

Extending Professional Regulation

Stakeholder Event – Delegate Pack

Centre for Life, Newcastle

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Frequently Asked Questions

Q: Why is regulation of professional and occupational groups needed in the health arena?

A: The **primary purpose** of professional regulation is to ensure **patient safety**. In order to assure a safe and high-quality experience for patients when encountering health professionals there is a need for proportionate arrangements to be in place to ensure patient safety.

Q: What is regulation?

A: The simple definition of regulation is “the act of regulating or the state of being regulated”. However, regulation focuses on ensuring that members of an identified occupational or professional group reach and maintain the minimum threshold standards that are expected of that occupational or professional group. For example, in relation to, conduct, practice, and education. Any regulation operates, however, within a broader framework of regulatory procedures, such as complaints and capability procedures, clinical governance and staff governance.

In the UK health context there are two main branches of regulation: non-statutory and statutory.

Non-statutory regulation, on the one hand, is usually progressed voluntarily by a professional “governing” body and **not directly through legislation**. Although the majority of currently recognised health professional groups in the United Kingdom are statutorily regulated, the merits to patient safety of alternative methods need to be acknowledged before statutory regulation is extended to other professional/occupational groups. The additional benefits that statutory regulation brings over non-statutory methods needs to be clearly articulated and based on principles of public protection.

Under **statutory regulation** the Government is responsible for initiating the regulation of a profession where a risk to the public from poor practice is perceived. It is **effected through legislation** in order to protect the public against the risk of poor practice. Usually this leads to **protection of title** with **agreed standards** of proficiency and codes of practice and conduct / ethics being set out, together with the **education and training requirements** necessary for entry to the professional register of practitioners, with breaches of the code usually **enforceable by the use of sanctions** imposed by the nominated statutory regulatory body.

Q: Why not offer statutory regulation to all groups who seek it?

A: Statutory regulation carries with it **significant impact**. With regulation by statute and protection of title come restrictions on scopes of practice. This can restrict the development of practice by those not regulated and can therefore restrict the flexibility needed on the part of the workforce to meet **changing healthcare requirements**.

There are also associated legal and **administrative requirements** for the healthcare professional/occupational group, which can take some time to finalise, as well as **financial costs** for the healthcare professional/occupational group, the employer, the tax payer and the Government. Therefore, the decision to extend statutory regulation to a new group is **not always clear-cut** and should not be taken lightly. It requires the input of a large number of stakeholders and consideration of many – often conflicting – factors.

Consequently, the Government has to ensure that the expenditure of that time and resource **adds real value** to patient care, providing **assurance and peace of mind** that allows patients to take the quality of care for granted, confident that they are being treated in a way **that maximises their safety**. In a health service facing demanding **challenges to deliver** for the public, these judgements are critical. The same concerns apply to those who employ health professionals in the private and independent sectors.

Q: What is the government's approach to regulation?

A: There has been a growing focus in Government, led by the work of the Better Regulation Commission to ensure a more rigorous approach to the field of regulation. The core principles of **proportionality, accountability, consistency, transparency and targeting** are bringing a more common-sense approach to regulation. These principles recognise that, in many spheres of life, people are prepared to tolerate a *level* of risk and that any proposals to seek to protect against risk need to be tested thoroughly to ensure they are not over-burdensome and that they do not unduly limit innovation and local and individual freedom of action.

Q: What is the role of a regulator?

A: The key function of a regulator in the health context is to **create a framework** to provide patients with confidence in those who care for them. The current health professional regulators have a number of core functions, including:

- **setting and promoting standards** for admission to the register and for remaining on the register;

- **keeping a register** of those who meet the standards and checking that registrants continue to meet those standards;
- **administering procedures** for dealing with cases where a registrant's right to remain on the register has been called into question; and
- **ensuring appropriate threshold standards** of education for the health professionals that they regulate.

To exercise these functions fairly and effectively, patients, the public and health professionals need to be assured that the regulators act objectively and without undue regard to any one particular interest, pressure or influence. This will ensure that the regulators are not only independent in their actions, but also, just as importantly, that they are seen to be independent in their actions and act, at all times, in the public interest.

Q: Why was the Extending Professional Regulation Working Group set up?

A: In February 2007 the Government White Paper "**Trust, Assurance, Safety – The regulation of health professionals in the 21st Century**" set out proposals for improving **public safety** by strengthening the system of professional **regulation** for health care professionals. The White Paper also considered plans for **extending statutory regulation** to more healthcare professions/occupational groups.

A Working Group of representatives from across the UK (the Extending Professional Regulation Working Group), including from health and social care sectors, academia, regulatory bodies, and government has been tasked with taking forward this complex area of policy.

Q: How will decisions regarding extending regulation be made?

A: That is where the group needs your input.

Our work, the **research** that we have commissioned, and the **input** which our **stakeholders** have given us, has helped the Working Group develop some basic **principles** for how extending professional regulation could be achieved. The purpose of this Stakeholder Event is to **test** out these principles, **build upon** them, and to gain the **innovative input** that we are confident that you, our **stakeholders**, can provide.

Varieties of Regulatory Models

SOURCE: Work commissioned by Working Group, and Skills for Health

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| Type of Regulation |
| Voluntary Professional Self-regulation |
| Description |
| Voluntary process where professionals collaborate and agree a set of standards and practices independent of direct government control for the purpose of protection of the public. This regulatory system is often also aimed at promoting professionalism in terms of ownership of standards and professional recognition. Profession responsible for registering and maintaining a register of practitioners |
| Main Benefits |
| <ul style="list-style-type: none"> • Professionals/industry may determine standards of practice and ethics & requirements for entry, allowing innovation and good use of the technical expertise of the practitioners to shape the regulatory model • Often proves a cost effective approach |
| Main Issues |
| <ul style="list-style-type: none"> • Perceptions that a self regulated profession could act in its own interests, and promote its professional interests over that of its users • Sanctions limited to reputational/organisational sanctions (e.g. withdrawal of seals of approval) and so not well suited to practice that might entail a high-risk danger to the public |
| Fitness to Practice Provisions |
| Professionals determine the definition of violations and set appropriate sanctions. Enforcement activity and procedures set up by professional body |
| CPD Provisions |
| CPD standards and requirements are set and monitored by professional body |
| Real life examples |
| <p>Chiropractors and osteopaths established voluntary self-regulation bodies prior statutory regulation being implemented for their professions</p> <p>CORGI is the national watchdog for gas safety in the United Kingdom. Since 1991 registration has been a legal requirement for anyone installing or repairing gas fittings or appliances. However, CORGI also operates a Certification and Quality Assurance Scheme for CORGI Registered Gas Installers. This is a voluntary scheme designed to assess the management systems and arrangements installers have in place for the control of safe gas work, with the aim of offering assurance to customers in the installer's ability to deliver a quality service.</p> <p>More information: http://www.trustcorgi.com</p> |

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| Type of Regulation |
| Employer-led regulation |
| Description |
| Employer has a duty to practice according to safe recruitment principles, to provide meaningful induction programmes for staff, to support staff to achieve agreed standards through personal development planning and review and to positively acknowledge that standards have been met |
| Main Benefits |
| <ul style="list-style-type: none"> • Real focus on driving up standards of training and skills by setting standards and monitoring performance against these, using personal development planning |
| Main Issues |
| <ul style="list-style-type: none"> • Employers may face service delivery pressures that could cause them to 'turn a blind eye' if faced with a difficult conduct issue, which could result in operational problems like shortage of staff |
| Fitness to Practice Provisions |
| Employer carries out fitness to practise procedures in line with normal human resources practice, and clinical and staff governance procedures |
| CPD Provisions |
| Employers induct and ensure ongoing training and development of employees against service needs and public protection requirements. Staff achieving agreed standards through personal development planning and review |
| Real life examples |
| <p>The Scottish Pilot on Employer Regulation for Healthcare Support Workers is a pilot for a form of employer-led regulation. The elements of the employer-led model being tested are:</p> <ul style="list-style-type: none"> • a set of induction standards that focus on concepts considered to be important for public protection; • a Code of Conduct for Healthcare Support Workers; • a Code of Practice for Employers, and, • a centrally held list of names of those who meet the standards required. <p>The Pilot is due to report its findings in Spring 2009</p> |

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| Type of Regulation |
| Licensing |
| Description |
| Complements employer-led regulation but is used when employees are undertaking controlled acts which are protocol led and would not have life threatening consequences for patients. The principles of licensing are in line with work done as part of the Scottish Pilot; i.e., safe recruitment practise, induction standards, assessment of achievement, codes of conduct for support workers and of practice for employers, listing of names and monitoring of employers' practise, structures and processes. It is a "light touch" approach to regulation |
| Main Benefits |
| <ul style="list-style-type: none"> Licensing could be appropriate for health practitioners who increasingly work within multi-professional, multi-agency and multi-disciplinary settings using a licensing model, with added accreditation for competence against function |
| Main Issues |
| <ul style="list-style-type: none"> Potential problems of inflexibility in movement between work places for health practitioners who work in different professions and deciding on who would licence practitioners in a multi-functional environment |
| Fitness to Practice Provisions |
| Licensors able to set rules regarding fitness to hold licence, and procedure for revoking licence if appropriate |
| CPD Provisions |
| Licensors able to set standards of training and checking as part of requirements to gain the license. |
| Real life examples |
| <p>The Security Industry Authority (SIA) runs a licensing scheme regulating the security industry. The SIA are an independent body reporting to the Home Secretary, established in 2003 under the terms of the Private Security Industry Act 2001.</p> <p>The provide license to people seeking to provide services in the Security Industry. Standards of training and competence are required to gain the licence, and misconduct can lead to it being revoked.</p> <p>As well as maintaining the licensing regime they also aim to raise standards of professionalism and skills within the private security industry and to promote and spread best practice.</p> <p>More information: http://www.the-sia.org.uk/home/</p> |

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| Type of Regulation |
| Distributed regulation |
| Description |
| Process by which a practitioner registered with one regulator (the initial regulator) extends their scope of practice to perform new functions, the standards for which are set by, or in partnership with, another (a second) regulator. The second regulator sets standards which are used to regulate the practice of those registered with the initial regulator but who widen their scope of practice to accommodate standards of the second regulator. Initial registration continues but dual registration not required. |
| Main Benefits |
| <ul style="list-style-type: none"> • Practitioners would not be required to meet the registration requirements of two different regulators and to pay for costly dual registration. • Safeguards patient safety through practitioners having to meet the required standards for the area they undertake duties in, irrespective of initial registration |
| Main Issues |
| <ul style="list-style-type: none"> • Needs to be acceptance that it is the “lead” regulator who sets the standards, in some cases in partnership with another professional or regulatory body, and that all relevant regulatory bodies sign-up to, and accept, these standards for professional practice • Potential of difficulties in progressing fitness to practise cases, where due regard would be given to expertise from the field of practice. |
| Fitness to Practice Provisions |
| Initial regulator could investigate FTP issues with assistance from other regulator, giving due regard to the clinical expertise required. |
| CPD Provisions |
| Standards may be set by both the initial and the second regulator. If these requirements are statutory then practitioner must meet demands of both. |
| Real life examples |
| This is a model that has not yet been fully tested in the UK health context. |

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| Type of Regulation |
| Meta regulation |
| Description |
| Meta-regulation is the process by which an external agency ensures that self-regulation is effectively carried out. In other words, it is the external independent assessment of self-monitoring with the aim of bringing about improvement in quality and safety. External clinical audit is one strategy that can be used within the meta-regulation model. Credentialing and accreditation are examples of outcomes of meta-regulation. |
| Main Benefits |
| <ul style="list-style-type: none"> Engages and involves practitioners in the regulation process (e.g. they may be interviewed as part of the accreditation / validation process, take part in peer performance/panel reviews, etc). |
| Main Issues |
| <ul style="list-style-type: none"> May not be applicable/appropriate to some health professionals / occupational groups |
| Fitness to Practice Provisions |
| External agency ensures that standards are adhered to by the professional body. Can be appropriate when there are a large number of small operators making it difficult to effectively cover them in terms of enforcement of standards and compliance |
| CPD Provisions |
| Separate bodies or boards maintain CPD |
| Real life examples |
| In the UK health context, a number of external bodies can undertake regular assessment of health services providers, investigate individual providers and recommend best practice. |

Five Principles of Good Regulation

SOURCE: Better Regulation Commission. The table below describes the **Five Principles of Good Regulation** and what regulators should bear in mind when devising, implementing, enforcing and reviewing regulations.

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| <p>Proportionality</p> <p>Regulators should only intervene when necessary. Remedies should be appropriate to the risk posed and costs identified and minimised.</p> <ul style="list-style-type: none">• Policy solutions must be proportionate to the perceived problem or risk and justify the compliance costs imposed – don't use a sledgehammer to crack a nut.• All the options for achieving policy objectives must be considered – not just prescriptive regulation. Alternatives may be more effective and cheaper to apply.• "Think small first". Regulation can have a disproportionate impact on small businesses, which account for 99.8% of UK businesses.• EC Directives should be transposed without gold plating.• Enforcement regimes should be proportionate to the risk posed.• Enforcers should consider an educational, rather than a punitive approach where possible. |
| <p>Accountability</p> <p>Regulators must be able to justify decisions and be subject to public scrutiny.</p> <ul style="list-style-type: none">• Proposals should be published and all those affected consulted before decisions are taken.• Regulators should clearly explain how and why final decisions have been reached.• Regulators and enforcers should establish clear standards and criteria against which they can be judged.• There should be well-publicised, accessible, fair and effective complaints and appeals procedures.• Regulators and enforcers should have clear lines of accountability to Ministers, Parliaments and assemblies, and the public. |
| <p>Consistency</p> <p>Government rules and standards must be joined up and implemented fairly.</p> |

- Regulators should be consistent with each other, and work together in a joined-up way.
- New regulations should take account of other existing or proposed regulations, whether of domestic, EU or international origin.
- Regulation should be predictable in order to give stability and certainty to those being regulated.
- Enforcement agencies should apply regulations consistently across the country.

Transparency

Regulators should be open and keep regulations simple and user-friendly.

- Policy objectives, including the need for regulation, should be clearly defined and effectively communicated to all interested parties.
- Effective consultation must take place before proposals are developed, to ensure that stakeholders' views and expertise are taken into account.
- Stakeholders should be given at least 12 weeks, and sufficient information, to respond to consultations.
- Regulations should be clear and simple, and guidance, in plain language, should be issued 12 weeks before the regulations take effect.
- Those being regulated should be made aware of their obligations, with law and best practice clearly distinguished.
- Those being regulated should be given the time and support to comply. It may be helpful to supply examples of methods of compliance.
- The consequences of non-compliance should be made clear.

Targeting

Regulation should be focused on the problem and minimise side effects.

- Regulations should focus on the problem and avoid a scattergun approach.
- Where appropriate, regulators should adopt a "goals-based" approach, with enforcers and those being regulated given flexibility in deciding how to meet clear, unambiguous targets.
- Guidance and support should be adapted to the needs of different groups.
- Enforcers should focus primarily on those whose activities give rise to the most serious risks.
- Regulations should be systematically reviewed to test whether they are still necessary and effective. If not, they should be modified or eliminated.

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Defining Risk

SOURCE: Skills for Health Research for Extending Professional Regulation Working Group

“Defining risk is very complex. In Ontario, Canada, they utilise the concept of the Controlled Act (Government of Ontario 1997) which is defined below:

A “controlled act” is any one of the following done with respect to an individual:

1. Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.
2. Performing a procedure on tissue below the dermis, below the surface of a mucous membrane, in or below the surface of the cornea, or in or below the surfaces of the teeth, including the scaling of teeth
3. Setting or casting a fracture of a bone or a dislocation of a joint.
4. Moving the joints of the spine beyond the individual’s usual physiological range of motion using a fast, low amplitude thrust.
5. Administering a substance by injection or inhalation.
6. Putting an instrument, hand or finger,
 - i. beyond the external ear canal,
 - ii. beyond the point in the nasal passages where they normally narrow,
 - iii. beyond the larynx,
 - iv. beyond the opening of the urethra,
 - v. beyond the labia majora,
 - vi. beyond the anal verge, or
 - vii. into an artificial opening into the body.
7. Applying or ordering the application of a form of energy prescribed by the regulations under this Act.

8. Prescribing, dispensing, selling or compounding a drug as defined in the Drug and Pharmacies Regulation Act, or supervising the part of a pharmacy where such drugs are kept.
9. Prescribing or dispensing, for vision or eye problems, subnormal vision devices, contact lenses or eye glasses other than simple magnifiers.
10. Prescribing a hearing aid for a hearing impaired person.
11. Fitting or dispensing a dental prosthesis, orthodontic or periodontal appliance or a device used inside the mouth to protect teeth from abnormal functioning.
12. Managing labour or conducting the delivery of a baby.
13. Allergy challenge testing of a kind in which a positive result of the test is a significant allergic response.
14. Treating by means of psychotherapy technique, delivered through a therapeutic relationship, an individual's serious disorder of thought, cognition, mood, emotional regulation, perception or memory that may seriously impair the individual's judgement, insight, behaviour, communication or social functioning.

This seems an appropriate definition of activities in relation to risk. However, in order to cover those who work with human tissue another clause needs to be added to make this fit for purpose within the UK healthcare context:

15. Testing, manipulating, storing or handling of human tissue to assist with the diagnosis or treatment of living individuals or the use of tissues from cadavers for similar outcomes"

Outline Assessment Process

