery Reference Group