



# MANAGING CONFLICTS OF INTEREST: STATUTORY GUIDANCE FOR CCGs

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# Managing conflicts of interest: statutory guidance for CCGs

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## Introduction

"If conflicts of interest are not managed effectively by CCGs, confidence in the probity of commissioning decisions and the integrity of clinicians involved could be seriously undermined. However, with good planning and governance, CCGs should be able to avoid these risks."

RCGP and NHS Confederation's briefing paper on managing conflicts of interest September 2011<sup>1</sup>

- Clinical commissioning groups (CCGs) manage conflicts of interest as part of their day-to-day activities. Effective handling of such conflicts is crucial for the maintenance of public trust in the commissioning system. Importantly, it also serves to give confidence to patients, providers, Parliament and tax payers that CCG commissioning decisions are robust, fair, transparent and offer value for money.
- 2. In May 2014, NHS England offered CCGs the opportunity to take on an increased responsibility for the commissioning of primary care. Those CCGs who opt to do so will be able to commission care for their patients and populations in more coherent and joined-up ways but they are also exposing themselves to a greater risk of conflicts of interest, both real and perceived, especially if they are opting to take on delegated budgets and functions from NHS England. The details of this policy initiative can be found in *Next steps towards primary care co-commissioning.*<sup>2</sup>
- 3. In light of this new development, NHS England, in consultation with national stakeholders, has developed strengthened guidance for the management of conflicts of interest. This guidance builds on and incorporates relevant aspects of existing NHS England guidance, and supersedes the extant NHS England guidance<sup>3</sup>. In other words, this guidance will supplant the previously issued NHS England guidance for CCGs.
- 4. Equality and diversity are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have given due regard to the need to:
  - Reduce health inequalities in access and outcomes of healthcare services
  - Integrate services where this might reduce health inequalities

<sup>&</sup>lt;sup>1</sup> 'Managing conflicts of interest in clinical commissioning groups:

http://www.rcgp.org.uk/~/media/Files/CIRC/Managing\_conflicts\_of\_interest.ashx <sup>2</sup> http://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2014/11/nxt-steps-pccocomms.pdf

<sup>&</sup>lt;sup>3</sup> <u>http://www.england.nhs.uk/wp-content/uploads/2013/03/manage-con-int.pdf</u> and <u>http://www.england.nhs.uk/wp-content/uploads/2012/09/c-of-c-conflicts-of-interest.pdf</u>

- Eliminate discrimination, harassment and victimisation
- Advance equality of opportunity and foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it.
- 5. In its own commissioning decisions and day-to-day business, NHS England is bound by the code set out in the Standards of Business Conduct<sup>4</sup> (and supplemented by the Standing Orders). However, when serving on a joint committee with one or more CCGs, NHS England staff also need to adhere to the guidance set out in this document.
- 6. This guidance also builds on guidance issued by other national bodies, in particular Monitor's guidance on the Procurement, Patient Choice and Competition Regulations<sup>5</sup>, and guidance issued by GP professional bodies such as the British Medical Association (BMA), the General Medical Council (GMC)<sup>6</sup> and the Royal College of General Practitioners (RCGP).
- 7. This document is issued as statutory guidance under sections 14O and 14Z8 of the National Health Service Act 2006 (as amended by the Health and Social Care Act 2012) ("the Act"). This means that CCGs must have regard to such guidance with the onus on them to explain any non-adherence.
- 8. The Act sets out clear requirements for CCGs to make arrangements for managing conflicts of interest and potential conflicts of interest, to ensure they do not affect, or appear to affect, the integrity of the CCG's decision making processes. These requirements are supplemented by procurement-specific requirements in the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.

When a CCG is seeking to take on delegated or joint commissioning responsibilities, their audit committee chair and accountable officer will be required to provide direct formal attestation to NHS England that the CCG has complied with this guidance. Subsequently, this attestation will form part of an annual certification. CCG approaches to management of conflicts of interest will also be considered on an ongoing basis as part of CCG assurance. Further details will be issued early in 2015 as to the forms that the initial attestation, the annual certification and ongoing assurance will take.

<sup>&</sup>lt;sup>4</sup> http://www.england.nhs.uk/wp-content/uploads/2012/11/stand-bus-cond.pdf

<sup>&</sup>lt;sup>5</sup> Substantive guidance on the Procurement, Patient Choice and Competition Regulations:

https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/283505/SubstantiveGui danceDec2013\_0.pdf <sup>6</sup> GMC | Good medical practice (2013) http://www.gmc-uk.org/guidance/good\_medical\_practice.asp

and http://www.gmc-uk.org/guidance/ethical\_guidance/21161.asp

## Aims of the guidance

- 9. The aims of this guidance are to:
  - enable CCGs and clinicians in commissioning roles to demonstrate that they are acting fairly and transparently and in the best interest of their patients and local populations;
  - ensure that CCGs operate within the legal framework, but without being bound by over-prescriptive rules that risk stifling innovation;
  - safeguard clinically led commissioning, whilst ensuring objective investment decisions;
  - provide the public, providers, Parliament and regulators with confidence in the probity, integrity and fairness of commissioners' decisions; and
  - uphold the confidence and trust between patients and GP, in the recognition that individual commissioners want to behave ethically but may need support and training to understand when conflicts (whether actual or potential) may arise and how to manage them if they do.
- 10. In developing this guidance, NHS England has worked closely with NHS Clinical Commissioners, and has engaged with the following stakeholders:
  - HealthWatch England;
  - Monitor;
  - the National Audit Office (in an informal capacity;
  - General Practitioners Committee;
  - Royal College of General Practitioners;
  - General Medical Council; and
  - CCG representatives.
- 11. The guidance incorporates the safeguards for the management of conflicts of interest set out in the previously issued guidance, including:
  - the nature of conflicts of interest;
  - arrangements for declaring interests;

- maintaining a register of interests;
- keeping a record of the steps taken to manage a conflict;
- excluding individuals from decision-making where a conflict arises; and
- engagement with a range of potential providers on service design.

12. In addition, it sets out:

- the additional factors that CCGs should address when commissioning primary medical care services, either under joint commissioning or delegated commissioning arrangements. This includes the factors CCGs should consider when drawing up plans for services that might be provided by GP practices; and it also includes the necessary aspects of the makeup of the decision-making committee which must have a lay and executive member majority;
- the steps that CCGs should take to assure their Audit Committee, Health and Wellbeing Board(s), NHS England and, where necessary, their auditors, that these services are appropriately commissioned from GP practices;
- procedures for decision-making in cases where all the GPs (or other practice representatives) sitting on a decision-making group have a potential financial interest in the decision;
- arrangements for publishing details of payments to GP practices;
- the potential role of commissioning support services; and
- the supporting role of NHS England.

### What are conflicts of interest?

13. A conflict of interest occurs where an individual's ability to exercise judgement, or act in a role, is or could be impaired or otherwise influenced by his or her involvement in another role or relationship. The individual does not need to exploit his or her position or obtain an actual benefit, financial or otherwise, for a conflict of interest to occur.

"For the purposes of Regulation 6 [*National Health Service (Procurement, Patient Choice and Competition) (No.2) Regulations 2013*<sup>7</sup>], a conflict will arise where an individual's ability to exercise judgement or act in their role in the **commissioning of services** is impaired or influenced by their interests in the **provision of those services**."

Monitor - Substantive guidance on the Procurement, Patient Choice and Competition Regulations (December 2013)

- 14. As well as direct financial interests, conflicts can arise from an indirect financial interest (e.g. payment to a spouse) or a non-financial interest (e.g. reputation). Conflicts of loyalty may arise (e.g. in respect of an organisation of which the individual is a member or with which they have an affiliation). Conflicts can arise from personal or professional relationships with others, e.g. where the role or interest of a family member, friend or acquaintance may influence an individual's judgement or actions, or could be perceived to do so. Depending upon the individual circumstances, these factors can all give rise to potential or actual conflicts of interest.
- 15. For a commissioner, a conflict of interest may therefore arise when their judgment as a commissioner could be, or be perceived to be, influenced and impaired by their own concerns and obligations as a provider. In the case of a GP involved in commissioning, an obvious example is the award of a new contract to a provider in which the individual GP has a financial stake. However, the same considerations, and the approaches set out in this guidance, apply when deciding whether to extend a contract.
- 16.NHS Clinical Commissioners has carried out a review of current guidance on conflicts of interest management and, together with the Royal College of General Practitioners and the British Medical Association, has developed a set of key principles that apply in this context. These principles are set out in Annex 1.
- 17.CCGs should provide clear guidance to their members<sup>8</sup> and employees on what might constitute a conflict of interest, providing examples of situations that may arise. Pertinent issues to bear in mind include:
  - a perception of wrongdoing, impaired judgement or undue influence can be as detrimental as any of them actually occurring;

<sup>&</sup>lt;sup>7</sup> http://www.legislation.gov.uk/uksi/2013/257/contents/made

<sup>&</sup>lt;sup>8</sup> Following the linguistic convention of the Act, within this guidance 'member' generally refers collectively to the members of a CCG, members of its governing body and to members of the committees or sub-committees of the CCG or its governing body. Where a member of a specific body is being referred to, this is made clear within the context. However the appropriate actions for a CCG to take in managing conflicts of interest will vary according to the role of particular members, including their role in influencing decision-making processes.

- if in doubt, it is better to assume the existence of a conflict of interest and manage it appropriately rather than ignore it; and
- for a conflict of interest to exist, financial gain is not necessary.

## Legislative framework

- 18. The starting point for CCGs is section 14O of the Act. This sets out the minimum requirements in terms of what both NHS England and CCGs must do in terms of managing conflicts of interest. For CCGs, this means that they must:
  - Maintain appropriate registers of interests;
  - Publish or make arrangements for the public to access those registers;
  - Make arrangements requiring the prompt declaration of interests by the persons specified (members and employees) and ensure that these interests are entered into the relevant register;
  - Make arrangements for managing conflicts and potential conflicts of interest (e.g. developing appropriate policies and procedures); and
  - Have regard to guidance published by NHS England and Monitor in relation to conflicts of interest.
- 19. Section 14O also imposes a duty on NHS England to publish guidance for CCGs on the discharge of their functions under this section.
- 20. Section 14O is supplemented by the procurement specific requirements set out in the National Health Service (Procurement, Patient Choice and Competition) (No.2) Regulations 2013<sup>9</sup>. In particular, regulation 6 requires the following:
  - CCGs must not award a contract for the provision of NHS health care services where conflicts, or potential conflicts, between the interests involved in commissioning such services and the interests involved in providing them affect, or appear to affect, the integrity of the award of that contract; and
  - CCGs must keep a record of how it managed any such conflict in relation to NHS commissioning contracts it enters into. (As set out in section 8 below, details of this should also be published by the CCG.)

<sup>&</sup>lt;sup>9</sup> http://www.legislation.gov.uk/uksi/2013/500/contents/made

- 21. An interest is defined for the purposes of regulation 6 as including an interest of the following:
  - a member of the commissioner organisation;
  - a member of the governing body of the commissioner;
  - a member of its committees or sub-committees or committees or subcommittees of its governing body; or
  - an employee.
- 22. As with section 14O, regulation 6 sets out the basic framework within which CCGs must operate. The detailed requirements are set out in the guidance issued by Monitor (*Substantive guidance on the Procurement, Patient Choice and Competition Regulations*) and, in particular, section 7 of that statutory guidance (included as Annex 6 to this guidance).
- 23. Monitor's view is that care must be taken to ensure that conflicts do not affect, or appear to affect, the integrity of the award of commissioning contracts. It is important to ensure that the management of conflicts of interest includes the management of perceived conflicts and that there is an appropriate record of how such issues are managed, particularly in the context of specific procurement decisions. Please see below for further guidance on how such information should be recorded and published. Clear and robust decision-making processes must be put in place to deliver co-commissioning and give the public and providers confidence in the integrity of the decisions made.
- 24. Finally, as explained bove, section 14Z8 gives NHS England the ability to issue statutory guidance regarding commissioning. CCGs must have regard to such guidance with the onus on them to explain any departure from the guidance.

## Principles and general safeguards

25. The general safeguards that will be needed to manage conflicts of interest will vary to some extent, depending on at what stage in the commissioning cycle decisions are being made. The following principles will need to be integral to the commissioning of all services, including decisions on whether to continue to commission a service, such as by contact extension.

26. Conflicts of interest can be managed by:

• **Doing business appropriately.** If commissioners get their needs assessments, consultation mechanisms, commissioning strategies and

procurement procedures right from the outset, then conflicts of interest become much easier to identify, avoid and/or manage, because the rationale for all decision-making will be clear and transparent and should withstand scrutiny;

- **Being proactive, not reactive.** Commissioners should seek to identify and minimise the risk of conflicts of interest at the earliest possible opportunity, for instance by:
  - considering potential conflicts of interest when electing or selecting individuals to join the governing body or other decision-making bodies;
  - ensuring individuals receive proper induction and training so that they understand their obligations to declare conflicts of interest.

They should establish and maintain registers of interests, and agree in advance how a range of possible situations and scenarios will be handled, rather than waiting until they arise;

- Assuming that individuals will seek to act ethically and professionally, but may not always be sensitive to all conflicts of interest. Rules should assume people will volunteer information about conflicts and, where necessary, exclude themselves from decision-making, but there should also be prompts and checks to reinforce this;
- **Being balanced and proportionate.** Rules should be clear and robust but not overly prescriptive or restrictive. They should ensure that decision-making is transparent and fair, but not constrain people by making it overly complex or cumbersome;
- **Openness.** Ensuring early engagement with patients, the public, clinicians and other stakeholders, including local Healthwatch and Health and Wellbeing Boards, in relation to proposed commissioning plans;
- Responsiveness and best practice. Ensuring that commissioning intentions are based on local health needs and reflect evidence of best practice – securing 'buy in' from local stakeholders to the clinical case for change;
- **Transparency.** Documenting clearly the approach taken at every stage in the commissioning cycle so that a clear audit trail is evident;
- Securing expert advice. Ensuring that plans take into account advice from appropriate health and social care professionals, e.g. through clinical senates and networks, and draw on commissioning support, for instance around formal consultations and for procurement processes;
- Engaging with providers. Early engagement with both incumbent and potential new providers over potential changes to the services commissioned for a local population;

- Creating clear and transparent commissioning specifications that reflect the depth of engagement and set out the basis on which any contract will be awarded;
- Following proper procurement processes and legal arrangements, including even-handed approaches to providers;
- Ensuring sound record-keeping, including up to date registers of interests; and
- A clear, recognised and easily enacted system for dispute resolution.
- 27. These general processes and safeguards should apply at all stages of the commissioning process, but will be particularly important at key decision points, e.g., whether and how to go out to procurement of new or additional services.
- 28. Particular considerations pertain to CCGs who hold responsibilities for delegated or joint commissioning of primary care. These are set out later in this guidance.

## Maintaining a register of interests and a register of decisions

#### **Statutory requirements**

CCGs must maintain one or more registers of interest of: the members of the group, members of its governing body, members of its committees or sub-committees of its governing body, and its employees. CCGs must publish, and make arrangements to ensure that members of the public have access to these registers on request.

CCGs must make arrangements to ensure individuals declare any conflict or potential conflict in relation to a decision to be made by the group as soon as they become aware of it, and in any event within 28 days. CCGs must record the interest in the registers as soon as they become aware of it.

- 29. CCGs must ensure that, when members declare interests, this includes the interests of all relevant individuals within their own organisations (e.g. partners in a GP practice), who have a relationship with the CCG and who would potentially be in a position to benefit from the CCG's decisions.
- 30. When entering an interest on its register of interests, the CCG should ensure that it includes sufficient information about the nature of the interest and the details of those holding the interest.

31.CCGs will need to ensure that, as a matter of course, declarations of interest are made and regularly confirmed or updated. This includes the following circumstances:

#### On appointment:

Applicants for any appointment to the CCG or its governing body should be asked to declare any relevant interests. When an appointment is made, a formal declaration of interests should again be made and recorded.

#### At meetings:

All attendees should be asked to declare any interest they have in any agenda item before it is discussed or as soon as it becomes apparent. Even if an interest is declared in the register of interests, it should be declared in meetings where matters relating to that interest are discussed. Declarations of interest should be recorded in minutes of meetings.

#### **Quarterly:**

CCGs should have systems in place to satisfy themselves on a quarterly basis that their register of interests is accurate and up to date.

#### On changing role or responsibility:

Where an individual changes role or responsibility within a CCG or its governing body, any change to the individual's interests should be declared.

#### On any other change of circumstances:

Wherever an individual's circumstances change in a way that affects the individual's interests (e.g. where an individual takes on a new role outside the CCG or sets up a new business or relationship), a further declaration should be made to reflect the change in circumstances. This could involve a conflict of interest ceasing to exist or a new one materialising.

- 32. In keeping with the regulations, individuals who have a conflict should declare this as soon as they become aware of it, and in any event not later than 28 days after becoming aware.
- 33. Whenever interests are declared, they should be reported to the person designated with responsibility for the register of interests (as identified by the CCG or its governing body), who should then update the register accordingly.

**Note:** CCGs will need to set out the process that they will follow if an individual fails to comply with its polices on managing conflicts of interest as set out in its constitution. This could include that individual being removed from office.

See Annexes 2 and 3 for declaration of interests templates

34. CCGs must update their register of interests whenever a new or revised interest is declared.

## **Register of procurement decisions**

- 35. CCGs also need to maintain a register of procurement decisions<sup>10</sup> taken, including:
  - the details of the decision;
  - who was involved in making the decision (i.e. governing body or committee members and others with decision-making responsibility); and
  - a summary of any conflicts of interest in relation to the decision and how this was managed by the CCG.

36. The register should be updated whenever a procurement decision is taken.

- 37. In the interests of transparency, the register of interests and the register of decisions will need to be publicly available and easily accessible to patients and the public including by:
  - ensuring that both registers are available in a prominent place on the CCG's website; and
  - CCGs making both registers available upon request for inspection at their headquarters.
- 38. CCGs will also need to consider any particular access needs that their stakeholders have. For example, individuals without internet access could be directed to the local library or invited to view the register(s) at the CCG's headquarters.
- 39. The registers will form part of the CCG's annual accounts and will thus be signed off by external auditors. Further work will be carried out by NHS England on the specific arrangements for this.

## **Procurement issues**

40. CCGs will need to be able to recognise and manage any conflicts or potential conflicts of interest that may arise in relation to procurement.

<sup>&</sup>lt;sup>10</sup> Regulation 9 of the NHS (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 requires that a record of procurement decisions is maintained on an NHS England website. The register of decisions described above is intended to supplement this as a more detailed record of the decision.

- 41. The NHS Act, the Health and Social Care Act ("the HSCA") and associated regulations<sup>11</sup> set out the statutory rules with which commissioners are required to comply when procuring and contracting for the provision of clinical services. They need to be considered alongside the Public Contract Regulations<sup>12</sup> and, where appropriate, EU procurement rules. Monitor's *Substantive guidance on the Procurement, Patient Choice and Competition Regulations* advises that the requirements within these create a framework for decision making that will assist commissioners to comply with a range of other relevant legislative requirements.
- 42. The Procurement, Patient Choice and Competition Regulations place requirements on commissioners to ensure that they adhere to good practice in relation to procurement, do not engage in anti-competitive behaviour that is against the interest of patients, and protect the right of patients to make choices about their healthcare.

43. The regulations set out that commissioners must:

- manage conflicts and potential conflicts of interests when awarding a contract by prohibiting the award of a contract where the integrity of the award has been, or appears to have been, affected by a conflict; and
- keep appropriate records of how they have managed any conflicts in individual cases.
- 44. Monitor has a statutory duty under section 78 of the HSCA to produce guidance on compliance with any requirements imposed by the regulations and how it intends to exercise the powers conferred on it by these regulations. Monitor's *Substantive guidance on the Procurement, Patient Choice and Competition Regulations* is the relevant statutory guidance. NHS England works closely with Monitor with regard to these matters and has engaged with Monitor in developing this revised guidance.

#### General considerations and use of the template

45. The most obvious area in which conflicts could arise is where a CCG commissions (or continues to commission by contract extension) healthcare services, including GP services, in which a member of the CCG has a financial or other interest. This may most often arise in the context of co-commissioning of primary care, particularly with regard to delegated or joint arrangements, but it will also need to be considered in respect of any commissioning issue where GPs are current or possible providers. CCGs are advised to address the

<sup>&</sup>lt;sup>11</sup> The NHS (Procurement, Patient Choice and Competition) Regulations (No. 2) 2013, issued under section 75 of the HSCA

<sup>&</sup>lt;sup>12</sup> <u>http://www.legislation.gov.uk/uksi/2006/5/contents/made</u>. It is also important to bear aware that, at the time of issuing this guidance, draft new public contract regulations have been issued (<u>https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/356494/Draft\_Public\_C\_ontracts\_Regulations\_2015.pdf</u></u>). CCGs should ensure that they observe the final version of these when they come into effect.

factors set out in the procurement template at annex 4 when drawing up their plans to commission services where this potentially is the case.

- 46. CCGs will be expected to make evidence of their deliberations on conflicts publicly available. The template is one way of CCGs evidencing this and will support CCGs in fulfilling their duty in relation to public involvement. It will further provide appropriate assurance:
  - that the CCG is seeking and encouraging scrutiny of its decision-making process;
  - to Health and Wellbeing Boards, local Healthwatch and to local communities that the proposed service meets local needs and priorities; it will enable them to raise questions if they have concerns about the approach being taken;
  - to the audit committee and, where necessary, external auditors, that a robust process has been followed in deciding to commission the service, in selecting the appropriate procurement route, and in addressing potential conflicts; and
  - to NHS England in their role as assurers of the co-commissioning arrangements.

#### **Designing service requirements**

- 47. It is good practice to engage relevant providers, especially clinicians, in confirming that the design of service specifications will meet patient need. Such engagement, done transparently and fairly, is entirely legal. However, conflicts of interest can occur if a commissioner engages selectively with only certain providers (be they incumbent or potential new providers) in developing a service specification for a contract for which they may later bid.
- 48. Commissioners should seek, as far as possible, to specify the outcomes that they wish to see delivered through a new service, rather than the process by which these outcomes are to be achieved. As well as supporting innovation, this helps prevent bias towards particular providers in the specification of services.
- 49. Such engagement should follow the three main principles of procurement law, namely equal treatment, non-discrimination and transparency. This includes ensuring that the same information is given to all.
- 50. Other steps include:

- advertise the fact that a service design/re-design exercise is taking place widely and invite comments from any potential providers and other interested parties (ensuring a record is kept of all interactions);
- as the service design develops, engage with a wide range of providers on an ongoing basis to seek comments on the proposed design, e.g. via the commissioner's website or via workshops with interested parties;
- use engagement to help shape the requirement to meet patient need but take care not to gear the requirement in favour of any particular provider(s);
- if appropriate, engage the advice of an independent clinical adviser on the design of the service;
- be transparent about procedures;
- ensure at all stages that potential providers are aware of how the service will be commissioned; and
- maintain commercial confidentiality of information received from providers.
- 51. When engaging providers on service design, CCGs should bear in mind that they have ultimate responsibility for service design and for selecting the provider of services. Monitor has issued guidance on the use of provider boards in service design<sup>13</sup>.
- 52. CCGs will also need to ensure that they have systems in place for managing conflicts of interest on an ongoing basis, for instance, by monitoring a contract that has been awarded to a provider in which an individual commissioner has a vested interest.

### **Governance and decision-making processes**

#### Statutory requirement

CCGs must make arrangements for managing conflicts of interest, and potential conflicts of interest, in such a way as to ensure that they do not, and do not appear to, affect the integrity of the group's decision-making.

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https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/284832/ManchesterCaseeClosure.pdf

- 53. CCGs should review their governance structures for managing conflicts of interest to ensure that they reflect current guidance and are appropriate, particularly in relation to any co-commissioning roles which the CCG proposes to undertake. This should include consideration of the following:
  - the make-up of their governing body and committee structures (including, where relevant, the approach set out below for decision-making in delegated or joint commissioning of primary care);
  - whether there are sufficient management and internal controls to detect breaches of the CCG's conflicts of interest policy, including appropriate external oversight and adequate provision for whistleblowing;
  - how non-compliance with policies and procedures relating to conflicts of interest will be managed (including how this will be addressed when it relates to contracts already entered into). As well as actions to address non-compliance, CCGs should also have procedures in place to review any lessons to be learned from such cases, e.g., by the CCG's audit committee conducting an incident review;
  - reviewing and revising approaches to the CCG's registers of interest, together with the introduction of a record of decisions, as set out above;
  - whether any training or other programmes are required to assist with compliance, including participation in the training offered by NHS England, as set out below.

#### Appointing governing body or committee members

- 54. CCGs will need to consider whether conflicts of interest should exclude individuals from being appointed to the governing body or to a committee or sub-committee of the CCG or governing body. These will need to be considered on a case-by-case basis but the CCG's constitution should reflect the CCG's general principles.
- 55. The CCG will need to assess the materiality of the interest, in particular whether the individual (or a family member or business partner) could benefit from any decision the governing body might make. This will be particularly relevant for any profit sharing member of any organisation but should also be considered for all employees and especially those operating at senior or governing body level.
- 56. The CCG will also need to determine the extent of the interest. If it is related to an area of business significant enough that the individual would be unable to make a full and proper contribution to the governing body, that individual should not become a member of the governing body.

57. Any individual who has a material interest in an organisation which provides, or is likely to provide, substantial services to a CCG (either as a provider of healthcare or commissioning support services) should not be a member of the governing body if the nature of their interest is such that they are likely to need to exclude themselves from decision-making on so regular a basis that it significantly limits their ability to effectively operate as a governing body member. Specific considerations in relation to delegated or joint commissioning of primary care are set out below.

#### Decision-making when a conflict of interest arises: general

#### approaches

- 58. Where certain members of a decision-making body (be it the governing body, its committees or sub-committees, or a committee or sub-committee of the CCG) have a material interest, they should either be excluded from relevant parts of meetings, or join in the discussion but not participate in the decision-making itself (i.e., not have a vote).
- 59. The chair of the meeting has responsibility for deciding whether there is a conflict of interest and the appropriate course of corresponding action. In making such decisions, the chair may wish to consult the member of the governing body who has responsibility for issues relating to conflicts of interest. All decisions, and details of how any conflict of interest issue has been managed, should be recorded in the minutes of the meeting and published in the registers.
- 60. CCGs will need to decide in advance who will take the chair's role for discussions and decision-making in the event that the chair of a meeting is conflicted, or how that will be decided at a meeting where that situation arises.
- 61. Depending on the nature of the conflict, GPs or other practice representatives could be permitted to join in discussions by the governing body, or such other decision-making body as the CCG has created, about the proposed decision, but should not take part in any vote on the decision.
- 62. In many cases, e.g., where a limited number of GPs have an interest, it should be straightforward for relevant individuals to be excluded from decisionmaking. In the context of delegated and joint commissioning, the committee structure set out below in relation to decision making for primary medical care below has been designed to ensure that lay member and executive involvement ensures that robust decisions can be taken even where there are actual or potential conflicts of interest identified.
- 63. In some cases, all of the GPs or other practice representatives on a decisionmaking body could have a material interest in a decision, e.g., where the CCG is proposing to commission services on a direct award basis from all GP practices in the area, or where it is likely that all or most practices would wish to be qualified providers for a service under AQP. Where such a situation relates to primary medical services, the arrangements set out below provide a mechanism for decision-making. (It could also be used for any other CCG

responsibilities where decision-making has been delegated to the committee responsible for primary medical care decision making and where such a conflict of interest arises).

- 64. For decision making where such a conflict arises and which are not covered by the primary medical care arrangements, CCGs are advised to:
  - where the initial responsibility for the decision does not rest with the governing body, refer the decision to the governing body and exclude all GPs or other practice representatives with an interest from the decisionmaking process, i.e., so that the decision is made only by the non-GP members of the governing body including the lay and executive members and the registered nurse and secondary care doctor;
  - where the decision rests with the governing body, consider
    - a) co-opting individuals from a Health and Wellbeing Board or from another CCG onto it (although care should be taken to ensure, particularly if the other CCG is from a nearby locality, that their representatives do not also have a conflict of interest and are not excluded from governing body membership under the relevant regulations. It would also be necessary for the CCG's constitution to allow such an arrangement); or
    - b) inviting the Health and Wellbeing Board or another CCG to review the proposal – to provide additional scrutiny. Any such arrangements would need to be compliant with the CCG's constitution; and
  - ensure that rules on quoracy (set out in the CCG's constitution) enable decisions to be made.
- 65. CCGs will need also to have arrangements in place where more than 50% of the members of a governing body or committee are prevented from taking a decision because of conflicted interests. Decisions could still be made by the remaining members of the governing body or committee (assuming that the meeting remains quorate), especially if constituted with lay, executive or other independent members. CCGs may need to have arrangements to secure additional external involvement in these decisions, perhaps through the involvement of a neighbouring CCG. These arrangements should be set out in the CCG's constitution.
- 66. Specific issues and potential approaches in relation to delegated or joint commissioning of primary care are set out below.

### Decision-making when a conflict of interest arises: primary

#### medical care

- 67. Procurement decisions relating to the commissioning of primary medical services should be made by a committee of the CCG's governing body. This should:
  - for joint commissioning take the form of a joint committee established between the CCG (or CCGs) and NHS England; and
  - in the case of delegated commissioning, be a committee established by the CCG.
- 68. In either case, the membership of the committee should be constituted so as to ensure that the majority is held by lay and executive members. In addition to existing CCG lay members, members may be drawn from the CCG's executive members, except where these members may themselves have a conflict of interest (e.g. if they are GPs or have other conflicts of interest). Provision could be made for the committee to have the ability to call on additional lay members or CCG members when required, for example where the committee would not be quorate because of conflicts of interest. It could also include GP representatives from other CCG areas and non-GP clinical representatives (such as the CCG's secondary care specialist and/or governing body nurse lead).
- 69. Any conflicts of interest issues would need to be considered on an individual basis. CCGs could also consider reciprocal arrangements with other CCGs in order to support effective clinical representation within the committee. The specific composition is a matter of determination for individual CCGs, subject to the provisions of their constitution. However, the chair and vice-chair must always be lay members of the committee.

#### Examples

- Regulations require that a CCG governing body has at least 6 members, including its chair and deputy chair. The members must include the CCG's Accountable Officer, chief financial officer, registered nurse, secondary care specialist and two lay members. The committee with responsibility for commissioning primary care could consist of the above plus GP members. If GP members had to withdraw from decision making for conflict of interest reasons, the committee would still be quorate with a lay and executive majority.
- Alternatively the committee could be made up of the CCG's two lay members, two additional lay people (not members or employees of the CCG), the chief financial officer, a GP member of the governing body and one other CCG member (executive or otherwise). That would create a committee of seven people and ensure that lay and executive membership was in the majority.

- 70. A standing invitation must be made to the CCG's local Healthwatch and Health and Wellbeing Board<sup>14</sup> to appoint representatives to attend commissioning committee meetings, including, where appropriate, for items where the public is excluded from a particular item or meeting for reasons of confidentiality. These representatives would not form part of the membership of the committee.
- 71. As a general rule, meetings of these committees, including the decisionmaking and the deliberations leading up to the decision, should be held in public (unless the CCG has concluded it is appropriate to exclude the public).<sup>15</sup>
- 72. In joint commissioning arrangements, the joint role of NHS England in decision-making will provide an additional safeguard in managing conflicts of interest. However, CCGs should still satisfy themselves that they have appropriate arrangements in place in relation to conflicts of interest with regard to their own role in the decision-making process.
- 73. CCGs may wish to include decisions on other commissioning issues within the remit of the committee. They also may wish to designate an existing committee to incorporate the above responsibilities within their remit. Where a CCG does this, they should ensure that the membership and chairing arrangements are compliant with the above requirements, or that, when dealing with primary care procurement issues, the participating membership and chairing arrangements are adjusted to meet these requirements. Where an existing committee is so designated, the above requirements on Healthwatch and Health and Wellbeing Board participation and on meeting in public would apply for co-commissioning decisions.
- 74. The arrangements for primary medical care decision making do not preclude GP participation in strategic discussions on primary care issues, subject to appropriate management of conflicts of interest. They apply to decision-making on procurement issues and the deliberations leading up to the decision.

#### **Record keeping**

75. As set out above a clear record of any conflicts of interest should be kept by the CCG in its register of interests. It must also ensure that it records procurement decisions made, and details of how any conflicts that arose in the context of the decision have been managed. These registers should be available for public inspection as detailed above.

<sup>&</sup>lt;sup>14</sup> Where there is more than one local Healthwatch or Health and Wellbeing Board for a CCG's area, the CCG should agree with them which should be invited to attend the committee.

<sup>&</sup>lt;sup>15</sup> As per the process for governing body meetings in paragraph 8(3), Schedule 1A of the NHS Act 2006 (as amended). In joint commissioning arrangements, NHS England should follow the process in the Public Bodies (Admission to Meetings) Act 1960.

76. CCGs should ensure that details of all contracts, including the contract value, are published on their website as soon as contracts are agreed.<sup>16</sup> Where CCGs decide to commission services through Any Qualified Provider (AQP), they should publish on their website the type of services they are commissioning and the agreed price for each service. Further, CCGs should ensure that such details are also set out in their annual report. Where services are commissioned through an AQP approach, they should ensure that there is information publicly available about those providers who qualify to provide the service.

#### **Role of commissioning support**

- 77. Commissioning support services (CSSs) can play an important role in helping CCGs decide the most appropriate procurement route, undertake procurements and manage contracts in ways that manage conflicts of interest and preserve integrity of decision-making. CCGs are advised to ensure that any services they commission from CSSs, or that they secure through inhouse provision, include this type of support. When using a CSS, CCGs should have systems to assure themselves that a CSS' business processes are robust and enable the CCG to meet its duties in relation to procurement (including those relating to the management of conflicts of interest).
- 78. Where a CCG is undertaking procurement, one way to demonstrate that the CCG is acting fairly and transparently is for the CSSs to prepare and present information on bids, including an assessment of whether providers meet prequalifying criteria and an assessment of which provider provides best value for money.
- 79. A CCG cannot, however, lawfully delegate commissioning decisions to an external provider of commissioning support. Although CSSs are likely to play a key role in helping to develop specifications, preparing tender documentation, inviting expressions of interest and inviting tenders, the CCG itself will need to:
  - determine and sign off the specification and evaluation criteria;
  - decide and sign off decisions on which providers to invite to tender; and
  - make final decisions on the selection of the provider.

#### **Role of NHS England**

80.NHS England will support CCGs, where necessary, in meeting their duties in relation to managing conflicts of interest. In the context of co-commissioning,

<sup>&</sup>lt;sup>16</sup> In doing so, CCGs will need to comply with the requirements of regulation 9 of the Procurement, Patient Choice and Competition Regulations.

NHS England will work with NHS Clinical Commissioners to develop a governance training programme for lay members to assist them with their role as members of joint or delegated commissioning committees. It will be important for CCGs to support their lay members to attend this training.

- 81.NHS England will also need to assure itself that CCGs are meeting their statutory duties in managing conflicts of interest, including having regard to the statutory guidance published by Monitor and NHS England. Where there are any concerns that a CCG is not meeting these duties, NHS England or Monitor could ask for further information or explanation from the CCG or take such other action as is deemed appropriate.
- 82. During 2015/16, NHS England will work with a randomly selected sample of a small number of CCGs who have taken on delegated or joint commissioning responsibilities in order to jointly review with them the effectiveness of this guidance and the practical experiences in implementing it. Further details of this process will be issued early in 2015.

#### **Transparency of GP earnings**

83. As previously advised<sup>17</sup>, in line with commitments on transparency of GP earnings, there will be a new contractual requirement for GP practices to publish on their practice website by 31 March 2016, the mean net earnings of GPs in their practice (to include contractor and salaried GPs) relating to 2014/15 financial year. Alongside the mean figure, practices must publish the number of full and part time GPs associated with the published figure. The figure will include earnings from NHS England, CCGs and local authorities for the provision of GP services that relate to the contract and which would have previously been commissioned by PCTs. Costs relating to premises will not be included. Fuller details will be included in the implementation guidance for the 2015/16 GP contract, due to be published in February 2015. This is an interim solution until arrangements are finalised for publishing individual GP net earnings in 2016/17.

#### Statement of conduct expected of individuals in the CCG

84. We recommend that CCGs set out in their constitution a statement of the conduct expected of individuals involved in the CCG, e.g. members of the governing body, members of committees and employees, which reflect the safeguards in this guidance. This should reflect the expectations set out in the *Standards for Members of NHS Boards and Clinical Commissioning Groups.*<sup>18</sup>

See Annex 4 for the procurement template

<sup>&</sup>lt;sup>17</sup> <u>http://www.england.nhs.uk/commissioning/gp-contract/</u>

<sup>&</sup>lt;sup>18</sup> http://www.professionalstandards.org.uk/docs/psa-library/november-2012---standards-for-board-members.pdf?sfvrsn=0

## Annexes

**Annex 1:** NHS Clinical Commissioners, Royal College of General Practitioners and British Medical Association principles on conflicts of interest

Annex 2: Declaration of conflict of interests for bidders/contractors template

Annex 3: Declaration of interests for members/employees template

Annex 4: Procurement template

Annex 5: 10 key questions for commissioners

**Annex 6:** Section 7 of Monitor's Substantive Guidance on the Procurement, Patient Choice and Competition Regulations

## Annex 1: NHS Clinical Commissioners, Royal College of General Practitioners and British Medical Association -Shared principles on conflicts of interest when CCGs are commissioning from member practices

December 2014

#### 1. Introduction

The ability for CCGs to become involved in co-commissioning General Practice and primary care services has the potential to bring many benefits but it also brings with it the potential for perceived and actual conflicts of interest.

NHS Clinical Commissioners (NHSCC), the Royal College of General Practitioners (RCGP) and the British Medical Association (BMA) have decided to collectively outline their high level starting principles in managing conflicts of interest when CCGs commission from member practices. In large part this has brought together principles articulated in previous lines/guidance/steer from the above organisations and NHS England.

Our principles are applicable to each of the three primary care commissioning models open to CCGs and should not be seen as being directive or be interpreted to mean that we prefer one model over another. These decisions need to remain a local, professionally led, decision.

In developing these shared principles we would like them to sit alongside NHS England's updated guidance on Managing Conflicts of Interest (December 2014). We are on a journey regarding the co-commissioning of primary care and we will review these principles when needed and as CCGs work through the guidance.

It should be noted that this paper is not designed to address the issue of perceived or actual conflicts of interest in CCGs holding and performance managing GP contracts under co-commissioning arrangements.

#### 2. Our headline shared principles around conflicts of interest

We collectively agree the following in relation to managing conflicts of interest when CCGs commission from member practices:

- If CCGs are doing business properly (needs assessments, consultation mechanisms, commissioning strategies and procurement procedures), then the rationale for what and how they are commissioning is clearer and easier to withstand scrutiny. Decisions regarding resource allocation should be evidence-based, and there should be robust mechanisms to ensure open and transparent decision making.
- CCGs must have robust governance plans in place to maintain confidence in the probity of their own commissioning, and maintain confidence in the integrity of clinicians.
- CCGs should assume that those making commissioning decisions will behave ethically, but individuals may not realise that they are conflicted, or lack awareness of rules and procedures. To mitigate against this, CCGs should ensure that formal prompts, training and checks are implemented to make sure people are complying with the rules. As a rule of thumb, 'if in doubt, disclose'
- CCGs should anticipate many possible conflicts when electing/selecting individuals to commissioning roles, and where necessary provide commissioners with training to ensure individuals understand and agree in advance how different scenarios will be dealt with.
- It is important to be balanced and proportionate the purpose of these tools is not to constrain decision-making to be complex or slow.

#### 3. Addressing perceived as well as actual conflicts of interest

Conflicts of interest in the NHS are not new and they are not always avoidable. The documents we reviewed to produce this paper were all clear that the existence of a conflict is not the same as impropriety and focus on how to avoid potential or perceived wrongdoing. Most importantly all acknowledge that perceived wrongdoing can be as detrimental as actual wrongdoing, and risks losing confidence in the probity of CCGs and the integrity of wider clinicians such as GPs in networks/federations, individual practices and partners.

The RCGP/NHS Confederation also notes evidence from the BMJ that people think they aren't biased by potential conflicts but often are so the common theme is - *if in any doubt it's important to disclose.* 

The RCGP/NHS Confederation and NHS England Guidance identify four types of potential conflict of interest:

- direct financial;
- indirect financial (for example a spouse has a financial interest in a provider);
- non-financial (i.e. reputation) and;
- loyalty (i.e., to professional bodies).

The BMA recognises that for CCGs there will be situations where the best decision for the population and taxpayers is not in the best interest of individual patients (for

whom GPs are required to advocate) and that this can create a perceived conflict. The RCGP/NHS Confederation paper acknowledges this but in terms of the governance when commissioning services.

#### 4. Planning for populations

CCGs must always demonstrate that their commissioned services meet the needs of their local populations, as such CCGs will need to work with their Health and Wellbeing Board's or other local strategic bodies to ensure there is alignment to local strategic plans.

What is clear from all the existing guidance is that CCGs will need to identify the situations where they are involving their governing body clinicians to strategically plan for their population, and situations where their governing body clinicians need to be separated from procurement, planning and decision-making processes. In the former it is critically important to secure clinical expertise. In the latter, the CCG will need to manage risks around perceived and actual conflicts in relation to the tendering of services.

The BMA outlines that decisions regarding resource allocation should be evidence based, and there should be robust mechanisms to ensure open and transparent decision making. As such, GP involvement must be agreed at each stage of the commissioning and procurement process so that potential risks of conflicts are appropriately defined and mitigated early on.

#### 5. Good practice - for CCGs

All the guidance suggests CCGs must have robust governance plans in place to maintain confidence in the probity of their own commissioning, and maintain confidence in the integrity of clinicians.

The RCGP/NHS Confederation suggests using existing NHS guidance as a starting point:

- Identify potential conflicts
- Declare interests in a register Exclude individuals from discussion or decision making if financial interest exceeds 1% equity in the provider organisation - depending on the nature of the discussion (we would also add that includes considering the share of the contract value to make sure there are no loopholes, this might also apply to practices with profit sharing arrangements).
- Continue to manage conflicts post-decision i.e. contract managing (carefully separating overall strategy development for populations from individual procurement processes. The former will be important for CCG lay involvement will be important and include secondary care clinicians and non-executive board nurses, the latter can be managed by managers).

NHS England guidance also says that an individual with a 'material interest' in an organisation which provides or is likely to provide significant business should not be member of CCG governing body. The BMA suggests anything above 5% equity is a material interest. The RCGP/NHS Confederation reference this threshold but also

say that something lower than a 1% stake could also be a material interest (if the size of the bid is significant).

Clearly these thresholds need to be considered in relation to individual practices and GP partners once co-commissioning is in place. The perceived risks must be recognised early on and we feel some worked case study examples would be helpful for CCGs as they work through the updated guidance. NHSCC, the RCGP and the BMA are planning to work with NHS England and Monitor to identify these examples.

NHSCC believe that CCG lay members, secondary care doctors and nurses on governing bodies play a vital role in both the design, implementation, leadership and monitoring of conflicts of interest systems and processes. They can provide robust challenge and ultimately a protection for GPs working in both the commissioning and provision of health care. Enabling them to carry out their roles in this regard is vital.

CCGs should also be proactive in their approach when considering conflicts when electing/selecting people, doing a proper induction (i.e. include continuous training and review at both Governing Body and membership (assembly level) and ensuring understanding from individuals, and agree in advance how different scenarios will be dealt with. The CCG should ensure individuals are prompted to declare an interest but not absolved from their responsibility to declare as well. Again, CCG lay members, secondary care doctors and nurse members of the governing body have a critical role in this process, as an independent arbiter and as those providing appropriate scrutiny and oversight.

NHS England's <u>Code of Conduct</u> guidance specifically explores when CCGs are commissioning services from their own GP member practices. When CCGs are commissioning from federations of practices, the same guidance should apply.

As practical support NHS England have also produced an updated code of conduct template for use when drawing up local plans (see their updated guidance). The template asks a series of questions to provide assurance to Health and Wellbeing Boards that the service meets local needs, and to the Audit Committee or external auditors that robust process was used to commission the service, select the appropriate procurement route and address potential conflicts of interest.

#### 6. Good practice - for individuals

The current guidance suggests that individuals making decisions in CCGs do so with the Nolan principles of public life in mind: selflessness, integrity, objectivity, accountability, openness, honesty, and leadership.

They also refer to the <u>guidance</u> the General Medical Council (GMC) has produced for doctors including:

- You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.
- If you are faced with a conflict of interest, you must be open about the conflict, declaring your interest informally, and you should be prepared to exclude yourself from decision making.

• You must not try to influence patients' choice of healthcare services to benefit you, someone close to you, or your employer. If you plan to refer a patient for investigation, treatment or care at an organization in.

NHS England guidance indicates that individuals must declare an interest as soon as they come aware of it, and within 28 days. More informally, the RCGP/NHS Confederation also suggested the simple 'Paxman test' - whether explaining the situation to an investigative reporter/journalist like Jeremy Paxman would cause embarrassment. We think it would be helpful to develop this type of text into a tool for CCGs to use locally.

NHS England guidance indicates that individuals must declare an interest as soon as they come aware of it, and within 28 days.

Finally, the BMA suggested that commissioner doctors:

- Declare all interests, even if they are potential conflicts or the individual is unsure whether it counts as a conflict, as soon as possible.
- Update a register of interests every three months.
- Doctors must be familiar with their organisation's formal guidance.
- If individual doctors have any questions, they should seek advice from colleagues, err on the side of being open about conflicts of interest, or seek external advice from professional or regulatory bodies.

In addition to the above, the RCGP suggests there should also be a requirement to update the register of interests if a material difference arises in the circumstances of an individual at any point.

#### 7. Procurement processes – CCGs and member practices

According to the BMA guidance, when CCGs are procuring community level services, these contracts are often below threshold requiring a competitive tender process.

There are a number of procurement options for CCGs in this situation – for example a few may include:

- 1. Competitive tender where GP practices are likely to bid
- 2. AQP where GP providers are likely to be among the qualified providers
- 3. Single tender from GP practices

From the guidance that exists different questions arise around conflicts of interest when the above procurement processes are used. For example:

- Identifying whether approaches such as AQP are being used with the safeguards to ensure that patients are aware of the choices available to them.
- If single tender is the route used, CCGs will need to demonstrate a few things

   depending on the nature of the procurement. For example that there are no
   other capable providers, why the successful bid was preferred to the others
   and the impact of disproportionate tendering costs. (Monitor's procurement
   guidance provides many useful steers on what CCGs will need to
   demonstrate)

For primary care co-commissioning, NHSCC believes one of the elements to include on procurement processes are the issues around standing financial orders and schemes of delegation which should not allow CCGs to divide primary care budgets into smaller budgets to circumvent the procurement process. NHSCC's lay member network will have examples/steer on the correct wording to use from previous local experiences.

Regardless of what the local application is the most important part of this process is transparency. NHS England says to set out the details, including the value of all contracts on the CCG website. If they are using AQP, the types and prices of services they are commissioning should be on the website. All of this information should also be in the CCG's annual report.

When making procurement decisions, the current guidance suggests that anyone with a perceived or material conflict should be excluded from decision making, either both excluded from voting or from discussion and voting. What is not clear in the guidance is how far back this rule goes – i.e. to the planning stage or just the development of the specification and procurement. CCGs will need to agree that line locally.

According to the reviewed guidance if all GPs and practice representatives due to make a decision are conflicted, then the CCG should be:

- Referring decisions to the governing body, so that lay members / the nurse / the secondary care doctor can make the final decision. However this may weaken GP clinical input into decision making.
- Co-opting individuals from the HWB or another CCG onto the governing body, or invite the HWB / another CCG to review proposal to provide additional scrutiny (these individuals would only be able to participate in decision making if this was set out in the CCG constitution)
- Ensure that quoracy rules enable decisions to be made in this circumstance
- Plan ahead to ensure that agreed processes are followed.
- Use an appropriately constituted arms-length external scrutiny committee to ensure probity (recommended by the BMA)

CCGs can use commissioning support services (CSS) to reduce potential conflicts, for example a CSS can help select the best procurement route and prepare bids etc. However, this cannot completely eliminate the conflict as CCGs are responsible for signing off specification and evaluation criteria, signing off which providers to invite to tender, and making the final decision on the selection of the provider. The CCG is responsible for ensuring that their CSS or other third parties are compliant with regulations in the same way that the CCG must be.

NHS England also suggest any questions about the service going beyond the scope of the GP contract should be discussed with NHS England area teams, clearly that would need review in light of new delegated co-commissioning arrangements.

#### Networks and Federations

We note that the increasing number of GP networks and federations could potentially present an added complication to local procurement processes. If most or all CCG

member practices are part of the local federation, then this could mean that a practice not part of the federation/excluded from a federation may not have the opportunity to win contracts through competitive tender – because the process is more suited to federated organisations. One way to mitigate this would be for the CCG to always design and procure service specifications according to best practice (with openness and transparency), thereby supporting all practices to bid. One area to be careful about is when all the GPs on a governing body have a declared interest in local federations – this makes decision making and accountability complex and the CCG will need to work that through carefully with the input of its lay members and wider clinicians on the governing body. Again, an external scrutiny committee with non-conflicted clinicians such as from a neighbouring CCG may be helpful.

#### 8. Local engagement

Separately, the BMA suggests that LMCs should be involved in CCGs either by formal consultation, a non-voting seat on governing body, or as an observer on governing body. They indicate that a non-voting governing body seat would be the best option. Neither of the other two papers we reviewed address this.

#### 9. Other conflicts of interest issues for consideration

#### Personal conflict

The RCGP/NHS Confederation highlight that in CCG governing bodies a personal conflict can arise because CCG leaders are elected by their constituent GP members. There could be a perception that CCG governing bodies are favouring the most vocal or influential of their GP practice members. Related to this is the potential indirect interest for elected GPs to build a constituency of supporters within their CCG.

The CCG is responsible for ensuring that their CSS or other third parties are compliant with regulations in the same way that the CCG must be.

NHS England guidance suggests that in the case of every GP governing body member being conflicted, the lay members, registered nurse and secondary care doctor make the decision (and that the constitution is written so that this is quorate). This could however mean that decisions would be taken without a GP perspective. Alternatively, CCGs may bring in members of the Health and Wellbeing Board or another CCG to provide oversight, or as the BMA suggests use an external scrutiny committee to make decisions.

#### Use of primary care incentive schemes

In its guidance, the BMA highlights its concerns about the professional and ethical implications of CCGs applying incentive schemes to reduce referral or prescribing activity. The BMA urges any doctor, whether commissioner or provider, to consider the schemes carefully and ensure that scheme is based on clinical evidence. NHSCC suggests that one solution is to ensure the expertise of secondary care clinicians and nurses on governing bodies plays an important part in providing clinical input and lay members can scrutinize commercial/ financial and performance data.

The RCGP acknowledge that it is not ethical to under-treat or under-refer for financial gain, but is not unethical to 'review and reflect' on variations in referral/prescribing rates and try to reduce referrals in line with evidence or best practice.

#### Note to the reader:

This paper has been developed from a review of three guidance documents and brings together previous lines/guidance from NHSCC, NHS England, the RCGP and the BMA.

- <u>BMA</u> 'Conflicts of interest in the new commissioning system: Doctors in commissioning roles' April 2013
- <u>RCGP/NHS Confederation</u> 'Managing conflicts of interest in clinical commissioning groups' September 2011
- <u>NHS England</u> 'Managing conflicts of interest: guidance for clinical commissioning groups.' March 2013 (includes Commissioning Board Document that precedes it). We have also read across the paper to the new version of this document published December 2014.

NHSCC have also supplemented the principles raised in this paper with some points for steer that have been raised by members of its lay member network.

## Annex 2: Declaration of conflict of interests for bidders/contractors template

#### NHS [geographical reference] Clinical Commissioning Group Bidders/potential contractors/service providers declaration form: financial and other interests

This form is required to be completed in accordance with the CCG's Constitution, and s140 of the NHS Act 2006 (as amended by the Health and Social Care Act 2012) and the NHS (Procurement, Patient Choice and Competition) (No2) Regulations 2013 and related guidance

#### Notes:

- All potential bidders/contractors/service providers, including sub-contractors, members of a consortium, advisers or other associated parties (Relevant Organisation) are required to identify any potential conflicts of interest that could arise if the Relevant Organisation were to take part in any procurement process and/or provide services under, or otherwise enter into any contract with, the CCG, or with NHS England in circumstances where the CCG is jointly commissioning the service with, or acting under a delegation from, NHS England. If any assistance is required in order to complete this form, then the Relevant Organisation should contact [*specify*].
- The completed form should be sent to [specify].
- Any changes to interests declared either during the procurement process or during the term of any contract subsequently entered into by the Relevant Organisation and the CCG must notified to the CCG by completing a new declaration form and submitting it to [*specify*].
- Relevant Organisations completing this declaration form must provide sufficient detail of each interest so that the CCG, NHS England and also a member of the public would be able to understand clearly the sort of financial or other interest the person concerned has and the circumstances in which a conflict of interest with the business or running of the CCG or NHS England (including the award of a contract) might arise.
- If in doubt as to whether a conflict of interests could arise, a declaration of the interest should be made.

Interests that must be declared (whether such interests are those of the Relevant Person themselves or of a family member, close friend or other acquaintance of the Relevant Person), include the following:

 the Relevant Organisation or any person employed or engaged by or otherwise connected with a Relevant Organisation (Relevant Person) has provided or is providing services or other work for the CCG or NHS England;

- a Relevant Organisation or Relevant Person is providing services or other work for any other potential bidder in respect of this project or procurement process;
- the Relevant Organisation or any Relevant Person has any other connection with the CCG or NHS England, whether personal or professional, which the public could perceive may impair or otherwise influence the CCG's or any of its members' or employees' judgements, decisions or actions.

#### **Declarations:**

Name of Relevant Organisation:		
Interests		
Type of Interest	Details	
Provision of services or other work for the CCG or NHS England		
Provision of services or other work for any other potential bidder in respect of this project or procurement process		
Any other connection with the CCG or NHS England, whether personal or professional, which the public could perceive may impair or otherwise influence the CCG's or any of its members' or employees' judgements, decisions or actions		

Name of Relevant Person	[complete for all Relevant Persons]	
Interests		
Type of Interest	Details	Personal interest or that of a family member, close friend or other acquaintance?
Provision of services or other work for the CCG or NHS England		
Provision of services or other work for any other potential bidder in respect of this project or procurement process		
Any other connection with the CCG or NHS England, whether personal or professional, which the public could perceive may impair or otherwise influence the CCG's or any of its members' or employees' judgements, decisions or actions		

To the best of my knowledge and belief, the above information is complete and correct. I undertake to update as necessary the information.

Signed:

On behalf of:

Date:

# Annex 3: Declaration of interests for members/employees template

NHS [geographical reference] Clinical Commissioning Group Member / employee/ governing body member / committee or sub-committee member (including committees and sub-committees of the governing body) [delete as appropriate] declaration form: financial and other interests

This form is required to be completed in accordance with the CCG's Constitution and section 14O of *The National Health Service Act 2006, the NHS (Procurement, Patient Choice and Competition) regulations 2013 and the Substantive guidance on the Procurement, Patient Choice and Competition Regulations* 

# Notes:

- Each CCG must make arrangements to ensure that the persons mentioned above declare any interest which may lead to a conflict with the interests of the CCG and /or NHS England and the public for whom they commission services in relation to a decision to be made by the CCG and/or NHS England or which may affect or appear to affect the integrity of the award of any contract by the CCG and/or NHS England.
- 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 [*specify*].
- The completed form should be sent by both email and signed hard copy to [*specify*].
- 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 [specify how, or how otherwise made available to the public and whether there will be any circumstances where information will be redacted].
- Any individual and in particular members and employees of the CCG and/or NHS England- must provide sufficient detail of the interest, and the potential for conflict with the interests of the CCG and/or NHS England 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.

Interests that must be declared (whether such interests are those of the individual themselves or of a family member, close friend or other acquaintance of the individual) include:

- roles and responsibilities held within member practices;
- directorships, including non-executive directorships, held in private companies or PLCs;

- ownership or part-ownership of private companies, businesses or consultancies likely or possibly seeking to do business with the CCG and /or with NHS England
- shareholdings (more than 5%) of companies in the field of health and social care;
- a position of authority in an organisation (e.g. charity or voluntary organisation) in the field of health and social care;
- any connection with a voluntary or other organisation (public or private) contracting for NHS services;
- research funding/grants that may be received by the individual or any organisation in which they have an interest or role;
- any other role or relationship which the public could perceive would impair or otherwise influence the individual's judgment or actions in their role within the CCG.

If there is any doubt as to whether or not an interest is relevant, a declaration of the interest must be made.

#### Name: Position within or relationship with, the CCG or NHS **England:** Interests Type of Interest Details Personal interest or that of a family member, close friend or other acquaintance? Roles and responsibilities held within member practices Directorships, including nonexecutive directorships, held in private companies or PLCs **Ownership or part**ownership of private companies, businesses or consultancies likely or possibly seeking to do business with the CCG and/or with **NHS England**

#### **Declaration:**

Shareholdings	
(more than 5%) of	
companies in the field of health and	
social care	
Positions of	
authority in an	
organisation (e.g.	
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	
[Other specific interests?]	
Any other role or	
relationship which	
the public could	
perceive would	
impair or otherwise influence the	
individual's	
judgment or	
actions in their role within the CCG	
and/or with NHS	
England.	

To the best of my knowledge and belief, the above information is complete and correct. I 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 CCG's Constitution and published accordingly.

Signed:

Date:

# **Annex 4: Procurement template**

#### Template

[To be used when commissioning services from GP practices, including provider consortia, or organisations in which GPs have a financial interest]

# NHS [geographical reference] Clinical Commissioning Group

Question	Comment/Evidence
How does the proposal deliver good or improved outcomes and value for money – what are the estimated costs and the estimated benefits? How does it reflect the CCG's proposed commissioning priorities? How does it comply with the CCG's commissioning obligations?	
How have you involved the public in the decision to commission this service?	
What range of health professionals have been involved in designing the proposed service?	
What range of potential providers have been involved in considering the proposals?	
How have you involved your Health and Wellbeing Board(s)? How does the proposal support the priorities in the relevant joint health and wellbeing strategy (or strategies)?	
What are the proposals for monitoring the quality of the service?	
What systems will there be to monitor and publish data on referral patterns?	

Have all conflicts and potential conflicts of interests been appropriately declared and entered in registers which are publicly available? Have you recorded how you have managed any conflict or potential conflict?	
Why have you chosen this procurement route? <sup>19</sup>	
What additional external involvement will there be in scrutinising the proposed decisions?	
How will the CCG make its final commissioning decision in ways that preserve the integrity of the decision-making process and award of any contract?	

Additional question when qualifying a provider on a list or framework or pre selection for tender (including but not limited to any qualified provider) or direct award (for services where national tariffs do not apply)

How have you determined a fair price for the service?

Additional questions when qualifying a provider on a list or framework or pre selection for tender (including but not limited to any qualified provider) where GP practices are likely to be qualified providers

How will you ensure that patients are aware of the full range of qualified providers from whom they can choose?

Additional questions for proposed direct awards to GP providers		
What steps have been taken to demonstrate that the services to which the contract relates are capable of being provided by only one provider?		
In what ways does the proposed service go above and beyond what GP practices should be expected to provide under the GP contract?		

<sup>&</sup>lt;sup>19</sup>Taking into account all relevant regulations (e.g. the NHS (Procurement, patient choice and competition) (No 2) Regulations 2013 and guidance (e.g. that of Monitor).

# **Annex 5: 10 key questions**

These questions are provided as a prompt to CCGs in considering key issues when reviewing their current arrangements for managing conflicts of interest.

- Do you have a process to identify, manage and record potential (real or perceived) conflicts of interest that could affect, or appear to affect, the integrity of an award of a contract, including those that could arise in relation to cocommissioning of primary care?
- 2. How will the CCG make its final commissioning decisions in ways that preserve the integrity of the decision-making process?
- 3. Have all conflicts and potential conflicts of interests been appropriately declared and entered in registers, including an explanation of how the conflict has been managed?
- 4. Have you made arrangements to make registers of interest accessible to the public?
- 5. Have you set out how you will you ensure fair, open and transparent decisions about:
  - priorities for investment in new services
  - the specification of services and outcomes
  - the choice of procurement route?
- 6. How will you involve patients, and the public, and work with your partners on the Health and Wellbeing Boards and providers (old and new) in informing these decisions?
- 7. What process will you use to resolve disputes with potential providers?
- 8. Have you summarised your intended approach in your constitution, and thought through how your governing body will be empowered to oversee these systems and processes both how they will be put in place and how they will be implemented?
- 9. What systems will there be to monitor the patterns of decision making and how any conflicts of interest were managed?
- 10. Has your decision making body identified and documented in the constitution the process for remaining quorate where multiple members are conflicted?

# Annex 6: Section 7 of Monitor's Substantive Guidance on the Procurement, Patient Choice and Competition Regulations

# 7.1 Introduction

This section provides guidance for commissioners on handling conflicts of interest. Regulation 6(1) of the Procurement, Patient Choice and Competition Regulations prohibits commissioners from awarding a contract for NHS health care services where conflicts, or potential conflicts, between the interests involved in commissioning such services and the interests in providing them affect, or appear to affect, the integrity of the award of that contract.

Regulation 6(2) requires commissioners to maintain a record of how any conflicts that have arisen have been managed.

S.14O of the National Health Service Act 2006 includes further requirements relating to conflicts of interest. Guidance on how to comply with these requirements (including managing conflicts of interest) has been published by NHS England and is available on NHS England's website.

Members of commissioning organisations that are registered doctors will also need to ensure that they comply with their professional obligations, including those relating to conflicts of interest. These are described in the General Medical Council's guidance, *Good Medical Practice* and *Financial and commercial arrangements and conflicts of interest.* These are available on the General Medical Council's website.

## 7.2 What is a conflict?

Broadly, a conflict of interest is a situation where an individual's ability to exercise judgment or act in one role is/could be impaired or influenced by that individual's involvement in another role.

For the purposes of Regulation 6, a conflict will arise where an individual's ability to exercise judgment or act in their role in the **commissioning of services** is impaired or influenced by their interests in the **provision of those services**.

## 7.3 What constitutes an interest?

Regulation 6 of the Procurement, Patient Choice and Competition Regulations makes it clear that an interest includes an interest of:

• a member of the commissioner;

- a member of the governing body of the commissioner;
- a member of the commissioner's committees or sub-committees, or committees or sub-committees of its governing body; or
- an employee.

Other interests that might give rise to a conflict include the interests of any individuals or organisations providing commissioning support to the commissioner, such as CSUs, who may be in a position to influence the decisions reached by the commissioner as a result of their role.

# 7.4 What interests in the provision of services may conflict with the interests in commissioning them?

A range of interests in the provision of services may give rise to a conflict with the interests in commissioning them, including:

- **Direct financial interest** for example, a member of a CCG or NHS England who has a financial interest in a provider that is interested in providing the services being commissioned or that has an interest in other competing providers not being awarded a contract to provide those services. Financial interests will include, for example, being a shareholder, director, partner or employee of a provider, acting as a consultant for a provider, being in receipt of a grant from a provider and having a pension that is funded by a provider (where the value of this might be affected by the success or failure of the provider).
- Indirect financial interest for example, a member of a CCG or NHS England whose spouse has a financial interest in a provider that may be affected by a decision to reconfigure services. Whether an interest held by another person gives rise to a conflict of interests will depend on the nature of the relationship between that person and the member of the CCG or NHS England. Depending on the circumstances, interests held by a range of individuals could give rise to a conflict including, for example, the interests of a parent, child, sibling, friend or business partner.
- Non-financial or personal interests for example, a member of a CCG or NHS England whose reputation or standing as a practitioner may be affected by a decision to award a contract for services or who is an advocate or representative for a particular group of patients.
- **Professional duties or responsibilities.** For example, a member of a CCG who has an interest in the award of a contract for services because of the interests of a particular patient at that member's practice.

Commissioners will also need to consider whether any previous or prospective roles or relationships may give rise to a conflict of interest. A conflict of interest may arise, for example, where a person has an expectation of future work or employment with a provider that is bidding for a contract.

### 7.5 Conflicts that affect or appear to affect the integrity of an award

Even if a conflict of interest does not actually affect the integrity of a contract award, a conflict of interest that appears to do so can damage a commissioner's reputation and public confidence in the NHS. Regulation 6 of the Procurement, Patient Choice and Competition Regulations therefore also prohibits commissioners from awarding contracts in these circumstances.

As well as affecting the decision to award a contract and to which provider, a conflict of interest may affect a variety of decisions made by a commissioner during the commissioning cycle in a way that affects, or appears to affect, the integrity of a contract award decision taken at a later point in time. For example, conflicts of interest might affect the prioritisation of services to be procured, the assessment of patients' needs, the decision about what services to procure, the service specification/design, the determination of qualification criteria, as well as the award decision itself.

Conflicts might arise in many different situations. A conflict of interest might arise, for example where the spouse of a staff member of a local area team at NHS England is employed by a provider that is bidding for a contract. A conflict could also arise where a CCG is deciding whether to procure particular services from GP practices in the area or from a wider pool of providers, or where it is deciding whether to commission services that would reduce demand for services provided by GP practices under the NHS General Medical Services contract.

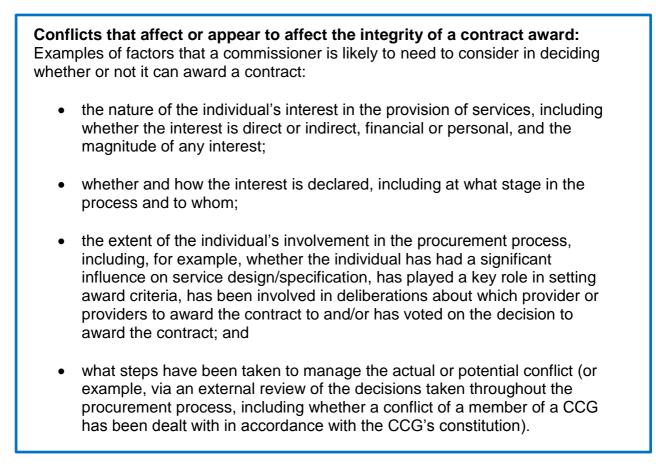
Depending on the circumstances of the case, there may be a number of different ways of managing a conflict or potential conflict of interest in order to prevent that conflict affecting or appearing to affect the integrity of the award of the contract.

It will often be straightforward to exclude a conflicted individual from taking part in decisions or activities where that individual's involvement might affect or appear to affect the integrity of the award of a contract. The commissioner will need to consider whether in the circumstances of the case it would be appropriate to exclude the individual from involvement in any meetings or activities in the lead up to the award of a contract in relation to which the individual is conflicted, or whether it would be appropriate for the individual concerned to attend meetings and take part in discussions, having declared an interest, but not to take part in any decision-making (not having a vote in relation to relevant decisions). It is difficult to envisage circumstances where it would be appropriate for an individual with a material conflict of interest to vote on relevant decisions.

Where it is not practicable to manage a conflict by simply excluding the individual concerned from taking part in relevant decisions or activities, for example because of the number of conflicted individuals, the commissioner will need to consider alternative ways of managing the conflict. For example, depending on the circumstances of the case, it may be possible for a CCG to manage a conflict affecting a substantial proportion of its members by:

- involving third parties who are not conflicted in the decision-making by the CCG, such as out-of-area GPs, other clinicians with relevant experience, individuals from a Health and Wellbeing Board or independent lay persons; or
- inviting third parties who are not conflicted to review decisions throughout the process to provide ongoing scrutiny, for example the Health and Wellbeing Board or another CCG.

Whether a conflict of interests affects or appears to affect the integrity of a contract award (such that the commissioner may not award the contract) will depend on the circumstances of the case. The list of factors in the box below is not exhaustive, but covers some of the core factors that a commissioner is likely to need to consider in deciding whether it is appropriate to award a contract. See box below.



#### 7.6 Recording how conflicts have been managed

Regulation 6 of the Procurement, Patient Choice and Competition Regulations also requires commissioners to maintain a record of how any conflicts that have arisen have been managed.

Commissioners will need to include all relevant information to demonstrate that the conflict was appropriately managed. See box below.

#### Examples of what information a record might contain:

Commissioners might include the following information in a record of how a conflict of interest has been managed:

- the nature of the individual's interest in the provision of services, including whether the interest is direct or indirect, financial or personal, and the magnitude of any interest;
- whether and how the interest is declared, including at what stage in the process and to whom;
- the extent of the individual's involvement in the procurement process, including, for example, whether the individual has had a significant influence on service design/specification, has played a key role in setting award criteria, has been involved in deliberations about which provider or providers to award the contract to and/or has voted on the decision to award the contract; and
- what steps have been taken to manage the actual or potential conflict (or example, via an external review of the decisions taken throughout the procurement process, including whether a conflict of a member of a CCG has been dealt with in accordance with the CCG's constitution).