

**The future regulation of health and adult social care in England: A consultation on the framework for the registration of health and adult social care providers.
Response by the King's Fund.**

17 June 2008

Summary

We broadly welcome proposals for a single set of registration requirements in the context of a range of non-NHS providers offering care to NHS-funded patients and some specialist services being moved to community settings. We agree that it is services rather than organisations that ought to be registered, but there needs to be a clearer definition of what constitutes a 'service' and this ought to take account of the current shift towards organising services around care pathways and through clinical networks.

We strongly believe that practical questions of how compliance will be monitored ought to be considered alongside the initial design of the registration system; the value of the proposed system will depend critically on the enforcement strategy adopted, its costs and the benefits to be achieved.

There needs to be greater clarity about the purpose of including primary care providers in the system of registration before the design of that system can be established. It is currently unclear whether this proposal is about regulating new risks or rectifying existing shortfalls in quality. The relationship between this system and existing arrangements for quality assurance, such as professional regulation, the Quality and Outcomes Framework and primary care trust contracting arrangements, also needs to be spelt out in clear terms.

If primary care providers are to require registration, they ought to be brought into the system at the same time as all other providers. We disagree that requirements relating to healthcare-acquired infections ought to be introduced in advance of all other requirements; this is not based on an assessment of risk and would place a considerable burden on the new Care Quality Commission in the first year of its operation.

We propose to introduce a generic set of registration requirements (set out in regulations) for all providers offering services that are within scope. These requirements will be supplemented by compliance criteria, to be developed by the Care Quality Commission, that are specific to the type of activity. These will be consulted on at a later date. Do you agree with this approach? Do you have any comments?

We broadly welcome the proposal for a single set of registration requirements where the criteria for requiring registration relate to service types rather than organisational forms; we also welcome the fact that these requirements are consistent across both NHS and independent sector providers and primary and secondary care. Reform is necessary in the context of a range of non-NHS providers offering care to NHS-funded patients and the government's policy of shifting some diagnostic and specialist services into community settings. Patients should feel confident that the care they receive is safe irrespective of the care setting. It is also important that the burden of regulation should be consistent across potentially competing providers.

However, there is one higher order issue relating to the practicalities of monitoring compliance. The proposals for registration would increase significantly the number of organisations and the range of services that are regulated. The value of such a comprehensive system will depend critically on the enforcement strategy adopted, its costs and the benefits to be achieved. There is a significant risk that the new arrangements may not be sufficiently effective to justify the system's cost. We believe therefore that the practicalities of implementation are considered before the decision to go ahead with this form of registration is made. For example, a more detailed evaluation of the costs and benefits might suggest that registration should only be introduced on a highly selective basis. We do not believe that these practical considerations should be deferred until after the registration system has been designed.

Do you agree with our proposed list of regulated activities in Annex B to be included within the scope of registration?

Basing registration on services rather than organisations has the advantage of ensuring that the system assures similar levels of safety for patients irrespective of the setting in which they are treated; it also creates an even-handed approach for potentially competing providers. However, how 'services' are defined may require further thought. For example, the proposed list includes some system-wide services defined by the nature of patient need - for example, 'emergency and urgent care', or 'specialist mental health services' - but others that are defined by the specific service being delivered - such as 'diagnostic services'. Given the increasing emphasis in health policy on clinical networks and patient pathways, the former approach may be more appropriate.

Does the list of activities in Annex B appropriately capture the services, where people might be at risk of harm provided in primary care settings? In particular, do you agree with our proposal that ultimately all GP and primary dental services should be within the scope of registration? If not, what are your views?

There is a lack of clarity about whether the principal purpose of bringing primary care into the regulatory system is related to managing new risks or rectifying existing shortcomings in quality. The scope and requirements of the system will be different depending on which of these two approaches is prioritised.

It may be justified to focus initially on physical harm, but the system should be designed to deal with all potential quality shortfalls and so decisions about what is included should be made against all the standards set out and not just physical safety. If the main focus remains limited to physical harm, then greater care needs to be taken in defining the types of risks that are likely to arise.

The criteria for determining which services should be registered, listed in the main consultation document (Table 2), are based on whether activities have the potential to cause harm. Although primary care as currently practised is seen to pose a low risk to safety, the volume of patient contact with primary care services is such that the overall risks may be significant enough to justify regulation of primary care. Furthermore, as more complex services are going to be conducted in community settings, the safety of such services ought to be assured in the same way as if they were provided in a hospital.

Further work should be undertaken to develop a more detailed, evidence-based picture of the risks posed by different services, taking into account service volumes. It is not clear to us that GPwSI status, which signals only that a GP has received additional training, is a suitable proxy for risk. It violates the principle of registering services rather than organisation types; other GPs without this status and specialists providing community-based services may be delivering services that have an equivalent (or higher) level of risk, but under this system they would not be subject to the same regulation as GPwSI-approved practitioners. Furthermore, there are no grounds for relating risk of physical harm to complexity. Existing data shows that the main risks of physical harm from primary care arise from the management of medicines and failure to diagnose serious conditions. These risks are not discussed in the paper.

The partial impact assessment states that an additional aim of introducing registration into primary care is that ‘the current system of NHS primary care does not ensure a consistent level of safety and quality across the country, with poorer areas being overrepresented among the areas with lower and even insufficient levels of quality.’ While we welcome a commitment to rectifying inequalities in provision, a registration system introduced on this basis is at odds with the commitment to a service-orientated, risk-based approach. If the registration system is designed to assure or improve the quality of services, rather than just protect patients from harm, then how this system relates to existing systems of professional regulation, primary care trust requirements and the centrally managed Quality and Outcomes Framework needs to be set out more clearly to ensure that wasteful overlap of functions and duplication of regulatory requirements are avoided.

Are there any high-risk services not covered? If so, what are they?

On the basis of the criteria listed in Table 2 of the main document, it is not clear why optometry, pharmacy and complementary therapies should (at least in the first instance) be excluded from the list of services requiring registration.

Optometrists have the right to refer directly to specialists in cases of glaucoma and cataracts, which surely constitutes having the potential to ‘impact on other parts of the care pathway’.

The increasing role of pharmacists in management and prescribing of medicines clearly involves ‘the use of medication’.

Services in complementary medicine also involve the ‘use of medication’ and have the potential to ‘impact on other parts of the care pathway’. The Department of Health is working towards a system of statutory professional regulation for selected practitioners in this area, and the World Health Organization has recommended that governments should develop suitable regulatory systems for the practices of complementary medicine. It is therefore not clear why this area should be excluded as a special case.

Both pharmacy and complementary medicine are recognised parts of an effective cancer care plan; it’s not clear why some parts of such a care pathway should be regulated while others are excluded.

The criteria of registering those services with the potential to ‘impact on other parts of the care pathway’ would require registering NHS Direct, and the potential to ‘risk psychological harm’ should require the inclusion of counselling and all psychotherapy.

Have we determined the right situations in which to register a manager? If not, what do we need to change?

The proposal that registered managers are likely to be required in social care and independent health care providers is at odds with the principle guiding the rest of the registration system, namely, to register services on the basis of risk irrespective of their ownership or the service sector in which they operate. More consistent with this approach would be the identification of the particular characteristics of a service or care pathway that would warrant the requirement for a registered manager.

Are the areas covered by the registration requirements (set out in Annex A) the right ones to provide the assurance of the essential levels of safety and quality that we are aiming for? If not, are there any we need to add or take out?

We welcome the proposal that the physical environment of care will form one of the main standards. Once the high-level framework has been agreed we would be interested to hear how the more detailed work on individual standards is to be taken forward in the autumn and we would like, if possible, to contribute to this work.

What are your views on the transition arrangements for existing providers to enter the new registration system?

We agree that automatically transferring providers who are already registered with the Healthcare Commission or the Commission for Social Care Inspection is a sensible approach, so long as there are sufficiently robust processes to ensure ongoing compliance with the new registration requirements.

It is not clear why requirements relating to healthcare-acquired infections should be introduced in advance of the registration system as a whole. This area does not pose a proportionately greater risk than all other areas and insisting on an early implementation will put considerable pressure on the Care Quality Commission in its first year of operation.

When should services provided in primary care settings be required to register? Should we phase in registration?

As discussed above, we think that the basis on which part or all of primary care is brought into the system of registration requires further work. If as a result of this work it is decided that some or all primary care providers should require registration, then this ought to be implemented at the same time as registration for all other providers.

What are your views on the proposals for the registration of agencies who supply workers to other registered providers, under the 'Personal Care' and 'Nursing Care' activity topics?

As these organisations are not themselves providers of services, we believe they should be excluded from the registration system.