INDEPENDENT HEALTHCARE ADVISORY SERVICE

THE NHS CONFEDERATION

# What's it all for?

## Removing unnecessary bureaucracy in regulation

This report was jointly produced by the NHS Confederation and the Independent Healthcare Advisory Services.

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# The NHS Confederation

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- providing independent challenge
- creating dialogue and consensus.

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# Executive summary

NHS and independent sector providers of healthcare consider that despite various initiatives to reduce it, the bureaucratic burden of regulation, inspection and accreditation is worsening. Recommendations from earlier reports have yielded some tangible benefits, but healthcare providers continue to experience a significant bureaucratic burden.

This is a complex area of work, added to by the current reforms of health and social care regulation. The merger of three main regulators into the Care Quality Commission (CQC) should reduce the burden, but other new initiatives are likely to result in further increases.

We have undertaken sufficient review, analysis and survey of user perceptions to confirm that there is urgent need for action. The level and quantity of overlap is alarming. In total, the 35 regulators, auditors, inspectorates and accreditation agencies (RAIAs) included in our review have 698 standards that map to *Standards for better health* (SfBH) and a further 166 standards that do not. Detailed examination of the standards and definitions used by the individual RAIAs indicate very subtle differences in wording or timescales. For example, 25 bodies asked questions relating to Healthcare Standard C11a (recruitment and training of staff).

Providers have limited right to refuse and have increased staffing to handle this work, with the bulk of administration and the compliance evidence being produced by non-clinical staff. Clinical engagement is low, which we believe is a significant weakness of today's approach. Process compliance, not outcome measurement, is heavily relied upon.

Providers can do more. They must take full responsibility for the assurance of the quality and safety of the services they provide, and not abdicate these responsibilities to regulatory bodies. They can do more to challenge unnecessary and duplicative requests. In the case of voluntary inspections or data collections, they should also evaluate the costs and benefits of participating, and decide accordingly.

The Department of Health (DH) board could do more for both the NHS and the independent healthcare sectors to protect them from these pressures, which waste resources and often do little to improve patient care, safety or experience. The DH has control or major influence over approximately 35 of the bodies listed in our report. Some could be merged or put under common directorship. Lead regulators should be appointed for different domains with the mandate that the others 'look there first'.

Providers could be given a right of veto (a 'yellow card') which would give them a formal right to challenge the need for such a similar question being asked again.

Much can be achieved to reduce the burden on organisations through improved information-sharing between RAIAs. A common database to hold this sort of material is unlikely to be a practical option. However, a web portal, which all RAIAs could use to access the data for each provider, has merit.

RAIAs and the DH should seek to align the information they request more closely with the information that high-quality, effective healthcare organisations already collect in order to run their organisations and ensure they achieve their goals.

In the short term, RAIAs should be under the same 'target pressures' that have so effectively driven up NHS performance. They should be urged to revise their questions, not only by reducing the number but also by developing forms of wording that satisfy them all, reducing the need for multiple versions of essentially the same question.

# Key recommendations

Our recommendations are shown below.

### Government, particularly the Department of Health, should:

- undertake a review of the remit of current RAIAs to consider the scope for rationalisation
- adopt a new approach to managing or targeting RAIAs that should include:
  - tough targets for simplification
  - a requirement to share data
  - creating leads for themes
  - sponsor or directorship
- issue robust information-sharing guidance for RAIAs
- take urgent action to ensure that NHS Next Stage Review quality initiatives do not duplicate existing requirements or add significantly to the burden of bureaucracy
- undertake a national study to consider how the respective roles of regulators, commissioners and strategic health authorities (SHAs) fit together to minimise unnecessary duplication and facilitate easy information-sharing between processes
- extend a review of central returns (ROCR) type discipline to SHA data returns and information requests.

### The Information Centre for Health and Social Care should:

- establish a web portal, accessible by RAIAs and providers by 2013, to facilitate improved information-sharing
- operate a strengthened ROCR process with:
  - all RAIAs required to submit any requests for data through ROCR
  - new powers for the Information Centre for Health and Social Care to refuse any data collection request where it believes the information is already collected
- publish an annual report on the operation of ROCR and progress made towards data simplification targets
- promote the principles and discipline of ROCR actively to SHAs, primary care trusts (PCTs) and RAIAs, and publicise what information is already held centrally.

### The Care Quality Commission should:

- ensure it operates in accordance with better regulation principles and uses its gatekeeping powers to minimise regulatory burden
- establish effective mechanisms to secure cooperation between the individual RAIAs; Monitor and SHAs should also participate in this process
- maintain and develop collaborative risk summits to foster cooperation between RAIAs at a local level
- maximise the use of existing data collections and information from other RAIAs in the compliance criteria for the registration requirements
- work with other parts of the system to drive improvement and promote patient safety, including sharing any concerns with commissioners
- maintain an advisory group to inform its work.

### Providers should:

- take active responsibility for the quality and safety of services they provide
- have the right to challenge those RAIAs which ask for the same or similar information that has been asked for by others, by issuing a 'yellow card' to the body concerned; the Information Centre for Health and Social Care or the CQC could act as an independent adjudicator of such challenges
- rationalise their internal processes for information collection and responses to RAIAs to promote greater efficiencies in dealing with RAIAs.

# Introduction

This report presents work undertaken by the Provider Advisory Group (PAG) in the area of healthcare regulation. Our premise has been to assume nothing, and we have worked to challenge both objectives and strategy from the perspective of the organisations that deliver care in the NHS and independent sectors. We recognise the value of regulation in the high-risk world of healthcare, but challenge its value when it becomes disproportionate and repetitive.

## The Provider Advisory Group

**The NHS Confederation and the Independent Healthcare Advisory Services established the Provider Advisory Group (PAG) in November 2007. Its purpose is to advise the Department of Health and the Healthcare Commission (and its successor body, the Care Quality Commission) on the impact of existing or proposed regulatory frameworks for providers, with a focus on reducing duplication and the bureaucratic burden. Membership of the PAG has been drawn from across the NHS and independent sector, and has involved key regulatory, audit and inspection bodies. Appendix 1 gives details of the terms of reference and membership of the PAG.**

This report looks systematically at the overlaps and duplications which exist in the requirements of key statutory and voluntary RAIAs with a remit for healthcare organisations in England.

Inevitably, this is a retrospective analysis and for practical reasons its coverage is limited. So, this report does not explicitly include areas such as social care or children's services, even though these are often important considerations for healthcare providers.

This report draws on the experiences of NHS organisations and independent sector providers of how these different systems operate at the front line. The primary focus of the report is on acute and mental health sector providers, but the messages are as relevant to other sectors of healthcare, including the growing numbers of community and primary care providers. It makes recommendations which should benefit all healthcare organisations and ultimately patients.

The introduction of the CQC as a single health and social care regulator, and the regulatory framework and system of registration that comes into force for all NHS and independent sector healthcare providers from April 2010, present real opportunities for change. A new system and approach is needed that builds on the lessons and mistakes of the past, and which fully embraces the principles of better regulation.

As well as the work presented in this report, we have helped to secure improved cooperation between the NHS Litigation Authority (NHSLA) and the Healthcare Commission; achieved reclassification of independent sector long-term condition facilities; and developed guidance for new clinical registrations. We have shared our thinking with the DH to influence the emerging registration requirements in the new regulatory framework, and are actively engaging with the CQC as it develops the detailed guidance on compliance.

While we have sought feedback from across the wider PAG, this is a provider-focused report, which seeks to present the view of healthcare regulation as it is experienced at the front line of healthcare provision. This report, its conclusions and recommendations are those of the PAG and are supported by the NHS Confederation and the Independent Healthcare Advisory Services (IHAS). It is independent of our sponsors, although we have shared this final report with the DH and the CQC to seek their formal response to the proposals for change, and hopefully their commitment to act.

# The current picture

## Regulation and a growing burden of bureaucracy

Over the years, health and social care regulation has increased, and organisations experience burden as assessments are duplicated and the same or similar information is requested from different sources. There have been 14 Acts of Parliament dedicated to health and social care in the past decade, which have often reinforced and added layers of regulatory burden with complicated relationships between government, regulators and providers.

The current regulatory and quality landscape is complex, with a combination of standards, contracting, licensing, and state or voluntary independent accreditation to assure quality across an increasingly diverse provider base. The Health Bill 2009 promises further amendments to the quality landscape and significant additional reporting requirements for NHS and independent sector providers, including annual quality accounts.

The distinction between performance management, regulation and contract management is not always clear. For providers of NHS care, performance and contract management initiatives from the DH, SHAs and PCTs often appear to duplicate the requirements of regulatory and inspection bodies. The need for rationalisation and better coordination has never been greater.

## Background and earlier studies

Development of the PAG built upon earlier studies of this problem, including two NHS Confederation reports – *Smarter reporting* in 2003[1] and *The bureaucratic burden in the NHS* in 2007.[2] These reports highlighted a picture of regulatory processes that were piecemeal and complex, with the same information having to be reformatted several times to suit the different requirements of individual regulators or inspectors.

*Smarter reporting* concluded that benefits could be achieved by:

- drawing up clear principles for performance management and reporting
- auditing what information is needed and why
- creating feedback forums, expanding the gateway systems and introducing a 'justification for request' check
- implementing a coherent IT strategy
- establishing a 'data warehouse'.

Key observations and recommendations from *The bureaucratic burden in the NHS* were:

- the SfBH have not produced a single framework for use by monitoring bodies and should be reviewed and reduced to become a regulatory market entry-level base
- all other standards should be coordinated with the minimum set of standards
- information collections should be streamlined
- bodies which monitor the NHS and want information prepared differently must prove the need
- sharing of information between regulators should become the norm
- the Concordat should be strengthened and made more effective, as it has failed to align the content of information requested
- the number of inspections and data collections must be rationalised and driven down
- further 'creep' amongst retained inspections must be prevented.

There has been limited progress on these recommendations, such as the establishment of the Information Centre for Health and Social Care and an extended ROCR process, which should improve matters. Additionally, the new registration requirements that come into force

from 2010 will provide a single set of requirements for NHS and independent sector providers across health and adult social care.

However, many of the recommendations and conclusions remain as valid today (May 2009) as they were at the time of the reports. What improvements have been made are now being offset by new requirements, including those arising as a result of performance and contract management, such as World-class commissioning, quality accounts and patient-reported outcomes.

## Initiatives to reduce the bureaucratic burden

Major initiatives have been established to reduce or remove unnecessary burdens resulting from inspection, accreditation and audit. These include establishment of the Concordat, setting up of gateways and development of the ROCR process to reduce the burden of data collections in the NHS. Creation of a single regulator for health and adult social care in England under the CQC represents a significant step forward in the reform of health and adult social care regulation and inspection.

For foundation trusts, the operation of their regulator, Monitor, could help to reduce the burden from data collections by up to 60 per cent, with a focus on risk-based regulation. However, these benefits do not extend to non-foundation trusts.

The NHSLA, in response to requests from NHS providers, has also made significant reductions in its assessment programme in recent years, and adopts a risk-based approach with the frequency of assessment related to the performance of the organisation. For example, it has agreed to assess PCT providers of clinical services in 2009/10 and beyond on a risk basis only; and for independent sector providers of NHS care, the NHSLA has suspended mandatory assessments until April 2010. It has also worked constructively with other Concordat partners to share information on assessments.

### The Concordat

**The Concordat has worked to improve coordination and collaboration amongst regulators and inspection bodies, particularly of inspection visits. For example, it secured greater cooperation between the NHS Litigation Authority and the Healthcare Commission, with the Healthcare Commission accepting some NHS Litigation Authority evidence for certain standards for the Annual Health Check. Despite these national agreements, individual local Healthcare Commission inspectors did not always abide by this approach.**

The Government has committed to simplifying the administrative burden of complying with regulations and has set targets for:

- reducing the burden on business by 25 per cent, or £3.4 billion, by 2010
- reducing public sector data burdens by 30 per cent by 2010.

The DH has an ambitious work programme and publishes annual simplification plans setting out progress towards these targets.

There has been some progress towards meeting the target for reducing independent sector administrative burden:

- in 2006, the DH had delivered 11 per cent of the target
- a further 2 per cent saving towards the overall target was achieved in 2007
- in year three, a further 4 per cent saving was achieved, reaching 17 per cent (£206.4 million) of the DH's total burden.

However, of the overall reduction in burden identified by the DH, over 90 per cent comes from two business areas – medicines regulation and adult social care. More savings are in the pipeline and the DH fully expects

to exceed its 25 per cent target by 2010, but there needs to be greater focus in this work on reducing the burden for healthcare providers.

Progress has also been made in reducing public sector data burdens, with current savings of about 12 per cent towards the current target. However, there are significant concerns that initiatives associated with the NHS Next Stage Review may well offset both existing savings and those that are in the pipeline. It is clear that more needs to be done to help the NHS, which is not included in the administrative burden target.

## The changing regulatory context of health and social care

The Health and Social Care Act 2008 introduced significant changes to the regulatory landscape:

- a single regulator for health and adult social care across the NHS and independent sector – the CQC – bringing together the Healthcare Commission, Commission for Social Care Inspection (CSCI) and the Mental Health Act Commission, with effect from 1 April 2009
- a new, unified regulatory framework and system of registration which will require all providers of health and adult social care in England to register with the CQC in order to provide services
- a system of responsible officers for designated healthcare organisations, to provide a local dimension to the professional regulation of doctors and link to the General Medical Council (GMC).

### The CQC and registration

The CQC registration will replace the existing SfBH, which are used to assess NHS care provided either by NHS or independent sector providers, and National Minimum Standards which apply to independent sector healthcare and social care providers. All providers of defined health and social care services will be legally required to register with the CQC in order to provide care, including community and primary care medical and dental services. This introduces for the first time a requirement for NHS providers to be registered with the regulator on the same basis as the independent sector.

Registration will be phased over the period 2010–12. As part of the transition to the new system, NHS providers have been registered with the CQC from 1 April 2009, but only in relation to healthcare-acquired infections and the hygiene code. Full registration for NHS providers comes into effect from April 2010. Independent sector providers already registered with the Healthcare Commission will have to register with the CQC by October 2010. Registration for primary care medical and dental services will come into force during 2011/12.

Registration will be dependent on demonstrating compliance with the registration requirements. These cover essential standards of safety and quality that all providers must meet, and include key aspects of care such as safety, patient focus, environment and amenities. These will be underpinned by detailed compliance guidance, currently being developed by the CQC.

The CQC also has review and investigation powers. These include periodic reviews of NHS providers and commissioners, replacing the current Annual Health Check. It can also conduct special reviews or studies of particular services or care pathways.

The CQC is required to be proportionate, targeted, accountable, transparent and consistent in how it operates. It also has a 'gatekeeper' role in relation to other government regulators and inspectors, but it is not yet clear how it will operate this role. Which regime it will put in place will be seen as a test of how far the organisation has adopted the better regulation principles.

Transition to the new system of regulation is likely to mean an element of 'double running' as organisations are still required to comply with existing standards and regulatory requirements but need to prepare for registration by demonstrating compliance with the new

registration requirements. This is likely to be felt as additional regulatory burden by frontline providers.

### Revalidation and responsible officers

Any designated healthcare organisation employing doctors will be legally required to appoint a responsible officer. Under these provisions, which are intended to improve patient safety and quality of care, every doctor will relate to one, and only one, responsible officer for the organisation.

The responsible officer will be a licensed medical practitioner and a member of the board (or the highest decision-making body) of the organisation, fulfilling a role similar to that of the medical director. They will be accountable for ensuring that their organisation has appropriate systems and processes in place to identify poor performance and conduct early. They also have prime responsibility for:

- processes underpinning revalidation of doctors, making recommendations, through the board, to the GMC about the revalidation of individual doctors for whom they are responsible
- processes underpinning referral of individual doctors to the GMC if there are doubts concerning fitness to practice.

Several issues still need to be resolved about how the system will operate in practice. However, the key challenge will be to ensure that introduction of responsible officers and revalidation is well integrated with other RAIA requirements that focus on assuring quality and safety of healthcare. Responsible officers have the potential to drive better clinical engagement with regulatory and assurance processes. If they merely become an add-on, they are likely just to add more burden and give the appearance of better quality and safety controls, without providing the benefits of improved service quality and safety for patients.

### NHS Next Stage Review and quality accounts

The NHS Next Stage Review and the introduction of quality accounts under the Health Bill 2009 represent an important shift of focus to more outcome-based assessment using indicators and outcome measures. Quality accounts will cover all aspects of service provision, including measures for patient experience and patient-reported outcomes. They present a real opportunity for organisations and their boards to demonstrate their commitment to delivering high-quality, safe services, and shifting the balance from seeking assurance through processes to a focus on securing evidence of outcomes.

In the independent sector, the IHAS and the NHS Partners Network (part of the NHS Confederation) are taking forward a clinical indicator and data management programme – the Hellenic Project. This will give the independent sector and those undertaking NHS activity the ability to undertake peer group benchmarking of patient-level key performance indicators (KPIs).

The world of regulation and oversight for healthcare providers is changing significantly, particularly with the growing emphasis on contract management, and with commissioners rightly holding providers to account for the quality of services provided. It is therefore all the more important that there is better understanding of the links between regulation, performance and contract management and the role that each has to play in the system. For example, the CQC should work closely with commissioners, sharing any concerns, if it is to drive up quality. However, the danger is that each separate part of the system goes its own way and there is a failure to link in actively to the regulatory and oversight systems, which will result in greater burden and duplication for providers.

# Findings

## Studies undertaken for this review

This review has three key elements:

1. Identification of key RAIAs with some remit for the assessment of healthcare providers (see Appendix 2).
2. A mapping of all the questions asked by 35 RAIA bodies against the SfBH, to identify duplication and overlap.
3. A 'perceptions study' undertaken among NHS Confederation and IHAS members to identify aspects of regulatory processes felt to be duplicative and onerous.

## Mapping the current regulatory environment

To illustrate the extent of duplication and the burden this places on individual provider organisations, the questions and standards from 35 RAIAs (including the CQC) were mapped against the SfBH. The SfBH consist of 24 core standards in seven domains, plus 13 developmental standards, with several hundred accompanying criteria or lines of enquiry. These standards cover safety, clinical cost-effectiveness, governance, patient focus, accessible and responsive care, environment and amenities, and public health.

Appendix 2 provides a list of RAIAs accountable to or working closely with the DH, together with other bodies that have powers to regulate or inspect healthcare providers. It identifies the 35 RAIAs used for this mapping, including mandatory and voluntary RAIAs, and the 13 Royal Colleges. For the sake of brevity only Level 3 of the NHSLA Risk Management Standards was included in this mapping.

This detailed mapping analysis is extensive and is available to download from the NHS Confederation and IHAS websites. This could be of value to the individual RAIAs. It should prove particularly valuable to the CQC as it shapes the detailed compliance guidance for the registration requirements; the PAG has already shared its findings with the CQC.

Table 1 provides a summary of the duplications and overlaps identified in relation to the SfBH. This clearly demonstrates the extent of duplication across the RAIAs. For example, there are 25 different bodies (column 5) asking about 47 different standards (column 4) relating to Standard C11a on recruitment, training and skill mix.

Generally, columns 5 and 6 indicate the extent of overlap and duplication. There are just four standards of SfBH that are not duplicated by another RAIA:

- safety alerts
- NICE interventional procedures
- integrated governance
- research governance.

For five of the 77 elements of SfBH identified in Table 1, there are ten or more different RAIAs asking between 19 and 47 questions about the issue:

- clinical supervision
- updating clinical skills and techniques
- corporate and clinical governance
- recruitment and skill mix
- safe, secure environment.

The 35 RAIAs included in this review have 698 standards which map to SfBH and a further 166 standards that do not (for more details, see the full mapping available from the NHS Confederation and IHAS websites). Detailed examination of the individual RAIAs' standards and definitions indicate very subtle differences in wording or timescales.

## Table 1. Mapping RAIAs' standards to *Standards for better health* (SfBH)

| Domain | SfBH | Area covered | Number of standards | Number of RAIAs | High overlap |
|---|---|---|---|---|---|
| Safety | C1a | Incidents – Reporting & Learning | 8 | 3 | |
| | C1b | Safety Alerts | 1 | 1 | |
| | C2 | Safeguarding Children | 10 | 6 | |
| | C3 | NICE Interventional Procedures | 1 | 1 | |
| | C4a | Infection Control | 9 | 7 | |
| | C4b | Safe Use of Medical Devices | 9 | 7 | |
| | C4c | Decontamination | 7 | 5 | |
| | C4d | Medicines Management | 6 | 4 | |
| | C4e | Clinical Waste | 6 | 4 | |
| | D1 | Safely Transferring Patients | 10 | 5 | |
| Clinical and Cost-Effectiveness | C5a | NICE Technology Appraisals | 12 | 4 | |
| | C5b | Clinical Supervision | 23 | 11 | |
| | C5c | Updating Clinical Skills & Techniques | 26 | 12 | |
| | C5d | Clinical Audit & Review | 18 | 7 | |
| | C6 | Partnership | 20 | 9 | |
| | D2a | Nationally Agreed Best Practice | 6 | 5 | |
| | D2b | Individual Requirements | 5 | 4 | |
| | D2c | Coordinated Care Across Providers | 19 | 8 | |
| | D2d | Evidence-based Practice | 4 | 4 | |
| Governance | C7a | Corporate & Clinical Governance | 21 | 10 | |
| | C7b | Honesty, Probity etc. | 11 | 6 | |
| | C7c | Corporate & Clinical Governance | 17 | 9 | |
| | C7d | Value for Money | 10 | 5 | |
| | C7e | Discrimination | 11 | 9 | |
| | C7f | Performance Requirements | 19 | 8 | |
| | C8a | Whistle-blowing | 6 | 4 | |
| | C8b | Personal Development etc. | 10 | 7 | |
| | C9 | Records Management | 15 | 6 | |
| | C10a | Employment Checks | 8 | 3 | |
| | C10b | Professional Codes of Conduct | 4 | 2 | |
| | C11a | Recruitment, Training & Skill Mix | 47 | 25 | |
| | C11b | Mandatory Training | 18 | 8 | |
| | C11c | Professional Development | 17 | 7 | |
| | D3 | Integrated Governance | 1 | 1 | |
| | D4a | Working Together (Clinical Governance) | 3 | 3 | |
| | D4b | Working Together (Quality Improvement) | 5 | 4 | |
| | D4c | Working Together (Leadership) | 2 | 2 | |
| | D5a | Working Together (Workforce) | 13 | 7 | |
| | D5b | Working Together (Service Improvement) | 10 | 6 | |

| Domain | SfBH | Area covered | Number of standards | Number of RAIAs | High overlap |
|---|---|---|---|---|---|
| Governance cont. | D5c | Working Together (Maintaining clinical skills) | 4 | 3 | |
| | D5d | Working Together (Clinical audit) | 5 | 3 | |
| | D6 | Integrated IT | 23 | 4 | |
| | D7 | Human Resource Management | 9 | 4 | |
| | C12 | Research Governance | 1 | 1 | |
| Patient Focus | C13a | Dignity & Respect | 12 | 7 | |
| | C13b | Consent | 20 | 9 | |
| | C13c | Confidentiality of Patient Information | 27 | 8 | |
| | C14a | Accessible Complaints Procedure | 13 | 9 | |
| | C14b | Complainants & Discrimination | 7 | 5 | |
| | C14c | Complaints Response | 6 | 4 | |
| | C15a | Food – Provision | 6 | 5 | |
| | C15b | Food – Individual Needs | 7 | 5 | |
| | C16 | Accessible Information | 12 | 9 | |
| | D8 | Service User Feedback | 8 | 3 | |
| | D9a | Patient Preferences | 15 | 6 | |
| | D9b | Shared Decision-making | 7 | 5 | |
| | D10 | Self-care | 5 | 4 | |
| Accessible and Responsible Care | C17 | Patient & Public Involvement | 13 | 7 | |
| | C18 | Equity & Choice | 7 | 4 | |
| | D11a | Care Reflects Views of Population | 5 | 3 | |
| | D11b | Patient Choice Maximised | 4 | 2 | |
| | D11c | Service Access | 11 | 4 | |
| | D11d | Admission & Discharge Protocols | 14 | 7 | |
| Care Environment and Amenities | C20a | Safe Secure Environment | 19 | 12 | |
| | C20b | Privacy & Confidentiality | 10 | 8 | |
| | C21 | Clean, Well Designed Environments | 8 | 6 | |
| | D12a | Patient & Staff Well-being | 7 | 6 | |
| | D12b | Infection Control | 4 | 4 | |
| Public Health | C22a | Public Health Partnerships | 7 | 5 | |
| | C22b | Local Health Needs | 3 | 2 | |
| | C22c | Local Partnership Arrangements | 5 | 3 | |
| | C23 | Public Health Cycle | 6 | 5 | |
| | C24 | Emergency Preparedness | 5 | 2 | |
| | D13a | Public Health Problems | 3 | 3 | |
| | D13b | Nationally Agreed Best Practice | 3 | 3 | |
| | D13c | Health Hazards | 2 | 2 | |
| | D13d | Emerging Policies and Knowledge | 2 | 2 | |
| No match to SfBH | | | 166 | | |

Having several regulators asking the same or similar questions clearly wastes time and resources, both for the regulator and the regulated, which could be better used for patient care. It also creates uncertainty as differing interpretations can be made of the same data. There must be some scope for simplification or rationalisation to remove duplication and ambiguity, real or perceived.

The DH's 2008 Health Informatics Review highlighted the need to move towards common definitions and time periods to rationalise reporting requirements. A timetable for implementation of the commitments set out in the review would help as it is clear that slight changes in the wording of these standards could save thousands of hours (and therefore money) across the health sector.

Although this mapping is extensive, it is not a comprehensive picture of the current regulatory and reporting burdens on healthcare providers, not least because the landscape is rapidly changing with the introduction of the CQC and emerging requirements as a result of the NHS Next Stage Review. Appendix 2 shows other RAIAs with some remit in relation to healthcare providers that were not included in this study, including Ofsted and the Health and Safety Executive. The mapping also does not include the significant requests for information from the wider NHS, including PCTs and SHAs, which, while quite legitimate, often duplicate requests from key RAIAs. Nor does it include new requirements resulting from initiatives such as quality accounts or World-class commissioning.

## Case study: duplication and conflicting assessments

**Where several regulatory, audit, inspection and accreditation bodies cover similar areas, there is the potential for conflicting assessments. Both the Healthcare Commission's and the NHS Litigation Authority's Clinical Risk Management Standards assessments are intended to provide assurance on the effective functioning of the systems/services within organisations, so their inspection criteria should not be materially different.**

**For St. Mary's Hospital (part of Central Manchester University Hospitals NHS Foundation Trust) this was not the case. In January 2008, the trust had two inspections of maternity services, both involving significant resources.**

**One – the NHS Litigation Authority Risk Management Standards level two assessment – resulted in 100 per cent compliance with all the 74 areas covered. The other – a review by the Healthcare Commission – gave the hospital a good score but with several areas for improvement.**

**Both reviews looked at maternity care, but produced a confusing picture of quality of care at Central Manchester University Hospitals NHS Foundation Trust. While each review had a different purpose, there was considerable overlap and duplication in the questions asked and the areas covered.**

**The key question is: "Is it really necessary to have two separate assessments that are both fundamentally looking at quality, safety and patient care?"**

## User perceptions

The general message from all sectors† was that the burden created by duplication of questions from RAIAs is significant, despite some achievements. For example, there have been benefits in the sharing of information between the Healthcare Commission and the NHSLA, and some other requests for information have been dropped recently. However, despite these initiatives, the general view was that the burden is growing, and is likely to grow significantly more in the coming months with the introduction of quality metrics, patient-reported outcomes and increased demand for performance measures from other parts of the NHS and the DH.

There was recognition that creation of the CQC should help to simplify and coordinate regulation, particularly for providers such as care or mental health trusts, who were subject to regulation by the Healthcare Commission, the Mental Health Act Commission and CSCI. But there was also concern that some of the progress achieved by the Healthcare Commission might be lost in the reorganisation and there was potential to add to bureaucracy – for example, as a result of duplication between the CQC and the Audit Commission. Feelings about the value of the Concordat were mixed. Some felt that it had helped regulators and their processes had become less burdensome, while others felt that the aspiration had not always been achieved and so it had only had limited effect. Overall, the view was that the Concordat's voluntary nature and its lack of real impact raised questions about the need for its existence in its current form.

### Provider feedback

**"In addition, PCTs are now sensibly looking to include quality metrics in their commissioning schedules. This is a positive step forward but there is already concern about duplication across some key areas. For example, in relation to incident reporting and serious incident investigation, this organisation will now be expected to report on different aspects of process and outcome to the National Patient Safety Agency, the CQC, Monitor, the NHSLA and the local PCT."**
***Provider***

**"Several of us spend all our time gathering evidence for the various RAIA bodies, driven by the fact that the same information is requested in different ways, necessitating a reformatting of the evidence. The administrative burden has doubled over the last four years."**
***Large hospital NHS foundation trust***

### One step forward, one back

**A concern is that despite agreement at national level between RAIA bodies to collaborate and use each other's information, this approach is not always reflected in local inspections.**

**For example, despite agreement between the Healthcare Commission and the NHSLA to accept assurance from each other's information where overlaps occur, one provider told us that this has not worked quite as expected in practice. Each organisation was still undertaking its own assessments, with the Healthcare Commission using the NHSLA information to inform its risk assessment, hence reducing the possibility of an inspection visit. However, this now appears to have been reviewed – the information will still inform the risk assessment but achievement of level two in any standard will not necessarily mean the Healthcare Commission accepts the organisation's self-assessment.**

† This is based on responses to a survey of NHS Confederation and IHAS members during December 2008 and January 2009. Responses were received from a range of providers, excepting ambulance services.

## Overlaps and duplications

There were significant criticisms from several providers about overlapping and contradictory frameworks, with repeated requests for information, including conflicting requests from the DH and SHAs. There were criticisms of several bodies using different formats and time bases, but also that the same information was often requested in slightly different formats, which meant that the same evidence had to be reformatted to satisfy different regulators. Some criticised the level of evidence required to demonstrate compliance with Healthcare Commission core standards as disproportionate, and suggested that there should be a closer synergy between the information required by any RAIA and the information that is needed to run the business.

But despite overlapping requests to collect extensive quantities of data, there can be a lack of alignment that makes it impossible to compare performance between different types of providers. For example, under the Independent Sector Treatment Centre (ISTC) Programme providers are required by the DH to collect extensive information as part of the contractual framework, in order to develop their KPIs; hospital episode data (HES) was also required. However, despite extensive data and KPIs, the requirements were not always well defined and did not allow effective comparison with the quality of care provided by the NHS.

### Comments from trusts

**"Now we are a foundation trust, almost everything requested by the SHA is a duplicate of what we provide to Monitor, the Healthcare Commission, the CSCI, the Mental Health Act Commission and the Deanery. Requests unfortunately come in different formats and so we end up reporting things more than once. However, the greatest burden is from commissioners."**
***Mental health partnership NHS foundation trust***

**"Whilst individual processes are in themselves reasonable, it is the level of duplication that creates problems."**
***Acute NHS foundation trust***

**"There is overlap between assurance requirements/evidence collection for World-class commissioning and the Annual Health Check/use of resources regimes. They do cross-refer to an extent but in practice we still have to feed both separately."**
***Primary care trust***

**"The SHA and the Healthcare Commission carried out reviews of records management within weeks of each other, but neither would accept the other's evidence; then the NHSLA did another."**
***Acute NHS trust***

### Definition of standards

**"There is no single, consistent set of standards in healthcare. The DH sets standards, but then each regulator sets its own compliance standards, again leading to tremendous overlap. There are only so many headings in this space – governance, safety, patient focus, accessibility, staff and public health, care environment, clinical effectiveness and outcomes – and rewriting them really makes no tangible difference. As a consequence of not having a single set of standards, there is variation in the definition of similar standards, which leads to IT issues such as differing numerators, denominators, time frame, standard target and audit targets, which usually result in bespoke data capture for very similar areas."**
***Independent sector provider***

## Moving the goalposts

Particular concern was expressed about delays in notification of key indicators and supporting information required to demonstrate compliance and "constantly changing requirements", including changing targets mid-year or even, in some cases, post submission of the data. The main culprit here was the Healthcare Commission, and hospitals and PCTs alike struggled with the

delayed announcement of the detailed compliance measures which provide the basis for the 2008/09 Annual Health Check, some of which were not published until as late as December 2008. As one chief executive put it: "How can we be assessed against a measure if we are not told what it is until the year is nearly over?"

### Process-driven approaches

There were strong criticisms of current approaches to demonstrating that standards have been met as being too focused on system documentation (such as committee terms of reference, and policy documents) and system outputs (committee minutes, and reports). It was felt that this resulted in a 'tick-box' mentality that was too process-driven and focused on the content of policies, rather than practice and outcomes. It was also felt to be more about back-covering than improving standards or public accountability.

Such approaches are resource-intensive, cause the most frustration, and yet the assurance received can be doubtful and contribute little to driving up standards. While good processes are important to good outcomes, a more intelligent approach to identifying the required information is needed. This should be linked to the regular monitoring of service quality and decisions about service improvements.

### The need to hold regulators to account

Some providers felt that there were far too many regulators, which contributed unnecessarily to burden and did not deliver effective regulation. Some identified individual regulators (such as the Audit Commission) as indulging in 'mission creep'. There were strong feelings that the Government, and particularly the DH, needed to take a much tougher line in rolling back the number of RAIAs and cutting their budgets.

## Case study: process-driven regulation

**This photograph illustrates the massive data collection undertaken by one provider for an NHSLA Risk Management Standards level two assessment. Even if this information had been made available electronically, it would not have significantly reduced the overall administrative burden.**

## Views on process-driven approaches

**"The Healthcare Commission reporting is the most time-consuming. The process demands undertakings of omniscience, which cannot possibly be justified. We are hitting the targets but missing the point."**
***Large NHS foundation trust hospital***

**"Hygiene standards are ridiculous, as the content focuses on policies and not practice."**
***Acute NHS trust***

**"The completion of the self-assessment in the manner which is now required, whilst apparently reducing the burden of inspection, does duplicate a great deal in a larger healthcare provision organisation. Many of the documents which are submitted are superfluous and there is little or no feedback on the quality or otherwise of the information requested."**
***Independent sector provider***

# Principles of better regulation

Since April 2008, many regulators have been under a statutory duty to have regard to the *Better regulation* principles[3] and best practice standards set out in the Compliance Code[4], which provides statutory force to the Hampton principles.[5] Most public sector regulators were omitted from the scope of these principles and the Compliance Code. Instead, they are covered by Government policy on inspection of public services.[6]

The need for better regulation and good risk assessment is as vital to the NHS as it is to the independent sector. Without it, there is a danger of the lack of comprehensive risk assessment, which can lead to, among other things, unnecessary inspections and too many, often overlapping, forms and data requirements. Ultimately, this may result in a needless regulatory burden in terms of the costs of regulators' inspections and enforcement activities.

The introduction of a single regulator for all providers of health and adult social care (the CQC) and the increasing provision of NHS care by independent sector providers open up the arguments for including healthcare RAIAs within the scope of the better regulation principles and the Compliance Code. Indeed, the CQC is legally required to operate according to the *Better regulation* principles, and the Government is now proposing to extend the Compliance Code to the CQC's operation.

The five principles for better regulation and the Compliance Code provide a strong basis for shifting the balance of healthcare regulation and inspection towards a more outcome-based approach. Under these, regulation should be:

**Proportionate** – regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.

**Accountable** – regulators must be able to justify decisions and be subject to public scrutiny.

**Consistent** – Government rules and standards must be joined-up and implemented fairly.

**Transparent** – regulators should be open and keep regulations simple and user-friendly.

**Targeted** – regulation should be focused on the problem and minimise side effects.

Regulators are expected to intervene only when there is a clear case for protection. They are expected to use comprehensive risk assessments to concentrate resources in the areas that need them most, and provide authoritative, accessible advice easily and cheaply. No inspection should take place without a reason, and businesses should not have to give unnecessary information or give the same piece of information twice. Finally, regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take.

The current Government policy on inspection of public services includes many similar principles. Its principles of inspection policy include recognition that inspection should:

- focus on outcomes, considering service delivery to end users rather than concentrating on internal management arrangements
- focus on the experience of those for whom the service is provided, as well as on internal management arrangements

*"The need for better regulation and good risk assessment is as vital to the NHS as it is to the independent sector."*

- be proportionate to risk, with resources concentrated on areas of greatest risk
- use impartial evidence that is validated and credible
- represent value for money for both the inspected and the inspectors, and demonstrate that it delivers benefits commensurate with its cost, including the cost to those inspected.

Inspectorates are expected to work together on cross-cutting issues in the interests of greater cost-effectiveness and of reducing the burden on those inspected. They have a duty to collaborate with other inspectors, auditors and regulators and, where appropriate, to make use of each other's findings so as to minimise the burden and maximise the benefit of review. Sponsoring departments are expected to facilitate this process of cooperation.

Creation of the CQC provides a real opportunity to translate the principles of better regulation into practice both through the operation of its gatekeeping powers and in providing clear leadership in how it organises its own work and compliance requirements. There are already welcome indications that the CQC intends to use data already collected in the system by SHAs and for World-class commissioning to inform its assessments. This should be a guiding principle for the CQC in all its work, including seeking compliance evidence for registration requirements and in the periodic and special reviews of healthcare services.

*"There are already welcome indications that the CQC intends to use data already collected in the system by SHAs and for World-class commissioning to inform its assessments."*

Many of the bodies highlighted in this report are not strictly regulators, although they impose significant administrative burdens on individual providers through their reporting and inspection requirements. There is no reason why they should not seek to abide by the principles of better regulation or Government policy on the inspection of public services in their work. If voluntary efforts continue to fail to yield sufficient benefits for frontline providers, the DH should hold those bodies that come under its control or influence to account for promoting a better regulation approach in their operation.

# Conclusions

Despite Government focus on promoting better regulation and minimising the burden of regulation and inspection, this report demonstrates that healthcare providers continue to experience over-regulation. There continues to be significant overlap and duplication between the many bodies whose remit includes oversight of healthcare providers.

There was little difference for NHS and independent healthcare providers. Many perceive that the bureaucratic burden has significantly increased, and believe that it is likely to get worse. For providers of NHS care, the prospect of more robust systems of performance and contract management, and initiatives associated with implementation of the NHS Next Stage Review, promise considerable expansion of reporting requirements driven by the DH and other parts of the system.

The same (or similar) questions are still being asked over and over again by many different agencies that have no real need to share with others. Data and information is held in a large number of warehouses, but there is no common portal to allow simple access.

Processes are often bureaucratic and administratively inefficient, consuming significant resources for both the regulated and the regulators. The non-productive load and cost placed upon providers is considerable and needs to be addressed.

Clinical engagement with the process is at best messy and at worst almost non-existent. Much of the work of collating evidence is undertaken by administrative staff and at best signed off by clinicians. This is a serious indictment of the regulatory system as a whole.

The 'system' does not work well – it is complex and confused. There are too many bodies whose remit covers healthcare organisations that have grown in a piecemeal manner. This has been added to by the recent growth in accreditation schemes, often sponsored by the medical Royal Colleges, which organisations see as key validation of the quality of their services.

There is over-reliance on prescriptive adherence to meeting detailed targets and performance management, with significant rewards and penalties for meeting or failing to meet standards. This has resulted in a few boards focusing too much on hitting the target and losing sight of the overall objective of delivering high-quality care to meet patients' needs.

Approaches are too process-focused and do not provide adequate assurance of the quality of care. This has much in common with early ISO 9000 accreditation, which called for detailed and exact process specification but often resulted in accredited companies making products which were consistent and identical but of low quality. While effective processes are important to delivering good outcomes, a more outcome-focused approach is needed, which will address many of the weaknesses associated with this approach, so that:

- all factors are taken into account
- inspection reflects current performance
- resources of both the regulator and the regulated are focused on the organisations and areas needing attention
- RAIAs use data that is already compiled by providers for internal monitoring purposes
- detailed benchmarking is possible to allow comparison between providers, helping to drive improvement.

A more systematic and coordinated approach is needed for the regulation and assessment of healthcare providers to achieve:

- a clear focus on quality and outcomes
- greater clarity about whose job it is to do what
- greater acceptance by individual RAIAs of evidence from reliable sources to demonstrate compliance with their standards
- RAIAs are held to account, to prevent mission creep.

Regulation must recognise the balance between inspection, self-assessment or audit, risk-assessed quality data, and patient satisfaction or outcome measures. It should be proportionate to risk, generated from core datasets. How that information is collected and the manner in which inspections take place should be designed to minimise administrative costs and disruption to providers. Government, the DH and the NHS should be more engaged in this issue, and focused on a more effective approach to the regulation and oversight of health organisations across Government generally.

## Opportunities for change

The CQC, with its specific gatekeeping powers, and the creation of a common registration framework for all health and social care providers, offer real opportunities for a more strategic and coordinated approach to regulation. The challenge will lie in how the CQC uses its powers and implements the detail of the new registration framework, including what evidence it will require from providers to demonstrate compliance and how it coordinates its work with other RAIAs and SHAs.

*"The CQC and the creation of a common registration framework for all health and social care providers, offer real opportunities for a more strategic and coordinated approach to regulation."*

Action is needed throughout the healthcare system to effect change and have a significant impact on the bureaucratic burden on healthcare providers. Our key recommendations identify actions for all involved in providing and assuring the quality of healthcare, individual providers, the RAIAs, and Government, particularly the DH. They all have key roles to play in making the system more effective and reducing costs. There is a particular role for the CQC as it takes on the mantle of the primary regulator for health and social care.

# Recommendations

## Improved information sharing

Much can be achieved to reduce the burden experienced by healthcare providers through improved information collection and data sharing between RAIAs. No RAIA should be seeking assurance on issues in which the regulated has no interest. The main barriers to this at present include:

- different definitions and time periods
- the absence of effective systems to facilitate easy sharing of information and partnership working, including compatible IT systems[7]
- the failure of individual RAIAs to accept other RAIAs evidence as assurance against their standards.

The Information Centre for Health and Social Care has a key role in overcoming these barriers and achieving better information-sharing. It is already undertaking valuable work with the review of NHS and social care information standards, the data streamlining board initiatives to rationalise data collections and ROCR. We support these moves and efforts to standardise data formats, definitions and time periods for reporting, but there needs to be greater pace and a clear focus on delivery of this important strand of work which we would like to see extended.

In particular, we would want to see ROCR operate a more robust, constructive change function with decisions supported by ministers and DH officials. To give real teeth to the ROCR process, the Information Centre must be able to say "no". We would also like to see a ROCR-type discipline extended to requests for information from SHAs, which would not only subject SHA information requests to appropriate scrutiny, but also open up opportunities for improved information-sharing between SHAs and RAIAs.

Action is needed to create an easily accessible central database or repository to facilitate the commitment to sharing information. This could be achieved through a central, web-based information portal that would allow RAIAs and organisations secure access to a central repository of information, overcoming many of the limitations and lack of flexibility associated with a central database. Providers would be able to collate and upload the necessary evidence as assurance by any RAIA, such as documents, spreadsheets and so on, in any format, using any computer with Internet access. Reports produced by RAIAs could be uploaded to be accessed by other RAIAs[8], adding to the pool of evidence. We recognise that such an approach would need to meet very strict data security protocols.

We acknowledge that the Information Centre is already working towards creating a web portal under two key work programmes in its business plan for 2009/10 and beyond. These include:

- **signposting of information**: to deliver a web portal for customers to access and use health and social care information, with the aim of directing users to relevant information (whether data, information or knowledge)
- **a syndication service**: a means of acquiring, processing and delivering data and other content to customers. The DH and the Information Centre should continue to give both these projects high priority as they offer the prospect of significant cost savings for providers and regulators alike, with a view to establishing a working web portal, accessible by RAIAs and providers by 2013.

Improved use of information for regulatory and oversight purposes would be greatly enhanced by robust information sharing guidance from government and a positive duty placed on individual regulators and designated bodies

to collaborate within the sector. This should help to avoid duplication and overlap in information requests, and facilitate the sharing of information between RAIAs.

In order to promote improved information-sharing and better use of data, we recommend:

- The Information Centre to establish a working web portal, accessible by RAIAs and providers by 2013, to facilitate improved information sharing.
- The Information Centre to support initiatives to facilitate improved information sharing between RAIAs and the simplification of data collections including:
  - securing greater standardisation of data formats, definitions and time periods
  - continued efforts to streamline data collections.
- A more robust and challenging ROCR process with:
  - all RAIAs required to submit any requests for data from providers through ROCR
  - new powers for the Information Centre to refuse any data collection request where it believes the information is already collected, and to discourage new returns where similar information already exists.
- Extension of a ROCR-type discipline to data returns and information requests from SHAs.
- The Information Centre to publish an annual report on the operation of ROCR, and progress made towards streamlining data collections, highlighting any reductions or increases in the burden of reporting.
- The Information Centre to promote the principles and disciplines of ROCR actively to SHAs, PCTs and RAIAs and to publicise what information is already held centrally in order to minimise duplicative requests for information.
- The DH issues guidance on information and data sharing by RAIAs within healthcare, emphasising the importance of these bodies being expected to share information collected by others, and accepting similar, even if it is not an exact match.

*"The board must not abdicate responsibility for the quality assurance process to regulatory and other bodies."*

## Empowering providers

More effective and efficient regulation relies upon action by providers. True risk-based regulation needs providers to focus on quality, safety and outcomes and to monitor these issues actively, taking appropriate action when necessary. Ultimately, responsibility for the quality and safety of patient care lies with the board and it must decide what constitutes reasonable assurance that services provided meet the appropriate safety and quality standards. The board must not abdicate responsibility for the quality assurance process to regulatory and other bodies.

Changes associated with the NHS Next Stage Review and transition to the CQC should provide a catalyst for organisations to shift their focus to developing meaningful quality management systems. This approach should highlight at an early stage areas that need attention, and those organisations that may need help from the regulators. It should also mean that regulators will only need to intervene when necessary; that is, organisations struggling to meet outcomes will become more of a focus for the regulator.

Providers can also play an active part in reducing the burden of reporting requirements by:

- rationalising their internal processes and systems for dealing with RAIAs and their requests as part of a more coordinated approach to external RAIAs

*"We believe that providers should be able to challenge duplicate requests."*

- reviewing and questioning whether all the returns and data requests they are completing are strictly necessary – Monitor states that up to 60 per cent of reporting can be reduced for foundation trusts.

Greater clarity about what is needed by whom, and more standardised definitions, will help providers in this process.

We also believe that providers should be able to challenge any RAIA asking for data that has not been through a ROCR process or for information that is the same or very similar to what has already been provided to another, by issuing a 'yellow card' to the RAIA involved. Such a system would need to be designed to enable providers to instruct RAIAs to seek their assurance elsewhere, and the process should be overseen by an independent adjudicator, such as the Information Centre.

Further work is needed to develop the detail of a workable scheme, and we suggest that the CQC and Information Centre should work together on this. Such a scheme would provide important feedback for the CQC and the Information Centre on those reporting requests that are duplicative or where it has not been through the ROCR process.

## Government and the DH

The PAG supports moves to risk-based regulation, but clarity is needed about the role of government in this. We believe that the proper role for government is to:

- **set standards** relating to quality and safety, with data collection and management information devolved to the executive
- **secure a consistent approach** to the regulation and oversight of healthcare providers across government, including not just those agencies that come under the influence of the DH, but also others such as the Audit Commission (sponsored by the Department of Communities and Local Government) and Ofsted (sponsored by the Department for Children, Schools and Families)
- **take a strategic overview** of the working of the system, holding individual RAIAs to account for their actions and for the burden placed on providers, and minimise the potential for 'mission creep'.

We believe that government should undertake an urgent review of the remit of the RAIAs and consider any scope for rationalisation, particularly where they have similar objectives. This should result in a simpler regulatory landscape, with regulatory roles clearly understood by all, which would be consistent with a key recommendation from the Hampton Review[9] to have fewer themed regulators. Appendix 2 lists most of the RAIAs currently under the control or influence of the DH and ministers and would provide a good starting point for such a review. The DH Board should demand and oversee restructuring of those bodies under its remit.

A regulatory compendium should be created across health and social care which should then be mapped to the various sectors. A lead regulator could be assigned to each chapter or section. Any regulatory impact assessment associated with policy initiatives should clearly delineate regulatory lead roles, data collection and provider financial impacts.

The success of such an action will be increased if the chosen RAIA includes all best practice within its inspection criteria for its designated area. At present, several RAIAs have a remit and interest in the area of patient safety, each with its own reporting requirements on individual providers. However,

in a letter to the PAG, the Health and Safety Executive (HSE) states: "The HSE is the single independent regulatory body responsible for patient safety regulation in England, Scotland and Wales and was established by the Health and Safety at Work Act 1974".[10]

This raises two important questions. Firstly, why do so many other RAIAs see this as their job? Secondly, if the HSE has been responsible since 1974 for patient safety, why has it not been held to account for its lack of effective progress in dealing with this task?

Government should hold RAIAs to account and set them stretching, simplification targets. The purpose of each data return should be clearly stated to help to identify whether the purpose of the return has already been met elsewhere within the system. Feedback from providers should be used as a key, if not the main, component of any assessment on delivery of targets. Such a simple action will help to avoid over-regulation.

The DH should undertake a national review to clarify the distinct and relative functions of commissioning, performance management and regulation in ensuring patients receive safe and effective care. At present, these functions often require similar information, which leads to overlap and duplications. There is considerable scope for greater synergy between performance and contract management reporting requirements and regulatory and inspection standards so that information can be shared easily between processes and unnecessary duplication minimised.

Throughout this report we have highlighted that many initiatives associated with the NHS Next Stage Review will result in additional reporting requirements for providers. Many of these changes are to be welcomed as they mark a shift to a more outcome-focused approach that incorporates patients' views. However, it is important that these new requirements do not duplicate existing

*"If the HSE has been responsible since 1974 for patient safety, why has it not been held to account for its lack of effective progress?"*

requirements or add significantly to the burden of bureaucracy.

## RAIAs

The greatest differences to the level of bureaucratic burden will come from greater partnership working and information-sharing between individual RAIAs. Despite duties to collaborate and the existence of the Concordat, progress so far has been limited.

Continuance of a Concordat-type arrangement under the CQC could make a real difference to frontline providers, but only if there are more robust mechanisms to hold individual RAIAs to account for greater cooperation and collaboration on inspections and information requirements. The Concordat has been hampered in its work to date by its voluntary nature and by some key absences from the table – notably SHAs and Monitor. It is only likely to succeed if significant pressure and sanctions could be applied. While they remain autonomous it is hard to see this happening.

Early experiences of collaborative risk summits suggest that these might be a better forum for bringing together key RAIAs at the local level and fostering cooperation and coordinated action. We urge the CQC to continue such arrangements.

## The future and the CQC

The scope and remit of the CQC offers significant potential to minimise the burden of regulation, particularly given its potential gatekeeping powers. Creating a common regulatory framework for independent sector and NHS providers by bringing together the

work of the three predecessor bodies to the CQC should bring benefits, particularly for providers of services that cross health and social care (such as many mental health trusts) and for independent sector providers of services to NHS patients. However, the CQC must maintain an active dialogue with providers, not only as it shapes the practicalities of the new registration system but also to monitor the impact of the implementation of the new registration system on frontline providers.

Creation of the CQC and simplification of the system for independent sector health and social care providers is expected to yield significant savings in administrative burdens. The impact assessment published by the DH alongside the response to the 2008 consultation on the regulatory framework[11], estimates administrative burden savings of between £80 million and £147 million will be achieved from the simplification of the regulatory system for providers currently registered under the Care Standards Act, mainly from adult social care.

The impact assessment describes the impacts on the NHS, independent health providers and social care providers in terms of complying with the regulations. However, for many healthcare providers, transition from current systems to registration requirements will involve added burden and administrative costs, which have tended to be underestimated but need to be taken into account.

In exercising its new functions, the CQC should:

- establish effective mechanisms to facilitate greater cooperation between individual RAIAs, building on the work of the Concordat
- drive much greater acceptance of assurance from other RAIAs as evidence of compliance with the registration requirements
- accept achievement of approved accreditation schemes as evidence of compliance with registration requirements
- engage effectively with the wider NHS, particularly SHAs, as there is little point coordinating gatekeeping of RAIAs if the information collected for performance management is allowed to mushroom in an uncoordinated way
- maintain and develop local collaborative risk framework summits as a way of facilitating a coordinated approach to local review, inspection and improvement action
- establish effective mechanisms to ensure the lessons from local collaborative risk summits are translated into actions at the national level
- establish an advisory group to inform its work as it puts the new regulatory system into practice.

# Appendix 1. Terms of reference and Provider Advisory Group membership

## The role of the PAG

The aim of the group is to ensure on-going and meaningful engagement with the front line and to:

- provide feedback on the impact of current regulatory or inspection regimes
- advise on areas where duplication remains an issue and facilitate workable solutions
- promote agreement on regulatory processes and ensure that regulators remain committed to share information more intelligently
- assist the Information Centre in streamlining data collections to prevent unnecessary or disproportionate burdens on the service
- find outcomes for quality patient care
- assist in the development of policy and advise on proposals for new regulatory/inspection frameworks and activity
- assess (on an annual basis) progress against aims, and make recommendations as appropriate for areas where further action needs to be taken
- review and give feedback on the success of the Concordat work programme.

The PAG has two objectives:

1. Regulators will look to this group for a view from providers
2. This is, however, not intended to prevent regulators and policy-makers talking to individual providers as necessary.

## Membership of the PAG

Chair: Peter W Mount CBE, Chair, Central Manchester University Hospitals NHS Foundation Trust

Vice-Chair: Dr Andrew Jones, Group Medical Director, Nuffield Health

Frances Blunden, Senior Policy Manager, the NHS Confederation (joint secretariat)

Sally Taber, Director, Independent Healthcare Advisory Services (joint secretariat)

Dr Khandee Ahnairmugan, formerly of MDI Health

Alison Bartholomew, Risk Management Director, NHS Litigation Authority

Mitali Begum, Commercial Advisor, Foundation Trust Network

Sue Bentley, Director of Performance and Quality, Barnsley PCT

Fleur Booty, Clinical Lead, Circle

Pauline Cichy, formerly Head of Clinical Governance, New Victoria Hospital

Sarah Corcoran, Associate Director of Clinical Governance, Central Manchester University Hospitals NHS Foundation Trust

Paul Duhig, Hospital Manager, the Classic Hospitals Group (now Spire Healthcare)

Brigitte Harrison, Director of Nursing, Healthcare at Home

Jonathan Horbury, Director of Development, Oxfordshire and Buckinghamshire Mental Health Partnership NHS Trust

Chris Horsey, Better Regulation Team, Department of Health
Nick Jones, Deputy Head of Strategy, Healthcare Commission
Graham Kendall, Consultant, NHS Partners Network
Richard Laurence, Group Head of Clinical Performance, Care UK
David Monkman, Director of Nursing and Clinical Governance, Royal Hospital for Neurodisabilities
Dr Bruce Moore, Medical Director, 5 Boroughs Partnership
Barrie Oldham, Chief Executive, Disabilities Trust
Angela Payne, formerly of the Classic Hospital Group (now Spire Healthcare)
Carolyn Parkinson, Project Lead: Gatekeeping, Better Regulation Team, Department of Health
Cathy Regan, Senior Manager (Concordat Strategy & Implementation), Healthcare Commission
Paul Sabapathy CBE, Chairman, Birmingham East and North Primary Care Trust
Graeme Sandell, Assistant Director Health, Better Regulation Executive, Department for Business, Enterprise and Regulatory Reform
Martin Sutton, Consultations Co-ordinator, Better Regulation Team, Department of Health
Hilary Thomas, Medical Director, Care UK
David Tomlinson Medical Director Partnership Health Group
Eileen Walsh, Director of Assurance, Guys & St Thomas NHS Foundation Trust
Steve Webster, Head of Information Standards, the Information Centre for Health and Social Care

## PAG support team

Peter Jenkinson, Head of Corporate Services, Winchester and Eastleigh Healthcare NHS Trust
Lara McGuigan, formerly Information Quality and Compliance Manager, Birmingham Children's Hospital
Karen Murray, Company Secretary, University Hospital of North Staffordshire

# Appendix 2. Regulators, auditors, inspectorates and accreditation agencies

| **Agency (those highlighted in green were included in the mapping)** | **Accountable to DH, subject to Ministerial direction or work closely with DH** | **Statutory or voluntary** | |
|---|---|---|---|
| Care Quality Commission (from 1 April 2009 | Yes | Statutory | Regulator |
| Healthcare Commission | Yes | Statutory | Regulator |
| Commission for Social Care Inspection | Yes | Statutory | Regulator |
| Mental Health Act Commission | Yes | Statutory | Regulator |
| Monitor (regulator of NHS foundation trusts) | Yes | Statutory | Regulator |
| Human Fertilisation & Embryology Authority | Yes | Statutory | Regulator |
| Human Tissue Authority | Yes | Statutory | Regulator |
| Medicines and Healthcare Products Regulatory Agency | Yes | Statutory | Regulator |
| Audit Commission | | Statutory | Auditor |
| National Audit Office | | Statutory | Auditor |
| NHS Litigation Authority | Yes | Special health authority | NHS only |
| National Patient Safety Agency (NPSA) | Yes | Arm's-length body of the DH | |
| NPSA – patient environment action teams (formerly NHS Estates) | Yes | Arm's-length body of the DH | |
| Connecting for Health: Information Governance toolkit | Yes | Directorate of the DH | |
| NHS Estates – cleaning | Yes | | |
| Health Protection Agency | Yes | Non-departmental public body | |
| National Institute for Innovation and Improvement | Yes | Special health authority | |
| NHS Business Services Authority: Counter Fraud and Security Management Service | Yes | Special health authority | |
| NHS Business Authority: NHS Pensions Agency | Yes | Special health authority | |
| NHS Business Authority: Dental Practice Division programmes | Yes | Special health authority | |
| NHS Business Authority: Prescription Pricing Division | Yes | Special health authority | |

| | | | |
|---|---|---|---|
| Council for Healthcare Regulatory Excellence | Yes | Statutory | Regulator |
| Postgraduate Medical Education and Training Board | Yes | Statutory | Regulator |
| General Medical Council | Yes | Statutory | Regulator |
| Nursing and Midwifery Council | Yes | Statutory | Regulator |
| General Dental Council | Yes | Statutory | Regulator |
| Royal Pharmaceutical Society of Great Britain | Yes | Statutory | Regulator |
| General Optical Council | Yes | Statutory | Regulator |
| General Osteopathic Council | Yes | Statutory | Regulator |
| Health Professions Council | Yes | Statutory | Regulator |
| British Association for Counselling and Psychotherapy | | Voluntary | Professional body. |
| Accreditation scheme for tissue banks | Yes | Voluntary | Accreditor |
| Accreditation for acute inpatient mental health services | | Voluntary | Accreditor RCP |
| Clinical Pathology Accreditation Ltd | | Voluntary | Accreditor |
| Health Information Accreditation Scheme | Yes | | Accreditor |
| Health Quality Services | | CHKS company | Accreditor |
| Hospital Accreditation Programme | | CHKS company | Accreditor |
| Investors in People | | Voluntary | Accreditor |
| Royal Colleges (13) | | | Accreditor |
| North Central London SHA library accreditation | Yes | | |
| Cancer Peer Review | Yes | Mandatory | |
| Cancer screening quality assessment | Yes | | |
| NHS Breast Cancer Screening Programme | Yes | | |
| Peer Review of Cancer Registries | Yes | | |
| National Treatment Agency for Substance Misuse | Yes | Statutory | |
| Quality in Drugs and Alcohol service (QUADS) | | Voluntary | Advisory |
| Quality Network CAMHS (QUINMAC) | | Voluntary | RCPsych |
| Quality Inpatient CAMHS (QUINIC) | | Voluntary | RCPsych |
| Skills for Health | | Voluntary | Advisory |
| Standards for Health Promotion in Hospitals | | Voluntary | WHO |
| Service Standards for Addiction Therapeutic Communities (SSATC) | | Voluntary | RCPsych |
| Local involvement networks (LINks) | | Statutory | |
| Ofsted | | Government department | Regulator |
| Health and Safety Executive | | Non-departmental body | Regulator |
| Environment Agency | | Public body | Regulator |
| Local authority environmental health departments | | Local authority | Regulator |
| Fire authorities | | Local authority | Regulator |

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The PAG commissioned Dean Flanagan to undertake the detailed mapping and analysis work.

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# What's it all for?

## Removing unnecessary bureaucracy in regulation

**The bureaucratic burden of regulation, inspection and accreditation for NHS and independent sector providers of healthcare is worsening despite various initiatives to reduce it. There continues to be significant overlap and duplication between the many bodies whose remit includes oversight of healthcare providers. Healthcare providers continue to experience over-regulation.**

**Much of the effort to date has focused on reducing the burden for the independent sector, but for many providers the initiatives to achieve better and more effective regulation have failed to deliver significant improvements.**

**This report looks at the overlaps and duplications that exist, and makes a number of recommendations for reducing the bureaucratic burden.**

**This report was jointly produced by the NHS Confederation and the Independent Healthcare Advisory Services.**

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