

GOVERNANCE COMMITTEE

15 January 2014

Subject Heading:	DEVELOPMENT AND AUTHORISATION OF PATIENT GROUP DIRECTIONS (PGDS)
CMT Lead:	Dr Mary Black, Director of Public Health
Report Author and contact details:	Mark Ansell, Consultant in Public Health, x1818
Policy context:	In certain circumstances, PGDs are necessary to deliver health improvement services now commissioned by the Council as a result of the Health And Social Care Act 2012
Financial summary:	The cost of the health improvement services to which PGDs relate is met by a ring fenced public health allocation provided for this purpose by central government.

The subject matter of this report deals with the following Council Objectives

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SUMMARY

The Health and Social Care Act transferred responsibility for aspects of health improvement from the NHS to top tier Local Authorities. The delivery of some health improvement services is dependent on Patient Group Directions (PGDs). PGDs are written directions enabling health professionals to supply and/or administer a named medicine to a group of patients, who may not be individually identified prior to presentation for treatment. Local Authorities now have the power to authorise patient group directions (PGDs) relating to their health improvement

responsibilities and this report sets out what this entails and how the process might best be governed.

RECOMMENDATIONS

That the Committee recommend to the Council that the following paragraph is added to Section 3.9.1 in Part 3 of the Constitution relating to the Director of Public Health's role:

(m) To authorise Patient Group Directions on behalf of the Council.

REPORT DETAIL

What are Patient Group Directions?

- 1 Patient Group Directions (PGDs) are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.
- 2 The majority of clinical care should be provided on an individual, patientspecific basis. The supply and administration of medicines under PGDs is reserved for those limited situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability.
- 3 For example, community pharmacists are easily accessible, have a high footfall and are used by some population groups who may be less likely to attend general practice e.g. young people. As such they are well placed to offer chlamydia testing. However, they do not usually prescribe and therefore patients testing positive must subsequently attend their GP or sexual health services to be treated. This is inconvenient and increases the likelihood that treatment will be delayed. A PGD allows community pharmacists to offer this treatment where the patient meets specified criteria which serve to ensure patient safety.

Legal basis for Council authorisation

- 4 Patient group directions must be authorised by the relevant appropriate body as set out in legislation.
- 5 As a result of the Health and Social Care Act 2012, the responsibility for commissioning health improvement services was transferred to local authorities. In some cases delivery of these services is dependent on a PGD. The National Treatment Agency (Abolition) and the Health and Social

Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013¹ amended existing legislation to give Local Authorities the power to authorise PGDs in the exercise of their new public health functions.

6 The same order states that this power should be authorised by the Chief Executive or Director of Public Health of the local authority.

The Role of the Director of Public Health

- 7 NICE published <u>Patient Group Directions Good Practice Guidance</u>² in August 2013 which covers the legislation, systems and processes used when commissioners and providers of NHS services are considering the need for developing, authorising, using and updating PGDs.
- 8 NICE states that an individual person should have designated responsibility for signing PGDs on behalf of the authorising body. This person has responsibility for ensuring PGDs are developed in line with legislation and local organisational policies and governance arrangements, with full consideration of the service in which the PGD is to be used. Legislation requires this person to be the Chief Executive or the Director of Public Health (DPH). Given that authorisation will entail judgments as to whether use of a PGD is consistent with appropriate professional relationships and provides advantages for patient care without compromising patient safety, a detailed knowledge of health improvement services will be necessary and hence this responsibility would be best placed under the remit of the Director of Public Health.
- 9 The overall process of PGD development and authorisation is summarised schematically in Appendix 1. Key groups and their role in the process are outlined in subsequent sections of this report. A detailed protocol, based on the NICE PGD Good Practice Guidance, which will guide the development of PGDs in the Council, will be developed by the Council's Public Health Directorate and approved by the DPH.

The Patient Group Direction Approval Group

- 10 Prior to final authorisation by the Director of Public Health on behalf of the Council, any PGD would be approved by a multidisciplinary group of health professionals.
- 11 NICE Good Practice Guidance suggests that this PGD approval group should as a minimum include the following people:
 - Prescribing or clinical governance lead
 - Medicines optimisation lead or chief pharmacist
 - Representative from other local medicines decision-making groups.

¹ The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013' <u>http://www.legislation.gov.uk/uksi/2013/235/contents/made</u> (relevant sections are paragraph **176** of Schedule **2** and paragraph **28** of Schedule **3**).

² NICE (2013) 'Good Practice Guidance: Patient Group Directions'

- 12 If additional expertise is needed, the DPH will invite other professionals to participate including:
 - Specialists with appropriate expertise to provide clinical advice in a specific area, such as a
 - Local specialist in microbiology (for PGDs containing an antimicrobial) or a paediatric specialist (for PGDs to be used for treatment in children)
 - Lead practitioner in the area in which the PGD is to be used
 - Patient and public representatives
 - Controlled drugs accountable officer (if the PGD includes a controlled drug)
 - Service commissioner or provider representatives
 - Finance representative.
- 13 Clinical Commissioning Groups (CCGs) also have the power to authorise PGDs pertaining to the services that they commission and have staff with the required professional competencies and previous experience of PGD development and authorisation. Havering Clinical Commissioning Group (HCCG) has agreed to assist the Council to access the health professional expertise needed to authorise and develop PGDs.

The Patient Group Direction Working Group

- 14 A separate PGD working group will be established to develop each PGD and thereafter periodically review and update it.
- 15 Legislation does not specify who must be involved in developing PGDs. The Health Service Circular (HSC 2000/026) states that PGDs 'should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD'³.
- 16 The NICE Guidance Development Group (GDG)⁴ reviewed evidence that an individual PGD is usually developed by a named 'lead author' who has overall responsibility. This author may be part of a multidisciplinary 'PGD working group'. The lead author may be a doctor (or dentist), pharmacist or representative of any other professional group who will practise under the PGD, or another person such as the service lead. The roles and responsibilities of each person, how they work together to develop the PGD and how the group operates should be determined locally and clearly defined.
- 17 A PGD working group should be established for each individual PGD, although the same group may be responsible for developing a number of

³ NICE (2013) 'Good Practice Guidance: Patient Group Directions' (pg 48)

⁴ NICE. (2013) *GPG2 Patient Group Directions.* Available: http://publications.nice.org.uk/patient-groupdirections-gpg2/how-this-guidance-has-been-developed#guidance-development-group. Last accessed 02.01.2014.

PGDs. The PGD working group is separate from, but would need to liaise with, the PGD approval group.

- 18 The NICE Guidance agreed that members of the PGD working group developing a PGD should include⁵:
 - a lead author
 - a doctor (or dentist)
 - a pharmacist
 - a representative of any other professional group who will practise under the PGD, such as a nurse.
- 19 The GDG concluded that whatever local arrangements are in place, the expertise of a doctor (or dentist), pharmacist and representative of any other professional group who will practise under the PGD is needed when developing a PGD.
- 20 If additional expertise is needed, other professionals who may be involved in developing a PGD include:
 - a specialist with appropriate expertise, such as a local specialist in microbiology for PGDs containing an antimicrobial
 - the people responsible for ensuring that only fully trained and competent professionals work under the PGD
- 21 With regard to the development of PGDs within the Council, it is envisaged that the lead author would normally be a consultant in public health who would be charged with engaging the support of a wider team of health professionals as necessary.
- In some instances, a PGD may be developed by a national or regional expert group e.g. established by Public Health England or NHS England. Nonetheless, a local lead will be required to put in place and report on robust arrangements for the implementation and audit of the PGD (see below). Prior to authorisation, the DPH and Patient Group Direction Approval Group will consider and be reassured regarding the training and competency of people involved in developing all PGDs.

Implementation and audit of PGDs

- 23 As part of the documentation submitted to the Authorisation Group, the PGD Working Group will describe: -
 - how relevant health professionals will be trained to supply and administer the stated medication as specified in the PGD
 - how the competence of health professionals will be assessed and recorded
 - how compliance with the PGD will be audited
 - who, how and when implementation and audit of the PGD will be reported to the PGD Approval Group.

⁵ NICE (2013) 'Good Practice Guidance: Patient Group Directions' (pg 49)

24 The PGD Approval Group will consider and be reassured regarding the robustness of these arrangements before authorising the PGD.

Annual Report regarding PGDs authorised by the Council

25 It is proposed that the DPH, supported by the PGD Approval Group will publish an Annual Report detailing any PGDs authorised and information regarding their subsequent usage. The Report will be shared with the chair and members of the Health and Wellbeing Board.

Conclusions

- 26 Patient Group Directions can offer a significant advantage to patient care by improving access to appropriate medicines where prescribing is impractical. Hence the legal framework of a PGD allows services to be redesigned and health professionals to work more flexibly for the benefit of patients.
- 27 The proposed governance arrangements set out in this paper will give the Director of Public Health the responsibility to authorise PGDs on behalf of the Council having been scrutinised by an appropriately constituted PGD Approval Group which will assess and provide reassurance regarding PGDs, and related plans for implementation and audit, developed by separate PGD Working Groups.
- 28 These arrangements will ensure that PGDs in Havering improve outcomes and experience of care whilst preserving patient safety.

IMPLICATIONS AND RISKS

There is a **corporate** requirement to set out the implications and risks of the decision sought, in the following areas

Financial implications and risks:

There are no additional financial implications as these costs are contained within the existing contracts with the providers.

Patient Group Directions serve to reduce costs to the public purse as a whole, as they enable a one stop shop approach and prevent follow up appointments for the prescribing of medication which otherwise would happen.

Legal implications and risks:

The legal risk would arise from the authorisation of a high risk process or medication that should for patient safety reasons be administered by an independent prescriber. However, as the subject matter for PGDs are inherently low risk procedures or medication, and the approval process before final authorisation is substantial and multi-layered the outlined risk is minimal.

Human Resources implications and risks:

There are no significant HR implications or risks that can be identified from the recommendation made in this report. The role of Director of Public Health (DPH) is wide-reaching in terms of the public health function and already encompasses all the key responsibilities in this area of the work of the Council. Any potential impact on the DPH role can be appropriately explored under the Council's HR policy framework, with advice from the HR service.

Equalities implications and risks:

It is anticipated that Patient Group Directions (PGDs) will improve outcomes and experience of care and increase access to appropriate medicines whilst preserving patient safety. The groups that are most likely to benefit from the proposed arrangements are young people, men and people from certain ethnic groups and nationalities who are less likely to attend general practice.

BACKGROUND PAPERS

The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions), 2013, No. 235. http://www.legislation.gov.uk/uksi/2013/235/contents/made

NICE (2013) Good Practice Guidance: Patient Group Directions. http://www.nice.org.uk/mpc/goodpracticeguidance/gpg2.jsp

NICE (2013) Evidence and recommendations – Patient Group Directions - <u>http://publications.nice.org.uk/patient-group-directions-gpg2/evidence-and-</u> recommendations#authorising-patient-group-directions-3

NHS. (2013). Who are the PGD signatories? Available: <u>http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/FAQs/Who-are-the-PGD-signatories/?query=local+authority&rank=21</u> Last accessed 02.01.2014.

Appendix 1: PGD development chart

