Pennine Care
NHS Foundation Trust

DOCUMENT CONTROL	
Title:	**Patient Group Direction Policy**
Version:	**10**
Reference Number:	**CL012**

Scope:

This policy applies to nurses, midwives, optometrists, pharmacists, chiropodists, podiatrists, radiographers, physiotherapists, speech and language therapists, dieticians, occupational therapists, prosthetists, orthoptists, dental therapists, dental hygienists, orthoptists and paramedics.

They can only supply or administer medicines as named individuals and once signed-off as competent, must sign the PGD under which they are operating. They must be working for Pennine Care NHS Foundation Trust.

Purpose:

The purpose of this document is to provide written instruction for the supply and administration of a specified medicine to a group of patients who may not be individually identified before presentation for treatment in an identified clinical situation.

Requirement for Policy

Health Services Circular HSC 2000/026 Patient Group Directions.

Keywords:

PGD, Patient Group Direction

Supersedes:

Version 9

Description of Amendment(s):

General review to ensure clarity
Clarity in respect of agency/ locum staff
Update of references

Owner:

Chief Pharmacist

Individual(s) & group(s) involved in the Development:	
This document has been developed in collaboration with the following interested parties: • Elise Evans - Medicines Information Pharmacist	
Individual(s) & group(s) involved in the Consultation:	
The document has been circulated for consultation and comments have been taken into consideration and the document amended accordingly • Drugs and Therapeutics Committee	
Equality Impact Analysis:	
Date approved:	4th of December 2018
Reference:	CL012 – EIA012
Freedom of Information Exemption Assessment:	
Date approved:	12th of February 2019
Reference:	POL2018-98
Information Governance Assessment:	
Date approved:	12th of February 2019
Reference:	POL2018-98
Policy Panel:	
Date Presented to Panel:	11th February 2019
Presented by:	Lesley Smith
Date Approved by Panel:	11th February 2019
Policy Management Team tasks:	
Date uploaded to Trust's intranet:	12th February 2019
Date uploaded to Trust's internet site:	12th February 2019
Review:	
Next review date:	February 2022
Responsibility of:	Chief Pharmacist

Other Trust documentation to which this policy relates (and when appropriate should be read in conjunction with):	
CL122	Safeguarding Families Policy
CL015	Medicines Policy

Policy Associated Documents:	
TAD_CL012_01	Title of Patient Group Direction
TAD_CL012_02	Guidance on how to prepare a PGD using the PGD Template
TAD_CL012_03	Process for Changes to PGD's
TAD_CL012_04	New PGD Process
Other external documentation/resources to which this policy relates:	
CQC Regulations **This guideline supports the following CQC regulations:**	
Regulation 12	Safe care and treatment
Regulation 17	Good governance
Regulation 18	Staffing

Contents Page

1. INTRODUCTION

A Patient Group Direction (PGD) is a set of written instructions permitted in law that allows specified health care professionals (HCPs) to supply and/or administer specified medicines to patients who may/may not be individually identified before presentation for treatment, without the need to refer back to a prescriber for an individual prescription or instruction. HCPs are responsible for assessing the patient and ensuring that the patient fits the criteria specified in the PGD (they cannot deviate from them). PGDs are designed for short-term use, and are not intended to be used for planned treatment. Unlike prescribing, registered HCPs entitled to work with a PGD require no additional formal qualifications, however organisations have a responsibility to ensure that only fully competent and trained registered HCPs use them.

A PGD should only be developed where there are clear benefits of patient care. Patient Group Directions (NICE guideline MPG2) (2013) states that the majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under PGDs should be 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.

Using a PGD is not a form of prescribing. The supply and/or administration of medicines under a PGD cannot be delegated. A PGD is not meant to be a long-term means of managing a patient's clinical condition.

This policy has been written to provide guidance on all aspects of developing, implementing and auditing PGDs within Pennine Care NHS Foundation Trust.

This policy covers the development and use of PGDs for patients of Pennine Care NHS Foundation Trust.

2. PURPOSE

The purpose of this document is to provide written instruction for the supply and administration of a specified medicine to a group of patients who may not be individually identified before presentation for treatment in an identified clinical situation.

3. RESPONSIBILITIES, ACCOUNTABILITIES AND DUTIES

Healthcare professionals must only undertake their role under PGD where they are competent to assess all aspects of the patient’s clinical condition and take responsibility for the supply, administration and related decisions.

A healthcare professional authorised to supply and administer under PGD cannot delegate the task to another member of staff.

Healthcare professionals must act within their appropriate Code of Professional Conduct.

4. THE DEVELOPMENT OF A PGD

PGDs can be developed by any specialist multidisciplinary group either in a single ward, department, division, directorate or community health borough/ service. PGD may also be developed in conjunction with other colleagues. The group **must** include a representative OR representatives of the professional group expected to supply / administer the medicine under the PGD, a pharmacist and / or a Medical Officer.

Development of a PGD should not be initiated until managerial approval to proceed has been obtained.

Any manager giving approval should contact the Chief Pharmacist's office OR the Medicines Management Team to register the intention to develop a PGD.

The content and format of PGDs must comply with the Trust template for PGDs (TAD_CL012_01), https://www.penninecare.nhs.uk/media/1042/patient-group-directions-policy-v8.pdf

Guidance on how to prepare a PGD using the PGD template is available (TAD_CL012_02), https://www.penninecare.nhs.uk/media/1042/patient-group-directions-policy-v8.pdf

The Patient Group Direction sub- group of the Drugs and Therapeutics Committee reviews, approves and provides support to staff developing PGDs to ensure they are clinically correct and comply fully with the regulations.

5. MANAGEMENT OF PGD'S

Staff involved in the writing of the PGD, a pharmacist and / or a Medical Officer must sign the PGD to approve the use of the PGD in the clinical area.

PGDs should be reviewed by Organisational Learning and Development (OL&D) prior to submission for approval if they contain reference to learning and development.

PGDs will be submitted to the Patient Group Direction sub-group (mental health and community health services) of the Drugs and Therapeutics Committee for review and approval and then authorised by the Medical Director, Director of Nursing and Chief Pharmacist.

A senior person within the service using the PGD should be designated to take responsibility for ensuring that only fully competent qualified and trained professionals operate within the PGD.

The Chief Pharmacists office OR the Medicines Management Team will be responsible for distributing PGDs in line with current arrangements for policy distribution. An electronic version of all PGDs will be available via the Trust's Intranet.

The original paper copies of all signed off PGDs will be lodged with the Chief Pharmacist's office and an electronic version uploaded on to the trust intranet

Each ward, department, division, directorate or community health borough/ service will maintain a current list of professionals approved to supply and administer medicines under a PGD.

There must be comprehensive arrangements for the security, storage and labelling of all medicines and a secure system for recording and monitoring medicine use from which it should be possible to reconcile incoming and outgoing stock on a patient by patient basis.

The names of the health professionals providing treatment, patient identifiers and medicine provider should all be recorded.

Only employees of the Trust and Registered Nurses contracted to work via the Central Trust Staffing Department (Trust Bank) may administer medicines under a PGD. All such staff must have been assessed as competent to work under the latest version of a particular PGD.

Agency and locum staff may administer medicines under a PGD if they have been assessed as competent to do so.

6. THE CONTENT OF A PGD

Each PGD must include the following information:

- The name of the location or speciality to which the direction applies
- 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 supporting medical officer OR pharmacist
- Authorisation by the Trust (signature of Medical Director, Director of Nursing and Chief Pharmacist)
- The clinical condition or situation to which the direction applies
- A description of those patients excluded from treatment under the PGD
- A description of the circumstances in which further advice should be sought from a doctor or other healthcare professional and arrangements for referral
- 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 record for the supply and administration of medicines under a PGD must be kept for audit purposes

- Details of any training associated with being able to administer treatment under the PGD

The content and format of PGDs must comply with the Trust template for PGDs (TAD_CL012_01).

https://www.penninecare.nhs.uk/media/1042/patient-group-directions-policy-v8.pdf

7. LEARNING OUTCOMES / COMPETENCE

Learning outcomes and how competence will be assessed must be specified in each PGD.

Healthcare professionals supplying or administering medicines under PGD must be named and have evidence of competence, training, knowledge, experience and continuing education relevant to the clinical condition to which the PGD applies. This must be done for each subsequent version of the PGD.

Each member of staff trained and deemed competent to use the PGD should have a signed copy of the direction.

The manager responsible for the clinical area in which the PGD is used must be able to demonstrate that systems are in place for training and assessment of competence and updating these when a new version of the PGD is approved.

8. EXCLUSIONS

Medicines used outside of their licence (off-label usage) will not be included in PGDs unless it is well established in clinical practice and widely supported in the medical literature e.g. Levonelle.

Unlicensed medicines i.e. those without a UK Medicines and Healthcare Products Regulatory Agency (MHRA) marketing authorisation and medical devices (products with a 'CE' mark) cannot be included in a PGD.

Certain medicines for emergency use e.g. adrenaline used in the treatment of anaphylaxis do not need a PGD.

Controlled drugs, except those contained in Schedule 4 (Part 1) and schedule 5 of the Misuse of Drugs Act 1971, will not be included in PGDs.

Medicines with black triangle status ▼ (that is recently licensed and/or subject to special reporting arrangements for adverse reactions) will not be included in PGDs unless that use is well established in clinical practice and widely supported in the medical literature e.g. Fluenz Tetra influenza vaccine

9. NEW PGD'S

A healthcare professional who identifies the need for a new PGD must consult with their team and Medicines Management to discuss this further (refer to TAD_CL012_04 for the process).

10. WITHDRAWAL OF PGD'S

In the event of the need to withdraw a PGD the Chief Pharmacist / Medicines Management will liaise with the manager concerned for this to be carried out.

11. IMPLEMENTATION AND TRAINING

The Trust will ensure that the Patient Group Directions Policy has been issued and implemented as follows:

Issue and Implementation

- A variety of dissemination methods are in place to make sure that all staff are aware of, have access to and comply with, the Patient Group Directions Policy.
- Lists of all new policies are published in the Trust's Corporate Brief including a brief description and its intended audience.
- All policies are held on the Trust's intranet to which all staff have access. Staff should always consult the intranet for the latest version.
- All approved PGDs are held on the Trust's intranet under the Medicines Management site to which all staff have access.
- Where a hard copy is kept on a ward/clinical area, it is the responsibility of the Ward Manager/Team Leader to ensure that the current version is on file.
- Following approval, the Chief Pharmacist / Medicines Management is responsible for cascading details of the latest version of all policies to all healthcare professionals.
- Ward and team managers are responsible for ensuring staff in their area of managerial control are fully aware of the content of the Patient Group Directions Policy.
- All healthcare staff are responsible for ensuring they understand the content of the Patient Group Directions Policy and to act accordingly.

Training

Training in medicines management and in relation to the Patient Group Directions Policy forms part of the Trust's mandatory and essential training programme for identified staff groups.

The format of the mandatory medicines management training is described as per the Trust Training Needs Analysis.

Checking and monitoring of non-completion of mandatory medicines management training is undertaken by the Learning and Development Department.

Where pharmacy staff provide additional training on medicines on an ad hoc basis or at the request of managers within the Trust, attendance records will be completed and forwarded to the Training Department for inclusion on the Training database.

Pharmacy staff input on an ongoing basis to the induction programme of junior medical staff.

Further training will be made available when necessary to support initiative of the National Reporting and Learning System (NRLS) and/or NICE along with other training required to be compliant with the PGD.

Training required for individual members of staff is identified through the Trust's IPDR process and arranged as appropriate. Any non- attendance is reported via e-mail from the Learning and Development department to the individual's authorising manager for action and future attendance to be arranged.

12. EQUALITY IMPACT ANALYSIS

As part of its development, this document was analysed to consider / challenge and address any detrimental impact the policy may have on individuals and or groups protected by the Equality Act 2010. This analysis has been undertaken and recorded using the Trust's analysis tool, and appropriate measures will be taken to remove barriers and advance equality of opportunity in the delivery of this policy / procedure

13. FREEDOM OF INFORMATION EXEMPTION ASSESSMENT

Under the Freedom of Information Act (2000) we are obliged to publish our policies on the Trust's website, unless an exemption from disclosure applies. As part of its development, this policy was assessed to establish if it was suitable for publication under this legislation. The assessment aims to establish if disclosure of the policy could cause prejudice or harm to the Trust, or its staff, patients, or partners. This assessment has been undertaken using the Trust's Freedom of Information Exemption Guide, and will be reviewed upon each policy review.

14. INFORMATION GOVERNANCE ASSESSMENT

This Policy has been analysed to ensure it is compliant with relevant information law and standards as in place at the time of approval, and are consistent with the Trust's interpretation and implementation of information governance components such as data protection, confidentiality, consent, information risk, and records management.

Compliance will be reviewed against any changes to legislation / standards or at the next review of this document.

15. SAFEGUARDING

All staff have a responsibility to promote the welfare of any child, young person or vulnerable adult they come into contact with and in cases where there are safeguarding concerns, to act upon them and protect the individual from harm.

All staff should refer any safeguarding issues to their manager and escalate accordingly in line with the Trust Safeguarding Families Policy and Local Safeguarding Children/Adult Board processes.

16. MONITORING

The effective application of this policy, including adherence to any standards identified within will be subject to monitoring using an appropriate methodology and design, such as clinical audit.

Monitoring will take place on a biannual basis and will be reportable to the Quality Group via the Clinical Effectiveness and Quality Improvement Team.

Compliance with this policy will be monitored using an analysis of incidents and complaints, by the Managing Prescribing Risk group on a quarterly basis, where there has been a failure to follow procedure.

Quarterly medication error/incident reports (Safeguard) prepared and reviewed by Managing Prescribing Risk group Analysis allows identification of trends and themes.

Action plans to manage improvement in compliance will be developed by the Managing Prescribing Risk group on a quarterly basis where necessary.

Key findings of both audit and monitoring of compliance will be reported to the Drugs and Therapeutics Committee Part 2.

The Learning and Development department will provide a monthly report to Service Line Managers detailing staff attendance at required training. In addition the Learning and Development department will provide a six monthly report of staff attendance for all required training to the Educational Governance group for monitoring. The Educational Governance Group will be responsible for the development of any actions required in relation to training which will be implemented and monitored by Divisional and Borough Integrated Governance Groups.

17. REVIEW

This policy will be reviewed three-yearly unless there is a need to do so prior to this; e.g. change in national guidance.

18. REFERENCES

NHS Executive, 2000. *Patient Group Directions [England only].* London: Department of Health. Health Services Circular HSC 2000/026 Available from: http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf [Accessed 5 February 2019]

NICE, 2013. *Medicines practice guideline (MPG 2): patient group directions*. London: NICE. Available from: https://www.nice.org.uk/guidance/mpg2 [Accessed 5 February 2019]

Specialist Pharmacy Service, 2018. *To PGD or not to PGD? That is the question: a guide to choosing the best option for individual situations*. Specialist Pharmacy Service. Available from: https://www.sps.nhs.uk/articles/to-pgd-or-not-to-pgd-that-is-the-question/ [Accessed 5 February 2019]

Specialist Pharmacy Service, 2018. *When is a PGD not necessary?* Specialist Pharmacy Service. Available from:

https://www.sps.nhs.uk/articles/when-is-a-pgd-not-necessary/ [Accessed 5 February 2019]

Equality Act 2010

Freedom of Information Act 2000