

## **NHS Norfolk and Waveney ICB**

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# **Policy for managing Primary Care Rebate schemes offered by the Pharmaceutical Industry**

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## Document Control Sheet

This document can only be considered valid when viewed via the ICB's intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one online.

Approved documents are valid for use after their approval date and remain in force beyond any expiry of their review date until a new version is available.

<b>Name of document</b>	<b>Policy for managing Primary Care Rebate schemes offered by the Pharmaceutical Industry</b>
<b>Version</b>	<b>2</b>
<b>Date of this version</b>	<b>August 2023</b>
<b>Produced by</b>	Medicines Optimisation Team
<b>What is it for?</b>	This policy is to provide transparency and governance to this area of work.
<b>Evidence base</b>	No Applicable
<b>Who is it aimed at and which settings?</b>	Colleagues within the ICB
<b>Consultation</b>	
<b>Impact Assessment:</b>	
<b>Other relevant approved documents</b>	
<b>References:</b>	<ul style="list-style-type: none"> <li>NHS PrescQIPP Pharmaceutical Industry Scheme Governance Review Board's Operating Model <a href="#">PISGRB Operating Model v4.3 (prescqipp.info)</a></li> <li>NHS PrescQIPP Pharmaceutical Industry Scheme Governance Review Board <a href="#">Primary care rebates   PrescQIPP C.I.C</a></li> <li><a href="#">Bribery Act 2010</a>.</li> </ul>
<b>Monitoring and Evaluation</b>	This policy will be monitored by the Medicines Optimisation Team
<b>Training and competences</b>	None required
<b>Reviewed by:</b>	
<b>Approved by:</b>	Finance Committee
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<b>Review Date:</b>	August 2025 or before if statutory change is required.
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## Version Control

Revision History	Summary of changes	Author(s)	Version Number
July 2020		Medicine Management / Corporate Affairs	1
August 2023	<p>Policy reviewed and updated to reflect change from CCG to ICB.</p> <p>Approval of rebate schemes that are proposed to roll over/continue without any change in terms can be approved by the Executive Director of Finance.</p>	Medicine Optimisation Team	2

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## 1. INTRODUCTION

1.1 Within the NHS medicines are generally purchased in one of two ways:

- In primary care, medicines are paid for through the Prescription Pricing Division of the NHS Business Services Authority who reimburses pharmacists for the drugs they dispense on the NHS at drug tariff prices.
- In hospitals drugs are purchased direct from the manufacturers (or through purchasing hubs) and as a result are able to tender their business and obtain discounts through therapeutic tendering.

1.2 Over the past few years the pharmaceutical industry has sought to emulate the hospital model through offering retrospective discounts to commissioners based on sales in the community that is on volume of drug prescribed and dispensed on NHS prescriptions.

1.3 In recent years commissioners within primary care have seen the introduction, and significant increase in numbers, of rebates offered within primary care. At present there are tens of schemes offered by companies ranging from the smallest to the largest, with schemes varying in composition and size.

1.4 Primary care rebates could provide significant efficiency savings if correctly and transparently governed. Failure to ensure transparency and governance could perversely affect local prescribing and affect the reputation of the ICB.

1.5 To address the issues of transparency and governance NHS Norfolk and Waveney ICB (the ICB) have developed this policy. The overarching principle of which is that drugs which are currently on the primary care formulary will be considered. The availability of a rebate does not override the clinical decision making process in relation to formulary choice. This policy notes the obligations of the ICB, its staff and committee members with regard to the [Bribery Act 2010](#).

These drugs (and devices) should in the main have been assessed by the PrescQIPP NHS Programme's Pharmaceutical Industry Scheme Governance Review Board (Review Board) and given either GREY or AMBER status. In exceptional circumstances, where the drug is first line on the ICB formulary and has yet to be evaluated by PrescQIPP the medicines optimisation team will review the scheme using PrescQIPP's assessment tool as detailed in appendix A of the Review Board's Operating Model: [PISGRB Operating Model v4.3 \(prescquipp.info\)](#) and make recommendations for the Finance Committee based on the outcome of this assessment.

1.6 In 2012, the PrescQIPP NHS Programme established the Pharmaceutical Industry Scheme Governance Review Board, then offering governance on behalf of PCTs, which has now grown to be the largest governance provider on behalf of the majority of ICB in England, Health and Social Care Board Northern Ireland and the Health Boards of Wales [Primary care rebates | PrescQIPP C.I.C.](#)

## 2. SCOPE AND PURPOSE

- 2.1 This policy outlines NHS Norfolk and Waveney ICB's mechanism and governance arrangements for agreement to participate in any primary care pharmaceutical industry rebate scheme.

## 3. DEFINITIONS

<b>Primary Care Formulary</b>	List of agreed cost-effective drugs for use first line in primary care.
<b>PrescQIPP NHS Programme's Pharmaceutical Industry Scheme Governance Review Board</b>	<p>A board consisting of pharmacists' representatives from primary and secondary care; East Anglia Medicines Information Service and procurement specialist pharmacist and a PrescQIPP project manager.</p> <p>The board works to a standard operating model and assess the schemes using a standardised assessment tool encompassing a clinical assessment; a contractual assessment and a financial assessment.</p>
<b>Pharmaceutical Industry scheme - Rebate</b>	Rebate schemes are predominantly offered by medicines manufacturers as a way of reducing the effective price of a medicine to a ICB without affecting the list price.

## 4. ROLES AND RESPONSIBILITIES

### 4.1 Medicines Optimisation Team

- Identify primary care formulary drugs for which it would be appropriate to consider a rebate.
- Review rebate schemes that have been through NHS PrescQIPP Pharmaceutical Industry Scheme Governance Review Board.
- Review the detail of the contract.
- Send rebates to the ICBS's GP Prescribing Lead for their approval to proceed and signature.
- Once the GP Prescribing Lead has approved and signed the rebate the Medicines Optimisation Team will send the rebate to the Finance Committee for final approval and Executive Director of Finance signature. The Executive Director of Finance can sign renewals of rebates, provided they are at the same level as the original without the renewal going to the committee.
- Manage the process including record keeping; providing data for finance team to raise appropriate invoices; identify opportunities and report to the relevant groups and committee.
- Submit an annual report to the Audit and Risk Committee and Finance Committee.

### 4.2 Finance Committee

- Seek assurance with regards to transparency and governance in relation to Pharmaceutical Industry Rebate Schemes.

- Review, and where appropriate, agree rebate schemes proposed by the Medicines Optimisation Team
- Receive monthly updates on performance (contained within the monthly finance report).
- Review impact of rebate schemes on primary care prescribing patterns.
- Seek assurance with regards to transparency and governance

#### **4.3 Audit and Risk Committee**

- Monitor compliance with this policy.
- Review this policy.
- Receive an annual report from the Medicines Optimisation Team

#### **4.4 Board Sponsor**

- Executive Director of Finance, who will be the signatory to the rebates.

#### **4.5 Policy Authors**

- Review and update policy at intervals not exceeding two years from the date of approval (or sooner should circumstances dictate this is necessary) on behalf of the Audit and Risk Committee.

## **5. PROCESS / REQUIREMENTS**

### **5.1 Governance Process**

#### **NHS PrescQIPP Pharmaceutical Industry Scheme Governance Review Board**

NHS PrescQIPP has established a Pharmaceutical Industry Scheme Governance Review Board which provides a central function, to ensure that this is managed with focus on open, quality-orientated, robust decision-making around rebates. This process also allows greater efficiencies through economies of scale and reduces challenges from other pharmaceutical companies by providing comprehensive and transparent assessments.

The primary output of the Review Board is an Advisory Note summarising the recommendations for the Scheme submitted. Each Advisory Note includes a Red, Amber, Grey Status depending on the outcome of the assessment stage. The classification of the three colours is as follows:

**Grey** – Scheme Considered; No issues identified.

**Amber** – Scheme Considered; Not fully appropriate.

**Red** – Scheme Considered; Inappropriate.

Submitted schemes must demonstrate compliance with the following five principles in order to achieve a Grey/Amber status:

- The therapeutic initiative has a place in clinical practice.
- A long-term view of appropriateness is evident.
- There is a transparent, sensible plan for payment and tracking.
- The governance on what the scheme is, and is not, going to be used for is robust.
- There is a plan for on-going review.

The process of reviewing schemes submitted by pharmaceutical companies consists of 6 major stages:

- a) Submission (Online)
- b) PrescQIPP Assessment
- c) Independent Review
- d) Board Assessment
- e) Response
- f) Ratification
- g) Publication

Full details can be found in the Operating Model.

## 5.2 Finance Committee

This Committee will review the rebates proposed by the Medicines Optimisation Team. The Committee will ensure that any approved rebates meet the ICB's prescribing priorities and conform to the ICB's formulary.

Medicines rebate schemes that were not proposed to be rolled over/continues without any change in terms (i.e. rebate %s would not change), can be approved by the Director of Finance.

## 5.3 Dissemination And Communication to Staff

This policy will be available on the ICB's public [website](#).

This policy will be highlighted in the Prescribing Update

Document Control Including Archiving Arrangements. Document owned by Medicines Optimisation Team.

## 5.4 Implementation Plans

Named responsible person within Medicines Optimisation Team will manage process including horizon scanning and preparing relevant documents and reports.

# 6 MONITORING EFFECTIVENESS

- Finance Committee
- Monthly finance reports
- Policy oversight by the Audit and Risk Committee

# 7 REVIEW

The ICB in conjunction with the Medicines Optimisation Team will be responsible for monitoring and reviewing this policy.

Policy will be reviewed and refreshed at intervals not exceeding two years from the date of approval.



## APPENDIX A: EQUALITY IMPACT ASSESSMENT

### Step 1: Aims and purpose of the proposal / policy being assessed

(This should reflect what the policy is intending to achieve and how it seeks to achieve, it is this intention that the assessment seeks to measure, consider who benefits and how and who doesn't and why, also consider the impact of associated aims).

### Step 2: Screening process for relevance to equality & diversity issues

#### Does this proposal / policy have any equality & diversity relevance in the following areas?

(This should be considered in relation to the formulation and application of the policy. As far as possible engagement with the relevant staff network groups should take place to identify any potential areas of relevance).

**A** Age

**B** Disability

**C** Gender reassignment

**D** Marriage and Civil Partnership

**E** Pregnancy and maternity

**F** Race

**G** Religion or belief

**H** Sex

**I** Sexual orientation

**J** Other issues

**Step 3: If you have answered, "Yes", to any of the protected characteristic boxes in Step 2, a full impact assessment is required**

**Are any of the protected characteristic boxes in Step 2 marked "Yes"?**

**Step 4: Examination of available information (sources can include but are not restricted to – ESR data; MI relating to Recruitment /Employee Relations/Attrition; Industry best practice; legal overview; research articles; matters arising from judgements tested during consultation; consider four-fifths rule to assess difference).**

<b>Step 5: Full Impact Assessment Process</b>				
<b>Step 5a: Consultation Log</b>				
Where are the consultation records stored?				
<b>Step 5a: Consultation Log</b>	Step 5a: Consultation Log	Step 5a: Consultation Log	Step 5a: Consultation Log	Step 5a: Consultation Log
<b>Step 5b: EIA Action Plan: Workforce Impacts (internal)</b>				
Potential issues or impacts (positive and negative)				
<b>Step 5c: EIA Action Plan: Service Delivery Impacts (external)</b>				
Potential issues or impacts (positive and negative)				
<b>Step 6: Monitoring and review arrangements</b>				
How will the implementation of the proposal / policy be monitored, and by whom?				
What is the timetable for monitoring, with dates?				
<b>Step 7: Public availability of reports / result</b>				