# EXPLANATORY MEMORANDUM TO

## The Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010

1. **Introduction**

1.1. This Explanatory Memorandum has been prepared by the Department of Health, Social Services and Public Safety to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2. The Statutory Rule is made under sections 45A of the Medical Act 1983 and section 120 of the Health and Social Care Act 2008 and is subject to the draft affirmative resolution procedure.

2. **Purpose**

2.1. These Regulations establish arrangements for the introduction of "Responsible Officers" ("ROs") under the Medical Act 1983. ROs will be appointed by health care organisations and will have responsibility relating to the evaluation of the fitness to practise of doctors who work in the organisation.

3. **Background**

3.1. The Statutory Rule fulfils the obligations of the Department under sections 45A of the Medical Act 1983 and section 120 of the Health and Social Care Act 2008.

4. **Consultation**

4.1. A consultation on the draft Regulations ran for 9 weeks from 4th December 2009 to 5th February 2010. A total of 19 responses were received with the majority of them coming from organisations who are designated under these Regulations or who represent the medical profession. In general responses were supportive of the Regulations. A copy of the Consultation Report has been published on the Department's website.

5. **Equality Impact**

5.1. As the measure has no adverse impact upon Section 75 Groups the Department has concluded that it is not necessary to submit this matter to a full EQIA.

6. **Regulatory Impact**

6.1. A Regulatory Impact Assessment was carried out as the regulations require any designated organisation to appoint or nominate a Responsible Officer. This role is currently carried out by the designated bodies but the Assessment identified a small cost to bodies once the responsibilities became statutory.

7. **Financial Implications**

7.1. The cost impact of the Regulations is negligible.

## 8. Section 24 of the Northern Ireland Act 1998

8.1. These Regulations do not breach section 24 of the Northern Ireland Act 1998, as they are not incompatible with any of the convention rights or community law, and they do not discriminate against a person on the grounds of religious belief or political opinion. Nor do these Regulations modify or amend any of the enactments stated in section 7 of the Northern Ireland Act 1998.

## 9. EU Implications

9.1. Not applicable.

## 10. Parity or Replicatory Measure

10.1. The proposed Regulations broadly reflect the legislative changes which are being introduced in Great Britain under "The Medical Profession (Responsible Officers) Regulations 2010". This will maintain parity across the UK.

## 11. Additional Information

11.1. Not applicable

# REGULATORY IMPACT ASSESSMENT – ROLE OF RESPONSIBLE OFFICER

## 1. TITLE OF PROPOSAL

1.1 The Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010

## 2. PROBLEM UNDER CONSIDERATION

2.1 Over the past decade there has been significant patient, public and professional concern about the capacity and capability of local and national systems to address concerns about the conduct and performance of healthcare workers.

2.2 The White Paper, *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st century*[1] reviewed recent developments in the processes available to healthcare organisations and national regulators to identify and deal with such concerns. The White Paper concluded that further steps were needed to:

a. Enhance public confidence in the competence of the health professions;

b. Enhance confidence of the professions themselves that individual cases of apparent poor performance will be handled fairly, with the intention wherever possible of enabling individuals to remedy agreed defects; and

c. Bridge the "regulatory gap" between healthcare organisations, responsible for local handling of performance issues, and national regulators. The proposals in this Regulatory Impact Assessment (RIA) relate specifically to the medical profession.

2.3 At present, the GMC has no specific powers to instigate an investigation unless the matter is reported to it or it learns of a concern from a public source (e.g. a newspaper article). The White Paper, drawing on earlier proposals in the CMO for England's review of medical regulation[2], proposed introducing a system of locally based GMC officials, linked to "responsible officers" in individual healthcare organisations. These local GMC officials would provide support to local healthcare organisations in addressing emerging concerns about doctors and independently quality assure local revalidation processes, thus acting as an interface with the GMC nationally and filling the "regulatory gap".

[1] *Trust Assurance and Safety – The Regulation of health professionals in the 21st century* (The Stationery Office, February 2007)

2.4 A "regulatory gap" has been identified in the handling of poor performance between local employers and the GMC requires a solution that only government can address. The intention is to address this through the establishment of a ‘responsible officer’ role.

2.5 The responsible officers would be under a statutory duty to cooperate with the GMC. Since the publication of the White Paper further pilot work on developing the role of locally based GMC officials has been undertaken. The outcome of this work is the creation of local solutions to best enhance liaison between the GMC and responsible officers. In Northern Ireland the format of this liaison with GMC is currently under development.

2.6 The primary legislation to create the statutory role of responsible officer in regulations is contained in the Health and Social Care Act 2008.

2.7 The main provisions of the regulations enables the Department of Health, Social Services and Public Safety (the Department) through regulations to require specified healthcare organisations (designated bodies) to appoint a “responsible officer” with prescribed responsibilities in relation to revalidation and the evaluation of doctors’ fitness to practise, and to liaise with the GMC over these issues. Other regulations give responsible officers additional responsibilities relating to clinical and social care governance more generally.

## 3. RATIONALE FOR INTERVENTION

3.1 Locally accountable responsible officers, will liaise with the GMC, to help address the “regulatory gap”, ensuring effective handling of cases involving apparent poor professional conduct and behaviour; and play an important role in implementing the government’s revalidation proposals in a cost effective and appropriate way. Responsible officers will liaise with the GMC, working together to ensure consistency of approach and ensure that local clinical and social care governance and nationally regulatory actions are proportionate, effective, fair and focussed on patient safety.

## 4. POLICY OBJECTIVES AND INTENDED EFFECT OF MEASURES

4.1 **The objectives** are to:

a. Enhance public confidence;

b. Enhance confidence of the profession in the regulatory system; and

c. Bridge the regulatory gap.

4.2 The primary strategic aims of this policy are focused on patient safety and on delivering quality in healthcare and high professional standards among those who provide care. The

responsible officers will evaluate doctor's fitness to practise and will help to raise the already high standards of the majority of professionals, whilst ensuring that the small number of staff who let people down are swiftly identified and dealt with fairly and effectively.

## 5. RISK ASSESSMENT

5.1 The policy is part of a programme intended to enhance the confidence of the public and the profession in professional regulation and to bridge the so-called "regulatory gap" between local employers and the national regulator. Although it builds on and formalises best practice already undertaken by medical directors there are still risks that the policy may not be seen to be successful if there are high profile cases of individual failures.

5.2 Changes in other policies, such as revalidation and the development of closer links with the GMC will impact on the responsible officer because they are closely linked. Lack of success in these policies could be attributed to responsible officers.

5.3 The main benefits of this policy are discussed below. Benefits are expected from improved local processes that deal effectively with poor performance in doctors. Earlier intervention, providing remediation, re-skilling and rehabilitation and bringing failing doctors back on track to the benefit of patients, doctor and employer. All of this should increase confidence in the profession and regulatory processes and avoid the costs associated with the protracted national disciplinary process. The increased scrutiny on the conduct of doctors is expected to result in improved patient safety, better quality of care and improved public confidence.

## 6. OPTIONS

Three possible options have been considered:

6.1 **Option 1**: **Do nothing and continue with the current system.** This would mean the policy objectives stated above of bridging the regulatory gap and enhancing public and professional confidence in the conduct and performance of doctors and in the regulatory system would not be met. The actions of employers and those contracting medical services would not be fully co-ordinated with those of the GMC.

6.2 **Option 2**: **Build on existing clinical and social care governance structures to introduce an enhanced role for existing clinical leaders/medical directors.** This option focuses on the greatest risk to patients' safety. Under this option certain organisations that deliver health and social care will be designated, along with organisations with a role in setting policy and standards for the delivery of healthcare. Under this option designated

organisations exclude universities, research companies and insurance companies that also employ licensed doctors. Under option 2 senior doctors who fulfil the necessary criteria and already have an overall responsibility for many of the functions of the responsible officer (i.e. Trust Medical Directors) will be nominated within each designated organisation as responsible officers. Although many senior doctors have responsibilities relating to the fitness to practise of doctors, this policy will address the so-called "regulatory gap" by giving them statutory responsibilities, ensuring that they are trained and that they have the necessary resources to carry out their duty in this respect.

6.3 **Option 3**: **This option is a further extension of option 2 and will also build on existing clinical and social care governance structures, but will designate *all* employers of doctors to nominate or appoint a responsible officer.** Under this option all employers who employ doctors will be required to nominate or appoint a responsible officer (including those doctors employed in a non clinical capacity setting).

6.4 Section 7 of this impact assessment outlines the benefits associated with each option. Section 8 sets out the option costs.

## 7. ASSESSMENT OF OPTION BENEFITS

7.1 ***Option 1: (do nothing)***

Continue with the current system whereby the actions of employers and those contracting medical services are not fully co-ordinated with those of the GMC. Less robust systems may increase the risk that concerns are not properly or fairly addressed in the appropriate settings. Under option 1 the policy objectives of bridging the regulatory gap and enhancing public and professional confidence in the conduct and performance of doctors and in the regulatory system would not be met. Option 1 is the baseline against which other actions are assessed so its benefits are by definition zero.

7.2 ***Option 2:*** **Build on existing clinical and social care governance structures to introduce an enhanced role for existing clinical leaders/medical directors.**

Under this option the assessed benefits are:

7.2.1 ***Better Quality Care***

The early detection of any concerns about a doctor and appropriate and timely to address same should improve patient safety and the quality of care for two reasons. Firstly, any poor practice will be recognised and remedied and secondly it should motivate doctors to avoid poor practice.

7.2.2 ***Fewer missed cases***

Once responsible officers are appointed and carrying out their duties, concerns about doctors should be picked up and addressed earlier. This is because of the improved scrutiny of doctor performance and better connections between employing and regulatory organisations. There is currently insufficient information to estimate the extent of this benefit. This benefit relates to the Clinical and Social Care Governance aspect of the introduction of responsible officers.

7.2.3 ***Bridging the regulatory gap***

Under option 2 better liaison arrangements will be created between responsible officers and the GMC. On this basis the current risks of cases being left incomplete because of poor communication between employers and the GMC or because they move from one employer to another, should be reduced.

7.2.4 ***Fewer referrals to GMC***

Responsible officers should reduce referrals to GMC because they will provide local expertise in managing cases of suspected poor practice. This will act in two ways. Firstly, early detection of potential problems should prevent cases from escalating so that they never reach the threshold for referral to the GMC. Savings may arise for the GMC from a reduction in workload and the suspensions that accompany investigations. Secondly, the responsible officers' better understanding of thresholds for referral may reduce inappropriate referrals from employers and colleagues (although inappropriate referrals from patients would remain unaffected). This benefit relates to the Clinical and Social Care Governance aspect of the introduction of responsible officers.

The greater level of scrutiny, together with the revalidation process should act as a strong incentive to avoid poor practice. According to principal/agent theory in economics, the performance of doctors should improve when the level of performance monitoring increases. This is difficult to quantify with any accuracy, even more so because of the difficulty of assigning benefits between overlapping policies i.e. the introduction of responsible officers and the introduction of revalidation.

Although there is little evidence that doctors would necessarily respond to negative incentives in this way, there is evidence that other forms of feedback do have an effect. Grol's (1992) review of the literature led him to conclude that "face to face instruction, assessment, and feedback by well respected peers…combined with practical support…seem to be particularly effective in improving the quality of care." To support this, a study on the influence of observation on community health workers' practices found

evidence of a decrease in the frequency of treatment errors when workers "were not observed, but knew they were being studied" (Rowe et al. 2006). It is therefore be reasonable to suggest the possibility that a respected doctor might identify and act upon a medic's areas of poor practice would encourage them to maintain minimum acceptable standards. This benefit relates to the Clinical and Social Care Governance aspect of the introduction of responsible officers.

7.2.5 ***Enhanced confidence of the profession*** **in the regulatory system**

The introduction of responsible officers should increase doctors' confidence that their professional performance will be considered fairly and evaluated on the basis of solid evidence and their own testimony. The consistency of decision making that responsible officers will bring to the process should further reduce the uncertainty doctors face when concerns are raised about their conduct and performance because they will know that the same clear and fair process will be followed every time.

Inappropriate referrals to the GMC are detrimental to doctors because they are stressful and can tarnish reputations long-term undeservedly. Responsible officers should reduce the percentage of cases investigated, which are inappropriately referred to GMC and therefore further enhance the confidence of the profession.

This benefit relates to the Clinical and Social Care Governance aspect of the introduction of responsible officers.

7.2.6 ***Enhanced public confidence***

Patients and the public in general should also have greater trust in the medical profession because of the improved quality of care and patient safety, as discussed above and also because of more positive experiences whenever complaints are made. Further gains in public confidence will depend on how aware patients are of the policy. This benefit relates to the Clinical and Social Care Governance aspect of the introduction of responsible officers.

7.3 **Option 3 - Build on existing clinical and social care governance structures and designate *all* employers of doctors to nominate or appoint a responsible officer.**

The benefits of Option 3 are likely to be the same as those of Option 2, as the same number of healthcare and social care organisations will benefit from having a responsible officer. The additional non-health/social care organisations will not benefit from having a responsible officer, as they do not have any doctors providing healthcare in their workforce.

## 8. ASSESSMENT OF COSTS

8.1 Option 1 is the baseline against which other actions are assessed, so its costs and benefits are by definition zero. The costings below are based on the assumption that there are approximately 5,500 doctors on 'head count' basis currently practising in Northern Ireland (source: HRMS and GMC) who will be overseen by responsible officers. **The additional costs as a result of the introduction of responsible officers are related to support and training.**

8.2 ***Support Costs***

As the duties of a RO are currently, to all intents and purposes, being carried out by roles such as the Medical Directors in Trusts there are no direct costs for carrying out this function. However in each of the designated bodies, where the largest volume of doctors work, there will be a requirement for a support officer for the responsible officer - probably at Agenda for Change Band 4 at a cost of £27,713 per annum (based on full costs - including employer costs and top point of Band 4 payscale). Of the designated organisations who will be required to nominate or appoint a responsible officer there are eight organisations who will undertake the responsible officer function for the majority of licensed medical practitioners in HSC in Northern Ireland. These organisations are:

- The five health and social care trusts;
- The Northern Ireland Medical and Dental Training Agency;
- The Regional Agency for Public Health and Social Wellbeing; and
- The Regional Health and Social Care Board.

It is estimated that 1 WTE support officer at Band 4 will be required for each of the above organisations. The annual cost of the support officers is £221,704 (only 6 months of these costs will be incurred in Year 1 as the responsible officer role will be implemented wef October 2010).

8.3 ***Training Costs***

For the majority of senior doctors (Medical Directors), who are currently performing the duties of responsible officer within their existing role, there will be minimal training required to take on the responsible officer role. On this basis in Year 1 (pre the introduction of responsible officers in October 2010) a one day training session is estimated for each responsible officer nominated/appointed by a designated organisation. Thereafter refresher

training will be provided on an annual basis (or training for any new responsible officers as a result of turnover). Training will be provided by the Department of Health, Social Services and Public Safety. Training costs therefore relate only to the provision of venues, hospitality, production of materials, travel etc. Training costs have been estimated at £5,000 in year 1 and £3,000 per annum thereafter.

### 8.4 Factors which may affect Costs

#### 8.4.1 *Fitness to Practice Referrals*

Cases referred for investigation are managed on an individual basis and can therefore take a variety of pathways. Referrals are investigated formally or informally before either being referred to the GMC, undergoing remediation or deciding that no further action is required. In 2009, 109 enquiries were made to the GMC about doctors in Northern Ireland. Of these, 49 were closed with no further action being taken and 25 were investigated under Stream 2 procedures - where the information received is in itself less serious but would be of concern if part of a wider pattern. The GMC make enquiries with the doctor's employers or contractors to establish if they have any wider concerns about their practice. The remaining 34 enquiries were investigated under GMC Stream 1 procedures - where if the information raises serious allegations which in themselves would call into question the doctor's fitness to practice the GMC carry out a full investigation. In 2009 GMC Case Examiners made 30 decisions following a Stream 1 investigation about doctors in Northern Ireland; eight resulted in no further action, nine concluded with advice, one with a warning being issued, four with undertakings being agreed and the remaining eight referred to a Fitness to Practise Panel hearing. Nine doctors from Northern Ireland appeared before a Fitness to Practise panel hearing in 2009; five were erased, one suspended, two given conditions and one given a reprimand.

It is difficult to say whether closer liaison between responsible officers and the GMC will result in an increase in the number of cases referred to the GMC. Certainly one would expect that earlier detection of cases should enable more to be managed informally. The proportion of cases resulting in remediation should increase due to improved scrutiny of performance and having one local port-of-call for any performance or professional practice issues. Consequently it is assumed that informal resolution of cases may require a greater time commitment from the responsible officer from the outset (though it is impossible to estimate this accurately).

8.4.2 ***Suspensions***

The effect of the introduction of responsible officers on the total level of suspensions apart from those resulting from GMC Fitness to Practise panels is difficult to ascertain. On one hand, it could be assumed that a greater number of cases will be detected (the *volume* effect), but on the other, the proportion of investigated cases that result in suspensions will be expected to fall as cases are detected earlier and doctors will have incentives to improve their performance (the *composition* effect). In 2009, 4 doctors in Northern Ireland were suspended outside GMC Fitness to Practise panels (in these instances suspensions were initiated by the employing Trust).

8.4.3 As also explained above, the introduction of responsible officers may change the proportion of cases investigated that result in suspensions and this change would constitute the *composition* effect. There is currently no assumption on the magnitude of this decrease, but if the total number of suspensions was to stay the same, the proportion of investigations that result in suspension may fall.

8.4.4 There is no evidence on which of these two effects is stronger, the direction and magnitude are left unquantified and should be revisited when the policy is reviewed.

8.4.5 ***Ensuring quality of appraisal systems to support revalidation***

The responsible officer would have to ensure that his or her health and social care organisation has a cohort of trained appraisers, that doctors undergo annual appraisal and that the organisation has a system that collects the evidence needed for appraisals. In many organisations, these systems will already exist. The additional workload will relate to ensuring the systems are able to capture the information needed for a fair appraisal.

Nearly all HSC organisations and the majority of the Independent Healthcare providers will already have appraisal systems in place, so the costs are likely to be very small. This benefit relates to the Clinical and Social Care Governance aspect of the introduction of responsible officers.

8.4.6 ***Total cost impact***

Based on the costing information contained in this RIA the total estimated costs associated with the implementation of this policy in **year 1 is £115,852** (this includes support costs as outlined in section 8.2 (only required for 6 months in Year 1) and training costs of £5,000 as outlined in section 8.3). **From year 2 onwards the total costs per annum are £224,704.** The Net Present Cost of the project over 10 years and assuming a discounting rate of 3.5% is £1,984,626.

## 9. OTHER IMPACT ASSESSMENTS

The following impact assessments have also been considered:-

### 9.1 Competition Impact Assessment

The creation of the role of responsible officer will only have marginal effects on competition. The proposals have been deliberately framed to minimise the impact on smaller health and social care organisations.

### 9.2 Legal Aid Test

The primary legislation allows for the possibility of enforcement of some of the requirements against either individuals or organisations. However, we are not proposing to create offences where it would be necessary to take formal enforcement action against individuals. The proposals in this document will therefore have no implications for legal aid.

### 9.3 Sustainable Development

The legislation creates a role within organisations that enhances the confidence of the public and the professions in the system of professional regulation, and bridges an existing regulatory gap. As such it will contribute to the principles of sustainable development of ensuring a strong, healthy and just society and promoting good governance.

By having a clear role in legislation responsible officers will build confidence with the public that the systems to protect them are strong and healthy. We expect that the role will be filled in the main by medical directors who understand the local issues and will build the confidence of the profession in a system which will be seen to be just.

The role of responsible officer will be held by a senior licensed medical practitioner in an organisation, one with the power to raise issues at board level ensuring that processes and consideration of issues is built into the governance process.

### 9.4 Health Impact Test

This policy is designed to protect the health and safety of the public by enhancing the processes that will identify poor conduct and performance by doctors.

### 9.5 Equality

See separate Equality Impact screening. The screening has not identified any equality issues.

## 9.6 Rural Proofing

The intention is to ensure that all designated bodies (as prescribed in the regulations) must appoint or nominate a responsible officer. We do not think this will impact differently on different communities or doctors in rural communities differently.

## 9.7 Small Business Impact Test

9.7.1 The impact of the policy will fall more heavily on small organisations if no provision is made because not all costs vary according to the size of an organisation. The costs to train the responsible officer will not vary for different sized organisations and although the time taken to oversee referrals and the revalidation of doctors will be lower for smaller businesses, the variation in costs will probably be less than the variation in size.

9.7.2 A larger additional cost will be born if the organisation does not already employ a doctor that fulfils the requirements to be appointed as the responsible officer. In this case, they may decide to employ a new doctor in order to comply with the regulations. The total on cost of the annual salary of employing an appropriate doctor is in the range £125,000 to £200,000, but the net additional cost to the organisation would be considerably smaller because they would benefit from all the other work that doctor would do. Alternatively the organisation could enter into an arrangement with another organisation to provide responsible officer services. The list of designated bodies at this time leaves few organisations for which this could apply, i.e. organisations which provide health and social care but do not employ any doctors suitable to be responsible officers. Still, the impact on these predominantly small organisations could be significant if no provisions are made.

9.7.3 Provisions have been made which should reduce the impact of the policy on small organisations for whom employing a doctor to appoint as the responsible officer would impose too great a burden. The relevant regulations are:

- Regulation 6: "Nomination or appointment of one person as responsible officer for two or more designated bodies"
- Regulation 12: "Provision of resources to responsible officers."

9.7.4 If small organisations meet Regulation 12, that is, they pay the larger organisation for the costs of the responsible officer's time and no more, it is assumed that larger organisations will be neither inclined nor disinclined to provide a responsible officer because they will be no better or worse off either way.

9.7.5 There are financial and non-financial ways of making larger organisations inclined to help smaller counterparts in this way. Larger organisations might choose to provide responsible officer time to smaller ones because of business linkages or strong network relationships. A desire to preserve vendor-client relationships could provide the incentive for a large firm to help. Alternatively, decision-makers within both organisations could have developed relationships through networks so that the decision takes on a more inter-personal (rather than simply inter-organisational) dimension.

9.7.6 If these non-financial incentives are not enough to induce the larger organisation to provide responsible officer services to the smaller one, the latter could introduce financial incentives. Any additional payment beyond the minimum of covering costs will make larger organisations better off if they choose to provide a responsible officer than if they do not. Although this suggests that the additional cost need only be very small, the larger organisations may try to benefit more from the agreement by charging more.

9.7.7 The maximum that larger organisations could charge will be the cost to small organisations of employing a new part-time doctor to be the responsible officer. If they go beyond this small organisations may choose to employ a new doctor on a part-time basis, since this would leave them better off.

9.7.8 Given the small number of firms affected, the likelihood of strong non-financial links and the fact that any financial incentives to provide doctors will be capped by the cost of appointing a part-time doctor, it is reasonable to assume that the cost for a small firm of obtaining a responsible officer will be similar for a small firm and a larger organisation.

9.7.9 When the policy is reviewed, it will be necessary to examine available evidence to confirm whether this assumption still holds.

## 10. MONITORING AND REVIEW

10.1 The introduction of responsible officers will be monitored and reviewed as part of the wider process of introduction of revalidation.

## 11. CONSULTATION

11.1 To allow the Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010 to complete passage through the Assembly ahead of an operational date of 1st October 2010, the Department must introduce the regulations before the summer recess of 2010.

11.2 This Regulatory Impact Assessment is available on the Department's website at http://www.dhsspsni.gov.uk/showconsultations?txtid=39497. A consultation on the role of responsible officer was issued for consultation by the Department of Health (DH) in England on a UK-wide basis from July to October 2008. DH published the response[1] to the consultation on 5 May 2009. In taking forward the Northern Ireland regulations the Department consulted for 9 weeks on the draft legislation from 4 December 2009 to 5 February 2010. The consultation was issued in line with OFMdFM guidance. All designated bodies listed under regulation 2(2) of the regulations were invited to respond. A complete circulation list for the consultation is provided at Appendix 1.

11.3 In total 19 responses were received to the consultation from the following organisations:

The Royal College of Radiologists
Northern Ireland Medical and Dental Training Agency (NIMDTA)
DRC Locums
Central Medical Advisory Committee, Northern Health and Social Care Trust
Northern Ireland Ambulance Service Health and Social Care Trust
Medical Protection Society
The Regulation and Quality Improvement Authority
Child and Adolescent Mental Health in the Belfast Health and Social Care Trust
General Medical Council
Royal College of Nursing Northern Ireland
Royal College of General Practitioners
British Medical Association
Belfast Health and Social Care Trust
Western Health and Social Care Trust
Northern Ireland Judicial Appointments Commission
Southern Health and Social Care Trust
Belfast City Council
Primary Care, Health and Social Care Board
Independent Healthcare Advisory Services

**The overall message was one of support for the proposals.**

[1] The role of the responsible officer – response to consultation (DH May 2009) http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098851

## 12. SUMMARY AND RECOMMENDATION

12.1 Option 1: Do nothing and continue with the current system. This would mean the policy objectives stated above of bridging the regulatory gap and enhancing public and professional confidence in the conduct and performance of doctors and in the regulatory system would not be met. The actions of employers and PCTS would not be fully co-ordinated with those of the General Medical Council (GMC).

12.2 Option 2: Will build on existing clinical and social care governance structures to introduce an enhanced role for existing clinical leaders/medical directors. This option will focus on the greatest risk to patients' safety. Option 2 will designate certain organisations that deliver healthcare, including organisations with a role in setting policy and standards for the delivery of healthcare. Under this option organisations such as universities, research companies and insurance companies will not be designated.

12.3 Option 3: This option will also build on existing clinical and social care governance structures but will designate all employers of doctors to nominate or appoint responsible officers. This will mean requiring those employers who employs doctors in non clinical capacity settings to have responsible officers.

12.4 Options 1 and 3 were not considered viable for the following reasons:

- Option 1: Given the level of concern it will not be acceptable to do nothing and fail to achieve the policy objectives; and
- Option 3: Designating all organisations that employ doctors including organisations who employ them in a non clinical capacity (e.g. Law firms, Insurance companies, Manufacturing companies, etc.). This option will have greater costs but the same benefits as Option 2. As doctors working in these organisations do not have direct patient contact there are no added benefits or additional patient/public protection by the creation of responsible officers for these doctors.

12.5 **Option 2 is the preferred option.** Option 2 builds on existing structures and processes and will:

- Closely align with the system regulation under the Regulation and Quality Improvement Authority and focus on organisations where there is a greater risk to patient safety; and
- Limit the burdens of policy implementation in line with patient risk.

## 13. DECLARATION

**"I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs."**

**Signed______________________________**

**Date April 2010**

**Michael McGimpsey MLA**
**Minister for Health, Social Services and Public Safety**
**Castle Buildings**
**STORMONT**
**Belfast**

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## Appendix 1 – Circulation List for Consultation on Responsible Officer Regulations

| Organisation |
|---|
| Accident Medical Negligence Association |
| Association of Local Authorities in Northern Ireland |
| Association of Independent Advice Centres |
| British Association of Social Workers (NI) |
| British Dental Association |
| British Geriatric Society (NI) |
| British Medical Association |
| Business Service Organisations |
| Chartered Society of Physiotherapy |
| College of Occupational Therapists |
| Diabetes UK |
| Down Cardiac Support Group |
| Four Seasons Healthcare |
| General Consumer Council for NI |
| General Medical Council (NI) |
| General Medical Council |
| Institute of Public Health |
| Marie Curie Cancer Care (Belfast) |
| Mental Health Commission |
| NI Cancer Registry |
| NI Hospice |
| NI Medical & Dental Training Agency |
| Northern Ireland Confederation for Health & Social Services |
| Northern Ireland Social Care Council |
| Pharmaceutical Contractors Committee |
| Pharmaceutical Society of Northern Ireland |
| Equality Commission for Northern Ireland |
| The Human Rights Commission |
| UNISON |
| Antrim Borough Council |
| Ards Borough Council |
| Armagh City and District council |
| Ballymena Borough Council |
| Ballymoney Borough Council |
| Banbridge District Council |
| Castlereagh Borough Council |
| Coleraine Borough Council |
| Cookstown District Council |
| Craigavon Borough Council |
| Derry City Council |
| Down District Council |
| Belfast City Council |

| Organisation |
| --- |
| Carrickfergus Borough Council |
| Dungannon & South Tyrone District Council |
| Fermanagh District Council |
| Larne Borough council |
| Limavady Borough Council |
| Lisburn City Council |
| Magherafelt District Council |
| Moyle District Council |
| Newry & Mourne District Council |
| Newtownabbey Borough Council |
| North Down Borough Council |
| Omagh District Council |
| Strabane District Council |
| NI Ambulance Service |
| Business Services Organisation |
| The Patient Client Council |
| The Patient Client Council |
| The Patient Client Council |
| The Patient Client Council |
| Health and Social Care Board Headquarters |
| Public Health Agency HQ |
| Belfast Health and Social Care Trust HQ |
| Southern Health & Social Care Trust HQ |
| Northern Health and Social Care Trust HQ |
| South Eastern Health & Social Care Trust HQ |
| Western Health & Social Care Trust HQ |
| NI Blood Transfusion Service Agency |
| NI Guardian Ad Litem Service Agency |
| NI Regional Medical Physics Agency |
| Regulation & Quality Improvement Authority |
| Royal College of General Practitioners (NI) |
| Royal College of Midwives |
| Royal College of Nursing Northern Ireland |
| Royal College of Obstetrics & Gynaecologists |
| Royal College of Psychiatry |
| NI Chair, Royal College of Obstetrics & Gynaecologists |
| NI Division, Royal College of Psychiatry |
| Royal College of Speech & Language Therapists |
| Ulster Independent Clinic |
| North West Independent Hospital |
| Direct Medics |
| Locum Link Ltd (NI) |
| Templar Company Limited |
| Nationwide Locum Services Ltd |

| Organisation |
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| Independent Clinical Services |
| Medical Personnel Solutions |
| JCJ Locums |
| Medacs Healthcare PLC |
| Hays Healthcare |
| Locum Link Associates |
| Reed Management Services plc |
| Interact Medical |
| Locum Consultant |
| HCL Thames Medics |
| DRC Locums |
| Grafton Healthcare |
| Global Medics Ltd |
| Pulse Staffing |
| Minutes Medical Staffing |
| ID Medical |
| Fresh Medical |
| Universal Locums |
| Locum Linx |
| Coyles Medical |
| Midas Medical Recruitment |
| The Executive Council of the Inn of Court of NI |
| Belfast Solicitors Association |
| The Law Society of NI |
| School of Law, QUB |
| The Head of the School of Law, UU |
| Head of Business Development Group, NI Court Service |
| HM Council of County Court Judges |
| Law Centre (NI) |
| Civil Law Reform Division |
| Northern Ireland Court Service |
| District Judge (Magistrates Court) |
| Human Rights Commission |
| Northern Ireland Ombudsman |
| Equality Commission for NI |
| The General Consumer Council for Northern Ireland |
| Confederation of British Industry |
| NI Chamber of Commerce & Industry |
| Federation of Small Businesses |
| NI Association of Citizens Advice Bureaux |
| Northern Ireland Chamber of Trade |
| Food Standards Agency NI |
| NIC/ICTU |

| Organisation |
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| The NI Council for Voluntary Action |
| Northern Ireland Local Government Association |
| Society of Local Authority Chief Executives |
| Ministry of Defence |
| Northern Ireland Judicial Appointments Commission |
| Catholic Bishops of Northern Ireland |
| Community Relations Council |
| Participation & the Practice of Rights Project |
| NI Law Commission |
| HM Revenue & Customs |
| Victims Groups |
| TUV |
| North Down Ulster Unionist Office |
| DUP |
| Sinn Fein Office |
| SDLP |
| UUP |
| MLAs |