

Responsible officers in the new health architecture

**A consultation on draft amendment regulations
and response to the policy consultation
“Responsible officers in the new health
architecture”**

A combined consultation and consultation response document

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A combined consultation and consultation response document

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A consultation on draft amendment regulations and response to the policy consultation “Responsible officers in the new health architecture”

Prepared by the Clinical Governance Team

Contents

Executive summary	6
Chapter one	7
Introduction	7
The document	7
Background.....	7
Chapter two	11
Responses to the consultation	11
Overview	11
The National Health Service Structure	11
Postgraduate trainees	13
Public Health.....	13
Language checking	15
Chapter three	19
What we are proposing for the Regulations	19
The National Health Service	19
Postgraduate trainees	20
Public health	20
Proposed connections for Doctors	20
Language checking	23
Summary of other changes	23
Additions to the list of other designated bodies.....	25
Chapter four	27
Responding to the consultation	27
Consultation principles	27
Summary of the consultation.....	28
Information Handling and Freedom of Information	28
Bibliography	30
Abbreviations	31
Annex A	32
The Medical Profession (Responsible Officer) (Amendment) Regulations 2013.....	32
Annex B	33
The Medical Profession (Responsible Officer) Regulations 2010 showing the effect of draft amendments	33
Annex C – Consultation Questionnaire	34

Executive summary

The Medical Profession (Responsible Officer) Regulations 2010¹ came into force on 1 January 2011. The Regulations created the role of responsible officer and set out the requirements of the role and its functions. They also detail which bodies must appoint a responsible officer. In April of this year, we consulted on proposed changes in policy that would require amendments to be made to the Regulations.² The proposed changes include those required as a result of the Health and Social Care Act 2012, changes in the structures for public health, changes for postgraduate trainees and proposals for assuring the language competence of doctors.

The April consultation closed in July. This document serves two purposes: it provides the Department's response to the results of the April consultation; and consults on the draft amendment regulations, which are provided at **Annex A**. In order to make these changes clear, we have also included a draft of the 2010 Regulations that show the effect of the changes, at **Annex B**.

The consultation on the amendment Regulations will run for **4 weeks**. The deadline for responses is **4 January 2013**. Once the responses have been received, we shall collate and analyse the information. We plan to publish a formal response to this consultation process early in 2013. The information received will assist in producing the final regulations, which, subject to Ministerial approval, we intend to lay before Parliament in early 2013.

¹ The Medical Profession (Responsible Officers) Regulations 2010 (SI 2010 No.2841), available at: <http://www.legislation.gov.uk/ukxi/2010/2841/contents/made>

² Responsible officers in the new healthcare architecture: A public consultation on the amendments to the Medical Profession (Responsible Officers) Regulations 2010, Department of Health, 2012
http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_133601

Chapter one

Introduction

The document

This document sets out the response to the April consultation (Responsible officers in the new health architecture)³ on amendments to the Medical Profession (Responsible Officer) Regulations 2010⁴ that was held between 18 April 2012 and 25 July 2012. It also seeks views on whether we have translated the policy into the draft amendment Regulations that we propose to lay before Parliament.

- 1.1 The April consultation sought views about the role of responsible officers in three areas:
 - the new structures in the health service;
 - the new structures in public health; and
 - checking the language competence of doctors.
- 1.2 In this chapter we provide background on responsible officers and the consultation.
- 1.3 Chapter two provides a broad summary of the responses we received in each of the three areas.
- 1.4 Chapter three sets out the changes we intend to implement in each area, including details of additions to the list of designated bodies.
- 1.5 Chapter four provides details on how to respond to the consultation and other information on Department consultations.
- 1.6 Annex A provides a copy of the draft amendment Regulations.
- 1.7 Annex B shows how the 2010 Regulations will look when the proposed changes are made.
- 1.8 Annex C provides the consultation questionnaire.

Background

- 1.9 The Medical Profession (Responsible Officer) Regulations 2010 came into force on 1 January 2011. From that date, designated organisations were required to nominate or appoint a responsible officer with statutory functions relating to the evaluation of the fitness to practice and monitoring of the conduct and performance of doctors with whom the body had a connection. The Regulations also set out the connections between different doctors and designated bodies.

³See n2, above.

⁴See n1, above.

Responsible officers in the new health architecture

A combined consultation and consultation response document

- 1.10** The primary legislation enabling the role of the responsible officer to be established in Regulations is contained in the Health and Social Care Act 2008⁵ in the form of amendments to the Medical Act 1983. The 2008 Act also establishes free-standing regulation-making powers in relation to clinical governance functions which apply in England only. In addition to giving responsible officers specific functions, the Regulations also designate certain bodies that must nominate or appoint a responsible officer.
- 1.11** The white papers, *Equity and Excellence: Liberating the NHS*⁶ and *Healthy Lives, Healthy People: Our Strategy for Public Health in England*,⁷ set out a series of reforms for the delivery of healthcare and public health. These reforms were given a statutory basis in the Health and Social Care Act 2012.⁸ The Act abolishes Primary Care Trusts (PCTs) and Strategic Health Authorities (SHAs) from 31 March 2013. There are specific groups of doctors that are currently connected to these bodies and therefore the Regulations will need to be amended to reflect the changes made by the 2012 Act. The Act sets out a new structure where responsibility for local clinical commissioning rests with clinical commissioning groups (CCGs). CCGs will be supported and overseen by the NHS Commissioning Board (NHS CB). The 2012 Act also transfers public health functions from PCTs to local authorities.
- 1.12** The Department has set out a new approach to education and training in *From Design to Delivery*.⁹ Health Education England (HEE) will provide national leadership and oversight on strategic planning and development of the health and public health workforce, and allocate education and training resources. Local Education and Training Boards (LETBs) will be responsible for leading local healthcare education and training and the associated expenditure.
- 1.13** In public health, the reforms will see local authorities taking the lead for improving health and co-ordinating local efforts to protect the public's health and wellbeing, and ensuring health services effectively promote population health. Local political leadership will be central to making this work. A new executive agency, Public Health England (PHE), will:
- deliver services (health protection, public health information and intelligence, and services for the public through social marketing and behavioural insight activities);
 - lead for public health (by encouraging transparency and accountability, building the evidence base, building relationships promoting public health);
 - support the development of the specialist and wider public health workforce (appointing Directors of Public Health with local authorities, supporting excellence

⁵ The Health and Social Care Act 2008 (2008 c.14), available at:

<http://www.legislation.gov.uk/ukpga/2008/14/contents>

⁶ *Equity and Excellence: Liberating the NHS*, Department of Health, 2010,

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_117353

⁷ *Healthy Lives, Healthy People: Our Strategy for Public Health in England*, Department of Health, 2012,

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_127424.pdf

⁸ The Health and Social Care Act 2012 (2012 c.7), available at:

<http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted>

⁹ *Liberating the NHS: Developing the Healthcare Workforce: From design to delivery*, Department of Health, 2012,

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132087.pdf

in public health practice and bringing together the wider range of public health professionals).

- 1.14** There have been persistent concerns about the skills and competencies of some foreign doctors, particularly in respect of language skills. Currently, disparate systems exist for the checking of language competency for those doctors from the EEA member states, and those from the wider world. For non-EEA overseas qualified doctors the General Medical Council requires such doctors to undergo language and competency tests before being recognised as doctors in the UK. For EEA qualified doctors, the principle of automatic recognition, from the MRPQ Directive¹⁰ limits such an approach. However, the Directive does provide for checks on language knowledge to be undertaken before healthcare professionals access patients, provided that such checks are undertaken separately to the process of recognition of qualifications.
- 1.15** It is for this reason that, in England, a system of local checks is in place whereby employers or contracting bodies, as part of the recruitment process, should ensure that doctors they employ or contract with are suitable for their role, and this should include consideration of factors such as their ability to communicate.
- 1.16** For General Practitioners, under the Performers List Regulations 2004¹¹ there are a number of checks that a PCT is required by law to carry out before admitting a doctor onto its lists. Regulation 6(2)(b) states that a Primary Care Trust must refuse to include a performer in its performers lists where “it is not satisfied he has the knowledge of English, which, in his own interests or those of his patients, is necessary in performing the services...”.
- 1.17** As a result of the current arrangements, which are localised and permit different approaches by organisations, there are doubts as to whether the existing system is sufficiently robust to ensure doctors have satisfactory language skills and are subject to appropriate language checking prior to taking up a post. This Government considers that there is considerable scope for strengthening the existing arrangements and *The Coalition: our programme for government*,¹² stated: “We will seek to stop foreign healthcare professionals working in the NHS unless they have passed robust language and competence tests”.
- 1.18** The policy proposal aimed to address concerns about inconsistency in the application of checks on the language ability of doctors by the introduction of strengthened proportionate checks at local level. Responsible officers in England have a role in their designated body in ensuring that medical practitioners have qualifications and experience appropriate to the work to be performed. By placing an explicit statutory requirement on responsible officers, responsible officers should ensure that a doctor has sufficient language skills for the work to be performed before appointing a doctor to their organisation. Our view is that placing a statutory requirement on responsible officers in this way will greatly strengthen the current protections. However, it is more

¹⁰ Mutual Recognition of Professional Qualifications Directive (2005/36/EC)

¹¹ The National Health Services (Performers Lists) Regulations 2004 (as amended) (SI 2004 No.585), <http://www.legislation.gov.uk/uk/si/2004/585/contents/made>

¹² The coalition: our programme for government, HM Government, 2010 http://www.direct.gov.uk/prod_consum_dg/groups/dg_digitalassets/@dg/@en/documents/digitalasset/dg_187876.pdf

Responsible officers in the new health architecture

A combined consultation and consultation response document

difficult to ensure these checks are carried out for locum staff that may be with organisations for only a very short period of time and arriving late at night. For this reason we need to give further consideration to whether the proposed approach provides adequate assurance about the competence of locum doctors.

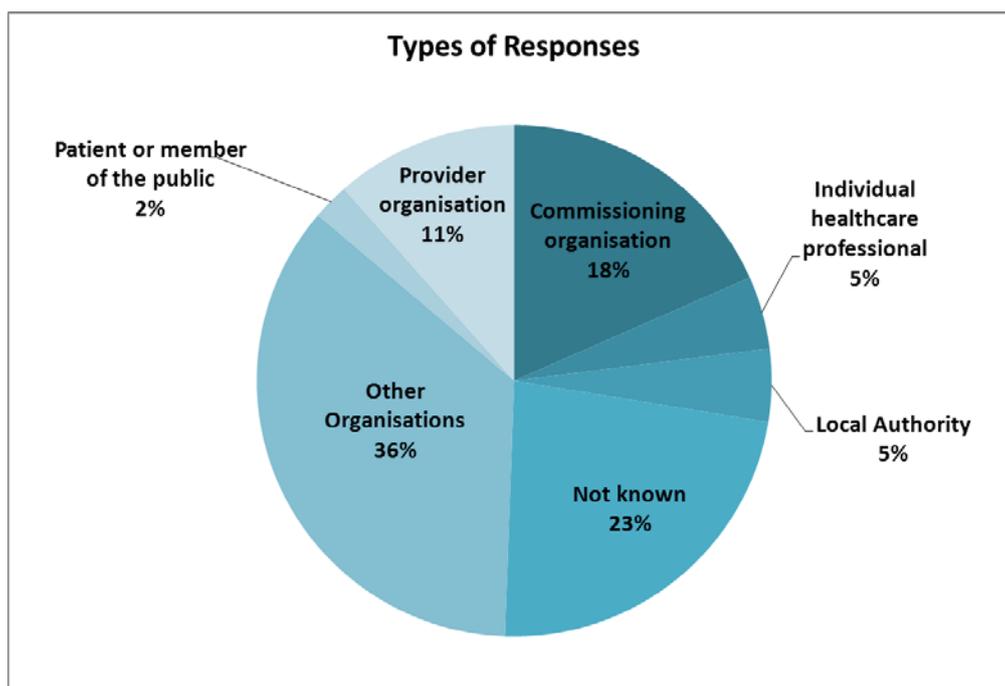
Chapter two

Responses to the consultation

Overview

- 2.1** In total, we received 88 responses. We rejected one response because the data for the response to each question was corrupted. For 20 responses, information on the source of response was not available.
- 2.2** A number of organisations responded on behalf of their members, including: NHS Employers, the British Medical Association (BMA), Royal College of Surgeons (RCS), the Local Government Association and Independent Healthcare Advisory Services. These organisations represent the views of large numbers of doctors and other organisations that are affected by the proposals.

Figure 1



- 2.3** The largest number of responses (36%) came from 'other organisations'. These include the membership organisations in paragraph 2.2, the health regulators such as the General Medical Council and Care Quality Commission, and the Royal Colleges. We were unable to identify the organisation in 23% of responses.

The National Health Service Structure

- 2.4** The proposals are for the NHS CB to nominate or appoint a responsible officer for GPs on a performers list, responsible officers in certain designated bodies and for a small group of secondary care locums. The NHS CB would also be the designated body for

Responsible officers in the new health architecture

A combined consultation and consultation response document

any doctors it employs. The consultation proposed that the NHS CB should have the flexibility to appoint as many responsible officers as necessary.

- 2.5** The majority of respondents supported the proposals for connecting responsible officers, GPs and some locums to the NHS CB (see Figure 2).

Figure 2

Question	Yes	No	No response	Total
Q2.1 Do you agree that the NHS CB should be designated and required to nominate or appoint responsible officers for primary care?	71 (81%)	5 (6%)	11 (13%)	87
Q2.2 Do you agree that the NHS CB should be given the flexibility to appoint the number of responsible officers it considers appropriate?	68 (78%)	7 (8%)	12 (14%)	87
Q2.3 Do you agree that the NHS CB should be designated in the Regulations and required to nominate or appoint responsible officers for this very small group of secondary care locum doctors?	63 (72%)	10 (12%)	14 (16%)	87
Q2.4 Do you agree that the NHS CB should be the responsible officer's responsible officer in the new architecture?	63 (72%)	11 (13%)	13 (15%)	87
Q2.5 Do you agree that the national mandate is the most appropriate method of addressing potential conflicts of interest between responsible officers in the NHS CB?	59 (68%)	12 (14%)	16 (18%)	87

- 2.6** There were two major concerns that arose from respondents. The first was a concern that it was not clear how the NHS CB would manage conflicts of interest or appearances of bias. The consultation suggested that a structure with three levels of responsible officers would be necessary within the NHS CB. The BMA commented "...there should be a separation between the roles of the responsible officer and the role of individuals in the NHS CB responsible for implementing commissioning policies". The National Clinical Assessment Service (NCAS) also commented that "...there could be conflict between the corporate responsibilities of the [medical director] and the individual responsibility of the [responsible officer]..."
- 2.7** The second issue also reflects concerns about the number of responsible officers the NHS CB will nominate or appoint. There is a concern that an insufficient number of responsible officers will be nominated or appointed to carry out the duties. This could result in overloading those responsible officers, or placing undue pressure on other parts of the system. While we understand the concern, the NHS CB will be the same as any other designated body and will be required to comply with the legislation, which includes the requirement "...to provide funds and other resources necessary to enable

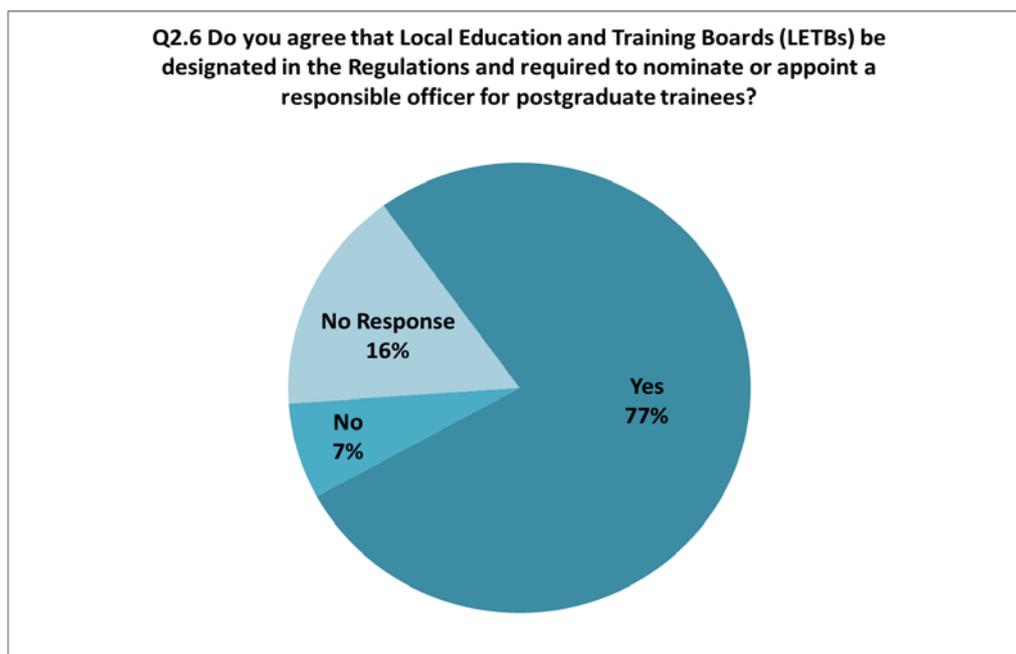
the officer to discharge their responsibilities”.¹³ In chapter three, we set out proposals to update the existing power held by the Secretary of State to appoint a responsible officer where an organisation has failed to do so. This will provide further assurance that doctors will be properly supported by responsible officers.

Postgraduate trainees

2.8 The April consultation proposed that postgraduate trainees should continue to have a connection to the organisation responsible for their training (LETBs). At the time it was proposed that the LETBs would be independent statutory bodies. Since we published the April consultation, it has become clear that LETBs will be committees of HEE rather than bodies with a separate legal identity.

2.9 We understand that deaneries and deans will continue to exist but will become part of the LETB and it will be the LETB that will be responsible for the management of postgraduate trainees. Respondents to the consultation agreed overwhelmingly (77%) that the connection between postgraduate trainees and the organisation responsible for their training is maintained. Of the 7% that did not agree that LETBs should be designated, the majority thought that the responsibility should remain with the deanery. Of the total replies, 16% did not respond to the question. This is illustrated in Figure 3, below.

Figure 3



Public Health

2.10 The consultation considered the hierarchy of responsible officers that would be appropriate for the new public health structures. In particular, it considered which organisations should have to nominate or appoint responsible officers for local authority doctors and what the connection should be for those responsible officers. The responses showed a more even division of views compared to those in the other main areas. It is worth noting that we were able to identify only four respondents from local

¹³The Medical Profession (Responsible Officers) Regulations 2010, Regulation 14.

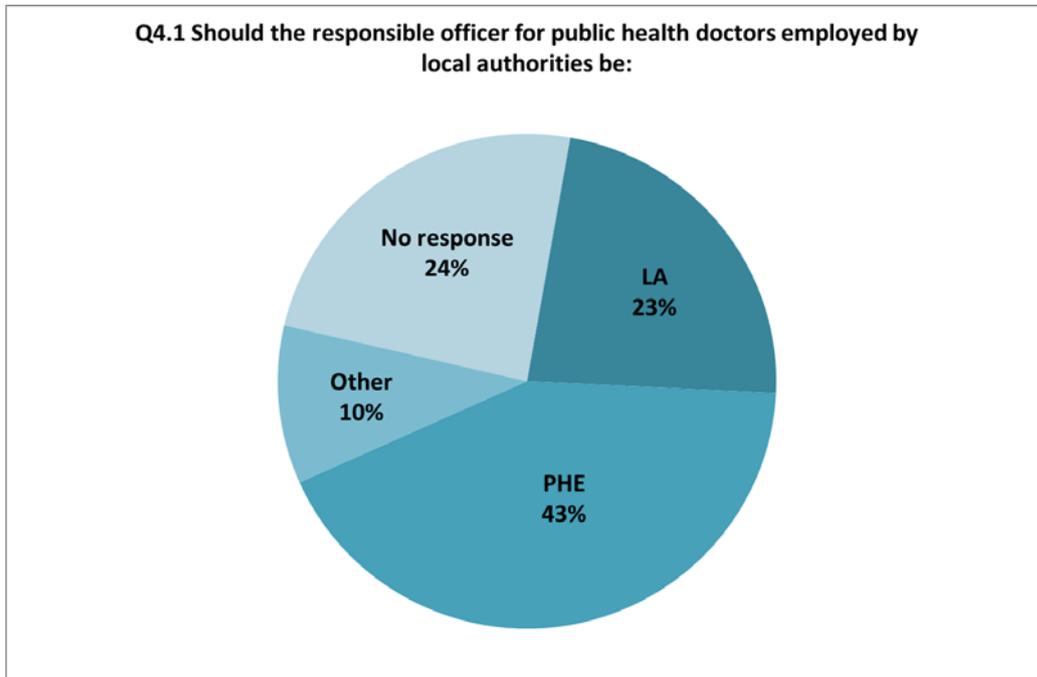
Responsible officers in the new health architecture

A combined consultation and consultation response document

government, although one of these, the Local Government Association, is the national voice of local government.

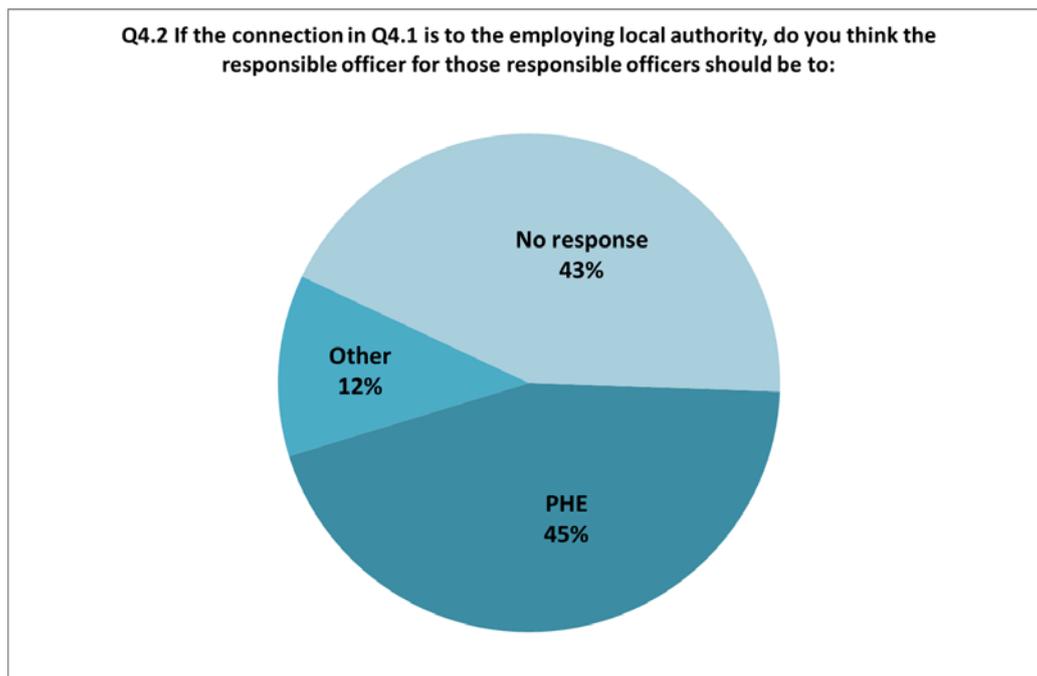
- 2.11** The majority (43%) of responses thought that the responsible officer for doctors employed by local authorities should be in PHE (see fig.4).

Figure 4



A similar proportion thought that if local authorities had to nominate or appoint responsible officer their responsible officer should be in PHE (see fig.5).

Figure 5

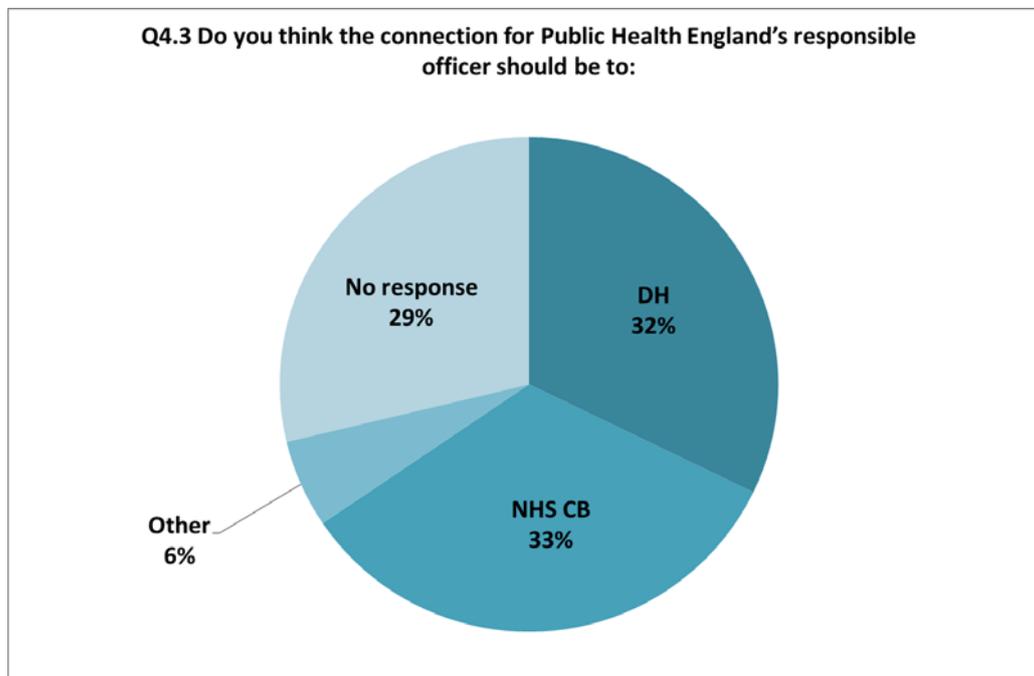


Responsible officers in the new health architecture

A combined consultation and consultation response document

When it came to the question of the responsible officer for the responsible officer for PHE, views were evenly divided with 33% thinking it should be the NHS CB, 32% thinking it should be the Department of Health and 29% offering no view at all (see fig.6).

Figure 6



2.12 The Local Government Association thought that there was “a good deal of logic in a PHE base for these ROs” because of the relatively few posts in councils. The Association expressed a concern, however, that there is a need to ensure that councils are involved in the process. Three out of the four local government respondents thought that if local authorities were designated then their responsible officers should be connected to PHE. Two of the four thought that the connection for PHE’s responsible officer should be to the Department of Health and one thought it should be to the NHS CB.

Language checking

The role of the responsible officer in language checks

2.13 The consultation asked whether the requirement to check the language competence of doctors in England should be set out in the Responsible Officer Regulations. The majority of respondents (65%) were supportive of this proposal, with only 25% opposing.

2.14 Several of the respondents considered that the checking of language competency should be the responsibility of the General Medical Council (GMC) as part of the registration process. Some respondents made the related point that European Union (EU) doctors should be treated the same as other overseas migrant doctors. Non-EEA doctors are subject to language and competency tests during registration by the GMC. We note the responses on this suggesting a potential role for the GMC, the difficulty

however is existing European law. This limits the extent to which language tests and competency tests can be applied at the point of registration for EU doctors that are entitled to automatic recognition on the basis of their qualifications. Consequently, at this time the GMC cannot have a role at the point of registration in applying language controls to all EU doctors. However, European law does provide for checks on language knowledge to be undertaken before healthcare professionals access patients, provided that such checks are undertaken separately to the process of recognition of qualifications. EU law in this area is under review and we are continuing to explore further measures to ensure that all doctors are subject to robust checks on their language and competence.

- 2.15** There was also concern that if language checking became the explicit responsibility of responsible officers, then responsible officers would become legally liable for their actions. Responsible officers in England already have a stated role in the recruitment process under Part 3 of the Regulations, to ensure that those recruited are suitable. The amended regulations make it explicit that language checks should be undertaken as part of the recruitment process to ensure that such checks are being done. As such, the proposals merely strengthen the existing function.
- 2.16** There was also some concern on the consistency of decision-making. The consultation suggested the use of guidance for this, which is discussed at paragraph 2.19 below.
- 2.17** A wide range of issues relating to language checking were raised overall, for example, that evidence of language skills for nurses was also important, the costs of language checks, which is discussed at paragraph 2.25, and the importance of performance management of the responsible officers.

Use of guidance

- 2.18** The consultation suggested that the regulations should not expressly provide exactly how language competence should be ascertained, but that guidance should be issued on this. The majority of respondents (71%) supported this proposal.
- 2.19** A number of respondents (20%) considered that the regulations should explicitly state how language competence should be assessed and that guidance should not be issued. The Department has noted the views concerning placing the detail of checking language competence within the regulations rather than through issuing of subsequent guidance. Related to this we also note the concerns on ensuring consistency in decision-making. Placing explicit detail in the Regulations would remove any flexibility to take account of local circumstances, and the different requirements of the particular post or type of post the doctor is looking to undertake. On balance the Department considers that flexibility may be needed to take account of the needs of patients locally and local circumstances, and that by being too prescriptive, there would be a risk that we would be less able to take account of changes in a timely and flexible manner.
- 2.20** We have suggested that guidance be issued jointly by the NHS CB and GMC. However, we would like to explore whether guidance should be placed on a statutory footing, so that responsible officers under the Regulations will be required to have due regard to the guidance. Under the existing authority in the Regulations, the Secretary of State may issue guidance in relation to Part 3 of the Regulations, concerning the role of the responsible officer in recruitment, which would include language checking guidance. However, we would like to consider whether this power should be extended so that the

NHS CB also has a statutory power to issue guidance in relation to language checking. This would also fit with the intended role that the NHS CB will have in the Performers List Regulations relating to language checking, where GPs cannot be admitted to the list unless they have satisfactory language skills. The proposed draft of the Regulations includes a statutory power for the NHS CB to issue guidance in relation to language checking. The GMC have power to issue guidance under Part 2 of the Regulations relating to their regulatory role. However, we are also continuing to give consideration to unequivocal statutory provisions about the way that checks on language knowledge should be undertaken to be set out in regulations.

Annotation of the GMC's register

2.21 We asked the question as to whether there was benefit in the GMC annotating their register confirming that the doctor was suitable for their first post in England and language competence for that post, and whether this had sufficient merit to outweigh practical difficulties relating to its non-application in Northern Ireland, Scotland and Wales. The majority of the responses were positive, with 60% supporting the proposal and 23% disagreeing. However, the consultation did identify concerns and a number of practical difficulties, and there are clear perceived issues with introducing such a restricted approach to the register.

2.22 These concerns were reflected, in the related question, where we asked whether, by annotating the register in such a manner, this may impact on different groups in different ways. The majority agreed. Of the responses, 54 out of 84 (64%) considered that there would be different impact on the groups. Twenty-three, amounting to 27%, did not answer or were uncertain. Only 8% stated there would be no difference in treatment.

Notification to the GMC on significant language concerns

2.23 We asked whether responsible officers in the UK should be required to notify the GMC where they have significant concerns on the language competence of individuals. This proposal received wide support, with 75% of respondents agreeing, although most considered this should already be occurring, and that amending the Regulations is unnecessary.

2.24 Under Part 2 of the Regulations, responsible officers already have a duty where appropriate to refer concerns on medical practitioners in relation to fitness to practice to the GMC (see regulation 11(2)(c)), and a further duty to co-operate with the GMC (see regulation 11(5)). In recognising that we no longer intend on continuing with the annotation of the register, the existing power is viewed to be sufficient.

Costs

2.25 We asked a question on the likelihood of increased costs and the current approach to the payment of language tests within the organisation. A small majority 27 out of 84 (32%), as opposed to 26 out of 84 (31%) did not support the assumption that it is likely costs would not increase. However, a larger proportion (37%) did not answer or were uncertain.

2.26 The Department considers that this is a strengthening of existing processes, to ensure that the responsible officer has a clear role in ensuring the suitability of a doctor's language competency for the role for which they are being recruited. As responsible officers already have a role in recruitment under Part 3 of the Regulations, the impact on

Responsible officers in the new health architecture

A combined consultation and consultation response document

cost should be negligible, particularly where there are satisfactory processes already in place.

- 2.27** It is recognised that where language tests are used there is a related cost. This policy is focused on the application of language controls and it may be that language competency is satisfied by some means other than language tests. In addition, it is a matter for the individual organisation as to whether the doctor applicant or the organisation is responsible for the cost of any language tests applied. The current position for non-European Union overseas doctors, is that the applicant pays for such checks as part of registration with the GMC.

Call for further evidence

- 2.28** In the consultation document we made a request for evidence/data on the potential benefits of a strengthened language system, and evidence/data on the impact on equality. The majority of respondents replied in the negative or failed to answer the question. Overall, we received little further directly relevant empirical evidence on the potential benefits or impact on equality. We did receive some anecdotal evidence, and in particular there was reference to the World Health Organisation which has reported that communication skills are the leading cause of inadvertent patient harm. We have again requested further evidence as part of this consultation exercise.

Chapter three

What we are proposing for the Regulations

Please note: in this chapter, references to particular provisions of the regulations are to be read as references to the regulations presented at Annex B, unless otherwise stated.

The National Health Service

- 3.1** As outlined in chapter two, the connections currently made between GPs and PCTs and responsible officers and SHAs will be replaced with connections to the NHS CB from 1 April 2013 in line with the responses to the consultation.
- 3.2** We understand the concerns that were raised about conflicts of interest in the NHS CB. The existing Regulations make provision for the designated body to nominate or appoint a second responsible officer for a doctor when there is a conflict of interest or an appearance of bias between the doctor and their first appointed responsible officer. The Regulations also require the designated body to ensure that there are no further conflicts of interest when appointing the second responsible officer. It is also true, as one respondent said, that, “conflicts of interest are there to be identified and managed”. Potentially, the NHS CB may have up to three tiers of responsible officers. These responsible officers will need to deal with possible conflicts of interest between their role as responsible officer and their managerial relationships. We recognise that managing conflicts of interest that arise could be more difficult for some than others.
- 3.3** Respondents were in favour of addressing possible conflicts of interest through the national mandate (see fig.2, above). However, it has become increasingly clear during the intervening period since the publication of the April consultation, that this would not be the appropriate mechanism to address these issues.
- 3.4** In order to provide some separation, we intend to connect the National Medical Director and the National Medical Director’s deputies in the NHS CB to an independent body, the Faculty of Medical Leadership and Management. The Faculty has been established to improve the quality of medical management. We consider that the Faculty is best placed to take on the role of responsible officer for these doctors. The Faculty will be able to provide independent advice to the NHS CB where conflicts of interest or appearances of bias are claimed. The NHS CB will also set out in its policies and procedures how it will ensure that conflicts of interest or the appearance of bias are managed.
- 3.5** The other major concerns raised through the consultation were about the appointing and resourcing of responsible officers. We consider that the existing requirement for each designated bodies to provide the responsible officer nominated or appointed for that body with sufficient funds and other resources necessary to enable them to discharge their statutory responsibilities are sufficient to address concerns about resourcing. We also think that the documents setting out the structure of the NHS CB¹⁴

¹⁴Design of the NHS Commissioning Board, NHS Commissioning Board, February 2012
<https://www.wp.dh.gov.uk/commissioningboard/files/2012/01/NHSCBA-02-2012-5-Organisational-Design->

provide further assurance that the NHS CB will appoint an appropriate number of responsible officers.

- 3.6** While we think the existing provisions provide assurance we think updating an existing power will provide further assurance. The existing provision enabling the Secretary of State to nominate or appoint a responsible officer where a designated body has failed to appoint one is being updated to reflect the powers of the NHS CB to appoint the number of responsible officers it thinks sufficient. We are proposing to amend this provision to enable the Secretary of State to appoint further responsible officers where the NHS CB has not appointed a sufficient number as required under the Regulations.¹⁵

Postgraduate trainees

- 3.7** While it is clear that deaneries and deans will continue to exist within LETBs, we agree with the majority of respondents that trainees' responsible officers should remain with the bodies supervising their training programmes. We think that it makes sense to align the role the responsible officer performs with the role of responsibility for the supervision of trainees' training, reducing duplication. This was supported by respondents to the April consultation. Therefore, in the draft Regulations we have designated LETBs and made a connection to the trainees for whom they are responsible. As discussed, LETBs are to be constituted as committees of HEE and will not have legal status in their own right. We consider, however, that they are sufficiently identifiable for the purposes of designation and we have set this out in the Regulations at regulation 10(1)(a)(ia). LETBs will have their own connection to HEE. Whilst HEE operates across the system, it is acknowledged that the majority of the doctors within/reporting to the organisation have a connection to the NHS CB and therefore HEE's responsible officer will be connected to the NHS CB.
- 3.8** There are, however, three deaneries that will continue to exist outside of LETBs. These are the Wales Deanery, the Defence Deanery and the National Deanery for Pharmaceutical Medicine. These organisations continue to be designated under the Regulations (see paragraph 10 of the Schedule) and will continue to make the relevant connections under regulation 10(1)(a)(i).

Public health

- 3.9** In the light of the consultation responses and further consideration by the Chief Medical Officer of the issues of burden, capacity and public health leadership we are proposing that doctors employed by local authorities (except those with a higher connection such as the performers list) are connected to PHE (see regulation 10(1)(ba)). Furthermore, to reflect the Department of Health's focus on public health we are proposing that the connection for the responsible officer appointed by PHE should be to the Department of Health.

Proposed connections for Doctors

- 3.10** The revised structures outlined above are represented in flow diagram on page 22. This diagram visualises how doctors will be connected to a designated body. Responsible

[Recommendations-Final.pdf](#); NHS Commissioning Board: Local Area Teams and Clinical Senates, NHS Commissioning Board SpHA, June 2012; <https://www.wp.dh.gov.uk/commissioningboard/files/2012/06/lat-senates-pack.pdf>

¹⁵See regulation 9(1)(a)

Responsible officers in the new health architecture

A combined consultation and consultation response document

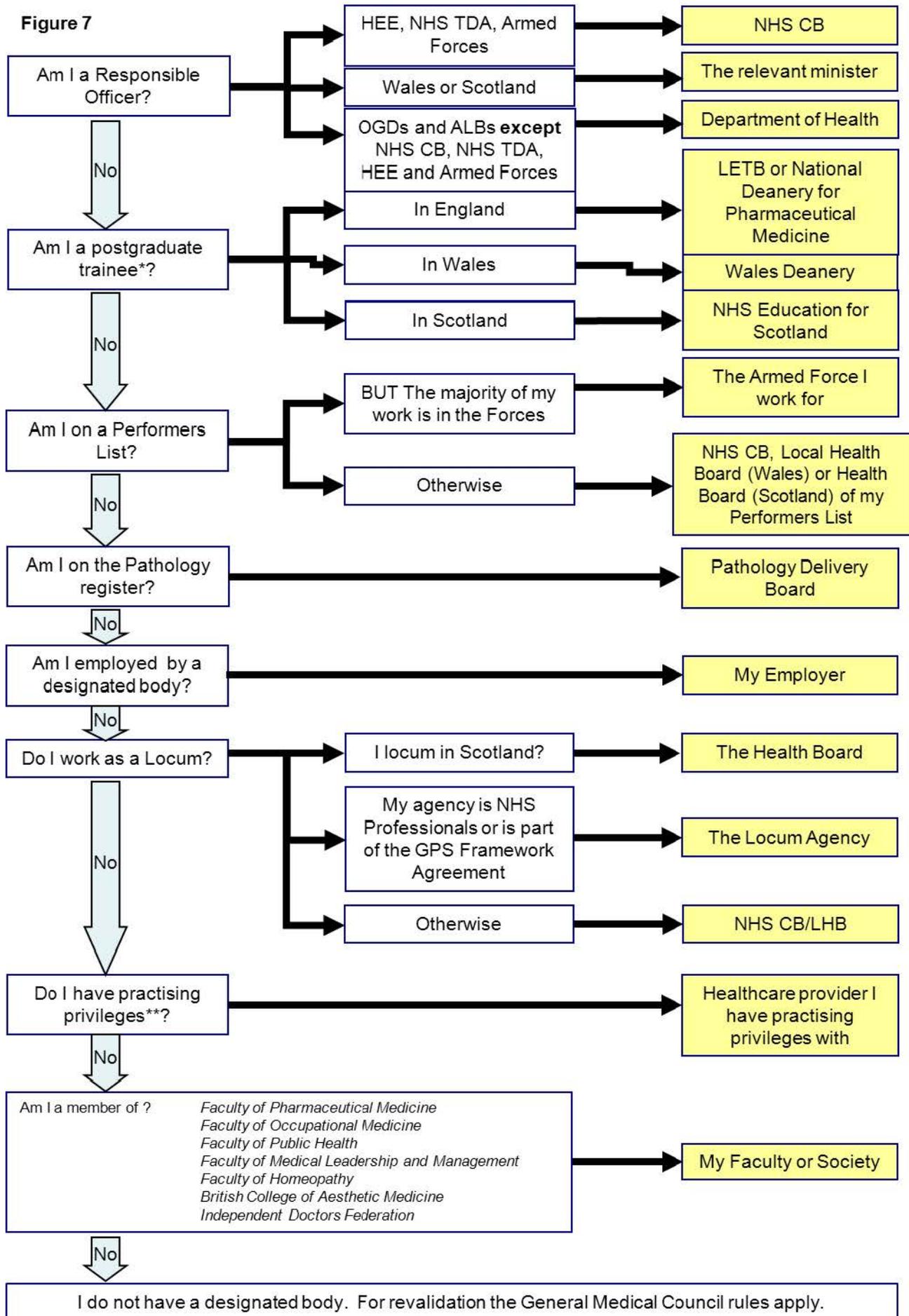
officers for other Government departments and most Department of Health arm's length bodies will be connected to the Department of Health.

- 3.11** Given that the NHS Trust Development Authority (NHS TDA) and HEE are significant NHS service delivery partners, their connections will be to the NHS CB and not the Department of Health. A connection to the NHS CB will also be made for the NHS Litigation Authority and the NHS Leadership Academy. Responsible officers for the armed forces (Army, Navy and Air Force) will be connected to the NHS CB, whereas the Surgeon General (the responsible officer for doctors at the Ministry of Defence) will be connected to the Department of Health.
- 3.12** The diagram attempts to capture these connections. It is, however, primarily a guide for doctors to determine who their responsible officer will be, and so does not consider all the connections for responsible officers. A final version of this flow diagram will be produced in future guidance.

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A combined consultation and consultation response document

Figure 7



Question 3.1: Do you think that the model of connections in figure 7 addresses the connections discussed in paragraphs 3.1 to 3.12? If not, please explain why not.

Language checking

3.13 In the light of the responses we have decided that the only change to the Regulations we will make at this time is to clarify that responsible officers in England must ensure that medical practitioners have sufficient knowledge of English language necessary for the work to be performed. This will form part of the pre-appointment checks that any good organisation will carry out to ensure that patients are not put at risk by someone who cannot communicate clearly in English. We are proposing to give power to the NHS CB to issue guidance on language checks, to which responsible officers will be required to have regard. The GMC already have a power under the existing regulations in relation to their regulatory function. However, we are continuing to explore further measures to ensure that all doctors are subject to robust checks on their language and competence and in particular the details of the process for undertaking language checks to be set out in regulations.

Question 3.2: Do you consider that language checking guidance should be placed on a statutory footing so that responsible officers have to pay due regard to the guidance?

Question 3.3: If you answered 'yes' to question 3.2, do you consider that the NHS CB should be given an explicit power to issue guidance on language checking?

Question 3.4: Are you able to provide any additional evidence or analysis on the costs of the proposed language checking policy including the cost of additional recruitment processes (for example relating to any additional time spent by responsible officers resulting from the explicit language checking responsibility and including further recruitment as a result of candidates unsatisfactory language skills) and cost of actual language tests?

Question 3.5: Are you able to provide any additional evidence or analysis on the benefits of strengthening the language checking system, and any data on the impact of equality through the use of language controls?

Summary of other changes

3.14 We have taken this opportunity to clarify the Regulations, as follows:

- **organisations with a connection to only one doctor:** we have clarified that where an organisation is listed in Part 2 of the Regulations and has only one doctor (who is appointed as a responsible officer) that organisation will still be required to nominate a responsible officer (where that responsible officer is connected to another designated body)(see regulation 5(6));

Responsible officers in the new health architecture

A combined consultation and consultation response document

- **ophthalmic medical practitioners:** these dually qualified doctors are required to be on a performers list and so we have extended the connection for these doctors to the NHS CB (see regulation 10(1)(b));
- **doctors with practising privileges:** we have clarified that doctors with practising privileges will only have a connection with the hospital that has granted them those privileges and where the doctor actually treats patients at the hospital (see regulation 10(1)(f));
- **membership of more than one Faculty:** we have clarified which faculty a doctor has a connection with, where they have membership of more than one of the designated faculties in regulation 10(1)(g);
- **Department of Health:** the NHS Medical Director is moving from the Department of Health to the NHS CB. The Department of Health's new role only requires one responsible officer and we are removing the requirement for the Department of Health to appoint two responsible officers; and
- **NHS Ambulance Trusts:** these Trusts are designated along with other NHS Trusts and Foundation Trusts in Part 1 of the Regulations and have to nominate or appoint a responsible officer. Not all of them employ doctors and therefore it seems nonsensical for them to require them to have a responsible officer. We are amending the designation so that Ambulance Trusts will only be required to appoint a responsible officer if they employ and have a connection to one or more doctors.

The new NHS Framework Agreement for the supply of secondary care locums

3.15 The NHS Framework Agreement for the supply of secondary care locums has been re-negotiated to include agencies who directly provide locums and, additionally, those that sub-contract the provision of services. Those agencies that sub-contract will now be designated bodies under the Regulations.

Question 3.6: Do you think that it is still appropriate that the agencies are designated under the Regulations?

Question 3.7: Do you consider there to be a category of doctors that are not adequately covered by the responsible officer policy: e.g. doctors that may not have responsible officers or where the risks are perceived to be greater, for example, locums?

Question 3.8: If you answered 'yes' to question 3.7, do you have any evidence that you can provide or any suggestions for data sources that would assist in quantifying the risk, or any suggestions about how to strengthen the system in respect of those groups of doctors?

3.16 We have also taken the opportunity to update the Regulations to reflect :

- New Performers List Regulations due to come into force on 1 April 2013.
- The transfer of NCAS to the NHS Litigation Authority.

Additions to the list of other designated bodies

- 3.17** We are also taking this opportunity to designate a number of additional bodies. These are organisations or groups of organisations that have approached the Department since the 2010 Regulations were made seeking to be included in the Regulations.
- 3.18** In each case, the basis for designation has been that they have a link to a group of doctors that have no prior connection to a designated body under the Regulations. Additionally, the organisations have worked with the Revalidation Support Team to ensure that they have the appropriate clinical governance processes in place and are capable of ensuring the role is properly carried out.
- 3.19** The organisations include:
- Resident Medical Officer organisations: these organisations employ doctors that are responsible for the care of patients overnight. They operate mainly in independent hospitals but sometimes in the NHS as well. (See Schedule 1, Part 2, paragraph 25A).
 - Medical Defence Organisations: these are organisations that provide support to doctors with medico-legal problems. They employ licensed doctors to give advice to other doctors. (See Schedule 1, Part 2, paragraph 25B).
 - Pathology Delivery Board: the Board registers and regulates independent forensic pathologists who are licensed doctors. In some cases, pathologists registered with the Board may also be employed. We think that a connection based on the regulation should take precedence over one based on employment. The draft regulations reflect this (See Schedule 1, Part 2, paragraph 14B).
 - Faculty of Medical Leadership and Management: there are a number of senior medical leaders without a connection to a designated body but who are members of the Faculty of Medical Leadership and Management. We think it is right that this highly influential group should have a responsible officer. We also think the Faculty is ideally placed to act as that responsible officer and is appropriate to provide the responsible officer for the NHS Medical Director in the NHS CB (See Schedule 1, Part 2, paragraph 22).
 - British College of Aesthetic Medicine and the Faculty of Homeopathy: doctors who are members of these bodies are treating patients but do not have a connection under the existing regulations. We consider that it is appropriate to include them in these regulations. The Revalidation Support Team has been working closely with the Faculties to ensure that their clinical governance structures and processes are in place in order for the responsible officer to fulfil their obligations. We are satisfied that they are ready to be designated. (See Schedule 1, Part 2, paragraphs 25D and 25E).

Question 3.9: In the hierarchy that determines a doctor's designated body (see figure 7), do you think that the connection to the Pathology Delivery Board should:

Responsible officers in the new health architecture

A combined consultation and consultation response document

- a) take precedence over an employment connection and come immediately before employment;**
- b) have a lesser connection than employment and come immediately after employment; or**
- c) other?**

Question 3.10: If you think 'other', please explain why.

Question 3.11: Do you think we have adequately addressed the addition of the designated bodies listed in paragraphs 3.17 to 3.19 in the draft regulations? If not, please explain why not.

Chapter four

Responding to the consultation

Below we outline the consultation period, the deadline for submitting your responses and how to respond to the consultation.

There are three ways to respond: online, by e-mail or by post. It also includes a contact address if you have a complaint or wish to submit any comments about the consultation process.

The consultation runs from the **7 December 2012** and will close on **4 January 2013**.

You can respond to this consultation on the web at www.dh.gov.uk/liveconsultations or in writing.

Responding on the web:

If you wish to respond online the questionnaire can be found at:

www.dh.gov.uk/liveconsultations

The online questionnaire will be available from **7 December**:

Responding by e-mail:

If you wish to respond by e-mail please use the questionnaire at the back of this document.

Once it is completed please e-mail to:

<mailto:responsibleofficer@dh.gsi.gov.uk>

Responding in writing:

If you wish to respond in writing it would be helpful if you could do so by completing the consultation response form and sending it to the address below. If you do not want to use the consultation response form or are unable to do so, then please write with your answers and comments to the address below.

Consultation on Responsible Officers
Department of Health
602A, Skipton House
80 London Road
London, SE1 6LH

Consultation principles

Responsible officers in the new health architecture

A combined consultation and consultation response document

The consultation principles can be found on the Cabinet Office's website at:

<http://www.cabinetoffice.gov.uk/resource-library/consultation-principles-guidance>

The principles inform Government departments of the considerations that should be made during consultation. These include consideration of the subjects of consultation, the timing of consultation, making information useful and accessible, and transparency and feedback.

We confirm that this consultation has been guided by these principles.

If you have any complaints or comments about the consultation process (but not responses to the consultation itself), please send them to:

Consultations Co-ordinator
Department of Health
Room 3E58, Quarry House, Quarry Hill
Leeds
LS2 7UE

E mail: consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address

Summary of the consultation

A summary of the response to this consultation will be made available within three months of the end of the live consultation period and will be placed on the Consultations website at:

<http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm>

Information Handling and Freedom of Information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter. For further details on the Information Charter, please see:

<http://transparency.dh.gov.uk/dataprotection/information-charter/>

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000, the Data Protection Act 1998 and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the Freedom of Information Act 2000 there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the

Responsible officers in the new health architecture

A combined consultation and consultation response document

information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the Data Protection Act 1998 and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

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Abbreviations

BMA: British Medical Association

CCG: Clinical Commissioning Group

HEE: Health Education England

LA: Local Authority

LETB: Local Education and Training Board

NCAS: The National Clinical Assessment Service

NHS CB: The National Health Service Commissioning Board (currently a Special Health Authority)

NHS TDA: NHS Trust Development Authority

PCT: Primary Care Trust

PHE: Public Health England

RCS: Royal College of Surgeons

SHA: Strategic Health Authority

Annex A

The Medical Profession (Responsible Officer) (Amendment) Regulations 2013

Annex B

The Medical Profession (Responsible Officer) Regulations 2010 showing the effect of draft amendments

Annex C – Consultation Questionnaire

Annex C provides a list of all the questions that we have asked in this consultation. If you need to look back at the main document, each question lists the chapter number followed by a second question number.

Responsible officers in the new health architecture

A combined consultation and consultation response document

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