EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGISTRATION OF REGULATED ACTIVITIES) REGULATIONS 2009

2009 No.

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009 prescribe the activities carried on by certain NHS bodies that are to be regulated activities for the purposes of the Health and Social Care Act 2008 ("the Act"). The Regulations require the Care Quality Commission ("the Commission") to keep a register of persons (called "service providers") carrying on a prescribed regulated activity, and those service providers are then subject to registration requirements with which they must comply. The Commission has certain enforcement powers and fixed penalties that can be imposed for certain offences and, in addition, a service provider will commit an offence (punishable, on summary conviction, with a fine not exceeding £50,000) if it fails to comply with the registration requirements.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The Commission was established under section 1 of the Act on 1st October 2008. From 1st April 2009, the Commission will be responsible for the regulation of service providers carrying on the regulated activities set out in these Regulations and, for a transitional year, for private and voluntary healthcare providers and adult social care providers in England who are registered under the Care Standards Act 2000. As from 1st April 2010, it is intended that regulation under the Care Standards Act 2000 will cease for service providers in England and registration under the Act will be extended to service providers carrying on additional prescribed regulated activities in the field of health and social care.

4.2 The Health and Social Care Act 2008 (Commencement No. 6, Transitory and Transitional Provisions) Order 2008 (S.I. 2008/3168) comes into force on 12th January 2009 and commences a number of provisions in the Act to enable the Commission to undertake the process of registration of the NHS bodies concerned as from 12th January 2009. It also contains transitory and transitional provisions, mainly to deal with applications for registration as a service provider under Chapter 2 of Part 1 of the Act.

4.3 These Regulations prescribe the activities that will render certain NHS bodies liable to registration and also contain the registration requirements with which those bodies must comply as from 1st April 2009. They provide for an offence where service providers fail to comply with the registration requirements and make provision in relation to the Commission's enforcement powers, including the imposition of penalty notices for prescribed Part 1 offences. They also make provision about the publication of information relating to enforcement action, notification of certain matters, and the keeping by the Commission of a register of service providers.

4.4 As from 1st April 2010, it is intended that registration will be extended to service providers carrying on additional prescribed regulated activities in the field of health and social care. Further Regulations will be needed to prescribe that wider range of regulated activities and to set out the expanded requirements with which those providers will have to comply.

5. Territorial Extent and Application

5.1 This instrument applies in relation to regulated activity carried on in England.

6. European Convention on Human Rights

The Secretary of State for Health has made the following statement regarding Human Rights:

"In my view the provisions of the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009 are compatible with the Convention rights".

7. Policy background

7.1 The Health and Social Care Act 2008 creates a new system of registration for providers of health and adult social care and also provides for the Commission to be the new single regulator responsible for regulating health care and adult social care and monitoring the operation of the Mental Health Act 1983.

7.2 From 1st April 2009, the Commission will replace the Commission for Healthcare Audit and Inspection (known as the Healthcare Commission), the Commission for Social Care Inspection and the Mental Health Act Commission. It will be responsible for the registration, review and inspection of certain health and adult social care services in England. In addition, the functions currently performed by the Mental Health Act Commission will transfer to the Commission.

7.3 The policy objective was to achieve the integration and alignment of health and adult social care regulation across all types of providers whether public, private or third sector. There was a ministerial commitment to create a system of enforcement against NHS providers. Powers of enforcement in the Care Standards Act 2000 only apply to providers of private and voluntary health care and adult social care sectors that are required to register under that Act; NHS providers are not subject to registration under the Care Standards Act 2000 and therefore the enforcement powers in that Act do not apply to such providers. It was considered that the most effective way of applying enforcement powers to NHS providers was to bring them into a system of registration from 1st April 2009. This change aims to bring NHS providers into line with private and voluntary healthcare and adult social care providers and to improve the provision of health and social care services by ensuring that essential quality and safety standards are met across the board.

7.4 In accordance with this ministerial commitment and the intention of the Act, from 1st April 2009, the registration system set out in the Act will be introduced for certain NHS providers of prescribed health care services (including NHS ambulance services) and will focus on the prevention, detection, control and treatment of HCAIs. At present, the "Health Act 2006: Code of Practice for the Prevention and Control of Health Care Associated Infections" ("the Hygiene Code") sets out the ways in which healthcare providers should protect patients, staff and visitors from contracting HCAIs. A copy of the existing Hygiene Code, which contain the compliance criteria which NHS providers must comply with until 1st April 2009, can be found at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_081927

7.5 The Hygiene Code currently applies to NHS trusts, NHS foundation trusts, Primary Care Trusts, Ambulance Trusts, Mental Health Trusts and NHS Blood and Transplant.

7.6 The Department of Health launched a consultation on 11th August 2008, entitled "Changes to arrangements for regulating NHS bodies in relation to healthcare associated infections for 2009/10: a consultation for the NHS". The outcome of this consultation is outlined at paragraph 8 below.

7.7 From 1st April 2009, those NHS bodies currently subject to the Hygiene Code will be required to register with the Commission and to meet requirements set out in these Regulations in relation to the prevention, detection, control and treatment of HCAIs. The Regulations will be underpinned by a revised HCAI Code of Practice, which will set out the criteria against which compliance with the Regulations will be judged. This will be published by the Secretary of State and must be taken into account by the Commission in the making of any decisions about registration, compliance with the criteria and any breaches of the Regulations. A copy of the Code of Practice is attached to this Memorandum and can be found at:

http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_092312

7.8 Through the registration system, the Commission will continue the Healthcare Commission's current role of monitoring compliance in relation to the prevention, control and treatment of HCAIs by NHS providers. The Commission will be able to use enforcement powers set out in the Act, which include powers that the Healthcare Commission does not have under the Care Standards Act 2000, to take prompt action where patients and others are at risk. For example, the Commission will be able to suspend registration, using the normal or urgent procedure. Other new enforcement powers include the power to issue a warning notice and to give a penalty notice in respect of prescribed offences under Part 1 of the Act. These new powers give the Commission a broader set of tools which will allow it to take rapid and appropriate action against service providers to ensure compliance with the terms of registration.

7.9 This instrument sets out the registration requirements in relation to dealing with HCAIs, which prescribed NHS bodies will be required to meet in order to be, and remain, registered with the Commission. It provides for an offence (punishable, on summary conviction, by a fine not exceeding £50,000) of failing to comply with the registration requirements, and also provides for penalty notices to be given under section 86 of the Act in relation to this and other prescribed Part 1 offences. It sets out supplementary provisions in relation to the Commission's powers to issue penalty notices, including the penalty levels. It also makes provision for publication of information relating to enforcement action, notification of certain matters, the power to require an explanation under section 65 of the Act and the keeping of a register of persons registered as service providers.

8. Consultation outcome

8.1 The consultation with the NHS, on proposals for how the Care Quality Commission will carry out its functions in respect of HCAIs in 2009/10, closed on 20th October 2008. This was a 10-week consultation and 44 responses were received. The consultation can be found at:

http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_086926

8.2 There was a 10-week consultation period, in order for wider enforcement powers to be available to the Commission with effect from April 2009 and to ensure the protection of patients and the public. The Department of Health committed itself to bringing in

provisions for the registration of NHS providers in respect of HCAIs and the wider enforcement powers in April 2009.

8.3 A code of practice in relation to HCAIs, already exists for the NHS. The existing Hygiene Code was introduced as part of the Health Act 2006 and applies to NHS providers only (although separate requirements in regulations made under the Care Standards Act 2000, to protect persons at risk against HCAIs, also apply to independent healthcare and care homes). Since the existing Hygiene Code already provides a framework on how NHS services can prevent and control HCAIs, the intention was to carry forward this framework through a revised Code of Practice, underpinning the new legislative framework on registration.

8.4 It was considered to be of particular importance for the Commission to have the additional power to suspend a provider's registration for a specified period in order to give providers the opportunity to rectify any breach and then allow them to resume service provision. The Commission can take urgent action to suspend registration where it is felt that a person may be exposed to a risk of harm if it does not immediately suspend registration.

8.5 Extra effort has been made to make sure that the NHS is fully aware of the timetable leading up to April 2009 and the implications for them, particularly in relation to the new enforcement regime.

8.6 The responses to the consultation were broadly supportive of the proposals on HCAIs and no major areas of concern or particular issues were consistently raised. A copy of the Department of Health's response to the consultation is attached to this Memorandum and can be found at:

http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_092312

8.7 The Commission's own consultation on its enforcement policy was launched on 24th October 2008. The consultation document sets out the draft enforcement policy and how the Commission intends to use its enforcement powers under the Act, which include three new powers not available to the Healthcare Commission under the Care Standards Act 2000 . In addition to the existing enforcement powers the Commission will be able to issue warning notices, suspend registration and issue financial penalty notices. This is a 12-week consultation, which will close on 16th January 2009. The consultation can be found at:

http://www.carequalitycommission.org.uk/consultation/enforcement_policy-1.aspx

9. Guidance

9.1 The Commission published "Guidance for Trusts 2009/10: Registering with the Care Quality Commission in relation to healthcare associated infections" in October 2008. A copy of this Guidance is attached to this Memorandum and can be found at:

http://www.carequalitycommission.org.uk/policies__reports/hcai_registration_system.aspx

9.2 The Secretary of State will publish a revised Code of Practice on HCAIs prior to April 2009. This will set out the criteria against which compliance with HCAI Regulations by a service provider will be judged. A service provider will need to demonstrate, for example, that they have in place and operate effective management systems for the prevention and control of HCAIs that are informed by risk assessments and analysis of infection incidents and that they provide and maintain a clean and appropriate environment that facilitates the prevention and control of HCAIs.

9.3 A copy of the revised compliance criteria is attached to this Memorandum. This will be published along with supporting guidance, which will set out the basic steps which NHS providers should take into account to ensure that the criteria can be met.

10. Impact

10.1 There is no impact on business, charities or voluntary bodies.

10.2 The impact on the public sector is detailed in the attached Impact Assessment.

10.3 An Impact Assessment, which includes an Equality Screening Assessment, has been prepared and is attached to this Memorandum. The Impact Assessment covers the costs and benefits to NHS bodies required to register with the Commission pursuant to these Regulations, and to the provisions of the Health and Social Care Act 2008 (Commencement No. 6, Transitory and Transitional Provisions Order 2009. The Equality Screening Assessment relates only to these Regulations as the Order is not considered to raise equality issues.

11. Regulating small businesses

11.1 The legislation does not apply to small businesses.

12. Monitoring and review

12.1 The Regulations aim to ensure: (a) that NHS bodies will comply with registration requirements contained in the Regulations in relation to HCAIs; and (b) the ability of the Commission to take enforcement action where such providers fail to comply.

12.2 The Regulations will be subject to internal review after April 2009 and lessons learned will be carried forward into the full registration system in 2010 when these provisions will be incorporated (together with any necessary amendments) into a new set of regulations that will set out registration requirements for a wider range of health and social care providers.

13. Contact

Joanna Shaw at the Department of Health, Tel: 0113 2546204 or E-mail: joanna.shaw@dh.gsi.gov.uk, can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
Department of Health	**Impact Assessment of regulations to require NHS bodies to register with CQC and meet a requirement on HCAI in 2009**	
Stage: Final	**Version:** 1	**Date:** 4 December **2008**
Related Publications: The Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009		

Available to view or download at:

http://www.

Contact for enquiries: Alison Smith **Telephone:** 0113 2545709

What is the problem under consideration? Why is government intervention necessary?

At present the Hygiene Code (which sets out how healthcare providers should protect patients, staff and visitors from Healthcare Associated Infections (HCAI)) applies to NHS Trusts, Foundation Trusts, PCTs, Ambulance Trusts, Mental Health Trusts, and the NHS Blood & Transplant. However, current powers of enforcement have not achieved the reduction in HCAI that research suggests is attainable. Stronger action is therefore required to bring down these rates and reduce the instances of mortality and morbidity.

What are the policy objectives and the intended effects?

Reducing HCAI by making enforcement powers available to the regulator to ensure that NHS providers comply with the registration requirements set out in the Regulations.

What policy options have been considered? Please justify any preferred option.

Option 1 - make no changes to the enforceability of the Hygiene Code.

Option 2 (preferred) - require NHS Trusts to register with the Care Quality Commission and meet a high level requirement on infection control. The Care Quality Commission can use a wide range of enforcement powers (as set out in the Health and Social Care Act, 2008) to encourage compliance.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

Review of the impact of the Care Quality Commission wil be integrated into the Health Reform Evaluation programme being commissioned by DH. This will include the review of these regulations.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

Dawn Primarolo .....Date:***23rd December 2008***

Summary: Analysis & Evidence

Policy Option: 1	Description: Make no changes to the enforceability of the Hygiene Code for 2009/10

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups' No change in administrative requirements, compliance required or regulatory activity.
One-off (Transition) **Yrs**	
£ 0	
Average Annual Cost (excluding one-off)	
£ 0	**Total Cost** (PV) £

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups' No change
One-off **Yrs**	
£ 0	
Average Annual Benefit (excluding one-off)	
£ 0	**Total Benefit** (PV) £

Other **key non-monetised benefits** by 'main affected groups'

Key Assumptions/Sensitivities/Risks

Price Base Year	Time Period Years	**Net Benefit Range** (NPV) £	**NET BENEFIT** (NPV Best estimate) £

What is the geographic coverage of the policy/option?				England
On what date will the policy be implemented?				NA
Which organisation(s) will enforce the policy?				Care Quality Comm
What is the total annual cost of enforcement for these organisations?				£ 0
Does enforcement comply with Hampton principles?				No
Will implementation go beyond minimum EU requirements?				No
What is the value of the proposed offsetting measure per year?				£ 0
What is the value of changes in greenhouse gas emissions?				£ 0
Will the proposal have a significant impact on competition?				No
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease of £ **Net Impact** £

Key:	**Annual costs and benefits: Constant Prices**

Summary: Analysis & Evidence

Policy Option: 2	Description: NHS Trusts complete a light we Care Quality Commission. Regulations on i level"

COSTS

ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition) **Yrs**	New cost is cost of registration borne almost equally by Care Quality Commission and NHS Trusts. Compliance cost for NHS Trusts very uncertain but evidence suggests that cost of controlling HCAI is lower than cost of managing infections.
£ 860,000 - £1.6m	
Average Annual Cost (excluding one-off)	**Total Cost** (PV) **£ 860,000-£1.6 m**
£	

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups'
One-off **Yrs**	Benefit to acute Trusts of reducing infection is £3.2m - 28m. (See link to costs - above)
£	
Average Annual Benefit (excluding one-off)	**Total Benefit** (PV) **£ 3.2m - 28m**
£ 3.2m - £28m	

Other **key non-monetised benefits** by 'main affected groups'

Key Assumptions/Sensitivities/Risks 1)the threat of enforcement action will improve compliance by 5% to 30%. 2) We're uncertain about the amount of enforcement activity the Care Quality Commission will undertake and how this will compare cost-wise with the current actions of the Healthcare Commission.

Price Base Year 2008	Time Period Years 1	**Net Benefit Range** (NPV) **£ 1.6m - 27.1m**	**NET BENEFIT** (NPV Best estimate) **£ 12.75m**

What is the geographic coverage of the policy/option?				England
On what date will the policy be implemented?				April 2009
Which organisation(s) will enforce the policy?				Care Quality Comm
What is the total annual cost of enforcement for these organisations?				£ 140,000 +
Does enforcement comply with Hampton principles?				Yes
Will implementation go beyond minimum EU requirements?				N/A
What is the value of the proposed offsetting measure per year?				£
What is the value of changes in greenhouse gas emissions?				£ 0
Will the proposal have a significant impact on competition?				No
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease of £ **Net Impact** **£**

Key: **Annual costs and benefits:** **(Net) Present**

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Introduction

The **Code of Practice for the Prevention and Control of Healthcare Associated Infections (the "Hygiene Code")** came into effect on 1 October 2006. It applies to NHS bodies (NHS Trusts, Foundation Trusts, PCTs, Ambulance Trusts, Mental Health Trusts, and the NHS Blood & Tissue Authority). Currently the powers of enforcement for this have limited effect. The Healthcare Commission can issue Improvement Notices or report an NHS body for significant failings and recommend it is placed on 'special measures'. To date the Healthcare Commission has issued five Improvement Notices.

The Prime Minister and the Secretary of State made commitments in September 2007 to give the Care Quality Commission greater enforcement powers to fine hospitals and close wards in response to Healthcare Associated Infections.

The new registration system set out in the Health and Social Care Act 2008 provides the mechanism by which these new enforcement powers can be applied to NHS bodies. In order that the Commission can use these new powers, the NHS bodies in question must first be registered with the Care Quality Commission as providers carrying on a regulated activity. The Government response to the consultation, *The Future Regulation of Health and Adult Social Care* committed to phasing in the new registration system over the period April 2009 to April 2010 – with healthcare associated infections as the first priority for NHS registration.

This impact assessment considers the following options for providing the Care Quality Commission with greater enforcement powers to address Healthcare Associated Infections in NHS Trusts and other NHS bodies in 2009/10:
Option 1 – Do minimum (i.e. no change to the current system until 2010); or
Option 2 – Require NHS bodies to register with the Care Quality Commission in April 2009 and meet a single high-level requirement (preferred).

This assessment presents the incremental costs and benefits associated with implementing the policy. There is only an indirect relationship with budgets for the bodies concerned because budgeting takes into account factors such as the timing of expenditure and the structure of the body. The assessment considers the following costs and benefits:

- Administration costs of 2009 registration (if required) for NHS providers and Care Quality Commission;
- Compliance costs and benefits with registration requirements for providers and patients;
- Self assessment and inspection costs for providers and the Care Quality Commission; and
- Costs of enforcement for providers, the Care Quality Commission and the First Tier Tribunal.

It only considers the impacts in 2009/10 as a further consultation and an impact assessment on new regulations for all health and social care providers to be implemented from 2010 will be published. A previous consultation on the regulations and discussions with stakeholders have led to refinements of some of the estimates in the previous assessment. This assessment does include some one-off costs that will be incurred in 2009/10 but will support registration from

2009 onwards. These one-off costs will not be included in the impact assessment for all health and social care providers. Specific impact tests are provided in Annex 3.

Description of options

Option 1

Continue with the existing system for 2009. This would mean that NHS providers would self assess against the hygiene code and would be expected to comply with the code. The current enforcement powers would remain unchanged.

There would be no registration of NHS providers in 2009. Following a further consultation, all providers carrying on regulated activities (to be defined in Regulations) would be required to register in respect of those activities, and to meet the registration requirements as from April 2010.

Option 2 - preferred

Require NHS bodies to register with the Care Quality Commission in April 2009 and meet a single high-level requirement that requires providers to protect people from health care associated infections. The form of this requirement will be as follows,

1.(1) A person registered as a service provider in respect of the carrying on of a regulated activity must, so far as reasonably practicable, ensure that patients, persons (whether employed or not) working for the purpose of the carrying on of the regulated activity and others who may be at risk of acquiring a health care associated infection, are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

(2) The means referred to in paragraph (1) are—

- *(a) the effective operation of systems designed to assess the risk of, prevent, detect, treat and control the spread of a health care associated infection; and*
- *(b) the maintenance of appropriate standards of design, cleanliness and hygiene in relation to—*
  - *(i) premises occupied for the purpose of the carrying on a regulated activity; and*
  - *(ii) equipment used in those premises.*

(3) For the purpose of this regulation, "premises" includes a vehicle owned or used by the person registered as a service provider for transporting—

- *(a) patients for the purposes of treatment; and*
- *(b) materials to be used in the treatment of patients in circumstances where such materials are at risk of being contaminated with a health care associated infection.*

The Care Quality Commission will determine how the process of registration will operate, within the framework of the legislation, for 2009/10.

Once a provider is registered the full range of enforcement powers provided for in the Health and Social Care Act 2008 become available to the Commission in order to ensure compliance with the registration requirements.

Assessment of costs and benefits

Option 1

Administration cost of registration

No administration cost of registration would be incurred by the Care Quality Commission or the NHS Trusts in 2009.

Compliance cost and benefits

NHS Trusts would continue to follow the guidance set out in Hygiene Code.

The new sanctions would not be available so we would not expect to see a change in compliance. Based on figures for 2007/8 we might expect five severe breaches of the Code by acute Trusts and ten severe breaches by non-acute Trusts.[1]

Costs of self assessment and inspection
NHS Trusts currently have to prepare a declaration on their compliance with the Code. This activity would continue unchanged.

In 2008/9 the Healthcare Commission has £4 million allocated to inspect all 172 acute Trusts to investigate their compliance with the detail of the Hygiene Code.

It is expected that inspections of all acute Trusts will continue in 2009/10 and that the new Commission will take a risk based approach to HCAI inspection for non-acute Trusts.

Enforcement costs
The cost of enforcement vary with the action being taken and whether it is appealed by the provider. It is not possible to anticipate the number, type or likelihood of appeals for future enforcement so we have not attempted to assess total enforcement costs.

Option 2 - preferred

Administration cost of registration
There will be a one-off cost of registration as NHS providers register against the HCAI requirement. In 2010 providers carrying on a regulated activity (which will be defined in Regulations) will be required to register with the Commission, and will have to comply with all the registration requirements applying to them.

The Care Quality Commission has determined the process for registration for 2009. The guidance for this is set out in detail in *Registering with the Care Quality Commission in relation to healthcare associated infection - Guidance for trusts 2009/10.*[2]

The process of registration will introduce new costs of £719,500 in 2009/10. Of this most will be one off costs of creating an information system for registration and communicating the requirements to providers. The costs to the Care Quality Commission of registration of NHS Trusts is likely to be very small thereafter as we would expect very few new NHS Trusts applying for registration each year (see Annex 1).

The cost to the NHS trust of registration will be between £250 and £1,100 based on the cost of a minor administrative requirement and the cost currently incurred by an independent provider when completing registration forms. The *Guidance for trusts 2009/10* describes the process that the Trust would need to go through for registration. The additional costs to Trusts are associated with understanding the new system and completing the registration form.

The total administrative cost would therefore be between £820,000 and £1.1m.

Compliance cost and benefits with broad registration requirement
The introduction of a broad registration requirement does not place new requirements on NHS Trusts as it does not add obligations over and above the Hygiene Code which is statutory already.

Evidence on the impact of sanctions on compliance

[1] Five Improvement Notices were served on acute Trusts in 2007/8. This is just under half the number declaring non-compliance with the Core Standards for infection control. We assume that a similar proportion on non-compliant non-acute Trusts are in severe breach. See annex 2 for details.
[2] (http://www.carequalitycommission.org.uk/policies__reports/hcai_registration_system.aspx).

In introducing a range of sanctions for non-compliance with the terms of registration, the regulations are following the approach recommended in *Regulatory Justice: Making Standards Effective*.[3] This report set out six principles for penalties. Improvement notices only meet these principles in a limited way and so a wider range of sanctions is proposed to provide enforcement tools for the regulator that are proportionate to the infringement.

It is expected that the introduction of new sanctions will increase compliance with the registration requirements. Evidence from other sectors supports the view that the availability of fines and criminal powers reduces the undesirable workplace events that regulations are targeting.[4] The range of this reduction appears to be between 5% and 30%. For example,

- Gray and Sholtz[5] find sanctions imposing penalties for contraventions of United States Occupational Health and Safety Administration (OSHA) regulations induced a 22% decline in injuries.
- Baggs et al[6], found that compensation claims were between 5% and 15% lower for employers who had been subject to OSHA enforcement activity than those that had not.
- Gunningham and Johnstone[7] observed that when the state of Oregon increased its OHS penalties threefold as part of a package of measures, workers' claims fell by over 30%.
- In the UK Baldwin and Anderson[8] survey top UK executives and found that 71% of companies that experienced a punitive sanction reported that the sanctioning impacted very strongly on their approach to regulatory risk and, for many, the imposition of the first sanction produced a sea change in attitudes.

We will therefore use 5% as a lower bound of increased compliance from the new enforcement powers and 30% as an upper bound.

Estimates of current non-compliance

We first consider the extent to which Trusts are compliant with the code and then assess how the new powers available to the Care Quality Commission will improve NHS Trusts' compliance.

The number of Trusts that might not be compliant with the registration requirement is based on the following information;

1. From June 2007 to June 2008 the Healthcare Commission issued five improvement notices to acute Trusts. Of these, two had actually declared compliance with the Core Standards with regard to infection control.
2. In their 2007/8 self assessment of compliance with Core Standards C04a, C04c and C20, 11 acute and 23 non-acute Trusts indicated that there were ongoing concerns.[9] There is not a direct read across from this information to non-compliance with the revised code but it would indicate a weakness in the system of the provider.

[3] R. Macrory, 2006

[4] The studies look at the impact on undesired events. Clearly these are linked with increased compliance but the studies do not actually measure the increase in compliance itself.

[5] Gray, W.B. & Scholz, J.T. Analysing the equity and efficiency of OHSA enforcement. Law and Policy, July 1991

[6] Baggs, Silverstein and Foley, Workplace health and safety regulations: Impact of enforcement and consultation on workers' compensation claim rates in Washington State. American Journal of Industrial Medicine, 2003

[7] Gunningham, N and Johnston R, Regulating Workplace Safety: Systems and Sanctions, Oxford University Press, 1999

[8] Baldwin, R and Andersen, J, Rethinking regulatory risk, DLA/LSE, 2002

[9] These requirements are, "Health organisations keep patients, staff and visitors safe by having systems to ensure that the risk of healthcare acquired infection to patients is reduced, with particular emphasis on high standards of hygiene and cleanliness, achieving year-on-year reductions in MRSA," "Health care organisations keep patients, staff and visitors safe by having systems to ensure all re-usable medical devices are properly decontaminated prior to use and that the risk associated with decontamination facilities and processes are well managed" and "Health care services are provided in environments which promote effective care and optimise health outcomes by being well designed and well maintained with cleanliness levels in clinical and non clinical areas that meet the national specification for clean NHS premises". Although providers would be expected to comply with all duties of the code, non compliance with the factors above is the best current measure of whether the duty in the regulation has not been complied with. Annex 2 has more detail of these figures.

3. The Healthcare Commission in its 2007/8 inspections for HCAI found that 90% of Trusts had minor breaches of the current Code.[10]

Based on the evidence that the threat of stronger sanctions increases compliance by between 5% and 30% we would expect the following improvements:

- Up to two fewer acute Trusts would get into the position of being in severe breach (5% - 30% of 5),
- Between one and three fewer non-acute Trusts would get into the position of being in severe breach (assuming same proportion of non-compliant non-acute Trusts have severe breaches),
- Between eighteen and 108 Trusts would address their minor breaches or compliance weaknesses.

For the remaining severely non-compliant Trusts formal enforcement action would be appropriate.

Benefits of improved compliance

In 2006 there were approximately 6,500 deaths associated with MRSA and C difficile infections in 218 NHS communal establishments.[11] There are also infections associated with healthcare such as urinary tract infections, though data is not collected on the instance of these. Some of these would have arisen despite the best procedures, whereas some of them may be arising in hospitals where significant improvements in processes are required.

The Healthcare Commission report, "*Healthcare Associated Infection: what else can the NHS do?*", 2007 provides qualitative evidence of a link between the specific activities required by the code and their impact on infection rates. Studies of the effectiveness of processes with reducing infection suggest that 15% to 40%[12] of infection can be avoided. We assume that the higher range of improvement can be achieved in severely non-compliant Trusts and the lower range in Trusts with minor problems.

In the section above we estimated the number of Trusts that would improve their infection control in response to the threat of greater sanctions. It is very difficult to translate this improvement into an estimate of reduction in death or morbidity. However, we can give some figures that are indicative of the magnitude of the impact. If we assume that compliance is improved in a non-compliant acute Trust with an average number of infections in 2007 then we would expect 350 fewer over 65s to suffer C. difficile infection and 36 fewer MRSA cases.[13]

The data is not available to allow us to carry out similar calculations for non-compliant non-acute Trusts. From the data available we can only say that more than 15 people would not suffer C. difficile infection.[14]

Finally, if infection is reduced by 15% in 18 to 106 of the Trusts with minor breaches we would expect a reduction in C. dificile infection in 400 to 2,400 patients.[15] These improvements bring

[10] Information provided by Healthcare Commission.

[11] Calculated from ONS data: data taken from death certificates 2006 mentioning MRSA or C. Difficile adjusted for proportion of deaths arising in trusts, other communal residences and elsewhere from 2001-6. There are significant caveats concerning this data. In particular, death certification practices differ and the location of death does not indicate where an infection was picked up. See http://www.statistics.gov.uk/downloads/theme_health/HSQ38_MRSA_CDiff.pdf for further information.

[12] NAO, 2000 suggested 15% could be achieved, Pittet et al (2000) estimated 40% reductions were possible. Other studies find values between these figures.

[13] Based on Health Protection Agency data (http://www.hpa.org.uk/web/HPAweb&Page&HPAwebAutoListName/Page/1191942126541) we took the total number of infections for 2007 for the acute Trusts that were non compliant with core standards and assumed that the 40% reduction in infection was at 2 hospitals with average infection.

[14] We do not have numbers of infections for each non-acute Trust so cannot identify infection levels associated with non-compliance. There were 1600 infections in PCT hospitals from April 2007 to April 2008 so we have used this to give a rough average.

about benefits to patients in terms of improved health which we have not attempted to quantify here.

Reducing infection also creates savings for the NHS of around £4,000 to £10,000[16] per person. Using our lowest assumptions concerning reduced infection and a cost of £4,000 per infection we estimate that £3.2 million would be saved. Using our higher assumptions concerning reduced infection and a cost of £10,000 per infection £28 million would be saved.[17] Such savings are likely to be experienced by acute Trusts directly but some of the saving arising from less infection in non-acute settings will reduce PCTs payments to acute Trusts thereby passing the savings back to them. It is not possible to assess the extent to which these flows balance out as it depends whether infected patients are taken to hospital.

Costs of improved compliance
The benefits described above are a consequence of two acute Trusts and one to three non acute Trusts making significant improvements in their infection control and 18 to 108 Trusts making minor improvements. The costs of compliance will vary significantly depending on the size and nature of the shortcomings of Trusts and could include cleaning, training or increasing isolation facillities. Following publication of a major investigation report, Maidstone and Tunbridge Wells Trust has indicated that it now spends £1 million more on cleaning.[18] Although this was an exceptional case, assuming a similar upper boundary costs in other Trusts, adjusted to be proportionate to size, it is likely that the cost of compliance will still be less than the avoided cost to the NHS of treating the infections.[19]

Costs of self assessment and inspection
The Healthcare Commission currently requires and examines NHS Trusts' self assessments with regard to Hygiene Code compliance. The introduction of registration will bring increased attention to this self assessment and therefore the Care Quality Commission may need to carry out more thorough review of the assessments with greater investigation of alternative information sources, particularly in the first year of operation. The additional cost compared to the previous review of self assessment could therefore be from £3,600 if the Care Quality Commission performed the same assessment as the Healthcare Commission, only 3 months earlier, to £416,000 for a much more detailed assessment.

The self assessment to be completed by Trusts is very similar to the existing self assessment under the Hygiene Code. The cost to Trusts of carrying out this self assessment earlier is estimated to be £35,000.

In 2008/9 the Healthcare Commission has £4 million allocated to inspect all 172 acute Trusts to investigate their compliance with the detail of the Hygiene Code. It is expected that inspections of all acute Trusts will continue in 2009/10 and that the new Commission will take a risk based approach to HCAI inspection for non-acute Trusts.

Cost of enforcement
The benefits above arise from the deterrence effect of more credible sanctions. We anticipate that enforcement action may need to be taken against Trusts remaining non-compliant with the high level registration requirement. We cannot currently estimate the total cost of enforcement as this will depend on the enforcement policy of the Care Quality Commission and the tendency

[15] We estimated the average number of infections in Trusts that weren't failing the core standards using Health Protection Agency data previously cited. We used the lower bound that improvement in infection control would reduce infection by 15% and applied this to 5% and 30% of these Trusts.
[16] Clean, safe care, DH, 2008
[17] Based on summing the number of avoided infections in both of the scenarios.
[18] Annual Report, 2007
[19] A recent study in Japan where infection control has also been a priority supports the view that the costs of controlling infection are significantly lower than the costs of infection (control cost is 0.55% – 2.57% of infection cost). Cost of hospital-wide activities to improve patient safety and infection control: A multicentre study, Fukuda et al, Health Policy 87 (2008)

of NHS Trusts to appeal decisions.[20] However, we can give an indication of the possible magnitudes of cost of a single enforcement action incurred by the Care Quality Commission[21], an NHS Trust and the First Tier Tribunal (formerly Care Standards Tribunal).

In the event of a breach the Care Quality Commission might determine on one of the following actions:

- issue a notice to suspend or impose conditions under an urgent procedure, which could cost around £20,000, or
- apply to magistrates for an order cancelling registration under an urgent procedure, which could cost around £40,000, or
- issue a notice to cancel, suspend or impose conditions under an ordinary procedure, which could cost around £10,000.

It is quite possible that the NHS Trust would appeal against this course of action, which would add around £30,000 to the Care Quality Commission's costs.

The Commission may also issue a penalty notice which could cost it £20,000 (gathering the evidence and preparing for a possible prosecution).

The Commission may choose to proceed to prosecution, either in addition to one of the actions described above or as a first course of action. The cost of this could be around £50,000 (£30,000 if the defendant enters a guilty plea).

We estimate that the costs to an NHS Trust of making an appeal would be similar to the cost to the Commission of handling that appeal, i.e. £30,000 and the cost of being prosecuted would be around £50,000.

The First Tier Tribunal will consider appeals against decisions by the Care Quality Commission. The estimated cost of handling a single appeal is approximately £6,150. (This is based on total costs of £1.2 million in 2007/8 and a case load of 198 cases.) The First Tier Tribunal has not dealt with appeals by NHS Trusts previously so there is some uncertainty in the cost provided.

Summary

	Option 1	**Option 2 - preferred**
Administration		
- NHS costs	None	£100,000 - £400,000
- CQC costs	None	£719,500
Compliance		
- patient benefits	No change	Approx. 800 – 2800 fewer C. dificile infections

[20] The Care Quality Commission has consulted on its enforcement policy but a final document is not currently available (http://www.carequalitycommission.org.uk/consultation/enforcement_policy-1.aspx).
[21] Information from the Care Quality Commission based on approximate costs of using external lawyers for enforcement action under the Care Standards Act.

- NHS benefits	No change	£3.2 million to £28 million
- NHS costs	No change	Ltd data but expected to be offset by NHS benefits
Self assessment and inspection		
- NHS costs	No change	£35,000
- CQC costs	No change	£3,600 - £416,000
Enforcement		

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	No

Annexes

Annex 1: Administrative burden of registration

As the NHS does not currently register its activities (with the Healthcare Commission), we cannot be certain of the cost of registration. However, we can use the cost of registration for an independent provider as a guide. This is currently estimated to be £1,020 for the provider.[22]

The Care Quality Commission has identified the following costs for the regulator associated with introducing registration for HCAI in 2009.

	£
Information services	665,100
Screening	12,400
Communications	42,000
Total	719,500

The costs associated with information services are largely set-up costs. It is likely that the information system being developed for HCAI will be incorporated into the information system required for all registration in 2010. This cost is therefore included in this impact assessment but will not be included in the impact assessment for 2010 registration. There may be further information system costs in 2010 in relation to the registration of all providers that carry out regulated activities and for all registration requirements.

Screening costs will be incurred annually but will be incurred as part of wider registration assessment that will be considered in the impact assessment for 2010 registration. We therefore only consider the screening costs for 2009/10.

The cost of communication will be a one off cost.

Annex 2: Compliance with core standards – Trusts' self declaration 2008

	No.of trusts	**Ongoing not met**	**Ongoing insufficient assurance**	**Ongoing concern**
Acute trusts	169	10	1	11
Ambulance trust	12	0	0	0
Care Trust/MH	7	0	0	0
Care Trust/PCT	6	1	1	2
Community Trust	1	0	0	0
Learning Disability	2	0	0	0
Mental Health	50	2	0	2
Primary Care Trust	134	12	6	17
Primary Care Trust/MH	13	0	2	2
Total	394			34

[22] Detail of this figure is presented in the Impact Assessments for the Health and Social Care Bill

Annex 3: Specific impact tests

Competition test

1. The regulation would not have a direct impact on the number of suppliers: the regulation creates an enforceable standard for infection control in NHS Trusts and other bodies. It does not place any limits on the numbers of suppliers.

2. The regulation would not indirectly limit the number of suppliers: although quality requirements can, in theory, reduce the numbers of providers the standards are set at the level to ensure patient safety and confidence. Furthermore, our evidence suggests that Trusts will save money as a result of reducing the number of infections so there is minimal risk of safe, efficient providers going out of business. Most costs of infection control are ongoing costs rather than sunk costs so the regulation would not create a significant entry barrier.

3. The regulation does not limit providers' ability to compete: NHS providers currently compete to a limited extent through the provision of good quality of service. This regulation does not prevent this competition above a baseline standard.

4. The regulation does not reduce providers' incentives to compete vigorously: it does not encourage collusive behaviour amongst providers, limit patient choice or reduce existing incentives to innovate.

Small firms impact test

The regulations only apply to certain NHS Trusts and other NHS bodies and not to small businesses.

Equality Screening Assessment

What is the purpose of the policy?

These regulations make provisions for the system that will apply for registering and assessing NHS organisations against requirements concerning healthcare associated infections (HCAI) in 2009/10. The regulations are designed to put in place a regulatory system that will encourage faster progress in reducing rates of HCAI and to provide patients with greater assurance that the services they use are safe and fit for purpose.

The regulations specify the providers which will need to be registered with the Care Quality Commission under the Health and Social Care Act 2008. NHS providers will come into registration for the first time. This will apply to the same NHS organisations currently covered by the Code of Practice for the prevention and control of healthcare associated infections. These are:

- NHS acute trusts, NHS ambulance trusts, NHS mental health trusts and primary care trusts (PCTs); and
- NHS Blood and Transplant.

The regulations set out the requirements for registration that NHS providers registered with the Care Quality Commission must meet in 2009/10. They require registered service providers to protect patients, workers and others who may be at risk from identifiable risks of acquiring an HCAI. This new legal requirement replaces the legal requirement to prevent and control HCAI

in accordance with the Code of Practice issued under the Health Act 2006. The action required of NHS bodies under the new requirement is essentially the same as that under the 2006 Act.

The regulations also set out enforcement powers available to the Care Quality Commission in addition to the enforcement powers available to the current regulators – the Healthcare Commission and the Commission for Social Care Inspection. The regulations set out the new enforcement powers that will be available to the Care Quality Commission in the following areas:

- **Penalty notices:** the levels of penalty notices, the offences for which these can be offered, the time by which the penalty is to be paid and the period during which proceedings may not be instituted;
- **Publication:** the authorisation and requirement for the Commission to publish prescribed information and the time by which the information is to be published;
- **Notification:** the bodies to whom the Commission must give copies of notices and the cases in which they do not need to do so.

A partial equality impact assessment was published in November 2007 alongside the Health and Social Care Bill. This can be found at:

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation?DH_080433

Impacts on diversity

There is no clear evidence that the creation of the Care Quality Commission will have a significant impact on equalities as was evidenced in the Equality Impact Assessment that accompanied the Health and Social Care Bill.

This set of regulations requires the same NHS providers of healthcare services to be registered with the Care Quality Commission that are currently required to comply with the Code of Practice for the prevention and control of healthcare associated infections. Compliance with this code is currently monitored by the Healthcare Commission. Since the regulations do not extend either the scope or the requirements of the current system, there is unlikely to be any major impact on equality resulting from these aspects of the regulations.

The regulations do require NHS providers to be registered for the first time and enable the Care Quality Commission to take a greater range of enforcement powers than are available to the existing commissions. As such we would expect these regulations to have an impact on ensuring compliance with the Code of Practice and to provide further incentives to NHS organisations tackle HCAIs. As such the regulations may result in quicker progress in tackling HCAIs and this will result in greater benefits for those groups who experience higher rates of HCAIs. This equality screening assessment has therefore been carried out with regard to prevalence of HCAIs across different population groups and the potential to reduce these rates.

Ethnicity

There is no evidence from the mandatory enhanced surveillance system to identify whether rates of HCAI are different in black and minority ethnic groups. There is nothing to suggest that there would be a significant positive or negative impact on people from minority groups as a result of this policy.

Disability

There is no evidence to suggest that HCAIs disproportionately affect disabled people, except that they mainly affect older people, who are also more likely to have disabilities. There is

nothing to suggest that there would be a significant positive or negative impact on people with a disability as result of this policy.

Gender
Surveillance of HCAIs shows that 64 per cent of cases of MRSA blood stream infections in the period April 2006 – March 2008 occurred in men. However, cases of *C. difficile* infection are more common in women. In the period April 2007 to March 2008 58 per cent of cases of *C. difficile* occurred in women. (*Surveillance of Healthcare Associated Infections Report: 2008,* Health Protection Agency). Since there is no clear pattern across all HCAIs with regard gender, there is likely to be little differential impact of this policy according to gender.

Age
Surveillance of HCAIs shows a significantly higher prevalence among older people. In the period April 2006 – March 2008, 76 per cent of MRSA blood stream infections occurred in people aged over 60 years. In the period April 2007 – March 2008, eighty two per cent of cases of *C. difficile* occurred in people aged over 65 years. As these regulations are expected to ensure greater compliance with measures to reduce rates of HCAIs it is expected that they will have a greater positive impact on older people than on the general population.

The broader impact assessment on the regulations estimates that the threat of stronger sanctions could lead to up to two fewer acute Trusts getting into the position of being in severe breach. If we assume that compliance is improved in a non-compliant acute Trust with an average number of infections in 2007 then we would expect 350 fewer over 65s to suffer *C. difficile* infection and 36 fewer MRSA cases.

Religion or belief
There is no evidence to suggest that rates of HCAI are different according to people's religion or belief. There is therefore no reason to believe that there would be a significant positive or negative impact on specific religious of belief groups as a result of these regulations.

Sexual orientation
There is no evidence to suggest that rates of HCAI are different according to sexual orientation. There is therefore no reason to believe that there would be a significant positive or negative impact on people of specific sexual orientations as a result of these regulations.

Implementation of the policy
The Care Quality Commission will be responsible for implementing these regulations. Like other public bodies, the CQC has a legal duty to promote equality and eliminate discrimination. New registration requirements for NHS organisations will come into force on 1 April 2009, and the additional enforcement powers set out in these regulations will come into force on the same date.

Next steps
The Department of Health will hold regular performance meetings with the CQC where it will report on progress on the registration of NHS organisations against the Code of Practice for the prevention and control of healthcare associated infections and on any enforcement action that it takes arising from non-compliance with the registration requirements.

It is anticipated that the new registration requirement on NHS organisations together with the additional enforcement powers available to the Care Quality Commission will contribute to quicker progress in reducing rates of HCAI. The mandatory and voluntary surveillance systems

overseen by the Health Protection Agency provides an annual opportunity to review progress in reducing HCAIs. Since this information is recorded on an individual NHS acute trust basis, this information will also be available to track progress over time in reducing HCAIs in organisations that the CQC identifies as being non-compliant with the Code of Practice. It is anticipated that further progress in reducing HCAIs will have a greater impact on older people, since rates of HCAIs are higher in this group, and the surveillance system will provide data to monitor progress in this area.

The Department of Health's MRSA/Towards Cleaner Hospital Team will continue to monitor progress on reducing HCAIs working with DH statistical colleagues via the existing national data collection systems (Mandatory Enhanced Surveillance System). This will data will be used to evaluate whether amendments and additions are required, including to the regulatory framework through the Care Quality Commission set out in these regulations.