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To consider

Department of Health (England) Consultation on the Responsible Officer Regulations and Guidance

Issue

1. The terms of our response to the Department of Health (England) consultation on Responsible Officer Regulations and Guidance.

Recommendations

2. To agree the terms of our response to the consultation on the Responsible Officer Regulations and Guidance (paragraphs 10-46).
3. To agree that the Chair of Council be authorised to finalise our consultation response in the light of members' further comments (paragraph 47).

Further information

4. If you require further information about this paper, please contact us by email: gmc@gmc-uk.org or tel. 0161 923 6602

Background

5. Key Aim Three in our Business Plan is to enhance assurance that licensed doctors are up to date and fit to practise by introducing licences to practise and preparing for revalidation. The introduction of Responsible Officers into local healthcare organisations is a key component of revalidation.

Responsible officers

6. The Chief Medical Officer for England's 2006 report *Good Doctors, Safer Patients* and the subsequent White Paper, *Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century* (2007), introduced the concept of the local responsible officer (RO). The RO would be a senior doctor within a healthcare organisation who would plug what was perceived to be a 'regulatory gap' by facilitating more effective liaison between the employer and the GMC in managing concerns about doctors, and ensuring the effective implementation of revalidation at local level.

7. The statutory basis for the RO role is set out in the Health and Social Care Act 2008 (HSCA 2008), which amends the Medical Act 1983. In broad terms, the RO will be responsible for the local evaluation of doctors' fitness to practise for the purposes of revalidation, for overseeing the operation of local clinical governance arrangements necessary to support revalidation (except in Scotland where this is a matter for medical directors), and for ensuring appropriate action where there are concerns about doctors' fitness to practise. In particular, ROs will be responsible for the revalidation recommendations made to the GMC regarding the doctors linked to their organisation. The HSCA 2008 provides that details of the RO role will be set out in statutory regulations.

8. On 23 July 2008 the Department of Health (England) launched an initial consultation on the detail of the RO function.

9. On 25 August 2009 DH(E) published a further consultation (Annex A) on the statutory regulations governing the RO role (Annex A, Appendix 1), and supporting guidance for doctors, ROs and healthcare organisations (Annex A, Appendix 2). The consultation closes on 25 October 2009.

Discussion

10. The key principle governing this consultation is that all licensed doctors will be linked to one, and only one, RO. The draft Regulations and Guidance set out how that connection will operate. That connection, and the way in which the RO function is delivered, raise a number of challenges, such as the potential for unfairness and bias, particularly for doctors in minority groups (see paragraphs 49 -53 below). This paper teases out some of those issues and considers the terms of our consultation response.

Consultation Question 1: Do you agree that Regulation 3 designates all those organisations that need to have a responsible officer?

Consultation Question 2: If you answered NO to Q1 which other organisations should be designated?

11. Regulation 3 sets out the bodies, and types of bodies, that will be required to appoint or nominate an RO. These are referred to as 'designated bodies'. They fall into three broad categories:

- a. Organisations, including the NHS, that employ or contract with doctors to provide healthcare.
- b. Organisations with a role in the provision of services that affect the treatment of individual patients, but only if they employ or contract with doctors. They include, for example, any organisation engaged in the termination of pregnancies, organisations engaged in the provision of services in slimming clinics and organisations involved in the management of blood supplies and the matching and allocation of donor organs for transplant.
- c. Organisations which do not treat patients but which provide advice or make decisions that affect large numbers of patients. These include government departments and agencies, medical Royal Colleges and Faculties, the GMC and the Office of the Health Professions Adjudicator, where these bodies employ or contract with doctors.

12. The consultation document suggests that the proposed designation of bodies required to appoint or nominate ROs will ensure that the vast majority of doctors are able to relate to an RO. It acknowledges, however, that there remain gaps and unresolved issues.

Locums

13. One of the unresolved issues is the position of locums in England. DH(E) proposes that locum agencies demonstrating good clinical governance systems should become designated organisations required to appoint ROs. But this begs a number of questions. First, there needs to be agreement about how the governance systems of locum agencies are to be assessed and quality assured, and who would undertake this. The position of locums associated with agencies that are not approved as designated bodies will also need to be clarified because there are no alternative proposals for how they would link with an RO. In addition, given the financial, legal and administrative implications for an organisation in having to appoint an RO, there could be a perverse incentive for some not to achieve designated body status.

14. In Scotland, by contrast, the intention is that each locum doctor will relate to the responsible officer for the appropriate Health Board. For those locums not attached to approved agencies in England, consideration should be given to whether an equivalent arrangement might be possible by enabling them to link with designated Trusts or SHAs.

Doctors outside managed clinical environments

15. Doctors outside managed clinical environments fall into a number of different groups. Some of these are accommodated within the current proposals, but others are not.

16. Doctors working in occupational medicine, pharmaceutical medicine or public health who are not employed by an organisation would be able to link with an RO within the relevant Faculty, provided that they are members of the Faculty. Similarly, doctors in wholly independent practice who are members of the Independent Doctors Forum (IDF) will link to an RO provided by the IDF. These are helpful provisions, but under the Regulations as drafted they extend only to members of those organisations. It might be more helpful if doctors who are not members were also able to access the RO facilities offered by the IDF or the relevant Faculty. No doubt those organisations would wish to charge for any service provided to non-members.

17. There is, though, a risk that some doctors in independent practice may choose not to link to an RO, even if one is available to them. For others, such as those who maintain a licence to practise while working overseas for non-UK based organisations, it may be unrealistic to maintain a meaningful link with a UK based RO.

18. The principal functions of the RO are to ensure that effective clinical governance and appraisal systems are in place to support doctors in their revalidation and provide a line of communication between the workplace and the GMC. Yet it is difficult to see how this is achieved where the doctor concerned works wholly outside a managed environment or, perhaps, in another country under a different regulatory jurisdiction.

Doctors working in commercial organisations

19. Another group of doctors identified by the consultation is those working for organisations such as law firms, universities, research companies, pharmaceutical companies and insurance companies. DH(E) states that it is neither practical nor appropriate to designate such organisations in the Regulations as bodies required to appoint ROs. However, we understand that at least some of them, for example, in the pharmaceutical industry, may wish to be able to appoint ROs. Where that is the case, it would seem sensible to allow them to be listed among the designated bodies included in the schedule to the regulations.

'Orphan' doctors and the GMC

20. If doctors are unable to link with an RO, there may be an expectation that the evidence in support of their revalidation would come, direct and unmediated, to the GMC for evaluation. Although the consultation document suggests that the number of doctors in this position would be small, on the basis of the current proposals this could still mean several thousand individuals. We have statutory powers that would enable us to charge a fee for revalidating doctors in these circumstances, but the resource implications would be considerable.

21. Moreover, insofar as the RO role involves ensuring good quality local appraisal and effective local governance arrangements to support doctors in their revalidation, it would be inappropriate and unrealistic to expect the GMC to fulfil this function. In any event, it seems that the principle of every licensed doctor relating to a single local RO is not one that can be meaningfully sustained in practice.

22. We may therefore conclude that the Regulations should allow more scope to enable doctors to link with an RO in an appropriate local organisation.

Quality assurance and the systems regulators

23. The organisations which are designated as bodies required to appoint or nominate ROs will be under a duty to ensure that the RO is able to carry out his or her statutory functions. Most of those organisations will be subject to the quality assurance regimes of the systems regulators, such as the Care Quality Commission in England and the equivalent bodies in the other countries of the UK. In our consultation response we will want to highlight the need for any quality assurance regime to take account of an organisation's delivery of the RO function. We will also ensure that this forms part of our ongoing discussions with the systems regulators about their role in revalidation. (We discuss in paragraphs 49-53 of this paper concerns that have been raised in respect of equality and the role of quality assurance in addressing them.)

Consultation Question 3: Do you think Regulation 5 provides sufficient safeguards in the event of a conflict of interest arising? If not, please explain what further measures should be considered.

24. Regulation 5 provides that where a conflict of interest arises between the RO and a medical practitioner a designated body must nominate or appoint a second RO. For practical reasons, it seems likely that organisations will need to have appointed and trained a deputy RO in advance, rather than waiting until a conflict of interest occurs. The Regulations may need to make explicit provision for this.

25. The issue for the GMC is whether the Regulations should make provision for situations where there is a conflict between the ROs responsibilities to the GMC and to his or her employing organisation. The consultation proposes that the medical managers who will carry out the RO role already face potential conflicts of this kind and are accountable to the GMC for their actions. It concludes that it is therefore unnecessary to attempt to address this further through regulations, although under Regulation 14 it will be a criminal offence for a designated body to prevent an RO from discharging their responsibilities.

26. Our guidance *Management for Doctors* (2006) considers the responsibilities of medical managers where conflicts of interest arise. The draft *Responsible Officer Guidance* (Annex A(ii)) which accompanies the consultation addresses the issue insofar as it concerns conflicts between the RO and the medical practitioner. It is silent, however, on the matter of conflicts between the RO and the employing organisation. Given that the Guidance is aimed both at ROs and employers it might be helpful, and provide a measure of support for ROs, for it to be explicit about the duties of both parties.

Consultation Question 4: Do you agree that Regulation 6 should require responsible officers to have a licence to practise?

27. Regulation 6 sets out the requirements for nomination or appointment as an RO. To be eligible for appointment, a person must be:

- a. A licensed medical practitioner.
- b. Have been a registered medical practitioner throughout the previous five years.
- c. Practise as a medical practitioner or have done so within the previous five years.

28. In our response to the DH(E)'s July 2008 consultation on the RO function we said that ROs should hold a senior position and have a licence to practise because it will be important that they have credibility with the doctors who will be linked to them for the purposes of their own revalidation. There seems no reason to resile from this view.

Consultation Question 5: In circumstances where the responsible officer acts for another body, are additional criteria to those in Regulation 7 needed?

29. Regulation 7 sets out the circumstances in which an RO may be nominated or appointed to act for two or more designated bodies. This is a matter for local arrangements and not an issue upon which we need to comment.

Consultation Question 6: Are the functions set out in Regulation 9, relating to the evaluation of a doctor's fitness to practise, appropriate?

Consultation Question 7: If you think there are other functions that should be specified, please explain what they are.

30. Regulation 9 sets out the functions of the RO relating to the evaluation of a doctor's fitness to practise. These appear to be appropriate. However, in Regulation 9(3)(a) it would be helpful to make it clear that the 'fitness to practise requirements' to be met are those of the GMC.

Consultation Question 8: Do you agree that Regulation 10(1) sets out the appropriate connections for doctors?

Consultation Question 9: Do you think Regulation 10(2) enables doctors in designated organisations to be linked to an appropriate responsible officer regardless of their working pattern?

Consultation Question 10: If the answer to either Q8 or Q9 is NO please explain.

Consultation Question 11: In particular, do you think there are any other alternatives to using the doctor's registered address as a final report to decide?

Consultation Question 12: Please comment on the appropriateness of the system set out in Regulation 11 to manage the conduct and performance of responsible officers.

31. Regulations 10 and 11 describe the connections between doctors and organisations in a range of different circumstances. It enables organisations to know which doctors they are responsible for and doctors to know where their RO will be based. This is particularly important for doctors with portfolio careers encompassing a number of different roles and employers. The proposals are summarised in Figure 1 on page 15 of the consultation document (Annex A).

32. In our response to the DH(E)'s July 2008 consultation we said that the underlying principle governing the connections between doctors and ROs should be that every doctor is able to link to an RO who works for an organisation that has a meaningful link with the work that the doctor carries out on a day to day basis. We acknowledged that this would create some challenges, particularly for doctors in peripatetic practice, doctors outside managed organisations and doctors working overseas. Earlier in this paper we noted that questions about how doctors in these situations will link with an RO have not yet been answered.

33. For the most part, the prescribed connections between doctors and organisations are sound. However, for some situations the connections are at odds with the principle of the meaningful link. For example, although in general it seems appropriate for a doctor who is on a Performers List to link with an RO in the Primary Care Organisation responsible for that list, the connection is less relevant if the vast majority of the doctor's work is undertaken in a different setting outside primary care. Elsewhere the regulations deal with the problem of doctors holding multiple roles by providing for the RO to be from the organisation where the doctor carries out the majority of his or her practice. This would seem to establish a more secure connection between the doctor and the RO.

34. However, a second difficulty arises because where doctors are employed or contracted by more than one organisation, the prescribed connection is with the body where they undertake most of their 'clinical practice' with patients. What constitutes 'clinical practice' is not defined, but there are plenty of disciplines and roles which involve no clinical practice whatsoever. The position of doctors in these roles is unclear. It might be more helpful, therefore, for the regulations to refer more generally to medical practice or professional practice.

35. The decision to give precedence to 'clinical practice' is because the primary focus is, understandably, on the quality of care for patients. However, this seems to conflate the role of the RO with the role of the appraiser. The appraiser will undoubtedly want to take account of all aspects of a doctor's practice. The role of the RO is to ensure that the appraisal takes place and that the outputs result in a recommendation to the GMC.

36. The consultation proposes that in cases where there is no significant difference between the amount of practice a doctor undertakes for different designated bodies, the location of his or her RO will be determined according to whichever of those organisations is closest to the doctor's GMC registered address. In such cases, this is probably the only option. Nevertheless, it is possible to envisage some challenges in cases where the registered address is outside the UK.

Consultation Question 13: Do you agree that the additional functions of a responsible officer set out in Regulation 16 are appropriate?

Consultation Question 14: If you think there are other functions that should be specified please explain what they are.

37. Regulation 16 sets out specific clinical governance responsibilities for ROs in England. Wales and Northern Ireland will make their own regulations. In Scotland, these responsibilities rest with medical directors.

38. Much of the emphasis in regulation 16 is on the RO's role in identifying and dealing with fitness to practise matters (referred to throughout as 'conduct and performance'). There is no explicit mention of the need to ensure that there are robust systems of clinical governance to support doctors in demonstrating that they are fit to practise so as to meet the requirements of revalidation (although regulation 16(3) hints at this). This is unfortunate because it implies that the principal function of the RO is to root out poor practice rather than the wider purpose of contributing to the quality agenda by supporting good practice. The accompanying guidance is clearer about this more positive role (for example, see paragraphs 3.3, 3.9 and 4.4) and it might be helpful, both to doctors and ROs, if this was explicit in the Regulations.

Consultation Question 15: Please comment on the extent to which regulations 12-14 and 17-19 achieve the policy objectives set out in the previous consultation paper on the role of the Responsible Officer.

39. These regulations impose a duty on designated organisations to provide ROs with sufficient funds to enable them to carry out their functions. They also provide that in certain circumstances doctors outside managed environments must themselves pay for the RO services they receive.

40. The regulations impose a duty on ROs to have regard to all relevant guidance, including guidance from the GMC.

41. The regulations make it an offence for a designated body (as defined in the regulations) to fail to appoint or nominate an RO, fail to provide an RO with appropriate resources or prevent an RO from discharging their responsibilities. We may wish to note that in our response to the July 2008 consultation we suggested that bringing criminal proceedings against organisations and individuals was unlikely to be desirable or practicable. We argued that instead of introducing criminality, a better approach would be to provide incentives for compliance.

Consultation Question 16: Please comment on the content, structure, layout and 'useability' of the draft guidance. Comments on the guidance can be submitted either as track changes or clearly annotated paragraph numbers.

42. Subject to the views of Council, we do not propose to comment in detail on the draft Guidance, since it is aimed at doctors, ROs and employers. However, some of our comments on the draft Regulations will have a direct bearing on the associated guidance. In addition, the following points will be made:

43. Paragraph 3.25 states: 'Doctors must demonstrate their fitness to practise in the areas in which they work, rather than in the specialty in which they originally gained their Certificate of Completion of Training (CCT) *or which they practice for only a minority of the working time* [our italics].' This may create the misleading impression that doctors do not need to be competent in areas of practice which only occupy a minority of their time.

44. Paragraph 4.6 considers the circumstances in which ROs may need to liaise with and take advice from the medical Royal Colleges and Faculties. The final sentence in that paragraph states: 'It is envisaged that this should happen only where there are concerns about fitness to practise.' This limits the circumstances in which ROs may wish to seek support from the Colleges and Faculties. It is inconsistent with the revalidation model that we have discussed with the Colleges and Faculties. It is also inconsistent with the broader engagement between ROs and the College representatives suggested in paragraph 4.8 of the guidance. We are firmly of the view that it is the ROs who must make the revalidation recommendation to the GMC, but we would not in any way want to constrain them in their ability to seek advice and support whenever appropriate.

45. Paragraph 4.15: In line 11, it is unclear whether the intended word is 'summative' or whether it should in fact be 'formative'.

46. Council is invited to agree the terms of our consultation response.

Recommendation: To agree the terms of our response to the consultation on the Responsible Officer Regulations and Guidance.

47. Subject to the outcome of this discussion, we propose that the Chair of Council should be authorised to finalise our consultation response.

Recommendation: To agree that the Chair of Council be authorised to finalise our consultation response in the light of members' further comments.

Resource implications

48. There are no immediate resource implications arising from the consultation or recommendations in this paper. However, the fact that there are unresolved questions about how some groups of doctors will relate to an RO means that we cannot rule out the possibility of significant resource implications if there is an expectation on the part of DH(E) that these doctors will revalidate by engaging directly with the GMC. At this stage any resource implications cannot be quantified. This will be a key issue in our further discussions with DH(E) about the arrangements for those doctors who are unable to link with a locally based RO.

Equality

49. DH(E) is preparing an equality impact assessment in relation to revalidation as a whole. The role of the RO will form part of that assessment. In the meantime, we know that some doctors and their representatives are concerned about the potential for unfairness or bias to impact adversely on doctors, particularly doctors in minority groups.

50. It will be essential that the arrangements are fair and seen to be fair. The provisions in respect of conflict of interest between an individual doctor and the RO (paragraph 24) will go some way to achieving this, but more is required. In particular, the quality assurance framework surrounding the work of ROs will need to be capable of detecting – and interrogating - any unusual decision-making patterns so that the potential for discrimination by a RO, whether conscious or unconscious, is mitigated.

51. There may also be merit in the NHS in each of the four UK countries publishing aggregate data on the demographic profile of their RO cohorts.

52. Finally, the RO is a manifestation of local systems rather than a GMC role. The training of ROs (for example, in equality and diversity issues) will therefore be a matter for the local organisation concerned to deliver. However, ROs will be crucial partners for us in delivering revalidation successfully and we will almost certainly want to, and need to, engage with the RO population and play a role in identifying and spreading good practice.

53. For the purposes of this response, we should make the above points and make clear our determination to work with our partners in addressing any concerns about the equality impact of the RO role.