Birmingham and Solihull
Clinical Commissioning Group

NHS Birmingham & Solihull Clinical Commissioning Group

Policy for Joint Working with the Pharmaceutical Industry, Commercial Sponsorship and Primary Care Prescribing Rebate Schemes.

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Ratified by	Senior Leadership Team
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Name of originator/author	Rebecca O'Connor
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Target audience	CCG staff/industry

Contents

1. Introduction

1.1. The Department of Health encourages NHS organisations to consider opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to patient health are advantageous.

1.2. Rebate schemes are a contractual agreement between CCGs and industry. In rebate schemes, the CCG is charged the manufacturer's list price for primary care prescriptions dispensed, with the manufacturer providing a rebate on an agreed amount.

1.3. Any such opportunities for either joint working or rebate must be objectively considered and documented in accordance with the guidance in this policy.

2. Policy Statement & Scope

2.1. This policy applies to employees, contractors and office holders (staff) who work with or for Birmingham and Solihull Clinical Commissioning Group (the CCG) who are considering sponsorship, joint working and training arrangements with the pharmaceutical industry or other organisations potentially supplying the NHS with clinical support (including third party commercial organisations).

2.2. Any such arrangement must be in accordance with the CCG's Standards of Business Conduct Policy.

3. Equality Statement

3.1. All public bodies have a statutory duty under the Equality Act 2010 to "set out arrangements to assess and consult on how their policies and functions impact on race equality". This obligation has been increased to include equality and human rights with regard to disability, age, gender, sexual orientation, gender reassignment and religion.

3.2. Birmingham and Solihull CCG endeavours to challenge discrimination, promote equality and respect human rights, and aims to design and implement services policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

3.3. All staff are expected to deliver services and provide care in a manner which respects the individuality of patients and their carers and as such treat them and members of the workforce respectfully, regardless of age, gender, race, ethnicity, religion/belief, disability and sexual orientation.

3.4 Managers, staff and providers where relevant, are expected to use the appropriate interpreting, translating or preferred method of communication for those who have language and/or other communication needs.

4. Equality Analysis

4.1. In order to meet these requirements, an equality analysis is used to assess all Birmingham and Solihull CCG policies, procedures and guidelines.

4.2. A full Equality Impact Assessment of this policy was undertaken on the 10/01/19 and is attached as an Appendix to this policy.

5. Aims

5.1. The CCG aims to develop innovative and mutually beneficial partnerships in order to enhance the health and wellbeing of the population of Birmingham and Solihull. This policy provides a framework enabling the CCG to objectively consider and assess potential collaborative projects; joint working and primary care prescribing rebate schemes with the pharmaceutical industry, based upon mutual benefit and recognition.

5.2. Core values of collaboration:

- Benefit the CCG's population with the principal beneficiary being the patient
- Behaviours in accordance with the principles of equality and positively recognising diversity
- Preserve patient care
- Preserve patient and clinician confidentiality
- Be most accessible
- Provide sustainable clinical benefits
- Highly cost effective
- Be able to stand the test of parliamentary scrutiny, public judgements of propriety and professional codes of conduct
- Be evidence based
- Be aligned with local and/or national priorities

6. Responsibilities

6.1. It is the responsibility of all staff to be familiar with the policy framework and guidance for joint working with the pharmaceutical industry and other commercial organisations. Line managers must ensure that all employees are aware of this policy.

6.2. All staff are reminded that they have a responsibility to comply with their own

professional codes of conduct, and in addition, all staff must comply with the CCG Standards of Business Conduct Policy.

6.3. In the interests of transparency, it is the duty of all staff to declare any direct or indirect conflicts of interest via the centrally-held Register of Interests that is supported and maintained by the Legal Team. Details of what should be declared are contained in the Standards of Business Conducts Policy.

6.4. Staff should also comply with the requirements of the Standards of Business Conduct Policy regarding the acceptance, non-acceptance and declaration of any form of gift or hospitality that might be offered to them by any outside person or body. The Legal Team is also responsible for maintaining the registers of gifts and hospitality. Details of what should be declared in this regard are also contained in the Standards of Business Conducts Policy.

6.5. The Medicines Management team should participate in the evaluation of any proposed service, project or collaboration with the pharmaceutical industry.

6.6. The Medicines Management, Legal, Finance and Governance teams have the collective responsibility for assessing the propriety of - and addressing any - contentious issues regarding collaboration with the pharmaceutical industry.

6.7. Approval for joint working should be sought from the Senior Responsible Officer, the Chief Finance Officer and a Lay Advisor.

6.8. Contracts resulting from a joint working agreement arrangement must be signed in accordance with the CCG Scheme of Delegation.

6.9. All representatives of the pharmaceutical industry must comply with the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry (2) as a condition of membership. The code of practice is designed to ensure a professional, responsible and ethical approach to promotion of prescription medication in the UK through self-regulation. Where the pharmaceutical company is not a member of the ABPI, the company code of conduct should be scrutinized to ensure it sets equivalent standards, and is supported by appropriate governance structures. The Senior Leaders' Team should be made aware that the company is not a member of the ABPI.

7. Definitions

7.1. Commercial Sponsorship:
NHS funding from an external source, including funding for all or part of the cost of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, cost associated with meetings, meals, gifts, hospitality, hotel and transport costs (including trips abroad), provision of free services and buildings/premises. Commercial sponsorship is considered with in the CCG's Standards of Business Conduct Policy.

7.2. Joint Working with the CCG:
A situation where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient-centred projects, and share a commitment to successful delivery. These arrangements are managed in an open and transparent manner. Sponsorship differs to joint working (please see above for the definition of sponsorship).

7.3. Joint Working with Member Practices:
Industry may approach practices direct regarding joint working. Practices are advised to consider the guidance set out in this policy, NHS England Statutory Guidance on Managing Conflicts of Interests and may wish to consult with the CCG's Medicines Management team when making their decision.
Industry may approach the CCG to work with our member practices or ask the CCG to make a recommendation to practices. In such cases, the CCG will follow the process outlined in this policy to form a view. However, the final decision will rest with the member practice.

7.4. Rebate Agreement:
The legal arrangement between the CCG and pharmaceutical company. These may be on a variety of schemes, including but not limited to straight discount and volume based.

7.5. Staff:
Refers to all staff employed by the CCG, temporary or agency workers, contractors Governing Body members, Governing Body committee members, clinical leads and any other healthcare professionals (i.e. locum employees).

8. Policy:

8.1. Joint Working Agreements:

8.1.1. Joint working agreements must never lead to higher costs or reduce the quality of services to patients. Only projects which have a positive impact for patients and the CCG will be acceptable.

8.1.2. Involvement of any joint working agreement must never compromise patient care, the CCG or any member of staff/officer in undertaking their duties within the NHS.

8.1.3. Patient confidentiality must be safeguarded at all times. Advised should be sought from the CCG's Caldicott Guardian and Information Governance lead and must comply with the Data Protection Act.

8.1.4. All joint working between the NHS and pharmaceutical industry should be conducted in an open and transparent manner. Arrangements should be of mutual benefit, the principal beneficiary being the patient.

8.1.5. The CCG is encouraged to consider partnership approaches for joint working against the following criteria, using the pro-forma in Appendix 1:

- Benefit the CCG's population with the principal beneficiary being the patient
- Partners act in compliance with the Public Sector Equality Duty
- Preserve patient care and patient/clinician confidentiality
- Be most accessible
- Provide sustainable clinical benefits
- Improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.
- Highly cost effective
- Be able to stand the test of parliamentary scrutiny, public judgements of propriety and professional codes of conduct.

8.1.6. Before entering into any joint working arrangement, the following must be clearly outlined using the consideration template in Appendix 1:

- The potential implications for patients, the NHS and other relevant stakeholders
- The benefits for all parties must be clearly defined
- The length of the arrangement
- The structure of the arrangements including clear roles and responsibilities
- The aims, objectives and outcomes of the arrangement including all measures of success, milestones and timelines
- The total potential commitment from all parties (all costs, materials and staff) and how these costs will be met
- How any cost overruns will be dealt with
- How the arrangements will be monitored, evaluated and reported
- Perceived benefits for all parties
- Disengagement/exit criteria including arrangements for early exit
- Risks associated with the arrangement

8.1.7. The following principles will also apply to joint working:

- Contract negotiations will be in line with NHS values
- Confidentiality of patient information must be protected and the CCG policies, the Data Protection Act 2018 and the General Data Protection Regulations 2018 must always be adhered to
- Joint working should be at a corporate rather than an individual level
- Clinical and financial outcomes will be assessed through a process of risk assessment
- All collaborations should be on the basis of prior written agreement
- Any arrangement must support the CCG strategy

8.1.8. The CCG should not rely on the pharmaceutical industry as a sole source of evidence. The Medicines Management team have access to the independent sources of evaluated information and can provide advice and support.

8.1.9. Samples of pharmaceutical products should not be accepted.

8.1.10. Schemes must not be linked to the purchase or supply of particular products. Industry representatives must be made aware that joint working agreements will have no effect on purchasing decisions made by the CCG.

8.1.11. Pharmaceutical company sponsorship for professional training should only be accepted if it can be assured that such training is in line with the CCG and national policy. Training events which rely heavily on sponsored materials should be discouraged, unless promoting good practice and agreed in advance by the CCG, and it must be made clear that the acceptance of sponsorship is not an endorsement of any product or company. Any sponsorship should be in line with the CCG's Standards of Business Conduct Policy.

8.1.12. Clinical guidelines and formulary applications should normally be written independently of industry. Where the pharmaceutical industry has been involved in the process of developing clinical guidelines/formulary applications, all involvement must be declared. Formulary applications and/or clinical guidelines must be considered and approved by the relevant committees, the Area Prescribing Committee or the Regional Medicines Oversight Committee, prior to publication. Industry names or logos should not appear on printed documents/published correspondence. However, for transparency, their contribution should be acknowledged. Any joint working with pharmaceutical companies should not counteract CCG policies/projects which promote clinical quality or cost effective prescribing.

8.2. The CCG's Expectations of the Pharmaceutical Industry:

8.2.1. The introduction of any new drug or other product authorised for prescribing must follow due processes of the Area Prescribing Committee or the Regional Medicines Oversight Committee. When promoting a drug, it would be expected that the formulary status is explicitly included before any discussions and that it is in line with the local health economy joint formulary.

8.2.2. To follow the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry, irrespective of individuals are ABPI trained or not. It is important to be mindful that the rules concerning relationships with patients (and the strict prohibition of the promotion of prescription only medicines to the public), also apply to the collaborative activity.

8.2.3. To be clear on the objectives of collaborating with healthcare professionals

8.2.4. Not to embark on collaborative working without being able to demonstrate the value of the collaboration to third parties who may know less about it.

8.2.5. Not to expect or encourage healthcare professionals to do things that are

outside their professional code of ethics and understand the obligations and limitations placed upon them.

8.2.6. Ensure transparency about involvement in any activity and meet the requirements of the ABPI Code of Practice and the CCG's Standards of Business Conduct Policy regarding declaration of payments to healthcare professionals.

8.2.7. If there is intention to work in collaboration with healthcare professionals, please ensure there is a written agreement or contract in place, setting out the details of the partnership.

8.2.8. Complete all relevant paperwork required by this joint working process

8.2.9. Agree details of and sign the Joint Working Agreement (please see Appendix 2)

8.2.10. Comply with all agreed aspects of the agreed Joint Working Agreement

8.3. Primary Care Prescribing Rebate Schemes (PCRS)

Principles for assessing rebate schemes: The CCG will use Appendix 3 (Rebate Scheme Consideration Form) and Appendix 1 (pro forma) during the assessment of each rebate scheme. The following will be used to determine the suitability of taking a rebate scheme to Birmingham and Solihull CCG for consideration and ratification:

Product related:

8.3.1. There should be a demonstrable clinical need for the product

8.3.2. All products should normally be recommended for prescribing in Birmingham and Solihull following approval at the relevant committees; Area Prescribing Committee and/or Regional Medicines Oversight Committee. All products should be listed on the Birmingham, Sandwell, Solihull and surrounds Formulary found at:http://www.birminghamandsurroundsformulary.nhs.uk/.

8.3.3. Products should not be included if they are detailed in the Formulary 'grey list' or 'black list' list that is in operation within the CCG, or have a negative decision by NICE.

8.3.4. There should be no directive for health professionals to prescribe a specific product, solely because a Primary Care Rebate Scheme (PCRS) is in place. Prescribing decisions should be made on assessments of an individual patient's clinical circumstances. The impact of a rebate scheme is a secondary consideration.

8.3.5. Any medicine considered under a PCRS must be licensed in the UK. Where there is more than one licensed indication for a medicine, a scheme should not be

linked to a particular indication for use.

8.3.6. Any device or nutritional supplement considered under a PCRS should be included within the relevant chapter of the published NHS Prescription Services Drug Tariff.

8.3.7. Vitamins, which are classed as food supplements, should be only those recommended for use by the CCG.

8.3.8. PCRS promoting unlicensed or off label uses will not be entered into. All recommendations for use of a medicine within a PCRS must be consistent with the marketing authorisation of the medicine in question.

8.3.9. Consistent savings must be achievable across all pack sizes where applicable.

8.4. Rebate Scheme Related:

8.4.1. The administrative burden to the CCG of setting up and running the scheme must be factored into the assessment of likely financial benefit of the scheme.

8.4.2. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.

8.4.3. PCRS which impose unacceptable obligations or requirements of the CCG (e.g. restricting responses to FOI requests or information requests from other NHS bodies) will not be entered into.

8.4.4. PCRS encouraging exclusive use of a particular brand of product will not be entered into. Where specific brand prescribing is required due to the nature of the product, e.g. glucose testing strips or some specific drugs (e.g. modified release products), then an increase in that particular product usage may be seen, but individual patient need, and choice where appropriate, must be the driver.

8.4.5. PCRS are not appropriate for medicines in Category M and some medicines in Category A of the Drug Tariff. This is due to the potential wider impact on community pharmacy reimbursement.

8.4.6. The PCRS will not be directly linked to requirements to increase market share or volume of prescribing. It is recognised that an increase in market share may be an indirect consequence of the PCSE. This principle may be waived if the scheme is available as a result of a formal open tender.

8.4.7. A volume based scheme should only be agreed if clinically appropriate. However, the administrative burden of monitoring such a scheme should be carefully considered.

8.4.8. Short term rebate schemes (less than two years) will not normally be considered. It is expected that the reduced price should be available to the CCG over an extended period of time.

8.5. Information and Transparency

8.5.1. The PCRS will not preclude the CCG from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so.

8.5.2. There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.

8.5.3. PCRS will not be entered into that require provision of patient specific data.

8.6. Commercial Sponsorship:

8.6.1. Commercial sponsorship arrangements are set out in the CCG Standards of Business Conduct Policy. Permission must be obtained from the CCG Solicitor in writing in advance, and will be recorded in the Gifts and Hospitality Register which is managed by the Legal Team.

8.7. Freedom of Information (FOI):

8.7.1. The CCG supports the principles of transparency enshrined in the Freedom of Information Act. PCRS often contain confidentiality clauses which may restrict what information may be disclosed under FOI. The CCG will not agree to PCRS which imposes restrictions on how the CCG responds to FOI requests.

8.7.2. The CCG will consider all FOI requests on rebate agreements on their individual merits, taking into account the public interest and whether the release of information will prejudice other parties to the agreements.

8.7.3. The CCG may publish a list of the schemes it participates in on its website. The full terms of the scheme may not be published, depending on the nature of the rebate scheme contract.

8.8. Decision making:

8.8.1. Proposed joint working and rebate schemes will be subject to review and approval by the CCG's Senior Management Team. These will not be considered without completion of either Appendix 1 and/or Appendix 3 as appropriate.

8.8.2. Once agreed, the completed pro forma and rationale for decision for Prescribing Rebates will be approved by the Chief Medical Officer and the Chief Finance Officer.

8.8.3. Once agreed, the completed pro forma and rationale for decision for Joint Working Agreements will be approved by the Senior Responsible Officer and the Chief Finance Officer.

8.8.4. Commercial sponsorship will be subject to approval by the CCG Solicitor. Any commercial sponsorship must be recorded on the gifts and hospitality register once approved.

9. Monitoring/Compliance

9.1. Compliance of this policy will be reviewed by the Senior Management Team.

10. Related Policies

10.1. The following CCG policies are relevant: -

- Standards of Business Conduct Policy
- Prime Financial Policies
- Fraud, Bribery and Corruption Policy

10.2. All CCG policies are published online and can be found at: - https://www.birminghamandsolihullccg.nhs.uk/about-us/publications/policies

11. Relevant Legislation/Guidance

11.1. Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry

11.2. Ethical Framework for Considering Rebate Agreements from Pharmaceutical, Nutrition and Device Companies. Greater Manchester Commissioning Support Unit, 2013.

11.3. Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme. 2012.

11.4. Freedom of Information Act, 2000

11.5. NHS Terms and Conditions of Service, 2018

12. Appendices

12.1. Appendix 1 – Pro forma for assessment of collaborations/joint working

12.2. Appendix 2 – Joint Working Agreement Template

12.3. Appendix 3 – Rebate Scheme Consideration Form

12.4. Appendix 4 – Equality Analysis

NHS
Birmingham and Solihull
Clinical Commissioning Group

Appendix 1: Pro Forma for Assessment of Collaborations

January 2019

Appendix 1 – Pro forma for assessment of collaborations

Section 1 – Pre Collaborative considerations

Negative responses to the following questions may stop the collaboration:

	Yes	No
Are you satisfied with your knowledge of the collaborative organisation i.e. evidence of audited accounts, ownership of organisation etc.?		
Is the proposal align with current evidence based clinical practice?		
Is the proposal consistent with current CCG priorities?		
Will the proposal deliver additional patient benefits/outcomes?		
Will the proposal improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health?		
Is the proposal independent of purchasing or prescribing decisions?		
Is the proposal compliant with the Public Sector Equality Duty?		
Is there a conflict of interest for the CCG in relation to the proposal?		

Section 2 – Partnership Project Summary

Names of the partners and lead representatives of each partner	
Project details: Exact nature; summary of aims & objectives	
Summary of expected outcomes/benefits to the NHS and patients	
Start Date	
End date	
Exit Strategy (termination arrangements)	

Section 3 – Resources and costs

Overall cost of project	

What are the direct and indirect cost commitments by each partner?	
How will the resources/costs be monitored & recorded?	
List valid & relevant information on cost effectiveness	
Has value for money been shown? (give details)	

Section 4 – Governance arrangements

Who was consulted prior to the proposed partnership being put forward for agreement / sign off& how was this done?	
Has an equality analysis been carried out?	
How will patients be informed of this partnership?	
What is the decision making process of the project	
What are the operation & management arrangements for the project	
How does the project relate to existing systems of care in both primary and secondary care sectors?	
Has a project been piloted? How was this done? Are there plans for a pilot? How will this be done?	

Is the sponsorship in line with local/national priorities?	
Does the sponsorship comply with NHS Birmingham and Solihull CCG – Policy for Joint Working with the industry, commercial sponsorship and primary care prescribing rebate schemes policy?	
Who provides indemnity for negligent harm?	
Who has entitlement to intellectual property rights and how will they be managed?	

Section 5 – Monitoring & Evaluation

What is the formal process of management for the process?	
Who has designated responsibility at each stage of the proposal?	
How will the project be evaluated in terms of patient benefits?	
What are the audit arrangements?	

Section 6 – Interests & Data governance

What interests do the company and the NHS have in relation to the partnership proposal – where do those interests coincide?	
Who 'owns' the data generated by the audit and the monitoring of the partnership?	

Who has access to the data and in what form i.e. aggregation and anonymisation criteria?	
What arrangements have been put in place to ensure patient confidentiality?	
How will data be used?	

Medicines/Prescribed
Devices Only:

Signature Medicines Lead
Name
Date

All Proposals:

Signature Finance Lead
Name
Date

Other Proposals:
Signature Commissioning Lead
Name
Date

Once the pro forma is signed as accurate, potential collaborations are to be reviewed and considered by the Programme Review Group who will recommend this pro forma to be approved or declined by the Chief Medical Officer or Senior Responsible Officer, the Chief Finance Officer and a Lay Advisor to rule out any potential conflicts of interest.

Programme Review Group Recommendation - Please circle **APPROVE** **or** **DECLINE**	
Senior Responsible Officer or Chief Medical Officer	**Date:**
Chief Finance Officer	**Date:**

Lay Advisor (to rule out any potential conflicts of interest)	**Date:**

Appendix 2: Joint Working Agreement Template

January 2019

Appendix 2 – Joint Working Agreement Template

AN AGREEMENT FOR
JOINT WORKING
BETWEEN

Birmingham and
Solihull Clinical
Commissioning
Group (BSolCCG)
AND
Insert second party (and any others as necessary)

FOR

Insert title of joint working initiative

This agreement is to set out the principles and values that should underpin the joint working arrangement, as well as the objectives and modus operandi for the *insert title of joint working initiative*.

1. <u>Name and Members of the Joint Working Arrangement</u>

The *insert title of joint working initiative* will be a joint working arrangement between:

- *Birmingham and Solihull Clinical Commissioning Group*
- *Insert second party (list further parties if more than two)*

The working members will be known as the *insert title of joint working initiative* Joint Project Group. The number of Joint Project Group members will be decided to enable decision making to be as effective as possible whilst ensuring inclusiveness. Joint Project Group members will be designated by the parties. No more than *insert number* core Joint Project Group members may be assigned to the joint working arrangement by any party, except by agreement of the parties. Joint Project Group members may be replaced by an individual from their organisation at any time by a party to ensure continuity. Ad hoc membership may be agreed by the parties from time to time.

Insert relevant name/party will provide secretariat and co-ordination support for the *insert title of joint working initiative*, by agreement with the Joint Project Group.

2. <u>Aims and Objectives</u>

Insert a paragraph giving a summary of the aims and objectives of the joint working project.

3. Values

The following values should underpin joint working:

- *Transparency and trust*
- *Appropriateness of projects*
- *Patient focused*
- *Value for money*
- *Reasonable contact*
- *Responsibility*
- *Impartiality and honesty*
- *Truthfulness and fairness*.

4. Principles of Joint Working

The following principles will apply to joint working:

- All joint working must be for the benefit of patients by improving patient outcomes;
- Joint working should improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health;
- Joint working will be conducted in an open and transparent manner;
- Joint working will take place at a corporate, rather than an individual, level;
- Arrangements will be of mutual benefit, the principal beneficiary being the patient;
- Contract negotiations will be negotiated in line with NHS values;
- Confidentiality of information received in the course of the arrangement will be respected and never used outside the scope of the project;
- All patient identifiers will be removed from data to preserve and respect patient confidentiality in line with the Data Protection Act;
- Reports and information pertaining to the agreement / projects will not be used or published without explicit permission given by all parties;
- Joint working must not be used or seen as endorsement or promotion of any specific medicine or product;

- Pharmaceutical companies must comply with the ABPI Code of Practice for the Pharmaceutical Industry at all times;
- All NHS employed staff must comply with NHS, and relevant professional body, Codes of Conduct at all times, and be aware of DH Guidance relating to joint working with the pharmaceutical industry (*Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry, February 2008*).

5. Procedures at Joint Project Group Meetings

- All members should make every effort to be present at Joint Project Group meetings;
- The quorum for meetings will be at least *insert number* member from each party;
- All discussions taking place in meetings will be confidential, unless stated otherwise, and not disclosed to any unauthorised person. In particular no view or opinion expressed will be attributed to any member by name;
- Decisions will be made by consensus of the parties;
- If any members of the joint working project are not present at a Joint Project Group meeting, their views will be requested either prior to or after the meeting;
- In the event of no consensus being achieved, a majority agreement will be accepted based on at least *insert number* Joint Project Group members from each party supporting the decision.

6. Powers of the Joint Project Group

- The Joint Project Group will decide by consensus what projects and plans the parties wish to undertake;
- The Joint Project Group may set up sub-committees or working groups which can include ad hoc members or non-members. The Joint Project Group will ratify recommendations made by sub-committees or working groups;

7. Selection of Consultancies *(if applicable)*

Where any work requires the involvement of a selected external consultancy, this will be selected by the following process:

- Drafting and sign-off of Terms of Reference for the consultancy input required;
- Drafting and sign-off of quantitative and qualitative Evaluation Criteria for potential suppliers;
- Agreement of a List of Suppliers to be invited to tender for the work;
- Issuing of Terms of Reference and Evaluation Criteria to potential suppliers;
- Receipt and evaluation of proposals from suppliers against the Evaluation Criteria;
- Short-listing of potential suppliers;
- Presentations by potential suppliers to the Joint Project Group;
- Final selection of successful supplier(s).

Any selection process will be open and transparent, and if undertaken by an NHS organisation, will comply with the requirements of the relevant Standing Financial Instructions and Standing Orders.

Consultancies will comply with the relevant Codes of Conduct and Practice referred to in 4 above.

8. Finances

- The finance provide by each party will be limited to that agreed. Additional finance may be provided from other sources if agreed by the Parties;
- All monies of the joint working arrangement will be held by *insert partner* and paid against approved invoices;
- The Joint Project Group will monitor finances and record costs incurred.

9. Outputs, Monitoring and Evaluation

The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, together with a mutually agreed exit strategy, will be clearly outlined before commencement of joint working.

The parties will agree arrangements for recording, monitoring and evaluating the joint working arrangement.

10. Data Ownership

- All data generated by the project will be owned *insert*

ownership arrangements by the parties;

- No data will be disclosed to any third party except on the explicit agreement of all parties;
- Patient confidentiality will be maintained at all times.

11. Communication

- All external communication regarding the joint working arrangement and associated projects will be agreed by the Joint Project Group;
- All internal communication will be deemed confidential except by the agreement of the Joint Project Group;
- Minutes will be taken of all Joint Project Group meetings for subsequent agreement at the following meeting.

12. Dissolution

- The joint working arrangement shall be dissolved at any time if any party wishes to withdraw; a notice period will be given of *insert notice arrangements*
- Any outstanding matters must be wound up by all parties by agreement.

13. Change of the Joint Working Agreement

Changes may be made to the Joint Working Agreement by consensus of all parties at a meeting convened for the purpose.

14. Declaration of Interests

All declarations of interest must be declared by any working member. Declarations of interest will be recorded *insert recording arrangements*.

15. Anti-Bribery and Corruption

In performing the Joint Working Project, neither Party shall, and shall procure that any and all of its personnel who are involved in the Joint Working Project (including, without limitation, that Party's members or non-members of the Joint Working Group) and the sub-committees and other working groups engaged in the Joint Working Project shall not, offer to make, make, promise, authorize, or accept any payment or give anything of value, including but not limited to bribes, either directly or indirectly, to any public official, regulatory authority or anyone else for the purpose of influencing, inducing or

rewarding any act, omission or decision which may secure an improper advantage, including to obtain or retain business

- Both Partises shall also comply with all applicable laws and regulations prohibiting offering to make, making, promising, authorizing, or accepting any payment of anything of value, including but not limited to bribes, either directly or indirectly, to any public official, regulatory authority or anyone else for the purpose of influencing, inducing or rewarding any act, omission or decision which may secure an improper advantage, including to obtain or retain business
- Neither Party shall, and shall procure that any and all of its personnel who are involved in the Joint Working Project (including, without limitation, that Party's members or non-members of the Joint Working Group) and the sub-committees and other working groups engaged in the Joint Working Project shall not, make any payment or provide any gift to a third party in connection with the performance of the Joint Working Project without first identifying the intended third party recipient to the Joint Working Group and obtaining the Joint Working Group's prior written approval
- Each Party agrees to participate in, and shall procure that any and all of its personnel who are involved in the Joint Working Project (including, without limitation, that Party's members or non-members of the Joint Working Group) and the sub-committees and other working groups engaged in the Joint Working Project shall participate in, any anti-corruption training reasonably required by the other Party
- The obligations set out in the preceding paragraphs in this Section constitute the "Anti- Corruption Obligations"
- Each Party shall immediately disclose in writing to the other all details of any breach of the Anti-Corruption Obligations by it or any of its personnel (including, without limitation, that Party's members or non-members of the Joint Working Group or other personnel who are involved in the Joint Working Project) or the sub-committees or other working groups engaged in the Joint Working Project
- The Anti-Corruption Obligations shall, for the avoidance of doubt, survive termination or expiry of this Joint Working Agreement
- Termination or suspension by either Party under Section 12

will be without prejudice to any claim that that Party may have against the other or any other person, whether in relation to breach of the Anti-Corruption Obligation, prior breaches of this Agreement or otherwise

- A Party (the "Indemnifying Party") shall indemnify the other (the "Indemnified Party") against all expenses, losses (including loss of profit), damages and legal costs that the Indemnified Party may sustain or incur because of any breach of the Anti-Corruption Obligation by the Indemnifying Party or any of its personnel (including, without limitation, that Party's members or non-members of the Joint Working Group)

I have read the above Joint Working Agreement and commit to the Terms.

Signed: ---------- on behalf of: ----------

Print Name: ---------- Date: ----------

Signed: ---------- on behalf of: ----------

Print Name: Date:

NHS
Birmingham and Solihull
Clinical Commissioning Group

Appendix 3: Rebate Scheme Consideration Form

January 2019

Appendix 3 - Rebate Scheme Consideration Form *Confidential*

Product	
Company	
Contact Details	

Question **(if any greyed out boxes are ticked the scheme may be less suitable for rebate authorisation)**	**Yes**	**No**
Is product listed on CCG/Acute Trust Formulary?		
Is the product is listed on the APC 'Grey List' or 'Black List'?		
Does the product does have a negative decision from NICE?		
Is there a requirement for a directive or guideline to be given to health care professionals to prescribe the specific product?		
If the product is a medicine, is it licensed in the UK?		
Is the company a member of ABPI?		
Is the rebate scheme 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 the product is a vitamin and classed as a food supplement, is it recommended for use in Birmingham and Solihull CCG?		
Does the rebate scheme require exclusive use of a specific brand? See principles re: caveats for specific product categories.		
Is the product contained in Category A or M of the Drug Tariff?		
Isthe rebate scheme is linked directly to a requirement for an increase in market share or volume of prescribing?		
Is the rebate scheme PresQIPP approved?		
Does the rebate scheme prevent consideration of other schemes?		
Is There is a requirement to submit additional information beyond the volume of prescribing of the product?		
Is There is a requirement to collect patient specific data?		
Is the scheme available for two years or more?		
Does the scheme place any unacceptable obligations on the CCG?		
Does the schemes require the CCG to collect or submit to the manufacturer any data other than volume of use as derived from ePACTdata?		
Does the scheme require the provision of patient specific data		
Does the scheme restrict how FOI requests are managed by the CCG?		
Are there clear arrangements for the CCG to exit the arrangement without penalty?		
Are there are any penalty clauses for the CCG?		
Could the arrangements be considered anticompetitive? Consider whether the arrangements could be considered to affect a bundle or portfolio of products.		

Does the arrangement seek to limit the CCGs freedom in any way?		
Does the arrangement seek to limit communication with any stakeholders? The CCG must be able to share information with the DH, NHSBSA and NHS England including the discount and terms of the arrangement.		

Clinical suitability/effectiveness:
Estimated potential savings
Have any other contractual or legal issues been identified during the evaluation? (outlined below)
Further information
Outline: • *Estimated administrative burden* • *Any legal or contractual issues uncovered* • *Governance issues* • *Freedom of Information issues* • *Any other pertinent issues*
Recommendation
Rationale
Evaluation

Signature Medicines Lead
Name
Date

Signature Finance
Lead Name
Date

Once the Proforma is signed as accurate, potential collaborations are to be reviewed and considered by the Senior Management Team who will recommend approval or otherwise to the Chief Medical Officer and the Chief Finance Officer.

Senior Management Team Recommendation - Please circle **APPROVED** **or** **DECLINED**	
Chief Medical Officer	**Date:**
Chief Finance Officer	**Date:**
Lay Advisor (if there is any potential conflict of interest)	**Date:**

Birmingham and Solihull
Clinical Commissioning Group

Appendix 4

Equality Analysis

(Health Inequalities, Human Rights, Social Value)

Policy for Joint Working with the Pharmaceutical Industry, Commercial Sponsorship and Primary Care Prescribing Rebate Schemes

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

1. Background

EA Title	Policy for Joint Working with the Pharmaceutical Industry, Commercial Sponsorship and Primary Care Prescribing Rebate Schemes		
EA Author	Balvinder Everitt – Senior Manager Equality Diversity Inclusion	**Team**	Nursing
Date Started	10 January 2019	**Date Completed**	10 January 2019
EA Version	V.1	**Reviewed by E&D**	

What are the intended outcomes of this work? Include outline of objectives and function aims

The Department of Health encourages NHS organisations to consider opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to patient health are advantageous.

This policy is to be used by staff employed by Birmingham and Solihull Clinical Commissioning Group (the CCG) who are considering sponsorship, joint working and training arrangements with the pharmaceutical industry or other organisations potentially supplying the NHS with clinical support (including third party commercial organisations).

The Policy has clear statements of commitment and core values for promoting access and recognising diversity and ensuring patient interest is at the centre of all decisions. The Policy ensures due regard to the Public Sector Equality Duty by ensuring its partners comply with the duty through the partnership.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

Patients
Providers
Staff

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
Policy for Joint Working with Pharmaceuticals, Commercial Sponsorship, and Primary Care Prescribing Rebate Schemes		Medicines Management

3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

The policy is applicable across the BSOL footprint.

All patients regardless of age will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for age.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

The policy is applicable across the BSOL footprint.

All patients regardless of disability (including mental health and learning difficulty) will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for disability.

Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:

The policy is applicable across the BSOL footprint.

All patients regardless of gender identity will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for gender identity.

Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

3. Impact and Evidence:

The policy is applicable across the BSOL footprint.

All patients regardless of marital or civil partnership status will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for marriage and civil partnership.

Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

The policy is applicable across the BSOL footprint.

All patients regardless of pregnancy and maternity will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for pregnancy and maternity.

Race: Describe race related impact and evidence**.** This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

The policy is applicable across the BSOL footprint.

All patients regardless of race, cultural, ethnic, or national background will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for race.

Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

The policy is applicable across the BSOL footprint.

All patients regardless of religion or belief will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for religion or belief.

3. Impact and Evidence:

Sex: Describe any impact and evidence on men and women. This could include access to services and employment:

The policy is applicable across the BSOL footprint.

All patients regardless of sex will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for sex.

Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

The policy is applicable across the BSOL footprint.

All patients regardless of sexual orientation will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for sexual orientation.

Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

The policy is applicable across the BSOL footprint.

All patients regardless of carer status will benefit from the policy. The criteria for seeking out opportunities for either joint working or rebate will be objectively considered with clear benefits to patients.

There are no known adverse impacts for carers.

Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

There are no known adverse impacts for other disadvantaged groups or communities.

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	No	The policy aims to establish minimal standards for partnership working improving access, quality, and value of pharmaceuticals to all patients groups across the BSOL footprint
Is there any impact for groups or communities living in particular geographical areas?	No	The policy applies to all patients across BSOL
Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	No	The policy applies to all patients across BSOL

How will you ensure the proposals reduce health inequalities?

The policy will work to ensure the application of joint working and partnership arrangements offer benefits and access to all patients across the BSOL footprint.

The policy will also allow for variation where there is an identified need and there is an objective case for a joint working arrangement / rebate for pharmaceuticals that would positively impact on a protected group or community E.g. transgender, pregnant women, mental illness etc.

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	The policy incorporates an equality statement and commitments to ensure fair access.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	The policy is aimed at benefiting patients.
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	The policy incorporates an equality statement and commitments to ensure fair access.
	How will this affect a person's right to freedom of	No impacts

	thought, conscience and religion?	
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	The policy incorporates an equality statement and commitments to ensure fair access.
Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	No impacts
Right to **Life**	Will or could it affect someone's right to life? How?	No impacts
Right to **Liberty**	Will or could someone be deprived of their liberty? How?	No impacts

6. Social Value

Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.

Marmot Policy Objective	**What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?**
Enable all people to have control over their lives and maximise their capabilities	The Policy does consider the potential for promoting social value within section 8.1.5 joint working arrangements and within Appendix 1 and 2. Appendix 3 prescribing rebates is a financial proposal only and this is not applicable.
Create fair employment and good work for all	
Create and develop health and sustainable places and communities	
Strengthen the role and impact of ill-health prevention	

7. Engagement, Involvement and Consultation

If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:

Engagement Activity	**Protected Characteristic/ Group/ Community**	**Date**

For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us …. So we will …..):

No engagement with protected groups and communities has been identified as necessary due to no adverse impacts identified.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The policy has overall positive benefits for patients. No adverse impacts for protected or vulnerable groups have been identified.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Changes recommended actioned within the policy.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

Compliance of this policy will be reviewed by the Audit Committee

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):

N/A

12. Publication

How will you share the findings of the Equality Analysis?

This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis

should be recommended for publication unless they are deemed to contain sensitive information.
The EA will be published on the CCG web pages.
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off

The Equality Analysis will need to go through a process of **quality assurance** by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee

	Name	Date
Quality Assured By:	Balvinder Everitt – Senior Manager Equality Diversity Inclusion	18 January 2019
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net