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NHS ENGLAND – BOARD PAPER

Title: Conflicts of interest in the NHS
Lead Director: Ian Dodge, National Director of Commissioning Strategy
Purpose of Paper: To update the Board on the work of the task and finish group on managing conflicts of interest in the NHS, including: • the responses to public consultation; • the group's consideration of these, and its conclusions; • the new guidance; • and next steps to support effective NHS adoption.
The Board is invited to: • endorse the publication of new guidance - Managing Conflicts of Interest in the NHS; and • offer its perspectives on implementation.

Conflicts of interest in the NHS

Purpose and process

1. To drive better management of conflicts of interest across the NHS, the Board agreed at its public board meeting in March 2016 to establish a task and finish group ('the group') drawn from senior leaders in statutory, representative and professional bodies.

2. The genesis of this initiative lay in a number of public concerns articulated in the media, Parliament, and NHS reviews – including, for example, the interim Carter report, which highlighted how some NHS staff were being inappropriately lobbied by industry. The task and finish group was needed to widen and complement the related NHS England action to improve management of conflicts specifically within CCGs: In 2015 NHS England issued the first statutory guidance for commissioners, enhancing this in June 2016 following evaluation and audit; and for 2016/17, we established new requirements on gifts and hospitality for services provided under the NHS standard contract.

3. Under Sir Malcolm Grant's chairmanship, the group met five times during 2016. Annex A describes its approach.

4. Its objectives were to protect taxpayers and the use of the NHS pound, by ensuring that spending of taxpayers' money is done so free from undue influence; and to safeguard the interests of NHS organisations by supporting staff to manage interests appropriately.

5. In so doing, the group sought to bring greater clarity and consistency to the rules, and mindful of the risk of imposing additional burdens, to make it as simple and easy as possible for both organisations and relevant individuals to comply.

6. In September 2016 the group issued proposals for public consultation. 250 submissions were received, and are analysed in Annex B along with the group's response. Post-consultation, the group reconvened to consider the submissions and confirm agreement to the final guidance. This is being published on 6 February and is attached at Annex C.

7. The detailed and constructive comments received were invaluable in shaping the final guidance. The group was grateful for the time expended, perspectives offered, and practical suggestions made by many organisations and individuals.

8. All the proposals received majority support, apart from the suggestion to introduce greater transparency to clinical private practice activity, specifically by publishing the earnings of clinicians who undertake it.

Learning from the consultation responses

9. Most aspects of public policy involve making finely balanced trade-offs between legitimate competing objectives, and managing conflicts of interest in the NHS is no exception. Four facets deserve particular mention:
    - declaration of private practice income
    - the scope of organisations to be covered
    - the scope of staff grades to be covered within relevant organisations, and
    - how best to expand the uptake of the ABPI's Disclosure UK initiative

Potential conflicts between NHS work and private practice

10. The first of these facets attracted most comment from respondents as well as dominating media coverage of the proposals. The group considered the potential for conflicts of interest by clinicians undertaking private practice outside of their NHS role, particularly when individual clinicians gain financially by undertaking private work for clients whom they first make contact with during their NHS role. The group recognised that the vast majority of clinicians behave appropriately in balancing these dual roles, but indicated that greater transparency was needed regarding these issues. The group suggested that the amount of income generated through private practice might be an effective proxy for the risk of conflict, and so consulted on proposals which would require clinicians to disclose earnings generated from private practice. This was in keeping with the earnings of other public sector workers becoming subject to greater transparency in recent years. For example information about the earnings of senior civil servants is published, Agenda for Change salary scales are publically available, and from 1 April 2015 it became a contractual requirement for GP practices to publish mean earnings for their GPs relating to the previous financial year.

11. The consultation revealed widespread agreement that programmed NHS commitments should take precedence over private work, and support for the principle of declaring that private practice does take place. We also heard strong opposition to declaration of earnings from Royal Colleges, professional bodies, NHS organisations and clinicians. Aligned to this was a perception that clinicians undertaking private practice were being treated differently to all staff who might undertake other outside employment.

12. The group listened carefully to this feedback, and has amended its proposals *(pages 19-22 of Annex B).* The issue of equity of treatment is an important one. In our proposals on outside employment for all groups of staff, we ask them to declare what their outside interests are, who they are with, and what time they spend involved in them. We believe that applying the same requirements to clinicians is just and equitable. Rather than asking for additional information on earnings we are asking for sessional activity to be published as that should already exist via job plans and appraisals.

13. The group were mindful of the fact that this area is complex and controversial. This is also an area where the terms and conditions of NHS employment are the primary mechanism through which to ensure systematic change. The group has therefore recommended that the Department of Health and NHS Employers should, as part of contract negotiations, reflect this revised proposal, and also consider whether or not further safeguards are needed to manage conflicts of interest between NHS practice and private practice.

Which organisations?

14. The group wished to drive consistency in how the whole health system manages conflicts of interest. Therefore in consultation it was proposed that the conflicts of interest guidance should apply to:

    'any formal or informal body that is commissioning or under contract to provide services which are funded by the NHS (including but not limited to NHS Trusts, General Practices, other primary care providers, and other private, independent and third sector organisations)'

15. Consultation respondents raised concerns that this scope was too broad *(pages 51-54 of Annex B)*, and that non NHS organisations (including primary care contractor groups)

should not be subject to the guidance because of their differing governance arrangements when compared to NHS organisations; the small scale of many of the contractor professions; and the proportionality of burden to benefit. We have listened carefully to these views.

16. Our objectives remain to protect taxpayers and safeguard the interests of provider organisations, so we would like to see our guidance on managing conflicts of interest reflected by organisations wherever the NHS pound is spent. But we are conscious of the need for guidance to be proportionate.

17. The group concluded it should apply the guidance to NHS bodies (CCGs, NHS Trusts and Foundation Trusts) and invite the boards/governing bodies of independent and private sector organisations, GP practices, social enterprises, community pharmacies, community dental practices, optical providers and local authorities to consider the guidance as good practice.

18. This does not preclude the need for all organisations to take all necessary steps to manage conflicts of interest effectively, in the interests of patients, the public and their own organisations. They should take appropriate steps to ensure that administrative and clinical decisions are not tainted by conflicts of interest and will continue to be subject to wider legal (for instance the Bribery Act 2010) and professional regulatory obligations.

19. Should significant material concerns emerge in relation to the handling of conflicts of interest by non-NHS organisations, NHS England will review options for seeking wider application and compliance.

Which staff?

20. The task and finish group agreed that the public had a legitimate right to access information about the interests of staff and organisations involved in making decisions about the use of taxpayers' money. Balanced against this was the need to ensure that such transparency was targeted and proportionate and subject to appropriate safeguards (e.g. the need to protect people who would be at risk of harm should personal information about them be published).

21. In consultation the task and finish group proposed that the interests of "senior staff" should be collected and published, to deliver this transparency. During consultation we heard concerns that our classification was too broad, and potentially burdensome to implement. Consequently the group concluded it should apply to "decision-making staff", which would include as a minimum band 8Ds and above, rather than band 7 and above.

Disclosure UK

22. In our consultation we noted the Disclosure UK initiative which was successfully launched by the Association of British Pharmaceutical Industries (ABPI) in July 2016. This initiative makes publicly available, for the first time, information about payments made by the pharmaceutical industry for activities such as research and development along with payments for speaking at and chairing meetings, training services, and, participation at advisory board meetings.

23. Around 70% of health professionals who received such payments from industry gave consent for their names to be published under this initiative. This is a high figure for the first year of such an innovative scheme; however in our consultation we asked whether

more could be done to encourage even greater compliance through reviewing existing contractual arrangements. 60% of respondents agreed *(detailed responses can be found on pages 47-48 of Annex B)*.

24. We should aim to achieve 100% coverage, and with this goal in mind, we therefore recommend that the Department of Health and NHS Employers consider if further contractual action could support greater levels of disclosure under the ABPI scheme.

Summary of the new guidance

25. The table below lists the main elements of the guidance:

On **gifts** staff should…	• Decline anything that may affect their professional judgement • Decline gifts from suppliers or contractors, save for low cost promotional items up to £6 in value • Not ask for gifts and decline all offers of cash (or cash vouchers) • Only accepts gifts with a value over £50 on behalf of their organisation and declare these. The same applies to multiple gifts from the same source with a cumulative value of over £50.
On **hospitality** staff should…	• Decline anything that may affect their professional judgement • Accept without declaration hospitality up to £25, declare hospitality between £25 and £75 and refuse hospitality over £75 (unless exceptional senior approval is given) • Declare modest offers of travel and accommodation and refuse offers which go beyond modest unless senior approval is given. These must also be declared.
On **outside employment** staff should…	• Declare any outside employment (where, when and what) • Where contracts permit, seek prior permission from their organisation to engage in outside employment
On **shareholdings** staff should…	• Declare any shareholdings and ownership interests in companies or organisations which might do business with their organisation • Not declare shares or securities held in collective investment or pension funds or units of authorised unit trusts
On **patents** staff should…	• Declare patents and intellectual property rights they hold which are or could be procured by their organisation • Seek prior permission before entering into agreement with bodies to develop products or other work that impacts on organisational time, equipment or resources
On **loyalty interests** staff should…	• Declare positions of authority in other organisations that could be seen to influence decisions they take in their NHS role • Declare when they sit on advisory groups or similar forums • Declare involvement in recruiting people they know • Declare when people they know do business with their organisation
On **donations** staff should…	• Seek prior organisational approval to engage in fundraising as part of their professional role • Not routinely accept donations from suppliers • Not solicit charitable donations unless this is a part of their role • Ensure donations are made to a charitable fund, not an individual
On **sponsored events** staff	• Declare involvement with a sponsored event • Not supply information which would allow a sponsor to gain

should…	commercial advantage • Ensure that sponsors do not have a dominant influence over events and make their involvement transparent
On **sponsored research** staff should…	• Declare involvement with sponsored research to their organisation • Ensure appropriate approvals are received
On **sponsored posts staff** should…	• Seek prior approval before undertaking a sponsored post • Not promote or favour sponsor's products or be unduly influenced
On **clinical private practice** staff should	• Seek prior organisational approval. • Declare any clinical private practice (where, when and what) • Ensure NHS commitments take precedence.

Supporting the NHS to implement the guidance

26. Staff across the NHS are working hard under conditions of unprecedented demand. The last thing they need is additional and unnecessary burdens. Instead they said they wanted clear, simple and standardised rules that help protect them as well as taxpayers, and apply across the NHS rather than vary organisation by organisation. We have therefore sought to develop a range of standard products as part of the guidance to support implementation:
    - consistent and practical definitions of conflicts of interest, with supporting information to explain what is meant by these terms
    - a standardised approach to declaring interests, supported by a simple template
    - practical guidance on the general approach to be adopted in managing interests, as well as more specific principles and rules to follow in specific common areas.
    - a standard approach to publishing interests of staff, supported by a simple template.
    - guidance on how breaches should be investigated, dealt with, and reported

27. The guidance comes into force on 1 June 2017. Organisations and staff will need time to familiarise themselves with the guidance and ensure that existing policies and processes meet the requirements by the autumn with evaluation to take place in early 2018/19.

28. NHS England will provide help to implement the guidance. In addition to the published templates, and prior to 1 June 2017, we will:
    - release a model conflict of interest policy, based upon the guidance, which organisations can use in whole or in part to update their current policies
    - issue short guides for different groups of staff to help them understand what the guidance means for them.
    - hold WebEx sessions and 'roadshows' for staff to raise awareness of the guidance, answer questions and signpost to supporting material.

29. NHS England is amending its own Standards of Business Conduct policy and processes to ensure alignment with the guidance.

30. In developing the guidance we have also worked with partners and other statutory, professional and representative bodies. Our arms' length body partners have agreed to review their own policy and processes in light of publication of this guidance and make appropriate changes, subject to consideration and approval by their own governance groups. Just as the guidance was developed through a wide collaboration, its implementation will be too.

Recommendation

31. The Board is asked to endorse the guidance and offer its perspectives on implementation.

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Commissioning Strategy Directorate

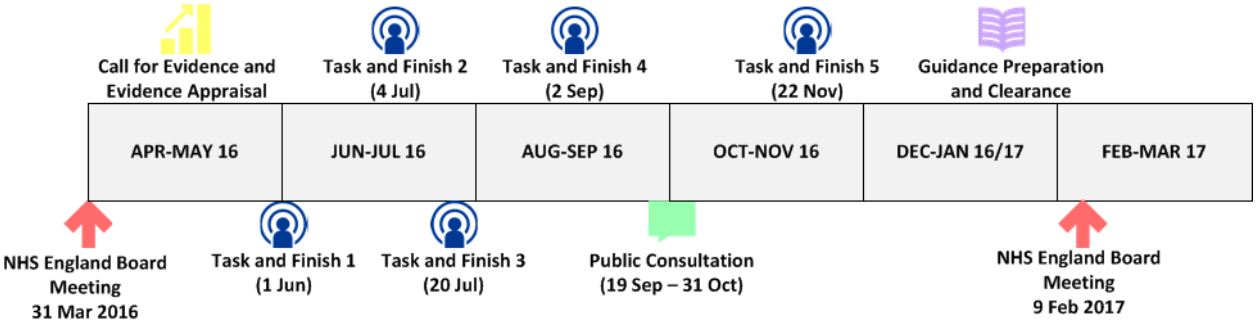
Cleared by: **Ian Dodge, National Director**

Date: **February 2017**

ANNEX A

Managing Conflicts of Interest in the NHS task and finish group

Timeline



Formation

The NHS England Board approved creation of the task and finish group ('the group') on 31 March 2016, and thereafter invited representatives from across the health system to join. Membership of the group is set out at the end of this Annex.

The NHS England secretariat supporting the group led an initial call for evidence. This considered current domestic practices around management of conflicts of interest in health and was supplemented by a wider overview of practice in other sectors, and internationally.

Terms of reference

At its first meeting the group considered and agreed terms of reference for their work, which aimed to:

- Develop a comprehensive understanding of the circumstances in which individuals and organisations in the NHS may be placed in a position of potential conflict between their private interests and those of the NHS (including gifts, inducements, other payments, other influences, personal and family relationships, and hospitality)
- Review current national and international best practice
- Determine a common set of principles applicable to the identification and management of such potential conflicts of interest across the NHS
- Develop a common approach to the processes for managing potential conflicts, such as registers of interest, making and handling declarations of interest, exclusion from participation in items of business when conflicted, and for declaring payments
- Develop detailed rules likely to be applicable to the majority of cases in which potential conflicts need to be managed, avoiding rigidity and a one size fits all approach, but at a level of principle and specificity sufficient to challenge all individuals and organisations with responsibility for spending NHS funds to review and align their current arrangements on a comply or justify basis
- Develop a common "sunshine" approach to transparency and public dissemination, institutional and public scrutiny, and whistleblowing
- Review the adequacy of current and potential sanctions, including institutional disciplinary action, criminal and civil proceedings, and professional regulatory action

Task and finish group meeting business

- Meeting 1 (1 June 2016)
    - As well as agreeing terms of reference the group also agreed a structured approach to progressing work, which broke down the task into the 5 core parts. Meeting 1 concluded with progression of the first part - definitions and scope: development of common definitions around conflicts of interest
- Meeting 2 (4 July 2016).
    - Core part 2 - Common principles and rules: consideration of development of common principles and rules around how common interests should be approached (e.g. gifts and hospitality, outside employment)
    - Core part 3 - Identification and management of interests: approaches which could be adopted to ensure more effective, consistent processes
- Meeting 3 (20 July 2016)
    - Core part 3 - Identification and management of interests: further work on this topic
    - Core part 4 - Publication and transparency: development of proposals for a reasonable and proportionate publication scheme
    - Core part 5 - Breaches and sanctions: development of proposals around how processes could be developed to drive greater consistency in these areas
- Meeting 4 (2 September 2016)
    - Review and comment on draft public consultation document which was launched on 19 September 2016
- Meeting 5 (22 November 2016)
    - Consideration of headline outputs from consultation and key issues arising
    - Input of views about most appropriate look and feel of final products from this process: which needed to be practical, easy to read, understand and implement for both staff and organisations.

Task and finish group membership

Sir Malcolm Grant (Chair)	Chair, NHS England
Harry Cayton	Chief Executive, Professional Standards Authority
John Chisholm	Chair, Medical Ethics Committee, British Medical Association
Niall Dickson	Chief Executive, General Medical Council *(representing the GMC to meeting 4)*
Ian Dodge	National Director of Commissioning Strategy, NHS England
Peter Ellingworth	Chief Executive, Association of British Healthcare Industries
Fiona Godlee	Editor in Chief, British Medical Journal
Chris Hopson	Chief Executive, NHS Providers
Gillian Leng	Deputy Chief Executive, National Institute for Health and Care Excellence
Arvind Madan	Director of Primary Care, NHS England
Johnny Marshall	Director of Policy, NHS Confederation
Phil McCarvill	Deputy Director of Policy, NHS Confederation
Gerry Murphy	Chair of the Audit and Risk Committee, Department of Health
Sarah Pickup	Deputy Chief Executive, Local Government Association
Keith Ridge	Chief Pharmacy Officer, NHS England
Mike Thompson	Chief Executive, Association of the British Pharmaceutical Industry
Caroline Thomson	Non-Executive Director, NHS Improvement
Chris Whitty	Chief Scientific Officer, Department of Health
Peter Wyman	Chair, Care Quality Commission

Members who took part in some group meetings:

Tamara Finkelstein	Chief Operating Officer, Department of Health *(meeting 1 only)*
Duncan Rudkin	Chief Executive, General Pharmaceutical Council *(from meeting 4)*
Professor Terence Stephenson	Chair, General Medical Council *(representing the GMC from meeting 5)*
Bruce Warner	Deputy Chief Pharmacy Officer, NHS England *(deputised for Keith Ridge at meeting 3)*

ANNEX B

Managing conflicts of interest in the NHS - consultation report

Summary

1. From September to October 2016 NHS England led a consultation exercise on draft Guidance on Managing Conflicts of Interest in the NHS ('the guidance'). The consultation[1] set out some proposed rules and principles, which were developed by a cross system task and finish group (the 'group') chaired by Professor Sir Malcolm Grant over the summer of 2016.

2. We want to thank everyone who responded to the consultation. The feedback was very constructive and enabled us to significantly improve our proposals. We have now taken account of the consultation responses and settled the final guidance. The main changes to the consultation proposals, having taken account of those responses, are:

    - We have clarified the status and application of the guidance with regard to different categories of organisation
    - We have aligned more closely proposals on declarations regarding private practice for clinical staff to provisions for non-clinical staff on outside employment
    - Where interests should be published (in addition to being declared), we have focused this on 'decision making staff' as opposed to 'senior staff'
    - We have simplified the definition of a conflict of interest

Introduction

3. The public rightly expect the highest standards of behaviour in the NHS. Decisions involving expenditure of NHS funds should never be influenced by expectations of private gain. The central purpose of the guidance is to support the effective management of conflicts of interest to ensure that personal interests do not prevail over the interests of the NHS.

The consultation process

4. During summer 2016 Professor Sir Malcolm Grant chaired the group, with broad representation from across a wide range of interest and expertise, to capture best practice wherever it could be found on management of conflicts of interest and develop a common set of practices, principles and rules for the NHS.

5. A public consultation ran from 19th September 2016 to 31st October 2016. The consultation document was publicly available on the NHS England website and was promoted on social media and through newsletters and eBulletins. It was also shared with regulators, industry membership bodies and Royal Colleges.

6. We received 250 responses to the consultation. The majority (224) responded through an online survey, whilst 26 responded via email. We received a broad range of responses from members of the public, representatives of NHS provider

[1] The consultation document is accessible at: https://www.engage.england.nhs.uk/consultation/managing-conflicts-of-interest-in-the-nhs/user_uploads/conflicts-of-interest-consultation.pdf

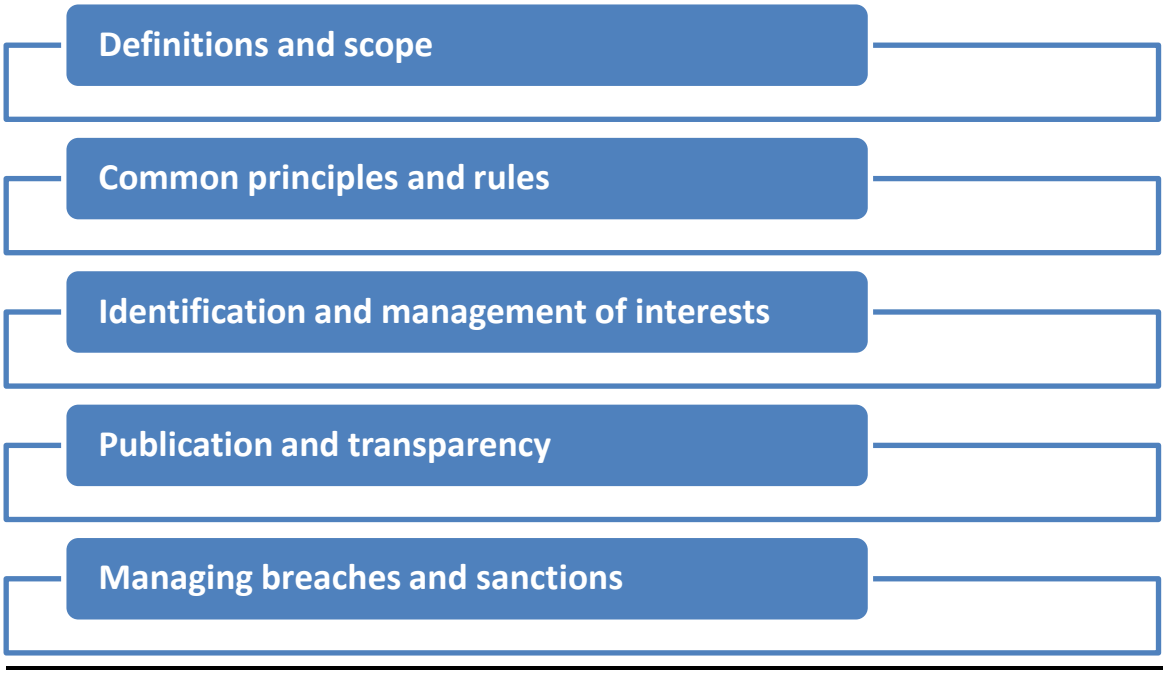
and commissioner organisations, professional bodies, Royal Colleges and the independent sector. We asked respondents to indicate which part of the health or wider system they were replying from as part of the consultation process, and respondents self-reported on this basis.

Headline consultation results

7. The consultation presented 26 questions in relation to the proposals developed by the group. Summary quantitative results are presented below in the table at the end of this Annex but, in summary:
    - For 18 out of 26 questions, 60% or more of respondents agreed with the proposal
    - For 7 out of the 26 questions, between 51-59% of respondents agreed with the proposal
    - For 2 out of the 26 questions, 50% or less of respondents agreed with the proposals – these areas related to private practice and the declaration of earnings

Detailed consultation results

8. In this section we describe what we heard in relation to the questions posed during consultation, and our response to this feedback. The content below is structured around the 5 core stages which the group worked through to make their proposals, being:



9. In relation to each of these stages we outline the original proposals and provide a summary of quantitative and qualitative feedback. We also explain what changes we have made in response to consultation responses.

Definitions and scope

Question 1: Do you agree with our definition of conflict of interest?

10. The intention of setting out a more standardised definition was in recognition of the fact that there are different definitions of conflicts of interest in the context of health used by different organisations, and that there was merit in organisations adopting a more consistent approach.

What we consulted on	Final proposal

• "A conflict of interest can occur when there is the possibility that a person's judgement regarding their primary duty to NHS patients may be influenced by a secondary interest they hold. Such a conflict may be:
  • Potential – i.e. there is the possibility of a conflict between the two interests in the future
  • Actual - i.e. there is a relevant and material conflict between the two interests now
  • Perceived – i.e. an observer could reasonably suspect there to be a conflict of interest regardless of whether there is one or not.
Conflicts can occur with interests held by the individual or their close family members,* close friends and associates, and business partners (dependent on the circumstances and the nature of such relationships)"
	• A conflict of interest is a set of circumstances by which a reasonable person would consider that an individual's ability to apply judgement or act, in the context of delivering, commissioning, or assuring taxpayer funded health and care services is, or could be, impaired or influenced by another interest they hold
	• A conflict of interest may be:
	  o Actual - i.e. There is a material conflict between one or more interests now
	  o Potential – There is the possibility of a material conflict between one or more interests in the future
	• Staff may hold interests for which they cannot see potential conflict. However, caution is always advisable because others may see it differently. It will be important to exercise judgement and to declare such interests where there is otherwise a risk of imputation of improper conduct.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our definition of conflict of interest?	65.6%	53.6%	74.4%	75.8%	36.4%	61.5%	65.0%

11. Overall 65.6% of respondents agreed with our definition of conflicts of interest.

Qualitative feedback

12. Some of those who didn't agree with the proposals suggested that the definition should specifically relate to taxpayer funded services (recognising that duties owed by individual staff are broader than just to patients) and would benefit from a "reasonable person" test regarding what constitutes an interest. Allied to this, and

to ensure that we are clear about what types of interest should be declared, we have introduced the concept of materiality (see the “Definitions” section of the guidance). A material interest is one which a reasonable person would take into account when making a decision regarding the use of taxpayer’s money because the interest has relevance to that decision.

13. We received feedback on the desirability of referencing “potential” and “perceived” conflicts of interest. Some respondents questioned the inclusion of potentially subjective categories of interest; one NHS Commissioner representative said:

“The definition is too complex to operate effectively across the wide sphere of NHS commissioning and service provision. I would suggest that we restrict our concerns to actual conflicts - potential or perceived conflicts only have a material impact when they become actualities.”

14. We have retained reference to potential conflicts in our definition. We felt that identification and disclosure of interests where there was a potential for a conflict to arise would be an important enabler for management action to prevent conflicts from arising in the future. On balance, we have removed explicit reference to the perceived category. Within the guidance we have recognised that staff may hold interests for which they cannot see potential conflict but that caution is always advisable because others may see it differently. Therefore it will be important for staff to exercise judgement and declare such interests where there is otherwise a risk of imputation of improper conduct.

Question 2: Do you agree with our sub-classifications of interests?

15. The intention of developing some basic and consistently used sub-classifications was intended to be helpful in terms of assisting staff and organisations to consider whether an interest risks becoming a conflict. This would lead to more consistent identification or interests and associated management responses.

What we consulted on

The group has based these sub-classifications on a model developed by the NAO and adapted them for the English health service context. These sub-classifications are:

Direct (or personal) financial interest	A direct financial interest is one where there is or appears to be opportunity for personal financial gain or financial gain to close family members, close friends and associates, and business partners (dependent on the circumstances and the nature of such relationships)
Indirect (or non-personal) financial interest	An indirect financial interest involves payment or other benefit to a department or organisation in which the individual is employed or otherwise engaged but which is not received personally.
Non-financial interests	A non-financial interest is one where there is or appears to be an opportunity for non-financial gain (e.g. status), or where an individual's decision making is or could be compromised for example due to a conflict of loyalty.

Final proposal

Financial interests	This is where an individual may get direct financial benefits* from the consequences of a decision they are involved in making
Non-financial professional interests	This is where an individual may obtain a non-financial professional benefit from the consequences of a decision they are involved in making, such as increasing their professional reputation or status or promoting their professional career
Non-financial personal interests	This is where an individual may benefit personally in ways which are not directly linked to their professional career and do not give rise to a direct financial benefit, because of decisions they are involved in making in their professional career
Indirect interests	This is where an individual has a close association** with another individual who has a financial interest, a non-financial professional interest or a non-financial personal interest who would stand to benefit from a decision they are involved in making

* A benefit may arise from the making of gain or avoiding a loss

** These associations may arise through relationships with close family members and relatives, close friends and associates, and business partners. A common sense approach should be applied to these terms. It would be unrealistic to expect staff to know of all the interests that people in these classes might hold. However, if staff do know of material interests (or could be reasonably expected to know about these) then these should be declared.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our sub-classifications of interests?	63.6%	50.0%	69.2%	72.7%	36.4%	69.2%	65.0%

16. Overall 63.6% of respondents agreed with our sub-classifications of interests

Qualitative feedback

17. Respondents welcomed the recognition that interests are not always financial. Others felt that the sub-classifications were not sufficient to account for the complex range of interests. One NHS Commissioner Representative said:

"The sub-classification does not appear comprehensive enough and fails to recognise that individual organisations such as CCGs have specific issues in respect of interests."

18. NHS Providers commented that:

"The sub-classifications appear to us to be more complex than is strictly necessary."

19. A clinical respondent felt that:

"The definition is too wide-ranging: the simpler the definition, the better."

20. We also received feedback that our sub-classifications should be aligned to those in recently published CCG guidance on conflicts of interest, which have been well-understood and implemented. NHS Clinical Commissioners said:

"We are concerned…that the definition and sub-classifications…are inconsistent with the standards set in the revised statutory guidance for CCGs earlier this year. We are supportive of a simplified definition for conflicts of interest that sets clear minimum standards but feel that this consultation should go as far as possible to draw on existing guidance and avoid unnecessary confusion."

21. In recognition of the feedback in this area, we have aligned our sub-classifications with those in the existing CCG guidance.

22. Consultation responses gave polarised views on whether the definition of 'family and friends' should be so tightly specified (this was previously part of our wider definition of conflicts but we have realigned content following consultation). We decided to keep the definition broad and set a clear expectation for individuals to exercise judgement in declaring interests of family and friends that are material to

NHS work. We have also, in response to several comments, clarified that benefits from interests can include not only gains but avoidance of loss.

Question 3: Are the circumstances we have identified sufficient to capture all instances?

23. Underneath the sub-classifications of interests in our consultation (at page 16) we mapped different circumstances or situations where interests arise which might give rise to risk of conflicts (e.g. receipt of gifts and hospitality, etc). We asked for views on whether these circumstances were comprehensive enough.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Are the circumstances we have identified sufficient to capture all instances?	58.0%	60.7%	53.8%	66.7%	36.4%	46.2%	65.0%

24. 58% of respondents agreed that we had identified sufficient circumstances to capture all interests.

Qualitative feedback

25. Some respondents suggested additional circumstances; one NHS Provider representative suggested:

"…more is required around integrated working and how this may impact on individual conflicts of interest and how they are to be declared, i.e. STP"

26. The need to account for integrated working also featured in this NHS Commissioner representative's response:

"The commissioning arena is increasingly featuring close working with Local Authorities, and this brings a need to expand the types of relationship covered to include Political conflicts of interest, including those arising from constituency duties."

27. Other feedback highlighted specific examples of industry-sponsored posts and prescription management services in the community, and raised concerns that clinicians could refer into units in which they have a financial interest.

28. At the other end of the spectrum, some respondents highlighted the risk of being too prescriptive. A representative of Bayer Plc. stressed the need to:

"…foster a positive approach to collaboration and partnership between different types of stakeholder organisations…without limiting the contribution of experts to debate or decisions."

29. Many clinical respondents questioned the definition of private practice as a conflict of interest; this particular topic is covered in the response to questions 8 and 9.

30. We accounted for the feedback on this question in our revised definition of a conflict of interest, in particular through introducing the “reasonable person” test. Individuals will need to exercise judgement about circumstances which could constitute a conflict, and it would not be possible to exhaustively account for all possibilities.

31. We discuss in more detail approaches to various circumstances and common situations from question 5 below (and within the Management section of the guidance). We also hope that the consultation and the guidance will spark conversations about individuals’ interests and assist that this dialogue will assist staff and organisations in working together to ensure that interests are identified and managed consistently.

Common principles and rules

32. The group believed that there was merit in providing some common principles and rules which should apply to management of interests in common scenarios. The following sections describe feedback on the proposals regarding these.

Question 4: Do you agree with the proposed definition of senior staff?

33. One of the aims of the consultation was to bring greater consistency to how interests are identified, and to bring greater transparency around the interests of groups of staff who play a key part in decisions on the use of taxpayers' money. The group recognised that risks of conflict were more acute for staff in senior roles – which it referred to as 'senior staff'. To manage these risks, but avoid applying disproportionate burdens on all groups of staff, it felt that people in this class should be proactively prompted to declare their interests each year, and that information about the interests of these staff should be published.

What we consulted on	Final proposal
• In applying our proposed principles and rules we recognise that the risks of conflicts arising are more acute for staff in senior roles, who have decision making responsibilities. Therefore, to avoid applying disproportionate burdens on all groups of staff, we have made a distinction between 'all staff' and 'senior staff'. We believe it is for individual organisations to determine who their senior staff are, but we would expect this to include the following groups: • Executive and non-executive directors • Medical Staff • Budget holders • Those at Agenda for Change band seven or above • Those involved in purchasing or formulary decisions • Members of advisory groups • Foundation Trust Governors • NHS contractor professions e.g. pharmacists, dentists, optometrists etc	**4.3.** Some staff are more likely than others to have a decision making influence on the use of taxpayers' money, because of the requirements of their role. For the purposes of this guidance these people are referred to as **'decision making staff'**. **4.4.** Because of their influence in the spending of taxpayers' money, organisations should ensure that, at least annually, decision making staff are prompted to update their declarations of interest, or make a nil return. **4.5.** Organisations should define decision making staff according to their own context, but this should be justifiable and capture those groups of staff that have a material influence on how taxpayers' money is spent. **4.6.** The following non-exhaustive list describes who these individuals are likely to be: • Executive and non executive directors* who have decision making roles which involve the spending of taxpayers' money • Members of advisory groups which contribute to direct or delegated decision making on the commissioning or provision of taxpayer funded services • Those at Agenda for Change band 8d** and above • Administrative and clinical staff who have the power to enter into contracts on behalf of their organisation • Administrative and clinical staff involved in decision making concerning the commissioning of services, purchasing of medicines, medical devices or equipment, and formulary decisions. * equivalent roles in different organisations carry different titles – this should be considered on a case by case basis ** reflecting guidance issued by the Information Commissioner's Office with regard to Freedom of Information legislation: https://ico.org.uk/media/1220/definition-document-health-bodies-in-england.pdf

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with the proposed definition of senior staff?	50.4%	39.3%	48.7%	51.5%	72.7%	30.8%	60.0%

34. Just over half of the consultation responses supported the proposed definition.

Qualitative feedback

35. We heard from respondents disagreeing with this proposal that the terminology of 'senior staff' should be changed to better reflect whether someone is in a position to decide on the use or application of public funds. "Seniority" was also felt to be a difficult concept to apply consistently across the breadth of NHS professionals and some respondents argued that trying to do this made the definition somewhat ambiguous. One NHS Commissioner Representative said:

"Could some consideration be given to an alternative to the term "Senior staff" as used in this context because members of advisory groups and other committees may well include patients or members of the public, other than Non executives or lay members, for whom the heading is inappropriate."

36. NICE commented that:

"It is not clear why some requirements…. would apply only to 'senior staff' whilst other aspects of the proposals would apply to all staff. If they do not apply to all staff, the proposals could risk a situation whereby the actions of a 'junior' staff member may be affected by a legitimately undisclosed interest (such as employment with pharma)."

37. The breadth of services provided and staff employed across the NHS might make it difficult to find a common definition. The Shelford Group said:

"The guidance will also need to be clearer when it refers to 'medical staff', which can of course span a broad range of seniority."

38. To account for these comments we have now set expectations for the minimum level at which organisations should consider staff to be 'decision making' as opposed to 'senior.' In the Declarations section of the guidance we have provided indications that describe the responsibilities of a role which might come into this category, rather than using "labels" of professional groups. We have asked organisations to use this guidance to identify their own 'decision making staff'.

39. With respect to the inclusion of pay grade in this guidance, some respondents agreed that an individual's pay band was a relevant factor; others queried whether this would always capture the correct cohort of staff. The Royal College of Nursing

and The Royal College of Surgeons of Edinburgh were among those who felt the proposals should not make any distinction between junior/senior staff on the basis of pay grade.

40. We also heard, for example from the Royal College of Psychiatrists and from the Shelford Group that if a pay grade was used, Agenda for Change Band 7 and above was too broad, and would capture many individuals who would not be responsible for either significant decisions or expenditure. Along the same lines, one NHS Provider Representative said:

"The Trust feels that the proposed definition of senior staff is excessive and would place an additional administrative burden on providers which is disproportionate to the issues attempted to be tackled."

41. To accommodate the range of views expressed, we retained a reference to pay bands in our guidance on "decision making staff" but brought our definition in line with that of the Information Commissioner's Office, identifying such staff as Agenda for Change Band 8D or above.

Question 5: Do you agree with our proposals regarding gifts?

What we consulted on	Final proposal
• Staff should not ask for or accept gifts or rewards that may affect, or be seen to affect, their professional judgement • Gifts of cash or cash equivalent should always be declined <u>Gifts from patients</u> • It is appropriate to accept gifts from patients as a legitimate expression of gratitude • Gifts up to the value of £50 may be accepted and need not be declared • Gifts over the value of £50 should be declined • Multiple gifts, received over a twelve month period from the same patient should not ultimately exceed more than £50 in total • Where it would cause offence to decline the gift it can alternatively be donated to charity <u>Gifts from actual or potential suppliers</u> •Gifts connected with procurement and/or service supply should be declined •However where low cost branded promotional aids are offered these may be accepted where they are under the value of £6 in total. In these circumstances they need not be declared <u>Gifts from foreign dignitaries</u> • Gifts up to the value of £50 may be accepted and need not be declared • Multiple gifts, received over a twelve month period from the same individual should not ultimately exceed more than £50 in total • Gifts over the value of £50 should be declined • Where it would cause offence to decline the gift it can alternatively be donated to charity	Overarching principle applying in all circumstances: • Staff should not accept gifts that may affect, or be seen to affect, their professional judgement. Gifts from suppliers or contractors: • Gifts from suppliers or contractors doing business (or likely to do business) with an organisation should be declined, whatever their value. • Subject to this, low cost branded promotional aids may be accepted where they are under the value of a common industry standard of £6* in total, and need not be declared. * The £6 value has been selected with reference to existing industry guidance issued by the ABPI: http://www.pmcpa.org.uk/thecode/Pages/default.aspx Gifts from others sources (e.g. patients, families, service users): • Gifts of cash and vouchers to individuals should always be declined. • Staff should not ask for any gifts. • Gifts valued at over £50 should be treated with caution and only be accepted on behalf of an organisation (i.e. to an organisation's charitable funds), not in a personal capacity. These should be declared by staff. • Modest gifts accepted under a value of £50 do not need to be declared. • A common sense approach should be applied to the valuing of gifts (using an actual amount, if known, or an estimate that a reasonable person would make as to its value). • Multiple gifts from the same source over a 12 month period should be treated in the same way as single gifts over £50 where the cumulative value exceeds £50.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding gifts?	59.2%	57.1%	59.0%	69.7%	63.6%	30.8%	65.0%

42. Overall, 59.2% of respondents agreed with our proposals on gifts but within this, there was a wide range of differing positions according to type of respondent: from 69.7% agreement (NHS Provider Representatives) to 30.8% agreement (Royal Colleges and Professional Bodies).

Qualitative feedback

43. A number of respondents made the argument that even small gifts could influence judgement, whereas large gifts are not guaranteed to attain influence:

"The value of the gift is… immaterial; the association (or not) with a conflict of interest is the issue." (Non-NHS Provider Representative)

"Evidence suggests that even small incentives influence prescribing and decision making and therefore no gifts of any value should be acceptable." (PharmAware)

44. For this reason, some respondents made the argument that the value of a gift was less important than the declaration – and that refusing gifts might cause offence:

"Not all gifts over £50 need be declined - and saying so will encourage covert behaviour. They must all be declared. But you are being too purist and wrongly so." (NHS Provider Representative)

"Whilst it is important to avoid high value gifts from patients, an arbitrary £50 maximum should not be enforced. If a patient wants to give a higher value gift, and does not wish the gift to be declined then it should be declared. Refusal may be more offensive than perceived conflicts of interest." (Member of the public)

45. After considering consultation responses we have maintained the absolute bar on gifts from suppliers (excepting for low value promotional items to the value of £6 of less), allowed for gifts up to £50 to be accepted without declaration, and accommodated the organisational acceptance of gifts over £50 in exceptional circumstances and accompanied by a declaration.

46. We have placed greater emphasis on individual judgement in the guidance, requiring gifts of any value to be refused if they could influence (or be seen to influence) judgement.

Question 6: Do you agree with our proposals regarding hospitality?

What we consulted on	Final proposal
• Hospitality includes offers of transport, refreshments, meals, accommodation, etc • Hospitality should only be accepted where it is secondary to a business event i.e. there is a legitimate business reason • Hospitality must be appropriate and not out of proportion to the occasion i.e. subsistence only • Hospitality up to the value of £25 may be accepted and need not be declared • Where hospitality over the value of £25 is received the acceptance of this hospitality should be declared, although there is no requirement to declare the actual or estimated value	Overarching principles applying in all circumstances: • Staff should not ask for or accept hospitality that may affect, or be seen to affect, their professional judgement. • Hospitality must only be accepted when there is a legitimate business reason and it is proportionate to the nature and purpose of the event. • Particular caution should be exercised when hospitality is offered by actual or potential suppliers or contractors – these can be accepted if modest and reasonable but individuals should always obtain senior approval and declare these. Meals and refreshments: • Under a value of £25 - may be accepted and need not be declared. • Of a value between £25 and £75* - may be accepted and must be declared. • Over a value of £75* - should be refused unless (in exceptional circumstances) senior approval is given. A clear reason should be recorded on an organisation's register(s) of interest as to why it was permissible to accept. • A common sense approach should be applied to the valuing of meals and refreshments (using an actual amount, if known, or an estimate that a reasonable person would make as to its value). *The £75 value has been selected with reference to existing industry guidance issued by the ABPI http://www.pmcpa.org.uk/thecode/Pages/default.aspx Travel and accommodation: • Modest offers to pay some or all of the travel and accommodation costs related to attendance at events may be accepted and must be declared. • Offers which go beyond modest, or are of a type that the organisation itself might not usually offer, need approval by senior staff, should only be accepted in exceptional circumstances, and must be declared. A clear reason should be recorded on an organisation's register(s) of interest as to why it was permissible to accept travel and accommodation of this type. • A non exhaustive list of examples includes: o offers of business class or first class travel and accommodation (including domestic travel). o offers of foreign travel and accommodation.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding hospitality?	55.2%	53.6%	64.1%	69.7%	54.5%	23.1%	51.7%

47. Overall, 55.2% of respondents agreed with the proposals regarding hospitality.

Qualitative feedback

48. Some of those who disagreed with our consultation proposals felt that the £25 figure was too low, whereas others felt it was too high. Many felt that the value of hospitality should match that of gifts. Others raised questions about the treatment of travel and accommodation expenses, and whether these should be handled differently to other types of hospitality given their likely value.

49. We have therefore split travel and accommodation from other hospitality to reflect the fact that a low limit on hospitality would unlikely to be practical due to the likely nature of travel and accommodation costs, geographic differences in pricing, etc. We have now also included provisions on first/class and foreign travel.

50. From the feedback received on this proposal we recognised that there is no 'right answer' for the value of hospitality which is appropriate. We have therefore retained our original proposals, and aligned them with industry standard practice, adding in a £75 upper limit over which hospitality in the form of meals and refreshments should be refused, unless circumstances are exceptional in which case it may be accepted if senior approval is given.

51. Although some respondents felt their declarations should always specify the precise value of hospitality received, we have not required this as we felt it in some circumstances it would be practically difficult to isolate this. However, our revised guidance does not prohibit exact values to be provided if known.

Question 7: Do you agree with our proposals regarding outside employment?

What we consulted on	Final proposal
• Senior staff (excluding non-executive directors) must seek the prior approval of their employer before taking up outside employment which relates to organisations that do or are likely to do business with the NHS • Where an individual has existing outside employment this must be declared on appointment • Outside employment where there is any potential for a conflict of interest to arise must be declared and recorded in the register of interests • Where a potential conflict of interest is identified a judgement must be made as to appropriate action; this can include: 1. Declining permission to take up outside employment 2. Amending an employee's duties to remove the risk of conflict of interest 3. Putting in place additional safeguards to mitigate the risk of conflict of interest e.g. absenting the employee from any decisions relating to their outside employer or competitor organisations • Where no conflict of interest is identified staff should be free to take up outside employment where this is in line with their terms and conditions of employment	• Staff should declare any existing outside employment on appointment, and any new outside employment when it arises. • Where a risk of conflict of interest is identified, the general management actions outlined in this guidance should be considered and applied to mitigate risks. • Where contracts of employment or terms and conditions of engagement permit, staff may be required to seek prior approval from an organisation to engage in outside employment. • Organisations may also have legitimate reasons within employment law for knowing about outside employment of staff, even this does not give rise to risk of a conflict. Nothing in this guidance prevents such enquiries being made.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding outside employment?	54.0%	32.1%	69.2%	65.2%	27.3%	46.2%	53.3%

52. Overall, 54% agreed with these proposals. Support was highest amongst NHS Commissioner Representatives (69.2%) and lowest amongst non-NHS Provider Representatives (27.3%).

Qualitative feedback

53. Concerns were raised about whether prior approval of outside employment was contractually possible, and whether declaration as opposed to permission should be the policy:

"'Declining permission to take up outside employment.' This is a step too far. Provided the member of staff declares the role, what the individual does outside their NHS contracted hours should not be controlled by the employer." (NHS Provider Representative)

54. We also heard that there could be an adverse effect for patients if clinicians are prevented from working with the independent sector:

"It is critical that NHS health care professionals and others are able to continue to work transparently with the pharmaceutical industry." (Association of the British Pharmaceutical Industry).

55. After considering the consultation responses we have taken out the requirement for prior approval, unless this is already permitted in existing contracts or terms of engagement, and replaced it with a duty to declare outside employment. We have also widened the scope of who should make these declarations to cover all staff (remembering that only the interests of 'decision making' staff would be published).

Question 8 and 9: Do you agree with our proposals regarding private practice? In particular, do you agree with the proposal regarding declarations of information about private practice, including information about earnings?

What we consulted on	Final proposal

• Clinical staff should declare all private practice including:
  • Where they practice (name of private facility)
  • When they practice (identified sessions)
  • What they practice (speciality, major procedures)
  • Their earnings from private practice (Gross earnings in the previous 12 months on the basis of less than £50K, less than £100K, more than £100K)
• The above information should be included on the employing organisation's register of interests
• Programmed NHS commitments should always take precedence over private work
• Clinical staff should not initiate conversations about private work with patients during the course of their NHS sessions
• Clinical staff should not accept direct or indirect financial incentives from private providers other than those allowed by Competition and Markets Authority guidelines
	• Clinical staff should declare all private practice on appointment, and/or any new private practice when it arises* including:
	  • where they practise (name of private facility)
	  • what they practise (specialty, major procedures).
	  • when they practise (identified sessions/time commitment)
	* Hospital Consultants are already required to provide their employer with this information by virtue of Para.3 Sch. 9 of the Terms and Conditions – Consultants (England) 2003: https://www.bma.org.uk/-/media/files/pdfs/practical advice at work/contracts/consultanttermsandconditions.pdf
	• Clinical staff should (unless existing contractual provisions require otherwise or unless emergency treatment for private patients is needed):
	  • Seek prior approval of their organisation before taking up private practice.
	  • Ensure that, where there would otherwise be a conflict or potential conflict of interest, NHS commitments take precedence over private work.**
	  • Not accept direct or indirect financial incentives from private providers other than those allowed by Competition and Markets Authority guidelines: https://assets.publishing.service.gov.uk/media/542c1543e5274a1314000c56/Non-Divestment_Order_amended.pdf
	• Hospital Consultants should not initiate discussions about providing their Private Professional Services for NHS patients, nor should they ask other staff to initiate such discussions on his or her behalf.**
	** These provisions already apply to Hospital Consultants by virtue of Paras.5 and 20, Sch. 9 of the Terms and Conditions – Consultants (England) 2003: https://www.bma.org.uk/-/media/files/pdfs/practical advice at work/contracts/consultanttermsandconditions.pdf)
	• Where clinical private practice gives rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding private practice?	36.0%	17.9%	64.1%	42.4%	18.2%	15.4%	25.0%
In particular, do you agree with the proposal regarding declarations of information about private practice, including information about earnings?	32.8%	21.4%	56.4%	39.4%	9.1%	7.7%	21.7%

56. 36% of respondents agreed with the proposals regarding private practice, and 32.8% agreed with the specific proposal to require declaration and publication of information about earnings.

Qualitative feedback

57. There was general agreement that programmed NHS commitments should take precedence over private work, but many respondents felt that existing safeguards, such as job planning arrangements, were sufficient to manage conflicts of interest. The Royal College of Physicians said:

"Job planning, if performed correctly using electronic tools, together with well conducted appraisal should ensure that consultants are clear about their contribution to the NHS and allow those wanting to do private practice to do so."

58. We heard views that it was the responsibility of employers to enforce these existing safeguards – although some questioned whether this was being done effectively. Two consultants responding noted:

"The 2004 Consultant contract required consultants to identify their private practice sessions. This is in their job plan and should be policed and enforced by their employer."

"If there is concern that a consultant is doing private practice when they are timetabled to be in the NHS, this should be pursued vigorously through normal disciplinary measures, as that could amount to fraud, and it must be a breach of contract."

59. On the proposal to declare and publish earnings, there was strong opposition from Royal Colleges, professional bodies and NHS organisations, and a concern that

clinical staff were being treated differently to non-clinical staff. There was, however, support for the principle of declaring that outside employment/private practice does take place and a suggestion that time spent, rather than earnings, was the thing that should be declared.

"Having studied the issue carefully, we can find no correlation between income and conflict of interest and find no justification to require consultants to disclose his or her income." (British Medical Association)

"How [will] disclosing earnings will identify an individual's conflict of interest any more than identifying the existence of their employment?...Surgeons who earn similar amounts from their private practice could be undertaking significantly different amounts of work" (The Royal College of Surgeons of England)

"Declarations should be more simplified i.e. I work privately for XX Hospital." (NHS Provider Representative)

"We agree that outside employment should be declared, especially to ensure that this does not affect performance of NHS functions." (Royal College of Anaesthetists)

"Time spent rather than income generated is a more accurate reflection of private practice commitment." (Clinician)

"No other Senior Staff are required to report in this way." (NHS Commissioner Representative)

60. There were mixed views on whether clinical staff should initiate conversations about private treatment during the course of NHS sessions; this was seen as a complex issue in the context of offering choice:

"We agree with the principle proposed that clinical staff should not initiate conversations about private work with patients during the course of their NHS work." (Hospital Consultants & Specialists Association)

"We agree that clinicians should not initiate conversations with patients about private work during the course of NHS session, although we must consider the right of patients to ask for such information." (Royal College of Psychiatrists)

"It can HELP the NHS service when patients (e.g. who have insurance) are made aware that they are coming out of an NHS queue (even to enter a PPU list) can help the NHS in terms of: opening capacity for others, income stream for NHS, etc. Therefore to broach the subject of PP should actually NOT be discouraged from NHS consultations, even if just to enter this at registration." (NHS Employee)

Having considered all the feedback in this area we have revised requirements for clinicians to declare outside activities more closely to requirements for all staff to declare outside employment interests, and we have specifically removed the requirement to declare earnings. However a number of consultation responses did however support some strengthening of policy in this area such as:

"Yes we do not consider the categories of declarations of gross earnings as being too onerous and consider them reasonable in the context. (NHS Protect)"

"Yes. We believe that the clinician's primary employer needs to know about all outside earnings so that the employer can for a well founded view on whether the clinician in question is managing potential conflicts of interest effectively. (NHS Providers)"

61. Therefore, in the Board Paper which accompanies this consultation report we have recommended that the Department of Health and NHS Employers consider whether any further safeguards are required.

62. We have also reiterated that clinical staff should get prior approval before taking up private practice (where existing contracts provide for this), and that programmed NHS commitments should take precedence over other work. We still maintain that conversations about private practice should not be initiated by consultants themselves where they would be providing the service in question, but have qualified this with reference to existing contractual provisions.

Question 10: Do you agree with our proposals regarding general sponsorship?

What we consulted on	Final proposal
• Commercial sponsorship agreements should always be declared • Before entering into a commercial sponsorship agreement written approval should be sought from the appropriate individual as defined by the organisation • Commercial sponsorship arrangements should only be approved where there is a clear benefit for the organisation including organisation benefit derived from individual sponsorship arrangements • No information should be supplied to a company for their commercial gain unless there is a clear benefit to the NHS. As a general rule, information which is not in the public domain should not normally be supplied • The commercial sponsor of an event, post or research etc. should always be clearly identified in the interest of transparency • The senior individual responsible for arranging the commercial sponsorship is responsible for declaring it	To not have a separate section on general sponsorship. But all core elements on aspects such as requirements for declaration, appropriate approvals, clear organisational benefit, and prohibition of supply of inappropriate information is included in the following sections: • Sponsored events • Sponsored research • Sponsored posts

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding general sponsorship?	73.6%	57.1%	94.9%	81.8%	63.6%	84.6%	70.0%

63. 73.6% of respondents agreed with our proposals regarding general sponsorship.

64. We have now simplified guidance on common situations relevant to sponsorship (contained in the Management section of the guidance) to avoid holding similar information in different places, so there is no longer a separate “general sponsorship” section. This has been incorporated into the other sections covering sponsorship, which we hope makes more sense to the reader.

Question 11: Do you agree with our proposals regarding sponsored events?

What we consulted on	Final proposal
• Sponsors should not have any influence over the content of an event, meeting, seminar, publication or training event • Attendance of the sponsor is at the discretion of the event organiser • The fact of sponsorship does not equate to endorsement of a company or its products • During dealings with sponsors there must be no breach of patient or individual confidentiality or data protection legislation • Sponsorship of events should be declared	• Sponsorship of events by appropriate external bodies should only be approved if a reasonable person would conclude that the event will result in clear benefit for the organisation and the NHS. • During dealings with sponsors there must be no breach of patient or individual confidentiality or data protection rules and legislation. • No information should be supplied to the sponsor from which they could gain a commercial advantage, and information which is not in the public domain should not normally be supplied. • At an organisation's discretion, sponsors or their representatives may attend or take part in the event but they should not have a dominant influence over the content or the main purpose of the event. • The involvement of a sponsor in an event should always be clearly identified in the interest of transparency. • Organisations should make it clear that sponsorship does not equate to endorsement of a company or its products and this should be made visibly clear on any promotional or other materials relating to the event. • Staff should declare involvement with arranging sponsored events to their organisation.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding sponsored events?	70.0%	53.6%	92.3%	81.8%	63.6%	69.2%	63.3%

65. 70% of respondents agreed with our proposals on sponsored events.

Qualitative feedback

66. One concern raised in a number of responses was the need to avoid unintended consequences which could compromise opportunities for medical and clinical education, conferences, and necessary collaboration with a range of industries, including the pharmaceutical industry:

"Given the pressures on NHS training budgets, the opportunity that sponsored educational events provide healthcare professionals is valuable. The ABPI Code of Practice ensures the emphasis of such events is educational…Health care professionals have an important role in shaping the thinking of the pharmaceutical industry on how NHS pathways and services function and how services will need to develop to deliver meaningful outcomes for patients. When services need to change, industry can work to support such change by providing investment, resources and skills to facilitate change. With this in mind, it is reasonable for meeting organisers to invite experts from a company, allowing them to collaborate on the agenda and to speak at the request of the meeting organiser, which is proportionate in scale to the overall programme. Acknowledging that the programme will include a talk from a sponsor would improve transparency, and such a declaration is required by the ABPI Code of Practice." (The Association of the British Pharmaceutical Industry)

"I do have some concerns, in so far as it is a pity to lose certain funding streams for education. Some sponsored educational events are excellent, and it would be a pity to lose those. To provide something too prescriptive might do so. This needs further thought." (Member of the public)

67. Other respondents felt that these proposals were an opportunity to be clear about sponsor involvement in events and associated safeguards:

"Sponsors may wish to plan an additional session as part of their financial support of a meeting. We believe this is acceptable, providing those lectures or workshops are clearly marked in the programme (and any promotional material) as a sponsored, additional session." (Association of Anaesthetists of Great Britain and Ireland) (AAGBI)

"We agree that greater transparency is needed in this area and that to achieve this there should be a requirement that any publicity and other materials for such events should make it very clear that 'the fact of sponsorship does not equate to endorsement of a company or its products'." (Healthcare Financial Management Association)

"The principle should be reinforced that the event being sponsored should have an obvious and genuine benefit to a department and/or the organisation as a whole." (NHS Provider Representative)

68. Accounting for this feedback, we have enhanced consultation proposals and introduced a "reasonable person" test to the benefits of event sponsorship. The updated guidance (see the Management section) emphasises that collaboration is appropriate, but that there needs to be transparency around this.

69. We also heard questions around the practicality of asking staff to declare event sponsorship; respondents queried where and how this declaration would be made, and whether the benefit would be worth the additional administrative burden. We have recommended that organisations should retain written records of such arrangements, to act as an audit trail of decision making.

Question 12: Do you agree with our proposals regarding sponsored research?

What we consulted on	Final proposal
• Commercial funding for research purposes must be transparent • Any proposed research must go through the appropriate Health Research Authority approvals process • There must be a written protocol and written contract between the health professional(s) and/or the institutes at which the study will take place and the sponsoring organisation, which specify the nature of the services to be provided and the payment for those services • The study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine • Sponsorship of such research should be declared	• Funding sources for research purposes must be transparent. • Any proposed research must go through the relevant health research authority or other approvals process. • There must be a written protocol and written contract between staff, the organisation, and/or institutes at which the study will take place and the sponsoring organisation, which specifies the nature of the services to be provided and the payment for those services. • The study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, medical device, equipment or service. • Staff should declare involvement with sponsored research to their organisation.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding sponsored research?	77.2%	71.4%	89.7%	78.8%	72.7%	84.6%	78.3%

70. 77.2% of respondents agreed with these proposals.

Qualitative feedback

71. In light of consultation support we have retained most of the original drafting, with minor amendments to the language used to be consistent with other updates after consultation. A number of responses pointed to existing safeguards around sponsored research, and questioned whether this section of the guidance was necessary. We think it is an important area to cover, given the potential for conflicts of interest. In achieving consistent management of interests the guidance rightly draws upon existing mechanisms. We have also recommended that organisations should retain written records of such arrangements to act as an audit trail of decision making, and that staff should declare individual relevant interests.

Question 13: Do you agree with our proposals regarding sponsored posts?

What we consulted on	Final proposal
• Prior to entering into an agreement regarding the commercial sponsorship of a post approval should be sought from the appropriate individual as identified by the organisation • Arrangements regarding the commercial sponsorship of a post should only be entered where there is written confirmation that the arrangements will have no effect on purchasing decisions • Sponsored health professionals should not be involved in the promotion of specific products • Sponsors should not have any influence over the duties of the post or have any preferential access to any services, materials or intellectual property relating to or developed in connection with the sponsored role • Sponsored posts should be declared	• Staff who are establishing the external sponsorship of a post should seek formal prior approval from their organisation. • Rolling sponsorship of posts should be avoided unless appropriate checkpoints are put in place to review and confirm the appropriateness of arrangements continuing. • Sponsorship of a post should only happen where there is written confirmation that the arrangements will have no effect on purchasing decisions or prescribing and dispensing habits. For the duration of the sponsorship, auditing arrangements should be established to ensure this is the case. Written agreements should detail the circumstances under which organisations have the ability to exit sponsorship arrangements if conflicts of interest which cannot be managed arise. • Sponsored post holders must not promote or favour the sponsor's specific products, and information about alternative products and suppliers should be provided. • Sponsors should not have any undue influence over the duties of the post or have any preferential access to services, materials or intellectual property relating to or developed in connection with the sponsored posts.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding sponsored posts?	74.8%	67.9%	87.2%	84.8%	63.6%	84.6%	75.0%

72. 74.8% of respondents agreed with the proposals regarding sponsored posts.

Qualitative feedback

73. We heard lots of useful suggestions for safeguards around particular issues, such as the sponsorship of nursing posts which carry an obligation to use a sponsoring company's products, and the need to ensure that posts are not automatically renewed without appropriate checkpoints. The Urology Trade Association suggested that:

"Sponsored posts whether part or full time should not renew automatically and should be put up for tender every two to three years to ensure value for money for the NHS…Ideally each patient should be given a short and simple briefing sheet explaining that the sponsored healthcare professional should offer them a choice of products & home delivery companies... This would help to provide protection for the healthcare professional as well as the patient."

74. And the Association of British Healthcare Industries (ABHI) suggested:

"Routine auditing and reporting of products and service to enable reviewed for any bias towards sponsoring company."

75. Much of the feedback to this question focused on urology care and issues specific to pharmacy were also raised. The Pharmaceutical Services Negotiating Committee said:

"Taking the example of pharmacy owners sponsoring posts within a medical practice – these are sponsored by organisations within the NHS family. They too should be within the scope of this section. In many cases, there may be nothing untoward, but the suspicion if these are hidden arrangements is that the post holder will direct prescriptions etc. to the sponsoring pharmacy."

76. In response to this feedback, the guidance reiterates the need for staff to seek approval from their organisation to take up a sponsored post, requires posts to be reviewed before rolling forward, requires written confirmation that the posts will have no effect on purchasing decisions or prescribing and dispensing habits, and requires written agreements detailing how an organisation can exit sponsorship arrangements if conflicts of interest arise which cannot be managed. It also makes specific reference to sponsored posts not being used to unduly promoting or favouring the sponsor's products or giving the sponsor any undue influence over the duties of the post or any preferential access to any associated services, materials or intellectual property.

77. We have also recommended that organisations should retain written records of such arrangements to act as an audit trail of decision making, and that staff should declare individual relevant interests.

Question 14: Do you agree with our proposals regarding shareholdings?

What we consulted on	Final proposal

• All shareholdings in private companies (including interests in partnerships and limited liability partnerships) where there is any potential conflict of interest must be declared
• Shareholdings in publicly listed companies held in blind trusts need not be declared
• Shareholdings in publicly listed companies with which the individual is aware or should be aware that the employing organisation contracts, or is considering contracting with, must be declared if the holding exceeds £5,000 market value or more than 1/100th of the nominal value of the issued share capital, whichever is less
• In this circumstance the individual should declare the existence of the shareholding and the name of the company but need not declare the size of the interest
• This guidance should not preclude the declaration of shareholdings of less value than the threshold described above where the owner recognises that a conflict of interest could be perceived
• Where shareholdings have been declared and are identified as being a specific conflict in relation to someone's role management actions can include:
  • Excluding the affected party from the discussion
  • Requiring the employee to divest themselves of the shares in specific organisational contexts (eg NICE requires this)
	• Staff should declare, as a minimum, any shareholdings and other ownership interests in any publicly listed, private or not-for-profit company, business, partnership or consultancy which is doing, or might be reasonably expected to do, business with their organisation.
	• There is no need to declare shares or securities held in collective investment or pension funds or units of authorised unit trusts.
	• Where shareholdings or other ownership interests are declared and give rise to risk of conflicts of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding shareholdings?	63.6%	50.0%	76.9%	74.2%	45.5%	61.5%	56.7%

78. 63.6% of respondents agreed with the proposals regarding shareholdings.

Qualitative feedback

79. Many respondents asked why individuals should have to declare shareholdings that they cannot direct (such as ISAs, pension schemes or blind trusts):

"There are numerous popular financial instruments which contain, within a broad range of holdings, equities in pharmaceutical, medical equipment and other organisations which would fall under the umbrella of a shareholding within the catchment of your definition. This would include private pensions, market ETFs, unit trusts and the like." (Clinician)

"This needs tightening. Your proposal as written suggests that I would have to declare a shareholding worth £5k in GlaxoSmithKline which is held within an ISA. This level of declaration is too intrusive, and not strategically relevant in terms of influence which could be perceived. "(Gloucestershire Anaesthetic Services)

80. There was also a range of opinion as to what threshold value of shareholdings should trigger a requirement to declare, and whether the declaration should disclose the actual value of the shareholding:

"There should be no £5000 limit."

"£500 is probably too low, £50,000 may be more appropriate."

"It would provide greater transparency if the size of the interest was required to be declared."

"In practice, shares traded on stock markets are subject to frequent movements and so there could be some difficulty in applying the >£5k or 1/100th nominal value of issued share capital rule."

81. In response to the broad range of views expressed we have adopted simplified guidance on the types of relevant interests to be declared. We believe that this approach is the best way to aid judgement as to what information needs to be declared. In line with the consultation proposals, we are not requiring shares or securities held in collective investment or pension funds or units of authorised unit trusts to be declared on the basis of the general absence of an ability to direct these.

Question 15: Do you agree with our proposals regarding patents?

What we consulted on	Final proposal
• Senior Staff should declare relevant patents and other intellectual property rights as these are a direct financial interest • Senior Staff should seek permission from their employing organisation before entering into any agreements with commercial companies regarding product development • The organisation should ensure that it is able to identify, protect and exploit potential intellectual property rights as and when they arise	• Staff should declare patents and other intellectual property rights they hold (either individually, or by virtue of their association with a commercial or other organisation) relating to goods and services which are, or might be reasonably expected to be, procured or used by their organisation. • Staff should seek prior permission from their organisation before entering into any agreement with bodies regarding product development, research, work on pathways, etc, where this impacts on the organisation's own time, or uses its equipment and/or resources. • Where holding of patents and other intellectual property rights give rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding patents?	61.6%	50.0%	71.8%	78.8%	18.2%	53.8%	60.0%

82. 61.6% of respondents agreed with our proposals regarding patents.

Qualitative feedback

83. Many respondents suggested that our proposals should apply to all staff (in consultation we suggested that they should only apply to 'senior staff'). Others felt that we needed to be clearer on the materiality of a patent, and the circumstances in which it would be right to require individuals to ask for permission:

"The requirement to declare and ask for permission to develop patented material is an unreasonable restriction on personal freedom." (NHS Provider Representative)

"Permission should only relate to products that have been developed using the organisation's own time, equipment or resources." (NHS Provider Representative)

"Where this work does not interfere with job planned activities with the primary NHS employer and providing IP issues have been correctly handled we see no reason to seek permission." (Association of Anaesthetists of Great Britain and Ireland 'AAGBI')

84. Some interesting questions were raised about how any benefits arising from patents should be shared out among interested parties. For the purpose of this work, these questions arguably go beyond issues of conflicts of interest. We have instead focused the guidance on issues where an individual's decision making role could lead to benefit from possession of a patent and are requiring staff to declare patents and other intellectual property rights they hold for products or services which are, or might reasonably be expected to be, procured or used by their organisation. We are asking individuals to seek prior permission from their organisations if NHS time and resources have been used in the development of a patented product, because this could specifically raise issues regarding conflicts of interest.

Question 16: Do you agree with our proposals regarding donations?

What we consulted on	Final proposal
• Staff should not actively solicit charitable donations and should not agree to receive a charitable donation in lieu of a professional fee • Donations should be made to a specific charitable fund and a receipt should be issued • Decisions about whether a donation should be accepted are ultimately for the Trustees of a Charitable fund to make, and Trustees should be willing to turn down donations if they are not confident of their legitimacy • Donations received should be declared by the individual receiving the donation • Where donations are from a private individual their identity does not need to be disclosed should they not wish it to be, unless the Trustees believe that it would be inappropriate to receive an anonymous donation • Donations from suppliers should be declared including the amount, the donor and the recipient	• Acceptance of donations made by suppliers or bodies seeking to do business with an organisation should be treated with caution and not routinely accepted. In exceptional circumstances a donation from a supplier may be accepted but should always be declared. A clear reason should be recorded as to why it was deemed acceptable, alongside the actual or estimated value. • Staff should not actively solicit charitable donations unless this is a prescribed or expected part of their duties for an organisation, or is being pursued on behalf of that organisation's registered charity (if it has one) or other charitable body and is not for their own personal gain. • Staff must obtain permission from their organisation if in their professional role they intend to undertake fundraising activities on behalf of a pre-approved charitable campaign. • Donations, when received, should be made to a specific charitable fund (never to an individual) and a receipt should be issued. • Staff wishing to make a donation to a charitable fund in lieu of a professional fee they receive may do so, subject to ensuring that they take personal responsibility for ensuring that any tax liabilities related to such donations are properly discharged and accounted for.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding donations?	65.6%	50.0%	82.1%	65.2%	54.5%	53.8%	71.7%

85. 65.6% of respondents agreed with our proposals regarding donations.

Qualitative feedback

86. A number of clinicians said they sometimes asked for a charitable donation to be made in lieu of payment for certain activities (such as speaking duties), and saw no merit in proposals that sought to prevent this. We agree with this principle, but also note that HM Revenue & Customs issue guidelines in this area. As such, we have revised proposals to provide for such situations but clarified that it is the responsibility of individuals to ensure that such approaches do not contravene HMRC guidance. Our revised guidance (in the Management section) emphasises the need for personal responsibility in this area.

87. A number of respondents asked for clarity on how our proposals related to staff legitimately soliciting donations to their organisation's charitable fund:

"Some staff have roles in which they will actively solicit charitable donations then donate fees into a charitable fund. This needs to be rewritten in the context of their organisations charitable fund arrangements." (NHS Provider Representative)

88. We have reviewed our drafting to ensure that there will be no unintended consequences inhibiting charitable giving, and to recognise that some staff may have a job that requires solicitation of charitable donations for their organisation.

89. We also heard views that these proposals needed to be carefully framed so as to avoid unintended consequences such as discouraging legitimate fundraising activity:

"The proposals as they stand may dissuade staff from small-scale fundraising (e.g. to buy Christmas gifts for patients on a ward; to do a sponsored event for a specific cause etc). Even some quite large-scale initiatives (e.g. buying scanners for hospitals) have been successfully carried out by a whole series of sponsored events initiated and supported by the staff of acute trusts." (NHS Commissioner Representative)

90. We believe that the guidance as drafted does not prohibit such activity.

Question 17: Do you agree with our proposals regarding loyalty interests?

What we consulted on	Final proposal
• Senior staff should declare any position of authority in a charity or voluntary organisation in the field of health and social care or contracting for NHS services • Senior staff should declare any familial or other relationships which could lead to perceived or actual conflicts of interest arising, eg declaring relationships with candidates during recruitment activity • Senior staff should declare any political affiliations where they hold an active role e.g. councillor etc	Loyalty interests should be declared by staff involved in decision making where they: • Hold a position of authority in another NHS organisation or commercial, charity, voluntary, professional, statutory or other body which could be seen to influence decisions they take in their NHS role. • Sit on advisory groups or other paid or unpaid decision making forums that can influence how their organisation spends taxpayers' money. • Are, or could be, involved in the recruitment or management of close family members and relatives, close friends and associates, and business partners. • Are aware that their organisation does business with an organisation with whom close family members and relatives, close friends and associates, and business partners have decision making responsibilities. Where holding loyalty interests gives rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals regarding loyalty interests?	70.8%	60.7%	79.5%	84.8%	54.5%	69.2%	68.3%

91. 70.8% of respondents agreed with our proposals regarding loyalty interests.

Qualitative feedback

92. Some felt this section could be even more comprehensive, explicitly addressing situations such as staff employed by more than one NHS organisation or other public body, and issues around whole population health models:

"It doesn't cover situations where a person is a member of an NHS provider. I would suspect that the NHS will insist on senior executives declaring potential conflicts where they are members of a MCP with delegated population budgets. As such any executive should declare their position of authority as there are potential conflicts of

interest driven by organisation need rather than population health." (NHS Commissioner Representative)

93. Our revised drafting aims to accommodate these points, covering a range of situations and being specific on the behaviours we are trying to prevent as well as the need for people to exercise judgement. We have, however, removed specific reference to political affiliations. Instead we would expect individuals who conduct political duties which are materially relevant to their NHS work to declare these as part of the provisions relating to outside employment. One clinician said:

"Political affiliations are a private matter. If they are on a council they should declare any COI relating to any decisions taken and recuse themselves but this should not be the scope of the NHS employer."

Identification and management of interests

94. In the consultation we put forward a suggested approach by which interests should be declared by staff, both generally (paragraphs 61-62 at pages 32 and 33) and in specific contexts - e.g. in the context of decision making groups such as boards and sub-committees, advisory groups and procurement panels (paragraphs 63-66 at pages 34 to 36) with a view to this leading to greater consistency and adoption of good practice.

Question 18: Do you agree with the proposals regarding identification of interests?

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with the proposals regarding identification of interests?	67.2%	67.9%	74.4%	74.2%	45.5%	76.9%	65.0%

95. 67.2% of respondents agreed with our proposals regarding identification of interests.

Qualitative feedback

96. We received little specific comment on these proposals but we did hear general concerns over administrative burdens. In order for our proposals to change behaviours, there will of course be some additional work for organisations and staff to comply with the guidance. However, concerns expressed about additional burdens were also linked to the potentially wide scope of the definition of 'senior staff' that we originally proposed. As set out in question 4 above, we have now revised this definition substantially to concentrate on people with decision making power and/or influence.

97. In the final guidance (within the Management section) we have presented common approaches to how interests should be managed once identified, based on our consultation proposals, feedback we received, and wider good practice. For the purposes of the guidance we call these 'general management actions'.

Question 19: Do you agree with the proposals regarding Boards and sub-committees, advisory committees and procurement?

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with the proposals regarding Boards and sub-committees, advisory committees and procurement?	65.2%	60.7%	66.7%	77.3%	54.5%	76.9%	65.0%

98. 65.2% of respondents agreed with our proposals.

Qualitative feedback

99. Some felt that the processes we commended were overly elaborate; one NHS Commissioner Representative said:

"We agree with the majority of the proposals, but think that in relation to board/sub-committee meetings, interests should be reviewed at the start of the meeting rather than against every agenda item as this could make meetings unwieldy." (NHS Commissioner Representative)

100. We have therefore clarified the points of meetings at which interests should be declared and emphasised the individual responsibility of each Board member to consider their interests against agenda items.

101. Other constructive feedback from organisations which routinely deal with issues in this area has led us to reconsider prescribing a checklist of actions for managing interests. Instead, we now restate basic principles of good governance and provide a menu of suggested management actions to support judgement and decision making. This should prevent the proposed actions becoming onerous and will also help apply the guidance across a spectrum of organisational sizes and contexts.

102. We heard strong warnings against rules which could lead to the loss of clinical advisory expertise. NHS Clinical Commissioners said:

"Sections 63 and 65 of the consultation can be interpreted to preclude individuals with any conflict from chairing advisory committees, and as a consequence may prevent expert advisers from being able to effectively contribute to discussions or support decision-making. This could have a significant impact on many core CCG functions,

particularly Area Prescribing Committees and the commissioning of primary care if clinical experts are unable to fully participate in discussions and inform clinical strategy… Equal weight needs to be given to the dangers of undue influence as to the dangers of commissioning decisions that are not fully informed by clinical expertise."

103. The Management section of the guidance now explicitly recognises the importance of clinical or relevant expertise informing decisions made by Boards, committees, and procurement panels.

104. In the guidance we also recognise that many organisations use differently described vehicles for the making of important decisions such as entering into (or renewing) large scale contracts, making procurement decisions. These include boards (or committees and sub-committees of boards), advisory groups, and procurement panels. For the purposes of the final guidance these are referred to in as 'strategic decision making groups'. In recognition of the fact that the interests of those who involved in these groups need to be well known in order to be managed we asks organisations to identify relevant such groups in their own context and ensure they operate in a manner consistent with common principles we set out in the guidance (in the Management section). These reflect wider standards of good governance and the comments we heard in consultation.

Publication and transparency

105. The group concluded that the public have a legitimate right to expect to be able to access information about interests of staff and organisations that make decisions which lead to the spending of public money. It also recognised that, balanced against this, were important issues of personal privacy – the rights to such should be respected and only interfered with if proportionate and for a legitimate purpose. Therefore, it proposed that the interests of 'senior staff' should be published.

Question 20: Do you agree that information on interests held by senior staff described above should be published?

106. Proposals in this regard are set out at paragraphs 72-75 (pages 37 to 38) of the consultation.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree that information on interests held by senior staff described above should be published?	56.4%	25.0%	84.6%	59.1%	36.4%	53.8%	56.7%

107. Overall 56.4% of respondents agreed with the publication of interests held by senior staff. However, this ranged from 84.6% of NHS Commissioner Representatives in support, to 25% of Members of the Public in support.

Qualitative feedback

108. Some respondents disagreed with this question because, in the consultation, it was inextricably linked to the definition of 'senior staff' which they did not support (this definition has now been refined as set out in Question 4 above). We are also conscious that some responses were given in the context of our proposal concerning the publication of earnings from private practice, which has now been refined as set out in questions 8 and 9 above. Some respondents felt they could agree with question 20 if the definition of "senior staff" was amended or if earnings from private practice were exempted.

109. Responses to these proposals covered a spectrum. Those in agreement felt that publication was the best way to achieve genuine transparency. For those against privacy was a key concern - with many respondents supporting the principle but raising concerns for those individuals whose information was published. One member of the public said:

"…There may be important issues of "privacy" but privacy must be trumped by a proper analysis of conflicts of interest in the important public service that is the NHS."

110. We heard some views that the interests held by all staff should be published:

"The CCG believes that information on interests should be published for all staff regardless of seniority." (NHS Commissioner Representative)

"In theory, yes, but subject to a number of changes; some information needs to be declared regardless of position (i.e. councillor), the definition (staff/senior staff etc) needs expanding…" (NHS Commissioner Representative)

"…The publication of information should relate to the post, and the potential for conflict of Interest, rather than necessarily when the seniority – particularly when, in the NHS, relatively senior doctors are classified as 'Junior'." (Member of the public)

111. However, other respondents felt that whilst all staff should declare interests, publication should be more focused on 'senior' (now 'decision making') staff. For example, NICE said:

"Whilst all staff should arguably be required to declare interests, routinely publishing information on the declarations of only the most senior staff would be a sensible approach to avoid disproportionate reporting burdens."

112. We also heard views on the declaration of nil returns, and have captured this in the Declarations section:

"In supporting your definitions of staff groups, would also suggest that there needs to be a nil declaration required from this staff group…at present within your consultation document you are only inferring that the requirement is to make a positive declaration. If I get 30 declarations per year .....how do I know this is an accurate reflection of what is going on in my organisation?" (NHS Provider Representative)

"Ensure that you capture this policy by making the distinction that if you fall into the senior category you have to declare a nil return and if you are lower than a seven but have an interest you still need to declare this." [NHS Commissioner Representative]

113. Regarding publication in general, concerns were raised about burdens on organisations and whether this would be the best use of resources:

"The reporting burden for NHS staff and organisations should be proportionate to the scale of the problem that is being addressed. The document acknowledges that such problems are difficult to quantify and the evidence provided is largely anecdotal. (The Shelford Group)

"While we have no issue with the intent of these proposals to increase transparency, the costs to individual organisations to publish this information on their websites may be prohibitive and may move resources away from patient care." (London Chief Pharmacists Network)

114. On the basis of the feedback we decided that publication of interests was appropriate for 'decision making staff' (see the Transparency section of the guidance), and have accommodated concerns relating to publication of private

practice earnings in our amendments covered in questions 8 and 9 discussed above. However, we also recognise that some organisations may wish to go further than just publishing information about decision making staff. Our guidance is permissive in this regard and those organisations wishing to publish information about wider classes of staff outside this group may do so if they wish.

Question 21: Do you agree that information on interests should be published in a consistent way across organisations, using the format described above? AND Question 22: Do you agree that information on interests should be published (at least annually) by organisations?

115. In the consultation (paragraphs 76-80 at pages 38 to 40) we proposed a standardised approach to what information on interests should be published, and suggested that publication of interests should be refreshed at least annually.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree that information on interests should be published in a consistent way across organisations, using the format described above?	64.0%	39.3%	84.6%	71.2%	54.5%	61.5%	58.3%
Do you agree that information on interests should be published (at least annually) by organisations?	66.4%	50.0%	94.9%	74.2%	27.3%	61.5%	58.3%

116. 64% of respondents agreed that interests should be published in a consistent way across organisations. 66.4% of respondents agreed that interests should be published at least annually.

Qualitative feedback

117. The main feedback on these proposals reiterated views on the appropriateness of publishing information in principle, and information about earnings from private practice specifically. For the reasons given above we do believe it is appropriate to publish information about the interests of decision making staff (as set out in the Transparency section of the guidance), and we have also refined ou4 proposals on private practice as discussed earlier in this document.

118. In the guidance (within the Management section) we have been more specific about what information should be recorded with regard to common situations where interests can give rise to risks of conflict. We have also provided templates for organisations to use, if they choose to, to collect information. Adoption of common templates is beneficial as it will assist staff with multiple roles to make returns more

easily if they don’t have to fill out differently structured returns for different organisations. We also have maintained the proposal requiring, as a minimum annual refreshes of published information.

Question 23: Do you think that further consideration should be given to aggregating returns on MyNHS, or another suitable web portal?

119. As part of consultation (paragraphs 81-84 at pages 41 to 42) we envisage more information being published by organisations, and we asked for views on the desirability of pulling this together in one place.

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you think that further consideration should be given to aggregating returns on MyNHS, or another suitable web portal?	52.8%	25.0%	59.0%	63.6%	27.3%	53.8%	51.7%

120. Overall, 52.8% of respondents agreed with the aggregation of returns on to a web portal. However, this ranged from 63.6% of NHS Provider Representatives in support, to 25.0% of Members of the Public in support.

Qualitative feedback

121. Some respondents objected to the concept of aggregation - either on its own merits or because of associated resource implications. NHS Providers said:

"The place at which conflicts of interest need to be managed is at organisation level. Aggregating information will lead to increased bureaucracy, but will not result in further action."

122. Some respondents agreed with this proposal because having all the information in one place would make it easier for the public to access. Pfizer Ltd. suggested that:

"A central NHS searchable database would be preferable to multiple registers."

123. Transparency International said:

"There is utility in aggregating returns centrally. This will easily allow the relevant oversight bodies in the NHS and the public to monitor conflicts of interest across the NHS. If organisations publish the information requested…in a consistent manner using an open data format, the logistical challenge of centralising the information…can be minimised."

124. However other respondents, such as the Royal College of Surgeons of Edinburgh and a number of NHS Commissioner Representatives were concerned that the costs of establishing such a portal might outweigh the benefits. A member of the public pointed out that web-based information would not be available to all. Other NHS Commissioner Representatives also suggested that members of the public would be more likely to go to the organisation's own website if they wanted to find this information, rendering an additional aggregated web portal unnecessary.

125. On the basis of these responses we think the concept of aggregating returns centrally merits further consideration in the future, when publication has been embedded in a consistent format at organisational level. However, in recognition of the issues raised in consultation, we are not pursuing this proposal at the present time.

Question 24: Do you believe that we should pursue the approaches described above to ensure greater compliance with the Disclosure UK initiative?

What we consulted on	Final proposal
During the course of its work the group were very supportive of the ABPI's Disclosure UK initiative. At the time of its launch, a number of national organisations also publicly declared their support for this scheme, including the General Medical Council, the Academy of Medical Sciences, the Faculty of Pharmaceutical Medicine, and the Royal College of Physicians. We believe, like them, that all health professionals should be transparent and give their consent to information about payments received from pharmaceutical companies being published by the ABPI but, at present, health professionals can refuse to give this consent. We would seek to pursue a variety of means in order to lead to greater compliance in this area: to make this a condition for doing business for and with the NHS, much have GSK have done in the context of working with them. Subject to the outcomes of this consultation we will consider whether, for instance, this is an issue which should take greater prominence in areas like clinical appraisals and eligibility for clinical excellence awards (unless there are exceptional circumstances – such as risk of harm – which mean it was inappropriate for information about individuals to be disclosed). These are live options which we believe we could and should pursue with our partners during implementation.	[O]rganisations should seek to ensure that staff who are subject to wider transparency initiatives such as the ABPI Disclosure UK scheme are aware of and comply with them: http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx)

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you believe that we should pursue the approaches described above to ensure greater compliance with the Disclosure UK initiative?	60.0%	32.1%	84.6%	71.2%	18.2%	69.2%	51.7%

126. 60% of respondents agreed with the approach to increasing uptake of the Disclosure UK scheme.

Qualitative feedback

127. Organisations such as the General Medical Council, the British Healthcare Trades Association, The Royal College of Surgeons, Pfizer Ltd., the Nursing and Midwifery Council, the Association of the British Pharmaceutical Industry, and Transparency International were supportive of these proposals.

128. Other individual respondents supported the idea of mandating the scheme, whereas others were concerned about the potential for excess bureaucracy or issues with data protection. We have therefore kept the reference to transparency initiatives such as Disclosure UK in the guidance. We reiterate the support of the group for such initiatives – it is absolutely right and proper that the involvement of individuals and organisations with industry is well known about to support public confidence.

129. In the NHS England Board Paper which accompanies this report we have made further recommendations to the Department of Health and NHS Employers to consider whether or not any contractual arrangements they oversee could and should be refined to drive greater compliance with this initiative.

Managing breaches and sanctions

130. Whilst recognising the individual cases will be different and require investigation and fact finding in order to resolve the group considered (paragraphs 87-89 at page 43 of the consultation) that provision of some standardised approaches to dealing with breaches and resultant sanctions for inappropriate behaviour in relation to management of conflicts of interest was desirable.

Question 25: Do you agree with our proposals on breaches and sanctions?

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Do you agree with our proposals on breaches and sanctions?	60.8%	57.1%	87.2%	69.7%	27.3%	53.8%	48.3%

131. 60.8% of respondents agreed with these proposals.

Qualitative feedback

132. We heard a range of views on the subject of national rules versus local processes. One clinician said:

"No teeth to this if all sanctions are local – an organisation may be delighted with a senior member of staff making regional commissioning decisions which favour their organisation, so would not sanction them."

133. Whereas in the view of NHS Providers:

"It should be for individual employers to deal with breaches and sanctions in line with local procedures."

134. In response to this feedback we have attempted to strike a balance between acknowledging the responsibility of local organisations and commending good practice in terms of the basic issues and management processes that they should consider when faced with breaches. This is set out in the 'Breaches' section of the guidance.

135. A number of respondents were of the view that referral of breaches to regulators should be a last resort. The drafting of the guidance places such referrals in the context of wider possible responses.

136. We heard a range of views on how the health system should learn from breaches, such as through publication of breach reports and reporting to local audit committees. One NHS Provider Representative said:

"Information on the number and nature of breaches should be collected at a national level, so that the system can see where the greatest problems are and can adapt appropriately."

137. An NHS Commissioner Representative said:

"The need to report breaches annually to the organisations governing body could be strengthened by a need for providers to send a copy of their annual return to their commissioners…ensuring the CCG governing body receives a system wide report, in public, which requires CCG discussion re adequacy of controls, lessons learnt in public would help."

138. We are conscious of the need to minimise the annual reporting burden on organisations, and feel that a step by step approach to achieving cross-system learning from breaches might be advisable. For this reason, we have made it optional for organisations to publish and report annually on breaches, but have strongly emphasised the value of reviewing any breaches that lead to management action. When evaluating the impact of the guidance as a whole we will return to this issue, to ascertain whether further action in this regard is necessary.

139. We are also conscious in the context of sanctions of the importance to investigate all relevant facts and circumstances before making decisions. However, it is important (and fair) that staff are aware of the potential consequences resulting from breaches for both them and their organisations. Therefore, Annexed to the guidance we have summarised the nature and extent of potential consequences regarding breaches.

Question 26: Do you agree that the underlying principles and rules in this consultation should (perhaps with some amendment) also apply to non NHS providers in respect of NHS funded services they provide? Do you agree that where services are delivered that don't relate to NHS funded work not all of the proposals in the consultation should apply?

140. As part of its deliberations the group recognised the diversity of organisations involved in delivering NHS services. These are a mix of public NHS bodies, private organisations and businesses, voluntary sector bodies, and groups of contractors (for instance in the context of the delivery of primary care). Each of these various classes of organisations operates under different statutory and governance contexts. However, as far as possible, the group wanted these organisations to operate under the same principles and rules for managing conflicts. Therefore, it asked a specific question on this (see paragraph 90 on page 45 of the consultation).

Quantitative feedback

QUESTION	Total Population (n=250)	Member of the public (n=26)	NHS Commissioner Representative (n=43)	NHS Provider Representative (n=59)	Non-NHS Provider Representative (n=41)	Professional Body / Royal College (n=12)	Other (n=69)
Question 26:	72.4%	53.6%	87.2%	81.8%	54.5%	69.2%	73.3%

141. 72.4% of respondents agreed with these proposals:

Qualitative feedback

142. We heard a range of views:

"The same principles should apply irrespective of who is providing the service" (NHS Provider Representative)

"Yes. Disclosure of interests for their senior staff in publically available format as a minimum." (NHS Commissioner Representative)

"Yes absolutely – this should be part of the NHS Standard Contract." (NHS Commissioner Representative)

143. We also received some constructive suggestions for amendments which could help the rules and principles to apply to non-NHS providers (independent and private sector organisations, GP practices, community pharmacies, community dental practices, optical providers) and local authorities:

"This is supported in principle but policing the application of the principle and rules in non-NHS providers could be impractical." (NHS Commissioner Representative)

"Yes, but organisations should be free to use their own systems of declarations. It should be for commissioners to decide whether those they contract with meet their required levels of probity."(NHS Providers)

"Yes, however we think there should be a minimum contract value limit for organisations to which this would apply. We would not want to see an increased burden on small third sector providers like care homes and charities." (NHS Commissioner Representative)

144. Challenge to consultation proposals was made by a number of primary care contractors and non-NHS providers. We heard views that because these providers deliver services for a pre-agreed price decided by the NHS, then they have no influence over NHS decision-making and as such there is no risk of conflict:

"In the case of optical practices and optical practitioners there is virtually no scope for conflict of interest in their normal activity as a provider of NHS funded services. Although part of primary care, optical practitioners do not sit on or advise Clinical Commissioning Groups and have no role in procuring goods or services with public funds… It would be excessive – and in some cases inappropriate – to expect private businesses and private employees to comply with these proposals where they are simply delivering a service under contract to an NHS body and with no financial decision making powers or influence." (Federation of Ophthalmic and Dispensing Opticians)

"For most pharmacy contractors, individual community pharmacists and pharmacy technicians, there is very limited scope for conflict of interest in their normal activity as a provider of NHS funded services… Community pharmacy contractors and professionals do not make decisions about the commissioning of NHS services or employment of NHS staff, and there are very few circumstances where they can commit NHS resources even through prescribing or referral decisions." (Pharmacy Voice)

145. We also heard the argument that because non-NHS providers do a combination of NHS and other work, it would be disproportionate to apply all the rules and principles to them – especially when they are already subject to wider provisions and obligations under the Bribery Act 2010, Company Law, contracts and professional codes of ethics:

"This would need to recognise that a non-NHS provider may have other non-healthcare income streams." (NHS Commissioner Representative)

"General dental practitioners also provide varying amounts of NHS and private work. The degree of commitment to the NHS varies with many dentists spending less than 20 per cent of their time on NHS work. It seems unreasonable for these dentists to be required to comply with all of the provisions of the policy." (British Dental Association)

146. However a common theme from non-NHS providers and representatives challenging these proposals was the recognition that their staff should be in-scope if they are fulfilling advisory roles:

"We do however agree that where a member of the optical professions…has any wider role for the NHS in providing advice on or in deciding the design, planning or commissioning of services or goods, then they should of course be covered by these provisions….We suggest that the concerns that this proposal appears to be seeking to address might be better addressed by ensuring that all of those who are members of NHS advisory groups and boards, or who provide clinical or commercial advice to

the NHS, must declare to that board or advisory group all conflicts of interest." (Federation of (Ophthalmic and Dispensing) Opticians)

147. Our overarching objectives remain to protect taxpayers and the use of the NHS pound and to help protect staff and organisations from risk. So we have developed a set of principles and rules for managing conflicts of interest that we would like to see reflected by organisations wherever the NHS pound is spent, or where NHS funded care is delivered.

148. However, we are conscious of the need for any guidance to be proportionate and enforceable. Many providers of NHS services have mixed private/public business models and are already subject to existing regulation such as the Bribery Act 2010, contracts and professional codes of ethics. It is arguable that the greatest risks and concerns regarding conflicts of interest arise in those either making significant commissioning/contracting decisions or in the larger NHS providers, which NHS England and its partners have legal/statutory influence over.

149. Contractor groups and private/independent sector providers, whilst an important part of care delivery, arguably pose fewer risks regarding conflict of interest because they deliver services under terms set by the NHS over which they have no direct influence. Different legal provisions also apply to such bodies influencing the method and the extent by which centrally issued guidance can be applied to these bodies.

150. In light of these considerations (in the Scope section of the guidance) we have clarified that the guidance is applicable to the following NHS bodies:

- Clinical Commissioning Groups ('CCGs'),
- NHS Trusts, all or most of whose hospitals, establishments and facilities are situated in England, and NHS Foundation Trusts, (which include secondary care trusts, mental health trusts, community trusts, and ambulance trusts)
- NHS England

151. CCGs must have regard to this guidance, through its inclusion of content in statutory guidance issued by NHS England pursuant to its powers under s.14O and s.14Z8 of the National Health Service Act 2006. We will be updating this CCG statutory guidance to reflect the contents of this wider guidance, and in light of emerging issues relating to new care model contracting, over the next couple of months.

152. NHS Trusts and NHS Foundation Trusts must have regard to this guidance through its incorporation into the NHS Standard Contract pursuant to General Condition 27

153. Its applicability to NHS England will be delivered through amendments to our Standards of Business Conduct. The NHS England secretariat supporting this work has been in close dialogue throughout the process with our arms' length body partners. They have agreed to review their own policy and processes in light of publication of this guidance and make appropriate changes, subject to consideration and approval by their own governance groups.

154. This guidance will, therefore, not apply to bodies not listed above (i.e. for profit and not for profit independent and private sector organisations, GP practices, community pharmacies, community dental practices, optical providers, and local authorities – who are subject to different legislative and governance requirements). However, we commend this guidance to them as a means to effectively manage conflicts of interest. However, GP practice staff should note that the requirements in the statutory guidance for CCGs on the management of conflicts of interest (referred to above) continue to apply to GP partners (or where the practice is a company, each director) and individuals in a practice directly involved with the business or decision making of their CCG.

155. During our evaluation of the impact of the guidance and will review the position regarding coverage and applicability of the guidance if material concerns in relation to other organisations not currently in scope arise.

Table – overall consultation responses (online survey and email responses)

#	QUESTION	YES	NO	NOT ANSWERED
n/a	As is explained in the Confidentiality section of the consultation document it is our intention to publish comments received in this consultation. Please indicate whether you consent to this.	74.8%	14.8%	10.4%
1	Do you agree with our definition of conflict of interest?	65.6%	29.6%	4.8%
2	Do you agree with our sub-classifications of interests?	63.6%	30.8%	5.6%
3	Are the circumstances we have identified sufficient to capture all instances?	58.0%	36.0%	6.0%
4	Do you agree with the proposed definition of senior staff?	50.4%	43.6%	6.0%
5	Do you agree with our proposals regarding gifts?	59.2%	36.0%	4.8%
6	Do you agree with our proposals regarding hospitality?	55.2%	38.8%	6.0%
7	Do you agree with our proposals regarding outside employment?	54.0%	38.8%	7.2%
8	Do you agree with our proposals regarding private practice?	36.0%	56.8%	7.2%
9	In particular, do you agree with the proposal regarding declarations of information about private practice, including information about earnings?	32.8%	58.0%	9.2%
10	Do you agree with our proposals regarding general sponsorship?	73.6%	18.0%	8.4%
11	Do you agree with our proposals regarding sponsored events?	70.0%	20.0%	10.0%
12	Do you agree with our proposals regarding sponsored research?	77.2%	14.8%	8.0%
13	Do you agree with our proposals regarding sponsored posts?	74.8%	15.2%	10.0%
14	Do you agree with our proposals regarding shareholdings?	63.6%	27.6%	8.8%
15	Do you agree with our proposals regarding patents?	61.6%	25.2%	13.2%
16	Do you agree with our proposals regarding donations?	65.6%	21.6%	12.8%
17	Do you agree with our proposals regarding loyalty interests?	70.8%	19.6%	9.6%
18	Do you agree with the proposals regarding identification of interests?	67.2%	22.0%	10.8%
19	Do you agree with the proposals regarding Boards and sub-committees, advisory committees and procurement?	65.2%	24.4%	10.4%
20	Do you agree that information on interests held by senior staff described above should be published?	56.4%	35.2%	8.4%
21	Do you agree that information on interests should be published in a consistent way across organisations, using the format described above?	64.0%	26.8%	9.2%
22	Do you agree that information on interests should be published (at least annually) by organisations?	66.4%	24.4%	9.2%
23	Do you think that further consideration should be given to aggregating returns on MyNHS, or another suitable web portal?	52.8%	35.6%	11.6%
24	Do you believe that we should pursue the approaches described above to ensure greater compliance with the Disclosure UK initiative?	60.0%	28.8%	11.2%

25	Do you agree with our proposals on breaches and sanctions?	60.8%	26.0%	13.2%
26	Do you agree that the underlying principles and rules in this consultation should (perhaps with some amendment) also apply to non NHS providers in respect of NHS funded services they provide? Do you agree that where services are delivered that don't relate to NHS funded work not all of the proposals in the consultation should apply?	72.4%	18.8%	8.8%

Managing Conflicts of Interest in the NHS

Guidance for staff and organisations

Publications Gateway Reference: 06419

NHS England INFORMATION READER BOX

Directorate		
Medical	Operations and Information	Specialised Commissioning
Nursing	Trans. & Corp. Ops.	**Commissioning Strategy**
Finance		

Publications Gateway Reference:	0
Document Purpose	Guidance
Document Name	Managing Conflicts of Interest in the NHS
Author	NHS England
Publication Date	07 February 2017
Target Audience	CCG Clinical Leaders, CCG Accountable Officers, CSU Managing Directors, Foundation Trust CEs , Medical Directors, Directors of Nursing, NHS Trust Board Chairs, NHS England Regional Directors, NHS England Directors of Commissioning Operations, All NHS England Employees, Directors of HR, Directors of Finance, NHS Trust CEs
Additional Circulation List	Care Trust CEs, GPs
Description	This guidance provides guidance for the management of conflicts of interest in the NHS. It is applicable to Clinical Commissioning Groups, NHS Trusts and NHS Foundation Trusts and NHS England. Other bodies involved in the provision of NHS services are invited to consider implementing this guidance.
Cross Reference	Managing Conflicts of Interest: Revised Statutory Guidance for CCGs
Superseded Docs (if applicable)	
Action Required	Review and update existing relevant organisational policies.
Timing / Deadlines (if applicable)	**This guidance comes into force 1 June 2017**
Contact Details for further information	england.psu@nhs.net

Document Status

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Scope of this guidance

This guidance is intended to protect patients, taxpayers and staff covering health services in which there is a direct state interest. It comes into force on 1 June 2017.

It is applicable to the following NHS bodies:

- Clinical Commissioning Groups ('CCGs')
- NHS Trusts (all or most of whose hospitals establishments and facilities are situated in England) and NHS Foundation Trusts - which include secondary care trusts, mental health trusts, community trusts, and ambulance trusts
- NHS England

For the purposes of this guidance these bodies are referred to as 'organisations'.

The principles of this guidance will be included in a revised version of the statutory guidance for CCGs issued by NHS England pursuant to its powers under s.14O and s.14Z8 of the National Health Service Act 2006. Until this guidance comes into force existing guidance issued under these powers continues to apply, and is accessible at: https://www.england.nhs.uk/commissioning/pc-co-comms/coi/"

NHS Trusts and NHS Foundation Trusts must have regard to this guidance through its incorporation into the NHS Standard Contract pursuant to General Condition 27.

Its applicability to NHS England will be delivered through amendments to our Standards of Business Conduct.

This guidance does not apply to bodies not listed above (i.e. independent and private sector organisations, general practices*, social enterprises, community pharmacies, community dental practices, optical providers, local authorities – who are subject to different legislative and governance requirements). However, the boards/governing bodies of these organisations are invited to consider implementing the guidance as a means to effectively manage conflicts of interest and provide safeguards for their staff. The requirements of GC27.2 of the generic NHS Standard Contract (2017/18 and 2018/19 edition) should be interpreted in that light.

* However, GP practice staff should note that the requirements in the statutory guidance for CCGs on the management of conflicts of interest (referred to above) continue to apply to GP partners (or where the practice is a company, each director) and individuals in a practice directly involved with the business or decision making of their CCG.

Contents

1. Purpose

1.1. Every year the taxpayer entrusts NHS organisations with over £110 billion to care for millions of people. This money must be spent well, free from undue influence.

1.2. To deliver high quality and innovative care organisations need to work collaboratively with each other, local authorities, industry and other public, private and voluntary bodies. Partnership working brings many benefits, but also creates the risk of conflicts of interest.

1.3. Organisations and the people who work with, for, and on behalf of them (referred to as **'staff'** in this guidance) want to manage these risks in the right way. Staff and organisations may already be taking steps to do this. However, how this should be done has not always been made clear and there is variation in current practice – implementation of this guidance will make things easier and enable greater consistency across the NHS.

1.4. By implementing this guidance staff and organisations will understand what to do to take the best action and protect themselves from allegations that they have acted inappropriately.

This guidance:

- Introduces consistent principles and rules for managing conflicts of interest.
- Provides simple advice to staff and organisations about what to do in common situations.
- Supports good judgement about how interests should be approached and managed.

2. Action: What should staff and organisations do?

Action for staff	Action for organisations
DO • Familiarise yourself with this guidance and your organisational policies and follow them. • Use your common sense and judgement to consider whether the interests you have could affect the way taxpayers' money is spent. • Regularly consider what interests you have and declare these as they arise. If in doubt, declare.	**DO** • Ensure that you have clear and well communicated processes in place to help staff understand what they need to do. • Identify a team or individual with responsibility for: - Reviewing current policies and bringing them in line with this guidance. - Providing advice, training and support for staff on how interests should be managed. - Maintaining register(s) of interests. - Auditing policy, process and procedures relating to this guidance at least every three years.
DON'T • Misuse your position to further your own interests or those close to you. • Be influenced, or give the impression that you have been influenced by, outside interests. • Allow outside interests you have to inappropriately affect the decisions you make when using taxpayers' money.	**DON'T** • Avoid managing conflicts of interest. • Interpret and deploy this guidance in a way which stifles the collaboration and innovation that the NHS needs.

Organisations should ensure their policies as a minimum meet the standards in this guidance. They can also introduce local requirements that are more stringent, on the basis of their own circumstances, should they think this is necessary. Organisations may wish to adopt or adapt the Model Policy at Annex A to assist with implementation.

3. Definitions: Conflict of interest

3.1. For the purposes of this guidance a 'conflict of interest' is defined as:

> "A set of circumstances by which a reasonable person would consider that an individual's ability to apply judgement or act, in the context of delivering, commissioning, or assuring taxpayer funded health and care services is, or could be, impaired or influenced by another interest they hold."

3.2. A conflict of interest may be:

Actual	Potential
There is a material conflict between one or more interests	There is the possibility of a material conflict between one or more interests in the future

3.3. Staff may hold interests for which they cannot see potential conflict. However, caution is always advisable because others may see it differently. It will be important to exercise judgement and to declare such interests where there is otherwise a risk of imputation of improper conduct.

3. Definitions: Interests

3.4. 'Interests' can arise in a number of different contexts. A material interest is one which a reasonable person would take into account when making a decision regarding the use of taxpayers' money because the interest has relevance to that decision.

3.5. Interests fall into the following categories:

Financial interests	Non-financial professional interests	Non-financial personal interests	Indirect interests
Where an individual may get direct financial benefit* from the consequences of a decision they are involved in making	Where an individual may obtain a non-financial professional benefit* from the consequences of a decision they are involved in making, such as increasing their professional reputation or promoting their professional career	Where an individual may benefit* personally in ways which are not directly linked to their professional career and do not give rise to a direct financial benefit, because of decisions they are involved in making in their professional career	Where an individual has a close association** with another individual who has a financial interest, a non-financial professional interest or a non-financial personal interest who would stand to benefit* from a decision they are involved in making

* A benefit may arise from the making of gain or avoiding a loss

** These associations may arise through relationships with close family members and relatives, close friends and associates, and business partners. A common sense approach should be applied to these terms. It would be unrealistic to expect staff to know of all the interests that people in these classes might hold. However, if staff do know of material interests (or could be reasonably expected to know about these) then these should be declared.

Further guidance on how to interpret these categories is at Annex B.

4. Declarations: Processes to follow

4.1. Organisations should support staff to understand that having interests is not in itself negative, but not declaring and managing them is.

4.2. All staff must be aware of how and to whom declarations should be made, declaring material interests at the earliest opportunity (and in any event within 28 days) via a positive declaration to their organisation. Therefore, declarations should be made:

- On appointment with an organisation
- When a person moves to a new role or their responsibilities change significantly
- At the beginning of a new project/piece of work
- As soon as circumstances change and new interests arise

4.3. Some staff are more likely than others to have a decision making influence on the use of taxpayers' money, because of the requirements of their role. For the purposes of this guidance these people are referred to as **'decision making staff'**.

4.4. Because of their influence in the spending of taxpayers' money, organisations should ensure that, at least annually, decision making staff are prompted to update their declarations of interest, or make a nil return.

4.5. Organisations should define decision making staff according to their own context, but this should be justifiable and capture those groups of staff that have a material influence on how taxpayers' money is spent.

4.6. The following non-exhaustive list describes who these individuals are likely to be:

- Executive and non executive directors* who have decision making roles which involve the spending of taxpayers' money
- Members of advisory groups which contribute to direct or delegated decision making on the commissioning or provision of taxpayer funded services
- Those at Agenda for Change band 8d** and above
- Administrative and clinical staff who have the power to enter into contracts on behalf of their organisation
- Administrative and clinical staff involved in decision making concerning the commissioning of services, purchasing of good, medicines, medical devices or equipment, and formulary decisions.

4.7. There may be occasions where staff declare an interest but, upon closer consideration, it is clear that this is not material and so does not give rise to the risk of a conflict of interest. The team or individual responsible for managing organisational policy should decide whether it is necessary to transfer such declarations to an organisation's register(s) of interests.

* equivalent roles in different organisations carry different titles – this should be considered on a case by case basis

** reflecting guidance issued by the Information Commissioner's Office with regard to Freedom of Information legislation: https://ico.org.uk/media/1220/definition-document-health-bodies-in-england.pdf

5. Management: Principles and situations

5.1. Organisations should manage interests sensibly and proportionately. If an interest presents an actual or potential conflict of interest then management action is required.

5.2. Some common sense management principles should be adopted by organisations which, for the purposes of this guidance, are referred to as 'general management actions':

- Requiring staff to comply with this guidance
- Requiring staff to proactively declare interests at the point they become involved in decision making
- Considering a range of actions, which may include:
  - deciding that no action is warranted
  - restricting an individual's involvement in discussions and excluding them from decision making
  - removing an individual from the whole decision making process
  - removing an individual's responsibility for an entire area of work
  - removing an individual from their role altogether if the conflict is so significant that they are unable to operate effectively in the role
- Keeping an audit trail of the actions taken

5.3. Each case will be different. The general management actions, along with relevant industry/professional guidance, should complement the exercise of good judgement. It will always be appropriate to clarify circumstances with individuals involved to assess issues and risks.

5.4. However, there are a number of common situations which can give rise to risk of conflicts of interest, being:

- Gifts
- Hospitality
- Outside employment
- Shareholdings and other ownership interests
- Patents
- Loyalty interests
- Donations
- Sponsored events
- Sponsored research
- Sponsored posts
- Clinical private practice

The following pages discuss the risks and issues posed in these situations, and the principles and rules that staff and organisations should adopt to manage them.

Gifts

What are the issues?	Staff in the NHS offer support during significant events in people's lives. For this work they may sometimes receive gifts as a legitimate expression of gratitude. We should be proud that our services are so valued. But situations where the acceptance of gifts could give rise to conflicts of interest should be avoided. Staff and organisations should be mindful that even gifts of a small value may give rise to perceptions of impropriety and might influence behaviour if not handled in an appropriate way. A gift means any item of cash or goods, or any service, which is provided for personal benefit, free of charge, or at less than its commercial value.
Principles and rules	Overarching principle applying in all circumstances: • Staff should not accept gifts that may affect, or be seen to affect, their professional judgement. Gifts from suppliers or contractors: • Gifts from suppliers or contractors doing business (or likely to do business) with an organisation should be declined, whatever their value. • Subject to this, low cost branded promotional aids may be accepted where they are under the value of a common industry standard of £6* in total, and need not be declared. *The £6 value has been selected with reference to existing industry guidance issued by the ABPI: http://www.pmcpa.org.uk/thecode/Pages/default.aspx

Gifts (continued)

Principles and rules	Gifts from others sources (e.g. patients, families, service users): • Gifts of cash and vouchers to individuals should always be declined. • Staff should not ask for any gifts. • Gifts valued at over £50 should be treated with caution and only be accepted on behalf of an organisation (i.e. to an organisation's charitable funds), not in a personal capacity. These should be declared by staff. • Modest gifts accepted under a value of £50 do not need to be declared. • A common sense approach should be applied to the valuing of gifts (using an actual amount, if known, or an estimate that a reasonable person would make as to its value). • Multiple gifts from the same source over a 12 month period should be treated in the same way as single gifts over £50 where the cumulative value exceeds £50.
What should be declared	• Staff name and their role with the organisation. • A description of the nature and value of the gift, including its source. • Date of receipt. • Any other relevant information (e.g. circumstances surrounding the gift, action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance).

Hospitality

What are the issues?	Delivery of services across the NHS relies on working with a wide range of partners (including industry and academia) in different places and, sometimes, outside of 'traditional' working hours. As a result, staff will sometimes appropriately receive hospitality. Staff receiving hospitality should always be prepared to justify why it has been accepted, and be mindful that even hospitality of a small value may give rise to perceptions of impropriety and might influence behaviour. Hospitality means offers of meals, refreshments, travel, accommodation, and other expenses in relation to attendance at meetings, conferences, education and training events, etc.
Principles and rules	Overarching principles applying in all circumstances: • Staff should not ask for or accept hospitality that may affect, or be seen to affect, their professional judgement. • Hospitality must only be accepted when there is a legitimate business reason and it is proportionate to the nature and purpose of the event. • Particular caution should be exercised when hospitality is offered by actual or potential suppliers or contractors – these can be accepted if modest and reasonable but individuals should always obtain senior approval and declare these. Meals and refreshments: • Under a value of £25 - may be accepted and need not be declared. • Of a value between £25 and £75* - may be accepted and must be declared. • Over a value of £75* - should be refused unless (in exceptional circumstances) senior approval is given. A clear reason should be recorded on an organisation's register(s) of interest as to why it was permissible to accept. • A common sense approach should be applied to the valuing of meals and refreshments (using an actual amount, if known, or an estimate that a reasonable person would make as to its value). *The £75 value has been selected with reference to existing industry guidance issued by the ABPI http://www.pmcpa.org.uk/thecode/Pages/default.aspx

Hospitality (continued)

Principles and rules	Travel and accommodation:
	• Modest offers to pay some or all of the travel and accommodation costs related to attendance at events may be accepted and must be declared.
	• Offers which go beyond modest, or are of a type that the organisation itself might not usually offer, need approval by senior staff, should only be accepted in exceptional circumstances, and must be declared. A clear reason should be recorded on an organisation's register(s) of interest as to why it was permissible to accept travel and accommodation of this type.
	• A non exhaustive list of examples includes:
	  o offers of business class or first class travel and accommodation (including domestic travel).
	  o offers of foreign travel and accommodation.

What should be declared	• Staff name and their role with the organisation. • A description of the nature and value of the hospitality including the circumstances. • Date of receipt. • Any other relevant information (e.g. action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance).

Outside employment

What are the issues?	The NHS relies on staff with good skills, broad knowledge and diverse experience. Many staff bring expertise from sectors outside the NHS, such as industry, business, education, government and beyond. The involvement of staff in these outside roles alongside their NHS role can therefore be of benefit, but the existence of these should be well known so that conflicts can be either managed or avoided. Outside employment means employment and other engagements, outside of formal employment arrangements. This can include directorships, non-executive roles, self-employment, consultancy work, charitable trustee roles, political roles and roles within not-for-profit organisations, paid advisory positions and paid honorariums which relate to bodies likely to do business with an organisation. (Clinical private practice is considered in a separate section).
Principles and rules	• Staff should declare any existing outside employment on appointment, and any new outside employment when it arises. • Where a risk of conflict of interest is identified, the general management actions outlined in this guidance should be considered and applied to mitigate risks. • Where contracts of employment or terms and conditions of engagement permit, staff may be required to seek prior approval from an organisation to engage in outside employment. • Organisations may also have legitimate reasons within employment law for knowing about outside employment of staff, even this does not give rise to risk of a conflict. Nothing in this guidance prevents such enquiries being made.
What should be declared	• Staff name and their role with the organisation. • A description of the nature of the outside employment (e.g. who it is with, a description of duties, time commitment). • Relevant dates. • Any other relevant information (e.g. action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance).

Shareholding and other ownership interests

What are the issues?	Holding shares or other ownership interests can be a common way for staff to invest their personal time and money to seek a return on investment. However, conflicts of interest can arise when staff personally benefit from this investment because of their role with an organisation. For instance, if they are involved in their organisation's procurement of products or services which are offered by a company they have shares in then this could give rise to a conflict of interest. In these cases, the existence of such interests should be well known so that they can be effectively managed.
Principles and rules	• Staff should declare, as a minimum, any shareholdings and other ownership interests in any publicly listed, private or not-for-profit company, business, partnership or consultancy which is doing, or might be reasonably expected to do, business with their organisation. • There is no need to declare shares or securities held in collective investment or pension funds or units of authorised unit trusts. • Where shareholdings or other ownership interests are declared and give rise to risk of conflicts of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.
What should be declared	• Staff name and their role with the organisation. • A description of the nature of the shareholding/other ownership interest. • Relevant dates. • Any other relevant information (e.g. action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance).

Patents

What are the issues?	The development and holding of patents and other intellectual property rights allows staff to protect something that they create, preventing unauthorised use of products or the copying of protected ideas. Staff are encouraged to be innovative in their practice and therefore this activity is welcomed. However, conflicts of interest can arise when staff who hold patents and other intellectual property rights are involved in decision making and procurement. In addition, where product development involves use of time, equipment or resources from their organisation, then this too could create risks of conflicts of interest, and it is important that the organisation is aware of this and it can be managed appropriately.
Principles and rules	• Staff should declare patents and other intellectual property rights they hold (either individually, or by virtue of their association with a commercial or other organisation), including where applications to protect have started or are ongoing, which are, or might be reasonably expected to be, related to items to be procured or used by their organisation. • Staff should seek prior permission from their organisation before entering into any agreement with bodies regarding product development, research, work on pathways, etc, where this impacts on the organisation's own time, or uses its equipment, resources or intellectual property. • Where holding of patents and other intellectual property rights give rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.
What should be declared	• Staff name and their role with the organisation. • A description of the patent or other intellectual property right and its ownership. • Relevant dates. • Any other relevant information (e.g. action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance).

Loyalty interests

What are the issues?	As part of their jobs staff need to build strong relationships with colleagues across the NHS and in other sectors. These relationships can be hard to define as they may often fall in the category of indirect interests. They are unlikely to be directed by any formal process or managed via any contractual means - it can be as simple as having informal access to people in senior positions. However, loyalty interests can influence decision making. Conflicts of interest can arise when decision making is influenced subjectively through association with colleagues or organisations out of loyalty to the relationship they have, rather than through an objective process. The scope of loyalty interests is potentially huge, so judgement is required for making declarations.
Principles and rules	Loyalty interests should be declared by staff involved in decision making where they: • Hold a position of authority in another NHS organisation or commercial, charity, voluntary, professional, statutory or other body which could be seen to influence decisions they take in their NHS role. • Sit on advisory groups or other paid or unpaid decision making forums that can influence how their organisation spends taxpayers' money. • Are, or could be, involved in the recruitment or management of close family members and relatives, close friends and associates, and business partners. • Are aware that their organisation does business with an organisation with whom close family members and relatives, close friends and associates, and business partners have decision making responsibilities. Where holding loyalty interests gives rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.
What should be declared	• Staff name and their role with the organisation. • A description of the nature of the loyalty interest. • Relevant dates. • Any other relevant information (e.g. action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance).

Donations

What are the issues?	A donation is a charitable financial payment, which can be in the form of direct cash payment or through the application of a will or similar directive. Charitable giving and other donations are often used to support the provision of health and care services. As a major public sector employer the NHS holds formal and informal partnerships with national and local charities. Staff will, in their private lives, undertake voluntary work or fundraising activities for charity. A supportive environment across the NHS and charitable sector should be promoted. However, conflicts of interest can arise.
Principles and rules	• Acceptance of donations made by suppliers or bodies seeking to do business with an organisation should be treated with caution and not routinely accepted. In exceptional circumstances a donation from a supplier may be accepted but should always be declared. A clear reason should be recorded as to why it was deemed acceptable, alongside the actual or estimated value. • Staff should not actively solicit charitable donations unless this is a prescribed or expected part of their duties for an organisation, or is being pursued on behalf of that organisation's registered charity (if it has one) or other charitable body and is not for their own personal gain. • Staff must obtain permission from their organisation if in their professional role they intend to undertake fundraising activities on behalf of a pre-approved charitable campaign. • Donations, when received, should be made to a specific charitable fund (never to an individual) and a receipt should be issued. • Staff wishing to make a donation to a charitable fund in lieu of a professional fee they receive may do so, subject to ensuring that they take personal responsibility for ensuring that any tax liabilities related to such donations are properly discharged and accounted for.
What should be declared	• Organisations should maintain records in line with their wider obligations under charity law, in line with the above principles and rules.

Sponsored events

What are the issues?	Sponsorship of NHS events by external parties is valued. Offers to meet some or part of the costs of running an event secures their ability to take place, benefiting NHS staff and patients. Without this funding there may be fewer opportunities for learning, development and partnership working. However, there is potential for conflicts of interest between the organiser and the sponsor, particularly regarding the ability to market commercial products or services. As a result there should be proper safeguards in place to prevent conflicts occurring.
Principles and rules	• Sponsorship of events by appropriate external bodies should only be approved if a reasonable person would conclude that the event will result in clear benefit for the organisation and the NHS. • During dealings with sponsors there must be no breach of patient or individual confidentiality or data protection rules and legislation. • No information should be supplied to the sponsor from which they could gain a commercial advantage, and information which is not in the public domain should not normally be supplied. • At an organisation's discretion, sponsors or their representatives may attend or take part in the event but they should not have a dominant influence over the content or the main purpose of the event. • The involvement of a sponsor in an event should always be clearly identified in the interest of transparency. • Organisations should make it clear that sponsorship does not equate to endorsement of a company or its products and this should be made visibly clear on any promotional or other materials relating to the event. • Staff should declare involvement with arranging sponsored events to their organisation.
What should be declared	• Organisations should maintain records regarding sponsored events in line with the above principles and rules.

Sponsored research

What are the issues?	Research is vital in helping the NHS to transform services and improve outcomes. Without sponsorship of research some beneficial projects might not happen. More broadly, partnerships between the NHS and external bodies on research are important for driving innovation and sharing best practice. However, there is potential for conflicts of interest to occur, particularly when research funding by external bodies does or could lead to a real or perceived commercial advantage. There needs to be transparency and any conflicts of interest should be well managed.
Principles and rules	• Funding sources for research purposes must be transparent. • Any proposed research must go through the relevant health research authority or other approvals process. • There must be a written protocol and written contract between staff, the organisation, and/or institutes at which the study will take place and the sponsoring organisation, which specifies the nature of the services to be provided and the payment for those services. • The study must not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, medical device, equipment or service. • Staff should declare involvement with sponsored research to their organisation.

What should be declared	• Organisations should retain written records of sponsorship of research, in line with the above principles and rules.
	• Staff should declare:
	  • their name and their role with the organisation
	  • a description of the nature of the nature of their involvement in the sponsored research
	  • relevant dates
	  • any other relevant information (e.g. what, if any, benefit the sponsor derives from the sponsorship, action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance)

Sponsored posts

What are the issues?	Sponsored posts are positions with an organisation that are funded, in whole or in part, by organisations external to the NHS. Sponsored posts can offer benefits to the delivery of care, providing expertise, extra capacity and capability that might not otherwise exist if funding was required to be used from the NHS budget. However, safeguards are required to ensure that the deployment of sponsored posts does not cause a conflict of interest between the aims of the sponsor and the aims of the organisation, particularly in relation to procurement and competition.
Principles and rules	• Staff who are establishing the external sponsorship of a post should seek formal prior approval from their organisation. • Rolling sponsorship of posts should be avoided unless appropriate checkpoints are put in place to review and confirm the appropriateness of arrangements continuing. • Sponsorship of a post should only happen where there is written confirmation that the arrangements will have no effect on purchasing decisions or prescribing and dispensing habits. For the duration of the sponsorship, auditing arrangements should be established to ensure this is the case. Written agreements should detail the circumstances under which organisations have the ability to exit sponsorship arrangements if conflicts of interest which cannot be managed arise. • Sponsored post holders must not promote or favour the sponsor's specific products, and information about alternative products and suppliers should be provided. • Sponsors should not have any undue influence over the duties of the post or have any preferential access to services, materials or intellectual property relating to or developed in connection with the sponsored posts.
What should be declared	• Organisations should retain written records of sponsorship of posts, in line with the above principles and rules. • Staff should declare any other interests arising as a result of their association with the sponsor, in line with the content in the rest of this guidance.

Clinical private practice

What are the issues?	Service delivery in the NHS is done by a mix of public, private and not-for-profit organisations. The expertise of clinicians in the NHS is in high demand across all sectors and the NHS relies on the flexibility that the public, private and not-for-profit sectors can provide. It is therefore not uncommon for clinical staff to provide NHS funded care and undertake private practice work either for an external company, or through a corporate vehicle established by themselves. Existing provisions in contractual arrangements make allowances for this to happen and professional conduct rules apply. However, these arrangements do create the possibility for conflicts of interest arising. Therefore, these provisions are designed to ensure the existence of private practice is known so that potential conflicts of interest can be managed. These provisions around declarations of activities are equivalent to what is asked of all staff in the section on Outside Employment.
Principles and rules	Clinical staff should declare all private practice on appointment, and/or any new private practice when it arises* including: • where they practise (name of private facility) • what they practise (specialty, major procedures). • when they practise (identified sessions/time commitment) *Hospital Consultants are already required to provide their employer with this information by virtue of Para.3 Sch. 9 of the Terms and Conditions – Consultants (England) 2003: https://www.bma.org.uk/-/media/files/pdfs/practical advice at work/contracts/consultanttermsandconditions.pdf

Clinical private practice (continued)

Principles and rules	Clinical staff should (unless existing contractual provisions require otherwise or unless emergency treatment for private patients is needed): • Seek prior approval of their organisation before taking up private practice. • Ensure that, where there would otherwise be a conflict or potential conflict of interest, NHS commitments take precedence over private work.** • Not accept direct or indirect financial incentives from private providers other than those allowed by Competition and Markets Authority guidelines: https://assets.publishing.service.gov.uk/media/542c1543e5274a1314000c56/Non-Divestment_Order_amended.pdf Hospital Consultants should not initiate discussions about providing their Private Professional Services for NHS patients, nor should they ask other staff to initiate such discussions on his or her behalf.** ** These provisions already apply to Hospital Consultants by virtue of Paras.5 and 20, Sch. 9 of the Terms and Conditions – Consultants (England) 2003: https://www.bma.org.uk/-/media/files/pdfs/practical advice at work/contracts/consultanttermsandconditions.pdf Where clinical private practice gives rise to a conflict of interest then the general management actions outlined in this guidance should be considered and applied to mitigate risks.
What should be declared	• Staff name and their role with the organisation. • A description of the nature of the private practice (e.g. what, where and when you practise, sessional activity, etc). • Relevant dates. • Any other relevant information (e.g. action taken to mitigate against a conflict, details of any approvals given to depart from the terms of this guidance).

5. Management: Strategic decision making groups

5.5. Many organisations use boards (or committees and sub-committees of boards), advisory groups, and procurement panels to make key strategic decisions about things such as:

- Entering into (or renewing) large scale contracts
- Awarding grants
- Making procurement decisions
- Selection of medicines, equipment, and devices

These are referred to in this guidance as 'strategic decision making groups'.

5.6. It is important that the interests of those who are involved in these groups are well known to those involved. Organisations must therefore identify relevant strategic decision making groups and ensure they operate in a manner consistent with the following principles, which reflect wider standards of good governance:

- Chairs should consider any known interests of members in advance, and begin each meeting by asking for declaration of relevant interests
- Members should take personal responsibility for declaring material interests at the beginning of each meeting and as they arise
- Any new interests identified should be added to the organisation's register
- The vice chair (or other non-conflicted member) should chair all or part of the meeting if the chair has an interest that may prejudice their judgement

5.7. If a member has an actual or potential interest the chair should consider the following approaches and ensure that the reason for the chosen action is documented in minutes or records:

- Requiring the member to not attend the meeting
- Ensuring that the member does not receive meeting papers relating to the nature of their interest
- Requiring the member to not attend all or part of the discussion and decision on the related matter
- Noting the nature and extent of the interest, but judging it appropriate to allow the member to remain and participate
- Removing the member from the group or process altogether

5.8. The default response should not always be to exclude members with interests, as this may have a detrimental effect on the quality of the decision being made. An example is the need for clinical involvement, when clinicians may hold and represent a diversity of interests. Good judgement is required to ensure proportionate management of risk. The composition of groups should be kept under review to ensure effective participation.

5. Management: Procurement decisions

5.9. Procurement should be managed in an open and transparent manner, compliant with procurement and other relevant law, to ensure there is no discrimination against or in favour of any provider. Procurement processes should be conducted in a manner that does not constitute anti-competitive behaviour - which is against the interest of patients.

5.10. Organisations should keep records that show a clear audit trail of how conflicts of interest have been identified and managed as part of procurement processes. At every stage of procurement steps should be taken to identify and manage conflicts of interest to ensure and to protect the integrity of the process. NHS Improvement and NHS England have published detailed and specific guidance on procurement processes which staff and organisations should consult.

5.11. For the avoidance of doubt, nothing in this section or this guidance waives or modifies any existing legal requirements relating to conflicts of interest and procurement decisions.

NHS Improvement Guidance on Procurement, Patient Choice and Competition: https://www.gov.uk/government/publications/procurement-patient-choice-and-competition-regulations-guidance

NHS England Guidance on Conflicts of Interest for CCGs**:** https://www.england.nhs.uk/commissioning/pc-co-comms/coi/

6. Transparency: Maintenance and publication of register(s)

Maintenance of Register(s)

6.1. Organisations must ensure that a nominated team or individual collates and maintains up to date organisational register(s) of interests. An interest should remain on the register(s) for a minimum of 6 months after the interest has expired. Organisations should retain a private record of historic interests for a minimum of 6 years after the date on which it expired.

6.2. Template declaration of interests and register of interests forms for organisations to use are provided at Annex C and D. They should always contain:

- The returnee's name and their role with the organisation
- A description of the interest declared (reflecting the content of section 5 of this guidance for common situations)
- Relevant dates relating to the interest
- Space for comments (e.g. action taken to mitigate conflict)

6.3. Using the common format in the templates will help minimise burdens on staff who might need to submit returns to multiple organisations.

Declaration of interests template

Publication

6.4. All staff should declare interests and, as a minimum, organisations should publish the interests of decision making staff at least annually in a prominent place on their website. Organisations without websites should maintain registers locally, available for inspection on request.

6.5. The format of published registers should be accessible and contain meaningful information. Adopting the templates and advice on content in this guidance will assist organisations in this task.

6.6. Organisations should put in place processes for staff to make representations that information on their interests should not be published. This will allow for, in exceptional circumstances, an individual's name and/or other information to be redacted from any publicly available registers where the public disclosure of information could give rise to a real risk of harm or is prohibited by law.

6.7. As well as taking these steps, organisations should seek to ensure that staff who are subject to wider transparency initiatives such as the ABPI Disclosure UK scheme are aware of and comply with them: http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx

Register of interests template

7. Breaches: How should these be dealt with?

7.1. There will be situations when interests will not be identified, declared or managed appropriately and effectively. This may happen innocently, accidentally, or because of the deliberate actions of staff or organisations. For the purposes of this guidance these situations are referred to as 'breaches'.

7.2. Organisations should identify a team or individual to be notified of breaches, and be clear as to how staff or other parties can raise concerns about these. Staff should be encouraged to speak up about actual or suspected breaches, in compliance with their organisation's whistleblowing policy.

7.3 Organisations should also identify a team or individual empowered to investigate breaches, involving organisational leads for human resources, fraud, audit etc. as appropriate. Each breach needs to be investigated and judged on its own merits and this should start with those involved having the opportunity to explain and clarify any relevant circumstances.

7.4. Following investigations organisations should:

- Decide if there has been or is potential for an actual breach and the severity
- Assess whether further action is required in response – this is likely to involve any staff member involved and their line manager, as a minimum
- Consider who else inside and outside the organisation should be made aware of the breach
- Take appropriate action, such as clarifying existing policy, taking action against the staff member(s) responsible for the breach, or escalating to external parties such as auditors, NHS Protect, the Police, statutory health bodies and/or regulatory bodies

7.5. When dealing with instances of breach organisations may want to take legal or other appropriate advice prior to imposing sanctions which could have serious consequences for those involved. A range of responses should be considered in terms of proportionate sanctions for breaches, including:

- Employment law action
- Reporting incidents to external bodies
- Contractual or legal consequences

Further information on the consequences of breaches and the range of potential sanctions is at Annex E.

7.6. Organisations should consider whether reports on breaches, the impact of these, and action taken (i.e. if strong management action or sanctions are taken) should be considered by their governing body, audit committee, executive team or similar on a regular basis.

7.7. To aid transparency organisations should consider whether anonymised information on breaches and action taken in response should be prepared and published on websites on a regular basis.

8. Resource Annexes

ANNEX A – Model Conflict of Interest Policy
[due for publication in March 2017]

ANNEX B – Types of interests

ANNEX C – Template interests declaration form

ANNEX D – Template interests register

ANNEX E – Potential sanctions for breach of conflicts of interest policies

Annex B – Types of interests

Type of interest	Description
Financial interests	Where an individual may get direct financial benefits* from the consequences of a decision their organisation makes. This could include: • A director (including a non-executive director) or senior employee in another organisation which is doing, or is likely to do business with an organisation in receipt of NHS funding • A shareholder, partner or owner of an organisation which is doing, or is likely to do business with an organisation in receipt of NHS funding • Someone in outside employment • Someone in receipt of secondary income. • Someone in receipt of a grant. • Someone in receipt of other payments (e.g. honoraria, day allowances, travel or subsistence). • Someone in receipt of sponsored research.
Non-financial professional interests	Where an individual may obtain a non-financial professional benefit* from the consequences of a decision their organisation makes, such as increasing their professional reputation or status or promoting their professional career. This could include situations where the individual is: • An advocate for a particular group of patients. • A clinician with a special interest. • An active member of a particular specialist body. • An advisor for the Care Quality Commission or National Institute of Health and Care Excellence. • A research role.

* A benefit may arise from the making of gain or avoiding a loss

Annex B – Types of interests (continued)

Type of interest	Description
Non-financial personal interests	This is where an individual may benefit* personally from a decision their organisation makes in ways which are not directly linked to their professional career and do not give rise to a direct financial benefit. This could include, for example, where the individual is: • A member of a voluntary sector board or has a position of authority within a voluntary sector organisation. • A member of a lobbying or pressure group with an interest in health and care.
Indirect interests	This is where an individual has a close association with another individual who has a financial interest, a non-financial professional interest or a non-financial personal interest who would stand to benefit* from a decision they are involved in making. This would include**: • Close family members and relatives. • Close friends and associates. • Business partners.

* A benefit may arise from the making of gain or avoiding a loss

** A common sense approach should be applied to these terms. It would be unrealistic to expect staff to know of all the interests that people in these classes might hold. However, if staff do know of material interests (or could be reasonably expected to know about these) then these should be declared.

Annex E – Potential sanctions

Disciplinary sanctions

Staff who fail to disclose any relevant interests or who otherwise breach an organisation's rules and policies relating to the management of conflicts of interest are subject to investigation and, where appropriate, to disciplinary action. This may include:

- Employment law action which might include:
  - Informal action – such as reprimand or signposting to training and/or guidance.
  - Formal action – such as formal warning, the requirement for additional training, re-arrangement of duties, re-deployment, demotion or dismissal.
- Referring incidents to regulators.
- Contractual action against organisations or staff.

Professional regulatory sanctions

Statutorily regulated healthcare professionals who work for, or are engaged by, organisations are under professional duties imposed by their relevant regulator to act appropriately with regard to conflicts of interest. Organisations should consider reporting statutorily regulated healthcare professionals to their regulator if they believe that they have acted improperly, so that these concerns can be investigated. These healthcare professionals should be made aware that the consequences for inappropriate action could include fitness to practise proceedings being brought against them, and that they could, if appropriate be struck off by their professional regulator as a result.

Information and contact details for the healthcare professional regulators are accessible from the Professional Standard Authority website:

http://www.professionalstandards.org.uk/what-we-do/our-work-with-regulators/find-a-regulator

Annex E – Potential sanctions (continued)

Civil sanctions

If conflicts of interest are not effectively managed, organisations could face civil challenges to decisions they make – for instance if interests were not disclosed that were relevant to the bidding for, or performance of contracts. In extreme cases, staff and other individuals could face personal civil liability, for example a claim for misfeasance in public office.

Criminal sanctions

Failure to manage conflicts of interest could lead to criminal proceedings including for offences such as fraud, bribery and corruption. This could have implications for the organisation concerned and linked organisations, and the individuals who are engaged by them.

The Fraud Act 2006 created a criminal offence of fraud and defines three ways of committing it:

- Fraud by false representation
- Fraud by failing to disclose information and
- Fraud by abuse of position.

In these cases an offender's conduct must be dishonest and their intention must be to make a gain, or a cause a loss (or the risk of a loss) to another. Fraud carries a maximum sentence of 10 years imprisonment and/or a fine and can be committed by a body corporate.

The Bribery Act 2010 makes it easier to tackle this offence in public and private sectors. Bribery is generally defined as giving or offering someone a financial or other advantage to encourage a person to perform certain activities and can be committed by a body corporate. Commercial organisations (including NHS bodies) will be exposed to criminal liability, punishable by an unlimited fine, for failing to prevent bribery.

The offences of bribing another person or being bribed carries a maximum sentence of 10 years imprisonment and/or a fine. In relation to a body corporate the penalty for these offences is a fine.