

Response to the Government Consultation: *Healthcare regulation: deciding when statutory regulation is appropriate*

March 2022

1. Introduction

- 1.1 The Professional Standards Authority for Health and Social Care ('the Authority') promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and social care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk
- 1.2 As part of our work we:
- Oversee the 10 health and care professional regulators and report annually to Parliament on their performance
 - Accredite registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
 - Conduct research and advise the four UK governments on improvements in regulation
 - Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General comments

- 2.1 We welcome this consultation and the Government's proposed approach to determining whether a group of health or social care workers should be regulated by law.
- 2.2 The plans set out in the consultation mirror our own thinking, rooted in the *Right-touch regulation* (RTR) principle of regulating only where it is necessary to protect the public from risk of harm. Our work on a methodology for assessing the risks of an occupation, *Right-touch assurance*, which is referenced in the consultation, builds on this principle.¹
- 2.3 At a time of accelerated change in the way that health and care services are delivered, it is right to ask whether the current scope of statutory professional regulation is protecting the public as effectively as possible. The powers for the Secretary of State and Scottish Ministers to bring new groups into professional regulation through secondary legislation are not new. However, the proposed extension of these powers to deregulation, and this accompanying consultation,

¹ Professional Standards Authority 2016, *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm*. Available at: [https://www.professionalstandards.org.uk/docs/default-source/publications/right-touch-assurance---a-methodology-for-assessing-and-assuring-occupational-risk-of-harm-\(october-2016\).pdf?sfvrsn=f21a7020_0](https://www.professionalstandards.org.uk/docs/default-source/publications/right-touch-assurance---a-methodology-for-assessing-and-assuring-occupational-risk-of-harm-(october-2016).pdf?sfvrsn=f21a7020_0)

are an opportunity to reconsider the scope of statutory regulation, and potentially to move to a model that is more agile and responsive.

- 2.4 We are pleased to see references in the consultation to alternative means of assurance, including the Authority's Accredited Registers (AR) programme. As we have stressed in our work on regulatory policy, statutory regulation is one of a range of possible means of protecting the public, which includes employer-led codes of practice, barring schemes and the AR programme.
- 2.5 Our feedback on the proposals relates primarily to the following areas:
- A comparison of the proposed criteria with those laid out in *Right-touch assurance*
 - How the Government plans to implement this approach and the current and future role of the Authority
 - Thoughts on approaching the question of deregulation.

3. The proposed criteria

- 3.1 The proposals in the consultation mirror much of the work the Authority has published on regulatory policy. *Right-touch regulation* recommends that regulation is proportionate to the risk of harm, and that regulatory policy is based on a qualitative and quantitative assessment of these risks. It stresses the importance of understanding the problem before the solution, and of basing policy on sound evidence of risk, rather than anecdotal information.
- 3.2 *Right-touch assurance (RTA)* is based on these principles and is a methodology for determining whether and how an occupation should be regulated. It involves an assessment of the intrinsic risk of the occupation by looking at the activities undertaken, the context in which professionals work, and the agency or vulnerability of the patients and service users they work with. A second stage looks at 'extrinsic' factors such as the size of the occupation, and the potential for unintended consequences of introducing regulatory measures, including workforce impacts.
- 3.3 We envisaged that where we were commissioned to carry out a right-touch assurance assessment, we would make recommendations to the Government on the best option for assurance, and that the ultimate decision would rest with Ministers and Parliament.

Question 1: Do you agree or disagree that a qualitative and quantitative analysis of the risk of harm to patients is the most important factor to consider when deciding whether to regulate a health or care profession?

Agree.

- 3.4 We support the proposed approach to these criteria, which has many similarities with the principles of *Right-touch regulation* and the methodology in *Right-touch assurance*, which were themselves based in part on the work of the *Better Regulation Executive*.

- 3.5 We therefore agree that decisions about whether to introduce statutory regulation should be based on:
- an assessment of risk to the public
 - both a qualitative and a quantitative assessment of risk
 - evidence of risk of harm.
- 3.6 We suggest that in order for this approach to be wholly consistent and effective, it may be helpful to establish an understanding of the level of unmanaged risk above which statutory regulation might be considered.

Question 2: Do you agree or disagree that proportionality, targeted regulation and consistency should also be considered in deciding whether to regulate a health or care profession?

Agree.

- 3.7 We support the view that regulation should be proportionate to risk of harm, and that alternatives to statutory regulation may be sufficient to respond to identified risks. In *Right-touch regulation*, we talk about using ‘the minimum regulatory force needed to achieve the desired result’, and the range of options for addressing risks sitting on a ‘continuum of assurance’.²
- 3.8 As the document stresses, policy in this area should be designed to target the risks identified and anticipate (and where relevant avoid) unintended consequences.
- 3.9 The principle that where possible new regulation should be coherent with existing regulatory mechanisms is sensible. It goes hand-in-hand with the RTR principle that new means of assurance should only be introduced once it has been established that existing means could not achieve the same result. We also agree that statutory regulation should be used neither to confer status and esteem, nor to support what is sometimes referred to as ‘professional protectionism’. The burdens and costs of statutory regulation are only justified by the protection it provides to the public.
- 3.10 As explained above, the RTA model recommends a two-stage process to separate the risk assessment from other important considerations. It is capable of identifying alternative means of managing identified risk, rather than simply asking the binary question of whether or not statutory regulation is needed. We suggest that the model proposed here lends itself to a similar approach.

4. How the Government plans to implement this approach

- 4.1 As explained above, we support the criteria set out in the document, and welcome the references to our work.

² Professional Standards Authority 2015, *Right-touch regulation*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=eaf77f20_20

- 4.2 We note however that following the public consultation further thinking will need to be done on how the process will work in practice. Areas where we would welcome greater clarity include, what would prompt an assessment using the criteria proposed in the document, and what would be expected of the Authority in the process.

What would prompt an assessment under the proposed criteria?

- 4.3 It is currently not clear how the Government intends to decide which groups should be put through the assessment, to support decisions on regulation or deregulation. If there is an appetite to make changes to the current scope of statutory regulation, we recommend that the Government prioritise bringing groups in, rather than removing them, as the primary driver should be to address any public protection gaps. Given this, our comments in the following paragraphs focus primarily on the process for bringing a group into, rather than out of, statutory regulation.
- 4.4 So how would the Government prioritise assessment of unregulated groups to maximise the public protection benefits of these policy proposals? A fair and transparent process may be needed, whereby not only practitioner groups, but also patient and service user representatives, and anyone privy to evidence of risk, including the Authority if appropriate (see below), could bring this evidence to the attention of the Government.
- 4.5 It would be important also for the Government to play a role in proactively considering whether there is a case for statutory regulation, where it is aware of evidence, for example through public inquiries. It should not always rely on concerns being brought to it, as not every practitioner group has an effective representative body, and certainly the burden should not always fall on patient or service user groups to raise concerns and make the case. The absence of a structured approach could mean that existing risks persist, despite the introduction of the policy outlined in the consultation.
- 4.6 There may be a place for an independent organisation, such as the Authority, with specific responsibility for determining where there appear to be regulatory gaps, and therefore where it might be most beneficial to consider the evidence for regulation (or another form of assurance) of a new group. This would effectively form a 'triage' stage ahead of full assessment of higher risk groups.

What would be expected of the Authority?

- 4.7 There are two main possible roles we foresee for the Authority:
- As a body with responsibility for carrying out the 'triage' stage referred to in paragraph 4.8 responsible for prioritising or identifying regulatory gaps, and recommending groups to be put through the in-depth risk assessment
 - As the body carrying out occupational risk assessments at the request of the Government, and consequently making recommendations for Government policy on who should be regulated and how (as is suggested in the consultation).
- 4.8 We see no issues with these two roles being carried out by the same organisation – indeed, it could be more efficient that way, as information

gathered as part of the triage exercise could form the starting point for a more in-depth risk assessment.

- 4.9 The consultation paper states, correctly, that the Authority can be commissioned to advise government on whether professions should be regulated or deregulated. This falls under a general power for the Secretary of State, or Ministers in the Devolved Administrations, to call on the Authority to advise on matters relating to professional regulation. As our legislation sets out, we do this for a fee, and cannot refuse any such request.
- 4.10 Alongside commissions, our business-as-usual work is funded primarily by the regulators we oversee under a statutory levy scheme. While the general functions of our legislation give us some latitude in how we can spend the levy funds, we do not consider that it should extend to in-depth risk assessments of unregulated groups, nor can it fund sustained levels of activity managing enquiries about who should and should not be regulated or carrying out a triage function.
- 4.11 Despite having previously expressed some support for giving the Authority a formal role in carrying out occupational risk assessments,³ the Government stops short of this in this consultation. Nonetheless, by virtue of our position in the sector, we are sometimes approached by groups who know of our RTA work and want to be regulated, or by stakeholder organisations who have views on whether there should be further assurance of unregulated groups. As a result, we have some understanding of the current unregulated landscape and where there could be gaps.
- 4.12 More importantly though, as part of our existing role accrediting registers, we can identify unmanaged risks linked to unregulated groups – particularly under our new Standard 1 assessment. In July 2021 we introduced a new ‘public interest test’ as part of our accreditation assessments for registers of unregulated roles. This allows us to consider whether the benefits of the practices outweigh the risks. It also provides a consistent source of data about risks of unregulated roles within the programme, broadly aligned to the criteria in our Right-touch assurance (RTA) tool.
- 4.13 The Authority is well placed to undertake both the risk assessment and the triage roles set out above, and would welcome any Government commissions along these lines. But we are a small, lean organisation. Should the Government expect the Authority to play anything more than an *ad hoc* role, we may need to consider a more sustainable funding and business planning model for this work. We would welcome further conversations with the Department of Health and Social Care on how this could be achieved.

³ In its report on its public consultation ‘Promoting professionalism, reforming regulation’, under *Question 1: ‘Do you agree that the PSA should take on the role of advising the UK Governments on which groups of healthcare professionals should be regulated?’* the Government stated: ‘The UK and Devolved Governments believe that the PSA is best placed to provide independent advice on which groups of healthcare professionals should be regulated.’ Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/820566/Promoting_professionalism_reforming_regulation_consultation_reponse.pdf

Managing conflicts of interest

- 4.14 We note that there may be concerns from stakeholders about a conflict of interest in the Authority undertaking either or both of these roles due to our current statutory role overseeing the statutory professional regulators and operating the Accredited Registers programme for practitioners not regulated by law.
- 4.15 There may be a view that it would be in the Authority's interests to recommend either statutory regulation or Accredited registration as a solution to the risks arising from an unregulated group. If a group is currently unregulated or unregistered, then in both scenarios this could lead to an increase in the number of practitioners who fall under a body which the Authority has oversight of and therefore may contribute either to the levy paid by the statutory professional regulators or the fee paid to the Authority for accreditation of a particular register. We note that both our oversight of the statutory regulators and the Accredited registers programme are run purely on a cost recovery basis.
- 4.16 Whilst we acknowledge this potential concern, we note that this is not referenced by the Government in the consultation document in relation to the Authority providing advice. In the Government response to the 2018 consultation, it is acknowledged that these issues were raised by some respondents, however the view of the UK Governments was still that the Authority was best placed to advise and that any potential conflict was mitigated by a transparent process and the final decision remaining with Ministers.⁴
- 4.17 It is also our view that this would not have any material impact on the Authority's ability to provide impartial, evidence-based advice. It is our position as oversight body for these two different groups of practitioners that makes us uniquely well placed to advise in this area. We have provided policy advice when commissioned by UK Governments at various points in the past and there has never been a concern raised about the ability of the Authority to advise in an impartial and independent manner.
- 4.18 If we were given a formal role in this area, we would of course ensure a clear separation between our different functions whilst utilising information gathered through them.

5. Thoughts on criteria for deregulation

- 5.1 We note that the Government has no plans to deregulate any currently regulated groups, and the statement in the consultation that this is not something for which there are many precedents around the world.
- 5.2 When we developed RTA, we considered primarily the scenario in which the assessment had been triggered due to a view that the group in question may require some additional means of assurance e.g. evidence of unmanaged risk. Although the model should also demonstrate if existing controls are sufficient to

⁴ Government response to 'Promoting professionalism, reforming regulation'. Available at: <https://www.gov.uk/government/consultations/promoting-professionalism-reforming-regulation>

manage risks, or potentially that these controls were having negative unintended consequences, it would be more difficult to use it to support decisions to remove these controls.

- 5.3 The difficulty with the use of any risk assessment model to support decisions to reduce the level of regulation is that the regulatory model in place is likely to mask the risks. This may not be insurmountable – there may be data from other jurisdictions where a similar profession is unregulated, or from other roles that undertake similar tasks which could be used to inform decisions. However, using this type of evidence may be likely to increase the risks of any decision to deregulate.
- 5.4 We therefore support the proposal to consider other safeguards, to mitigate the risks of removing a layer of assurance. As the consultation document acknowledges, Accredited Registers are one such option. We would add that they have the benefit, among other things, of fulfilling similar functions to statutory regulators, such as a complaints process and public registers, making for a smoother transition.

Question 3: Do you agree or disagree that the currently regulated professions continue to satisfy the criteria for regulation and should remain subject to statutory regulation?

Don't know.

- 5.5 We cannot comment on this in the absence of any robust risk-assessment, particularly given our above comments on the risks inherent in any decision to deregulate, and the difficulty of identifying and quantifying those risks. That said, we cannot see any strong case for deregulating any groups based on available information/evidence.

Question 4: Do you agree or disagree that currently unregulated professions should remain unregulated and not subject to statutory regulation?

Don't know.

- 5.6 As above, we do not have the evidence to make these sorts of judgements at this time.
- 5.7 We are however aware of some occupations or activities where regulatory gaps may be starting to appear, based primarily on information gathered through our AR programme, as well as knowledge of stakeholder views. These are social care occupations (England) and counselling and psychotherapy. We note also that some public inquiries and reviews have put forward arguments for regulation of NHS managers.
- 5.8 We suggest that these occupations might be considered higher priority for an occupational risk assessment of the type proposed in this consultation, with the important caveat that in the absence of a proper process, our attention may be drawn to groups somewhat arbitrarily, and that there are undoubtedly others.

- 5.9 We have recently commented separately on Government plans to introduce a licensing scheme for non-surgical cosmetic practice through an amendment to the Health and Care Bill.⁵

6. Further information

- 6.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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⁵ Authority responds to Government proposals to introduce a licensing scheme for non-surgical cosmetic treatments. Available at: <https://www.professionalstandards.org.uk/news-and-blog/latest-news/detail/2022/03/03/authority-responds-to-government-proposals-to-introduce-a-licensing-scheme-for-non-surgical-cosmetic-treatments>