NHS
Surrey Heartlands

Policy CLIN18

Policy for managing unwarranted variation in primary care prescribing

Policy number	CLIN18
Version	V1.0
Approved by	Medicines Optimisation Board
Name of originator/ author	Kevin Solomons
Owner (director)	Linda Honey
Date of last approval	June 2023
Next approval due	June 2028

Version control sheet

Version	Date	Author/Committee	Status	Comments / changes since last version
0.1 (1st draft)	11/04/23	Chief Pharmacist (Surrey Downs Place)	Draft	• Review of previous document (approved March 2017) • Additions highlighted in RED. • Deletions are struck through. • Appendix 1 – revised to incorporate new process
0.2	12/04/23	Chief Pharmacist (Surrey Downs Place)	Draft	Further additions highlighted in green following feedback from GP prescribing lead, Surrey Downs Place
0.3	13/04/23	Chief Pharmacist (Surrey Downs Place)	Draft	Further additions highlighted in light blue following feedback from GP prescribing lead, Surrey Downs Place
0.4	25/04/23	Primary Care Medicines Optimisation Clinical Reference Group	Draft	Minor change to flow chart Appendix 1 prior to consideration by PCMOCRG
0.5	17/05/23	Medicines Optimisation Board	Draft	• Addition to box 8 in Table 1 re antimicrobials • Change from 'Engage' To "Work" in Stage 4 box in Appendix 1, after discussion at PCMOCRG
0.6	21/06/23	Medicines Optimisation Board	Draft	• Transfer to ICB policy template • Addition of section 2.Legislative Framework / Core Standards • Addition of note regarding ICB duty to report to CDAO in relation to controlled drugs in Section 5.3 • Addition of line in stage 2 of Appendix 2, to include the LMC at this stage if it involves a CD • References to The NHS (General Medical Services Contracts) Regulations 2004 have been updated to reference the updated regulation in 2015 • Addition of points related to QEIA
1.0		Medicines Optimisation Board	Final	Medicines Optimisation Board approved

Equality statement

Surrey Heartlands Integrated Care Board (ICB) is committed to promoting equality and diversity in all its activities and to promoting inclusive processes, practices and culture.

- We will strive to work to eliminate any unlawful or unfair discrimination including direct or indirect discrimination, discrimination by association, discrimination linked to a perceived characteristic, harassment and victimisation.
- We will remain proactive in taking steps to ensure inclusion and engagement for all the people who work for and with us.
- We will continue to strive towards a culture that is diverse and inclusive that recognises and develops the potential of all staff and service users.
- We recognise the business benefits and opportunities of having a diverse community of staff who value one another and realising the contribution they can make to achieving the ICB's vision.

This includes promoting equality and diversity for all irrespective of:

- age*
- disability*
- ethnic group*
- sex*
- gender reassignment*
- religion or belief*
- sexual orientation*
- marriage and civil partnership*
- pregnancy and maternity*

*Under the Equality Act (2010) these are known as "protected characteristics".

In addition, it includes promoting equality and diversity for carers, people with diverse communication needs and veterans.

The ICB aims to meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. We take into account the Human Rights Act 1998 and promote equal opportunities for all. We embrace the seven staff pledges in the NHS Constitution that represent a commitment by the NHS to provide high-quality working environments for staff. This policy is consistent with these pledges.

This document has been assessed to ensure that no employee or member of the public receives less favourable treatment based on their protected characteristics.

Members of staff, volunteers or members of the public are invited to request assistance with this policy if they have particular needs. If the member of staff has language difficulties and difficulty in understanding this policy, the use of an interpreter will be considered.

Quality and Equality Impact Assessment

Completed	13/06/2023
Lead Author	Kevin Solomons, Chief Pharmacist (Surrey Downs Place)
Responsible Director	Linda Honey, Director of Pharmacy
Location of full QEIA	S:\Medicines Management\Governance\Unwarranted Prescribing Variation
Outcome	**Outcome 2 - Adjust the service/function/policy** to remove barriers identified by the QEIA or better advance equality. Are you satisfied that the proposed adjustments would remove the barriers you identified? Proceed with adjustments, amend and review QEIA periodically. A number of adjustments have been identified through the QEIA. These will be addressed in the implementation of the policy.

Contents

1. Introduction and Policy Objective

1.1 This Policy has been drawn up to manage potential unwarranted variation in prescribing within Surrey Heartlands Integrated Care Board (ICB). The British Medical Association (BMA) recognises that prescribing raises difficult issues and has produced guidance for health professionals (see section 3.1). It is the ICB's responsibility to engage with practices or individual prescribers where excessive, inappropriate or under-prescribing may have occurred and to work with them to support current best practice to and ensure that all prescribing is professionally appropriate in terms of quality, cost-effectiveness, and affordability in the context of the overall use of NHS resources.

1.2 The purpose of this document is to clarify and endorse the process for addressing identified issues occurring at any stage in the prescribing process that differ significantly from what may usually be expected. Discussions will take place with the GP Practice concerned, the ICB, and where appropriate the Local Medical Committee (LMC), before any punitive action is taken. Potential unwarranted variation in prescribing should be resolved in most instances through constructive dialogue, with the aim to ensure that recommended changes are made or that mitigations are put in place to protect patients and support clinicians to justify their decisions.

1.3 The policy impacts directly upon prescribers and indirectly upon patients

2. Review of this policy:

2.1.1 This policy will be reviewed every five years.

3. Legislative Framework / Core Standards

3.1 Under the Health and Care Act 2022, ICB's have a duty to promote improvements in the quality of services, reduce inequalities and make efficient and sustainable use of resources. By reducing unwarranted variation in prescribing, this policy will assist the ICB in achieving these duties.

3.2 Annex 8 of the revisions to the GMS Contract 2006-07 'Excessive or inappropriate prescribing: guidance for health professionals on prescribing NHS medicines' provides the contractual mechanism that underpins much of the content within this policy.

3.3 The Controlled Drugs (Supervision of Management and Use) Regulations 2013 requires the ICB to assist the NHS England & NHS Improvement Regional Controlled Drugs Accountable Officer (CDAO) to monitor and assess the management and use of CDs, to support incidents or concerns that require investigation, and to take appropriate action where these concerns are well-founded.

4. Scope

4.1 This Policy has been produced to support best prescribing practice in Primary Care within Surrey Heartlands Integrated Care Board (ICB) and is intended to inform all prescribers in relation to prescribing behaviour that could be considered unwarranted

and / or at significant variation to local peers. The main purpose of this document is to provide guidance on what constitutes potential unwarranted variation in prescribing and gives information and advice on how the ICB will manage these situations. It is expected that most situations will be resolved within the ICB, but this document also includes the escalation process in the rare event that formal referral to the commissioner of GMS services (NHS England) is required.

5. Duties

5.1 Duties within the Organisation

Background - Contractual requirements

The BMA recognises that by improving quality, cost effectiveness and affordability of prescribing in the context of the overall use of NHS resources would be of benefit to patients. The BMA have issued a supporting document1 called “Focus on excessive prescribing”, which was written in March 2013 and last updated in February 2018.

The Focus on Excessive Prescribing guide aims to provide background support to Annex 8 of the revisions to the GMS Contract 2006-07 ‘Excessive or inappropriate prescribing: guidance for health professionals on prescribing NHS medicines’ to support LMCs in their work with Primary Care Organisations (PCOs) on prescribing matters. The document references The NHS (General Medical Services Contracts) Regulations 2004 which was updated in 2015[2]:

> **Excessive prescribing - 64**
>
> *(1) The contractor shall not prescribe drugs, medicines or appliances whose cost or quantity, in relation to any patient is, by reason of the character of the drug, medicine or appliance in question in excess of that which was reasonably necessary for the proper treatment of that patient.*
>
> *(2) In considering whether a contractor has breached its obligations under paragraph (1), the Board must seek the views of the Local Medical Committee (if any) for the area in which the contractor provides services under the contract.*

Although the ICB has a responsibility for monitoring and working with local GP practices to manage the prescribing budget, there may be occasions where prescribing at an individual practice may appear at significant variation with local peers which includes under-prescribing as well as excessive prescribing. It is recognised that this is open to interpretation and subsequent challenge and the ICB therefore has the responsibility to employ a consistent and transparent approach when dealing with practices under these circumstances. A process outlining how this should be managed within the organisation is provided in Appendix 1; this should ensure that due process is followed enabling all interested parties to have a fair and reasonable opportunity to resolve prescribing disputes.

This document provides guidance for prescribers (GPs and non-medical prescribers), practice staff and other health care professionals about the prescribing behaviours that may give rise to further enquiries about prescribing activity.

5.2 Consultation and Communication with Stakeholders

The original version of this document had been developed in conjunction with the Surrey Local Medical Committee. Revision of the document has been consulted through the Primary Care Medicines Optimisation Clinical Reference Group and the LMC.

6. Context of policy

In 2021-22, 1.14 billion prescription items were dispensed in the community in England. Medicines contribute enormously to the health of the nation. The effective use of drugs has improved many people's quality of life, reduced the need for surgical intervention and the length of time spent in hospital and saved many lives (both in primary and secondary prevention). Our consumption of drugs is increasing and accounts for approximately 11% of the NHS budget. However, there are disadvantages in the increasing use of and reliance on medicines. The inappropriate or excessive use of medicines can cause distress, ill-health, hospitalisation and even death. Adverse drug reactions are responsible for about 6.5% of all admissions to hospitals in the UK.[3]

Prescribing data shows significant variability between GP practices, which may indicate that over- / under-prescribing and inappropriate prescribing may still be occurring in some areas. Professional guidance requires efficient use of the resources available and the impact on other patients to be considered. Changes in prescribing should take account of these criteria as well as clinical appropriateness and patient need at practice.

6.1 What constitutes unwarranted variation in prescribing?

In all areas of healthcare some variation is expected, often linked to levels of illness or patient-preference, but some is ‘unwarranted’ and cannot be explained by the same causes. Defining “unwarranted variation” in prescribing is complex and requires the appropriate use of data to identify variation that can then be questioned whether it is warranted or unwarranted. Within Surrey Heartlands ICB, a large range of resources are used and when variances are observed by the Medicines Optimisation Team, these are checked with the practices concerned and in the majority of cases are explained or resolved quickly.

For some medicines, a one-off prescription may trigger a conversation (e.g., if a practice prescribes a medicine that is considered ‘hospital-only’), but for higher volume medicines it may be that the practice is prescribing significantly higher or lower than expected for their practice population, potentially prompting a more in-depth review.

The situations highlighted below illustrate prescribing behaviour that has been locally or nationally identified as likely to raise questions about appropriateness of prescribing (this list is not exhaustive). Examples that may prompt a check with practices relating to each situation are given in Appendix 1.

1) Prescribing for private patients returning to NHS care where this differs significantly from usual NHS care.[4,5]

2) Prescribing of products for indications not recommended for prescribing on the NHS, including, “Items which should not routinely be prescribed in primary care: Guidance for CCGs” and “Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs.“ [6,7] It is accepted that there may be scenarios where these products may be clinically appropriate for an individual patient, and prescribing would only be questioned if the quantities prescribed (based on the practice population) are significantly different to other comparable practices.

3) Consistent/significant under-prescribing where there is evidence to suggest that there is a failure to adhere to good clinical prescribing practice.

4) Profligate prescribing may be considered to exist where the prescriber(s) consistently prescribes excessive amounts of high-cost products or inappropriate, high quantities of medicines that are significantly at variance with comparable clinical scenarios and where the prescriber(s) is / are unable to provide a reasonable explanation.

5) Prescriptions where the drug is initiated or switched, e.g., within a therapeutic class/indication, with the effect that reimbursement is based on a product that provides a larger purchase margin for the prescriber(s) and the product(s) selected cost the NHS more, unless there is good clinical evidence to support the switch.

6) Prescribing that is varied according to the impact on reimbursement to the practice, and where the prescriber(s) is / are unable to provide a reasonable explanation e.g., differences between patients to whom the practice directly supplies medicines (including personally administered drugs and through NHS dispensing) and those to whom they supply prescriptions for dispensing elsewhere.

7) Prescribing of drugs that introduce potential clinical risks for patients if inadequate supervision is in place and would usually be outside the scope of general practice or considered specialist care e.g., red (hospital only) drugs.

8) Prescribing of antimicrobials at persistent higher volume than expected compared to peers, or persistent higher use of high-risk antimicrobials.

9) Prescribing of controlled drugs at quantities in excess of national recommendations or at levels that are likely to increase clinical risk to patients or may indicate misuse.

6.2 Identification of potential unwarranted variation in prescribing

Prescribing is monitored routinely by the Medicines Optimisation team across the ICB. The ICB will also investigate complaints received. The standards used to judge unwarranted variation in prescribing are based on:

- Guidance issued locally, nationally and from professional bodies.

- Reviewing and benchmarking prescribing for all practices in all therapeutic areas, over time, against other practices locally and nationally using ePACT2 data and other information; identified population needs will be considered.

Where appropriate, the results of such monitoring will be discussed with an individual prescriber or with the practice to understand why prescribing is so different to others and agree appropriate actions. It is expected that most situations will be resolved informally with no need to escalate.

If a potential clinical risk has been identified, but the practice wishes to continue to prescribe, then a record of actions and mitigations should be documented in the Clinical Safety Risk Assessment Form Part A (Appendix 3). This should be shared with the Place GP Prescribing Lead and / or Chief Pharmacist / Deputy Out of Hospital Chief Pharmacist to consider if further escalation is required.

6.3 Process for managing unwarranted variation in prescribing

The process for managing unwarranted variation in prescribing is outlined in Appendix 2.

Note: the ICB has a statutory duty to inform the England & NHS Improvement Regional Controlled Drugs Accountable Officer (CDAO) if a practice or prescriber fails to engage with the ICB if a concern is raised regarding controlled drug prescribing. Support from the LMC is available in these situations and should be sought before escalation.

7. Bibliography

1. BMA, Focus on excessive prescribing, Feb 2018, https://www.bma.org.uk/media/1583/bma-focus-on-excessive-prescribing-feb-2018.pdf (accessed 11th April 2023)
2. GMS Contracts Regulations 2015, Part 8, paragraph 64, https://www.legislation.gov.uk/uksi/2015/1862/regulation/64/made (accessed 8th June 2023)
3. Pirmohamed M et al, Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. BMJ. 2004;329:15–19
4. DH, A code of conduct for private practice: guidance for NHS medical staff. 2003
5. DH, Guidance on NHS patients who wish to pay for additional private care. 2009
6. NHS England, Items which should not routinely be prescribed in primary care: Guidance for CCGs, Version 2, June 2019, https://www.england.nhs.uk/wp-content/uploads/2019/08/items-which-should-not-routinely-be-prescribed-in-primary-care-v2.1.pdf (accessed 11th April 2023)
7. NHS England, Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs, March 2018, https://www.england.nhs.uk/wp-content/uploads/2018/03/otc-guidance-for-ccgs.pdf (accessed 11th April 2023)

Appendix 1. Examples that may prompt a check with practices

Number	Definition	Examples that may prompt a check with practices
1	*Prescribing for private patients returning to NHS care where this differs significantly from usual NHS care*	a. Prescribing of products that would not usually be prescribed for NHS patients in primary care such as drugs that are "red" (Hospital only) on the Prescribing Advisory Database (PAD) *http://pad.res360.net/PAD/Search* b. Acceptance of prescribing responsibility for medicines that should be initiated, monitored and stabilised in secondary/tertiary care earlier than would normally be expected for a patient treated within the NHS, see "Private to NHS care AND Private prescriptions for NHS patients" on the PAD c. Prescribing of products that are not in line with ICB preferred products or National guidance on the basis of private patient/consultant request e.g., strontium, daily tadalafil, Saxenda for obesity (should be prescribed by Tier 3 services access to discounts needed to make cost-effective as per NICE)
2	*Prescribing of products for indications not recommended for prescribing on the NHS*	a. The prescribing of travel vaccines that are for holiday and business travel abroad where the reasons for vaccination fall outside of the Global Sum definitions for NHS eligibility. b. The prescribing of antimalarials for prophylaxis The prescribing of products to patients who do not meet the specific clinical conditions as indicated by "SLS" and "ACBS" recommendations stipulated by the Department of Health c. Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs. It is accepted that there may be scenarios where these products may be clinically appropriate for an individual patient, and prescribing would only be questioned if the quantities prescribed (based on the practice population) are significantly different to other comparable practices.
3	*Consistent/significant under-prescribing where there is evidence to suggest that there is a failure to adhere to good clinical prescribing practice*	Non-adherence to NICE guidelines e.g., anticoagulants in Atrial Fibrillation, failure to prescribe bisphosphonates to patients with history of fractures / falls where clinically indicated, inadequate treatment of hypertension.
4	*Profligate prescribing may be considered to exist where the prescriber(s) consistently*	a. If there is a significant reduction in price for products e.g., Drug Tariff or manufacturer's prices and a practice or individual prescriber, for a significant proportion of patients or in a systematic manner and without reasonable justification, refuses to change in line with a ICB or national policy, to a product with

Number	Definition	Examples that may prompt a check with practices
	prescribes excessive amounts of high-cost products or inappropriate, high quantities of medicines that are significantly at variance with comparable clinical scenarios and where the prescriber(s) is / are unable to provide a reasonable explanation	a lower NHS reimbursement cost. N.B this isn't specifically about switching patients but around prospective prescribing. b. First line and/or widespread use of isomeric or higher priced products where there are more cost-effective alternatives available that are effective for at least a majority of patients. Example therapies include esomeprazole, desloratadine, levocetirizine, dispersible preparations, and combination therapies which usually offer limited clinical advantage. c. Prescribing drugs routinely where national or local guidance has recommended a limited place in therapy e.g.: • high use of antibiotics, • inappropriate use of drugs of limited clinical value, • use of modified release products routinely where standard release products are recommended as equally effective for a majority of patients. d. Off-label prescribing of drugs in situations where there is a limited evidence base and alternative licensed, evidence-based treatments have not been fully explored. e. Long-term prescribing of a medicine, or dose that should only be prescribed for short period of time. f. First line or widespread use of black triangle drugs where, within the therapeutic class, there are evidence-based alternatives without black triangle status. g. Prescribing for longer than average periods shortly before or after dispensing moves from a practice to a newly opened pharmacy in the area. ✝ h. Prescribing routinely for periods of treatment that may lead to an increase in waste from unwanted, unnecessary or stopped medicines, i.e., in situations where the clinical condition is subject to change. Examples include wound management and other appliances, palliative care, initiation of new medicines, Controlled Drugs (prescribing for no longer than 30 days). i. Prescribing for longer than three months for registered patients travelling overseas or prescribing on NHS forms for patients who are not entitled to NHS treatment e.g., persons overseas. Prescribing should not exceed the amount that is usually issued and in most cases this would not usually exceed three months. However, in certain circumstances, longer duration of supplies, e.g., 6 to12 months supply of contraceptives or HRT, may be considered "usual".

Number	Definition	Examples that may prompt a check with practices
5	*Prescriptions where the drug is initiated or switched, e.g., within a therapeutic class/indication, with the effect that reimbursement is based on a product that provides a larger purchase margin for the prescriber(s) and the product(s) selected cost the NHS more, unless there is good clinical evidence to support the switch.* *** †**	a. Change from generic to brand or branded generic of the same drug or to another drug in the same therapeutic class where the alternatives chosen cost the NHS more without demonstrable clinical benefit. Examples may include the preferred use of perindopril arginine in place of generic perindopril. b. Refusal, without reasonable justification, to change prescribing behaviour in line with ICB or national policy when the cost of a drug drops significantly and becomes the most cost-effective in its class. c. Acceptance of associated discounts, or sponsorship or financial deals that could reasonably be perceived to affect the choice of treatment in a way that is financially beneficial to the prescriber but significantly increases NHS costs. In circumstances where there is clear evidence of clinical benefit to patients, then these discounts, sponsorship etc should be recorded in a register of "Gifts and Hospitality". This may include research projects.
6	*Prescribing that is varied according to the impact on reimbursement to the practice, and where the prescriber(s) is / are unable to provide a reasonable explanation e.g., differences between patients to whom the practice directly supplies medicines (including personally administered drugs and through NHS dispensing) and those to whom they supply prescriptions for dispensing elsewhere.* **†**	a. Decreasing the period of supply to patients in order to increase the payment of dispensing fees where for example, there is no clinical basis for that change, for example excessive use of seven-day prescriptions for dispensing patients. b. Using drugs with a higher purchase margin for dispensing patients in a different way than the same drugs may be used for prescribing-only patients. c. Not making locally, or nationally, recommended changes in prescribing that would release money for use elsewhere in patient care e.g., after price adjustments in the Drug Tariff, because the practice would get less income on dispensing patients if prescribing and dispensing patients were treated in the same way. d. Sending dispensing patients who need support or compliance devices under the Equality Act 2010 (incorporating its predecessor legislation the Disability Discrimination Act 1995) to a pharmacy to avoid the cost to the practice of providing that support or an appropriate compliance aid. (There is an allowance in the Dispensing Doctors' fee scale to cover compliance with the Equality Act, including supply of compliance aids, where appropriate)

* This does not apply when normal trading discounts apply to the purchase of medicines. Bonus deals would NOT be considered as 'normal trading discounts' for this purpose, as they may be perceived to affect the choice of treatment. This requirement applies whether or not the practice or prescriber feels that the discount, sponsorship etc affected their prescribing. The judgement on benefit to patients could be subject to challenge against the GMC criteria relating to the balance between individual patient benefit and the use of resources to benefit other patients. If there is a

Number	Definition	Examples that may prompt a check with practices
change in prescribing by a practice or individual prescriber, for a significant proportion of patients or in a systematic manner to a product with a higher NHS reimbursement cost but without any clinically significant advantage to the patient, then this may be subject to challenge. † This is a particular issue for Dispensing Doctors or medicines subject to personal administration.		
7	Prescribing of drugs that introduce potential clinical risks for patients if inadequate supervision is in place, and would usually be outside the scope of general practice or considered specialist care	a. Prescribing of any red (hospital only) drugs b. Prescribing of amber drugs without formal shared care agreements or that equivalent appropriate governance arrangements are in place to ensure a specialist clinician is available to support the care of the patient. [**Note**: it is understood that sometimes situations arise e.g., ADHD, where the service is inadequately commissioned, and the prescriber must make a judgement based on what they perceive is best for the patient.]
8	Antimicrobials	a. Prescribing of antimicrobials at a higher volume compared to peers. b. Prescribing of high-risk antimicrobials at a higher volume compared to peers. [Note: the measure used by CQC is based on high-risk antimicrobials as a % of all antimicrobials, and practices with lower overall volume of antimicrobial prescribing may appear as an outlier. The ICB Medicines Optimisation Teams will take this into account in any discussions with practices).
9	Controlled Drugs	a. Prescribing of one or more controlled drugs at levels that are likely to increase clinical risk to patients or may indicate misuse / misdirection b. Unusual growth in either cost or items compared to previous years' prescribing c. Unusual growth in either cost or items compared to other GP practices within the ICB d. More than 10% of CD prescriptions exceeding 30 days prescribing e. Best practice guidance not followed when prescribing medicines intended for short-term use f. Variations highlighted by the Safer Management of Controlled Drugs epact2 dashboards g. Other specific issues which may be based on local intelligence around drugs of misuse, for example testosterone

Appendix 2 - Process for Managing Unwarranted Variation in Prescribing

Stage 1a Identification of Variation in Prescribing

Identification may be through the regular monitoring of prescribing by ICB Medicines Optimisation Teams (MOT) or through a concern / complaint received by the ICB (see section 4.2).

Stage 1b Informing the Practice or Prescribing Lead

The ICB MOT member will meet with a relevant clinician within the practice to discuss issues identified. The clinical risk assessment form (Part A) may be used to document any clinical concerns and agreed actions / mitigations. The process will initially be informal, and focussed on relevant educational input, but may become formal if necessary (stage 2). If a practice fails to respond within an agreed timescale and do not respond to at least three attempts by the MOT to gain an update on progress the ICB will assume that no changes have been made and will move onto the next stage of the process, following discussion with Place GP Prescribing Lead and / or Chief Pharmacist / Deputy Out of Hospital Chief Pharmacist.

Practice and/or prescriber not able to justify to the ICB the significant variation compared with local peers.

Unresolved

Stage 2 – Escalation at Place - Additional Clinical Support

The Place GP Prescribing Lead and / or Chief Pharmacist / Deputy Out of Hospital Chief Pharmacist considers clinical risk (Clinical risk assessment form). Based on the assessment makes the practice aware of good practice guidance and works with the practice to agree to implement prescribing choices that are appropriate, and which balance individual patient benefit and the use of resources to benefit other patients. Advice may be sought from the LMC at this stage, particularly if Controlled Drugs are involved.

Unresolved

Stage 3 – Escalation to ICB

If further action is required a panel will be convened to recommend further actions. The panel should consist of:

- Director of Pharmacy
- Clinical Advisor to the Multi-Professional Leadership Directorate
- Head of Medicines Safety
- Relevant Place GP Prescribing Lead
- Relevant Place Chief Pharmacist or Deputy
- LMC Representative

Recommendations should be conveyed to the practice with agreed timelines for implementation.

Resolved

Practice agrees to make suitable changes **OR** can justify that prescribing behaviour shows clear evidence of clinical benefit to patients and takes account of available resources, national guidance, and local policies.

Data monitored to ensure change has occurred then return to standard monitoring of prescribing cost and quality indicators and continue dialogue between ICB and practice if change is not sustained.

Resolved

Unresolved

Stage 4 - Work with NHS England / Primary Care Contracting to consider whether there is sufficient evidence to demonstrate that the contractor's prescribing practice constitutes a breach of their contractual requirement.

Practice can invoke the Dispute Resolution Mechanism. If the contractor does not accept that they have breached their contract or that the ICB's action is appropriate. **(LMC may be involved and must be involved if this is a**

Appendix 3

Unwarranted Variation in Prescribing Policy
Clinical Safety Risk Assessment Form

Surrey Heartlands ICB Policy for Managing Unwarranted Variation in Primary Care Prescribing identifies circumstances when a GP practice's prescribing may be considered inappropriate and represents unwarranted variation, particularly with respect to patient safety. Local resolution through informal discussion with the practice by the ICB Primary Care Pharmacist is the usual route for resolving issues identified.

Very rarely local resolution is unsuccessful, and escalation is required where the identified unwarranted variation in prescribing is considered to represent a substantial risk to patient safety. Examples may include:

- National or local guidance recommends that the medicine requires highly specialist initiation and monitoring, so that prescribing remains in secondary care.
- Administration of the medicine requires a level of competency and training that the GP prescriber is unable to ensure through primary care prescribing.
- Where published safety warnings are in place but are not being followed, or suitable risk mitigation measures put in place to ensure patient safety.
- Off-label prescribing of drugs in situations where there is a limited evidence base and alternative licensed, evidence-based treatments have not been fully explored.

This form should be used to record the assessment of clinical safety risk, and advice given to the prescriber by the ICB Primary Care Pharmacist (Part A), and outcomes of subsequent discussions between the Place Based Chief / Deputy Chief pharmacist, Place GP prescribing lead and the prescriber (Part B). The completed form should be filed in the patient specific queries in the GP practice folder within the ICB and a copy sent to the GP practice.

Part A (to be completed by ICB Primary Care Pharmacist)

Date unwarranted variation identified:	**Practice**:
Prescriber (if identifiable) or Practice Prescribing Lead:	
Primary Care Pharmacist:	
Description of identified unwarranted variation in prescribing:	
Brief description of circumstances of prescribing and relevant patient background e.g., recommended by consultant, inherited prescribing:	
Brief description of patient safety risk:	
Description of advice given to prescriber by the ICB Primary Care Pharmacist and risk mitigation recommendations:	
Agreed Practice Actions:	
Agreed date for actions to be completed:	

Timeline of discussions and contact with practice (this should include a record of progress on agreed actions): [If the practice fails to respond to at least three attempts by the MOT to gain an update on progress of actions after the agreed date for completion this should be documented prior to escalation]
Outcome of discussion with practice ☐ **Resolved** Review data 3 months after action completed to ensure change has occurred then return to standard monitoring ☐ **Unresolved** Go to Part B

Part B (to be completed by Place based Chief / Deputy Chief pharmacist and Place GP prescribing lead)

Summary of discussion with GP practice and prescriber:
Agreed outcome, actions, and risk mitigations, including informing patient:

Agreed date for actions to be completed:	
Timeline of discussions and contact with practice (this should include a record of progress on agreed actions): [If the practice fails to respond to at least three attempts by the MOT to gain an update on progress of actions after the agreed date for completion this should be documented prior to escalation]	
Outcome of discussion with practice ☐ **Resolved** Review data 3 months after action completed to ensure change has occurred then return to standard monitoring	☐ **Unresolved** Escalate in line with Policy

Signed:

Practice Prescriber:	**Date:**
Place based senior pharmacist:	**Date:**
GP Prescribing Lead	**Date:**

*Copy to be filed in GP practice folder in ICB MOT shared drive and given to practice for filing (may be added to patient notes)*Appendix 4– Procedural Document Checklist for Approval

Appendix 4 – Corporate Compliance Checklist

Title of document being reviewed:		Yes/No/ Unsure	Comments/ Details
1.	**Sponsoring Director**		
	Is there a sponsoring director?	Yes	
	Have they approved **this version** of the policy?	Yes	
2.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
3.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
4.	**Development Process**		
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
5.	**New or review**		
	Is this a new document?	Yes	
	Is the ratification date stated on the front cover?	Yes	
	Is the ratification Committee stated on the front cover?	Yes	
	Is the review date stated on the front cover?	Yes	
	Is the version control detailing the version history of the document?	Yes	
	If this is a review document, has the version number been amended throughout?	Yes	
6.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target group clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
7.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
8.	**Quality and Equality Impact Assessment**		
	Has a QEIA been completed?	Yes	
	Is the QEIA attached?	Yes	

Title of document being reviewed:		Yes/No/ Unsure	Comments/ Details
9.	**Style and Format**		
	Is the style and format in line with the *Framework for the Production of Procedural Documents*?	Yes	
	Does the footer include the title, date of ratification and version number?	Yes	
	Are definitions provided for the key terms used in the document?	Yes	
	If applicable, are abbreviations written according to the guidance in *Framework for the Production of Procedural Documents*?	Yes	
10.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
11.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how the document will be disseminated and implemented amongst the target group? Please provide details.	Yes	Through Medicines Management Newsletters / Primary Care newsletter / relevant meetings
12.	**Process for Monitoring Compliance**		
	Have specific, measurable, achievable, realistic and time-specific standards been detailed to monitor compliance with the document? Complete Compliance & Audit Table.	Yes	
13.	**Review Date**		
	Is the review date identified?	Yes	
14.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for implementing and reviewing the documentation i.e. who is the document owner?	Yes	

Appendix 5 – Compliance and Audit Table

Criteria	Measurable	Frequency	Reporting to	Action Plan/ Monitoring
This is an over-arching policy. Compliance will be assessed through complaints and queries raised by GP practices	n/a	Quarterly (if any complaints or queries received)	Medicines Optimisation Board	Complaints Log