Somerset Partnership NHS
NHS Foundation Trust

PATIENT GROUP DIRECTIONS POLICY

To be read in conjunction with the Medicines Policy

and the Controlled Drugs Policy

Version:	5
Ratified by:	Senior Managers Operations Group
Date ratified:	August 2015 **October 2016 (Amendment)**
Title of originator/ author:	Chief Pharmacist - Head of Medicines Management
Title of responsible committee/group:	Drugs and Therapeutics Group
Date issued:	**August 2015 (November 2016)**
Review date:	**July 2018**
Relevant staff groups:	All registered health care professionals involved in producing or working under Patient Group Directions

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DOCUMENT CONTROL

Reference SDB/Aug15/PGDP	**Version** 4	**Status** Final	**Author** Head of Medicines Management
Amendments	Incorporating mental health and community health directorate policies into one. Reviewed and amendments integrated from D&T Group, PGD Review Group.		
Document objectives: This document outlines the process to be followed within the Trust for the development and implementation of Patient Group Directions (PGD) to ensure that the practice it supports is within the law and has the approval of the Trust.			
Intended recipients: All registered health care professionals involved in assessing the need for, developing and administering and / or supplying medication under a Patient Group Direction.			
Committee/Group Consulted: Drugs and Therapeutics Group, Clinical Policy Review Group, PGD Review Group, Clinical Governance Group			
Monitoring arrangements and indicators: Line managers will review the use of PGDs by individual practitioners at annual appraisal. An audit report on the use of each PGD will be provided to the Drug and Therapeutics Group every two years prior to review and re-authorisation.			
Training/resource implications: Administrative resource required to maintain the database of PGDs and individuals authorised to use each PGD in each relevant service. Medicines Management Team and other relevant professional group resource required to enable development of new PGDs and timely review of existing ones. Resources to ensure training is provided and relevant staff competencies for staff providing care using PGDs can be assured.			

Approving body and date	Clinical Governance Group	Date: July 2015 September 2016
Formal Impact Assessment	Impact Part 1	Date: June 2015
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Date of issue	**August 2015 (November 2016)**	
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Contact for review	Chief Pharmacist – Head of Medicines Management	
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CONTENTS

1. INTRODUCTION

1.1. This document outlines the process to be followed within the Trust for the development and implementation of Patient Group Directions (PGDs) to ensure that the practice it supports is within the law and has the approval of the Trust.

1.2. Modifications to the Medicines Act 1968 in 2000 formalised previous practices where supply and / or administration of medicines to certain patients under what were previously known as 'group protocols' the legal term for such became 'Patient Group Directions'.

1.3. Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

1.4. PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need or a prescription or an instruction from a prescriber. Using a PGD is not a form of prescribing.

1.5. The purpose of using a PGD is to:

- deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
- offer a significant advantage to patient care by improving access to appropriate medicines
- provide equity in the availability and quality of services when other options for supplying and / or administering medicines are not available
- provide a safe legal framework to protect patients
- reduce delays in treatment
- maximise the use of the skills of a range of health professionals.

1.6. The Human Medicines Regulations 2012 (as amended) consolidated the law concerning medical products for human use, including a majority of the legislation pertaining to PGDs, replacing most of the Medicines Act 1968 and a number of statutory instruments.

2. PURPOSE AND SCOPE

2.1. This policy applies to all Trust staff who may:

- assess the need for a Patient Group Direction within their service
- develop a Patient Group Direction
- legally supply or administer medicines under a Patient Group Direction.

2.2. All registered health care professionals groups that are authorised under Schedule 16 Part 4 of the Human Medicines Regulations 2012 (as amended) are permitted to supply or administer medicines under a Patient Group Direction as part of their clinical activities for the Trust when all other legal and Trust requirements have been met.

2.3. UK legislation may be amended in the future to included further qualified healthcare professional groups and this policy will be deemed to have been extended to includes these groups

2.4. The above professionals may only supply or administer medicines under a Patient Group Direction as named individuals.

3. DUTIES AND RESPONSIBILITIES

3.1. The **Trust Board** has a duty to care for patients receiving care and treatment from the Trust and has overall responsibility for procedural documents and delegates responsibility as appropriate.

3.2. The **Lead Director** is the **Medical Director** with devolved responsibility for the implementation of this policy.

- The **Medical Director** is one of the final statutory authorising signatories for approved PGDs to validate organisational approval.
- The **Medical Director** or their nominated senior doctor or dentist employed by the Trust is one of the final statutory authorising signatories for approved PGDs. Delegation of this responsibility to a senior doctor other than the Medical Director requires ratification by the Clinical Governance Group.

3.3. The **Chief Pharmacist** or their nominated senior pharmacist employed by the Trust is responsible as one of the final statutory authorising signatories for approved PGDs. Delegation of this responsibility to a senior pharmacist other than the Chief Pharmacist requires ratification by the Clinical Governance Group.

3.4. The **Consultant Microbiologist** is the microbiologist approved by the Trust for statutorily required contribution to development of PGDs for antimicrobial agents and as one of the final authorising signatories for approved PGDs for antimicrobial agents.

3.5. The **Identified Lead (Author)** will be responsible for producing written drafts of the document and for consulting with others and amending the draft as appropriate.

3.6. **Heads of Service / Senior Managers** have responsibility for implementing this policy and for ensuring high standards of clinical healthcare within the service for which they have overall responsibility and to ensure adherence to this policy.

3.7. **Line Managers** will ensure that staff adhere to this policy and are appropriately trained and competency assessed according to the policy.

3.8. Before a healthcare professional can supply or administer medicines under a specific patient group direction they must be “authorised” by their **line manager** and named in the patient group direction held within the area of practice.

3.9. To authorise a healthcare professional to use a PGD the **line manager** must:

- agree to operate in this extended role
- have completed the Trust Patient Group Direction training
- have written evidence of competence, training, knowledge, experience and continuing education relevant to the clinical conditions/situation to which the Patient Group Direction applies.

3.10. **All staff including temporary staff** are individually responsible for their actions including complying with this policy and undertaking any training and competency assessments in line with this policy.

3.11. It must be acknowledged by all members of staff that the interests and safety of every patient are paramount.

3.12. The extended role, with regard to administration and supply under PGDs, is not compulsory and each practitioner has the ability to exercise personal and professional judgement as to whether to accept the responsibility that the extended role will place upon them.

3.13. All **authorised practitioners** must only undertake the extended role under PGDs in circumstances where they are competent to assess all relevant aspects of the patient's clinical condition and take responsibility for supply, administration and related decisions.

- No **authorised practitioner** should undertake any aspect of patient care for which they are not trained and which is beyond their professional scope of practice. If the authorised practitioner is in any doubt about their competency they should not administer or supply in accordance with the PGDs and should seek advice.
- The **authorised practitioner** undertaking this extended role must do so in accordance with the appropriate current PGD.
- All **authorised practitioners** must act within their Professional Code of Conduct, be trained and assessed as competent in the use of PGDs.

NOTE: An authorised practitioner's delegated authority to supply and administer under a PGD cannot be re-delegated.

3.14. The **appropriate professional lead** is responsible for ensuring that only fully competent, qualified and trained healthcare professionals operate within a PGD.

3.15. **PGD authors** are responsible for ensuring that they have the appropriate training and theory competency to undertake this role. This requires completion of the Trust PGD Training Package and the theory component of the PGD Competency Assessment.

3.16. The **Patient Group Direction Review Group** has the role and function of a 'PGD working group' (as defined by NICE MPG2) and are responsible for the management of the review and updating of PGD process.

4. The **Medicines Oversight Group** acts on behalf of the Trust Board to ratify a PGD after all the legal requirements for authorisation have been me and act as the 'PGD approval group' (as defined by NICE MPG2).

EXPLANATIONS OF TERMS USED

4.1. **Patient Group Direction** is defined under Health Service Circular (HSC 2000/26) and can be defined as:

> *"a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is developed locally by doctors, pharmacists and other appropriate professionals, approved by the employer and advised by the relevant professional advisory committees. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment."*

4.1.1 A Patient Group Direction is NOT an authorisation to prescribe. It is NOT Non-medical Prescribing.

4.1.2 It must not be confused with a written direction as defined under the Medicines Act 1968 and the Prescription Only Medicine (Human Use) Order 1997 (SI 1997/1830) which is a Patient Specific Direction (PSD).

4.2. An authorised practitioner can be defined as:

> *A registered professional who is legally allowed to supply or administer medication under a Patient Group Direction, who has completed the Trust approved PGD training package, been assessed as competent in both the legal aspects of PGDs and the individual PGD as well as being authorised by their line manager to use an individual PGD.*

4.3. The roles and functions of the 'PGD working group', as defined under the relevant NICE Medicines Practice Guidance, is undertaken by the PGD Review Group and is a locally determined multidisciplinary group established for each individual PGD. The PGD Review Group is responsible for developing the PGD and its subsequent review and updating.

4.4. The roles and functions of the 'PGD approval group', as defined under the relevant NICE Medicines Practice Guidance, is undertaken by the Drug and Therapeutics Group and is a locally determined multidisciplinary group that considers and ratifies a proposed PGD on behalf of the Trust.

5. STATEMENT OF POLICY AND GUIDANCE

5.1. Appropriate Use of PGDs

5.1.1. The majority of clinical care should be provided on an individual patient specific basis. The supply and administration of medicines under Patient Group Direction should be reserved for those limited situations where this offers an advantage to patient care without compromising patient safety and be consistent with appropriate professional relationships and accountability (NICE Medicines Practice Guidance (MPG2): Patient Group Directions (Aug-13) as amended).

5.1.2. PGDs apply only to licensed medicines. Appliances and dressings can not be supplied or administered under a PGD. Although not legally required the Trust may, in exceptional circumstances, make a clinical governance decision to develop a PGD for:

- a medical device where that device contains a medicinal product

- administration of a GSL (General Sales List) or P (Pharmacy only) medicine or a medical gas
- supply of a GSL medicine.

5.1.3. The following drugs should **not** be included in Patient Group Directions:

- medicines unlicensed in the UK
- radiopharmaceuticals
- medicines which are not approved for use within the Trust
- **administration or supply** of Schedule 2 or 3 Controlled Drugs
- where exemptions from medicines legislation obviate the need for PSDs or PGDs

5.1.4. The following drugs can be included in Patient Group Directions in the circumstances outlined below:

- new drugs under intensive monitoring and subject to special adverse drug reaction reporting requirements ('Black Triangle drugs' ▼) – use must be supported by current best clinical practice. The PGD must state that a black triangle medicine is included and should refer to any supporting guidelines / written evidence
- medicines being used outside their licensed indications ('off-label indications') only when the indication is justified by current best practice as described in other Trust documentation, NICE guidance, or other nationally recognised guidance.
- morphine and diamorphine injection – **administration** by a nurse or pharmacist for the immediate necessary treatment of sick or injured persons
- midazolam and schedule 4 Part 1 CDs – oral preparations only, not an anabolic steroid and not for the treatment of addiction.

5.1.5. The inclusion of antimicrobial agents in a Patient Group Direction must be absolutely necessary and not jeopardise strategies to combat increasing resistance. A Consultant Microbiologist must be part of the multidisciplinary group developing the Patient Group Direction where it includes antimicrobial therapies.

5.2. Developing Patient Group Directions

5.2.1. PGDs will only be developed, in addition to conditions set out in Section 5.1 above, for medicines meeting at least one of the following criteria:

- The medicinal product is approved for use for the proposed indication and in the proposed patient group in the Somerset Prescribing Formulary, or
- The medicinal product is approved for use for the proposed indication and in the proposed patient group by Somerset Partnership NHS Foundation Drug and Therapeutics Group or
- Evidence can be presented that use of the medicinal product for the proposed indication and in the proposed patient group is accepted good practice

5.2.2. Anyone wanting to develop a Patient Group Direction (PGD) within their locality/speciality must first discuss the implications with their locality/speciality clinical lead and / or service manager, including potential training issues and costs.

5.2.3. A proposal form (Appendix A) should be completed submitted to the PGD Review Group (see form) for consideration.

5.2.4. Once approval for development of the PGD has been granted the lead author should draft a PGD for consideration by the PGD Review Group.

5.2.5. If a proposal for the development of a PGD is rejected by the PGD Review Group the proposer has the right of appeal to the PGD Review Group providing:

- Appeals are made within 30 calendar days of receipt of notification of the rejection of the proposal, *and*
- Appeals must provide additional supporting evidence to address the reasons given for the original rejection.

The appeal will be heard at the next scheduled meeting of the PGD Review Group provided the meeting is not within 14 calendar days of receipt of the appeal.

5.2.6. The PGD Review Group (see 3.16 for details of group role and responsibilities) is a multidisciplinary group including a senior doctor or dentist, a senior pharmacist, a senior nurse, will review the PGD with an invited representative of each of the professional groups involved in the specialist area concerned. The PGD Review Group may review the PGD by virtual means if needed.

5.2.7. Once the completed PGD has been reviewed and approved as ‘fit for purpose’ by the PGD Review Group the PGD will be forwarded to the Drug and Therapeutics Group (see **Error! Reference source not found.** for details of group role and responsibilities) for ratification.

5.3. **Content of Patient Group Directions**

5.3.1 It is a legal requirement that each patient group direction **must** contain the following information:

- the name of the clinical area in which the direction is applicable
- the date the direction comes into force and the date it expires
- a description of the medicine to which the direction applies
- the class of health care professional who may supply or administer the medicine
- the signature of a doctor or dentist, as appropriate, and a pharmacist who are responsible for the direction
- the signature of senior manager on behalf of the authorising body (the Trust)
- the clinical condition to which the direction applies
- a description of those patients excluded from treatment under the direction
- a description of the circumstance in which further advice should be sought from a doctor or dentist, as appropriate, 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 drug reactions
- details of any necessary follow up action and the circumstances
- a statement of the records to be kept for audit purposes.

5.3.2 The template (Appendix B) must be used for developing PGDs.

5.4 Medicines Management Arrangements

5.4.1 There must be comprehensive arrangements for the supply, security, storage and labelling of all medicines.

5.4.2 There must be a system for recording and monitoring medicine use under a Patient Group Direction to enable all stock receipts and all issues to individual patients to be reconciled.

5.4.3 Wherever possible, medicines should be supplied in pre-labelled packs supplied by a Trust-approved supply pharmacy. Supply pharmacies must hold all the relevant MHRA licenses for such a supply function.

5.4.4 Legislation requires that a patient information leaflet must be supplied with any medicines supplied to patients, including those supplied under a PGD.

5.4.5 Patient information leaflets are not required, under the legislation, to be supplied to patients are administered under a PGD, however, it is Trust policy that patient information leaflets should be made available to all patients to whom medicines are administered.

5.4.6 Legislation relating to prescription charges and exemptions (including pandemic influenza exemptions) also applies to patients receiving a supply of medicine(s) under a PGD from the NHS. Prescription charges do not apply when medicines are administered under a PGD.

5.4.7 There must be a system in place for collection of prescription charges or confirmation of exemption status where applicable.

5.4.8 When supplying or administering a medicine under a PGD for an unlicensed use ('off-label') health professionals must, where practicable, inform patients or carers about the proposed unlicensed prior to supply or administration, in line with the 'prescribing unlicensed medicines guidance' published by the GMC (2013).

5.4.9 Staff should ensure the patient is able to understand the information given to them and are able to give their informed consent. This may necessitate the use of a professional interpreter and the translation of written information. A capacity assessment should be considered for those patients who are unable to consent to the procedure and reference should be made to the relevant Trust policy.

5.5 Approval Procedure

5.5.1 After review by the PGD Review Group the completed Patient Group Direction must be forwarded to the Trust Drugs and Therapeutics Group for final approval. The Drugs and Therapeutics Group acts on behalf of the Trust Board and this final approval of the Patient Group Direction ensures that legal liability and hence indemnification of staff is given full consideration.

5.5.2 In exceptional circumstances PGDs may be approved for use on Drug and Therapeutics Group Chairman's approval in agreement with the Medical Director and the Chief Pharmacist.

5.5.3 If approved the PGD document will be signed and dated by the following signatories a doctor or dentist, a pharmacist, an Executive Director for organisational authorisation, and a microbiologist if the PGD is for an antimicrobial agent.

5.5.4 The following signatories are the approved Trust employees for authorisation of PGDs:

Role	Trust designation
Executive director for organisational authorisation	Medical Director
Doctor or dentist	Medical Director or delegated senior doctor or dentist
Pharmacist	Chief Pharmacist or delegated senior pharmacist
Governance Lead	Clinical Governance lead or delegated senior manager
Microbiologist (if for an antimicrobial agent)	Approved Consultant Microbiologist

5.5.5 The signatories authorise the content of the PGD and are accountable for ensuring that the correct governance procedures have been followed in developing and approving the PGD. The PGD must bear all signatures required to comply with legal requirements.

5.5.6 The master copy of the PGD will be held by the Medical Director.

5.6 Implementation of Approved Patient Group Directions

5.6.1 The individual practitioner and the line manager will complete the individual authorisation for use of PGD form (see Appendix C).

5.6.2 A copy of the signed Patient Group Direction and list of names and specimen signatures of all authorised practitioners will be held within the area of practice. A copy of all authorised practitioners will also be sent to the Medical Director to be held with the master copy of the PGD.

5.6.3 Each authorised practitioner will have access to a copy of the Patient Group Direction.

5.6.4 If a practitioner is no longer authorised to act within the Patient Group Direction it is the responsibility of that individual's line manager to remove the individual's name from the area of practices' list and inform the Medical Director.

5.6.5 The Trust accepts no responsibility for an authorised practitioner who attempts to act under a PGD in an area of practice to which the PGD does not apply.

5.6.6 A local audit of use (Appendix D) should be completed within 6 months of approval and implementation of any new PGD.

5.7 Review of Patient Group Directions

5.7.1 PGDs will have a review date set for two years after the effective date.

5.7.2 The content of a Patient Group Direction should be reviewed and re-authorised every two years. All PGDs that are past their stated review date can continue to be used until review for up to one year.

5.7.3 PGDs can only be used for greater than three-years from the effective date (greater than one year after the stated review date) without completion of the formal review process if such continued use is approved by the Drug and Therapeutics Group.

5.7.4 The content of a PGD should be reviewed immediately by the authors if there are evidence based changes to clinical practice that affect the PGD, regardless of the review date.

5.7.5 Any proposed changes to an existing PGD must be reviewed by the PGD Review Group and approved by the Drugs and Therapeutics Group in accordance with the original approval procedure. If the proposed changes are authorised the amended PGD will be countersigned.

5.7.6 A copy of the local audit of use of the PGD (Appendix D) should be submitted to the PGD Review Group prior to review.

5.7.7 Once approved by the Drugs and Therapeutics Group the amended PGD will immediately supersede the previous PGD for that area of practice. The **team managers** will ensure that:

5.7.8 The amended PGD shall be substituted as soon as possible for the previous PGD held in that area

- All copies of the previous PGD are destroyed
- All practitioners authorised under the previous PGD are advised of the changes and any additional training required under the new PGD is provided
- All practitioners are provided with a copy of the new PGD.

5.7.9 Until final approval by the Drugs and Therapeutics Group a PGD is invalid. The Trust accepts no responsibility for an authorised practitioner who acts in accordance with a PGD not yet approved, or acts in accordance with a superseded PGD.

5.8 Adoption of PGDs developed by other authorising bodies

5.8.1 Clinically authorised PGDs may be adopted for use by Somerset Partnership staff when the following conditions have been met:

- PGDs signed by a doctor or dentist and a pharmacist authorised by the authorising body for this responsibility
- It can be demonstrated, for PGDs for antimicrobial agents, that a microbiologist has been involved in the development
- The authorising body has approved adoption and use of the clinically authorised PGDs by other organisations providing services relevant to use of the PGD

- The PGD has been reviewed by the PGD Review Group and be deemed to be fit for purpose.
- The PGD has been approved for use in the Trust by the Drug and Therapeutics Group
- The PGD has been signed by Somerset Partnership's Medical Director to demonstrate Somerset Partnership's organisational approval for use.

5.8.2 After final approval and adoption of the PGDs developed by other authorising bodies the legal liability and hence indemnification of staff using the adopted PGD is the same as for all other PGDs developed and authorised by Somerset Partnership.

5.9 Adoption of Trust-approved PGDs by other organisations and authorising bodies

5.9.1 Use of clinically authorised PGDs by other organisations and / or authorising bodies results in the extension of the Trusts clinical responsibility and risk to those organisations and / or authorising bodies. Individual clinically authorising signatories will extend their clinical responsibility and risk to those third party organisations and / or authorising bodies.

5.9.2 Use of organisationally authorised PGDs by other organisations and / or authorising bodies results in the extension of the Trusts organisational responsibility and risk to those organisations and / or authorising bodies.

5.9.3 Clinically authorised Somerset Partnership PGDs may be adopted for use by other organisations that are **not** authorising bodies when the following conditions have been met:

- The organisation is providing services on behalf of Somerset Partnership NHS Foundation Trust
- The organisation is providing care to patients of Somerset Partnership NHS Foundation Trust
- Staff in the organisation that will be authorised to provide care under the PGD have the clinical qualifications and completed all the relevant training as defined in the PGD
- The PGD Review Group have explicitly authorised such use

5.9.4 Clinically authorised Somerset Partnership PGDs may be adopted for use by other organisations that **are** authorising bodies when the following conditions have been met:

- The authorising body providing services has authorised the PGDs organisationally and has accepted the organisational responsibility and risk for the PGDs.
- Staff in the organisation that will be authorised have to provide care under the PGD the clinical qualifications and completed all the relevant training as defined in the PGD
- The PGD Review Group have explicitly authorised such use

5.10 Use of PGDs by Trust staff providing services on behalf of other organisations

5.10.1 Use of Trust clinically and organisationally authorised PGDs by Trust staff sub-contracted to provide services on behalf of other organisations results in the extension of the Trusts clinical and organisational responsibility and risk to those organisations and / or authorising bodies.

5.10.2 Use of Trust clinically and organisationally authorised PGDs by Trust staff sub-contracted to provide services on behalf of other organisations must be explicitly identified as an inclusion of any contractual arrangements otherwise PGDs will be deemed to be excluded.

5.10.3 Use of Trust clinically and organisational authorised PGDs by Trust staff sub-contracted to provide services on behalf of other organisations will normally be subject to an annual licensing agreement between the Trust and the sub-contracting organisation.

5.10.4 Use of third party clinically and organisationally authorised PGDs not adopted for Trust use (see 5.9 above) by Trust staff sub-contracted to third-party organisations must be approved by the PGD Review Group and the Clinical Governance Group.

5.11 Appropriation of medicines costs incurred by the Trust as the result of PGD use by third-party organisations

5.11.1 Medicines supplied or administered under Trust clinically and / or organisationally authorised PGDs must be supplied in accordance with the requirements defined in the relevant PGD(s) and if supplied at Trust expense costs for the medicines the organisation responsible for the costs must be defined explicitly in any contractual arrangements or otherwise will be rechargeable to the third-party organisation on a pass-through basis with the addition of a discretionary processing fee.

5.11.2 Failure to reimburse the Trust for any medicines costs incurred not inclusive of any contractual fees or arrangements within 30 days of invoice will result in immediate removal of any authorisation of the relevant third party organisation to use the Trust clinically and / or organisationally approved PGDs.

6 TRAINING REQUIREMENTS

6.1 All healthcare professionals who wish to administer or supply medication under any PGD must have completed an approved Trust PGD training package and pass the approved competency assessment test.

6.2 To be authorised to supply medicines under a specific PGD staff must be assessed and deemed to have the relevant competencies by their line manager. Evidence of the assessment and demonstrated competencies must be held by the line manager.

6.3 PGD lead authors should also have completed a Trust-approved general PGD training package and theory competency assessment, but are not required to undertake other individual PGD competency assessments in order to be an author.

6.4 A PGD Training Pack for general PGD competencies to accompany training delivered by the Trust Training Department is available on the Trust Intranet or directly from the Training Department.

7 EQUALITY IMPACT ASSESSMENT

7.1 All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the Equality Act 2010. In addition, the Trust has identified Learning Disabilities as an additional tenth protected characteristic. If you, or any other groups, believe you are disadvantaged by anything contained in this document please contact the Equality and Diversity Lead who will then actively respond to the enquiry.

8 MONITORING COMPLIANCE AND EFFECTIVENESS

8.1 Line managers will review the use of PGDs by individual practitioners at annual appraisal.

8.2 An audit report template (Appendix D) must be completed by the line manager on the use of each PGD in each authorised area. This must be submitted to the PGD Review Group within six months of approval and implementation of any new PGD. A copy must also be submitted to the review group by the PGD author prior to review and re-authorisation of existing PGDs. The audit lead will be the professional working in the service requesting the PGD as stated on the front of the PGD.

8.3 The audit template should be modified depending on whether the PGD covers administration only, supply only, or administration and supply. Please contact the Medicines Management team for advice on which criteria to include in your audit.

8.4 The Medical Director will maintain a database of:

- PGDs approved for use within the organisation
- individuals authorised to operate under each PGD
- training and competency.

8.5 The line manager will ensure that individuals authorised have been appropriately trained and are competent. The PGD Review Group will organise the review of PGDs due to expire and monitor implementation of the PGD Policy.

9 COUNTER FRAUD

9.1 The Trust is committed to the NHS Protect Counter Fraud Policy – to reduce fraud in the NHS to a minimum, keep it at that level and put funds stolen by fraud back into patient care. Therefore, consideration has been given to the inclusion of guidance with regard to the potential for fraud and corruption to occur and what action should be taken in such circumstances during the development of this procedural document.

10. RELEVANT CARE QUALITY COMMISSION (CQC) REGISTRATION STANDARDS

10.1 Under the **Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3), the fundamental standards** which inform this procedural document, are set out in the following regulations:

Regulation 9:	Person-centred care
Regulation 10:	Dignity and respect
Regulation 11:	Need for consent
Regulation 12:	Safe care and treatment
Regulation 13:	Safeguarding service users from abuse and improper treatment
Regulation 16:	Receiving and acting on complaints
Regulation 19:	Fit and proper persons employed
Regulation 20:	Duty of candour
Regulation 20A:	Requirement as to display of performance assessments.

10.2 Under the **CQC (Registration) Regulations 2009 (Part 4)** the requirements which inform this procedural document are set out in the following regulations:

Regulation 16:	Notification of death of service user
Regulation 17:	Notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983
Regulation 18:	Notification of other incidents

10.3 Detailed guidance on meeting the requirements can be found at http://www.cqc.org.uk/sites/default/files/20150311%20Guidance%20for%20providers%20on%20meeting%20the%20regulations%20FINAL%20FOR%20PUBLISHING.pdf

11. REFERENCES, ACKNOWLEDGEMENTS AND ASSOCIATED DOCUMENTS

11.1 References

British National Formulary (BNF) – current edition.

General Medical Council (2013) Good practice in prescribing and managing medicines and devices (or current version)

MHRA (2009) Patient Group Directions in the NHS

National Prescribing Centre (2009) Patient Group Directions

NICE Medicines Practice Guidance (MPG2): Patient Group Directions (Aug-13) as amended

The Human Medicines Regulations 2012 (SI 2012/1916) as amended

The Medicines Act 1968 as amended.

The Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment (No2) Regulations 2000 (SI 2000/1918)

The Medicine (Pharmacy and General Sale – Exemption) Amendment Order 2000 (SI 2000/1919)

The Prescription Only Medicine (Human Use) Order 1997 (SI 1997/1830)

The Prescription Only Medicines (Human Use) Amendment Order 2000 (SI 2000/1917)

To PGD or not to PGD? That is the question. A Guide to choosing the best option for individual situations (Version 8.3, July 2014) NHS PGD website.

11.2 **Cross Reference to Other Procedural Documents**

Consent and Capacity to Consent to Examination or Treatment Policy

Medicines Policy

Non-Medical Prescribing Policy

Record Keeping and Records Management Policy

Untoward Event Reporting Policy and Procedure

All current policies and procedures are accessible in the policy section of the public website (on the home page, click on 'Policies and Procedures'). Trust Guidance is accessible to staff on the Trust Intranet.

12. LIST OF APPENDICES

For the avoidance of any doubt the appendices in this policy are to constitute part of the body of this policy and shall be treated as such. This should include any relevant Clinical Audit Standards.

A. Patient Group Direction proposal form

B. Patient Group Direction template

C. Individual Authorisation for use of PGD

D. Audit template for use of PGD.

Somerset Partnership NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION PROPOSAL FORM

Medicine to be supplied or administered:

Before submitting this form, please confirm you have worked through the attached "To PGD or not to PGD" flow chart. YES / NO

If an existing PGD is used in another area, please state which area/group:

_____

Team proposing the Patient Group Direction:_____

Proposal for multidisciplinary group to develop the Patient Group Direction

Name (PRINT)	Profession
	Lead Health Care Professional
	Pharmacist
	Medical / Dental Practitioner
	Consultant Microbiologist (antimicrobials)
	Other (please specify):

Clinical Condition to which the PGD applies:
Explain the current process in place for prescribing and administration.
How would the introduction of this PGD improve the quality and process of delivering care?
Professional group to whom the PGD will apply:

Agreed with Line Manager	
Name:	Job title:
Signature:	Date:

Please send completed form for submission to the PGD Review Group to:
Team Administrator, Medicines Management, Cheddon Lodge, Cheddon Road, Taunton, TA2 7AZ (sharon.drew@sompar.nhs.uk)

Approval for development by:	
Medical Director: Approved - Yes / No	Chief Pharmacist: Approved – Yes / No
Name:	Name:
Signature:	Signature:
Date:	Date:

TO PGD OR NOT TO PGD? – That is the question. A guide to choosing the best option for individual situations

You need to consider whether a Patient Group Direction (PGD) would be appropriate for an area of practice that involves the supply or administration of medicines.
This diagram takes you through a logical process that aims to assist decision-making to determine if a PGD can be used.
We have also added some useful links to help you find further information. To start – see NICE MPG2 PGD Guidance 2013

START

Could the current care pathway include issue of a prescription or a written Patient Specific Direction by a doctor or non-medical prescriber so that the patient receives the medicine in a timely manner?

Yes → A PGD should not be required if there is no advantage to patient care. **The preferred way for patients to receive medicines is for prescribers to provide care for individual patients on a one-to-one basis.**

No →

Is the treatment to be provided by:

- NHS Trust or NHS Foundation Trust
- GP or dental practice
- Independent hospital, agency or clinic registered with the Care Quality Commission in England.
- Defence medical services
- NHS Primary Care Organisation
- NHS commissioned service
- Prison healthcare service
- Police services

No → PGDs cannot be used in other organisations e.g. Care homes and independent schools providing healthcare entirely outside the NHS

Yes →

Are the practitioners:

- Registered Midwives
- Paramedics
- Optometrists
- Chiropodists or podiatrists
- Nurses working within an occupational health scheme

Yes → A PGD may not be required if the professional activity fits within the exemptions in the Human Medicines Regulations 2012 and associated statutory instruments. See NICE MPG 2PGD Guidance 2013

Are the medicines that these practitioners need to supply or administer listed in the exemptions?

Yes → A PGD is not required – practitioner has authority to supply or administer in accordance with Medicines Act. Note: some organisations use PGDs in these circumstances although not a legal requirement Link to FAQs

No → A PGD may need to be considered.

No →

Are the practitioners listed in the legislation as registered health professionals who can supply or administer medicines under a PGD?
See NICE MPG2 PGD Guidance 2013

No → An alternative will need to be sought for practitioners who cannot work under PGDs e.g. healthcare assistants

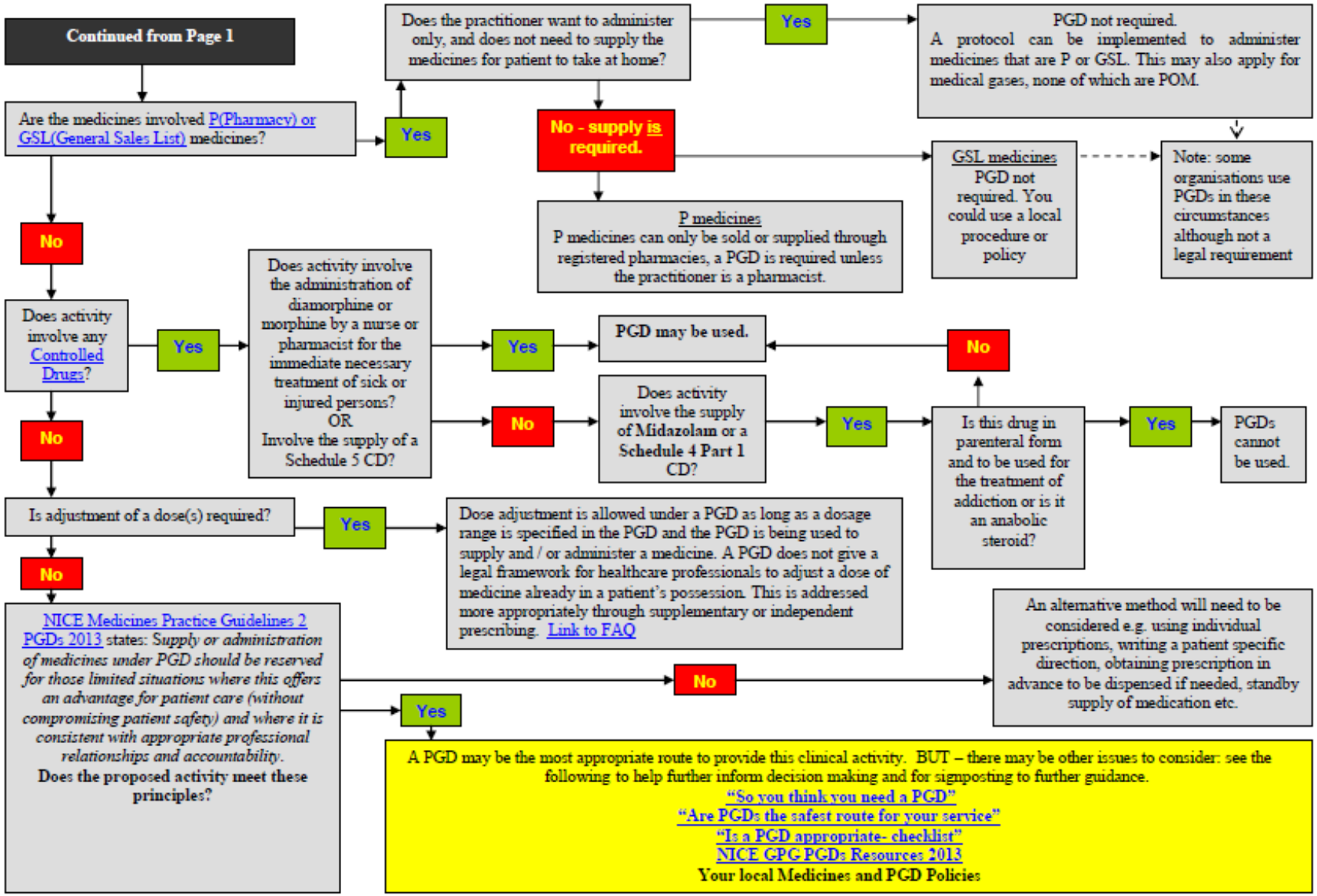
Yes →

Are the products involved all licensed medicines?

No → **PGD legislation applies only to licensed medicines.** Consider developing a local protocol or treatment guidelines for dressings and medical devices.

Yes → **Continued on Page 2**

Version 8.3 July 2014. Some links updated. Further copies available at www.pgd.nhs.uk THIS VERSION IS FOR ENGLAND ONLY.
If you are referring to a hard copy of this document – please check the PGD website to make sure that you are using the most recent version


Continued from Page 1
Are the medicines involved P(Pharmacy) or GSL(General Sales List) medicines?
Yes
No
Does activity involve any Controlled Drugs?
Yes
No
Is adjustment of a dose(s) required?
Yes
No
NICE Medicines Practice Guidelines 2 PGDs 2013 states: Supply or administration of medicines under PGD 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.
Does the proposed activity meet these principles?
Does the practitioner want to administer only, and does not need to supply the medicines for patient to take at home?
Yes
PGD not required.
A protocol can be implemented to administer medicines that are P or GSL. This may also apply for medical gases, none of which are POM.
No - supply is required.
GSL medicines
PGD not required. You could use a local procedure or policy
Note: some organisations use PGDs in these circumstances although not a legal requirement
P medicines
P medicines can only be sold or supplied through registered pharmacies, a PGD is required unless the practitioner is a pharmacist.
Does activity involve the administration of diamorphine or morphine by a nurse or pharmacist for the immediate necessary treatment of sick or injured persons?
OR
Involve the supply of a Schedule 5 CD?
Yes
PGD may be used.
No
Does activity involve the supply of Midazolam or a Schedule 4 Part 1 CD?
Yes
Is this drug in parenteral form and to be used for the treatment of addiction or is it an anabolic steroid?
No
Yes
PGDs cannot be used.
Dose adjustment is allowed under a PGD as long as a dosage range is specified in the PGD and the PGD is being used to supply and / or administer a medicine. A PGD does not give a legal framework for healthcare professionals to adjust a dose of medicine already in a patient's possession. This is addressed more appropriately through supplementary or independent prescribing. Link to FAQ
No
An alternative method will need to be considered e.g. using individual prescriptions, writing a patient specific direction, obtaining prescription in advance to be dispensed if needed, standby supply of medication etc.
Yes
A PGD may be the most appropriate route to provide this clinical activity. BUT – there may be other issues to consider: see the following to help further inform decision making and for signposting to further guidance.
"So you think you need a PGD"
"Are PGDs the safest route for your service"
"Is a PGD appropriate- checklist"
NICE GPG PGDs Resources 2013
Your local Medicines and PGD Policies

Appendix B

Somerset Partnership NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION No:	
Supply and / or administration of [please complete below]	
Name, form and strength of drug:	
Condition:	
Area of Practice:	
Locations / Teams:	

PGD approved by

Name	**Title**	**Signature**	**Date**
	Medical Director		
	Chief Pharmacist		
	Governance Lead		
	Microbiologist (antimicrobial agents only)		
Approval Date			
Expiry Date			

PATIENT GROUP DIRECTION No:	
Name, Form and Strength of Drug:	

Document Control

Version	Date Issued	Brief Summary of Change
Author(s) name and job title		
Approval Group:		**Drugs and Therapeutics Group**
Approval Date:		
Author fulfils requirements for training and competency as set out in Trust PGD Policy		**Yes / No (Please delete as appropriate)**

CONTRIBUTION LIST Key individuals involved in developing the document

Name	Designation or Group
Please complete for this revision	

Document History

Version	Date	Comments / Amendments

PATIENT GROUP DIRECTION No:	
Supply and / or administration of [please complete below]	
Name, Form and Strength of Drug:	
Condition:	

1. Clinical Condition

Locality / speciality to which the direction applies	
Definition of condition / situation to which the direction applies	
Criteria for inclusion	• Valid consent from patient or person with parental responsibility has been obtained
Criteria for exclusion Please refer to the current BNF and/or the Summary of Product Characteristics (SPC) for further information on drug interactions.	• Allergy / hypersensitivity to [name of drug]
Description or circumstances in which further advice should be sought from a doctor and arrangements made for referral	
Action if service user declines	
Description of follow-up for service users receiving treatment under the direction	

2. Staff Characteristics

Professional qualification to be held by staff undertaking this Patient Group Direction	*For example:* • Registered Health Care Professionals
Specialist qualifications, training, experience and competence considered necessary and relevant to the medicines administered and the clinical condition being treated under this Patient Group Direction.	• The healthcare professional has undertaken appropriate training to carry out clinical assessment of a patient leading to diagnosis that requires treatment according to the indications listed in this PGD • The healthcare professional has undertaken Somerset Partnership approved training in the supply of medicines under PGDs • You must be authorised by name, under the current version of this PGD before working under it.
Professional Responsibility	• The healthcare professional must be willing to be professionally accountable for this work and be working within his/her competence • The practitioner should be aware of any change to the recommendations for the medicine listed • Maintenance of own level of updating with evidence of professionals respective continued professional development requirements
Requirements for staff training and competency assessment for administering medicine under this Patient Group Direction.	• Trust PGD Training and theory competency assessment • Competency assessment for this PGD • To have undertaken drug calculation test if mandatory
System for recording names of individuals authorised to supply and / or administer drugs under this Patient Group Direction	• Healthcare Professional to complete Trust Individual Authorisation (Appendix C of PGD Policy) signed by authorising manager. Copy to be kept by authorising/line manager in department, copy to Medical Director and copy to individual nurse.

3. Description of Treatment

Name of medicine	
Legal status	
Strength and Form	
Route of administration	
Maximum dose/frequency per time period	
Maximum quantity to be supplied	
Description of pack in which medicines will be supplied	
Storage and security arrangements	
Relevant warnings including potential adverse reactions Always refer to the manufacturers Summary of Product Characteristics (SPC) for the medicine to be supplied / administered under this PGD for a more complete overview of adverse reactions.	
Advice to service user or carer	
Advice on concurrent medication Please refer to the current BNF and/or the Summary of Product Characteristics (SPC) for further information on drug interactions.	
Record of administration and a description of the records to be kept for audit purposes	It is essential to record the following in the patient notes: • Name of medicine / dose / quantity supplied • Advice given to patient / carer (to include side effects) • Signed and dated. (Where computer records are used health professionals must have individual identifier to enable audit trail).

INDIVIDUAL AUTHORISATION FOR USE OF PATIENT GROUP DIRECTION (PGD)

PATIENT GROUP DIRECTION No:	
Supply and / or administration of [please complete below]	
Name, form and strength of drug:	
Condition:	
Area of Practice:	
Locations / Teams:	

IMPORTANT: Please ensure you enter the PGD Number and Area of Practice

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the PGD and a photocopy of this document.

I have read and understood the Patient Group Direction. I have undertaken the Trust PGD training package and have been assessed as competent for this individual PGD. I agree to supply/administer this medicine only in accordance with this PGD.

PRINT Name of Professional	Job Title	Signature	Date
PRINT Name of Authorising Manager	**Job Title**	**Signature**	**Date**

Please ensure a copy of this page is kept by the Line Manager
Please return a copy to: Team Administrator, Medicines Management, Cheddon Lodge, Cheddon Road, Taunton, TA2 7AZ

AUDIT TEMPLATE FOR USE OF PATIENT GROUP DIRECTION (PGD)

Patient Group Direction No	
Approval Date	
Expiry Date	
Service / Locality*	
Audit completed by (line manager – 6 months; author of PGD prior to review / renewal)	
Name	
Title	
Date	

* A separate audit template must be completed by each service listed in the above PGD.

Tick as appropriate. If 'no', state action required	**Y**	**N**	**Action required**
Does the manager of the service listed on the PGD hold a current list of authorised staff?			
Are all staff authorised to work under the PGD			

members of one of the health professions listed in the PGD?			
Are all medicines supplied or administered under the PGD stored appropriately?			
Do the staff working under the PGD have access to a copy of the signed version of the PGD which is in date and available for reference at the time of consultation?			

Audit of Patient Records for supply and / or administration under PGD No:

Please complete this audit template for the last 10 patients who have been administered / supplied with medication under this PGD

Date and time given	Patient ID No	Was medicine given according to the inclusion criteria Y/N	Was a drug history taken? Y/N	Is allergy status docu-mented? Y/N	Were exclusion criteria checked? Y/N	Was the following recorded: route, batch number, expiry date, strength and quantity given, (and injection site if applicable) Y/N	Was the Health Professional authorised to use the PGD? Y/N	Was patient consent obtained ? Y/N	Was Patient Info Leaflet supplied to patient? Y/N	Does it state "given / supplied under PGD?" in the notes? Y/N	For PGD involving the supply of medicines only. Is there a separate log by drug name to show what was supplied / given including batch number or expiry date, etc? Y/N	Comments