Patient Group Directions
St Helens Council – Public Health Policy

Version 1

Authorised: November 2014
Review date: November 2015
Patient Group Directions – St. Helens Council Public Health Policy

1. Purpose of this policy
1.1 This patient group direction policy for public health sets out the requirements and authorisation processes required by the council to ensure that the patient group directions of our providers have been approved and are of the highest clinical standard.

2. Context
2.1 The Health and Social Care Act 2012 transferred the commissioning arrangements of many public health services over to the local authority and this was implemented on the 1st April 2013. Some commissioned services such as those provided by community pharmacies and those provided in Addaction may require that medicines or medical devices are provided by a health professional other than a doctor, this may be a nurse or a pharmacist. Legal frameworks have been developed so that some registered professionals can supply and administer specific medicines to pre-defined groups of patients without having to see a prescriber (prescriber could be a doctor or dentist). A local example of this is a community pharmacist is commissioned to provide Emergency Hormonal Contraception but can only do so under a Patient Group Direction.

3. What are patient group directions?
3.1 Patient Group Directions (PGDs) are written instructions for the supply or administration of Prescription Only Medicines to groups of patients by non-medical professionals. Legislation dictates the particular circumstances around which PGDs can be used. The relevant provisions are contained in Regulations 229-232 of the Human Medicines Regulations 2012. Amendments allow Local Authorities to authorise the use of PGDs from April 2013. The amendments to legislation can be found in Statutory Instrument 2013, No, 235, “The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Savings Provisions) Order 2013.

4. Patient Group Directions development
4.1 Patient group direction must be signed by a doctor (or, if appropriate, a dentist) and a pharmacist, both of whom should have been involved in developing the direction. Additionally the patient group directions must be authorised by the relevant appropriate body as set out in the legislation.

The legislation specifies that each PGD must contain the following information:
• the name of the business to which the direction applies (i.e. Local Authority)
• the date the direction comes into force and the date it expires
• a description of the medicine(s) to which the direction applies
• class of health professional who may supply or administer the medicine
• signature of a doctor or dentist, as appropriate, and a pharmacist
• signature by an appropriate organisation
• the clinical condition or situation to which the direction applies
• a description of those patients excluded from treatment under the direction
• a description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral
Appendix A

- details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered
- relevant warnings, including potential adverse reactions
- details of any necessary follow-up action and the circumstances
- a statement of the records to be kept for audit purposes.

5. Authorisation process

5.1 There are only 5 authorising bodies for PGDs, they are:
- Clinical commissioning groups (CCGs)
- Local authorities
- NHS trusts or NHS foundations trusts
- Special health authorities
- The NHS Commissioning Board (now called NHS England)

This means there are a number of services that Public Health within the local authority commission or could commission in the future where robust PGD processes need to be in place, for example, provision of emergency contraception in community pharmacy, supply of medicines by nurses within drug and alcohol treatment services.

5.2 There are also list of organisational requirements that support authorisation;

In order to ensure that authorisation is appropriate the commissioning organisation must ensure the following:

- For each PGD, the commissioning and provider organisation(s) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability.
- Develop or review the organisational PGD policy and associated procedures to ensure that robust and transparent processes are documented. Ensure that the PGD policy is publicly available.
- Ensure that a designated person has overall organisational responsibility for PGDs. This is usually the head of governance and can be the Director of Public Health or the Chief Executive of the Local Authority.
- Ensure that all Health and social care providers who will use the PGD comply with the Care Quality Commission’s Essential standards of quality and safety. http://www.cqc.org.uk/content/essential-standards-quality-and-safety; Where the provider is a Community Pharmacist they should comply with Standards for registered pharmacies as set by the General Pharmaceutical Council as well as quality standards set by NHS England.
- Ensure that patient safety incidents relating to PGD use are reported, collated and reviewed by the commissioning organisations in a planned programme, in line with national patient safety reporting systems and local safeguarding requirements of the Local Authority
- Agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.
- Ensure that appropriate organisational records are maintained, stored securely and archived, in line with relevant legislation and the Department of Health's code of practice on records management. These records should include:
  - patient safety incidents, such as medication errors, near misses and suspected adverse events
  - terms of reference and minutes or notes of the PGD approval group
  - a list of all PGDs in use within the organisation, including their review date and expiry date
Appendix A

- Master authorised copies of PGDs
- Expired versions of PGDs
- Members of the PGD working group
- Signatures of people signing a PGD
- A list of named, registered health professionals authorised to practise under each PGD used within the service
- Training records
- Results of monitoring and evaluation.

6. What this means for St Helens Public Health

6.1 Services which are commissioned from NHS organisations such as St. Helens and Knowsley Hospitals Trust and Bridgewater Community NHS Trust will have their own processes for signing off PGDs for nurses and other health care professionals that are part of their clinical governance processes. Smaller third sector organisations however may have the pharmacist and doctor that can develop the PGD but they will still need to be authorised by the Commissioning Organisation. Community Pharmacists and Nurses in general practices do not have the systems in place to develop PGD’s and these needs to be developed locally. There will generally there will be 3 processes for public health commissioned services that need to be followed to ensure the effective development of PGD’s, however if unsure the person should refer to NICE guidance http://www.nice.org.uk/guidance/mpg2/resources/guidance-patient-group-directions-pdf referred to in section 6.2

1. NHS acute and community trusts
   a. **No action** PGDs should be developed through internal clinical governance processes

2. Third sector providers including independent hospitals, clinics
   a. Need to clarify if the processes are in place to develop PGD’s e.g. a pharmacist and doctor
   b. If there are processes to develop PGD’s these should be agreed with the commissioner at least 4 months prior to the PGD start date for the PGD, plenty of time should be provided to ensure the process is smooth
   c. The commissioner needs to agree the process for clinical input from CCG Medicines Management Team for review of PGD’s or development of new ones
   d. Once review/PGD has been developed has taken place and the PGD’s have been agreed these can be signed off by the Director of Public Health

3. Community Pharmacies, General Practice, Third Sector Providers with no Doctor of Pharmacist
   a. Development of these PGD’s need to be managed locally, where services are being developed across the CHAMPs foot print a task group of CHAMPs can be set up to develop the PGD but a local doctor(specialist to the topic where the medicines will be used) and a pharmacist should be involved in the development. A PGD development group should be set up with clear terms of reference and authorisation process
   b. If the development of the PGD is solely a St. Helens service requirement the public health commissioner should liaise with Medicines Management of the CCG about the development of the PGD. Again this a PGD development group should be established with clear terms of reference. The final PGD will go through the CCG
Appendix A

Medicines Management Committee for a clinical view and the Clinical Quality Approvals of the CCG
c. Once clinical views have been sought both of the above can be signed off by the Director of Public Health

6.2 Patient group direction development group
The National Institute for Healthcare and Clinical Excellence have produced a document ‘Medicines practice guidelines: Patient Group Directions’, good practice for the development of PGD’s is highlighted in this document which states:

1. Establish a robust and transparent process for obtaining the agreement of the PGD i.e. authorising body (refer to section 6 for guidance locally)
2. Ensure that a multidisciplinary PGD approval group develops the PGD
3. Ensure clear line of accountability and delegated authority e.g.
   a. Terms of reference
   b. Conflicts of interest
   c. Setting agenda and minute taking
   d. Reporting arrangements
   e. Engaging stakeholders
   f. Liaising with commissioners and finance

7. Log of all PGD’s
7.1 It is good practice to keep a log of all PGD’s that have been authorised by the Director of Public Health, the drug authorised, who is authorised to use it and the dates the PGD’s will operate from and until. This should be kept up to date. The current log is stored in: G:\Public Health General\PGDs\Public Health PGDs signed off\PGD log.xls The spreadsheet will have the most recent date in the title.

7.2 All paper copies of the PGD’s should be stored with the contracts to which they relate.
Appendix A: PGD development Checklist

CHAMPS public health network provided a checklist for those authorising PGD’s as part of the process developing PGD’s across the network. This is included in this appendix as an aide to each person authorising PGDs.

For each PGD to be authorised check that the following sections have been satisfactorily covered in the PGD. It is not expected as part of authorisation to check clinical content of the PGD in detail but you should be confident that the doctor and pharmacist signatories (and anyone else involved in the development of the PGD) have adequate competency, skills and experience to carry out the role.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes/No</th>
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<tbody>
<tr>
<td>PGD is signed by a doctor (or, if appropriate, a dentist) and a pharmacist, both of whom should have been involved in developing the direction</td>
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<tr>
<td><strong>The PGD clearly states the following:</strong></td>
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<tr>
<td>the period during which the direction is to have effect</td>
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<tr>
<td>the description or class of medicinal product to which the direction relates</td>
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<tr>
<td>the clinical situations which medicinal products of that description or class may be used to treat or manage in any form</td>
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<tr>
<td>whether there are any restrictions on the quantity of medicinal product that may be sold or supplied on any one occasion and, if so, what restrictions</td>
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<td>the clinical criteria under which a person is to be eligible for treatment</td>
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<td>whether any class of person is excluded from treatment under the direction and, if so, what class of person</td>
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<tr>
<td>whether there are circumstances in which further advice should be sought from a doctor or dentist and, if so, what circumstances</td>
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<td>the pharmaceutical form or forms in which medicinal products of that description or class are to be administered or supplied</td>
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<td>the strength, or maximum strength, at which medicinal products of that description or class are to be administered or supplied</td>
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<td>the applicable dosage or maximum dosage</td>
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<td>the route of administration</td>
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<td>the frequency of administration</td>
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<td>any minimum or maximum period of administration applicable to medicinal products of that description or class</td>
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<td>whether there are any relevant warnings to note and, if so, what warnings</td>
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<tr>
<td>whether there is any follow up action to be taken in any circumstances and, if so, what action and in what circumstances</td>
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<td>arrangements for referral for medical advice</td>
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<tr>
<td>details of the records to be kept of the supply, or the administration, of products under the direction’</td>
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<tr>
<td>Appropriate qualifications and competencies of staff acting under PGD, including maintenance</td>
<td></td>
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Appendix B: Flow Chart for the development of PGD's and authorisation

1. **NHS acute and community trusts**
   - No action

2. **Third sector, independent hospital and/or clinics**
   - **Yes**
     - Provider develops PGDs and a system of liaising with Medicines Management with the CCG is developed
   - **No**
     - A group is set up either through CHAMPs or locally to develop the PGD

3. **Community Pharmacy or General Practice**
   - PGD signed off by the Director of Public Health

4. **If locally developed clinical view through Medicines Management Committee and Clinical Quality Approvals Committee**