Joint Working with the Pharmaceutical Industry

(Template based upon DH Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry, February 2008)

<table>
<thead>
<tr>
<th>Document Type: Corporate Policy</th>
<th>Status: Draft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version No: 1.0</td>
<td>Date of issue: Dec 2013</td>
</tr>
<tr>
<td>Author: Finlay Royle/Vanessa Burgess</td>
<td>Review date:</td>
</tr>
<tr>
<td>Director: Tamsin Hooton, Director of Service Redesign</td>
<td>Pages: 40</td>
</tr>
</tbody>
</table>
## Document control

<table>
<thead>
<tr>
<th>Version</th>
<th>Issue Date</th>
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</tr>
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<tbody>
<tr>
<td>1.3</td>
<td>Nov 2013</td>
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<td>Nov 2015</td>
<td></td>
<td>NHS Southwark CCG Medicines Management Team Email: <a href="mailto:souccg.medicines-management@nhs.net">souccg.medicines-management@nhs.net</a> Phone: 0207 525 3253</td>
</tr>
</tbody>
</table>

### Initial approval by & date

Dr Dianne Aitken Joint Chair NHS Lambeth CCG and NHS Southwark CCG Joint Prescribing Committee. 17.10.12
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1. Introduction

The Department of Health guidance, ‘Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry’,\(^1\) encourages NHS organisations and their staff 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 their health and well-being are clearly advantageous.

As described in the guidance, Joint Working is defined as: “Situations 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. Joint working agreements and management arrangements are conducted in an open and transparent manner.”

An example of such joint working is the ‘Rebate’ scheme offered by some pharmaceutical companies as follows:

NHS Acute Trusts are responsible for procuring their own drugs and negotiate prices directly with suppliers. In primary care, GPs and CCGs cannot do this, as the drug supply mechanism is very different, with pricing based on the Drug Tariff, where reimbursement prices for community pharmacists are set by the Department of Health. In such cases, some pharmaceutical companies offer a ‘rebate’ scheme which is a percentage rebate on the Tariff/list price for a given drug which is paid directly to the CCG.

1.1 Statement and aim

The aim of this policy is to:

- assist NHS Southwark Clinical Commissioning Group (CCG) achieve its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry
- inform and advise staff of their main responsibilities when entering into joint working arrangements with the pharmaceutical industry

Specifically it aims to:

- assist NHS employers and staff in maintaining appropriate ethical standards in the conduct of NHS business
- highlight that NHS staff are accountable for achieving the best possible health care within the resources available.

1.2 Objectives

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\(^1\) DH Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry, February 2008
The main objectives are to:

- provide all CCG employees a policy framework and guidance for independent contractors for communication with members of the pharmaceutical industry in an appropriate manner.
- make all employees and contractors aware of the limitations of the sponsorship they are at liberty to accept from the pharmaceutical industry.
- introduce mechanisms to recognise potential conflicts of interest
- ensure that all employees and independent contractors approached by the pharmaceutical industry respond in a consistent manner
- ensure the interests of patients, the public and the CCG are maintained
- ensure that any sponsorship accepted from the industry is declared publicly to ensure transparency
- ensure that clinical and financial decisions taken by NHS employees and independent contractors do not rely solely on the advice and interventions of the industry representatives

Staff are reminded that at all times they have a responsibility to comply with their own professional codes of conduct, and that representatives of the pharmaceutical industry must comply with the Association of British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry

2. Scope of document

This document is intended as policy for NHS Southwark Clinical Commissioning Group and its staff who are involved in working with the pharmaceutical industry. This will include joint working with the pharmaceutical industry as well as hospitality and sponsorship received from the pharmaceutical industry. For the purposes of this policy:

The term "staff" refers to all healthcare staff employed by NHS Southwark Clinical Commissioning Group and board members in their capacity as board members and as independent contractors, all other healthcare professionals including contractors and locum practitioners working under NHS terms and conditions.

Sponsorship is defined as situations where pharmaceutical companies simply provide funds for a specific event or work programme.
3. **Roles and responsibilities**

It is the responsibility of each individual employee to follow the policy framework when accepting any commercial support. They must also refer to their line-manager for approval.

It is the responsibility of line-managers to ensure that employees are fully aware of this policy. They are responsible for checking that requests from all employees to form collaborations with the pharmaceutical industry are thoroughly examined. They must ensure that the work is beneficial to the organisation, that there is no conflict of interest and the framework is adhered to.

It is the responsibility of the Head of Medicines Management to resolve any contentious issues and have the final say in determining the appropriateness of any collaboration with the industry.

The CCG will maintain a register of gifts, hospitality and sponsorship on the CCG website.

The NHS parties should be accountable for any agreement and be in a position to evaluate and monitor these agreements. No organisation should be given preferential treatment and individuals must be accountable for their reason for forming relationships with industry members.

Final consideration and approval for any joint working arrangements will be sought from the NHS Southwark Clinical Commissioning Group Integrated Governance and Performance Committee.

4. **Principles and values of joint working**

4.1. **Values**

The seven principles of public life set out by the Nolan Committee underpin the work of the NHS:

- Selflessness
- Integrity
- Objectivity
- Accountability
- Openness
- Honesty
- Leadership

Where staff enter into any joint working arrangement with the pharmaceutical industry, their conduct should also adhere to the following values:

- transparency and trust
• appropriateness of projects
• patient focused
• value for money
• reasonable contact
• responsibility
• impartiality and honesty
• truthfulness and fairness

4.2 Principles of Joint Working

Joint working must be for the benefit of patients or of the NHS and preserve patient care. Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner.

Arrangements should be of mutual benefit, the principal beneficiary being the patient. The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working.

The following principles will also apply to joint working:
• staff should be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct as described in existing NHS guidance
• contract negotiations will be negotiated in line with NHS values
• confidentiality of information received in the course of duty must be respected and never used outside the scope of the specific project
• joint working arrangements should take place at corporate, rather than at an individual level
• clinical and financial outcomes will be assessed through a process of risk assessment

NHS Southwark Clinical Commissioning Group shall implement a mechanism for recording and monitoring, and evaluating each joint working arrangement.

A mutually agreed and effective exit strategy will be in place at the outset of any joint working arrangement detailing the responsibilities of each party and capable of dealing with a situation where premature termination may become necessary. Any other risks or governance issues (clinical or business) need to be considered at the planning stage for any joint working to remove or minimise risk to the CCG or patients.
4.3 Principles of sponsorship and hospitality that are covered by this guidance

Sponsorship to the NHS in the form of cash, goods, services or other benefits include but are not restricted to the following:

- funding for all or part of the costs of a member of staff
- funding to support NHS research being carried out by NHS employees or independent contractors in Southwark
- sponsorship of any staff or patient training event that is undertaken or organised by NHS staff or contractors
- equipment being donated by an independent organisation in order to support the NHS or independent contractors

Hospitality should generally not be accepted and can only be provided to health professionals and managers as part of scientific or promotional meetings. Hospitality must be secondary to the meeting and of an appropriate standard i.e. not more lavish or deluxe than employees would usually have themselves e.g. sandwiches at lunch. Hospitality may include:

- meals
- meetings
- hotel and transport costs (including overseas travel) NB only economy air travel can be provided for delegates
- Samples of medicines should not be accepted under any circumstance by a health professional.
- Gifts from independent organisations to NHS Southwark Clinical Commissioning Group employees or independent contractors
- Donations to the cost of buildings or premises.

4.4 Exceptions to sponsorship covered by this guidance

Gifts of the value of £10 or under per gift are acceptable as long as they are relevant to the person's profession (e.g. pens, post-it notes, pill counting triangles). The gifts must be declared using the form in Appendix 4, in the register of gifts, hospitality and sponsorship if the total value is greater than £10 over a 12-month period.

Gifts for GPs from their patients: regulations concerning the acceptance by GPs of gifts from patients came into force in March 2004. The National Health Service (General Medical Service Contracts) Regulations 2004, statutory instrument 291, specify that a register should be kept of gifts from patients or their relatives which have a value of £10 or more unless the gift is unconnected to the provision of services.

Income generation schemes will be logged separately at a local level.
Discounts on particular pharmaceuticals, for example, where a community pharmacist or hospital pharmacy received a discount for buying a specified amount of a particular drug.

4.5 Confidentiality and Data Protection

Patient confidentiality must always be protected under the terms of the Data Protection Act. Patient consent must be obtained to disclose any information to another organisation. Disclosures should also be in line with the NHS South East London information sharing protocol.

All employees are responsible for maintaining the confidentiality of information gained during their employment with NHS Southwark Clinical Commissioning Group. The NHS Code of Confidentiality and NHS Southwark CCG constitution should be read and understood prior to any contract of employment or other confidentiality agreement being signed.

4.6 Declaring Conflicts of interest

Individuals involved in the development or consideration of any proposal must declare any potential conflict of interest they, or their immediate family, may have at the beginning of the process, using the form in Appendix 3. Examples could include:

- shareholding or directorship in a company
- speaking at industry sponsored events
- research or educational grant
- consultancy work

NHS employees are advised not to engage in outside employment which may conflict with their NHS work, or be detrimental to it. They are advised to tell their NHS employing authority if they think they may be risking a conflict of interest in this area: the NHS employer will be responsible for judging whether the interests of patients could be harmed, in line with the principles outlined.

Please refer to the NHS Southwark CCG Conflict of Interest Policy available on the staff intranet as well as the CCG website.

4.7 Payments

If any outside work for the pharmaceutical industry is carried out in NHS time i.e. during the normal working day, without the member of staff taking annual leave, any fee should either be refused, or if accepted, be
paid to a budget agreed with the line manager in advance of undertaking the activity.

A fee can be accepted for work carried out in the staff member’s own time.

4.8. Bribery legislation

The Bribery Act 2010 ("the Act") imposes extensive obligations on all commercial organisations, including those in the healthcare sector, to ensure that they have adequate procedures in place to prevent bribery from occurring within their organisation.

A bribe is an inducement or reward of a financial or other advantage that is offered, promised or provided to a person in order to gain any commercial, contractual, regulatory or personal advantage through the improper performance of a relevant function or activity as a result of the bribe.

- ‘Financial or other advantage’, - payments, gifts, hospitality or anything else that could be reasonably perceived as an “advantage” as understood by its normal, everyday meaning.
- “Improper performance” means performance in breach of an expectation that a person will act in good faith, impartially, or in accordance with a position of trust.
- A “relevant function or activity” means any function of a public nature, connected with a business, performed in the course of a person’s employment or performed by or on behalf of an incorporated or unincorporated body of persons.

All allegations or suspicions of bribery, fraud or corruption must be reported to the local Counter Fraud Specialist. Further information and guidance can be found in the NHS Southwark CCG Counter Fraud and Corruption Policy.

5. Audit and monitoring criteria

<table>
<thead>
<tr>
<th>Monitoring requirements</th>
<th>Monitoring requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>What in this document do we have to monitor</em> ( e.g. processes)</td>
<td>a ) The number of requests to joint working and their outcome</td>
</tr>
<tr>
<td></td>
<td>b) Monitor the source of the application (employee) and the sponsorship (commercial organisation) to ensure that the process is equitable to all concerned</td>
</tr>
<tr>
<td>Note specifically any monitoring needed to assure equality and equity of delivery</td>
<td></td>
</tr>
</tbody>
</table>

10
Monitoring Method:
(e.g. statistics, report)
a) Report

Monitoring prepared by :-
(name job titles)
a) Senior Prescribing Advisor, NHS Southwark CCG

Monitoring presented to:-
(e.g. Committees)
a) Joint Prescribing Committee

Frequency of presentation:-
(e.g. annually, six-monthly etc)
a) Annually

6. Statement of evidence/references


3. ABPI Code of Practice which can be found at:

4. ‘Standards of business conduct for NHS staff, and Commercial Sponsorship – Ethical Standards for the NHS (2000),
   www.kch.nhs.uk/EasysiteWeb/getresource.axd?AssetID=793&type=Full&servicetype=Attachment

5. ‘Moving beyond sponsorship : joint working between the NHS and the pharmaceutical industry’

6. NHS SE London Information sharing
   http://www.selondon.nhs.uk/your_resources/information_governance/information_sharing

7. Department of health confidentiality policy

7. Implementation and dissemination of document

Once this policy has been approved by NHS Lambeth CCG and NHS Southwark CCG Joint Prescribing Committee and the NHS Southwark CCG Integrated Governance and Performance committee it will be added to the intranet. Information will be included in the Southwark weekly
newsletter which is distributed to all practices. It will also be sent to all Southwark community pharmacists.

8. Associated Documents

NHS Southwark Clinical Commissioning Group Constitution
NHS Southwark Clinical Commissioning Group Counter fraud and corruption policy (2010)
NHS Southwark Clinical Commissioning Group Conflict of Interest Policy (2013)
Appendix 1 - Equality & Equity Impact Assessment Checklist

This is a checklist to ensure relevant equality and equity aspects of proposals, policy or guidance have been addressed either in the main body of the document or in a separate equality & equity impact assessment (EEIA)/ equality analysis. It is not a substitute for EEIA/ equality analysis which is normally required unless it can be shown that a proposal has no capacity to influence equality. The checklist is to enable the policy lead and the relevant committee to see whether the EEIA has covered the ground and to give assurance that the proposals will not only be legal but also fair and equitable and lead to reduced health inequality.

<table>
<thead>
<tr>
<th>Challenge questions</th>
<th>Yes/No/DK/NA</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the document set out the <strong>health care needs</strong> of the groups intended to</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>benefit from the proposal, including any differences in need in terms of the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>legally protected or other characteristics (such as socioeconomic position)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Does the document set out any known existing inequality in <strong>access</strong>, <strong>quality</strong>,</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td><strong>experience</strong> and <strong>outcome of care</strong> for populations relevant to the proposal (ie</td>
<td></td>
<td></td>
</tr>
<tr>
<td>as defined in 1. and in relation to the existing health or care service)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Are there any particular <strong>public concerns</strong> about equality about the policy</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>area than need to be addressed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Has the policy described any <strong>gaps in knowledge</strong> about 1 -3, and any action</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>taken to fill gaps (or recommendations for action)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Does the document set out <strong>risks to equity</strong> of access, quality, experience and</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>outcomes including <strong>risk of direct or indirect discrimination</strong>, and risk to **</td>
<td></td>
<td></td>
</tr>
<tr>
<td>good relations** between people of different groups?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Does the document describe any specific <strong>opportunities to promote equality and</strong></td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td><strong>human rights</strong>, good relations between people of different groups, to enhance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>participation, etc?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Does the document describe how the proposal, policy etc will <strong>address</strong> the</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>identified inequalities</strong>, and</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Does the document make recommendations to **mitigate risks** and **enhance the opportunities to promote** equality and equity?

Does the document describe how **monitoring and reporting** will take place to assure equality and equity in the future including to stakeholders. [audit and monitoring table may be used]

* Race/ethnicity, gender (including gender reassignment) age, religion or belief, disability, sexual orientation, marriage or civil partnership, pregnancy and maternity. This will include groups such as refugees and asylum seekers, new migrants, Gypsy and Traveller communities; and people with long term conditions, hearing or visual impairments, mental health problems or learning disability.
## Appendix 2 - Policy Consultation History

<table>
<thead>
<tr>
<th>Stakeholders Name</th>
<th>Area of expertise</th>
<th>Date sent</th>
<th>Date received</th>
<th>Comments</th>
<th>Changes made</th>
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<tr>
<td>Vanessa Burgess Head of Medicines Management</td>
<td>Medicines management</td>
<td>18.07.2012</td>
<td>23.07.2012</td>
<td>To amend in light of the new Lambeth CCG Standards of Business conduct</td>
<td>Incorporated the details from NHS Lambeth CCG standards of business conduct</td>
</tr>
<tr>
<td>Joint Prescribing Committee</td>
<td>Medicines Management</td>
<td>12.09.2012</td>
<td>01.10.2012</td>
<td></td>
<td>Corrected typos</td>
</tr>
<tr>
<td>Finlay Royle Senior Primary Care Pharmacist</td>
<td>Medicines Management</td>
<td>01.06.2013</td>
<td>01.06.2013</td>
<td>Updated to reflect NHS Southwark CCG policies and standards</td>
<td>Details incorporated</td>
</tr>
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</table>
Appendix 3 - Declaration of Interests Form

This form is required to be completed in accordance with the NHS Southwark CCG’s Constitution.

Notes:

- Within 28 days of a relevant event, NHS Southwark CCG Governing Body and its Sub Committees and Directors need to register their financial and other interests.
- If any assistance is required in order to complete this form, then the member or employee should contact the Chief Officer.
- The completed form should be sent by both email and signed hard copy to the Chief Officer.
- Any changes to interest declared must also be registered within 28 days of the relevant event by completing and submitting a new declaration form.
- Declarations of interest made by members of the CCG Governing Body will be published on the Southwark CCG website www.southwarkhealth.nhs.uk.
- The Register of Declarations of Interest will be reported to each meeting of the NHS Southwark CCG Audit Committee.
- Members and employees completing this declaration form must provide sufficient detail of each interest so that a member of the public would be able to understand clearly the sort of financial or other interest the member or employee has and the circumstances in which a conflict of interest with the business or running of the CCG might arise.
- If in doubt as to whether a conflict of interest could arise, a declaration of the interest should be made.

Interests that must be declared:

- Roles and responsibilities held within member practices
- Directorships, including non-executive directorships held in private companies or public limited companies (with the exception of those of dormant companies)
- Ownership or part ownership of companies, businesses or consultancies which may seek to do business with the CCG
- Shareholdings (more than 5%) of companies in the field of health and social care;
- Membership of or a position of authority or trust in an organisation (eg. charity or voluntary organisation) in the field of health and social care;
- Any connection with a voluntary or other organisation contracting for NHS services
- Research funding/grants that may be received by the individual or any organisation they have an interest or role in
- Interests in pooled funds that are under separate management (any relevant company included in this fund that has a potential relationship with the CCG must be declared)
- Formal interest with a position of influence in a political party or organisation
• Current contracts with the CCG in which the individual has a beneficial interest
• Any other employment, business involvement or relationship or those of a spouse or partner that conflicts, or may potentially conflict with the interests of the CCG.
• Any other role or relationship which the public could perceive would impair or otherwise influence the individual’s judgement or actions in their role within the CCG. Whether such interests are those of the individual themselves or of a family member or close friend of the individual.
• Other specific interests
Annex a – Declaration Form for Member / employee / governing body member / committee or sub-committee member

Guidance Notes:

This form is required to be completed in accordance with NHS Southwark CCG’s Constitution and Section 14O of The National Health Service Act 2006.

Notes:

- A declaration must be made of any interest likely to lead to a conflict or potential conflict as soon as the individual becomes aware of it, and within 28 days.

- If any assistance is required in order to complete this form, then the individual should contact Sheetal Mukkamala, Corporate Governance Manager.
  email: sheetal.mukkamala@nhs.net

- The completed hard copy of the form should be handed over/posted to:
  Sheetal Mukkamala,
  Corporate Governance Manager,
  NHS Southwark CCG,
  1st Floor, Hub 5, PO Box 64529
  London SE1P 5LX

- If sending by email, then a scanned signature will suffice.

- Any changes to interests declared must also be registered within 28 days by completing and submitting a new declaration form.

- The register will be published in the Annual Report as well as every month after the Governing Body meeting on the CCG public website. It will also be available to public on request and during each Governing Body meeting.

- Any individual – and in particular members and employees of NHS Southwark CCG - must provide sufficient detail of the interest, and the potential for conflict with the interests of the CCG and the public for whom they commission services, to enable a lay person to understand the implications and why the interest needs to be registered.

- If there is any doubt as to whether or not a conflict of interests could arise, a declaration of the interest must be made.

- Individuals are advised to review the completed example before completing their own declaration to ensure they correctly understand the information required.
A declaration must be made whether such interests are those of the individual, a family member, any other close relationship of the individual. Interests that must be declared include but are not limited to:

1. Roles and responsibilities held within member practices;

2. Directorships, including non-executive directorships, held in private companies or PLCs;

3. Ownership or part-ownership of private companies, businesses or consultancies likely or possibly seeking to do business with the CCG;

4. Shareholdings (more than 5%) of companies in the field of health and social care;

5. Positions of authority in an organisation (e.g. charity or voluntary organisation) in the field of health and social care;

6. Any connection with a voluntary or other organisation contracting for NHS Services;

7. Research/funding grants that may be received by the individual or any organisation they have an interest or role in;

8. Any other role or relationship which would impair or otherwise influence the individual’s judgement or actions in their role within the CCG.

An example of completed form is available with the Corporate Governance team.
| Name: |  |
| Position within or relationship with CCG |  |

### Interests

<table>
<thead>
<tr>
<th>Type of Interest</th>
<th>Details</th>
<th>Interests of relatives/ close relationship that you know of, likely or seeking to do business with the CCG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roles and responsibilities held within member practices</td>
<td>Materiality&lt;sup&gt;9&lt;/sup&gt; =</td>
<td>Materiality =</td>
</tr>
<tr>
<td>Directorships, including non-executive directorships, held in private companies or PLCs</td>
<td>Materiality =</td>
<td>Materiality =</td>
</tr>
<tr>
<td>Ownership or part-ownership of private companies, businesses or consultancies likely or possibly seeking to do business with the</td>
<td>Materiality =</td>
<td>Materiality =</td>
</tr>
<tr>
<td>Shareholdings (more than 5%) of companies in the field of health and social care</td>
<td>Materiality =</td>
<td>Materiality =</td>
</tr>
<tr>
<td>Positions of authority in an organisation (e.g. charity or voluntary organisation) in the field of health and social care</td>
<td>Materiality =</td>
<td>Materiality =</td>
</tr>
</tbody>
</table>

<sup>9</sup> Materiality (relevance or significance) of share/ ownership to be expressed as percentage. Value is not required.
Any connection with a voluntary or other organisation contracting for NHS services

| Materiality= | Materiality = |

Research funding/grants that may be received by the individual or any organisation they have an interest or role in

Other specific interests – e.g. users of health services commissioned by the CCG.

Any other role or relationship which would impair or otherwise influence the individual’s judgement or actions in their role within the CCG

To the best of my knowledge and belief, the above information is complete and correct. I have read the Conflict of Interest policy for the CCG and undertake to update as necessary the information provided and to review the accuracy of the information provided regularly and no longer than annually. I give my consent for the information to be used for the purposes described in the NHS Southwark CCG Constitution and published accordingly.

Signed: (please sign not print)

Dated:  

21
Appendix 4 - Declaration of Gifts and Hospitality Form

Under certain circumstances (see Section 9) the policy requires the declaration of gifts and hospitality offered to employees, members and member practices whether accepted or not.

It is the responsibility of all individuals to make any necessary declaration by completing this document, and submitting it to Corporate Governance Manager, NHS Southwark CCG, for inclusion in the register of gifts and hospitality that is maintained.

<table>
<thead>
<tr>
<th>Name</th>
</tr>
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<table>
<thead>
<tr>
<th>Job title/ Position in the CCG</th>
</tr>
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<table>
<thead>
<tr>
<th>Department or Practice</th>
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<table>
<thead>
<tr>
<th>Details of what has been offered, by whom.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Was the gift or hospitality accepted or refused?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date</th>
</tr>
</thead>
</table>

MANAGER REVIEW : Please delete as appropriate

I have reviewed the gift/hospitality*/sponsorship recorded above. I consider the action taken to be reasonable/ I have taken the following action with regard to the matter:
CHIEF FINANCIAL OFFICER REVIEW

I have reviewed the gift/hospitality* recorded above. I consider the action taken to be reasonable/ I have taken the following action with regard to the matter

Signed:..........................................................Date..........................

Guidance notes:

1. In accordance with its Conflict of Interest Policy, NHS Southwark CCG requires that declaration of gifts and hospitality offered to employees, members of Governing Body and member practices be made, stating whether accepted or not.

2. It is the responsibility of all individuals to make any necessary declaration by completing this document, and submitting it to Sheetal Mukkamala, Corporate Governance Manager, NHS Southwark CCG (email: sheetal.mukkamala@nhs.net), for inclusion in the register of gifts and hospitality.

3. Declarations of any gift or hospitality offered over £10 or equivalent should be recorded by submitting a completed declaration form.

4. One-off gift of low intrinsic value (less than £10 per item) such as pens, diaries, calendars and mouse mats need not be refused and do not need to be declared. However, if several such gifts are received from the same or related source such that their total value over any 12-month period exceeds £10, they should be declared.

5. This declaration will form part of the CCG Hospitality and Gifts Register which will be made publicly available.
Appendix 5 - Approval of Joint Working Arrangements

Collaborative working
CCG seeks, or pharmaceutical industry offers, collaborative working in relation to specific project/therapeutic area.

Complete joint working application form (see appendix 6) for submission to line manager.

Initial screening (appendix 6)
Chief Pharmacist reviews basic proposal and agrees/disagrees course of action. Signposting to suitable contact points within the CCG if applicable.

Proposal development

Approved

Not Approved

CCG approval process
Complete full proposal business case (appendix 7)

NHS Southwark CCG board level decision
Sanction final outcome

If approved, complete framework for joint working (appendix 8) and sponsoring organisation must sign the joint working agreement form (appendix 9)

Log in register of commercial sponsorship
Procedure and framework for the approval of joint working projects between NHS Southwark Clinical Commissioning Group and the Pharmaceutical Industry.

1. Identify potential collaborative work
   Any collaboration with the pharmaceutical industry must be transparent and defensible with agreed aims and objectives.

2. Complete joint working proposal (appendix 6, available on CCG internet or from medicines management team).
   It is the responsibility of each individual employee to follow the policy framework when accepting any commercial support. CCG staff must gain permission from their line manager and the Head of Medicines Management before undertaking any joint projects with the pharmaceutical industry.

3. Line manager and the Head of Medicines Management assess appropriateness of application
   The line manager must be satisfied that approval of the joint working project will not compromise trust decisions by using the checklist in appendix 6. They must ensure that the work is beneficial to the organisation, that there is no conflict of interests and that the framework is adhered to. They must refer to the Southwark medicines management team if they feel unable to judge the suitability of the proposal. In order to ensure congruence with the strategic aims of the CCG’s prescribing agenda, each project will require approval by the Head of Medicines Management. It is their responsibility to resolve any contentious issues and have the final say in determining the appropriateness of any collaboration with the industry.

4. Submission of full business case
   If the joint working proposal is approved then the applicant must submit a business case (appendix 7) to NHS Southwark CCG Integrated Governance and Performance Committee for approval. The decision should be recorded by the medicines management team and forwarded to the Chief Officer on an annual basis.

   Each project will require relevant documentation in place which includes a:
   - Business case for project with the pharmaceutical industry (appendix 7)
   - Framework for joint working (appendix 8)
   - Joint working agreements (appendix 9)

   This does not apply to procurement. One particular concern is the impact of commercial sponsorship on prescribing. This will need to be assessed against certain criteria e.g.

   - **Affordability**: an increase in prescribing in one area may deprive funding and resources for other areas of healthcare.
   - **Current evidence-based guidelines**: e.g. NICE, NSF’s, South London cardiac and stroke network guidelines, local formularies.
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- **Healthcare priorities**: does this fit with nationally and locally agreed healthcare priorities.
Appendix 6 - Joint working proposal form

Name of applicant…………………………………………………………………………………

Position/ directorate……………………………………………………………………………

Name of sponsoring organisation…………………………………………………………...

Sponsor contact name……………………………………….. Date…………

Please summarise the joint work proposal?

What is the proposed contribution by the sponsoring organisation?
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1. Is the joint working proposal consistent with the guidance given in the NHS Southwark Clinical Commissioning Group Guidance for working with the pharmaceutical organisation and commercial organisations? Y / N*

2. Is the proposed involvement of the sponsoring organisation of an appropriate level for the purpose? Y / N*

3. Is the CCG satisfied with its knowledge of the sponsoring organisation, e.g. is it known to the CCG? Is there evidence of audited accounts? Is it capable of being independently audited? Y / N*

4. Is the CCG satisfied that the offer is independent of purchasing or prescribing decisions? Y / N*

5. Can it be confirmed that there is no current conflict of interest for any parties in relation to the service offered? Y / N*

6. Are you satisfied that all materials and information supplies are valid, evidence-based, balanced and non-promotional? Y / N*

7. Have you reached an agreement with all members of your team involved that the service is appropriate? Y / N*

8. If patients are involved have arrangements been made to ensure the patients are aware of the service where appropriate? Y / N / Not applicable*

N.B. If the answer is no to any of the above questions the proposed sponsorship is likely to be unsuitable and should be reviewed before submission.

Once complete please pass this to your line manager and the Head of Medicines Management for approval.

Signature of approval…………………………………………… Date……………………

Name and position………………………………………………………………………………

Signature of Head of Medicines Management………………………………………………

Name of Head of Medicines Management………………………………………………..

* delete as appropriate
Appendix 7 - Business Case Template and Guidance

1. Purpose

This guidance is intended to provide practical support to those involved in developing or writing business cases. This includes practice-based commissioners and CCG staff. It includes a template which should be used as a guide to the key sections which should be included in any business case. The template is included as Appendix 1 to this guidance, along with guidance notes on completion.

Business Cases should be submitted using this template where there is a proposal that the CCG should commission a new service, or make a new investment in a service or resource. Applications for “Any Willing Provider” status are dealt with through a separate process. The concept of “Any Willing Provider” to supply elective services delivers a procurement route to encourage competition within a range of services and not for them. The CCG can approve a number of willing providers for the same service as long as they meet all required criteria and quality standards.

The business case template asks for information covering:

- how the business case fits with the local strategic direction for improving services
- the measurable outcomes to be achieved
- how the proposal represents value for money
- the cost of the development including any set up costs
- whether the initiative will release resources or efficiencies
- feedback from key stakeholders
- evidence of effectiveness
- risk management
- how the business case will address health inequalities
- details of planned implementation, including any supporting infrastructure required

2. Business Case Process

Business Cases should be submitted to the QIPP Delivery Group for consideration in the first instance. A template for assessing Business Cases is used, which scores proposals against a number of criteria. The business case appraisal template is included within this guidance for information, as Appendix 2. It will help in drafting a business case to consider how well the proposal would score against each of the appraisal criteria.

Business Cases supported by the QIPP Delivery Group will then be submitted to the Southwark Clinical Commissioning Committee for formal approval.

Business Cases should be submitted to: kieranswann@nhs.net
### 1. Business Case Details

<table>
<thead>
<tr>
<th>Title of Proposal:</th>
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<table>
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<tr>
<th>CCG Director Lead:</th>
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<tr>
<th>Project Lead:</th>
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<tr>
<th>Date of Proposal:</th>
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### 2. Introduction: Give a brief outline of the proposal, with any relevant context.

### 3.1 Describe how the service fits with local commissioning intentions, including the Southwark Strategic Plan and Pathfinder Priorities

### 3.2 Describe any national strategies, guidance or evidence base supporting this proposal.

### 3.3 What evidence is there from patients and/or the public in support of this proposal?

### 4. Description of the proposed service (including access criteria, care pathway, model of care and anticipated capacity)
5. Summary of expected outcomes (including details KPIs for each outcome).

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Key Performance Indicator</th>
<th>Timescale</th>
</tr>
</thead>
</table>

6.1 Demonstrate how this proposal represents value for money or supports delivery of the QIPP.

6.2 Financial details, including recurrent and set up costs, and projected savings:

6.3 Please ensure you include a completed financial template

7. Implementation Plan and Timescale:
### 8.1 Identification of Risks:
(Clinical, Financial, Implementation, Information Governance)

### 8.2 Please describe the mechanisms for managing risk related to the service (identification, evaluation, reporting, mitigating controls, monitoring):


### 10. Stakeholder engagement.

- Clinicians:-
- Patients:-
- Other stakeholders:-
Appendix 7
Annex b: BUSINESS CASE TEMPLATE – GUIDANCE NOTES ON COMPLETION

The purpose of the template is to ensure the inclusion of all the information the CCG needs in order to assess business cases.

The CCG Acute and Joint Commissioning and finance teams will facilitate and support business case development.

Notes on how to complete each section of the form are set out below.

1. Business Case Details.
Title of the proposal - this should be the working title that is used for the proposal/service development.
Please complete the contact details, including the name of the responsible CCG Director, and Clinical Commissioning lead or associate who is the sponsor of the business case. Each Business Case should have a clinical commissioning lead who has been involved in the development of the proposal and who supports the proposal in the authorisation process. The clinical lead should have no conflict of interest in relation to the proposal.

2. Introduction and context
Provide a brief outline of the service. This should enable someone with no previous knowledge of the proposal to understand what the proposal is for and how it will work.

3. Strategic fit and evidence base
This section should set out clearly how the proposed service fits with local or national priorities. This section should set out the evidence that the service improvement will be effective, including from pilots or from successful implementation elsewhere, or theoretical evidence.
Details of any support for the proposal from patients and the public should also be included here.

4. Description of the service
A more detailed description of the service should be provided here. Information provided should include:

- the access criteria or patient cohort, including any inclusion and exclusion criteria
- a description of the patient pathway and interface with other services
- details of the model of care to be provided
- a description of the likely capacity of the service, in terms of patient throughput and staffing resource
- a brief description of the benefits anticipated
- the location of the service, if known

If a number of options for providing the service were considered, these should be briefly described in this section along with a clear description of the preferred option, and the rationale for recommending it.
5. Summary of Outcomes
This section should describe:
- the key outcomes from the service: how will they improve health and well-being outcomes or services for patients?
- the key performance indicators that will demonstrate that the outcomes are being achieved
- the anticipated timescales for achieving outcomes (these should be phased in weeks and months rather than dates, as there may be slippage in the planned start date)

6. Financial Evaluation

6.1 The criteria for value for money are based around economy, efficiency and effectiveness. In assessing the business case for value for money the CCG will consider:
- Will the proposal provide further economies in providing an existing service?
- Will it improve effectiveness and service quality in terms of the required outcomes?
- Will it improve efficiencies in the throughput of services?
- Will the service contribute towards the CCG’s QIPP savings targets?
- Release of financial resource should be detailed explicitly in section 6.2

6.2 Costs of the Service
This section should include details of:
- The recurrent costs of the service (full year effect)
- Any set-up or non-recurrent costs including capital developments required, and project management
- Details of any expected savings to be released in a full year

6.3 Financial template
All business cases should be accompanied by a completed financial template, which gives more details of costs, savings and activity levels over three years of the proposal. This is at Annex 2. The CCG finance and information teams will provide support business case authors in developing assumptions, costings and completing the form.

7. Implementation Plan
This section should include details of how the service will be established or commissioned, including:
- Timescales for commissioning or setting up the service
- Details of any procurement exercise required to secure a provider for the service
- Details of any information systems required to record activity and clinical information
- Any other enabling work
8. Risk
8.1 This section should be used to summarise any known risks inherent to the service, or barriers to implementation. It is likely there are actions or circumstances which could prevent the proposed service from being delivered successfully. These risks could be around timescales, resource availability, external influences, reliance on new systems or processes being implemented or other foreseeable circumstances. Although at an early stage, it is possible that some of these risks may already be identified. Risks can fall into the following headings (not exhaustive) Clinical, Financial, Implementation, Information Governance.

8.2 This section should be used to detail how known risks included in section 8.1 will be recorded and monitored if the service is approved, and what mitigating actions or controls will be put in place to offset these risks

9. Health Needs Assessment and Impact on Equalities
The business case should demonstrate that health equity and equity of access have been considered. State whether an equalities impact assessment has been carried out and provide details if so. Business cases should be based on a brief health needs assessment of the target population. For most business cases this information and intelligence is available from practice profiles, the Director of Public Health annual report, the Joint Strategic Needs Analysis, audit information etc. The Public Health team can provide further advice on completing this section.

10. Stakeholder Consultation
Set out who has been consulted, with particular reference to clinicians and patients, with a summary of what their views were. Advice is available from the CCG’s Engagement and Communication team on how to take forward consultations, particularly for significant service developments.

In developing the business case, intelligence and insights gained from wider consultations and feedback should also be used. This includes taking account of feedback from Transforming Southwark, feedback from PALs and correspondence received by the CCG and other service specific consultation and feedback.
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Appendix 7
Annex c: NHS SOUTHWARK CCG BUSINESS CASE: FINANCE TEMPLATE

1. Title
2. Director Lead
3. Author

4. Activity Assumptions

<table>
<thead>
<tr>
<th>Activity Level</th>
<th>Quarter 1</th>
<th>Quarter 2</th>
<th>Quarter 3</th>
<th>Quarter 4</th>
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<tr>
<td>Year 3</td>
<td></td>
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5. Cost Assumptions

Text box: include assumptions for cost basis, timing assumptions, phasing, double running costs, assumed efficiencies and disinvestment

6. Non recurrent / start up costs
   (breakdown by heading e.g – project management (£000))
   - Year 1
   - Year 2
   - Year 3

7. Recurrent annual costs (breakdown by heading – salaries, on cost, training, equipment) (£000)
   - Year 1
   - Year 2
   - Year 3

8. Capital (by heading) (£000)
   - Year 1
   - Year 2
   - Year 3

9. Savings/disinvestment (by heading)
   (£000)
   - Year 1
   - Year 2
   - Year 3
Section A: Improving Quality

1. Will the proposal deliver improved clinical quality and patient experience?

- [ ] 1 2 3 4 5 6 7 8 9 10
- Risks of deterioration in quality
- Neutral
- Likely to improve quality/experience

Comments:

2. Is the proposal aligned with current national policy?

- [ ] 1 2 3 4 5 6 7 8 9 10
- Contradicts national policy
- Fully aligned

Comments:

3. Is the proposal aligned with current CCG Strategic and Commissioning plans?

- [ ] 1 2 3 4 5 6 7 8 9 10
- Contradicts local objectives
- Full aligned

Comments:
Section B: Equalities and Conflict of Interest
1. Have impacts on equalities been sufficiently considered in the business case?

Comments:

2. Does the proposal raise any risks in relation to Southwark CCG Conflict of Interest?

Comments:

Section C: Viability
1. Is the provider able to deliver the business case in full?

Comments:

2. Will the proposed business case deliver cash-releasing savings to Southwark CCG?

Yes

No

<table>
<thead>
<tr>
<th>Amount</th>
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<td></td>
</tr>
<tr>
<td>£1m+</td>
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</table>

Comments:
3. What is the risk that the provider does not deliver all the proposed cash-releasing savings?

1 2 3 4 5 6 7 8 9 10

High Risk Low Risk

Comments:

4. How robust is the evidence base used by the provider to support their business case?

1 2 3 4 5 6 7 8 9 10

Very limited/weak Very strong/robust

Comments:

Total Score

70

Reviewing Officer

Name:

Role:

Date:

Chair: Dr Amr Zeineldine
Chief Officer: Andrew Bland

The best possible health outcomes for Southwark people
The best possible health outcomes for Southwark people
## Appendix 8 – Framework for Joint Working Between the NHS and Pharmaceutical Industry

### I. JOINT WORKING PROJECT SUMMARY

1. **TITLE OF PROJECT**

2. **SUMMARY OF INTENDED AIMS & OBJECTIVES**

3. **SUMMARY OF EXPECTED OUTCOMES**

4. **NAMES OF THE PARTNER ORGANISATIONS INVOLVED IN THE JOINT WORKING ARRANGEMENT**

5. **NAMES OF LEAD REPRESENTATIVES FOR EACH ORGANISATION**

6. **EXACT NATURE OF THE JOINT WORKING PROPOSAL**

7. **START DATE**

8. **FINISH DATE**

9. **EXIT STRATEGY**

### II. RESOURCES AND COSTS

1. **OVERALL COST OF THE JOINT WORKING PROJECT**

2. **DIRECT AND INDIRECT RESOURCES / COST COMMITMENTS BY EACH PARTNER**

3. **METHOD FOR MONITORING AND RECORDING RESOURCE AND COSTS**

4. **INFORMATION ON COST EFFECTIVENESS (Has value for money been shown?)**
### III. GOVERNANCE ARRANGEMENTS

1. **Parties Consulted Prior to Initiating Joint Working Project and How Consultation Was Conducted**

2. **Method for Informing Patients of the Joint Working Project**

3. **Decision Making Processes Within the Joint Working Project**
   (To be open and transparent)

4. **Operational and Management Accountabilities**
   (Include identified conflicts of interest)

5. **Piloting Arrangements**
   (State if this project is a pilot)

6. **Relationship to Existing Systems of Care in Primary and Secondary Care Sectors**

7. **For Clinical Services, Professional Indemnity and Liability Arrangements**

8. **Written Agreement Stating Obligations of Confidentiality, Security Standards and Limits of Use of Information to the Purposes Specified**

### IV. MONITORING AND EVALUATION

1. **Management Arrangements**

2. **List Designated Responsibility at Each Stage of the Proposal**

---

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### V. DATA AND PATIENT PROTECTION

<p>| | |</p>
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<tbody>
<tr>
<td>1.</td>
<td><strong>LIST INTERESTS OF PARTNERS IN RELATION TO THE JOINT WORKING PROPOSAL, AND WHERE THESE COINCIDE</strong></td>
</tr>
<tr>
<td>2.</td>
<td><strong>LIST POTENTIAL CONFLICTS OF INTEREST</strong></td>
</tr>
<tr>
<td>3.</td>
<td><strong>IDENTIFY “OWNERSHIP” OF THE DATA GENERATED BY THE PROJECT</strong></td>
</tr>
<tr>
<td>4.</td>
<td><strong>DESCRIBE ACCESS ARRANGEMENTS FOR THE DATA, AND FORMAT (Bearing in mind the requirements of the Data Protection Act and patient confidentiality of healthcare records)</strong></td>
</tr>
<tr>
<td>5.</td>
<td><strong>USE DATA WILL BE PUT TO</strong></td>
</tr>
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</table>

### VI. DECLARATION OF INTERESTS

**YES** [ ]  **NO** [ ]

*If Yes, qualify by inserting a tick in one box in column A and one in column B*

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<thead>
<tr>
<th>A</th>
<th>B</th>
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<tbody>
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<td>Personal</td>
<td>Specific</td>
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</table>
The best possible health outcomes for Southwark people

Chair: Dr Amr Zeineldine
Chief Officer: Andrew Bland
AN AGREEMENT FOR JOINT WORKING BETWEEN
NHS Southwark Clinical Commissioning Group
AND
Insert second party (and any others as necessary)
FOR
Insert title of joint working initiative

1. Principles governing this Joint Working agreement
The following principles and those defined in the framework for joint working will apply:
   • All joint working must be for the benefit of patients;
   • Joint working will be conducted in an open and transparent manner;
   • Arrangements will be of mutual benefit, the principal beneficiary being the patient;
   • Confidentiality of information received in the course of the arrangement will be respected and never used outside the scope of the project;
   • The CCG retains overall control of the project outlined above
   • All patient identifiers will be removed from data to preserve and respect patient confidentiality in line with the Data Protection Act; Patient confidentiality will be maintained at all times.
   • Reports and information pertaining to the agreement / projects will not be used or published without explicit permission given by all parties;
   • No data will be disclosed to any third party except on the explicit agreement of 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;

2. Declaration of Interests
All declarations of interest must be declared. Declarations of interest will be recorded and maintained by the Medicines Management team and forwarded to the Chief Officer for NHS Southwark CCG.

I have read and commit to the terms of the Joint Working Agreement and the framework for Joint Working.

Signed: _______________________________ on behalf of: _______________________________
Print _______________________________ Date: _______________________________

Chair: Dr Amr Zeineldine  Chief Officer: Andrew Bland

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