

Patient Group Direction Policy

1. Version Control

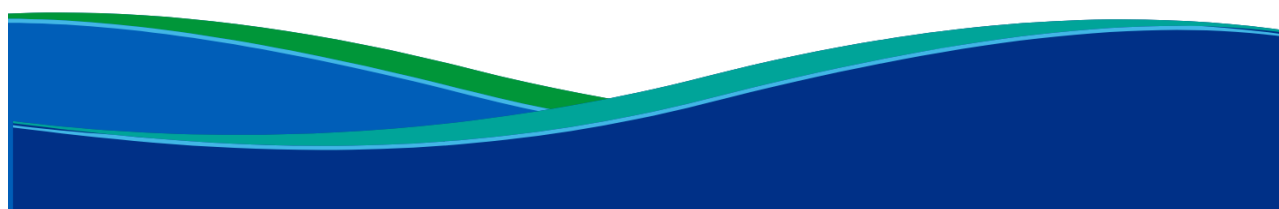
Version	Date	Author and Role	Detail of Change
1.0	23/09/2026	Catherine Butler, Head of Medicines Optimisation and Pharmacy – Quality, Medicines Governance and Safety Sandip Baker, Medicines Optimisation Pharmacist – Quality, Medicines Governance and Safety	New policy

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Responsible Committee: Therapeutic Advisory Committee/Integrated Medicines Optimisation Committee (TAGIMOC)

2. Next Review Date

The date this policy is due for review September 2029 or sooner if required



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4. Statement of Overarching Principles

- a. All Policies, Procedures, Guidelines and Protocols of the Norfolk and Suffolk Integrated Care Board (ICB) are formulated to comply with the overarching requirements of legislation, policies or other standards relating to equality and diversity

5. Introduction

- a. This policy sets out the principles and requirements for Patient Group Direction (PGD) management and assurance within Norfolk and Suffolk Integrated Care Board (ICB). It aims to ensure a consistent and effective approach that supports the organisation's objectives, complies with statutory and regulatory requirements and promotes best practice.
- b. 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.
- c. PGDs provide the 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 non-medical prescriber).
- d. 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.

6. Purpose

- a. The purpose of this policy is to establish a robust and compliant framework for the management of Patient Group Directions (PGDs) within Norfolk and Suffolk ICB.
- b. The policy describes the governance arrangements for the development, review and authorisation of PGDs and ensures compliance with all relevant legislation and national guidance. The full list of statutory and guidance documents that inform this policy is provided in the References section.
- c. Norfolk and Suffolk ICB will apply this framework to ensure PGDs are developed, authorised and managed in line with statutory requirements and recognised best practice.

7. Scope

- a. This policy applies to all Norfolk and Suffolk ICB staff, Board members, contractors, and others involved in the review and authorisation of PGDs. All staff are expected to adhere to the requirements set out in this policy.
- b. This policy applies to all provider organisations where the ICB commissions services and the ICB is the legal authorising body.
- c. This policy does not apply to providers or commissioners who are able to develop and authorise their own PGDs under legislation (such as NHS Trusts).
- d. The development of PGDs for privately funded services will not be supported by the ICB. The ICB is not legally permitted to authorise Patient Group Directions on behalf of Local Authorities under Section 75 partnership arrangements; responsibility for PGD authorisation remains with the relevant Local Authority.
- e. 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

8. Definitions

- a. *Patient Group Direction (PGD)* – Defined in the Health Service Circular (HSC 2000/026) as ‘written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment’ in an identified clinical situation.
- b. *Patient Specific Direction (PSD)* – A PSD is an instruction to supply and/or administer a medicine written and signed by the prescriber. It must include a list of individually named patients where each patient on the list has been individually assessed by that prescriber.
- c. *Unlicensed medicines* - Any medicine that meets the definition of a medicine but does not have a Marketing Authorisation valid in the UK.
- d. *Commissioning organisation/commissioner* - The organisation with which a contract or agreement for the provision of a service that may require the prescribing, supply or administration of medicines has been made.
- e. *Authorising body* - An organisation listed in The Human Medicines Regulations 2012 (regulation 229) (and subsequent amendments) that is legally able to authorise a PGD. The commissioning and/ or provider organisation may be an authorising body. In the NHS in England, these organisations include ICBs, NHS England, local authorities, NHS trusts and the UK Health Security Agency.

- f. *Provider* – A healthcare organisation acting as a direct provider of health care services.

9. Roles and Responsibilities

a. Integrated Care Board

The Integrated Care Board is responsible for establishing and maintaining the overall governance framework for PGDs. This includes approving the PGD policy, defining roles and decision-making pathways, and ensuring that organisational arrangements—such as authorised signatories and committee structures—are clearly designated and operating within statutory and regulatory requirements.

b. Director of Medicines Optimisation and Pharmacy

The Director of Medicines Optimisation and Pharmacy provides senior professional leadership for medicines governance and ensures that effective operational systems support PGD assurance and authorisation. The Director chairs the PGD Review Group and acts as the ICB's designated organisational authorising signatory for PGDs, operating within the governance framework set by the Board, Chief Executive and Executive Medical Director.

c. Therapeutic Advisory Group / Integrated Medicines Optimisation Committee (TAGIMOC)

TAGIMOC provides system-wide oversight and assurance of medicines governance on behalf of the Integrated Care Board. The Group receives reports of PGDs authorised by the Director of Medicines Optimisation and Pharmacy Optimisation for noting and system assurance, identifying any themes, risks or issues requiring escalation, and ensuring alignment with wider medicines commissioning priorities.

d. Policy Authors

Head of Medicines Optimisation and Pharmacy – Quality, Medicines Governance and Safety is responsible for updating this policy as required.

e. All Staff

All staff must be conversant with this policy and ensure that it is implemented and taken account of in their daily operations or interactions with Providers.

10. Patient Group Directions

- a. A Patient Specific Direction (PSD) i.e. individually prescribed for a patient remains the preferred option for the majority of care.

- b. PGDs must only be used in situations where there is no other suitable mechanism for the administration or supply of the medicine within the legislation. Careful consideration should be given to opportunities within the care pathway to use a prescription or a Patient Specific Direction (PSD) and consider the use of relevant Human Medicines Regulations 2012 Schedule 17 or 223 exemptions. There must be an agreed rationale for not having prescribers and a clear advantage for patient care without compromising patient safety. Clear governance arrangements and accountability arrangements are essential.
- c. Providers must have their own PGD policy as part of their expected medicines governance arrangements. Their PGD policy must support the safe development, authorisation, use and review of PGDs.
- d. The ICB expects providers to use [nationally developed PGD templates](#) (for example, immunisation and vaccination PGDs) wherever these exist. Providers should only develop local PGDs where no suitable national PGD/template or commissioner-produced PGD is available.
- e. Providers are responsible for identifying the need for, developing, and—where legally permitted—authorising their own PGDs in line with NICE guidance. Providers must ensure robust governance and clinical quality assurance of the PGD during development.
- f. Where a provider is not legally permitted to organisationally authorise a PGD (for example, some independent healthcare providers), a legally authorised body must undertake the organisational authorisation. In these cases, for ICB commissioned services, the provider must still complete its internal clinical and governance signoff and submit the PGD(s) to the ICB for authorisation via the Medicines Optimisation and Pharmacy team. The ICB will only authorise the PGD once assured that all legal requirements, correct signatories, and appropriate governance standards have been met.
- g. It is not generally expected that Norfolk and Suffolk ICB will develop PGDs itself. However, in exceptional circumstances—and only where necessary to support commissioned service delivery—the ICB may develop a PGD. Any national PGD templates available should be used in preference to local development, with local adaptation only where required to reflect local pathways or commissioning arrangements.

11. Developing Patient Group Directions

- a. Organisations must have a formal process for determining the need for, and developing, PGDs in line with NICE MPG2: Patient Group Directions.
- b. 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.
- c. The development of a PGD requires detailed understanding of the service model, including staff training requirements, clinical pathways and the

characteristics of the patient cohort.

- d. PGDs must be developed using current evidence-based guidance and best practice. Supporting references should be included within the PGD, with electronic links to full source documents.
- e. 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.
- f. Any patient group direction must follow the proforma as laid out in NICE guidance.
- g. The organisation developing the PGD (“owner”) must appoint a named lead author and convene a multidisciplinary PGD working group. As required by NICE guidance, the working group must include a doctor (or dentist), a pharmacist, and representatives of the professions who will use the PGD. Roles, responsibilities, and competency requirements should be clearly defined.
- h. The developing organisation (“owner”) is responsible for the clinical content and governance of the PGD. The provider implementing the PGD is responsible for ensuring staff are trained, competent, and working within an agreed competency framework, and that local governance and audit arrangements are in place.
- i. Where a PGD requires ICB commissioner authorisation, the provider must complete its own internal approval process before submitting the final PGD to the ICB for authorisation, through the ICB Medicines Optimisation and Pharmacy Team.
- j. Where the ICB develops a PGD, members involved in drafting or developing the PGD must not form part of the ICB authorisation or review group, to ensure appropriate separation of duties and governance.
- k. Review and renewal of PGDs should be done by the Provider PGD Working Group
- l. Any PGD must:

- i. Contain the names and signatures of the working group, including the Lead author/Practitioners, Pharmacist(s) and Doctor(s) who developed the PGD- who are responsible for signing off the clinical content of the PGD.
- ii. 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.
- iii. 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.
- iv. Specify the mechanism and time scale for regular updating of knowledge and review of relevant skill and knowledge of approved practitioners.
- v. Refer to an audit process by which administration and supply can be monitored.
- vi. Contain a means of reporting and recording errors and incidents relating to administration and supply by an approved practitioner.
- vii. Specify the review period and mechanism of review for the PGD.
- viii. It is the responsibility of the organisation developing the PGD to assure governance around clinical content.

m. Medicines That May Be Included in A Patient Group Direction

- i. Not all medicines are suitable to be included in a PGD
- ii. A PGD cannot be used for:
 - 1. unlicensed medicines
 - 2. dressings, appliances and devices
 - 3. radiopharmaceuticals
 - 4. abortifacients, such as mifepristone.
- iii. 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.
- iv. 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](#)

- v. A PGD should only be used for antibiotics
 - 1. if clinically essential and clearly justified by best practice guidance
 - 2. a local Consultant Medical Microbiologist or another doctor with equivalent knowledge has agreed that a PGD is needed and this is clearly documented
 - 3. the use of the PGD is monitored and reviewed regularly
- vi. In accordance with NICE guidance (MPG2), medicines needing frequent dosage adjustments or frequent or complex monitoring, should not be included in a PGD.
- vii. 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
- viii. The administration of a P or GSL medicine does not require a PGD

n. Who Is Permitted to Use Patient Group Directions (PGDs)?

- i. 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.
- ii. Staff authorised can only use PGDs as named individuals.
 - iii. 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.

12. **Authorisation of Patient Group Directions**

- a. The ICB PGD Review Group is a group responsible for assuring, and recommending for authorisation, PGDs that are either:
 - b. developed or adopted by provider organisations that are not legally permitted to authorise their own PGDs; or
 - c. developed or adopted by the ICB for inclusion within commissioned service specification(s).
- d. The ICB PGD review group is a subcommittee of TAGIMOC.
- e. This process does not apply to providers who, under legislation, are able to develop and organisationally authorise their own PGDs.
- f. Authorisation will only occur once the ICB PGD Review Group is satisfied that the PGD has been developed in line with national requirements, including [NICE MPG2](#), and that all necessary clinical and governance assurances are in place.
- g. ICB PGD review group members are:
 - i. Director Medicines Optimisation and Pharmacy (chair).
 - ii. Clinical Steward for Planned Care and Medicines Optimisation.
 - iii. Head of Medicines Optimisation and Pharmacy – Quality, Medicines Governance & Safety.
 - iv. Quality/patient safety lead-nurse.
 - v. Senior Pharmacist - Quality, Medicines Governance & Safety.

In addition, if appropriate

 - vi. 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).

- vii. A member of a representative body where the PGD will be implemented, e.g. Community Pharmacy England.
 - viii. Lead author for PGDs (not involved in the authorisation process).
 - ix. Other ICB pharmacist co-opted by review group (expert in relevant field, optional).
- h.** For ICB developed PGDs, all clinical review and specialist input must be completed during the development process. The subsequent organisational authorisation step is therefore kept entirely separate, ensuring the ICB assesses only the governance, legal and commissioning requirements before authorisation.
- i.** The responsibilities of the PGD Review Group are to:
- i.** Ensure application of the ICB PGD governance process and confirm that the organisation developing the PGD has followed appropriate governance requirements, including alignment with [SPS/NICE](#) guidance on PGD preparation.
 - ii.** Review all PGD documentation submitted, using the ICB PGD assurance checklist, in order to inform the PGD authorisation decision. The review will focus on confirming that the developing organisation's governance, clinical assurance and approval processes have been completed appropriately and safely, rather than undertaking a clinical re-review of content.
 - iii.** Provide clear, timely feedback to the developing organisation's PGD working group where issues are identified, and ensure all required actions are completed prior to PGD authorisation.
 - iv.** Assure that the developing organisation has appropriate arrangements in place for audit, monitoring, reporting and incident escalation to support the safe and effective use of the PGD.
 - v.** Ensure equality considerations have been appropriately addressed during PGD development and that no aspect of a PGD disadvantages people with protected characteristics.
 - vi.** Following successful completion of the review, the Director of Medicines Optimisation and Pharmacy will formally authorise suitable PGDs, in accordance with the ICB's PGD governance framework.
- j.** The PGD Review Group will prepare an assurance report summarising the outcome of the review and authorisation process for submission to TAGIMOC for noting.
- k.** The assurance report will include:

- i. Confirmation that the service is commissioned by the ICB and that a PGD is the appropriate legal mechanism.
 - ii. A summary of all governance and legal checks completed, using the ICB PGD Assurance Checklist, whether the PGD was developed by a provider organisation or by the ICB.
 - iii. Confirmation that appropriate clinical assurance has been completed by the developing organisation (provider or ICB), including verification of required clinical signatories and specialist input (e.g., microbiology for antimicrobial PGDs).
 - iv. Details of issues identified during review, how these were resolved, and confirmation that all conditions were addressed prior to PGD authorisation.
 - v. Assurance that all statutory and regulatory requirements have been met, including compliance with the Human Medicines Regulations 2012.
 - vi. Confirmation of robust audit, monitoring and incident reporting arrangements, including clarity on PGD review cycles and resubmission timelines.
 - vii. The report will confirm the PGD(s) authorised by the Director of Medicines Optimisation and Pharmacy, and is provided to the TAGIMOC for oversight, transparency and system assurance.
- I. TAGIMOC will receive the report and:**
- i. Note the PGD(s) authorised by the Director of Medicines Optimisation and Pharmacy, confirming transparency of decision making and adherence to agreed governance processes.
 - ii. Receive assurance that appropriate governance, clinical assurance, legal compliance and equality considerations have been applied.
 - iii. Consider any system-level themes, risks or learning arising from the PGD(s) authorised (e.g. recurring conditions, audit requirements, safety issues or workforce implications).
- m.** The Medicines Optimisation and Pharmacy Team will keep a copy of all PGDs authorised by the ICB.
 - n.** 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.
 - o.** Providers have full responsibility and legal liability for management of practitioners working to PGDs within services they are delivering.

13. Adoption of PGDs After Changes in ICB Commissioning Responsibility

- a. When an ICB is newly established or reconfigured and becomes the commissioner of services previously commissioned by a legacy ICB, or where there is a subsequent change in lead commissioning responsibility, all PGDs that were authorised by the legacy ICB(s) for use within those services must be formally adopted by the new ICB as the legal authorising body.
- b. This requirement reflects the Human Medicines Regulations 2012, which permit only legally recognised organisations to authorise PGDs. When an authorising body ceases to exist or is replaced or commissioning responsibility changes, the successor authorising body must adopt the PGDs associated with the services it is now responsible for and when previously authorised by the legacy body, in order to maintain their legal validity. Adoption by Norfolk and Suffolk ICB applies only to PGDs that were legally authorised by the legacy ICB(s) and that remain necessary for the ongoing delivery of services and does not apply to PGDs that providers or other commissioners are legally permitted to authorise themselves. Adoption does not require re-authorisation, re-signing or redevelopment of PGDs, provided they remain within their expiry date and there has been no material change to the service model or clinical pathway.
- c. To ensure continuity of care, clear governance and audit trail, Norfolk and Suffolk ICB will adopt legacy PGDs through a streamlined, proportionate process:
- d. **Identification of PGDs** - The ICB Medicines Optimisation and Pharmacy team will work with commissioners and providers to confirm the set of PGDs that were in use under the legacy commissioner and that remain necessary for the services now commissioned by Norfolk and Suffolk ICB.
- e. **Recording adoption** - Each PGD will be entered onto the Norfolk and Suffolk ICB PGD Register as “adopted”, including:
 - i. PGD title
 - ii. Version and originating authorising body
 - iii. Expiry date
 - iv. Date of adoption by Norfolk and Suffolk ICB
- f. **Notification to the provider** - The ICB will issue a Notification of Continued Authorisation to the provider. This confirms that Norfolk and Suffolk ICB have adopted the PGD and that the provider may continue to use it without any additional authorisation steps. The notification will be signed by the Director of Medicines Optimisation and Pharmacy acting as the ICB’s authorised PGD signatory.
- g. **Continued operational use** - Providers may continue to use the adopted

PGDs unchanged until their scheduled expiry date.

- h. **Review and renewal** - Before expiry, the PGD(s) must be reviewed by the organisation that originally developed it, updated where necessary, and resubmitted for authorisation through the Norfolk and Suffolk ICB governance process, but only where the provider continues to be commissioned to deliver the service to which the PGD relates.

14. PGD Record Keeping and Lifecycle Management

- a. The ICB Head of Medicines Optimisation and Pharmacy – Quality, Medicines Governance and Safety is responsible for maintaining a log of all PGDs authorised/adopted by the ICB and their review dates and a copy of the original signed PGD.
- b. PGDs are valid for up to three years after authorisation. Organisations must have a robust process in place to assure PGD review and re-authorisation before expiry of each PGD to ensure uninterrupted service delivery. All PGDs should have a governance box on them which states when it was written, who by, when it was authorised, when due for review and when it expires.
- c. An unscheduled review of a PGD may arise 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.
- d. **Timelines for PGD Authorisation** - To enable timely review and authorisation, all PGDs requiring ICB authorisation must be submitted to the ICB Medicines Optimisation and Pharmacy Team no later than four weeks before the required PGD authorisation date. This timeframe allows sufficient opportunity for the PGD Review Group to complete governance and assurance checks, resolve any queries with the developing organisation, and support formal authorisation by the Director of Medicines Optimisation and Pharmacy.
- e. 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.
- f. Expiry extensions should be reserved for exceptional circumstances where not extending would negatively impact patient safety. The Chair of the PGD Review Group will make the final decision on whether an extension is justified and will formally authorise any agreed extension.
- g. Providers are responsible for monitoring and auditing the use of PGDs within their service. This information must be available to the commissioner on a regular basis as part of the contract monitoring process.

15. Implementation of Patient Group Directions

- a. Providers will make available any necessary additional training to meet the required competencies before individuals are authorised to work under a PGD and have the responsibility for identifying appropriately qualified and trained healthcare professionals to operate within the PGD.
- b. Providers will ensure that each identified healthcare professional is competent to operate under the PGD, which includes receiving any additional training deemed necessary, and has been formally authorised to operate under the PGD, including completion of all necessary documentation.
- c. Providers 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.

16. Implementation and Staff Training

- a. This policy will be implemented through established ICB medicines governance processes and communicated to all relevant staff within the Medicines Optimisation and Pharmacy team and to commissioners and commissioned providers.
- b. Each provider organisation is responsible for ensuring that its staff involved in developing, authorising, or working under PGDs are appropriately trained and competent in accordance with their local PGD policy, national standards and professional requirements.

17. Arrangements for Review

- a. This policy will be reviewed no less frequently than every three years. An earlier review will be carried out in the event of any relevant changes in legislation, national or local policy/guidance, organisational change or other circumstances which mean the policy needs to be reviewed.

18. References

- a. This policy has been developed with reference to the following statutory and national guidance:
 - The Human Medicines Regulations 2012 [The Human Medicines Regulations 2012 \(legislation.gov.uk\)](https://www.legislation.gov.uk/ukmg/2012/612)
 - NICE Patient group directions Medicines practice guideline [MPG2] Published: 02 August 2013 Last updated: 27 March 2017 [Overview | Patient group directions | Guidance | NICE](https://www.nice.org.uk/guidance/ MPG2)
 - Competency framework for people developing and/or reviewing and updating patient group directions <https://www.nice.org.uk/guidance/ MPG2/resources>
 - Competency framework for health professionals using patient group directions. <https://www.nice.org.uk/guidance/ MPG2/resources>

- NICE PGD national template <https://www.sps.nhs.uk/articles/sps-nationalhttps://www.sps.nhs.uk/articles/sps-national-patient-group-direction-pgd-exemplar-templates/patient-group-direction-pgd-exemplar-templates/>
- NICE audit and monitoring link [Overview | Patient group directions | Guidance | NICE](#); [Auditing Patient Group Directions – NHS SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)
- SPS PGD [When PGDs can be used – NHS SPS - Specialist Pharmacy Service](#)
- SPS PGDs and ICBs [Understanding Patient Group Directions and Integrated Care Boards – NHS SPS - Specialist Pharmacy Service](#)
- [Writing a PGD – NHS SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

19. Equality Statement

- a. This Policy will operate alongside the ICBs Equal Opportunities, Diversity at Work Policy, and Equality Delivery System. The ICB values the diversity of its employees, volunteers and people who are entitled to our services, irrespective of their race, disability, age, gender including sexual orientation, religion or belief, status, or grade.
- b. The ICB assures employees, volunteers and people entitled to our services are treated fairly, equally and with respect and dignity. The ICB will challenge discriminatory attitudes and provide rules and standards of behaviour.
- c. The use of this Policy will not discriminate directly or indirectly on the grounds of race, gender, sexual orientation, ethnic or national origin, religion, culture, disability, age, membership of a trade union or staff organisation or political affiliation.
- d. The ICB will monitor the use of this Policy, as far as it is able, and take action if it appears that it has a disproportionate effect.

Appendices

Appendix 1: Responsibility of the Provider

The provider must demonstrate that there is no other suitable mechanism for the administration or supply of the medicine within the service. This will include training non-medical prescribers, considering the use of patient specific directions or referral to other healthcare professionals.

The provider must have a PGD policy in place which must specify:

1. **A named senior responsible person** with accountability for ensuring that only competent, qualified and appropriately trained healthcare professionals oversee and use the PGD.
2. **Arrangements to determine whether a PGD is required**, including consideration of alternative mechanisms for supply or administration, and local governance processes for approving the decision to develop a PGD.
3. **The process for PGD development and authorisation**, including agreed timescales (allowing a four-week period for ICB authorisation) and arrangements for assuring the clinical governance of the PGD's content.
4. **Arrangements for PGD review**, including consideration of alternative supply or administration mechanisms at review, and processes for ensuring new staff are trained and competent prior to using the PGD.
5. **Training and competency requirements** for staff using the PGD, including how competence is assessed, maintained and recorded.
6. **Audit arrangements**, including agreed audit criteria, templates and timescales.
7. **Assurance that the provider maintains a robust and up-to-date register of all PGDs in use**, including review and expiry dates, with clearly assigned responsibility for review and control.
8. **Assurance that the provider has effective document management and record-keeping arrangements** for authorised PGDs, including version control and retention of current and expired PGDs.
9. **Local governance arrangements**, including supporting processes, internal resources and oversight mechanisms relevant to PGD development and authorisation.
10. **Confirmation that relevant stakeholders have been consulted** and their views considered during PGD development.
11. **Confirmation that all legal and regulatory requirements have been met.**
12. **Requirements for antimicrobial PGDs**, including confirmation that a microbiology specialist is involved in development and that use of an antimicrobial PGD is:
 - clinically essential and justified by best practice guidance.

- agreed by the local microbiology specialist and clearly documented.
 - subject to regular monitoring and review.
13. Arrangements for medicines security, storage and labelling, including the provision of medicines in pharmacist-prepared pre-packs where appropriate, and requirements for patient advice, manufacturer's patient information leaflets and checks to ensure safe use.
 14. Secure systems for recording and monitoring medicines use, including stock control, patient identifiers, medicines supplied or administered, and identification of the healthcare professional involved.
 15. Confirmation that unlicensed medicines are not supplied or administered under PGDs.
 16. Use of medicines outside their licence, where permitted, must be clearly justified by best clinical practice, explicitly stated within the PGD, and include the rationale for use outside the Summary of Product Characteristics (SPC). Such use should be exceptional and supported by recognised guidance (e.g. NICE).
 17. Professional accountability, confirming that all staff operate within their relevant professional codes of conduct and scope of competence.

Implementation

The provider will make available any necessary additional training to meet the required competencies before individuals shall be authorised to work under a PGD. Providers have the responsibility for identifying appropriately qualified and trained healthcare professionals to operate under the PGD including completion of all necessary documentation.

The provider is responsible for monitoring and audit of the use of PGDs within their service setting and must have this available to the commissioner on request, including [SPS-PGD-audit-tool-v2.docx](#).

Providers must ensure that appropriate organisational records are maintained, stored securely and archived, in line with relevant legislation and the Department of Health and Social Care's code of practice on records management.
[Recommendations](#) | [Patient group directions](#) | [Guidance](#) | [NICE](#).

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.

The provider is responsible for updating PGDs within appropriate timeframes to ensure continuity of service delivery. Where commissioner authorisation is required, Provider must submit to the ICB at least four weeks before the PGD is required operationally to allow sufficient time for review and assurance processes to be completed.

Appendix 2: PGD Submission Checklist (to be completed by the PGD owner)

To be used for new PGDs, revised PGDs and extensions and renewals of PGDs.

Confirmation of Commissioning & Legal Context	
This PGD relates to an ICB commissioned service- state name of service and name of lead ICB commissioner.	
A justification has been provided explaining why PGD use is required and why PSD/prescribing is not feasible. <i>Provide a concise explanation of the service model, operational need and rationale for PGD use. Your explanation should include:</i> <ul style="list-style-type: none"> • Why a PSD is not appropriate? • Why prescribing is not feasible at all points in the pathway? • How patient safety is protected using a PGD? • How are risks balanced against operational need? 	
Governance & Development	
Provider has an up to date PGD policy aligned with SPS requirements for governance and development of PGDs including clinical governance of content.	
All required governance steps in the provider's own PGD policy have been followed.	
A multidisciplinary team has developed the PGD including: <ul style="list-style-type: none"> • doctor/dentist signatory, • pharmacist signatory, • relevant clinical experts. 	
Stakeholder engagement is documented (clinical, governance, quality, safety).	
Antimicrobial PGDs include documented microbiology involvement and justification	
Clinical Content (Provider self-certification) <i>The provider must certify the clinical safety and validity of the PGD. The ICB does not clinically review content.</i>	
Medicines Legality	
No unlicensed medicines are included.	
Off label use is clearly stated and justified where applicable.	
PGD complies with Human Medicines Regulations 2012 in full.	
Practitioner Governance	
Provider maintains an authorised practitioner list with training, competency and re-authorisation records.	
Provider confirms only eligible professions will operate under the PGD (per legislation).	
Provider confirms practitioners will have access to the current authorised PGD at point of care.	
Monitoring, Audit & Reporting	
Provider has an audit plan using the SPS PGD Audit Tool to monitor PGD usage, near-misses, adherence to inclusion/exclusion criteria, antimicrobial stewardship	

compliance (as appropriate) and training and re-authorisation intervals.	
Provider agrees to submit audit and assurance data when requested by the ICB.	
Provider has systems to report incidents, adverse drug reactions, safety concerns, and near misses to the ICB.	
Document Management	
PGD includes required version control (version (numbering, summary of changes, table of updates), authors, signatories, dates, expiry, review date). PGD includes required version control (version (numbering, summary of changes, table of updates), authors, signatories, dates, expiry, review date).	
Provider has processes for unscheduled review after alerts, safety issues, evidence updates.	
Provider retains PGDs according to record retention standards (8 years/25 years).	
Provider agrees to submit updated PGDs at least 4 weeks before operationally required.	
Submission Requirements	
PGDs must be submitted in PDF format and must be fully completed, incorporating all required authorising signatures, a unique PGD identification number, and confirmed implementation and expiry dates.	
Provider submission includes: <ul style="list-style-type: none"> • completed provider checklist, • signed clinical signatory pages (doctor + pharmacist), • supporting documents (risk assessment, references, microbiology emails, etc.). 	

► Provider declaration

I confirm that all elements of this checklist have been completed in full and that these PGD(s) have undergone full internal governance and clinical review.

Signed:

Role:

Organisation:

Dated:

Appendix 3: Assurance & Governance Checklist (ICB PGD Review Group)

This checklist ensures the ICB is assured that the **provider** has met *all* SPS requirements. This aligns with SPS guidance that ICB authorisation is **organisational**, not a clinical review. ICBs must check that **governance and legal processes** were followed, not re-validate clinical content.

Commissioning & Legal Assurance	
Service is commissioned by the ICB.	
Provider justification for PGD use (vs PSD/prescribing) is acceptable.	
Complex commissioning arrangements (if any) have been mapped and do not prevent PGD authorisation.	
Provider Governance Assurance	
Provider has submitted the completed provider checklist.	
Provider has demonstrated compliance with SPS expectations for PGD governance.	
Provider's PGD development followed their own PGD policy.	
Clinical signatories (doctor + pharmacist) are present and correct.	
Antimicrobial PGDs include microbiology involvement.	
Provider self certification for all clinical content checks is complete and reasonable.	
Provider confirms accuracy of all clinical elements (ICB does not re-validate).	
Governance & Safety Checks	
PGD follows statutory requirements of Human Medicines Regulations 2012 (structure, signatories, content headings).	
Governance components (review cycle, expiry, version control) are complete.	
Monitoring, audit and reporting arrangements meet commissioning expectations.	
Provider has agreed to supply audit/assurance data when requested.	
Incident reporting and escalation pathways to the ICB are confirmed.	
Version Control & Record Management	
Version number, authors, dates, and expiry are present and correct.	
Provider commitment to resubmission for re-authorisation at least 4 weeks before PGD is operationally required.	
PGD format is appropriate for publication/distribution.	
ICB Authorisation	
PGD has been formally authorised by the Director of Medicines Optimisation and Pharmacy acting on behalf of the Integrated Care Board.	

Authorised PGD has been recorded on the ICB PGD register and included in the next assurance report to the Norfolk and Suffolk TAGIMOC for noting and oversight.	
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Appendix 4: Notification of Continued Authorisation of Patient Group Directions (PGDs)

Service: *[Name of commissioned service]*

Provider: *[Provider name]*

Former Commissioner: *[Legacy ICB name]*

Dear *[Provider Lead Name]*,

Norfolk and Suffolk Integrated Care Board (ICB) is now the commissioner of the above service following *[describe commissioning transfer, e.g. "the establishment of Norfolk and Suffolk ICB on 1 April 2026" or "change in lead commissioner arrangements"]*. In line with the Human Medicines Regulations 2012 and Norfolk and Suffolk ICB's PGD Policy, this letter confirms the **continued authorisation** of the Patient Group Directions (PGDs) previously authorised by *[legacy ICB]* for use within this service.

1. Confirmation of Adoption and Continued Authorisation

Norfolk and Suffolk ICB has **formally adopted** the PGDs listed in the attached schedule as part of its responsibilities as the current legal authorising body. These PGDs remain valid for use within your service, without the need for re-authorisation or re-signing, provided that:

- the PGD(s) remains within its authorised expiry date; and
- the service model and clinical pathway have not materially changed.

2. Provider Responsibilities

As the commissioned provider, you must ensure that:

- practitioners continue to operate only under PGDs for which they have been individually authorised.
- training and competency records remain current.
- PGD use continues to follow all relevant governance, audit and reporting requirements; and
- Norfolk and Suffolk ICB is informed of any material change to the service that may affect the safe use of the PGD.

No practitioner re-authorisation or repeat training is required solely because of commissioner transfer.

3. Future Review and Renewal

These PGDs will require full review and re-authorisation at their scheduled expiry dates. Where your organisation continues to be commissioned for the service, revised PGDs should be submitted to Norfolk and Suffolk ICB in accordance with the PGD governance process.

4. Schedule of PGDs Adopted by Norfolk and Suffolk ICB

Please see the attached schedule detailing:

- PGD title
- version number
- expiry date

- originating legacy ICB authorising body
- date of adoption by Norfolk and Suffolk ICB

