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**Corporate ICB Policy for the Development and Authorisation of Patient Group Directions**

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**AMENDMENTS**

Amendments to the policy may be issued from time to time. A new amendment history will be issued with each change.

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# Introduction

The policy and supporting procedures and processes have been developed to meet the requirements for the Integrated Care Board (ICB) to consider and approve the use of Patient Group Directions (PGDs).

This policy applies to PGDs that have been authorised by the ICB for the treatment of NHS patients by authorised healthcare professionals, whether working in the ICB provider organisations or are directly employed healthcare professionals supporting the delivery of NHS commissioned services

The supply and administration of medicines is controlled by The Medicines Act 1968 and controlled drugs (CDs) are regulated by The Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.

The legislation enabling registered practitioners to operate under a PGD was outlined in the [Health Service Circular](https://webarchive.nationalarchives.gov.uk/ukgwa/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf) (HSC 2000/26) and consolidated in 2012 within [The Human Medicines Regulations 2012 (SI 2012 /1916).](https://www.legislation.gov.uk/uksi/2012/1916/part/12/made) This details the provision for PGDs and sets out the legal requirements to develop and operate under a PGD. Failure to comply with these criteria falls outside of the law and could result in criminal prosecution under the Medicines Act (Department of Health, 1968).

A PGD is not an authorisation to prescribe and the preferred way for patients to receive medicines is for an appropriately qualified health care professional to prescribe for an individual on a patient-specific basis. As such, 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.

Therefore, the use of 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.

## Where can a PGD be used

This ICB policy aligns with national guidance and regulation. PGDs may be used in all areas in which NHS healthcare is directly provided and where services in the private, voluntary or charitable sector are NHS funded. PGDs do not however, extend to independent and public sector care homes or independent sector schools that provide healthcare entirely outside the NHS and out of scope of this policy.

# Purpose

Patient group directions allow authorised healthcare professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription. This policy aims to ensure that patient group directions are used in line with legislation and appropriate governance.

The purpose of this Policy is to:

· To set out the process for the identification, development, adoption, dissemination, implementation, monitoring, audit, and review of Patient Group Directions (PGDs).

· To provide the framework for service, clinical and professional leads to assist in the identification of and outline the process for the development of PGDs.

· To outline the role the ICB has in the authorisation of PGDs used to support NHS health care services commissioned by the ICB.

· To provide a robust approach across the whole organisation and incorporates the recommendations made in the Patient Group Directions [NICE Guideline](https://www.nice.org.uk/Guidance/MPG2) [(MGG2)](https://www.nice.org.uk/Guidance/MPG2) NICE August 2013 (updated March 2017)

The policy applies to all ICB staff and to authorised healthcare professionals providing directly ICB-commissioned NHS services.

Private Practice - The development of PGDs for privately funded services will not be supported by the ICB, e.g., Hepatitis B vaccine given on a private basis for travel purposes, or NHS practices using private PGDs. This is out of the scope of this policy.

# Definition/ Explanation of Terms

* **A Patient Group Direction** (PGD) can be defined as:

*" a written instruction for the sale, supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment."* [HSC2000/026 'Patient Group Directions [England Only]](https://webarchive.nationalarchives.gov.uk/ukgwa/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf)

A PGD is NOT an authorisation to prescribe. PGDs allow health care professionals specified within the legislation to supply and/or administer a medicine directly to a patient with an identified clinical condition without the need for a prescription or an instruction from a prescriber. The health care professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD

* A **Patient Specific Direction (PSD)** can be defined as:

*“a written instruction from an independent prescriber (doctor, dentist or independent nurse/pharmacist prescriber) to another healthcare professional, to supply or administer a medicine directly to a named patient, or to several named patients.”*

* **Independent Healthcare Services (Providers)** - CQC define 'independent healthcare services' as health care provided by organisations that are not NHS trusts or NHS GP services. [CQC](https://www.cqc.org.uk/guidance-providers/independent-primary-medical/independent-doctor-clinic-services#:~:text=We%20define%20independent%20healthcare%20services,is%2C%20private%20sector%20services). The role of the Independent Healthcare Services (Providers) is further defined below – see section 6.
* **Authorising Body** – authorisation for the of use of the PGD, in the case of independent healthcare services is the responsibility of the commissioning organisation, in this case, Humber and North Yorkshire Integrated Care Board (ICB). The role of the authorising body (commissioner) is further defined below – see section 6.
* **Clinical signatory** – signing the individual PGD - must include a doctor/dentist AND a pharmacist – see <https://www.sps.nhs.uk/wp-content/uploads/2017/05/RESPONSIBILITIES-OF-SIGNATORIES-OF-PGDS_-Final-Sept-2020.pdf#:~:text=signatories>

# Scope of the Policy

The policy applies to NHS Humber and North Yorkshire and all its employees and must be followed by all those who work for the organisation, including the Integrated Care Board, Integrated Care Partnership, those on temporary or honorary contracts, secondments, pool staff, contractors and students.

# Duties/ Accountabilities and Responsibilities

**PGD Working Group** – act on behalf of the independent healthcare service/provider. The Health Service Circular (HSC 2000/026) states that PGDs ‘should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD’. The NICE MPG2 calls this the ‘PGD Working Group’. See 6.11 for further information.

**ICB PGD Governance Assurance Signatories** – act on behalf of the authorising body/the commissioner (HNY ICB) to ensure that independent healthcare service (the provider) has followed the correct governance processes for developing and using PGDs in the provider organisation. The ICB PGD Governance Assurance Signatories must include as a minimum 1 X Senior Medicines Optimisation Pharmacist and 1 X Clinical and Professional Director (Medic) and/or 1 X Director of Nursing/or nominated deputy. See section 6.8 for further detail.

**Designated Clinical Governance ICB Signatory for PGDs** – acts on behalf of the authorising body/the commissioner (HNY ICB) to formally authorise use of PGDs by independent healthcare services (the provider), after the ICB PGD Governance Assurance Signatories have reviewed and made a recommendation to the Designated Clinical Governance ICB Signatory for PGDs to sign. These decisions are then sent to the ICB Clinical and Professional Executive for information/ratification. The Designated Clinical Governance ICB Signatory for PGDs can be one of the following:

* ICB Director of Pharmacy and Medicines Optimisation/ICB Chief Pharmacist
* ICB Executive Director for Clinical and Care Professionals
* ICB Executive Director of Nursing

In exceptional circumstances, the above-named roles may delegate to a deputy but only if the deputy has the relevant knowledge and experience regarding the ICB clinical governance processes for PGDs.

# Policy Document Requirements - Development and management of PGDs

Specialist Pharmacy Service (SPS) provide useful [guidance](https://www.sps.nhs.uk/articles/how-to-develop-a-patient-group-direction/) for commissioning and provider organisations, potential authors and signatories of PGDs as a prompt, to think about and follow necessary procedures before and during the stages of developing and authorising PGDs.

**Who are the PGD signatories?**

**(Taken from** [SPS 'Responsibilities of Signatories' June 2020](https://www.sps.nhs.uk/wp-content/uploads/2017/05/RESPONSIBILITIES-OF-SIGNATORIES-OF-PGDS_-Final-Sept-2020.pdf#:~:text=signatories)**)**

* [*Legislation*](https://www.legislation.gov.uk/uksi/2012/1916/contents/made) *requires that a PGD must be signed by a doctor (or dentist) and a pharmacist and guidance states that they should be involved in the development of the PGD.*
* *Patient group directions (*[*NICE guideline MPG2, 2017*](https://www.nice.org.uk/guidance/MPG2)*) recommends that, although not required by legislation, it is good practice for PGDs to be signed by representative/s of the registered health professional group (s) intended to supply and/or administer the medicine/s under the PGD. Where the representative of the registered health professional group/s is a pharmacist, it would be good practice to involve an additional pharmacist with expertise in the specific clinical area of practice who would use the PGD.*
* *Additionally, the PGD must be authorised by a representative of the relevant authorising body.\*\** [*Human Medicines Regulations 2012 Schedule 16 Part 2*](https://www.legislation.gov.uk/uksi/2012/1916/schedule/16/part/2/made) *defines the organisations on whose behalf a direction must be signed. An organisation’s structure should determine which individual role incorporates the authority and responsibility to be the signatory in order to state that PGDs are fit for purpose. For example, this signatory is often the clinical governance or patient safety lead who has designated responsibility for signing PGDs on behalf of the authorising body. Authorising bodies need to consider the knowledge, skills and expertise needed by people who are developing, updating, authorising and using PGDs and ensure that they are aware of their responsibilities and can demonstrate their competency.*

## \*\*[Update to include ICBs as authorising bodies](https://www.sps.nhs.uk/articles/authorisation-of-independent-healthcare-provider-ihp-pgds-for-nhs-and-public-health-commissioned-services/)

*The Medicines and Health Regulatory Agency (MHRA) has advised that where a PGD is used for NHS/public health funded healthcare under arrangements made with an NHS or a local authority, the law requires that the PGD is authorised by that body.*

*This applies to PGDs used for the provision of NHS and local authority funded services under arrangements between NHS bodies/local authorities and CQC registered independent medical agencies.*

*Therefore, independent healthcare providers (IHPs) cannot provide organisational authorisation for PGDs used to deliver NHS or public health commissioned services.*

*The organisational authorisation in this case is the responsibility of the commissioning organisation who must be listed in the legislation as able to authorise a PGD in England. These are:*

* *Integrated Care Boards (ICBs)*
* *Local authorities*
* *NHS trusts or NHS foundation trusts*
* *Special health authorities*
* *NHS England*
* *UK Health Security Agency (UKHSA)*

*IHPs should note that each PGD must be authorised by each organisation which commissions the service. Commissioning in some circumstances may be across a number of organisational boundaries. Where this is the case, commissioners may wish to take advice to explore how to develop a formal agreement for sign off using a “single operating model” approach.*

* *Finally, an individual health professional must be authorised in writing to use the PGD by a senior person who is responsible for ensuring that only fully competent, qualified and trained health professionals use PGDs. An individual or multiple practitioner agreement may be used as a declaration of competence on behalf of the practitioner and as a designation of their authority and accountability for their decisions to supply and/or administer medicines using a PGD*

ICB-commissioned service providers (except for those providers that are also authorising bodies, such as acute trusts) are unable by law to authorise and implement PGDs.

A PGD must be developed by the commissioned service provider and submitted to the ICB (see below) for review and approval if deemed to meet the necessary criteria.

***CQC define 'independent healthcare services' as health care provided by organisations that are not NHS trusts or NHS GP services.*** [CQC](https://www.cqc.org.uk/guidance-providers/independent-primary-medical/independent-doctor-clinic-services#:~:text=We%20define%20independent%20healthcare%20services,is%2C%20private%20sector%20services)

IHPs include private healthcare providers, social enterprises and community interest companies who are appropriately registered with the CQC (the CQC registration for these services depends on the regulated activities that they are undertaking - in respect of them developing PGDs or operating with PGDs they would need to be registered for one of the Regulated Activities as stated in HMR (2012) reg 231 (2)).

The commissioned service provider is responsible for the implementation of the PGD.

A PGD must be developed, approved and used in accordance with legislation and national guidance as listed below.

· HSC 2000/026 – Health Service Circular – Patient Group Directions (England Only) [www.dh.gov.uk](http://www.dh.gov.uk/)

· Human Medicines Regulations 2012 (SI 2012 No 1916)

· Good Practice Guidance (No. 02) - Patient Group Directions (NICE 02/08/13, Updated 2017.

· The Misuse of Drugs Regulations 2001.

· Standards for the Medicines Management (NMC 2009)

· The Code. Standards of conduct, performance and ethics (NMC 2008)

· British National Formulary (current online edition)

· Immunisation against Infectious Disease (“The Green Book”) online edition available at <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

· Patient Group Directions – NHS Specialist Pharmacy Services PGD resources, accessed at <https://www.sps.nhs.uk/home/guidance/patient-group-directions/>

· Legislation relating to prescription charges and exemptions.

## Identifying the need for a Patient Group Direction

The need for a PGD should be established. The SPS Guidance [’When to use a PGD’](https://www.sps.nhs.uk/articles/when-to-use-a-pgd/#:~:text=to%20pgd%20or%20not%20to%20pgd) should be used to establish if a PGD is legal and/or appropriate.

## Limitations on PGD usage - When is the use of a PGD inappropriate?

A PGD is not required:

* If an exemption exists under the Medicines Act.
* If the medicine involved is on the General Sales List (classified as GSL).
* For medical gases: these are not usually classified as Prescription Only

Medicines (POMs).

* For dressings, appliances, medical devices, or chemical agents: these are not legally classed as medicines.
* For medicines e.g., adrenaline for anaphylaxis where exemptions in legislation allow their supply and/or administration without the need for a PGD.

Not all medicines are suitable to be included in a PGD.

A PGD cannot be used for the following:

* unlicensed medicines including:
* The mixing of two licensed medicines to form a new (unlicensed) product, unless one is a vehicle for administration, such as water for injection
* Special manufactured medicines
* Anabolic steroids, and any injectable preparation used for treating addiction
* For management of long-term conditions, such as hypertension or diabetes
* Where uncertainty remains about the differential diagnosis, particularly when further investigations or diagnostic tests are needed, for example, erectile dysfunction
* Where the medicine needs frequent dosage adjustments, or frequent or complex monitoring, for example, anticoagulants or insulin (<https://www.nice.org.uk/guidance/mpg2>)
* For unlicensed medicines
* Radiopharmaceuticals
* Abortifacients, such as mifepristone.

PGDs should not be used to circumvent the repeat prescribing systems used in general practice, therefore a PGD will not be permitted when a prescription (FP10), or a Patient Specific Direction (PSD) could be written in advance.

## Drugs requiring special consideration

Certain medicines require special consideration before inclusion in a PGD and some are restricted by legislation.

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

### Use outside the terms of Summary of Product Characteristics (SPC)

In exceptional circumstances, and justified by best practice, licensed medication can be used outside the terms of its product license (so-called ‘off label’ use) and as such may be included in a PGD (the status of the product must be clearly described).

In deciding whether to support inclusion in a PGD, the provider PGD working group and ICB PGD Governance Assurance Signatories will consider whether there is acceptable evidence for the use of that product for the intended indication, e.g., follows nationally agreed guidelines, such as the Joint Committee on Vaccination and Immunisation (JVCI).

### Drugs subject to special reporting arrangements (Black Triangle Drugs ▼)

Black triangle drugs (licensed in the previous 12 months) will only be considered in exceptional circumstances by the ICB.

Treatment guidelines must be followed and the PGD must clearly state the status of the product.

### Antimicrobial drugs

A PGD should only be used for antibiotics if:

* clinically essential and clearly justified by best practice guidance.
* a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented.
* the use of the PGD is monitored and reviewed regularly.

### Controlled Drugs

Only certain controlled drugs can be included in a PGD according to The Misuse of Drugs Regulations (2001).

The SPS provides useful information on the [Supply and/or administration of Controlled Drugs under a PGD](https://www.sps.nhs.uk/articles/who-can-supply-or-administer-controlled-drugs-under-the-terms-of-a-patient-group-direction-and-under-what-circumstances/)

* Schedule 2: Morphine and diamorphine may be used by registered nurses and pharmacists only, for the immediate necessary treatment of a sick or injured person. Not for treating addiction)
* Schedule 2: Ketamine
* Schedule 3: Midazolam
* Schedule 4: All drugs except anabolic steroids and injectable medications used for treating addiction.
* Schedule 5: All drugs

Not all professions listed in the PGD legislation can administer controlled drugs under a PGD. The following regulated professional groups cannot administer or supply any CDs in any of the five schedules under a PGD:

* Dietitians
* Speech and language therapists
* Dental therapists
* Dental hygienists

### Risk Minimisation Measures (RMM)

There are regulatory requirements 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.

## Obtaining agreement to develop a patient group direction

Once the need for a PGD is established by the provider organisation, an application for permission to develop a PGD should be completed by that provider organisation in accordance with the relevant SOP. This would also apply to the ICB in circumstances that require it to produce PGDs for a service (See Appendix B). This form will then be submitted to the ICB for consideration and approval by the ICB PGD Governance Assurance Signatories and Designated Clinical Governance ICB Signatory for PGDs.

(Please also refer to section 6.2)

## Who should be involved?

The legislation does not specify who must be involved in developing PGDs.

The Health Service Circular (HSC 2000/026) states that PGDs ‘should be drawn up by a multidisciplinary group involving a doctor, a pharmacist and a representative of any other professional group expected to supply medicines under the PGD’. The [NICE MPG2](https://www.nice.org.uk/guidance/mpg2) calls this the ‘PGD Working Group’.

The responsibility for the membership of the PGD Working Group will usually lie with the provider organisation developing the PGD. It is expected that the PGD Working Group is set up in line with NICE MPG2 Recommendations 2.3 ‘Developing Patient Group Directions’.

**For commissioned services** – The responsibility for the membership of the PGD Working Group will lie with the provider organisation, and it should be set up in line with NICE MPG2 recommendations.

**For PGDs developed by the ICB** – The responsibility for the membership of the PGD Working Group will be agreed with the ICB PGD Governance Assurance Signatories.

Review and renewal of PGDs should be done by the PGD Working Group.

## Who Is Permitted to Use Patient Group Directions

PGDs must only be used by those qualified registered healthcare professionals listed in the [current legislation](http://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them).

Staff authorised can only use PGDs as named individuals.

## Developing PGDs

The development of the PGD should follow the principles set out in the [How to develop a Patient Group Direction – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](https://www.sps.nhs.uk/articles/how-to-develop-a-patient-group-direction/)

If the request for PGD development is supported by the ICB PGD Governance Assurance Signatories and approved by the ICB Designated Clinical Governance Signatory for PGDs, approval should be communicated in writing and should include:

* Confirmation of the doctor, pharmacist and other members of the working group proposed or, if not identified in the request, identification of the persons to develop the PGD.
* Where appropriate to do so, staff employed by external organisations such as an NHS Commissioning Support Unit (CSU) may be involved in the development and governance assurance review of a PGD.
* Stipulation of any specific requirements or limitations to the PGD including:

- Minimum qualification/training requirements for those using the PGD

- Maximum doses or length of treatment

- Criteria for patients to be excluded from the PGD

- Criteria for exclusions or restrictions on the use of the PGD regarding service provision.

PGDs must comply with [legal requirements](https://www.legislation.gov.uk/uksi/2012/1916/schedule/16/part/1/made) and best practice, so must include specific information (See PGD Template: Appendix C). This template must not be amended.

Information about how the PGD will be audited should be included within the individual PGD.

The commissioning organisation may, or may not be, the organisation that develops the PGD.

**For ICB-developed PGDs:**

The PGD lead author will ensure that the draft PGD is put into the current ICB PGD template (See Appendix C). The current PGD template has been developed to comply with legal and best practice requirements as set out in HSC 2000/26 and the Human Medicines Regulations 2012 and NICE Guidance and should not be altered in any way.

**For PGDs developed by a commissioned independent provider:**

The lead author will ensure that their draft PGD is put into the current ICB PGD template (See Appendix f) or that their own PGD template complies with all legal and best practice requirements as set out previously, including HSC 2000/26, the Human Medicines Regulations 2012 and NICE Guidance.

Once complete these PGDs will need to be submitted to the ICB PGD Governance Assurance Signatories and will require to be governance assessed using the PGD governance authorisation checklist (See Appendix F)

**For PGDs adopted by the ICB or a commissioned independent provider:**

These are PGDs such as the national immunisation templates produced by the UKHSA.

The lead author will ensure that the draft PGD is either put into the current ICB PGD template (See Appendix C) or that their adopted PGD template complies with all legal and best practice requirements as set out previously.

Once complete these PGDs will need to be submitted to the ICB PGD Governance Assurance Signatories and will require to be governance assessed using the PGD governance review checklist (part 2 of the ICB Governance Authorisation Form (See Appendix F).

A clinical protocol must be developed and implemented in conjunction with the PGD.

Specific training needs for individuals working under a PGD must be identified within the individual PGD.

The PGD will be informed by legislation, local and national frameworks, policies, guidelines, local formularies, and other bodies with medicines expertise.

References – all relevant guidelines and pertinent reference sources must be consulted as part of the development/review. All reference sources must be noted in the PGD documentation.

A PGD should include processes to ensure NHS prescription charges are collected where necessary.

## Approving and Ratifying a PGD

For NHS-commissioned services, only Integrated Care Boards, local authorities, NHS Trusts, NHS Foundation Trusts, Special Health Authorities and NHS England can authorise PGDs.

National PGDs from the Specialist Pharmacy Service (SPS) will be adopted by the ICB, if appropriate.

### PGDs for Providers within Sub-ICB Locations (Places)

The ICB (Humber and North Yorkshire ICB) is the authorising body (commissioner). However, it is recognised that not all independent healthcare services (providers) provide services right across the geography of Humber and North Yorkshire. Some commissioned services only apply to Sub-ICB Locations (SICBLs) / Places. There are 6 Sub-ICB Locations in Humber and North Yorkshire.

* If the PGD applies across all 6 SICBLs then the ICB PGD Governance Assurance Signatories should consist, as a minimum:

1 X Senior Medicines Optimisation Pharmacist (from anywhere within the ICB)

1 X Clinical and Professional Director and/or 1 X Nurse Director/Deputy (from anywhere within the ICB)

* If the PGD applies only to specific SICBLs then the ICB PGD Governance Assurance Signatories should consist, as a minimum:

1 X Senior Medicines Optimisation Pharmacist (connected to the SICBL(s) the PGD applies to)

1 X Clinical and Professional Director and/or 1 X Nurse Director/Deputy (connected to the SICBL(s) the PGD applies to)

### For newly developed PGDs

The PGD is to be presented to ICB PGD Governance Assurance Signatories once it had been approved by a doctor/dentist and pharmacist (+/- practitioner) involved in the PGD development.

When the PGD authors have signed and submitted the proposed PGD, the ICB Governance Assurance Signatories will arrange for the PGD to be assessed, and can then recommend authorisation from the Designated Clinical Governance ICB Signatory for PGDs.

The assessment will include the completion of a governance review checklist (see Appendix F).

If the PGD is to be used by ICB employees, then a governance checklist will need to be completed by a senior pharmacist and approved by the relevant clinical professional leadership e.g., ICB Executive Director of Nursing (for nurses and AHPs) or ICB Director of Pharmacy and Medicines Optimisation (for pharmacists) (or nominated Deputies, where appropriate).

A copy of each PGD with the recommended paperwork (including details of any proposed training package and implementation plan) will be submitted to the ICB PGD Governance Assurance Signatories and then signed off by the Designated Clinical Governance ICB Signatory and ratified by the ICB Clinical and Professional Executive Committee to assure that the PGD has been developed with appropriate governance in place.

For each PGD, the provider organisation should:

1. Identify a senior, responsible clinical representative from within the service to authorise named, registered health professionals to practice under the PGD.
2. Ensure that authorised health professionals have signed the appropriate documentation.

Arrangements for sign-off and ratification of the PGD may diverge from the usual related processes during extraordinary circumstances (e.g., during a pandemic) or due to urgency, to ensure that PGDs remain within legislation and that patient safety is protected.

### For national PGDs adopted by the ICB

This will be similar to section 4.8.1, except that the governance review checklist, once completed can be submitted and approved by the Designated Clinical Governance ICB Signatory for PGDs where they are satisfied that all governance review criteria are met. (This is provided by the completion of the checklist). The PGD can then be presented to the ICB Clinical and Professional Executive Committee for a formal recording of approval.

### For PGDs adopted by the ICB for ICB healthcare staff

See the above processes.

### Summary Flowchart of Process – a simplified version

For a more detailed version please see Appendix G.

## Implementing a PGD

Once ratified the PGD will be shared with the proposers for implementation.

Providers will then disseminate this to relevant staff. They will ensure that those who are going to be operating under the PGD have access to the document, have signed to operate under it and that any training needs have been identified and addressed.

Professionals using a PGD must hold a current registration as identified within the PGD and act within their appropriate codes of conduct.

Providers will retain a copy of the signed authorisation sheet at the back of each PGD and keep a record of staff who have signed to use the PGD. These records may be inspected by relevant bodies e.g., ICB, CQC etc.

In the clinical setting where the PGD is being used the following must be in place:

· Copy of supporting protocol, SOP, or guideline

· Copy of current PGD

· List of staff authorised to work under the PGD

## PGD Review and Revalidation

PGDs must have an expiry date and must not be used beyond their expiry date because any supply and/or administration of a medicine(s) would be without legal authorisation.

The expiry date for a PGD should be considered and determined on a case-by-case basis with patient safety paramount. NICE recommend that this should be a maximum of 3 years from the date the PGD was authorised (or re-authorised following review).

The commissioned service provider is responsible for ensuring that PGDs are reviewed in good time to ensure continuity of care. It is also responsible for identifying/ensuring that appropriate persons form the PGD Working Group.

The commissioned service provider must advise the ICB PGD Governance Assurance Signatories of all the current/existing PGDs and their expiry dates, so the ICB PGD Governance Assurance Signatories can plan the schedule for reviews.

The commissioned service provider must provide the ICB PGD Governance Assurance Signatories with 3 months' notice before the PGDs expire – to allow the planning/scheduling of reviews.

PGDs should be reviewed and revised following the same processes as new PGDs and involve consultation with all stakeholders.

The expiry date of a PGD can only be extended if there is a justifiable delay in renewing a PGD. For PGDs where a review is not completed within 1 year of the expiry date will be withdrawn from use.

PGDs updated before their review will need to be re-ratified.

Each new or revised PGD should be re-signed by all appropriate staff to ensure competence is up to date.

PGD staff authorisation records must be kept for 10 years for adults and 25 years if they relate to children.

The Clinical Lead or manager of the provider service should establish a robust and transparent process for the unscheduled review and updating of a PGD when the need for this has been identified. This should include responding to:

* changes in legislation
* important new evidence or guidance that changes the PGD, such as new NICE guidance
* new information on drug safety
* changes in the summary of product characteristics
* changes to the local formulary

Any senior medical representative of a commissioned service or lead of a provider organisation can request an unscheduled review and updating of a PGD when the need for this has been identified.

Any proposed changes, including minor amendments, will require the PGD to go through the review process and be re-authorised.

Each version of the PGD must be kept for 10 years for adults and 25 years if they relate to children.

## PGD Version Control

The ICB PGD Governance Assurance Signatories will ensure PGD version control:

1. During the development process, strict version control must be followed, and draft versions must be watermarked on each page as “draft”.
2. A new PGD in development will begin as 0.1
3. Subsequent amended versions will become 0.2, 0.3, 0.4 etc. d) The first ratified PGD will be version 1.0
4. When a PGD is under review the version changes to 1.1. As different groups are consulted and changes are made, the version changes 1.2, 1.3 etc.
5. The next final reviewed and ratified guideline becomes 2.0, and so on.

## Duties and Responsibilities

Each PGD signatory has responsibilities appropriate to their role in PGD development, authorisation and implementation.

The doctor (or dentist) and pharmacist signatories must establish that the clinical and pharmaceutical content is accurate and supported by the best available evidence.

The doctor/dentist should have relevant expert clinical knowledge.

The representative of the professional group expected to supply medicines under the PGD must ensure that they are satisfied that the PGD is fit for purpose for the health professional (e.g., nurses) delivering care to patients in that particular service and locality.

Organisations have a responsibility to ensure that a PGD is authorised within the legal framework and local governance arrangements (see section 3.4 of NICE MPG2 PGD guidance).

Those signatories who have designated responsibility for signing PGDs on behalf of the ICB for an ICB-commissioned service must establish that:

* Processes and governance arrangements have been followed
* All legal requirements have been met
* There is effective implementation of the policy
* There has been full consideration of the service in which the PGD is to be used for governance purposes, the clinical governance signatory should not be involved in developing the PGD and will not practice under the PGD.

The clinical governance signatory on behalf of the authorising organisation should not be required to check the clinical content of the PGD in detail but should be provided with sufficient evidence to be assured that the doctor (or dentist) and pharmacist signatories (and anyone else involved in the development of the PGD) have the competency, skills and experience to carry out their role and responsibilities.

A satisfactory governance review checklist must have been completed by the ICB PGD Governance Assurance Signatories as part of the evidence to support ICB sign-off.

Note: Electronic signatures may be used in line with [MHRA guidance.](https://www.sps.nhs.uk/articles/questions-electronic-systems-and-pgds/) However, attaching a scanned picture of a signature is not acceptable.

All staff, including temporary and agency staff, are responsible for:

* Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken.
* Co-operating with the development and implementation of policies and procedures as part of their normal duties and responsibilities.
* Identifying the need for a change in policy or procedure because of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly.
* Identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager.
* Attending training/awareness sessions when provided.

## Implementation

A PGD may need to be 'adopted' by the provider organisation(s) if they have not been involved in developing and authorising it. For example, when a PGD is developed and authorised by an ICB for use across multiple GP practices, a process would need to be in place for each GP practice to adopt the PGD for use in their practice.

Organisations must follow the ICB Process of Adopting a PGD SOP.

## Record Keeping

When a health care professional is working to a PGD the following information must be recorded:

* Patient’s details: name, condition presented, medical history.
* Patient assessment and diagnosis.
* Contra-indications to any medicines.
* Medicines which have caused allergic reactions or side effects.
* Allergies to the drug and/or excipients.
* Current and recent prescription medicine, including over-the-counter (OTC) medicines and herbal preparations.
* Reasons for exclusion and referral.
* Medicine supplied and/or administered: name; form; strength; quantity; batch number; expiry date; information and advice given.
* Name and/or signature of the health care professional providing treatment and supplying the medicine.

All records must be signed, dated, and kept for 10 years after the last attendance, or up to the patient’s 25th birthday if longer than 10 years away.

Records should be kept in the patient’s notes and either sent to the patient’s GP or as detailed in the individual PGD.

Details of the administration of vaccines to children must be sent to the appropriate Child Health Information System.

Where available, an entry on the computer record under the healthcare professional’s individual identification and password is an acceptable alternative.

## Organisational Governance

For each PGD, the commissioning and provider organisation(s) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability and arrangements are in place to ensure compliance with the Organisational Governance recommendations in the NICE MPG 2.

## Incident reporting

Compliance with this policy will be monitored using an analysis of incidents and complaints where there has been a failure to follow procedure.

It is the contractual responsibility of the service provider to notify the ICB of errors/incidents.

Quarterly medication medicines error/incident reports will be reviewed by the ICB PGD Governance Assurance Signatories, and as appropriate reported to the Clinical and Professional Executive Committee and/or ICB Quality Committee. Action plans to manage improvement in compliance will be developed where necessary.

## Archiving

The ICB will ensure that archived copies of superseded policy documents are retained in accordance with Records Management: NHS Code of Practice 2021.

## Indemnity insurance

Those signing PGDs must ensure that adequate indemnity arrangements are in place.

Individual healthcare professionals should have their own Professional Indemnity Insurance and ensure that the insurance provider is aware that they are operating under PGDs.

Those employed (as opposed to being self-employed), may be covered for these purposes but individuals should check with their employer. Most employers provide vicarious liability insurance to cover the acts or omissions of their employees, but healthcare professionals must check that they are covered.

The service lead/manager authorising staff to operate under PGDs within their service should also ensure that their professional indemnity insurance covers their authorising PGDs for use within their service.

Health care professionals, who are members of a professional organisation, or trades union, may also be covered additionally by this body.

# Training

PGD development:

* This policy will be available to all staff who use/develop Patient Group Directives within the ICB.
* All directors and managers are responsible for ensuring that relevant staff within their own directorates and departments have read and understood this document and are competent to carry out their duties in accordance with the procedures described.

PGD Use:

* Specific training needs for individuals working under a PGD must be identified within the individual PGD.
* The senior medical representatives within the commissioned service are responsible for ensuring that all staff using a PGD are competent to assess all relevant aspects of the patient’s clinical condition, take responsibility for the supply and/or administration of the medicine and make related decisions.
* All staff supplying and/or administering medicines under PGDs must have written evidence of competence, training, knowledge, experience, and continuing education relevant to the clinical condition/situation to which the PGDs apply.
* The practitioner operating under the PGD must take personal responsibility for ensuring they maintain their competence and knowledge and attend additional training when appropriate.
* In the service provider organisation, it is the responsibility of the designated senior doctor/clinical lead to ensure competency and to countersign the documents for any nurse, or other authorised healthcare professional working under PGDs within the service.
* The provider organisation will keep these signed authorisations as both evidence of individuals’ competency and as a record of staff authorised to use the PGD.
* Adequate educational materials should be available to enable individual people and organisations to deliver safe and effective services in which PGDs are used.
* Training and re-training of health professionals using PGDs should incorporate a post-training assessment of competency.

# Monitoring Compliance

## Monitoring

The ICB Board will agree on a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database.

No deviation from this policy will be allowed.

Any PGD that has been developed independently of this policy will not be authorised for use by ICB.

## Audit

As stated in HSC 2000/026, care provided under a patient group direction must be audited.

It is a legal requirement as per HSC 2000/026 to keep records of administration and/or supply under PGD for audit purposes.

It is the responsibility of the service lead and/or provider to monitor and audit the use of PGDs within their setting to ensure compliance with procedures.

Information about how the PGD will be audited should be included within the individual PGD.

There must be a list of professionals who can work under the PGD available at any given time.

Monitoring and evaluation of PGDs within the ICB may be undertaken in conjunction with CQC or ICB PGD Governance Assurance Signatories. The results of the audit should be shared within the service and reported to the ICB Clinical and Professional Executive Committee.

The records of administration or supply against each PGD must be audited as frequently as determined by the commissioner by each provider so that the appropriateness of the supply or administration (or of not supplying or administering a medicine) can be reviewed.

It is the responsibility of the signatory senior medical representative or delegated other member of the provider to ensure that the audits are completed and that practitioners are working in accordance with the PGD.

It is recommended that an audit of PGDs is undertaken annually. For new staff, practice should be audited six months after commencing the post.

The results should highlight areas of best practice as well as areas of concern and identify any areas of training and development needs.

PGDs will not normally be accepted for revision unless an audit report has been provided.

## Compliance

No deviation from this policy will be allowed.

Any patient group direction that has been developed independently of this policy will not be authorised for use.

Key findings of both audit and monitoring of compliance will be reported to the ICB Clinical and Professional Executive Committee and/or the ICB Quality Safety Committee.

# Arrangements for Review

The ICB Board will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

Staff who become aware of any change which may affect a policy should advise their line manager as soon as possible. The Executive Director or nominated deputy will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

For ease of reference for reviewers or approval bodies, changes should be noted in the ‘document history’ table on the front page of this document.

**NB:** If the review consists of a change to an appendix or procedure document, approval may be given by the Designated Clinical Governance ICB Signatory for PGDs, and a revised document may be issued. Review of the main body of the policy must always follow the original approval process.

# Dissemination

Notification of newly published PGDs (new or updated) will be sent to a designated individual(s) to coordinate distribution to appropriately trained staff.

It is the responsibility of the designated individual (usually the Service Lead / Manager) to ensure new staff are authorised to use relevant PGDs. This means that they are responsible that all paperwork is correct (i.e., the current version on the intranet) and that all professionals using that PGD is signed up for it in advance.

Copies of this paperwork must be kept in a safe place e.g., in a folder specifically for that purpose and may be required for inspection.

# Associated Documentation

## Legislation and statutory requirements

[HSC 2000/026: Patient Group Directions (England only); Department of](https://webarchive.nationalarchives.gov.uk/ukgwa/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf) [Health, Health Service Circular 9th August 2000](https://webarchive.nationalarchives.gov.uk/ukgwa/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf)

[[ARCHIVED CONTENT] (nationalarchives.gov.uk)](https://webarchive.nationalarchives.gov.uk/ukgwa/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012260.pdf)

## Best practice recommendations

* NICE. Patient Group Directions. Medicines Practice Guideline (MPG2). (August 2013, updated March 2017). Available at: <https://www.nice.org.uk/guidance/mpg2>
* MHRA Guidance. Patient Group Directions: who can use them. (December 2017). Available at: [https://www.gov.uk/government/publications/patient-group-directions-pgds/patient- group-directions-who-can-use-them](https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them)
* NHS Patient Group Directions (PGD) website. Available at: <https://www.sps.nhs.uk/home/guidance/patient-group-directions/>
* Specialist Pharmacy Services (SPS). Retaining PGD documentation. Published 10 June 2021 · Last updated 5 April Available at: <https://www.sps.nhs.uk/articles/retaining-pgd-documentation/>
* Specialist Pharmacy Services (SPS) - Patient Group Direction (PGD) signatories – Updated September 2020 - <https://www.sps.nhs.uk/wp-content/uploads/2017/05/RESPONSIBILITIES-OF-SIGNATORIES-OF-PGDS_-Final-Sept-2020.pdf#:~:text=signatories>

# Appendices

Appendix A - Anti-Fraud, Bribery and Corruption

Appendix B - Request for the Development of a Patient Group Direction

Appendix C - (Template) Patient Group Direction (PGD)

Appendix D - Management & Monitoring of Patient Group Direction

Appendix E - PGD Service Specification

Appendix F – HNY ICB Governance Authorisation Form

Appendix G: Detailed flowchart for PGD approval process

# Impact Assessments

## Equality

NHS Humber and North Yorkshire ICB is committed to creating an environment where everyone is treated equitably and the potential for discrimination is identified and mitigated. It aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

It is required that a Impact Assessment is carried out on a new policy that is likely to impact on patients, carers, communities, or staff. As a result of this assessment no adverse impact was identified.

## Bribery Act 2010

Due consideration has been given to the Bribery Act 2010 in the development (or review, as appropriate) of this policy document, further details can be found in appendix A.

## General Data Protection Regulations (GDPR)

The UK General Data Protection Regulation (GDPR)/ Data Protection Act 2018 includes the requirement to complete a Data Protection Impact Assessment for any processing that is likely to result in a high risk to individuals. Consideration should be given to any impact the policy may have on individual privacy; please consult NHS Humber and North Yorkshire ICB Data Protection Impact Assessment Policy. If you are commissioning a project or undertaking work that requires the processing of personal data, you must complete a Data Protection Impact Assessment.

The ICB is committed to ensuring that all personal information is managed in accordance with current data protection legislation, professional codes of practice and records management and confidentiality guidance. More detailed information can be found in the Data Protection & Confidentiality Policy and related policies and procedures.

# Appendix A - Anti-Fraud, Bribery and Corruption

The ICB has a responsibility to ensure that all staff are made aware of their duties and responsibilities arising from the Bribery Act 2010.  Under the Bribery Act 2010 there are four criminal offences:

•           Bribing or offering to bribe another person (Section 1)

•           Requesting, agreeing to receive or accepting a bribe (Section 2);

•           Bribing, or offering to bribe, a foreign public official (Section 6);

•           Failing to prevent bribery (Section 7).

These offences can be committed directly or by and through a third person and, in many cases, it does not matter whether the person knows or believes that the performance of the function or activity is improper.

It should be noted that there need not be any actual giving and receiving for financial or other advantage to be gained, to commit an offence.

All individuals should be aware that in committing an act of bribery they may be subject to a penalty of up to 10 years imprisonment, an unlimited fine, or both.  They may also expose the organisation to a conviction punishable with an unlimited fine because the organisation may be liable where a person associated with it commits an act of bribery.

Individuals should also be aware that a breach of this Act renders them liable to disciplinary action by the ICB, whether or not the breach leads to prosecution.  Where a material breach is found to have occurred, the likely sanction will be loss of employment and pension rights.

To raise any suspicions of bribery and/or corruption please contact the Executive Director of Finance and Investment.  Staff may also contact the Local Counter Fraud Specialist (LCFS) at – Audit Yorkshire, email:  [nikki.cooper1@nhs.net](mailto:nikki.cooper1@nhs.net)  or mobile 07872 988939.

The LCFS or Executive Director of Finance and Investment should be the contact for any suspicions of fraud. The LCFS will inform the Executive Director of Finance and Investment if the suspicion seems well founded and will conduct a thorough investigation.  Concerns may also be discussed with the Executive Director of Finance and Investment or the Audit Committee Chair.

If staff prefer, they may call the NHS Counter Fraud reporting line on 0800 028 40 60 between 8am-6pm Monday-Friday or report online at [www.reportnhsfraud.nhs.uk](http://www.reportnhsfraud.nhs.uk).  This would be the suggested contact if there is a concern that the LCFS or the Executive Director of Finance and Investment themselves may be implicated in suspected fraud, bribery or corruption.

**Appendix B: Request for the Development of a Patient Group Direction**

**Request for the Development of a Patient Group Direction - Template**

The following document should be completed before the development of a full PGD.

**Request to Develop a Patient Group Direction**

|  |  |
| --- | --- |
| **Title of PGD (Drug and Clinical Indication)** |  |
| New PGD or review of existing PGD | New □ Review □ |
| Reference number (revision only) |  |
| Expiry date (revision only) |  |
| Timescale for development/revision |  |
| **Proposer details:** | |
| Name: | Job Title: |
| Organisation: | Email: |
| **Head of service details:** | |
| Name: | Job Title: |
| Organisation: | Email: |
| **Organisational details:** | |
| Commissioning organisation: |  |
| Provider organisation: |  |
| Organisation(s) delivering service where the PGD will be used |  |
| Setting(s) where the PGD will be used |  |
| Health professional groups working under the PGD |  |
| **Persons who will be writing the PGD (PGD Signatories):** | |
| Lead author: | Organisation: |
| Profession: | Email address: |
| Doctor/Dentist name: | Organisation: |
| Profession - doctor or dentist (delete as appropriate) | Email: |
| Name of pharmacist: | Organisation: |
|  | Email: |

|  |  |
| --- | --- |
| **Professional Group Representative (working to the PGD)** |  |
| Organisation: |  |
| Email: |  |
| **Service Manager/Lead:** |  |
| Organisation: |  |
| Email: |  |
| Clinical Lead (this may be a doctor or a dentist): |  |
| Organisation: |  |
| Email: |  |

**PGD Purpose and Benefit to Patient Care:**

Provide details to the criteria below and include supporting evidence:

|  |  |
| --- | --- |
| **Circumstances in which the PGD is to be used** | |
|  | |
| **Condition or health needs to be met and benefit to patient care** | |
|  | |
| **Medicine(s) to be included in PGD – further details** | |
| Name of drug |  |
| Dosage |  |
| Quantity |  |
| Formulation |  |
| Strength |  |
| Route of administration |  |
| Duration of treatment |  |
| License status (licensed, unlicensed or off-label use) |  |
| Class – POM, Black triangle, controlled drug etc. |  |
| Included in the local formularies that apply to the organisation? |  |
| Please tick below to indicate how the medicine will be provided:  Supply⬜ Administration⬜ Both⬜ | |
| **Professional group(s) to be included in PGD** | |
|  | |
| **Specific qualifications or training & competency requirements** | |
|  | |
| **Benefits and advantages of using a PGD over other methods of supply or administration e.g., prescribing, patient-specific direction** | |
|  | |
| **Is the PGD required to support a new service development? Yes / No**  **If yes please provide details including an indication as to whether service development has been approved and funded.** | |
|  | |
| **Potential risks to patient safety** | |
|  | |
| **Resources needed to deliver the service** (details of how medicine will be funded, purchased, stored, staff resources required, including development and implementation) | |
|  | |
| **Current and/or future service provisions for supplying and/or administering the medicine(s), including its position within the care** | |
|  | |
| **Other available options to provide the service – risks and benefits** | |
|  | |
| **Stakeholder View** | |
|  | |
| **Please send the completed form to: ICB PGD Governance Assurance Signatories** | |

**Part 2**

The request to develop a Patient Group Direction for use within NHS HNY ICB has/has not been (delete as appropriate) approved for development.

|  |  |  |
| --- | --- | --- |
| **ICB PGD Governance Assurance Signatories - One Member (on behalf of the group)** | Name |  |
| Job title |  |
| Email |  |
| Signature |  |
| Date |  |

Approval has been granted on the condition that the following requirements or restrictions are included in the Patient Group Direction.

|  |
| --- |
| **Qualifications, training and competency** |
|  |
| **Other requirements/restrictions** |
|  |
| **Other comments/reasons for not granting:** |
|  |

**Appendix C - Patient Group Direction (PGD) Template**

SPS National Patient Group Direction Exemplar Template:

<https://www.sps.nhs.uk/articles/sps-national-patient-group-direction-pgd-exemplar-templates/>

<https://www.sps.nhs.uk/wp-content/uploads/2019/06/National-PGD-template.docx>

**Appendix D - Management & Monitoring of Patient Group Direction**

*PGD Number* *Name of Medication*

Healthcare Professional Authorisation (service/practice list)

*This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.*

This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD.

The following healthcare professionals are authorised to administer

*Name of Medication* under the Patient Group Direction (*PGD number*)

PGD Valid from date: PGD Expiry Date:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Healthcare Professional | | | Authorised by: | | |
| Name | Signature | Date | Name | Signature | Date |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| PGD Valid from: | Review Date: | Expiry Date: |

**Appendix E - PGD – Title Service Specification**

|  |  |
| --- | --- |
| **Service Specification Number:** |  |
| **Service** |  |
| **Commissioner Lead** |  |
| **Provider Lead** |  |
| **Period** |  |
| **Date of Review** |  |

|  |
| --- |
| 1. Population Needs |
| 1.1 National/local context and evidence base |
| 1. Outcomes |
| 2.1 NHS Outcomes Framework Domains and Indicators |
| 1. Scope |
| * 1. Purpose   2. Aims and Intended Service Outcomes   3. This service should benefit patients when:   4. Scope of Service   5. Pharmacy and Pharmacist Accreditation   6. Population Covered   7. Any acceptance and exclusion criteria and thresholds   8. Interdependence with other services/provides |
| 1. Applicable Service Standards |
| 4.1 Applicable national standards (e.g., NICE)  4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g., Royal Colleges)  4.3 Additional reading/further learning options  4.4 Other local policies to note |
| 1. Applicable quality requirements |
| 5.1 Applicable Quality Requirements |
| 5.2 Clinical Incident Reporting |
| 5.3 Complaints Procedure |
| 1. Location of Provider Premises |
| The provider's premises are located at: |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Quality requirements | | | | |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**Appendix F: Governance Authorisation Form**

**(Includes Part 1 - ICB Commissioner Authorisation and Part 2 – Governance Review Checklist)**

Notes on use:

* Part 1 The HNY ICB Commissioner Authorisation section is not required for national immunisation PGD templates, as an authorising body sign-off section is already included within the national immunisation templates.
* For the adoption of National Immunisation Template PGDs that will be used by ICB-employed healthcare professionals, a governance review checklist must be completed and signed off by a senior pharmacist and approved by the relevant clinical professional leadership e.g., ICB Executive Director of Nursing (for nurses and AHPs) or ICB Director of Pharmacy and Medicines Optimisation (for pharmacists) or nominated Deputies.
* If the PGD does not meet the governance approval checklist, the nominated member of the ICB PGD Assurance Signatories (usually a senior pharmacist) (assessor) will work with the PGD authors to clarify/update any areas required for amendment.
* When the ICB Governance Assurance Signatories completes the governance review and is satisfied that the PGD meets all PGD statutory and best practice requirements they will sign the PGD Governance Review Checklist (Part 2) and the ICB Authorisation Form (part 1) as an additional signatory.
* For each PGD the completed Commissioner Authorisation (part 1) and governance review checklist (Part 2) of the form is sent together with the PGD(s) to the Designated Clinical Governance ICB Signatory for PGDs.
* These documents will then be submitted to the Clinical and Professional Executive Committee for a formal recording of approval.
* Once the ICB has authorised the submitted PGD (i.e., the ICB signatory and additional signatory have signed the Commissioner Authorisation section (Part 1)), the ICB will send to the provider the pdf version of the signed HNY ICB Commissioner Authorisation section (Part 1/front page only) of the ICB PGD Governance Authorisation Form + the providers final submitted PGD
* **NHS Humber and North Yorkshire Integrated Care Board (ICB) Patient Group Direction (PGD) Governance Authorisation Form**

**Part 1 - HNY ICB Commissioner Authorisation**

The PGD is not legally valid until it has had the relevant organisational authorisation by the appropriate Authorising Body.

The submitting NHS-commissioned provider is responsible for ensuring that any submitted PGD complies with all relevant statutory, governance and best practice requirements.

It is the responsibility of the organisation that has the legal authority to authorise the PGD to ensure that all legal and governance requirements are met.

The authorising body **NHS HNY ICB** is signing that **[insert name of provider organisation]** has followed the required processes and governance arrangements for this PGD

|  |  |
| --- | --- |
| PGD Title |  |
| Version |  |
| Reference number: |  |
| Provider |  |

**NHS HNY ICB** authorises this PGD for use by the services or providers listed below:

|  |
| --- |
| Authorised for use by the following organisations and/or services |
| <insert name of provider> providing services within NHS HNY ICB |
| Limitations to authorisation |
| The authorisation is limited to registered practitioners listed in the PGD who are employed by <add the name of provider>, commissioned by NHS Humber and North Yorkshire ICB to deliver NHS services within the whole of Humber and North Yorkshire region. |

|  |  |  |  |
| --- | --- | --- | --- |
| NHS HNY ICB Commissioner organisational approval (legal requirement) | | | |
| Role | Name | Sign | Date |
| Director of Pharmacy and Medicines Optimisation | Laura Angus |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Additional signatories, from the ICB Governance Assurance Signatories, required for the HNY ICB governance assurance review | | | |
| Role | Name | Sign | Date |
|  |  |  |  |
|  |  |  |  |

**Part 2**

Patient Group Direction (PGD) Governance Review Checklist

This PGD review checklist forms part of the governance assurance and approval process required by the Humber and North Yorkshire Integrated Care Board (ICB), to support their responsibilities in authorising or adopting PGDs used in the delivery of NHS-commissioned services, including PGDs previously commissioned by legacy CCGs within HNY ICB region.

To be completed on behalf of HNY-ICB by a nominated person from the ICB PGD Governance Assurance Signatories – usually a senior pharmacist.

(This completed signed form along with the reviewed PGD must be submitted to the nominated HNY ICB Designated Clinical Governance ICB Signatory for PGDs, for final review and governance approval).

As part of the governance review, a nominated person from the ICB PGD Governance Assurance Signatories must sign the checklist and the PGD Governance Authorisation Form for the PGD being reviewed as an “Additional Signatory” to indicate satisfactory governance review of the PGD being submitted for NHS HNY ICB governance authorisation/approval.

(NB. For ICB use PGDs the governance authorisation form may be included within the PGD document itself).

|  |  |
| --- | --- |
| Title and version of PGD |  |
| Reference number: |  |
| Provider name: |  |
| PGD was written by: |  |
| Valid from: |  |
| Name of ratification group: |  |
| Date ratified/approved: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Present and fully documented in the PGD? | Yes | No | N/A | Comments |
| Signatures and PGD validity details | | | | |
| Signatures of all health professionals who formally developed the PGD present? |  |  |  |  |
| Name of PGD and version included? |  |  |  |  |
| Date the direction comes into force and the date it expires? |  |  |  |  |
| Signature(s) of governance approval of the PGD by the provider organisation?  (Only required for private organisations with formal governance structures in place – e.g., Prison Healthcare Providers) |  |  |  |  |
| Name of the service(s) to which the direction applies |  |  |  |  |
| Staff characteristics section |  |  |  |  |
| Link to appropriate references (e.g., Green Book, BNF, NICE etc.)? |  |  |  |  |
| Alternative options considered? |  |  |  |  |
| Clinical condition or situation defined? |  |  |  |  |
| Inclusion/exclusion criteria documented? |  |  |  |  |
| Cautions section completed? |  |  |  |  |
| Does the PGD include circumstances in which further advice should be sought from a doctor or dentist, and if so, what these circumstances are? |  |  |  |  |
| Action to be taken if a patient is excluded? |  |  |  |  |
| Action to be taken if the patient or carer declines treatment? |  |  |  |  |
| Arrangements for referral for medical advice? |  |  |  |  |
| Name, strength, and formulation of drug |  |  |  |  |
| More than one medicinal substance? |  |  |  |  |
| Defines legal classification? |  |  |  |  |
| Black triangle medicine used? |  |  |  |  |
| Off-label use defined? |  |  |  |  |
| Route/method of administration? |  |  |  |  |
| Dose and frequency of administration? |  |  |  |  |
| Duration of treatment? |  |  |  |  |
| Quantity to be supplied/administered? |  |  |  |  |
| Storage and disposal? |  |  |  |  |
| Drug interactions? |  |  |  |  |
| Identification and management of adverse reactions? |  |  |  |  |
| Reporting procedure of adverse reactions |  |  |  |  |
| Written information to be given to the patient or carer |  |  |  |  |
| Patient advice/follow-up treatment |  |  |  |  |
| Special considerations/additional information |  |  |  |  |
| Records section included and fully defined? |  |  |  |  |
| Reference & PGD management details | | | | |
| References and bibliography section completed? |  |  |  |  |
| Practitioner authorisation section? |  |  |  |  |
| Authorising manager section? |  |  |  |  |
| PGD Governance Process | | | | |
| Does the organisation that has clinically developed the PGD have satisfactory PGD governance processes in place? (e.g., a PGD policy that adequately covers all aspects of PGD development, use and approval; PGD approval committee etc.) |  |  |  |  |
| Does the provider requesting NHS HNY ICB PGD approval as authorising body, have adequate /satisfactory formal governance structures in place? E.g., satisfactory PGD policy, governance approval processes that meet required standards. |  |  |  |  |
| Checklist completion details (carried out by nominated senior pharmacist and nurse, if required) | | | | |
| Outcome | State if meets PGD statutory and best practice standards  State your recommendation to the ICB signatory to approve or not to approve this PGD | | | |
| Completed by | Add the name of senior pharmacist/medic (and nurse if applicable) completing this form. | | | |
| Signature |  | | | |
| Title and role |  | | | |
| Date checklist review completed |  | | | |

**Appendix G: Detailed flowchart for PGD approval process**



**Ends**