NHS
Cornwall and Isles of Scilly

Standard operating procedure

Procedure: Reviewing and approving patient group directions developed by independent health providers.

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Author(s): Medicines optimisation team

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Procedure overview

This document is intended as a brief fact sheet in response to queries from independent health providers (IHPs) to NHS Cornwall and Isles of Scilly integrated care board (ICB) and does not cover all the required considerations and guidance when planning, developing or authorising patient group directions (PGDs). For comprehensive information and advice see the specialist pharmacy service (SPS) advice on PGD.

Contents

Legal authorisation of PGDs for IHPs.

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.

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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. This includes integrated care boards.

PGD signatories:

Legislation 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.

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.

Additionally, the PGD must be authorised by a representative of the relevant authorising body.

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.

Duties of each of the PGD signatories can be found in the specialist pharmacy service (SPS) guidance.

Authorising a PGD at NHS Cornwall and Isles of Scilly ICB:

Where a PGD is developed by an independent healthcare provider (IHP) for use in an ICB commissioned service, the authorisation will usually only be undertaken by the ICB. The clinical signatories should be part of the PGD working group within the provider organisation that developed the PGD.

If the ICB develops PGDs for use in commissioned services, then both clinical and authorising signatories will be the responsibility of the ICB.

As mentioned above, a pharmacist should be involved in the working group to develop PGDs and a signature from a pharmacist is required by law. Independent organisations should be seeking relevant pharmaceutical support to develop their PGDs.

It is up to the commissioned independent organisation how they source this support. If they do not employ a pharmacist this may be through agency/locum/sessional contracted basis. Organisations must assure themselves the pharmacy professional has the adequate skills and competency to undertake this work for them, as they will

be accepting legal responsibility in signing off as part of signatories for the independent organisation. PGDs submitted without a pharmacist signature will be rejected.

Once the PGD has been signed by the IHP working group, it can then progress to the ICB. PGDs can be sent to the prescribing team at the ICB, who can then submit them to the PGD working group (Prescribing team + Quality team) for review and final approval at QAM (Quality Assurance Meeting). When a PGD is submitted to the prescribing team, the IHP should include information about how the PGD is intended to be used as part of the ICB commissioned service. The ICB must be assured that the provider has the relevant systems and processes in place to ensure compliance with NICE MPG2 PGDs. The provider must demonstrate this in their submission to the prescribing team with supporting evidence. These arrangements may, for example, be supported by a service specification outlining key performance indicators or quality metrics to demonstrate that PGDs are being used appropriately and deliver a consistent level of care. Other evidence to support that the IHP meets requirements of NICE MPG2 PGDs would include the IHP organisational PGD Policy and evidence of PGD audit as well as any agreed data, such as audits. In addition, evidence of CQC registration is required. Once approved, the PGD(s) can be signed by the ICB designated signatories (Quality Assurance group).

There should be two signatory tables included in the PGD to show who has been involved in approving and signing off the PGDs. For example:

Organisation where PGD is to be used:

Lead Medical Director	
Lead Nursing Officer	
Lead Pharmacist	

ICB authorisation:

Quality Assurance group ICB	

Further guidance on authorising IHP PGDs can be found on the SPS website, including information on responsibilities of the IHP and responsibilities of the ICB for organisational authority of the PGDs. It is recommended that all signatories refer to questions about signatories of PGDs for detail of the responsibilities of signatories authorising PGDs before signing documents.

All PGDs must have a review and expiry date. It is the responsibility of the IHP to ensure all documents are reviewed and submitted for approval in advance of expiry dates. If the PGD is no longer required, please inform the prescribing team so that any copies can be archived.

Retention of documents:

In commissioned services not all PGD records will be held in one place or by one organisation. Master copies of PGDs should be kept by the authorising body (in this

case the ICB) with the lists of authorised practitioners and individual clinical records maintained by the organisation operating under the PGD according to local policy.

The final authorised copy of the PGD should be kept for 8 years after the expiry date of the document if it relates to adults only (10 years if relates to an implant) and for 25 years after the expiry date if it relates to children.

The main content of a PGD (i.e. an unauthorised final copy), which contains no individual identifiable information or staff authorisation records, may be retained by an organisation for up to 20 years for purposes of business planning/continuity if there is reason to do so (i.e. reference for future PGD development).

References:

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Other useful links:

How to develop a Patient Group Direction – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Patient Group Directions in Complex Commissioning Scenarios – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice