

Draft revised statutory guidance on managing conflicts of interest for CCGs: feedback report



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Introduction

1. In December 2014, NHS England published *statutory guidance on managing conflicts of interest for CCGs* to support the delegation of primary care commissioning to CCGs. An audit of conflicts of interest management in co-commissioning arrangements was undertaken in 2015/16 and in light of the findings, NHS England proposed a strengthened CCG framework for managing conflicts of interest at its March Board. *Draft revised statutory guidance on managing conflicts of interest for CCGs* was published for consultation between 1 and 29 April.
2. The guidance is being strengthened as part of a system-wide governance project aimed at strengthening conflicts of interest management across the NHS. As part of this project, a cross-system task and finish group, chaired by Sir Malcolm Grant, has been established. The purpose of this group will be to work with system partners to help establish a set of rules that can be applied consistently right across the health system.
3. The key proposed changes to the 2014 guidance included:
 - Increasing lay representation on CCG governing bodies to support with the management of conflicts of interest;
 - Introducing a conflicts of interest guardian in CCGs to act as a key point of contact for any issues;
 - Requiring CCGs to include an annual audit of conflicts of interest management within their internal audit plans and to publish the audit findings within their annual end-of-year governance statement;
 - Strengthening the provisions around gifts and hospitality;
 - Strengthening provisions around decision-making when a member of the group is conflicted;
 - Requiring CCGs to have a robust conflicts of interest breach policy and to publish any breaches on their website; and
 - Requiring all CCG staff and staff of their member practices to complete mandatory conflicts of interest on-line training on an annual basis.

We also invited specific feedback on the provisions in:

- Paragraphs 32 to 33 on declarations of interest and how best to collate this information from practices;
 - Paragraph 61 on supporting the recruitment of additional lay members;
 - Paragraph 87 on GP membership and voting rights in the primary care commissioning committee; and
 - Paragraphs 143 to 146 on conflicts of interest training and support.
4. This report summarises the responses received to the engagement exercise by theme. We would like to thank everyone who has shared feedback on the guidance.

Overview of the engagement exercise

5. NHS England's co-commissioning team managed the engagement exercise. The draft guidance was published on NHS England's website and shared with national partners and other interested groups by email. To raise further awareness, we delivered a number of presentations on the guidance and participated in a joint webinar with NHS Clinical Commissioners, specifically for CCG lay members.
6. We have received a total of 64 responses by email, online and via face-to-face meetings. This included from:
 - British Medical Association (BMA)/General Practitioners Committee (GPC);
 - 38 CCGs;
 - Department of Health (DH);
 - General Medical Council (GMC);
 - Healthwatch England;
 - Healthcare Financial Management Association (HFMA);
 - 9 individuals
 - 2 Local Medical Committees (LMC);
 - National Audit Office (NAO);
 - NHS Clinical Commissioners (NHS CC);
 - NHS England's working group for public participation in primary care;
 - NHS Improvement;
 - NHS Protect;
 - Pharmaceutical Services Negotiation Committee (PSNC);
 - Royal College of General Practitioners (RCGP);
 - The Association of the British Pharmaceutical Industry (ABPI);
 - 2 trade organisations.
7. The main feedback related to:
 - Declarations of interest;
 - Appointment of a third lay member;
 - Introduction of a Conflicts of Interest Guardian;
 - Chairing arrangements and decision-making processes;
 - Voting arrangements on the primary care commissioning committee and establishment of a separate GP-led clinical advisory committee; and
 - Conflicts of interest online training.
8. We have carefully considered all responses to inform the development of final *statutory guidance on managing conflicts of interest for CCGs*. This will be published in June 2016.

Summary of feedback

General themes

9. The draft revised guidance has been well received by CCGs and national partners. It was recognised that the current guidance needed to be strengthened in light of the changing role of CCGs, particularly in relation to primary care commissioning.
10. Proportionality has been a common theme in the feedback with some stakeholders favouring greater prescription, and others a more principle-based approach to conflicts of interest management.
11. It was recommended that the guidance emphasises more strongly the value of clinicians in commissioning. Concerns were raised about some of the language used in the guidance. It was seen as important to emphasise that the focus of the guidance is on prevention. It was also recommended that we clarify from the onset that conflicts of interest do not only affect clinical colleagues but any individual.
12. We have received requests for further guidance on the management of conflicts of interest in integrated care systems.

We will develop supplementary guidance in the autumn of 2016/17 to specifically address further developments in care models and integrated care organisations.

13. The RCGP recommended that any guidance on conflicts of interest provided to CCGs should be compatible with local authority guidance and practices within the local Health and Wellbeing Boards.

We have shared this recommendation with the cross-NHS task and finish group for review.

Definition of an interest

14. There were a number of proposed amendments to the definition of an interest:
 - It was felt that the list of financial interests should be extended to cover the receipt of all forms of payment from a conflicted organisation (e.g., day allowances, travel and subsistence or Honoria).
 - There was a request for the term “secondary employment” to be changed to “secondary income” so that it encompassed retainers, medical cover etc.
 - With regards to shareholdings, the 5% threshold for declaring interests was considered to be too high, particularly in the context of GP federations. There were also calls for shareholdings owned by immediate relatives to be declared.
 - Greater clarity was also requested on how GPs should manage declarations in respect of their partnership interests.

We have strengthened the guidance to provide greater clarity on the issues raised. We have revised the requirements around shareholdings to require that all shareholdings in health and care organisations must be declared. We consider this to be a simpler approach.

Principles

15. There was general support for the principles set out in the guidance:
16. One respondent requested the introduction of a standardised set of principles for the NHS to draw together the Nolan Principles¹, the Equality Act 2010² and the seven key principles of the NHS constitution³ etc. ***We agree that this would be helpful, but it goes beyond the scope of this guidance. We have shared this recommendation with the cross-NHS task and finish group for consideration.***

Declaring interests and register(s) of interests

17. Whilst the importance of declaring interests was recognised, concerns were raised about the extra work this would create for CCGs.
18. It was generally considered to be impractical to require all practice staff to declare interests. There were concerns that practices would find this bureaucratic and it would divert clinicians from the delivery of patient care. CCGs indicated this requirement would be difficult to administer, time consuming and resource intensive. The general view was that declarations of interest should only be collated from practice staff who are involved in CCG decision-making e.g., those who attend CCG locality boards, membership councils, committees etc.
19. Regarding the requirement for individuals to declare interests on a quarterly basis, some CCGs considered this to be excessive, with one CCG recommending that the process be undertaken annually. Another CCG considered the requirement for staff to provide a “nil” return (to indicate where there are no changes to their interests) to be disproportionate.
20. There were divergent views on whether practice declarations of interest should be displayed on CCGs’ websites or practices’ own websites.
21. There was also a recommendation that individuals declare interests they are pursuing and not just when they have arisen. There was also a recommendation for an online resource for declaring interests.

In light of the feedback received, we have amended the guidance to require only practice staff with involvement in CCG business or CCG decision-making processes to declare interests. Interests should be

¹ The 7 principles of public life <https://www.gov.uk/government/publications/the-7-principles-of-public-life>

² The Equality Act 2010 <http://www.legislation.gov.uk/ukpga/2010/15/contents>

³ The seven key principles of the NHS Constitution

<http://www.nhs.uk/NHSEngland/thenhs/about/Pages/nhscoreprinciples.aspx>

declared to the CCG, who should record them on their registers of interest. We have updated the guidance to clarify that interests being pursued should also be recorded and we are considering further the suggestion of an online system to collate declarations of interest.

In light of the feedback received and in order to reduce the administrative burden on CCGs, we have revised the guidance to require that CCGs update their registers of interest on a six-monthly basis as a minimum, but that individuals should be required to bring to the CCG's attention any change of declaration of interests in the intervening period.

Conflicts of interest registers

22. There were divergent views over the appropriateness of requiring individuals to record "actions to mitigate the risk" of the conflicts of interest. One respondent felt it would be helpful, but only if the actions were agreed with a senior manager in the CCG. Two CCGs felt it would be disproportionate and impractical since interests need to be managed on a case-by-case basis. One recommendation was to record the actions in meeting minutes and the register of procurement decisions.

We have reviewed the feedback received, but consider it to be important that conflicts of interest registers outline mitigating actions to provide transparency. We also consider this to be in the public's interests.

Registers of gifts and hospitality

23. The majority of stakeholders welcomed the gifts and hospitality register:
24. Two CCGs reported that they already routinely publish their register of gifts and hospitality online and there was general support for the principle of declining all cash gifts. It was requested that declarations of gifts and hospitality be limited to those received in relation to an individual's CCG role, and not their practice role. There were requests for further clarity on the requirements for one-off payments and honorariums for secondary employment or voluntary work.
25. NHS CC reported that its members felt that gifts and hospitality should be considered separately to wider conflicts of interest. They also felt the definition was too broad and that the maintenance of a full register, not only of goods received, but also offered, will place an excessive burden on individuals and CCGs.

We have considered the feedback received and clarified the requirements in relation to one-off payments and honorariums.

26. There was support for proactively publishing registers of CCGs' websites. However, one CCG recommended not publishing staff data for individuals working at band 7 or below to protect staff privacy and reduce administration.

We have reviewed this issue and consider that all staff should be included in a CCG's register of interest, since conflicts of interest can arise in any role. The guidance includes provisions for the redaction of an individual's name where the public disclosure of this information could give rise to a real risk of harm or is prohibited by the law (e.g., data protection and privacy laws).

Appointments and roles and responsibilities in the CCG

27. Greater clarity was requested on the definition of secondary employment, particularly in relation to short-term, temporary and contract roles, as well as governing body members with other interests such as directorships in GP federations.

We have clarified the definition of secondary employment in the guidance.

28. The Pharmaceutical Services Negotiation Committee (PSNC) recommended that all providers be excluded from governing body level appointments to avoid conflicts or perceived conflicts of interest.

We do not support this recommendation since it would exclude all practising GPs and clinicians from the CCG's governing body and significantly reduce clinical input in decision-making processes. We consider clinical input to be vital in commissioning.

CCG lay members

29. Many respondents supported the recommendation for CCGs to have three lay members, including the GMC, RCGP and NHS Protect.
30. There were requests for the third lay member to be compulsory, due to concerns that a voluntary status could undermine their role, particularly from a voting perspective.
31. NHS CC raised concerns about the cost implications of this requirement for CCGs, but reported that 64% of the CCGs they surveyed already had three or more lay members on the governing body. NHS CC suggested that we instead agree the number of hours lay members are expected to work.
32. It was recognised that it can be challenging in some parts of the country to recruit lay members. Views were divergent over whether CCGs should consider "sharing" lay members:
- The majority of respondents considered shared membership could bring useful additional insight and experience. It was felt to be a pragmatic and flexible approach, which could minimise costs.
 - Two respondents felt the option of 'sharing' lay members could have an impact upon the impartiality of the additional member.

33. It was felt to be important that the additional lay member meets the statutory eligibility criteria and has the requisite geographical knowledge and local insight to support decision-making.
34. It was considered important that lay members are supported in their role through training, to ensure they are confident and assertive when they perceive that there may be a conflict of interest.

We have considered the feedback and regard the recommended appointment of a third lay member to be an important addition to the guidance. We do not consider it to be appropriate for NHS England to set a minimum expectation of how many hours a CCG lay member should work, as this will be dependent upon the CCG's context.

We have clarified in the guidance that CCGs could consider sharing lay members in their STP footprint, provided those lay members have the requisite local knowledge and insight.

Conflicts of Interest Guardian

35. The introduction of a conflicts of interest guardian was generally well-received.
36. NHS CC reported that the majority of their members felt the audit chair was best placed to undertake this role. This view was supported by other organisations.
37. Some concerns were raised about the title, specifically that it could lead to the Conflicts of Interest Guardian being perceived to have an operational, rather than strategic role, in managing day-to-day conflicts of interest issues. Further, it was felt that conflicts of interest management was already part of an audit chair's role and did not warrant a separate title.
38. NHS CC recommended the appointment of a national lead for the management of competing interests, gifts and hospitality to provide support across the whole system, act as a focal point for decision-making and provide guidance on challenges as they arise. CCG lay members also recommended the establishment of a "hotline" where they can contact a member of the NHS England conflicts of interest team directly.
39. Given that some audit chairs only work a few days per month, there were a number of recommendations for a second CCG lead to be identified as a key point of contact for conflicts of interest matters.

We agree that the CCG audit chair is best placed to hold the position of Conflicts of Interest Guardian. We have further clarified that the role of the Conflicts of Interest Guardian is strategic and intended to support with the resolution of any conflicts of interest issues. We have recommended that the CCG's governance lead or equivalent be the day-to-day contact for general conflicts of interest matters.

We have shared the recommendation for the appointment of a national lead for the management of conflicts of interest with the cross-NHS task and finish group for consideration.

Primary Care Commissioning Committee Chair

40. Two respondents raised concerns over the requirement for the CCG audit chair not to hold the position of chair of the primary care commissioning committee, due to there being a limited pool of CCG lay members.
41. One respondent was supportive of the requirement, but recommended that the audit chair assume the position of vice-chair of the committee given their expertise. This respondent indicated that it was unlikely a CCG could allocate three lay members to each primary care commissioning committee due to competing priorities.

Our view remains that the CCG audit chair should not chair the primary care commissioning committee, but could in special circumstances assume the role of vice-chair. We have maintained the recommendation that three lay members attend the primary care commissioning committee, but recognise this may not be possible for all CCGs depending upon their local circumstances.

Managing conflicts of interest at meetings

Chairing arrangements and decision-making processes

42. The importance of maintaining a strong clinical voice in commissioning was emphasised.
43. NHS CC also highlighted the importance of differentiating between procurement and commissioning decision-making. It was recognised there needs to be a balance between good clinical input at a strategic level and the need for public assurance about the probity of procurement decision-making.
44. Views were divergent on whether conflicted members should be allowed to remain in meetings:
 - One CCG argued that a member should be able to remain in the meeting if their interest has been fully declared and if the potential conflict is judged to be small and indirect by the Conflicts of Interest Guardian and if the conflict can be managed effectively and transparently in the discussion.
 - PSNC argued that those who are conflicted should not be permitted to sit in the part of a meeting in which the conflicted issues are discussed. This view was supported by one CCG who argued that the conflicted member could in theory exert undue influence on proceedings by remaining in the room.

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- NHS Protect raised concerns that the attendance of conflicted persons at meetings could put an additional burden on the other attendees to challenge colleagues.

We consider clinical involvement in commissioning to be critical and regard the requirements set out in the guidance to be proportionate. We maintain the recommendation that the chair must ultimately decide on how to manage the conflict, which could include requiring a conflicted individual not to attend the meeting, requiring them to leave the discussion when the relevant matters are being discussed or to leave the meeting at the point of decision-making.

Primary care commissioning committees and sub-committees

45. There were divergent views on the establishment of a separate clinical advisory committee to the primary care commissioning committee:

- The GPC were supportive of the creation of an arms-length "external scrutiny committee", constituted with membership that included non-conflicted GPs from outside the CCG area. The establishment of a GP-led clinical advisory committee was similarly supported by PSNC and the HFMA. It was felt this committee would help to clearly delineate GPs' roles and minimise public perception of conflicts of interest. One CCG reported it already had a separate committee in place.
- The majority of CCGs did not support the proposal to establish a separate GP-led "Clinical Advisory Sub-Committee", considering it unnecessary and an administrative burden. Further, concerns were raised that it would remove GPs from discussions at the primary care commissioning committee where their specific expertise was needed.

46. Views were also divergent over whether GPs should have voting rights on the primary care commissioning committee:

- Some CCGs argued that GPs should have a voting right on the committee to ensure strong clinical input, but withdraw from the meeting when conflicts arise. There were concerns that it was unfair to expect GPs to have accountability at the primary care commissioning committee without having voting rights.
- Some CCGs reported that their GPs do not have voting rights and this was operating well in practice.

47. Only one response was received on the requirement for sub-committees/sub-groups to submit minutes to the primary care commissioning committee. The respondent considered this good governance practice.

In light of the feedback, we will retain the recommendation that primary care commissioning committees have clinical representation, but would

support the establishment of GP-led clinical advisory committees if CCGs consider this to be appropriate to their local circumstances.

To give greater confidence to the public in the probity of decision-making and to protect GPs, we maintain the recommendation that GPs should not be voting members of the primary care commissioning committee.

Managing conflicts of interest throughout the commissioning cycle

48. It was noted that the commissioning cycle is not just about procurement and that there are a number of other roles that CCGs perform where conflicts may arise, and in which members should be aware of their wider legal responsibilities.
49. There was a request for more guidance on how and when GPs should cease to be involved in the stages of working up a proposal to commission a service e.g., at the stage of setting priorities ahead of working up proposals.
50. There was support for the publication of a register of procurement decisions, as representing good practice. There was a request that the register should also set out the identity of officers and staff involved in a procurement decision to help allay any concerns that the decisions were biased by an individual participating in that exercise.

We have strengthened this section of the guidance in light of the issues raised.

Internal audit

51. There was agreement that conflicts of interest should feature in the audit cycle. Two CCGs supported an annual review, but two CCGs considered it should not automatically receive an annual priority unless the risk profile of the individual organisation warranted it.
52. There was a request for a standard national audit programme, with clarity on the scope of the audit and how many 'audit days' need to be allocated to its completion.

We consider the introduction of an annual conflicts of interest audit to be an important safeguard. To make the process as easy as possible for CCGs, we will develop a standardised template for the audit. This will be published in the summer 2016.

Raising concerns and breaches

53. NHS Protect welcomed the publication of breaches on CCGs' websites, the annual audit and the end-of-year governance statement "as a substantial step

towards a more uniform approach across CCGs". A number of CCGs supported the approach as a means of increasing transparency.

54. DH highlighted the importance of framing this requirement in a way that does not deter staff from declaring interests or breaches.
55. NHS CC raised concerns that the full disclosure of breaches could lead to a distorted perception of the CCG. Furthermore this requirement was felt to place an administrative burden on CCGs.
56. Further clarity was requested on what constitutes a breach and how it should be managed, and whether individuals' names should be published for breaches. This included advice on how to deal with breaches where contracts have been entered into. Practical worked examples were requested.
57. With regards to whistleblowing, concerns were raised that the current requirements could draw the Conflicts of Interest Guardian too far into the line management of CCG staff. It was recommended that the statutory guidance be less prescriptive in this area and recommend that CCGs should set out in their own whistleblowing policies how conflicts of interest should be managed.

We have provided further clarity in the guidance on what constitutes a breach and what should be recorded on CCGs' websites. To mitigate public concerns, we recommend that CCGs briefly summarise the breach and the actions put in place to address it. We have clarified in the guidance that individuals' names should not be published for breaches as this could act as a deterrent from individuals coming forward. We have also included some examples of breaches in the series of case studies we will publish alongside the guidance.

With regards to whistleblowing, we have clarified in the guidance that CCGs should include in their whistleblowing policies how conflicts of interest should be managed.

Conflicts of interest training

58. There was general support for the introduction of online conflicts of interest training and recognition that GP board members require advice and support to manage conflicts of interest:
59. However, there was little support for extending the mandatory online training to all practice staff, if they have no involvement in CCG business or decision-making. This was deemed to be an administrative burden and excessive.
60. It was agreed that any training provided should be relevant to the professional groups receiving it and be experience-based. There were requests that the online training includes case studies and that evaluation is built into the training so that the effectiveness can be measured.

In light of the feedback received and the commitments set out in the General Practice Forward View, we have amended this requirement so that only practice staff with a role in the CCG or with influence over decision-making processes, will be required to complete the mandatory training. We will ensure the training package is widely accessible so that all practice staff have the option of voluntarily completing it, if they so wish. We will establish a CCG reference group to support with the development of the online mandatory conflicts of interest training to ensure it best meets commissioners' needs.

61. The following recommendations were made in response to the question of what further support would be helpful to assist CCGs to manage conflicts of interest:

- Case studies on conflicts of interest management throughout the whole commissioning cycle;
- Conflicts of interest webinars;
- Short summary guides of the guidance for specific professional roles;
- More face-to-face training on a regional basis involving different professional groups, especially for CCG governance leads, the Conflicts of Interest Guardian and the Primary Care Commissioning Committee Chair. A further recommendation was for the provision of train-the-trainer sessions;
- Publication of a presentation/toolkit of resources for CCGs to adapt when delivering conflicts of interest training;
- Networking opportunities for lay members;
- Sharing of lessons learned.

We will publish conflicts of interest case studies alongside the guidance, to build overtime an on-line library of resources. In addition, we will publish short, 2-page summary guides to the revised guidance for specific groups including GPs, the Conflicts of Interest Guardian, CCG governance leads, admin teams and Healthwatch members of the primary care commissioning committee.

The NHS England co-commissioning team will deliver a series of webinars in June and July 2016 on the revised guidance to address any queries commissioners may have. We will scope further face-to-face conflicts of interest training and communicate the training opportunities in the summer of 2016.

We will continue to review what further support would be helpful to commissioners over the coming year.

Conclusion and next steps

The feedback summarised in this report has helped to inform the development of the statutory guidance on managing conflicts of interest for CCGs. The revised guidance will be taken to NHS England's Board in May 2016, with a view to publishing final guidance in June 2016. The revised guidance will be accompanied by a series of case studies and short summary guides.

In addition, we will publish a template internal audit plan for conflicts of interest in the summer 2016 and aim to roll out mandatory online conflicts of interest training by the autumn of 2016.

NHS England Co-commissioning Team
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