



**REVIEW OF THE STANDARDS
OF GOOD REGULATION**
Summary of consultation responses

November 2017

Professional Standards Authority
for Health and Social Care

REVIEW OF STANDARDS OF GOOD REGULATION

SUMMARY OF CONSULTATION RESPONSES

1. Introduction

- 1.1 The consultation 'A review of the *Standards of Good Regulation*' closed on 12 September 2017.
- 1.2 A total of 31 responses were received; each of the nine health and care regulators responded as did 11 other organisations (representative and specialist education bodies) as well as 11 individuals, most of whom appeared to be health and care registrants. This report uses the term 'organisations' to refer to bodies that are not regulators, identifying whether they are representative bodies where this is relevant. A list of the bodies responding is attached at Annex A.
- 1.3 This paper sets out the general themes of the responses to the areas of the consultation, as well as any more general comments provided by those who responded.

2. What should the Standards cover?

Question 1(a): Should the Standards cover the regulators' performance in respect of Standards and guidance?

Question 1(b): What aspects of the work related to setting standards and guidance for registrants should the Standards focus on?

- 2.1 The regulators were in general agreement that the Standards should continue to cover the areas of standards and guidance. It was felt that the focus of our Standards in this area of the regulators' statutory functions should shift towards demonstrating how well their published standards and guidance are implemented, and the outcomes achieved by the regulators through this work. There was support for the areas covered in the current Standards and support for the inclusion by those regulators that mentioned them of standards for professionalism, openness and transparency
- 2.2 More than one regulator noted that there needed to be continued scope for individual regulators to be able to develop their standards and guidance in a way that best addressed the risks and aspirations of their professions. Other regulators also emphasised the need to be able to demonstrate patient involvement in the development of standards.
- 2.3 The organisations were equally supportive of the continued inclusion of standards and guidance. Their emphasis was on the ability of the regulator to ensure its standards and guidance were 'preventative', effectively disseminated, clearly expressed the expectations of the regulators and addressed the lack of awareness of them by some professionals.
- 2.4 More than one organisation emphasised collaborative work between regulators to indicate how the guidance of other bodies should be followed, or adopted jointly. This was of particular importance to those areas where registrants may be subject to more than one regulatory body. The organisations also stressed the need for standards and guidance to demonstrably reflect the expectations of patients, service users and carers.

- 2.5 The responses we received from individuals were supportive of the continued focus on standards and guidance. Several registrants expressed concerns that a negative or risk averse approach to standards and guidance leads to 'defensive practice' where few practitioners wish to take on risky or innovative approaches for fear of how their actions may be interpreted.

Question 2a): Should the Standards cover the regulators' performance in education and training as set out in these proposals?

Question 2b): What aspects of the work related to education and training should the Standards focus on?

- 2.6 The regulators agreed that education is a key area for the Standards to cover. In general, there was support for the current areas of scrutiny, if not for the way in which these Standards are currently assessed, which some regulators felt was too process driven and not sufficiently 'outcome focused'.
- 2.7 Where the regulators did address the question on learning outcomes and safety, there was agreement that these were the appropriate focus. One went further, advocating that the outcomes measured by the Standards should also include ensuring that education programmes can meet a wide range of requirements beyond those concerned with registration. These included service and workforce needs and aspirational performance levels, knowledge and behaviours.
- 2.8 There was no agreement as to whether the Standards in this area should be broadened to include 'fairness and equality'. Whilst one welcomed this proposal another questioned if intervention in this area was a 'legitimate role'.
- 2.9 Other repeated themes included the need for the approach in this area to be proportionate in relation to risk and to acknowledge the challenges of different educational environments for each regulator.
- 2.10 The organisations who responded expressed a strong desire to see education remain as a key focus of the Standards and urged a strongly outcome focussed approach.
- 2.11 One organisation advocated an approach that was both 'agile' and 'proactive'. Whilst recognising the significant variations in the challenges faced by the regulators it urged that collaboration could stretch to joint quality assurance which could reduce the overall impact of regulatory oversight on the universities.
- 2.12 Other comments included the view that the Standards should assess whether learning from fitness to practise outcomes has been moved 'upstream' to education. Another respondent was keen that the Standards should ensure the regulators focus on ensuring that education programmes are at the forefront of the implementation of new technology. One of the representative bodies drew attention to the need for the knowledge of the regulator's inspectors to be demonstrably up to date.
- 2.13 The responses from individuals were mostly supportive of the continued focus of the Standards on education. One dissenting voice pointed out that universities are subject to the scrutiny of the Royal Colleges and that duplication of effort should be avoided.
- 2.14 More than one registrant respondent was keen to emphasise the need for the regulators to have the correct balance between theoretical and practical skills. A strong concern

was raised that dentists who are deemed 'competent' to enter practice have little or no experience of some 'standard' procedures.

Question 3a): Should the Standards cover the design and delivery of continuing fitness to practise schemes?

Question 3b): What aspects to the design and delivery of continuing fitness to practise schemes should the Standards include?

- 2.15 The regulators were unanimous that the Standards should consider continuing fitness to practise schemes and were also generally of the opinion that the scope of the Standards should be developed to consider more fully whether the schemes are meeting their aims.
- 2.16 Regulators broadly agreed that how well risks are assessed and addressed through their schemes was an appropriate measure. There was some concern about performance measurement with it being noted that many of these schemes are relatively new. It was proposed by one regulator that rather than a binary 'pass' or 'fail' the effectiveness of these schemes should be considered through a model assessing 'maturity'.
- 2.17 It was also noted that it is challenging for regulators to measure how these schemes impact upon registrant skills and behaviour. An option proposed by one regulator was to consider how far the regulators deliver schemes that either 'verify' practice or lead to changes.
- 2.18 The representative bodies that addressed this question were anxious that continuing fitness to practise should not be a 'one-size fits all' method of 'policing' registrants. They were keen that definitions of continuing professional development (CPD) were flexible enough to reflect the registrant's actual sphere of practice. In this area, particularly, they requested the opportunity to collaborate with the regulators on developing schemes that work to enhance and support professional potential, such as through peer-to-peer schemes.
- 2.19 The responses of individuals stressed that this was an area particularly suited to an outcome-based standard with the aim of ensuring the regulator addresses areas of practice found to need attention.

Question 4a): Should the Standards cover the delivery of the registration function as set out in these proposals?

Question 4b): What aspects of the registration function should the Standards focus on?

- 2.20 The regulators agreed that registration should continue to be a primary focus of the Standards. In respect of the proposals concerning accuracy and accessibility of the register, it was felt that this was already reasonably well-covered. Several of the regulators pointed to what they considered repetitions within Standards Three and Four for registration which they felt could be rationalised.
- 2.21 With regard to the registration process, it was suggested that there should be more prominent consideration of the fairness of decision-making in line with the Standards relating to fairness within fitness to practise.
- 2.22 The organisations that responded were also in favour of retaining the current approach to registration. They shared concerns about fairness, for example, that requirements

should be targeted at an appropriate level for applicants and not inadvertently disadvantage them.

- 2.23 Other organisations drew attention to concerns about inadvertent lapses from the register and how clumsy processes for addressing these disproportionately punished registrants. It was also suggested that the register should be capable of providing useful information that highlighted potentially unfair barriers to entry, such as for international candidates.
- 2.24 A number of possible enhancements were considered, such as the addition of information on qualifications and specialities. However, some doubted the proportionality of adding further information and raised concerns about the protection of the registrant's personal information.
- 2.25 One body had concerns about the management of CPD deadlines, with employers taking on staff who appeared to be compliant, but who subsequently lapsed their registration soon after. This body felt that the Standards should concern themselves with the proactive and timely management of this issue.
- 2.26 Individuals who responded agreed that registration should be a continued focus of the Standards. Concerns were raised that the process should not deny the public access to good registrants and that unnecessary obstacles should not be placed in the way.

Question 5a): Should the Authority continue to monitor the regulators' activities to prevent illegal or unregistered practice and what level of priority should be given to this work?

Question 5b): If yes, do you agree that the Standard(s) should be limited to the areas we have identified above?

Question 5c): In general, what aspects of the work related to the prevention of illegal or unregistered practice should the Standards focus on?

- 2.27 There was widespread agreement that activity to prevent illegal or unregistered practice should continue to be a focus for the Standards. While stressing the importance of outcome-based approaches to assessing performance, several were keen to point out the importance of measuring appropriate outcomes to measure. Regulators did not wish to be judged on the success of prosecutions arguing that this was not an outcome within their control.
- 2.28 The regulators suggested that the Standards should address:
- the effectiveness and timeliness of the triage response to concerns they receive
 - the quality of risk assessment applied
 - the proportionality of the action taken
 - proactive approaches, such as the through the work the regulators can do with their networks to raise public awareness of the potential for harm and
 - the effectiveness of their collaboration with other statutory bodies.
- 2.29 The view that concerns about illegal practice often stemmed from a desire to protect business interests was roundly rejected. The regulators were clear that their actions stemmed from their duties to protect the public and that the Standards should address

performance on this basis. It was also argued that if there was concern that there was the potential for business interests to drive this agenda that this was a reason for continued oversight by the Authority rather than against it.

- 2.30 The organisations agreed that it was vital that the work to prevent illegal practice continued to be considered through the Standards. The contention that this was not a matter of concern for the NHS was rejected and it was argued by one organisation that this was clearly an area where the regulators could demonstrate their role in maintaining confidence in a profession.
- 2.31 The individuals who responded to the consultation are mostly registrants and therefore were understandably very concerned about this area of the Standards. Some expressed understanding of their regulator's difficult position in addressing many instances of illegal practice subsequently dealt with leniently by the courts. Emphasis on the ability of the regulator to evidence effective work in collaboration with statutory bodies was urged.

Question 6a): Should the Standards cover fitness to practise?

Question 6b): Which aspects of the activities related to fitness to practise should the Standards focus on?

- 2.32 All the regulators considered that fitness to practise continues to require the most substantial scrutiny of any area through the Standards. It was also widely acknowledged that this is the area of greatest interest to the public.
- 2.33 A common theme amongst the regulators was a concern about the emphasis upon efficiency and timeliness. They preferred a qualitative appraisal of their management of risk and of the quality and fairness of the process, including customer service. Regulators emphasised that where quantitative measures were employed these needed to take account of how far matters were within the regulator's control.
- 2.34 Regulators strongly favoured an outcome based approach, although the outcomes were not always clearly defined in the responses. One tangible proposal from more than one regulator was to look at how well the fitness to practise process drives learning and contributes to reducing misconduct and poor performance. This was echoed by the desire of another regulator to tangibly move its activities 'upstream'. The concentration of resources towards fitness to practise was thought to work against this proactive aim.
- 2.35 Most regulators therefore felt there was room for significant rationalisation of the Standards in this area, particularly from those favouring a principles-based approach.
- 2.36 Organisations also unanimously saw fitness to practise as a central concern of the Standards. Representative bodies highlighted their members' experience of the process. In general, these bodies advocated the centrality of fairness and proportionality as guiding principles of the Standards.
- 2.37 There was criticism of the current approach as encouraging over-zealous prosecution, with the concentration on timescales leading to insufficient investigation of what took place once the threshold for a 'case to answer' had been reached. This, it is claimed, discourages open-minded regulatory investigation and disproportionately emphasises the failings of individuals against wider systemic failures, leaving the public unprotected. Under-investigation, it was contended by one respondent, also allows some fitness to practise cases to be driven further than they should by the vendettas of employers and the public.

- 2.38 The organisations echoed the language of the regulators in seeking an approach that worked to drive the response ‘upstream’ i.e. away from hearings towards methods such as consensual disposal and to preventative work in the areas of education and standards and guidance. One called for greater prominence in the Standards for evidence of reasonable and risk-based re-referral to local resolution.
- 2.39 The organisations also emphasised that registrant welfare required greater consideration through the Standards. They urged that recognising registrant vulnerability should be extended beyond health cases to consider the effect of the process upon registrants who may yet be found blameless. There was concern about cases where the complainant fails to engage, but the case is unnecessarily held open.

Question 7a): Should the Standards cover the governance activities of the regulators?

Question 7b): Which aspects of the activities related to governance should the Standards focus on?

Question 7c): Do you have other comments on our approach to governance?

- 2.40 The proposal to incorporate governance activities into the Standards split the regulators and was both welcomed and strongly objected to in equal measure. Nevertheless, there were similarities in outlook. All agreed that good governance was important and should be evidenced. Most felt that it could and should be addressed at least within the narrative of the performance review, if not through a specific Standard.
- 2.41 Additionally, the role of the Authority in delineating the characteristics of good governance was welcomed as was the chance to learn from each other’s successes and failures. One regulator proposed that the Corporate and Charity Governance Codes would provide stretching principles for the consideration of governance and for the Standards in general.
- 2.42 Those regulators who favoured introducing a Standard for governance felt that in this area a ‘pass/fail’ approach was inappropriate and could have the effect of punishing organisations that were transparent about their failures compared to those that were opaque about theirs. It was suggested that a useful criterion might be an evaluation of the extent to which decisions of the regulator’s council are made in the open. Others wished the scope of any proposed Standard to be limited with an emphasis on the council’s management of risk.
- 2.43 Those against the introduction of a governance Standard noted that the Council for Healthcare Regulatory Excellence (the former name for the Authority) had previously had a Standard relating to governance. It was argued that the reasons for its removal (that governance is not an outcome of regulatory activity and that failures of governance would be identified by focusing on outcomes) remained sound. Another respondent felt that the introduction of a new Standard would be an ‘unnecessary and disproportionate burden’ presenting considerable scope for ‘disagreement and duplication’. It questioned the Authority’s ability to reach ‘objective judgements’ in this area.
- 2.44 A further point was raised by one respondent that the performance measurement of governance could alter how the annual performance review is received by the councils of the regulators themselves. It was argued that their position, as recipients of the review

ready to use it to improve performance, would shift to being subjects of it, encouraging a more defensive culture.

2.45 The organisations who responded were largely in favour of governance being introduced into the Standards. However, there was scepticism about the Authority's ability to use a new Standard to bring about a change in behaviour.

2.46 One concern was the proposition that councils should be able to show their demonstrable independence from special interests. One representative body that felt its regulator should take more account of both its views, and those of its registrants, had reservations about this point.

2.47 There was some support expressed for the elements proposed in the consultation document,

- The demonstrable independence of the regulator from registrants, government and other special interests
- The transparency of its processes (many of which can be looked at as part of our review of individual aspects of the regulator's work)
- The quality and adequacy of processes for providing the Council with information to enable it to monitor performance and compliance. The effectiveness of the Council in addressing that information
- And for the possibility of triggering, in exceptional circumstances, a governance review.

One respondent organisation suggested that it was not always clear to what extent a council did understand the performance of the regulator. Any Standard should explore how the council has held the executive to account and exactly what it achieved.

2.48 Individuals responding were in favour of a new standard for governance to address their concerns about the efficiency and effectiveness of the regulators. They were concerned, however, that the Authority would not be able to exert enough influence on particular concerns such as the effective use of resources and the level of registrant retention fees.

Question 8) Should we introduce a new Standard that requires regulators to have mechanisms that enable them to gather information from students and tutors about compliance with minimum standards of safety?

2.49 The regulators agreed that this was an important concern. However, it was questioned whether a wholly new Standard was required and whether the issue could not be covered within the current first *Standard for education and training* or even within *Standards Two* and *Three*.

2.50 While giving a cautious welcome, one regulator noted that the requirement might equally be applied beyond tutors and students to registrants in training and their trainers. Gathering feedback outside of the NHS, for instance where students are on placement outside of their learning establishment or where education is provided by the independent sector might prove complex. It also noted that the vast majority of students are not subject to their future regulatory bodies and so their commitment to provide feedback to the regulator was unclear.

- 2.51 Several regulators highlighted the importance of moving beyond data capture to establishing how it should respond effectively to concerns. There was general agreement that this proposal needed further thought and those regulators who strongly favoured a 'principles'-based approach did not address the question at all in line with their wish not to agree to further new standards in the current format.
- 2.52 The response of organisations to this proposal was mixed, with several suggesting that this was either wholly unnecessary or did not require a separate standard.
- 2.53 Those in favour also emphasised the good management of concerns raised and the importance of applying the activity to those areas, such as practice placements, that may present risks for students, not easily managed by their education establishments.
- 2.54 The response of individuals was equally mixed with some pointing to the existence of a current student survey and the potential of a new requirement to simply produce more bureaucracy.

Question 9) Should we adjust the wording of the Standards to focus on regulators' work in ensuring the robustness of learning assessments?

- 2.55 While there was general agreement amongst the regulators that the Standards should consider the regulators work to ensure the robustness of learning assessments, there was no support for the proposition in the consultation document that this should be the primary focus of the Standards in respect of education.
- 2.56 Several regulators expressed concerns that this focus was too narrow and contended that learning assessments were only one part of much wider expectations of how courses prepared students for registration. In particular, aspirational qualities such as professionalism and patient-centred care are outcomes and behaviours that the regulators did not consider could be delegated to educational regulators. There was a repeated concern that educational regulators would be unable to fully grasp the professional context. It was proposed that continued oversight of wider course management was integral to delivering high quality outcomes.
- 2.57 Moreover, the evidential basis for the proposal (arising from *Regulation rethought*) was questioned. Regulators concluded that this was an area where further research and discussion was required.
- 2.58 Organisations and individuals also had a mixed response to this question. It was noted that registrants are often not as aware of their regulators' guidance as they should be, despite having successfully qualified, suggesting a need for a broader overview from the regulator.

Question 10) Should the Standard covering continuing fitness to practise be expanded to cover the efficacy of the scheme and the regulators' processes for using learning from the scheme to inform other functions?

- 2.59 There was general agreement that the Standard should cover the effectiveness of schemes and how learning is used to improve the regulators performance in other areas. However, there were significant caveats, particularly concerning how performance would be measured.

- 2.60 Regulators noted that almost all have schemes at different stages of implementation or maturity and were concerned as to how the performance of one could be reasonably compared against another regulator. Moreover, it was noted that measuring the impact of a single scheme against other regulatory outcomes would be a significant challenge. The regulators cautioned that any adoption of this measure into the standard needed to be proportionate and not narrow regulators into choosing 'one size fits all' options.
- 2.61 Organisations generally agreed that this Standard should be expanded to consider how learning is used and work to move regulator activity 'upstream'. Some were also cautious about assuming that the continuing fitness to practise schemes have impacts that are yet to be established through research, such as improving clinical practice.
- 2.62 Most individuals were in favour of the proposal and wanted this aspect of activity to be dynamic, for example by sharing learning with registrants through regular briefings.

Question 11) Should we introduce a Standard that covers the portion of the fitness to practise process between the IC/case examiner decision and the final panel?

- 2.63 The regulators had mixed views about this proposal. Several acknowledged that this was an area of concern for the Authority and a major theme for learning points arising from *Section 29* reviews. However, few felt this required a Standard of its own and several suggested that the current Standard Eight for fitness to practise¹ could easily be modified to accommodate further concerns about this part of the process.
- 2.64 Concerns were also raised about how an individual standard would be measured and that this might necessarily be too process driven and less 'right touch'. It was felt by some that there was therefore simply not enough information for them to answer definitively.
- 2.65 Other regulators who had ruled out any expansion of the existing Standards in their response did not address the matter and another suggested, that as the number of decisions appealable by the Authority was small, that this did not indicate a significant problem with the under prosecution of cases requiring a new or modified standard.
- 2.66 Most organisations were in favour of the proposal, but with a significantly altered emphasis. Several organisations questioned the Authority's approach in limiting the concern to 'under-prosecution' rather than a concern that adequate information was available to decision makers to reach decisions on a sound evidential basis. There was a concern expressed that a focus on 'under-prosecution' places pressure upon the regulator to add unnecessary charges, generally of 'dishonesty'.

Question 12) Should we introduce a Standard covering the operation of consensual mechanisms for disposal and the appropriateness of their outcomes?

- 2.67 There was general agreement amongst the regulators that their consensual fitness to practise mechanisms should feature within the Standards. It was noted that these mechanisms are now a key activity for regulators and that a Standard could assist the public to feel confident that these were working effectively to safeguard them.

¹ All decisions at every stage of the process are well reasoned, consistent, protect the public and maintain confidence in the profession.

- 2.68 There were concerns about how the differences in approach between regulators may be judged. Several regulators also felt that a standard of its own was unnecessary and that it could be incorporated into Standard Eight for fitness to practise.
- 2.69 One regulator was unsure of the necessity of an explicit standard when the issue was already scrutinised under our *Section 29* procedure.
- 2.70 Registrant representative bodies were highly in favour of these approaches and while they agreed that it was an area of activity that should fall under the Authority's scrutiny, they cautioned against any approach that may lead regulators to be more risk averse and avoid using these methods of disposal.

Question 13) Should we introduce Standards covering equality, diversity and fairness?

- 2.71 While the regulators were split as to whether there should be a new Standard in this area, most agreed that this was a fundamental area of activity. Those who favoured the introduction of a Standard supported the two performance indicators suggested in the consultation paper; to understand registrant diversity and the barriers that disadvantage people with protected characteristics, but also an acknowledgement that there may be a requirement for other indicators, for example that relate to their approach to the public.
- 2.72 There was concern about how performance would be measured. Some raised the difficulty of obtaining reliable information about individuals and wanted further exploration and sharing of what good practice would look like. Others noted the regulators' current equality duties under the law and cautioned against both repetition and the development of a Standard without careful consideration of the legal framework.
- 2.73 Those who did not wish to see a separate Standard did expect to have to evidence their approach as being 'woven into and through' all other areas of their activity. There was also the idea put forward that much of the work in this area could be considered under the theme of 'fairness'.
- 2.74 Representative bodies supported the proposal and highlighted the over-representation of Black and Minority Ethnic (BME) registrants within the FTP process as a key issue for the standard to consider. This was the subject of a lengthy submission from one respondent outlining the evidence base for such concerns within the NHS and proposing a number of strategies to counter discriminatory and disproportionate referrals of BME staff especially where systemic failures are suspected.
- 2.75 Another organisation highlighted inadvertent discrimination through the regulators' processes where a disabled registrant, who is unwell but expected to return to work, is denied registration on health grounds and thereby loses employment on the basis of not being registered.

Question 14) Do you agree with our proposals to rationalise the Standards in the areas we have suggested?

Question 15) Are there any other areas where you think the Standards could be rationalised or simplified?

- 2.76 Regulators welcomed the prospect of rationalising the *Standards* and agreed that the areas of *Standards and Guidance* and those relating to accessibility of information were

areas where this was possible. They felt that there was considerable room for rationalisation within other standards, especially fitness to practise.

- 2.77 There was a concern raised that rationalising the *Standards* would not necessarily ensure that they were proportionate. One broad standard could be as equally demanding to address as two framed more narrowly. Opportunities needed to be found to eliminate unnecessary or unworkable areas of scrutiny. It was noted, for example, that Standard Four for registration is a requirement to ensure 'Employers are aware...' which involves a judgement on the knowledge of others rather than the regulator.
- 2.78 As they had stated previously, some regulators favouring a principles-based approach did not wish to comment on the rationalisation of the Standards in the current format.
- 2.79 Individuals and organisations cautiously welcomed the proposals, with membership bodies keen to see more detail to ensure that key accountabilities are not lost.

Question 16) Do you think our Standards should specifically include consideration of the information governance arrangements of the regulators?

- 2.80 Only two of the regulators were in favour of the inclusion of information governance within the Standards. The others all considered that their activities in this area are covered by the 'well established and effective oversight' of the Information Commissioner's Office (ICO).
- 2.81 Moreover, it was noted that accountability in this area of public bodies is to be enhanced when the *General Data Protection Regulation* comes into force in May 2018. The concern was widely raised that further scrutiny by the Authority risked unnecessary duplication of effort.
- 2.82 The regulators who did wish to see the Standards continue to consider information governance continue noted that the sole focus upon the fitness to practise process of the current standard was irrational and that it should cover all functions. There was also a concern that the current approach based on breaches of data protection regulations punishes candour rather than addresses effective action taken.
- 2.83 The response of organisations and individuals was more mixed. In general, there was a view that the Authority should understand the regulator's performance in this area. One suggestion was that the Authority could seek an MOU with the ICO to ensure that it is informed about any breach by the regulators or other regulatory action taken.

3. How the Standards are presented: two options

Question 17) Do you agree with our assessment of the advantages and disadvantages of the current approach? Are there any considerations we should take into account?

Question 18) Do you agree with our assessment of the advantages and disadvantages of the principles-based approach? Are there any considerations we should take into account?

- 3.1 In general, the regulators agreed with the consultation paper's analysis of the current approach. It was considered that this approach does clearly identify the scope of the performance review and provides certainty and continuity for both regulators and the public.

- 3.2 It was generally felt that adaptations or revisions to this model would be relatively easy to make. However, there were concerns that the revisions would be likely to add to the coverage of the Standards rather than narrow the focus. One regulator wrote that the Authority's proposals to enhance this model would be 'restrictive to good regulation, stifle innovation...and likely demand additional resource'.
- 3.3 It was also felt that the current approach is not always sufficiently flexible to take into account differences between the ways the regulators have to operate and several criticised what they perceived as a focus on process rather than good outcomes.
- 3.4 There was greater disagreement over the assessment of the advantages of the principles-based approach. Some agreed this methodology has the potential to be less process-driven and take better account of the differences in the regulators approaches. Others were not convinced that this was any more likely than in the current model.
- 3.5 There was concern that it could prove hard through this model to be fair and consistent, for example that judging whether the response of a regulator to any given issue or area of work was 'proportionate' may be open to dispute. There was also disagreement that duplication would necessarily be avoided through a principles-based approach.
- 3.6 A significant number of the regulators disagreed with the implication that the choice between the methods was a binary one. Around half considered that there was scope to develop a hybrid model that built upon the existing Standards to cover 'core' activities with a set of overarching principles-based standards overlaid. This would allow specific and measurable activities to be defined without neglecting a focus on outcomes and positive behaviours.
- 3.7 Organisations and individuals expressed concern that a move to a principles-based approach may risk the clarity offered by the current approach. A view was expressed that it may not be a good time for change ahead of proposed regulatory reform. However, one organisation was hopeful that a principles-based approach could help regulators build more flexible approaches to registrants, less based upon fear of non-compliance.
- 3.8 The view that a mixed approach was possible was aired on several occasions with a stark choice between the two labelled by one body as a 'false dichotomy'.

Question 19) Do you think that the Authority should use the principles in *Right-touch regulation* as the underlying concepts for its assessment of regulators' performance?

- Proportionality: regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised
- Consistency: rules and standards must be joined up and implemented fairly
- Targeted: regulation should be focused on the problem, and minimise side effects
- Transparency: regulators should be open, and keep regulations simple and user-friendly
- Accountability: regulators must be able to justify decisions, and be subject to public scrutiny
- Agility: regulation must look forward and be able to adapt to anticipate change.

20) Should the Authority add the principles of Fairness and Efficiency?

- 3.9 The regulators, bar two who did not explicitly answer, were in favour of utilising the principles (listed above) in the assessment of the regulators performance, should a

principles-based approach be favoured. One regulator wrote that the *Standards* should not be considered in isolation from the vision for regulation set out in *Right-touch regulation*.

- 3.10 There were caveats expressed, in particular that ‘consistency’ should not stifle innovation and that the constraints of each regulator’s legislative framework must be recognised when ‘agility’ is considered.
- 3.11 Several regulators made the point that the Authority should revisit its engagement with the regulators if attempting to utilise these concepts in the performance review process. It was claimed that more interaction between the Authority and the regulators would be required to understand their performance within a principles-based format.
- 3.12 Respondents were also asked to consider whether ‘fairness and efficiency’ were suitable concepts to be used in assessment. All bar one who responded agreed that ‘fairness’, which already appears within the *Standards*, should be used, but there were mixed feelings about ‘efficiency’, with one regulator commenting that this was a matter for its board alone to consider.
- 3.13 One regulator had a different vision urging a similar approach to the CQC’s ‘five key questions’ with their supporting ‘lines of key enquiry’.² It was not clear if this regulator meant that the approach should be similar, utilising right-touch concepts within this type of framework, or if the Authority should adopt the concepts utilised by the CQC.
- 3.14 The views of organisations and individuals were in accordance with most of the regulators. Almost all agreed that ‘right-touch’ principles should be employed along with the concept of fairness. Again, there was support for ‘efficiency’, particularly from those concerned that registrant fees should be used wisely and without unnecessary inflation.

Question 21) Are there other principles that should be added or different ways of expressing the concepts which might suit our performance review better?

- 3.15 There was a limited response to this question, possibly because the consultation presented many other opportunities to discuss the model the regulators wished to see. However, several themes featured often; that the principles employed should,
 - be outcome-focused
 - drive good practice
 - Be customer-focused
 - demonstrate collaboration with other bodies
 - be proactive, judged on the extent regulatory impact is driven ‘upstream’, for example from fitness to practise to continual professional development
 - recognise the ‘maturity’ of the regulator’s work, how well implemented, reviewed and sophisticated the regulator’s approach is.

Another regulator urged focus upon specific problems with the Authority articulating what ‘good’ looks like in advance.

- 3.14 Amongst the comments made by organisations and individuals, one professional body called for a principle that emphasised the regulator’s statutory objective to protect the public by demonstrating its learning from events. An individual also called for regulators to be able to demonstrate corporate responsibility had been taken for their ‘failures’.

² <http://www.cqc.org.uk/what-we-do/how-we-do-our-job/five-key-questions-we-ask>

Question 22) Have you any initial comments on the draft wording used in the example (Annex B)?

- 3.16 This question was generally not answered, or not answered fully, with a small number of exceptions. One regulator described it as 'consistent' and another raised a concern about the use of the word 'patients' universally rather than 'patients and service users'. It was noted that additional guidance would be required to narrow down to how the expression of the principles would lead to a judgement on the work of a regulator.
- 3.17 One body replied extensively to this question, in general to promote consideration of the potentially disproportionate and damaging effects of regulatory activity upon registrants. It was keen the *Standards* promoted thorough investigation of events by the regulator so that an individual's conduct can be addressed in the light of systemic failures.

Question 23) Do you have any observations about difficulties that may arise for regulators or the Authority in gathering information and evidence to operate the performance review under a principles-based approach?

- 3.18 Several of the regulators noted that with principles-based approach there may be less clarity about what activity belongs within each Standard. One regulator felt this meant that the outcome of the performance review could be subject to greater challenge.
- 3.19 It was proposed by one respondent that this would require the Authority to provide detailed guidance on how we intend to measure each principle. This regulator proposed that the Authority, if it adapts this model, should consider publishing 'decision-maker's guidance'. However, it also noted that a prescriptive approach may necessarily lead to less flexibility as to how to meet the *Standards*.
- 3.20 A concern was expressed widely about the possibility of an increased burden on the regulators to produce evidence, with a potential for duplication. Two of the regulators in favour of this approach advocated the use by the Authority of independent sources, such as independent audits, that may contribute to an efficient approach.
- 3.21 One of the respondent organisations echoed the opinion that a wide range of inputs should be drawn upon, suggesting that the Authority reviews which stakeholders it will need to approach for supporting evidence. Another explicit proposal was to use information drawn from surveys of registrants and stakeholders as a way of ensuring 'third party' confidence. Another organisation raised its concern that too much flexibility afforded to the regulators about the evidence required could lead to issues of concern being hidden.

Question 24) Do you think the Authority should adopt the first or second option?

- 3.22 There was no general agreement amongst the regulators as to which approach to adopt. Whilst three regulators were strongly in favour of moving to a principles-based approach the other six had varying degrees of reservation, with three preferring no change at all. The three regulators proposed a hybrid version of the two options, to maintain a foundation of core standards aligned to regulatory functions overlaid by broader principle-based standards.
- 3.23 Reasons given for this third approach included a wish to avoid the uncertainty of wholesale change, to allow direct comparison with previous years to continue, but also to

incorporate some aspects of the principles-based approach and thereby establish a more outcome-focused approach.

- 3.24 The regulators who favoured the principles-based approach argued that a shift from concentrating on process and quantitative data towards one based on desirable behaviours and outcomes would allow regulators to be proactive, innovative and flexible. More than one urged the Authority to outline the characteristics of 'good outcomes' and 'good practice' and embed these in the Standards to drive success. Between them they stressed that this approach alone was proportionate and 'right-touch'. It may be worth noting that this model was the preference of several of the larger regulators
- 3.25 Those regulators who wished to retain the current model generally did not object to the incorporation of principles and 'behaviours' to guide and shape their response. Overall, their concerns were of practicality, fairness and consistency. One regulator supporting the current model stressed the importance of retaining some structured and consistent measures of performance to ensure that the public is clear how the regulators have performed in key areas.
- 3.26 Not for the first time in the consultation it was noted that the detail of what the Authority decided to measure and how was of equal importance to the effectiveness of the Standards as the overarching approach.
- 3.27 The other organisations and individuals echoed the response of the regulators inasmuch as there was also support to be found for both options and for a hybrid approach. Two large representative bodies shared concerns about a move to a principles-based approach at this time favouring the current 'clarity' and 'transparency'. However, another large representative body urged change to the new approach to counter the 'rigid implementation' of regulation upon its profession.

4. Measurement

Question 25) Do you think that the Authority should continue with its 'met/not met' approach? If not, what other approach would you prefer?

Question 26) Are there other ways of reporting on performance that the Authority should consider?

- 4.1 The consultation paper recognised concerns that the 'met/not met' approach may be a blunt tool with which to measure performance. It proposed two approaches for discussion; a purely narrative review which does not address if the Standard was met or not, and a more nuanced one to grade performance as follows:
- The regulator has met the Standard
 - The regulator has met the Standard with concerns which it is/is not addressing but there is insufficient evidence to say that the Standard is not met
 - The regulator has not met the Standard and is/is not addressing the concerns.
- 4.2 The responses of the regulators were mixed. Four regulators supported the proposal for a more nuanced performance rating as outlined in the consultation, with one stressing that this was for reasons of clarity. One suggested that rather than meeting the Standard, the measure should be whether the regulator was 'protecting the public' and if it was 'innovating', 'requiring improvement' or 'inadequate'. Another regulator suggested that within a principles-based approach it might be better to describe this as a 'consistent' or

'inconsistent' application of the principles and that the rating should also indicate if this 'application' was improving or getting worse.

- 4.3 Two regulators supported the proposal for a purely narrative approach, one disagreeing with the contention in the consultation that a consideration of maturity/capacity would not assist public understanding of performance. One of those that did not support a purely narrative approach stressed the importance of the performance review being able to provide an 'easily digested snapshot' for stakeholders.
- 4.4 Two other regulators had wholly different approaches they wished to propose,
 - to copy the OFSTED type model with the regulator receiving one overall grading, with a series of sub-gradings for functions, but not a grading for each of the Standards,
 - to adopt the CQC model utilising a sliding scale to assess performance based upon an expectation of what 'good' is.³
- 4.5 One final regulator did not support a purely narrative approach, but declined to propose a method. This regulator was concerned that it may not be appropriate to do so until the criteria to be used for the basis of the assessment is made clear.
- 4.6 The other organisations and individual respondents also proposed a variety of methods of judging performance. Various nuanced graded options, such as the one proposed in the consultation, were the most popular. However, there was also support for the current model, an approach based on 'maturity' of the regulator's approach and for a purely narrative model.
- 4.7 There was a concern expressed several times that the Authority should be 'tough' with the regulators and be more candid in its assessments, whatever grading model is adopted.

5. Impact assessment of the proposals

Question 27) Are there any aspects of these proposals that you feel could result in differential treatment of, or impact on, groups or individuals based on the following characteristics as defined under the Equality Act 2010:

- Age
- Gender reassignment
- Ethnicity
- Disability
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation
- Other (please specify)
- If yes to any of the above, please explain why and what could be done to change this.

³ Pages 5-6, [School inspections in England: Ofsted - HOC Library](#)

5.1 There were no impacts noted, though one respondent did point out that our list of protected characteristics as defined under the *Act* was incorrect, having substituted 'Ethnicity' (which falls under 'Race') for *Marriage and Civil Partnership*.

6. Next steps

6.1 The Authority's Board considered the summary of the responses to the consultation at its meeting in November 2017. Following its initial discussion, further work to refine the options for the new Standards is being undertaken, and it is anticipated that this will be discussed by the Board at its January 2018 meeting.

Annex A: Respondents to the consultation

The Regulators:

- **The General Chiropractic Council (GCC)** which regulates chiropractors in the UK.
- **The General Dental Council (GDC)** which regulates dentists, dental nurses, dental technicians, dental hygienists, dental therapists, clinical dental technicians and orthodontic therapists in the UK.
- **The General Medical Council (GMC)** which regulates doctors in the UK.
- **The General Optical Council (GOC)** which regulates optometrists, dispensing opticians and student opticians in the UK. **The General Osteopathic Council (GOsC)** which regulates osteopaths in the UK.
- **The General Pharmaceutical Council (GPhC)** which regulates pharmacists and pharmacy technicians in Great Britain.
- **The Health and Care Professions Council (HCPC)** which regulates arts therapists, biomedical scientists, chiropodists/podiatrists, clinical scientists, dieticians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists and orthotists, radiographers and speech and language therapists in the UK, and social workers in England.
- **The Nursing and Midwifery Council (NMC)** which regulates nurses and midwives in the UK.
- **The Pharmaceutical Society of Northern Ireland (PSNI)** which regulates pharmacists in Northern Ireland.

Respondent organisations:

- **The Regulation and Quality Improvement Authority (RQIA)** which is the independent body responsible for monitoring and inspecting the availability and quality of health and social care services in Northern Ireland.
- **The Northern Ireland Practice and Education Council for Nursing and Midwifery (NIPEC)** which supports the development of nurses and midwives in Northern Ireland by promoting high standards of practice, education and professional development.
- **The Royal College of Midwives (RCM)** which is a professional organisation and trade union dedicated to midwifery.
- **The Centre for the Advancement of Interprofessional Education (CAIPE)** is an independent organisation which aims to promote and develop inter-professional education, research, learning and practice globally.
- **The Council of Deans for Health (CDH)** which represents the UK's university faculties engaged in education and research for nurses, midwives and allied health professionals.
- **The Medical and Dental Defence Union of Scotland (MDDUS)** which is a medical defence organisation providing indemnity and cover for regulatory and disciplinary matters throughout the UK.
- **The Royal College of Nursing (RCN)** which is a membership organisation and trade union for nursing professionals.

- **The National Community Hearing Association (NCHA)** which represents community hearing care throughout the UK and is committed to better hearing care for all.
- **The Optical Confederation** which is a trade association representing optometrists, dispensing opticians and optical businesses.
- **The Welsh Pharmaceutical Committee (WPC)** which is a committee of the Welsh Government advising on matters relating to pharmacy and the pharmaceutical profession.
- **The British Dental Association (BDA)** which is the professional association and registered trade union for dentists.

Individual respondents:

- **Roger Kline** is a writer and research fellow at Middlesex University with interests in organisational governance, the NHS and discrimination. He replied to the consultation to raise his concerns about discrimination towards black and ethnic minority staff within the fitness to practise processes of the regulators. He specifically addressed question 13 which asked 'Should we introduce Standards covering equality, diversity and fairness'.
- **There were 10 anonymous individual respondents.** It could be discerned that several were current or previous GDC registrants. In total seven of these respondents mentioned the GDC or dentistry.