

## RECOMMENDATIONS FOR MANAGING UNWARRANTED VARIATION IN PRESCRIBING

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## 1 Scope

These recommendations have been produced to support best prescribing practice within Surrey and North West Sussex CCGs, and are 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 unwarranted variation in prescribing and give information and advice on how Clinical Commissioning Groups (CCG) may wish to manage this prescribing prior to formal referral to the commissioner of GMS services (NHS England); those CCGs that are co-commissioners of GMS services will need to develop local escalation processes, if required.

## 2 Purpose

These recommendations have been drawn up by the Medicines Commissioners Group to manage any unwarranted variation in prescribing within Surrey and North West Sussex CCGs. The British Medical Association (BMA) recognises that prescribing raises difficult issues and has produced guidance for health professionals. It is the CCGs responsibility to engage with practices where excessive or inappropriate prescribing may have occurred and to work with practices to encourage current best practice to 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.

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. It is assumed that discussions will take place with the GP Practice concerned, the CCG, and where appropriate the LMC, before any action is taken. Potential unwarranted variation in prescribing should be resolved in most instances through constructive dialogue.

## 3 Duties

### 3.1 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 document called "Focus on excessive prescribing", which was written in March 2013 and last updated on 20 September 2016:

<https://www.bma.org.uk/advice/employment/gp-practices/service-provision/prescribing/focus-on-excessive-prescribing>

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) and Clinical Commissioning Groups (CCGs) on prescribing matters. The document mentions that "Within the GMS and PMS regulations and APMS directions there are clauses in relation to prescribing and dispensing":

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*(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 sub-paragraph the Primary Care Trust shall seek the views of the Local Medical Committee (if any) for its area.*

Although local CCGs have a responsibility for monitoring and working with local member 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 CCG 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 General Practitioners (GPs), practice staff and other health care professionals (including other prescribers) the prescribing behaviours that may give rise to further enquiries about prescribing activity.

### **3.2 Consultation and Communication with Stakeholders**

The original version of this document developed in 2010 had been developed in conjunction with the Surrey Local Medical Committee. Revision of the document has been consulted through the Medicines Commissioner Group which includes a member from the LMC.

### **3.3 Approval of Procedural Documents**

Agreed by the Medicines Commissioners Group on 1<sup>st</sup> March 2017.  
Ratified by the relevant CCG.

## **4 Context of policy**

In 2015 1,083.6 million prescription items were dispensed in England. Medicines contribute enormously to the health of the nation. The effective use of drugs have 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 12% 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<sup>1</sup>.

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.

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<sup>1</sup> Pirmohamed M *et al*, Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. *BMJ*. 2004;329:15-19

#### **4.1 What constitutes unwarranted variation in prescribing?**

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 relating to each situation are given in table 1:

- 1) Prescribing for private patients returning to NHS care where this differs significantly from usual NHS care<sup>2,3</sup>
- 2) Prescribing of products for indications not recommended for prescribing on the NHS
- 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.

#### **4.2 Identification of unwarranted variation in prescribing**

Prescribing is monitored routinely by the Medicines Management teams in each CCG. The CCG will also act on 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 ePACT.net data and other information; identified population needs will be taken into account.

Where appropriate, the results of such monitoring will be discussed with an individual prescriber or with the practice and appropriate actions agreed.

#### **4.3 Process for managing unwarranted variation in prescribing**

The process for managing unwarranted variation in prescribing is outlined in Appendix 1.

### **5 Acknowledgement**

Adapted from the previous NHS Surrey PCT policy on which this document is based.

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<sup>2</sup> DH, A code of conduct for private practice: guidance for NHS medical staff. 2004

<sup>3</sup> DH, Guidance on NHS patients who wish to pay for additional private care. 2009

**Table 1**

<b>Number</b>	<b>Definition</b>	<b>Examples</b>
1	<i>Prescribing for private patients returning to NHS care where this differs significantly from usual NHS care</i>	<ul style="list-style-type: none"> <li>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) <a href="http://pad.res360.net/PAD/Search">http://pad.res360.net/PAD/Search</a></li> <li>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 NHS Prescribing Recommended Before and After an Episode of Private care.</li> <li>c. Prescribing of products that are not in line with CCG preferred products or National guidance on the basis of private patient/consultant request e.g. rosuvastatin recommended when simvastatin would usually be the appropriate first-line choice; or tadalafil, for erectile dysfunction when sildenafil would usually be the appropriate first-line choice.</li> </ul>
2	<i>Prescribing of products for indications not recommended for prescribing on the NHS</i>	<ul style="list-style-type: none"> <li>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</li> <li>b. The prescribing of antimalarials for prophylaxis</li> <li>c. 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</li> <li>d. Off-label prescribing of drugs in situations where there is a limited evidence base.</li> </ul>
3	<i>Consistent/significant under-prescribing where there is evidence to suggest that there is a failure to adhere to good clinical prescribing practice</i>	<ul style="list-style-type: none"> <li>a. Non-adherence to NICE guidelines e.g. failure to prescribe bisphosphonates to patients with history of fractures / falls where clinically indicated, inadequate treatment of hypertension .</li> </ul>
4	<i>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</i>	<ul style="list-style-type: none"> <li>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 CCG or national policy, to a product with a lower NHS reimbursement cost. N.B this isn’t specifically about switching patients but around prospective prescribing.</li> <li>b. First line and/or wide spread use of a drug that costs the NHS more where, within the therapeutic class, there are more cost effective evidence based alternatives available. For example, low</li> </ul>

	<p><i>where the prescriber(s) is / are unable to provide a reasonable explanation</i></p>	<p>percentage of patients on generic atorvastatin where there is no clear therapeutic benefit from the use of higher cost products.</p> <p>c. 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</p> <p>d. 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.</p> <p>e. First line or widespread use of black triangle drugs where, within the therapeutic class, there are evidence based alternatives without black triangle status.</p> <p>f. Prescribing for longer than average periods shortly before or after dispensing moves from a practice to a newly opened pharmacy in the area. †</p> <p>g. 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, palliative care, initiation of new medicines, Controlled Drugs (prescribing for no longer than 30 days).</p> <p>h. 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 to 12 months supply of contraceptives or HRT, may be considered “usual”.</p>
<p><b>5</b></p>	<p><i>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</i></p>	<p>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</p> <p>b. Refusal, without reasonable justification, to change prescribing behaviour in line with CCG or national policy when the cost of a drug drops significantly and becomes the most cost-effective in it's class.</p>

	<i>support the switch. * †</i>	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".
6	<i>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. †</i>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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)</p>

\* 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 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.



### Identification of Unwarranted Variation Prescribing

Identification may be through the regular monitoring of prescribing by CCG's Medicines Management Teams (MMT) or through a concern / complaint received by the CCG. The standards used to judge unwarranted variation in prescribing are based on:

- Guidance issued locally, nationally and from professional bodies
- Reviewing prescribing for all practices in all therapeutic areas, over time, against other practices locally and nationally using ePACT.net and other information.

**Stage 1** - Local resolution for issues identified through routine monitoring will usually be sought through informal discussion with the practice by a member of the MMT. In the event of a concern / complaint a more rapid intervention will be sought involving a senior member of the team or GP clinical lead, if required.

**Stage 2a** - If informal discussions are unsuccessful, unwarranted variation in prescribing will be discussed at a CCG Prescribing Group e.g. Medicines Optimisation Group (MOG), or equivalent, to decide on any further action to be taken.

### Stage 2b - If further action is required - Informing the Practice or Prescribing Lead

The CCG Medicines Management Team will meet with the practice to discuss actions identified by the Prescribing Group. The process will initially be informal, and focussed on relevant educational input, but may become formal if necessary. If a practice fails to respond within the defined timescale the CCG will assume that no changes are made and will move onto the next stage of the process, keeping the CCG Prescribing Group informed of outcomes.

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

**Stage 3 – Additional Clinical Support** The CCG GP Prescribing Lead and / or Head of Medicines Management 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.

### Monitoring

Practice prescribing is monitored through ePACT.net and other information to ensure that changes are being made to confirm that none of its prescribers act in a way that may appear at significant variation with local peers.

**Appropriate changes made**

Return to standard monitoring of prescribing cost and quality indicators and continue dialogue between CCG and practice.

Practice is able to justify that prescribing behaviour shows clear evidence of clinical benefit to patients and takes account of available resources, national guidance and local policies.

Return to standard monitoring of prescribing cost and quality indicators and continue dialogue between CCG and practice.

**No changes made**

**CCG to consider:**  
**1. Board level intervention**  
**2. Engage with NHS England** [NHS England will need to consider whether there is sufficient evidence to demonstrate that the contractor's prescribing practice constitutes a breach of their contractual requirement].

**Failure to engage at early stage**

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