

Policy for managing rebates on prescribed products in primary care

Ratification Process Lead Author:	Chief Pharmacist
Developed by:	Medicines Management
Approved by:	Strategic Clinical Priorities Group
Ratified by:	CCG Governing Body
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Review date:	May 2018, or earlier if required by changes in local or national requirements

Document Control Sheet

Development and Consultation:	This Policy has been developed by the Chief Pharmacist
Dissemination	This policy will be disseminated to all services within the CCG via the CCG website/Extranet
Implementation	Policy implementation involves all staff, managers and will be monitored by the Director of Corporate Affairs.
Training	No training required.
Audit	The Policy will be audited as part of the annual review of the CCG Constitution
Review	The document will be reviewed in May 2018 or earlier dependent on local or national changes.
Links with other policies and procedures	<p>The Policy should be read in conjunction with:</p> <p>Standing Orders</p> <p>Prime Financial Policies</p> <ul style="list-style-type: none"> • Anti-bribery Policy • Conflicts of Interest Policy • Private Practice – Policy on Conduct for Clinical Staff • Standards of Business Conduct and Commercial Sponsorship Policy • ABPI Code of Practice 2016
Equality Impact Assessment	The Medicines Management team has conducted an Equality Impact Assessment which has been approved by the Equality & Diversity Lead.

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1. Introduction

Primary care rebate schemes are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular medicine(s).

Rebates are increasingly being offered by suppliers of products prescribed on FP10 in primary care. This allows suppliers the commercial flexibility to achieve the following:

- Offer NHS organisations a lower price without adjusting list price. This prevents parallel trade and maintains the UK list price as a European reference point.
- Develop a commercial approach specific to individual organisations or groups of organisations.

The concept of rebating is established for some aspects of prescribing, for example, oral nutrition and some secondary care Patient Access Schemes. Manufacturers of new premium price, potentially high volume medicines are also offering rebates to the NHS which could result in significant cost avoidance or greater access for patients. Rebating is also accepted as normal practice in other countries. Rebating may also provide a vehicle for value based pricing in primary care in the future where prices paid are linked to outcomes achieved.

While there are no legal barriers *per se*, the way in which rebates are handled within an organisation is an important consideration. Risks vary from an organisational 'discomfort' with the concept of rebates to serious breach of European Competition Laws or the Bribery Act. There are, however, potentially significant opportunities to improve the efficient use of the prescribing budget and facilitate access to valuable products for patients.

2. Purpose

This policy provides a framework for managing rebates in a legal and ethical way.

3. Bribery Act 2010

The Cambridgeshire & Peterborough CCG follows good NHS business practice as outlined in the Standard of Business Conduct & Commercial Sponsorship Policy and has robust controls in place to prevent bribery as outlined in the Anti-Bribery Policy. Due consideration has been given to the Bribery Act 2010 in the development of this policy document and it is felt that the Bribery Act is particularly relevant to this policy. CCG staff should be aware that they cannot make any promises to participants regarding influencing changes to future policies or CCG decisions in return of their support and engagement.

It should be noted that the Act makes bribery a criminal offence and there are four offences:

- bribing, or offering to bribe, another person
- requesting, agreeing to receive, or accepting a bribe

- bribing, or offering to bribe, a foreign public official
- failing to prevent bribery

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.

If you are found to be in breach of CCG policy and/or the Bribery Act 2010, you will face action which may include an investigation by the Local Counter Fraud Specialist (LCFS) that could result in criminal and/or disciplinary action being taken against you, and may also lead to loss of NHS employment and superannuation rights.

To report any concerns please use the following contact information:

Counter Fraud Specialist: Lisa George

Tel: 07825 827024

Email: lisa.george4@nhs.net or lisa.george@tiaa.co.uk

You can report concerns using the on-line referral form or by calling the National NHS Fraud and Corruption reporting line on: 0800 028 40 60.

Further information on the Bribery Act can be found at www.opsi.gov.uk/acts

4. Scope

This policy applies to Cambridgeshire & Peterborough CCG and all of its employees, members of the CCG, co-opted members, members of the Governing Body and its committees. All must comply with arrangements outlined in this policy. The policy should be used in conjunction with the following policies:

CCG Standing Orders

Prime Financial Policies

- Anti-Bribery Policy
- Standard of Business Conduct & Commercial Sponsorship Policy
- Conflict of Interest Policy

[ABPI Code of Practice 2016](#)

5. Confidentiality

Anyone voluntarily involved in CCG business may have access to information of a sensitive nature. Where this is the case, they will be required to sign a confidentiality agreement. It is the responsibility of the relevant Project Lead to ensure they have access to this, as appropriate.

They will also be required to adhere to all policies and procedures relating to this policy.

6. Policy Purpose and Aims

Rebate agreements usually take the form of legal agreements between the manufacturer and CCG. It is important that Cambridgeshire & Peterborough CCG has a policy to support evaluation and sign off of rebate schemes to ensure that each scheme is only signed off if it provides good value for money to the public purse and its terms are in line with organisation vision, values, policies and procedures and to ensure that the CCG is transparent in its process for considering these schemes. This policy provides a framework for managing rebates in a legal and ethical way. The principles outlined in this policy document allow for the objective evaluation of schemes submitted to the CCG and a clear process for approving and scrutinising agreements.

7. Roles Responsibilities/Duties

7.1 Chief Finance Officer

- Provides oversight of all aspects of this policy to ensure organisational compliance
- Is authorised to sign rebate agreements of behalf of the CCG Governing Body
- Ensures rebates are claimed in a timely fashion

7.2 CCG Rebate Governance Board (membership includes Chief Pharmacist or deputy, GP Clinical Lead for Prescribing or deputy and Finance representation)

- Reviews rebates in conjunction with the principles within this policy and makes a recommendation to the Strategic Clinical Priorities Group.

7.3 CCG Chief Pharmacist

- Ensures this policy is adhered to in all decisions relating to acceptance or refusal of rebates.
- Is authorised to sign rebate agreements of behalf of the CCG Governing Body

7.4 Strategic Clinical Priorities Group

- Ensures this policy is adhered to in all decisions relating to acceptance of rebates and provides oversight for ratification by the Governing Body.

7.5 Finance & Performance Committee or other delegated committee

- Monitors the compliance and effectiveness of this policy

8. Overarching principles

It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS. Any medicine should only be agreed for use within a rebate scheme if it is believed to be appropriate for a defined cohort of patients within a population. It is important that all patients continue to be treated as individuals, and acceptance of a scheme should not constrain existing local decision making processes or formulary development. This is in line with DH document on Strategies to Achieve Cost-Effective Prescribing (2010). This states that the following principles should underpin local strategies:

- i. *The decision to initiate treatment or change a patient's treatment regime should be based on up-to-date best clinical evidence or guidance, e.g. from the National Institute for Health and Clinical Excellence (NICE) or other authoritative sources;*
- ii. *Health professionals should base their prescribing decisions on individual assessments of their patients' clinical circumstances, e.g. patients whose clinical history suggests they need a particular treatment should continue to receive it;*
- iii. *The individual patient (and their guardian or carer where appropriate) should be informed about the action being taken and suitable arrangements should be made to involve the patient, ensuring they have an opportunity to discuss a proposed switch of medicines, and to monitor the patient following any switch;*
- iv. *Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;*
- v. *Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.*

9. Good Practice Principles for Primary Care Rebate Schemes

The detailed content of primary care rebate schemes offered to primary care organisations will differ between schemes. Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources. These Good Practice Principles can help the CCG in assessing these schemes, the CCG will need to be assured that the schemes offered do not breach any other UK legislation, in particular, reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the DH's controls on pricing made under the 2006 Act, the Medicines Act, the Human Medicines Regulations 2012, the Bribery Act, EU law and the public law principles of reasonableness and fairness.

Cambridgeshire & Peterborough CCG will adopt the following Principles when deciding whether to participate in a primary care rebate scheme or not:

9.1 Product Related

- Cambridgeshire & Peterborough CCG will consider a rebate that has been assessed by a regional / national primary care rebate governance board and has a positive or neutral outcome.
- Cambridgeshire & Peterborough CCG will consider a rebate for medicines where the clinical need has previously been evaluated and established by the

Cambridgeshire & Peterborough Joint Prescribing Group i.e. formulary decision making happens first and is not influenced by any information regarding potential rebate schemes.

- Any and all decision making processes will be clinically-led and involve all appropriate stakeholders, where appropriate.
- Health professionals should always base their prescribing decisions primarily on assessments of the individual patient's clinical circumstances. The impact of a rebate scheme is a secondary consideration.
- Cambridgeshire & Peterborough CCG will not consider unlicensed or 'off-label' uses of medicines as part of a primary care rebate scheme. Furthermore, a rebate scheme for a drug or product must be linked to total use of that drug and not limited to particular indications for which that drug can be used, and in line with the Specific Product Characteristics (SPC) for the drug in question.
- All recommendations for use of a medicine within a primary care rebate scheme must be consistent with the UK Marketing Authorisation of the medicine in question.
- Medicines recommended by NICE not to be prescribed will not be considered under a primary care rebate scheme.
- Primary care rebate schemes are not appropriate for medicines in Category M and some medicines in Category C of the Drug tariff because of potential wider impact on community pharmacy reimbursement.

9.2 Rebate Scheme Related

- Primary care rebate schemes should not be solely linked to requirements to increase market share or volume of prescribing.
- All rebate schemes should be approved through robust local governance processes that include the CCG Rebate Governance Board and Strategic Clinical Priorities Group, reporting to the CCG Governing Body.
- The administrative burden to the NHS of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement. There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.

10. Interface with the pharmaceutical industry

The CCG Rebate Governance Board may discuss a rebate with the pharmaceutical industry (supplier) where a medicine or group of medicines have been evaluated by the Cambridgeshire and Peterborough Joint Prescribing Group and clinical need has been established. The CCG Rebate Governance Board will also consider rebates against the principles within this policy.

The CCG must be able to demonstrate that all suppliers wishing to discuss rebates are provided with equal access.

When appointments to discuss a rebate offer are accepted, the supplier should be provided with a copy of this policy. Details of the proposed rebate should be made in writing to the prescribing partnership e-mail address:

CAPCCG.prescribingpartnership@nhs.net.

Suppliers should not make guideline or formulary positioning conditional to any rebate offer. Equally, the CCG must not offer or expect any favourable positioning of a product with respect to the local formulary in return for a rebate offer. To avoid misunderstandings, meetings pertaining to rebates must not discuss or consider formulary or guidelines status, positioning relative to competitor products or any other actions resulting from the rebate offer. This includes the execution of any medicines change programmes by the CCG. Suppliers must not discuss within meetings pertaining to rebates any potential joint working arrangements, medical education goods and services, sponsorship offers or patient support programmes. Exceptions are where these elements are explicitly part of the commercial offer and are included in a legal contract.

In the event of the above not being adhered to in a meeting, the meeting must be terminated immediately and the incident should be reported to the Accountable Officer to ascertain appropriate action. A report to the ABPI (Association of the British Pharmaceutical Industry) should also be considered.

11. Contracts

The CCG Chief Pharmacist and Chief Finance Officer must ensure that a formal written contract is in place, signed by both parties, the CCG and the Pharmaceutical Industry or third party company, to ensure:

- The terms of the scheme are clear
- Legal protection is maximised.

All negotiations around a scheme should be expressed as being "subject to contract" i.e. not binding until the formal contract has been signed by both parties.

Primary care rebate scheme agreements should include a right to terminate on notice with a sensible notice period e.g. three or six months. The need for exit criteria and an exit strategy should be considered before a scheme is agreed. It is essential to allow flexibility to respond to emergence of significant new clinical evidence, or significant changes in market conditions. A shorter notice period should be agreed in these circumstances.

Freedom of Information issues (see section 12 – Information Governance) should be discussed with the manufacturer before a commissioner enters into any agreement with them and should be contained in the contract.

12. Information Governance

Cambridgeshire & Peterborough CCG supports the principles of transparency enshrined in the Freedom of Information Act. Primary care rebate schemes often contain confidentiality clauses which may restrict what information may be disclosed under Freedom of Information.

Whilst manufacturers often attempt to impose requirements for confidentiality that would restrict the CCG from disclosing the existence and level of any discount to any third party, the CCG recognise that such agreements are likely not to be in the interests of the NHS. This is on the basis both that it will compromise the ability of the CCG to evaluate whether it is obtaining the best possible terms and that in the medium to longer term it is likely to lead to price inflation.

The CCG will ensure that all primary care rebate scheme agreements meet the requirements of the Data Protection Act, and patient confidentiality must never be compromised.

12.1 Sharing of Information with prescribers and other stakeholders

Individual contracts will contain details of any confidentiality agreements but such agreements must not preclude the sharing of information, including discounts and scheme details, within the wider NHS.

Cambridgeshire & Peterborough CCG will publish a list of the schemes it participates in on the CCG website. The full terms of the scheme may not be published depending on the nature of the rebate scheme contract.

12.2 Freedom of Information Requests

Any decision from the Information Commissioners Office to disclose information must be adhered to.

13. Use of Rebates

It is vital that any funds received by the CCG as part of a rebate are managed in a transparent, legal and ethical way. Oversight for any spending plans, redistribution of funds and control of destination budgets will be provided by the Finance and Performance Committee.

No one individual should be in a position to benefit personally from the level of rebate received by the CCG.

Examples of unacceptable practice:

- A GP LES for diabetes is funded by an insulin rebate. The higher the rebate payment, the more funds will be available for the LES.
- The medicines management team create a budget for special projects. All rebates are paid into this budget and the team can use this for short term posts.

Examples of acceptable practice:

- A diabetes 'invest to save' project is approved by the CCG. The business case includes an investment that is offset by a rebate scheme. The projected savings are in line with analysis of appropriate use and the project funding is secure even if rebate savings are not fully realised. Any surplus is not automatically allocated to the project.

14. Payment mechanisms

A clear process for generating the required information should be determined for each rebate agreement which will be managed by the medicines management information team and finance accountant. This should include:

- Information required
- Reporting intervals
- Generation of purchase orders if required
- Invoicing arrangements

15. Implementation

The CCG Rebate Governance Board will be responsible for assessing schemes against the principles outlined in section 9 above. The 'Rebate Scheme Decision Form' (appendix 3) will be used to record assessment against the principles and provide a recommendation to the Strategic Clinical Prioritisation Group who will provide oversight for ratification by the Governing Body..

16. Monitoring the Compliance and Effectiveness of this Policy

Annual reports will be provided as a minimum to the Finance and Performance Committee. Frequency of reports will be reviewed against the size of the CCG portfolio of rebate schemes.

17. Policy Review

This policy will be reviewed by a period of no longer than 2 years as stated or in response to any relevant changes in local and/or national policies and guidance, whichever is sooner.

18. References

1. London Procurement Programme Legal Response from DAC Beachcroft LLP – Personnel Communication
2. Department of Health. Strategies to Achieve Cost-Effective Prescribing (2010)
3. Scarborough & Ryedale CCG – CCG Primary Care Rebate Scheme Policy (Feb 2015)

19. Associated Documents

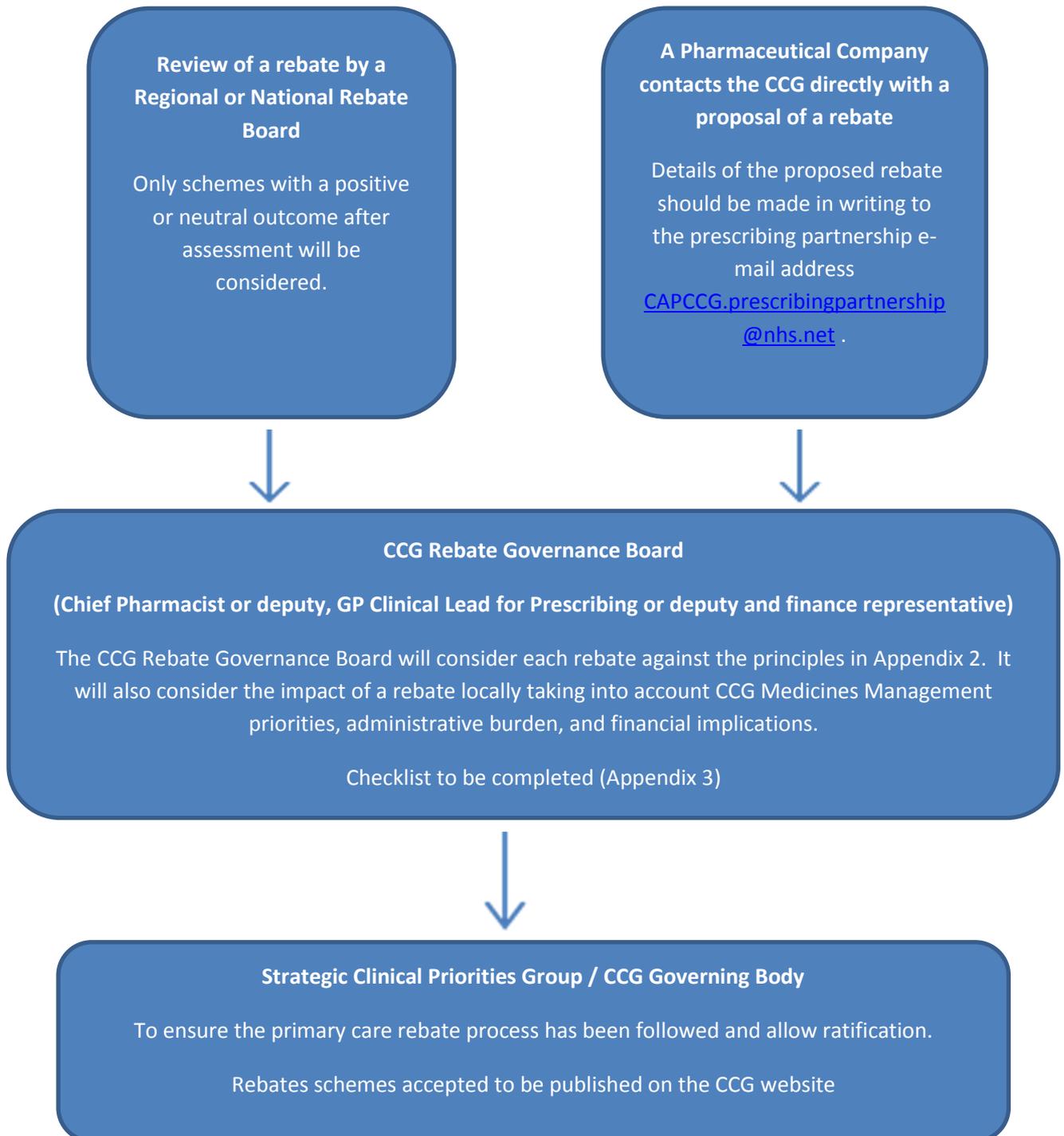
The following were used as the basis of this policy:

- Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme, 2012.
- Ethical Framework for Considering Rebate Agreements from Pharmaceutical, Nutrition and Device Companies. Greater Manchester Commissioning Support Unit, 2013.
- PrescQIPP Pharmaceutical Industry Scheme Governance Review Board, 2014.

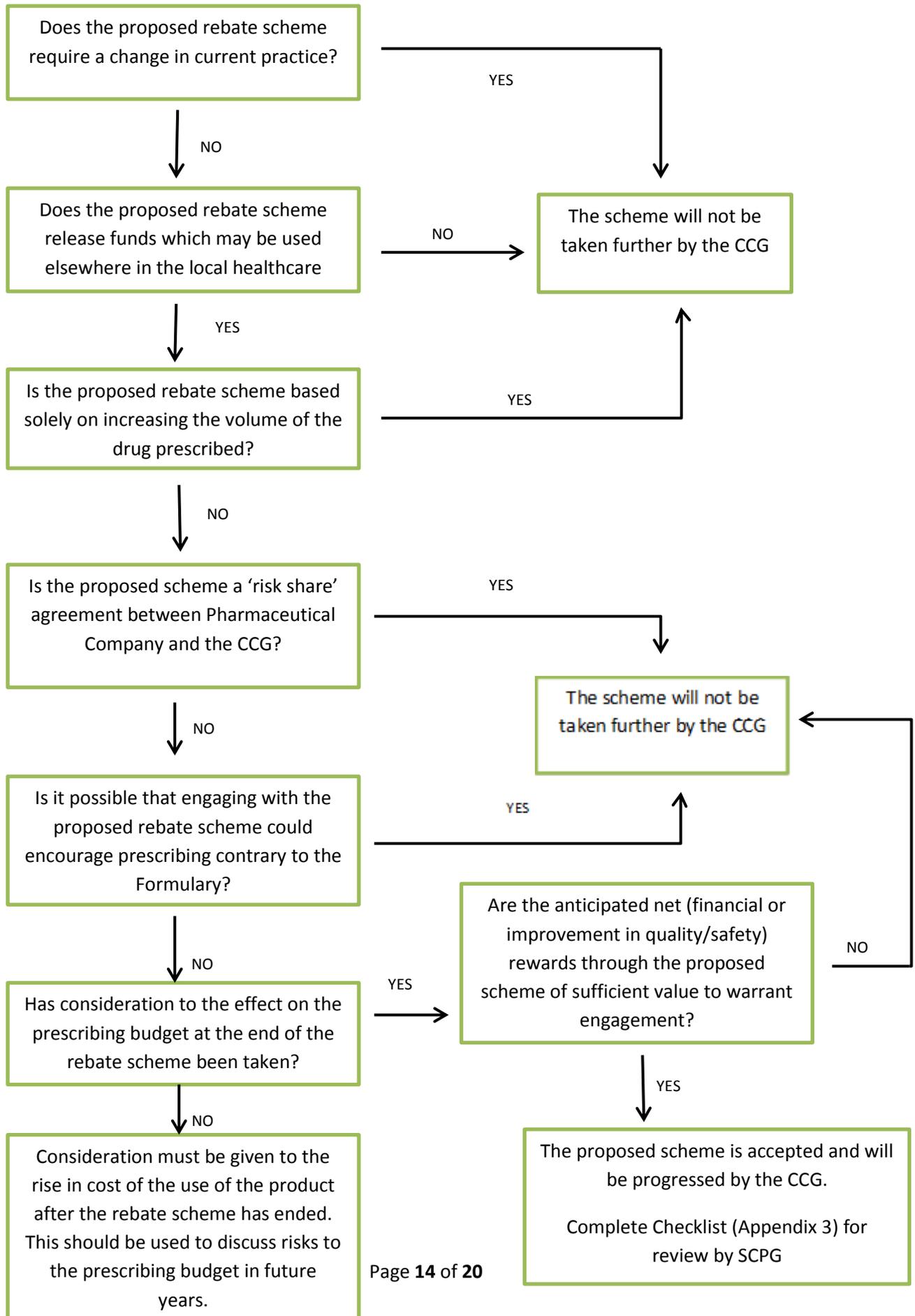
Appendices

- Appendix 1: Primary Care Rebate Scheme Approval Process
- Appendix 2: Screening Questions when considering Rebate Schemes
- Appendix 3: Primary Care Rebate Scheme Decision Form
- Appendix 4: Equality Impact Assessment

Appendix 1: Primary Care Rebate Scheme Approval Process



Appendix 2 - Screening questions when considering rebate schemes



Appendix 3: Primary Care Rebate Scheme Decision Form *Confidential*

Product	
Manufacturer	
Contact Details	

Brief details of the scheme	
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Assessment Criteria	Yes / No
The product has been assessed by a regional or national rebate board and has a positive or neutral opinion?	
If the product is a medicine, is it licensed in the UK?	
The product does not have a negative decision from NICE?	
The contract does not include any requirement for a directive or guideline to be given to health care professionals to prescribe the specific product?	
The rebate scheme is not designed to increase off label use of the drug?	
If the product is a device or nutritional supplement is it contained in the current Drug Tariff?	
If it is not a medicine, it has not been excluded from use within primary care?	
The rebate scheme does not require exclusive use of a specific brand?	
The product is not contained in Category M of the Drug Tariff?	
The rebate scheme is not linked directly to a requirement for an increase in market share or volume of prescribing?	
The rebate scheme does not prevent consideration of other schemes?	
There is no requirement to submit additional information beyond the volume of prescribing of the product?	
There is no requirement to collect patient specific data?	

Other considerations:

Regional or national rebate board assessment outcome		
No. of years scheme is available? (Is it >2 years?)		
Termination period and exit criteria		
Estimated potential savings (per patient and for CCG population per annum)?	£ /pt/annum	£ /C&PCCG/annum
Further information <i>For example:</i> • <i>Administrative burden</i> • <i>Governance issues</i> • <i>Freedom of Information issues</i> • <i>Any other pertinent issues</i>		
Recommendation		
Rationale		
Evaluation carried out by (Name, Title & Date)		
Reviewed by (Name, Title & Date)		

CCG Rebate Governance Board:

The CCG Rebate Governance Board does/does not support this primary care rebate scheme

Name Signature..... Date.....

CCG Governing Body Decision:

Cambridgeshire & Peterborough CCG Governing Body does/does not support the decision to agree to this primary care rebate scheme

Name Signature..... Date.....

Appendix 4: Equality Impact Assessment - Form

Name of Proposal (policy/strategy/function/service being assessed)	Policy for managing rebates on prescribed products in primary care
Those involved in assessment:	Specialist Pharmacist – C&PJPG / HCD Clinical Lead for Prescribing and Clinical Policies
Is this a new proposal?	Update
Date of Initial Screening:	December 2015 (updated April 2016)

What are the aims, objectives?	To ensure a consistent approach to managing rebates on prescribed products in primary care is adopted throughout the CCG
Who will benefit?	The CCG and members of the public
Who are the main stakeholders?	The CCG and members of the public
What are the desired outcomes?	To secure a consistent approach to policy review, development and approval.
What factors could detract from the desired outcomes?	Lack of awareness and/or non-enforcement of the policy.
What factors could contribute to the desired outcomes?	Awareness raising of the Policy via the CCG Website.
Who is responsible?	SCPG
Have you consulted on the proposal? If so with whom? If not why not?	Medicines Management, Strategic Clinical Prioritisation Group & Governing Body.

Which protected characteristics could be affected and be disadvantaged by this proposal (Please tick)		Yes	No
Age	<u>Consider:</u> Elderly, or young people		✓
Disability	<u>Consider:</u> Physical, visual, aural impairment Mental or learning difficulties		✓

Gender Reassignment	<u>Consider:</u> Transsexual people who propose to, are doing or have undergone a process of having their sex reassigned		✓
Marriage and Civil Partnership	<u>Consider:</u> Impact relevant to employment and /or training		✓
Pregnancy and maternity	<u>Consider:</u> Pregnancy related matter/illness or maternity leave related mater		✓
Race	<u>Consider:</u> Language and cultural factors, include Gypsy and Travellers group		✓
Religion and Belief	<u>Consider:</u> Practices of worship, religious or cultural observance, include non-belief		✓
Sex /Gender	<u>Consider:</u> Male and Female		✓
Sexual Orientation	<u>Consider:</u> Know or perceived orientation		✓

What information and evidence do you have about the groups that you have selected above?

N/A

Consider: Demographic data, performance information, recommendations of internal and external inspections and audits, complaints information, JNSA, ethnicity data, audits, service user data, GP registrations, CHD, Diabetes registers and public engagement/consultation results etc.

How might your proposal impact on the groups identified? For example you may wish to consider what impact it may have on our stated goals: Improving Access, Promoting Healthy Lifestyles, Reducing Health Inequalities, Supporting Vulnerable People

Examples of impact re given below:

- a) Moving a GP practice, which may have an impact on people with limited mobility/access to transport etc.
- b) Planning to extend access to contraceptive services in primary care without considering how there services may be accessed by lesbian, gay, bi-sexual and transgender people.
- c) Closure or redesign of a service that is used by people who may not have English as a first language, and may be excluded from normal communication routes.

Please list the positive and negative impacts you have identified in the summary table on the following page.

1 Summary

Positive impacts (note the groups affected)

- Services are commissioned, procured, designed and delivered to meet the health needs of all groups of the local communities.
- Achieve the greatest possible improvement in health outcome for our population, within the resources that we have available.
- Individual people's health needs are assessed and met in appropriate and effective ways.
- Improved patient access and experience.

Negative impacts (note the groups affected)

None

Summarise the negative impacts for each group:

N/a

What consultation has taken place or is planned with each of the identified groups?

N/a

What was the outcome of the consultation undertaken?

N/a

What changes or actions do you propose to make or take as a result of research and/or consultation?

Briefly describe the actions then please insert actions to be taken on to the given Improvement Plan template provided.

N/a

Will the planned changes to the proposal:

Please state Yes or No

Lower the negative impact?	N/a
Ensure that the negative impact is legal under anti-discriminatory law?	N/a
Provide an opportunity to promote equality, equal opportunity and improve relations i.e. a positive impact?	N/a

Taking into account the views of the groups consulted and the available evidence, please clearly state the risks associated with the proposal, weighed against the benefits.

N/a

What monitoring/evaluation/review systems have been put in place?

Overview by CCG Senior Medicines Management Team and Strategic Clinical Priorities Group

When will it be reviewed?

May 2018, or earlier if required by changes in local or national requirements.

Date completed:	19 th April 2016
Signature:	Kelly Broad
Approved by:	Soomitra Kawal
Date approved:	27 th April 2016