NHS
Suffolk and
North East Essex

Patient Group Directions Policy

1. Introduction

1.1. The preferred way for patients to receive medicines is for an appropriately qualified health care professional to prescribe for an individual patient-specific basis. The use of Patient Group Directions (PGDs) should be limited to specific situations where they offer an advantage to patient care, without compromising patient safety, and where there are clear governance arrangements and accountability. A PGD should not be used when it is reasonable to expect that a prescription (FP10) or a PSD (patient specific direction) could be obtained.

1.2. PGDs provide a legal framework that allows some registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber (such as a doctor or nurse prescriber).

1.3. Many providers can both develop and legally authorise their own PGDs. However, some providers, whilst they can develop their own PGDs in line with NICE guidance, are not, under the current legislation, legally able to authorise them for use. In such circumstances the ICB can authorise the PGDs for use in the services which they commission and that is when this policy is applicable.

1.4. As a commissioner, the Integrated Care Board (ICB) must confirm that the PGD development and organisational process is thorough and has the correct signatories before it can legally authorise the PGD for use. It is the responsibility of the organisation developing the PGD to assure governance around clinical content.

1.5. Legislation establishing PGDs was introduced in 2000 and the Health Service Circular (HSC 2000/026) provided additional guidance. The current legislation for PGDs is included in The Human Medicines Regulations 2012 and subsequent amendments.

2. Purpose

2.1. The purpose of this policy is to

- set out the process for the identification, development, dissemination, implementation, monitoring, audit, and review of PGDs.
- provide the framework for service, clinical and professional leads to assist in the identification of and outline the process for the development of PGDs.
- outline the role the ICB has in the authorisation of PGDs used to support NHS health care services commissioned by the ICB.
- provide a robust approach across the whole organisation, and incorporates the recommendations made in the Patient Group Directions NICE Guideline (MPG2) NICE August 2013 (updated March 2017).

3. Scope

3.1. PGDs are usually developed by healthcare providers to support delivery of healthcare services purchased by the ICB.

3.2. This policy will not apply to providers or commissioners who are able to develop and authorise their own PGD under legislation.

3.3. The development of PGDs for privately funded services will not be supported by the ICB.

3.4. Where expedient to do so, the ICB may develop PGDs to be used by providers for services it commissions. Where this is required, the PGD will be developed in line with this policy and NICE guidance.
3.5. SNEE ICB may, with permission, adopt and use PGDs developed/authorised by another organisation.
3.6. It must be noted that a PGD is not an authorisation to prescribe. A PGD is an authorisation to administer a medication or make a supply of a medicine to a patient to self- administer in accordance with the defined circumstances and criteria. Failure to comply with the criteria falls outside the law and could result in criminal prosecution.

4. General Principles

4.1. Providers must have in place their own PGD policy as part of a suite of Medicines Management/Medicines Optimisation policies to support safe handling of medication.
4.2. PGDs developed by providers who are not legally able to authorise them must be clinically signed off by the provider organisation before being submitted to the ICB for authorisation.
4.3. The organisation developing the PGD ('owner') is responsible for the clinical content of PGDs it develops; the provider implementing the PGD is responsible for ensuring that staff are trained and competent to operate the PGDs and for ensuring that appropriate governance and audit of development and management of PGDs is in place. A competency framework is available.
4.4. The ICB expects that providers will, whenever possible, use nationally developed template PGDs e.g., immunisations and vaccinations if available, and only develop their own PGDs if suitable national/commissioner versions are not available.
4.5. Providers requiring ICB commissioner authorisation must submit their PGDs to the ICB via the Medicines Optimisation team. See Authorisation Process (Section 6).

5. Development and management of PGDs

5.1 Developing PGDs requires a detailed knowledge of the service being delivered, the staff training requirements and the cohort of patients presenting for treatment.
5.2 PGDs must be produced in the light of current best practice. Supporting references should be included in the PGD document with links to the full references available electronically.
5.3 The NHS Specialist Pharmacy Service (SPS) provides useful guidance for organisations and potential authors and signatories of PGDs as a prompt, to think about and follow necessary procedures before and during the stages of developing and authorising PGDs.

5.4 **Identifying the need for a PGD**: The NHS SPS Guidance 'When PGDs can be used' and 'When not to use a PGD' should be used to establish if a PGD is legal and/or appropriate.

5.5 **Medicines That May Be Included in A Patient Group Direction**

- Not all medicines are suitable to be included in a PGD.
- A PGD cannot be used for:
  - unlicensed medicines
  - dressings, appliances and devices
  - radiopharmaceuticals
  - abortifacients, such as mifepristone.

- Controlled drugs, black triangle medicines and off-label use of a licensed medicine should be included in a PGD only when clearly justified by best clinical practice and

legally permitted. The PGD must state when the product is being used outside the terms of the SPC and why this is necessary or if it is a black triangle medicine.

- Only certain controlled drugs can be included in a PGD according to The Misuse of Drugs Regulations (2001). The NHS SPS provides useful information on the Supply and/or administration of Controlled Drugs under a PGD.

- A PGD should only be used for antibiotics:
  - if clinically essential and clearly justified by best practice guidance
  - a local Consultant Medical Microbiologist or another doctor with equivalent knowledge has agreed that a PGD is needed and this is clearly documented
  - the use of the PGD is monitored and reviewed regularly.

- In accordance with NICE guidance (MPG2), medicines needing frequent dosage adjustments or frequent or complex monitoring, should not be included in a PGD.

- Risk Minimisation Measures (RMM) are a regulatory requirement for some medicines and are a critical part of the product licence (marketing authorisation) to help maintain a favourable benefit-risk profile. Medicines with a requirement for RMM may not be suitable for inclusion in a Patient Group Direction (PGD)If a decision is taken to include a medicine with RMM in a PGD, the requirements of the RMM must be included in the PGD.

- The administration of a P or GSL medicine does not require a PGD.

5.6 **Obtaining agreement to develop a PGD**

- Once the need for a PGD is established, an application for permission to develop a PGD should be completed and submitted via email to the Suffolk and North East Essex Integrated Medicines Optimisation Committee (IMOC) via imoc@snee.nhs.uk . This must list the individuals who will form part of the PGD working group.
- Controlled drugs, black triangle medicines and off-label use of a licensed medicine should be included in a PGD only when clearly justified by best clinical practice and legally permitted.
- A PGD should only be used for antibiotics if clinically essential and clearly justified by best practice guidance. A local Consultant Medical Microbiologist or another doctor with equivalent knowledge has agreed that a PGD is needed and this is clearly documented and the use of the PGD is monitored and reviewed regularly.
- If the request for PGD development is supported by IMOC, approval should be communicated in writing, including any feedback/criteria specified by the committee.

5.7 **Who should be involved?**

- 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'. The NICE MPG2 calls this the 'PGD Working Group'.
- The organisation developing the PGD ('owner') will ensure that a named lead author has responsibility for developing a PGD, supported by a locally determined multidisciplinary PGD working group. The responsibility for the membership of the PGD Working Group will lie with the organisation developing the PGD ('owner'). Where the owner is the ICB, the ICB will

coordinate the working group membership. It is expected that the PGD Working Group is set up in line with NICE MPG2 Recommendations 2.3 'Developing Patient Group Directions'.

- Review and renewal of PGDs should be done by the PGD Working Group.
- Where the PGD has been developed by the ICB, the PGD working group will not include members of the ICB authorisation/review group. The PGD must be clinically signed off before it is submitted to the ICB authorisation/review group.

5.8 **Who Is Permitted to Use Patient Group Directions**

- PGDs must only be used by those qualified registered health care professionals listed in the current legislation:
    - Pharmacists.
    - Registered chiropodists and podiatrists.
    - Registered dental hygienist.
    - Registered dental therapist.
    - Registered dietitians.
    - Registered midwives.
    - Registered nurses.
    - Registered occupational therapists.
    - Registered optometrists.
    - Registered orthoptists.
    - Registered orthotists and prosthetists.
    - Registered paramedics.
    - Registered pharmacy technicians.
    - Registered physiotherapists.
    - Registered radiographers.
    - Registered speech and language therapists.
- Staff authorised can only use PGDs as named individuals.
- The organisation using the PGD should ensure a senior person in each profession locally is designated with the responsibility to ensure that only fully competent, registered, and trained professionals operate within directions.

5.9 **Developing PGDs**

- PGD must be developed in accordance with legislation and national guidance as listed below (this is not an exhaustive list):
    - MHRA Patient group directions (PGDs) Guidance
    - Human Medicines Regulations 2012
    - NICE MPG2 Patient Group Directions
    - Specialist Pharmacy Service Patient Group Directions resources
    - British National Formulary (current online edition)
    - Immunisation against Infectious Disease (The Green Book) (current online edition)
    - The Misuse of Drugs Regulations 2001.

- Any PGD must follow the proforma as laid out in NICE guidance.
- Any PGD must:
    - Contain the names and signatures of the working group, including the Lead author/Practitioners, Pharmacist(s) and Doctor(s) who developed the PGD and are responsible for signing off the clinical content of the PGD.
    - Recognise that administration and supply under PGD must only be undertaken by approved practitioners where there are clear benefits of improved patient care or organisational advantages without any reduction in patient care.

- Specify the additional training process and competency for approval a practitioner must undergo before authority is granted to that individual to supply and/or administer under a PGD, as an approved practitioner. This will be developed by the (provider) working group developing the PGD and approved as part of the PGD approval process.
- Specify the mechanism and time scale for regular updating of knowledge and review of relevant skill and knowledge of approved practitioners.
- Refer to an audit process by which administration and supply can be monitored.
- Contain a means of reporting and recording errors and incidents relating to administration and supply by an approved practitioner.
- Specify the review period and mechanism of review for the PGD.

▪ It is the responsibility of the organisation developing the PGD to assure governance around clinical content.

6 Authorisation of Patient Group Directions

6.1 The ICB review group is a virtual group and meets as and when required. It is responsible for assuring and authorising PGDs that are prepared by provider organisations or developed by the ICB for providers it commissions - See flow chart (Appendix 1). This will not apply to providers or commissioners who are able to develop and authorise their own PGDs under legislation.

6.2 The ICB PGD review group is a subcommittee of the Integrated Medicines Optimisation committee (IMOC).

6.3 **Organisational Authorisation for PGDs is dependent on review by the ICB group.**

6.4 **ICB PGD review group members:**

- Director Medicines Optimisation & Pharmacy (chair)
- Associate Medical Director – Medicines Optimisation
- Alliance Chief Pharmacist
- Alliance Deputy Chief Pharmacist – Quality & Safety Lead
- Quality/patient safety lead-nurse

In addition, if appropriate

- Clinician with expertise in the clinical area (this may be a representative from the provider organisation who would therefore be excluded from the authorisation process).
- A member of a representative body where the PGD will be implemented, e.g. Community Pharmacy England.
- Lead author for PGDs (not involved in the authorisation process).
- Other ICB pharmacist co-opted by review group (expert in relevant field, optional).

6.5 Responsibilities of this group are:

- To ensure that this ICB PGD process is applied and that appropriate governance relating to PGD preparation is in place by the organisation preparing the PGD.
- To review all PGD documentation submitted and inform the PGD authorisation decision by assuring the safety and quality of the PGD including the development process.

- To feedback to the PGD working group and ensure that appropriate action is taken where issues relating to the PGD have been identified.
- To ensure that the provider organisation has an appropriate audit process in place to assure safe and effective service provision using the PGD.
- To ensure that the equality impact of the PGD has been considered and appropriately addressed.

6.6 The chair of the review group has designated responsibility for signing PGDs on behalf of the authorising body.

- The responsibilities of the chair of the review group are to be assured that:
  - The PGD has been agreed as the most appropriate mechanism for supply and administration of the medicine.
  - Patient treatment and care is optimised by using a PGD pathway rather than reverting to a standard prescription.
  - Local processes and governance arrangements have been followed.
  - The views of all stakeholders have been considered.
  - Legal requirements have been met.

6.7 The decision to authorise the PGD by the chair of the review group will be ratified by the SNEE Integrated Medicines Optimisation Committee (IMOC).

6.8 The chair of the PGD review group is responsible for submitting PGDs to the SNEE IMOC for ratification.

6.9 The Medicines Optimisation Team will keep a copy of all PGDs authorised by the ICB.

6.10 Until authorised by the ICB PGD review group, a PGD or amendments to an existing PGD are invalid. The ICB accepts no responsibility for an approved practitioner who acts in accordance with a PGD not authorised as above or acts in accordance with an expired/superseded PGD.

6.11 Providers have full responsibility and legal liability for management of practitioners working to PGDs within services they are delivering.

7 Implementation

7.1 The Provider will make available any necessary additional training to meet the required competencies before individuals shall be authorised to work under a PGD and have the responsibility for identifying appropriately qualified and trained healthcare professionals to operate within the PGD.

7.2 The Provider will ensure that each identified healthcare professional is competent to operate the PGD and has received any additional training deemed necessary, and has been formally authorised to operate the PGD, including completion of all necessary documentation.

7.3 The Provider will ensure that a copy of each authorised PGD is available within the service area where it is in use for immediate reference of staff.

8 Governance Arrangements

8.1 PGDs will be authorised and ratified as laid out in section 6 (Authorisation of PGDs).

8.2 PGDs are valid for up to three years after authorisation. A robust process must be in place to assure PGD review. Review and renewal of PGDs should be done by the owner organisation PGD Working Group and does not fall within the remit of the ICB PGD group. All PGDs should include the following information to ensure good governance: when it was written, who by, when it was authorised and when it expires. An unscheduled review of a PGD may arise such as due to a change in the licence of the product, new national guidelines, following a patient safety incident or other important new evidence which requires changes in clinical practice under the PGD.

8.3 The final authorised PGDs must be kept for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children.

8.4 It is the responsibility of the Provider service lead to monitor and audit the use of PGDs within their service setting.

8.5 The Chair of the PGD review group is responsible for maintaining a log of all PGDs authorised by the ICB PGD review group and their review dates and a copy of the original signed PGD.

Appendix 1: PGD development and authorisation process

