Consultation Outcome

Good practice guidance

in support of regulatory reform

professional standards authority
for Health and Social Care

2025

About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care (PSA) is the UK's oversight body for the regulation of people working in health and social care. Our statutory remit, independence and expertise underpin our commitment to the safety of patients and service-users, and to the protection of the public.

There are 10 organisations that regulate health professionals in the UK and social workers in England by law. We audit their performance and review their decisions on practitioners' fitness to practise. We also accredit and set standards for organisations holding registers of health and care practitioners not regulated by law.

We collaborate with all of these organisations to improve standards. We share good practice, knowledge and our right-touch regulation expertise. We also conduct and promote research on regulation. We monitor policy developments in the UK and internationally, providing guidance to governments and stakeholders. Through our UK and international consultancy, we share our expertise and broaden our regulatory insights.

Our core values of integrity, transparency, respect, fairness, and teamwork, guide our work. We are accountable to the UK Parliament. More information about our activities and approach is available at www.professionalstandards.org.uk.

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Executive Summary

1. The Government is currently reforming healthcare professional regulation. It is changing the legislation for nine out of the ten healthcare professional regulators we oversee,[1] giving them a range of new powers that will allow them to operate in a different way. The first regulator to be granted new powers is the General Medical Council (GMC). The powers will apply to the regulation of Anaesthesia Associates (AAs) and Physician Associates (PAs) in the first instance, under the Anaesthesia Associates (AA) and Physician Associates (PA) Order[2] (AAPA Order). The new powers are expected to be extended to the GMC's regulation of doctors, as well as to the other regulators in scope in due course.

1.1 These new powers will give regulators greater freedom to decide how they operate, including the flexibility to set and amend their own rules. Our guidance on rule-making seeks to set out good practice in this area, to limit unhelpful variations in approach, and support the development of rules that protect the public effectively.

1.2 The reforms will also create an entirely new process for handling the process by which concerns about healthcare professionals are dealt with, known as 'fitness to practise'. This new process will mean that some fitness to practise cases can be resolved using an 'accepted outcome'.

1.3 An accepted outcome involves a case examiner, who is an employee of the regulator, carrying out a detailed assessment of the case from the written information and evidence – sometimes referred to as 'on the papers'. They use this information to decide whether the registrant's fitness to practise is 'impaired' and if so, what the appropriate sanction should be. If the registrant accepts the case examiner's findings and proposed sanction the case can be resolved using an accepted outcome, without the need for a panel hearing.[3]

1.4 The AAPA Order provides case examiners with a binary choice about whether to resolve a case themselves or refer to a panel hearing. The legislation does not favour one approach over the other, nor does it suggest cases should only be referred as a matter of last resort. Regulators will therefore be required to provide guidance to case examiners on when referral to a panel might be appropriate. This guidance seeks to assist them with that task in a way that is both proportionate and compatible with the legislation.

[1] Regulators within the scope of the reforms are: the General Medical Council, the Nursing and Midwifery Council, the Health and Care professions Council, the General Dental Council, the General Pharmaceutical Council, the General Optical Council, the General Chiropractic Council, the General, Osteopathic Council and the Pharmaceutical Society of Northern Ireland.
[2] The Anaesthesia Associates and Physician Associates Order 2024 (legislation.gov.uk)
[3] For the GMC, panel hearings are sometimes referred to as 'tribunals'.

1.5 In Spring 2024 we consulted on draft guidance on 'Rulemaking' and 'The use of accepted outcomes in fitness to practise'. We developed these documents to help regulators use their new powers effectively, and in a way that protects the public.

1.6 This guidance is intended to encourage best practice and consistency in regulators' approaches. It is not binding on regulators to whom it applies. We expect regulators to have their own policies and guidance in place for staff, but suggest it would be beneficial for these to be informed by these documents.

1.7 It remains open for regulators to take a different approach however, and we will not necessarily criticise regulators for doing so. We will have regard to the guidance when we assess how regulators are using their new powers under our review of their performance. Departing from the guidance would not automatically mean a regulator did not meet a Standard. Where they have taken a different approach, we may ask them to explain how they have assured themselves that it is compatible with the legislative framework and their overarching duty to protect the public.

1.8 Responses to our consultation have demonstrated that there is strong overall support both for the PSA issuing guidance on accepted outcomes and rulemaking, and for the broad content of the draft guidance.

1.9 Where concerns have been raised about some aspects of the guidance we have carefully considered these and made changes. The key changes we are making are:

Accepted outcomes guidance -

- **splitting it into two documents – the guidance itself, and the evidence to support the guidance – a number of respondents felt that the length of the document was unhelpful**
- **removing the factor relating to whether the registrant has accepted the facts of the case – it was brought to our attention by one respondent that this factor was not consistent with the regime set out in the AAPA Order**
- **clarifying our expectations relating to complex cases**

Rule-making guidance -

- **recognising fairness as standalone key principle**
- **making clearer that differences are acceptable where there is a compelling justification, such as public protection or fairness grounds**
- **explaining the consistency tool more clearly**
- **strengthening references to Equality, Diversity and Inclusion (EDI).**
- **strengthening the section relating to the complainant voice in the process, to make clear that the complainant should be granted opportunities to provide further evidence where appropriate.**

1.10 We will issue final versions of the guidance documents and distribute these to the regulators we oversee and to our stakeholders. They will also be available on our website.

1.11 Regulatory reform of the healthcare professional regulators is still at an early stage and the details of the reforms may be subject to change. We will review the guidance as the reform programme progresses and update it as necessary. This will include reviewing how well the guidance works in practice and ensuring that it aligns with any new legislation that regulators are subject to.

1.12 As regulatory reform is rolled out across the regulators we will continue to monitor and review their performance through our performance review function. This will include reviewing how regulators are making use of their new powers around rulemaking and fitness to practise.

About the consultation and who responded

2. We ran a 12-week public consultation on both the Rulemaking and Accepted Outcomes guidance between 22 January and 15 April 2024. The consultation document and online survey asked 32 questions in total and sought views on the contents of our draft guidance, whether it would be helpful, and any impacts it may have on organisations and on groups or individuals with protected characteristics. We collected both quantitative and qualitative data.

2.1 Responses were received from a wide range of stakeholders including patient representative bodies, health and care professional regulators, registrants of a health or care regulator, NHS bodies, professional associations, professional defence organisations, Royal Colleges, Accredited Registers, unions and members of the public.

2.2 We received 52 responses to the online survey[4] and 31 responses by email, meaning that 83 responses were received in total.

2.3 In addition to the consultation survey we also held two roundtable events: one for patient and service user organisations, and another for professional and representative groups. We have incorporated points raised during these roundtables into our consultation analysis.

2.4 Where the responses submitted by email clearly indicated an answer to a specific closed question that was posed in the consultation (where the options presented in the consultation document were yes/no/don't know) these have been included in the quantitative data. Where this was not the case, responses have been considered as part of the qualitative analysis only, although where the questions and responses lent themselves to this, we have highlighted any stark differences between the numbers agreeing and those disagreeing. Not all respondents answered every question.

2.5 A full breakdown of the quantitative response data is available at Annex A.

2.6 All references to paragraph numbers in this document refer to the guidance as consulted on, available here.

[4] This is total number of responses where at least one of the substantive questions was answered. We have removed a number of 'dummy' responses from the total.

Accepted outcomes guidance: what people said and how we've responded

3. Under the AAPA Order, case examiners are provided with a binary choice about whether to resolve a case themselves or refer it to a panel for a hearing. Regulators will therefore be required to provide guidance to case examiners on when referral to a panel might be appropriate.

3.1 Our guidance seeks to help regulators develop their own guidance and processes for using accepted outcomes in a way that best protects the public. In line with the regulators' legislation, and established case law, the regulators' public protection duty involves: protecting the health safety and wellbeing of the public, maintaining public confidence, and upholding professional standards.

Question 4. Do you think that our fitness to practise guidance will help regulators to make best use of accepted outcomes, and use them in a way that is fair, transparent and protects the public? [Free text box][5]

What people said

3.2 Most respondents who answered this question agreed that the guidance would help regulators to make best use of accepted outcomes and use them in way that is fair, transparent and protects the public.

3.3 Comments included:

"We consider the guidance to be necessary and having reviewed the content it will help regulators make best use of accepted outcomes" [other body]

"Yes, the guidance will help regulators decide which cases are most suitable to be assessed by a case examiner and which ones should be reviewed by an expert panel and provides a level of consistency across regulators" [Registrant body]

[5] Questions 1-3 asked respondents for the name of their organisation (if applicable), the role of their organisation, and whether they consented to their comments being attributed to them or their organisation.

"We do think it will help regulators to make the best of accepted outcomes and appreciate the risks associated with the new process to help bring fairness and transparency." [Registrant body]

"The draft guidance carefully enables the benefits of the new legal framework to be operationalised whilst recognising the risks" [Healthcare professional regulator]

3.4 Of those who disagreed that the guidance would be beneficial, some thought that parts of the guidance were inconsistent with the AAPA Order. This concern will be explored further in our responses to the questions below.

3.5 One respondent thought that the guidance would cause confusion for stakeholders where regulators chose to take a different approach to that outlined in the guidance:

"We consider that the guidance will cause unnecessary confusion and undermine confidence in the accepted outcome process and the regulator's own guidance where the regulator properly presents a different approach in line with the legislation". [Healthcare professional regulator]

3.6 Some respondents raised concerns about specific sections or aspects of the guidance, such as those relating to registrants' acceptance of the findings and the assessment of insight. Responses to these points are covered in our analysis of the questions relating to those sections.

3.7 A number of respondents who were unsure whether the guidance would be helpful, or who gave an ambiguous answer, raised concerns that the guidance will not be binding on regulators. This was felt to undermine its potential impact:

"We hope that regulators will adhere to the guidance, however as it is not mandatory we are concerned that there will be some shortfall in regulators complying with all aspects. We would like to see compliance with the guidance forming part of the audit and review of regulators' performance". [Professional association]

"[The fact that the guidance is not mandatory] increases the risk that individual regulators will adopt the guidance in an inconsistent manner." [Professional defence organisation]

"No [the guidance will not be helpful]. As it is the regulators are not accountable to anybody and can act as they like." [Registrant]

3.8 Some respondents raised concerns that the guidance overall placed too much emphasis on protecting patients and not enough on protecting registrants.

3.9 A number of respondents highlighted the need for our performance review process to change to take account of the new powers regulators will have and how they manage the risks we have identified.

3.10 Finally, some respondents used this question as an opportunity to raise concerns that the guidance is too long, and that parts I and II are unnecessarily repetitive.

How we've responded

3.11 We have given careful consideration to the concern that our guidance may cause confusion where regulators choose to take a different approach. However, we believe that the benefits of our guidance in terms of promoting good practice outweigh the risk of any potential confusion. We have made clear that our guidance is not binding on regulators and that they may take a different approach as long as that approach remains compatible with the legislative framework and regulators' overarching duty to protect the public.

3.12 We will keep the guidance under review as legislative reform is rolled out across the regulators and the practical implication of the reforms become better understood. We will assess how regulators are making use of their new powers and use this information to update our guidance as necessary. This may mean that we revise the guidance to accord with examples of good practice and/or to amend sections of the guidance that do not work as intended or cause practical difficulties.

3.13 We acknowledge the concerns of some respondents that as our guidance is not mandatory it may not be followed by some of the regulators we oversee. However, as regulators are independent bodies it is not our role (and nor do we have the power) to direct them to carry out their functions in a certain way. We will however expect regulators to be transparent in how they exercise their new powers, including providing a rationale for their policies and procedures regarding the operation of accepted outcomes. We expect that in developing these policies, regulators will give due consideration to our guidance and provide a reasoned explanation where they have taken an alternative approach.

3.14 We agree that combining Part I of the guidance (the guidance itself) with Part II (the context, evidence and explanation of factors) makes the guidance document unnecessarily long. We acknowledge that some respondents found the two parts confusing, and we further believe that the length may make the guidance less accessible.

3.15 Based on the feedback received, we will:

- Issue our accepted outcomes guidance as planned, subject to the revisions we intend to make as detailed in this report
- Split the guidance that was consulted on into two separate documents: the guidance itself (the current Part I) and a separate report on the background and evidence (the current Part II).

Question 5. Factor 1: 'Has the registrant failed to accept the findings and/or impairment?' Do you agree that regulators should consider this when deciding whether to resolve a case using an accepted outcome? [Yes/no/don't know]

What people said

3.16 Question 5 was answered by 67 respondents, with 77.6% agreeing that regulators should take the registrant's acceptance of the findings and their own impairment into account when deciding whether to resolve a case using an accepted outcome. 11.9% disagreed and 10.4% didn't know.

Question 6. Do you have any comments on this factor, or the bullet points listed in our guidance under this factor? [Free text box]

The bullet points listed in our guidance under this factor were:

- *Does the registrant dispute any material facts (such as those that form the basis of a regulatory concern)? If so, are there reasons as to why the case is still best dealt with using an accepted outcome?*
- *Is there certainty amongst all parties about the factual basis on which the findings have been reached?*
- *Does the registrant clearly accept current impairment?*

What people said

3.17 While there was strong support overall for this factor being included in the guidance, a number of respondents raised concerns over the wording of the factor. Several respondents suggested that using the phrasing 'failed to accept' implied that there was an obligation for registrants to accept the findings and/or impairment, and there would be negative consequences for registrants if they didn't. Some respondents suggested alternative wording:

> ***"the use of the word 'failed' in this part of the proposed guidance is inappropriate as it presumes that the registrant is at fault and should therefore accept the findings/proposed outcome." [Professional defence organisation]***
>
> ***"This would appear less negative and adversarial if expressed as 'does the registrant accept the findings and/or impairment.'" [Trade union]***

3.18 In addition to concerns about how this factor was phrased, some respondents raised more fundamental concerns about its compatibility with the AAPA Order; a number of respondents highlighted that a registrant accepting the case examiner's findings and their own impairment is a prerequisite for using an accepted outcome. They therefore questioned the legitimacy of the interpretation of 'acceptance' implied by the guidance:

> ***"Confusing as the registrant MUST accept the findings and impairment. Therefore, if the registrant fails to accept the findings and / or impairment at the final stage, the case will automatically be referred onwards." [Healthcare professional regulator]***
>
> ***"if the registrant has rejected the case examiner's findings and/or impairment, then the case examiner is obliged to refer the matter to a panel.... we question whether the guidance adds anything to what is provided in the legislation." [Healthcare professional regulator]***

3.19 In contrast, a number of respondents welcomed the suggestion in the guidance that only material facts needed to be admitted. Some respondents believed that the guidance struck the right balance in this regard:

> ***"We do agree with the guidance that not every single finding has to be accepted, as minor discrepancies may not be material if the proposed***

outcome and impairment have been accepted." [Healthcare professional regulator]

"we agree that there are situations (particularly where individual immaterial findings are denied) where an accepted outcome may still be appropriate. We feel (7.6) provides pragmatic guidance balancing these discrepancies in agreement with the need for public scrutiny." [Healthcare professional regulator]

3.20 Others felt that an accepted outcome should still be capable of being used even where not all material facts or allegations had been admitted:

"proportionality needs to be considered - it may not be necessary to accept all findings especially where they relate to less serious matters." [Healthcare professional regulator]

"We have some reservation about there being a need for the registrant to accept the allegations. Whilst some clarity is provided in the currently proposed documents, it would accord with principles set out by the Administrative Court for there to be some analysis of the basis on which a registrant denies an allegation before dismissing the prospect of a consensual disposal." [NHS body]

3.21 A number of respondents agreed with the assertion in the guidance that impairment as a concept is not well understood. It was suggested that the guidance be strengthened to require regulators to outline the meaning of impairment and what it means to agree to an accepted outcome.

3.22 Finally, some questioned what the impact would be of rejecting a case examiner's findings and/or impairment where the case went on to be considered by a panel. There was concern that a finding against a registrant by a case examiner may prejudice a future panel. It was suggested that a panel should consider the case independently of the original process, and without being influenced by it.

How we've responded

3.23 Having carefully considered the feedback received in response to this question, we agree that this factor is not compatible with the AAPA Order.

3.24 We remain of the view that it would be disproportionate to refer a case to a panel where the disputed facts are minor, or do not add anything to the gravity of the admitted ones. However, as registrants will be required to either accept or reject the case examiner's findings, we agree that, as drafted, this factor is not compatible with the AAPA Order.

3.25 The concern raised by some respondents that a finding against a registrant by a case examiner may prejudice any future panel hearing is outside the scope of this guidance. This is a point that regulators going through the reform programme may nonetheless need to be aware of, and we will further consider how this is handled in practice through our oversight of the GMC and others as their legislation is updated.

3.26 Based on the feedback received, we will:

- Remove the factor 'Has the registrant failed to accept the findings and/or impairment?' from our guidance.

Question 7. Factor 2: 'Is there a dispute of fact/conflict of evidence that can only be fairly tested at a hearing?' Do you agree that regulators should consider this when deciding whether to resolve a case using an accepted outcome? [Yes/no/don't know]

What people said

3.27 Question 7 was answered by 67 respondents, with 82.1% agreeing that regulators should consider whether there is a dispute of fact/conflict of evidence that can only be fairly tested at a hearing when deciding whether an accepted outcome is appropriate. 10.4% disagreed and 7.5% didn't know.

Question 8. Do you have any comments on this factor, or the bullet points listed in the guidance under this factor? [Free text box]

The bullet points listed in our guidance under this factor were:

- *Are there material disputes about facts where two or more competing accounts are plausible and the dispute cannot be resolved with reference to the other evidence that is available?*

- *Is there uncertainty about the background to, or seriousness of, the conduct?*
- *Would the written accounts of the registrant or any of the witnesses benefit from further exploration/examination at a hearing?*
- *Does the case lie on the borderline between sanctions and if so would testing the evidence have the potential to assist with assessment of seriousness?*

What people said

3.28 There was strong support amongst respondents for the inclusion of this factor in the guidance and wide agreement that some conflicts of evidence are best resolved at a hearing. However, there were divergent views on what this factor should mean in practice.

3.29 Many respondents agreed that the guidance struck the right balance and highlighted the benefit of panels in terms of being able to test the evidence of witnesses through cross-examination:

> ***"Hearings allow for a dynamic assessment through cross-examination and questioning, which can be crucial for cases where the credibility of evidence or the interpretation of facts is in question. Resolving such disputes through accepted outcomes without a thorough examination might not adequately protect the public or maintain confidence in the profession." [Patient body]***

> ***"Yes, the guidance here is robust and should be considered as part of the fundamental delivery of fair and equitable decision-making." [Professional association]***

3.30 Our draft guidance outlines that only certain disputes may require resolution at a hearing, for example where competing evidence is plausible, material to the case, and cannot be resolved with reference to other available evidence. Some respondents however either directly stated, or implied, that all disputes of fact should be heard by a panel:

"In cases where facts are disputed, our expectation is that in line with judicial practice and the human right to a fair hearing, these cases would proceed to a panel hearing." [NHS body]

"Any dispute of fact or conflict of evidence must be tested at a hearing. It is not for the CEs [case examiners] to come to a conclusion in this situation on evidence presented only on papers... there must be an opportunity for in-person cross examination in front of a panel in these circumstances. Fairness is otherwise compromised." [Professional association]

3.31 Of the respondents who disagreed with the inclusion of this factor in the guidance, a number pointed to the fact that case examiners will be able to ask for further evidence, and suggested that this should be done before any consideration of referral to a panel:

"Where there is uncertainty about the background to, or the seriousness of the conduct, we consider that this should be resolved by further investigation, which case examiners will have the power to direct. Referral to a panel for this reason alone is not proportionate or fair when case examiners can direct the gathering of additional information themselves." [Healthcare professional regulator]

3.32 One respondent objected to the notion that a hearing was likely to lead to a more robust assessment of the evidence, while another stated that referral to a hearing for this reason may lower the standard of investigations:

"reference to evidence only being capable of being 'fairly tested' at a hearing is too subjective and wrongly gives the impression that conflicts of evidence can only be tested at hearing, suggesting other approaches are unfair. There is no evidence to support that view." [Healthcare professional regulator]

"that evidence may be more rigorously 'tested' at a hearing should not be a reason in and of itself to refer a case to a hearing; such an approach could lead to lower standards in the initial investigation of cases and a disproportionate number of cases proceeding to a hearing." [Professional defence organisation]

3.33 One of the respondents who expressed the view that conflicts of evidence can be fairly tested outside a hearing was also concerned that the guidance suggested a hierarchy of decision makers, with panel decisions sitting above case examiner decisions.

3.34 Other respondents pointed out that even where a conflict of evidence arises, case examiners will be able to weigh the evidence and decide which is more plausible. Some felt that instances where case examiners were unable to decide between conflicting versions of events would be rare.

How we've responded

3.35 We remain of the view that where there are significant conflicts of evidence, such as when two or more accounts are plausible and the dispute cannot be resolved with reference to the other evidence that is available, a hearing is likely to be the most appropriate way to test the evidence.

3.36 Panel hearings provide a more effective forum for resolving contested issues of fact than case examiner decisions, which are based on written evidence only. This is because panels can hear live evidence being challenged and have the opportunity to challenge it themselves. A panel has the opportunity to test and assess the credibility of witnesses in a way that cannot be achieved with written evidence only.

3.37 We do not agree that this position suggests that other approaches are unfair. There are strengths and weaknesses of both panel and paper-based decision-making models, and both are fair when they are used appropriately. This need not imply a hierarchy of decision-makers. Our position reflects the fact that for some cases, panels may be better placed to resolve contested issues of fact.

3.38 However, we also do not agree with those respondents who believe that *all* disputes of fact should be resolved at a hearing. In many cases the weight of the evidence will mean that case examiners are able to make a robust decision, for example if the evidence of one or more parties is inconsistent, implausible or improbable. Case examiners should have the training and expertise to determine when they are able to resolve a case themselves, and when a case would benefit from referral to a hearing. We believe that it is not necessary for public protection to refer all cases where there are disputes of facts to a hearing, and that to do so would undermine some of the benefits of accepted outcomes.

3.39 We acknowledge the point raised by some respondents that regulators may allow case examiners to ask for further evidence. There is nothing within the AAPA Order that allows for, or prohibits, case examiners from seeking further information and there is no requirement for them to do so before making a referral to a panel. However, in recognition of the fact that regulators have signalled an intent to use the powers in this way, we believe it is important for the guidance to acknowledge that case examiners may wish to consider whether there is further paper evidence that could be obtained that would enable them to reach a decision. We would not

recommend that case examiners refer a case to a hearing simply because they had insufficient evidence, where further documentary evidence could effectively fill the gap.

3.40 Written evidence is nonetheless not a direct substitute for oral testimony and is not capable of being tested in the same way. We would always expect case examiners to assure themselves that they had sufficient information on which to base their decisions. There may still be instances where the case examiner determines that, even with the benefit of the additional information, a hearing is needed to fairly test a dispute of fact or conflict of evidence.

3.41 Based on the feedback received, we will:

- Amend the guidance to acknowledge that case examiners may wish to consider whether there is further written evidence that could be obtained that would enable them to reach a decision.

Question 9. Factor 3: 'Does the complexity of the case suggest that a hearing may be beneficial?' Do you agree that regulators should consider this when deciding whether to resolve a case using an accepted outcome? [Yes/no/don't know]

What people said

3.42 Question 9 was answered by 66 respondents, with 78.8% agreeing that regulators should consider the complexity of the case when deciding whether to resolve it using an accepted outcome. 10.6% disagreed and the same percentage didn't know.

Question 10. Do you have any comments on this factor, or the bullet points listed in the guidance under this factor? [Free text box]

The bullet point listed in our guidance under this factor was:

- *Are the complexities of the case such that the evidence/issues under consideration would benefit from*

further exploration/examination at a hearing? Would a hearing support understanding and decision-making?

What people said

3.43 The majority of respondents to this question agreed that some complex cases may benefit from referral to hearing. The reasons given by respondents included that a hearing may allow for greater exploration of the subtleties and/or intricate details of a case, and that the ability of a panel to probe the evidence may assist with developing a fuller understanding of what had occurred. Comments included:

"A hearing... allows the subtleties of a complex case to be explored in a way that disposal on the papers does not." [Healthcare professional regulator]

"Complex cases, especially those involving intricate clinical details, a multitude of evidence, or many witnesses, might benefit from the depth of scrutiny that a hearing can provide." [Patient body]

"We agree that probing questions from the panel and cross-examination available at a hearing can help develop an understanding of complex evidence and might also lead to a fuller understanding of relevant context." [Healthcare professional regulator]

"There will be some cases where the complexities are such that it may be difficult to unravel through a paper-based exercise. As a result, the risk may be that full consideration of the case and subsequent outcome will not be achieved". [Registrant body]

3.44 Of those who disagreed that regulators should consider complexity as a factor for referring to a hearing, the main reason given was that case examiners should be capable of dealing with complex cases. Some respondents also cited that fact that case examiners will be able to seek further evidence or clarification where required. Comments included:

"Case examiners will be able to make decisions on complex cases. It is unclear why panel members would be better placed to have a greater understanding of complex cases than case examiners.... case examiners will be able to require further information on anything which requires more clarity." [Healthcare professional regulator]

"As is currently the case, independent expert evidence can be obtained by the regulator to explain, in simple terms, any treatment or procedures in question. Whilst this may take more time and allocation of resource in the more document heavy cases, this would still be negligible compared to the time and costs associated with proceeding to a hearing." [Professional defence organisation]

"We do not agree with the example given at paragraph 7.15 of a case involving complexities, namely a clinical case involving a number of expert witnesses, as a reason for a case to be referred to a tribunal. Our case examiners routinely consider a wide range of case types, with differing features and volumes of evidence, that vary on the spectrum of seriousness and sometimes raise new or unique issues. They make high volumes of decisions and are well equipped to assess and resolve issues such as raised in the example." [Healthcare professional regulator]

3.45 One respondent also stated that they disagreed with the inclusion of this factor because it would undermine Parliament's intention to achieve the benefits of a less adversarial approach.

3.46 A number of respondents felt that the guidance did not provide enough detail on what constituted a complex case, and requested further clarity on what elements might lead to a case being considered complex.

How we've responded

3.47 The inclusion of this factor stemmed from our pre-consultation exercise with the regulators we oversee. In their feedback to us, some suggested that more complex cases may be more appropriately resolved by a hearing. The public consultation exercise has demonstrated that there is strong support for this view, although three professional regulators disagreed with this factor. We remain of the view that some complex cases – or cases displaying particular complexities – may benefit from further examination and exploration at a hearing.

3.48 We agree with the position of some respondents that case examiners should be able to deal with complex cases. For most cases this will be true, and this is referenced in our guidance, which states that: "We would expect case examiners to be generally capable of dealing with complex cases without the need to refer to a panel." Our guidance does not suggest that all complex cases should be referred to a panel, and neither does it seek to prescribe types of cases for which referral is required. We believe that this approach strikes the right balance between flexibility and public protection.

3.49 However, in light of feedback that further clarity is required about what constitutes a complex case, we will update the guidance to include illustrative types of

complexity. We will also set out the reasons why panels may sometimes be better placed to resolve complex cases.

3.50 We will keep these types of complexity under review and may update the guidance in future, based on what we learn about regulators' handling of cases under the new fitness to practise arrangements.

3.51 We do not agree that the inclusion of this factor undermines Parliament's intention to achieve the benefits of a less adversarial approach. It is intended to help regulators to consider what is required to properly resolve cases involving complexity of different sorts. The guidance makes clear that such cases should only be referred to a hearing where it would be beneficial for understanding and decision-making to do so.

3.52 Based on the feedback received, we will:

- Amend the guidance to clarify what we mean by 'complex cases'.

Question 11. Factor 4: 'Would it be beneficial and proportionate to test insight at a hearing?' Do you agree that regulators should consider this when deciding whether to resolve a case using an accepted outcome? [Yes/no/don't know]

What people said

3.53 Question 11 was answered by 66 respondents, with 72.7% agreeing that regulators should consider the need to test insight at a hearing. 16.7% disagreed and 10.6% didn't know.

Question 12. Do you have any comments on this factor or the bullet points listed in the guidance under this factor? [Free text box]

The bullet points listed in our guidance under this factor were:

- *Are there significant doubts over the registrant's insight? (this may be due to the content of the registrant's reflective statement or the nature of the concern)*
- *Would it be both beneficial and proportionate to test insight at a hearing?*
- *Is this a case that involves serious attitudinal issues?*

What people said

3.54 While there was strong support for the inclusion of this factor in the guidance, a number of respondents expressed uncertainty about how insight could be reliably assessed, with some stating that assessment of insight is subjective. Others were unsure whether a panel hearing was the most effective forum for demonstrating insight, or believed that case examiners were well equipped to make an assessment. These concerns are explored further below.

3.55 Of those who agreed that some cases may benefit from referral to a hearing to assess insight, many pointed to the crucial role that the evaluation of insight plays in determining impairment and sanction. Amongst this group of respondents it was widely felt that panels were better able to make an assessment of insight, and that evaluation on the papers alone may lack robustness. Comments included:

"The demonstration of insight is central in fitness to practise... We agree with the points made in 7.18 concerning the difficulty determining insight based on papers and reflective statements. We agree that a panel is likely to be in a better position to be able to identify insight." [Healthcare Professional Regulator]

"In cases where there are significant doubts about a registrant's insight or where the evidence of insight is incomplete or lacks credibility, a hearing can provide a platform to evaluate this aspect more comprehensively. This is especially relevant for cases that may indicate serious attitudinal issues, where understanding the registrant's perspective and level of insight can be crucial for determining the risk to public safety and the need for remedial actions." [Patient body]

"We believe that in many cases it would be difficult for a case examiner to fully assess insight from written evidence alone, and therefore many cases would need to be referred to a panel hearing" [Registrant body]

"Where a registrant's insight is in question, an accepted outcome process would lack the ability to assess the nuance of a case" [Professional defence organisation]

3.56 Some respondents felt that the guidance should go further in respect of the need to refer to a panel to assess insight. This included some respondents who thought that cases should be referred to a panel where there was *any* doubt about a registrant's insight, and one who stated that even where insight could be demonstrated on the papers, some cases may still warrant consideration by a panel:

"We support the factors to consider in paragraph 7:20 albeit we think the word "significant" should be removed from the first bullet point – if there is any doubt the case should be referred to a panel." [Patient body]

"There may be some cases where the registrant demonstrates insight but might, nonetheless, be more appropriately considered by a panel. These include cases that are so egregious that evidence of insight and remediation may be contested." [Healthcare professional regulator]

3.57 While many respondents supported referral to a panel to assess insight, others felt that a panel hearing might not be the best forum for insight to be expressed, and further, that it may discriminate against certain groups. It was felt by some that cultural or personal factors, language barriers, and the stress of a hearing may negatively impact on a registrant's ability to demonstrate insight in person:

"There is no principle that supports the idea that insight expressed orally under questioning is more reliable. Quite the contrary, cultural and personal factors might be quite inhibitory and intimidating for insight to be tested in adversarial hearing settings" [Healthcare professional regulator]

"A formal hearing with the possible delay and stress involved seems unlikely to be a situation where the registrant can give their best." [Regulatory body]

"Case Examiners should take into consideration a number of factors relating to their demonstration of insight, such as whether a registrant is legally represented, if there are any language barriers, and whether

there are any health concerns. Registrants who are unable to provide high quality evidence demonstrating insight due to one of these factors should not be penalised... this could lead to a disproportionate number of hearings involving unrepresented registrants and those with language barriers or health concerns." [Legal firm representing registrants]

3.58 Others felt that insight was too vague a concept to warrant assessment at a hearing or that it may be complex to prove whatever the setting:

"There is not an agreed measure of what amounts to 'insight' and so this could impact the fairness and consistency of this process" [NHS body]

"Lack of insight is an important characteristic that could impair someone's fitness to practice but perhaps complex to prove" [Registrant body]

3.59 Of those who disagreed that cases should ever be referred to a panel to assess insight, most cited the ability of case examiners to make this decision. A number of respondents highlighted the fact that case examiners are already experienced at assessing insight from written evidence alone, and that where doubts about insight existed, less weight could be attached to this evidence:

"Insight can generally be effectively assessed by decision makers on the papers and the discretion of the case examiners to weigh the evidence and to decide whether they can determine impairment on the papers should not be fettered. If there are doubts over insight, or the case involves serious attitudinal issues, then a case examiner will properly attach less weight to that evidence". [Healthcare professional regulator]

"Insight may be demonstrated in a variety of ways and there should not be a focus on an outward demonstration of showing "insight" at a hearing. Competent case examiners (who have suitable training to consider how a registrant may demonstrate insight and have access to clear guidance) should be able to determine whether a registrant has demonstrated insight from the written submissions." [Professional defence organisation]

3.60 There were varying views expressed about the role of artificial intelligence (AI) or other assistance in helping registrants to produce reflective statements. Some respondents felt that the possibility of registrants having used AI or received help was relevant and may contribute to the need for a hearing. Conversely, others felt that this factor was not relevant, or that by raising this concern the PSA was undermining the accepted outcomes legislative framework:

> ***"We also share the concern about the potential challenges in reliably assessing the depth of insight expressed in reflective statements, especially when registrants may have had substantial assistance or used Artificial Intelligence (AI) in their creation. We would appreciate further guidance to mitigate the impact of significant assistance or AI usage by registrants, and to establish best practices in this regard."***
> ***[Healthcare Professional Regulator]***

> ***"We note the concerns raised at paragraph 7.18 about support received in producing reflective statements or the use of Artificial Intelligence (AI) but in raising these you are questioning the creation of the accepted outcomes legislative framework which has been consulted on and been given statutory effect by Parliament."***
> ***[Healthcare professional regulator]***

3.61 Finally, some respondents were concerned that registrants would not be able to demonstrate insight where they had denied the allegations up until the case examiner stage, and that this may result in all such cases being referred to a hearing. One respondent asserted that contesting the charges should not be treated as evidence of lack of insight.

How we've responded

3.62 We remain of the view that insight plays an integral role in fitness to practise and this should be accounted for in our guidance on accepted outcomes. The assessment of insight can be key to understanding the ongoing risk posed by a registrant whose fitness to practise is in question and determining the appropriate regulatory action. It is important in determining both impairment and sanction.

3.63 We expect that in a large proportion of cases, case examiners will be capable of reasonably assessing insight. However, we remain of the view that in some cases the extent of a registrant's insight may be difficult to determine on the papers alone. This view was supported by a significant number of respondents to our consultation, many of whom stated that panels were better placed to assess insight.

3.64 A key concern about the ability of case examiners to assess insight using only written evidence is the risk that registrants will have received help drafting their

reflective statements either from an individual or using AI. We could not find any basis for the assertion of one respondent that raising this concern amounted to questioning the accepted outcomes legislative framework. Furthermore, given that we have identified a risk in the process – namely that a lack of insight may indicate an increased risk to the public, and that the insight expressed on paper may not be genuine – a failure on our part to act on this could arguably be at odds with our overarching objective of public protection.

3.65 We have carefully considered the concern expressed by some respondents that a registrant will be unable to demonstrate insight where they have denied the allegation until the point at which the case examiner proposes an accepted outcome. Some were concerned that our draft guidance may imply that all such cases should be referred to a panel, as insight would be in doubt.

3.66 Although case law sets out that a registrant's denial of the allegations is relevant to insight and risk of repetition, admissions are not necessary for a finding of insight to be made. It is not our intention that our guidance results in referral of cases to a hearing only on the basis that there have been denials. We agree that our guidance should therefore be clearer on the fact that a registrant may demonstrate insight even where the allegations and/or their own impairment have been denied prior to the offer of an accepted outcome.

3.67 Insight may be demonstrated through, for example, proactively undertaking training in relation to the allegation at an early stage and reflecting on how their practice could be improved and what they would do differently. Further, even where insight has not been demonstrated, this should not automatically result in referral to hearing where it would not be beneficial for public protection to do so.

3.68 Based on the feedback received:

- We will make clear within the guidance that a registrant may demonstrate insight even where the allegations and/or their own impairment have been denied prior to the offer of an accepted outcome.

Question 13. Factor 5: Lay representation in decision-making. Do you agree that regulators should continue to ensure lay representation at some point in the fitness to practise decision-making process? [Yes/no/don't know]

What people said

3.69 Question 13 was answered by 69 respondents, with 78.3% agreeing that regulators should continue to ensure lay representation in fitness to practise decision-making. 10.1% disagreed and 11.6% didn't know.

Question 14. Factor 6: The use of single decision-makers. Do you agree that some fitness to practise cases may benefit from more than one decision-maker? [Yes/no/don't know]

What people said

3.70 Question 14 was answered by 72 respondents, with 83.3% agreeing that regulators should consider whether some fitness to practise cases may benefit from more than one decision-maker. 11.1% disagreed and 5.6% didn't know.

Question 15. Do you have any comments on the bullet points listed in the guidance relating to the composition of decision makers? (See paragraph 7.29) [Free text box]

The bullet points listed in our guidance under this factor were:

- *Is at least one case examiner a lay person? If not, is there lay involvement at some stage in the fitness to practise decision-making process?*
- *Does the case involve complex issues, large amounts of evidence or significant ambiguity?*
- *Are cultural considerations a significant factor in the case? If so, does the case examiner have relevant cultural competence?*

What people said

3.71 The comments in response to this question reflected the high level of support for lay involvement and multiple decision-makers seen in the answers to questions 13 and 14.

3.72 Of the majority who agreed that regulators should ensure lay representation at some point in the fitness to practise decision-making process, many highlighted the importance of lay decision-makers to fairness and perceptions of fairness and their ability to act as representatives of patients or the public. Others pointed to the progression of professional regulation away from a model of 'self regulation' and the importance of maintaining this. Some also cited evidence of distrust amongst the public that regulators were truly independent of the professions they regulated. Upholding public confidence was thought to be an important reason to retain lay involvement, and some cautioned against moving away from this approach.

3.73 Comments in favour of lay involvement in decision-making included:

"There are strong arguments for there to be a lay component of any final decision – to do otherwise defeats the purpose of modern regulatory models which have moved beyond pure professional self-regulation." [Healthcare professional regulator]

"There is huge distrust of the independence of regulators from the professions. It is therefore very important to ensure that measures are taken by regulators to ensure independence and transparency of the FtP processes. Lay members would be one part of this." [Patient representative]

"We have found that the inclusion of lay members is crucial to ensure that patient and public perspectives are considered in the fitness to practice process. We concur that the integration of lay input into the proposed system is indispensable." [Healthcare professional regulator]

3.74 Some respondents felt that the guidance should go further and be more prescriptive in terms of mandating lay case examiners in every case. Most respondents who suggested this thought that lay case examiners should work alongside registrant ones. Some respondents suggested other ways that lay people could be involved in decision-making, for example by undertaking audits of accepted outcomes cases.

3.75 Of those who disagreed that lay people should be involved in fitness to practise decision-making, the main reason given was that they lacked expertise in the field. Comments included:

> ***"We don't feel a lay member is needed as we have found they can have little knowledge of the profession under scrutiny and can make massive assumptions on their scope or who they treat." [Professional association]***
>
> ***"It is our view that in cases which are primarily related to clinical or health concerns, the involvement of a lay case examiner may add little to no value." [Professional defence organisation]***

3.76 Others who disagreed that lay people should be involved in decision-making stated that as this was not a requirement of the AAPA Order it should not be a matter for PSA guidance, and that regulators' discretion in this regard should not be fettered.

3.77 Whilst there was very strong support overall for lay involvement, a number of respondents felt strongly that our guidance should also recommend registrant involvement in decision-making, and that this should go hand-in-hand with lay involvement. Comments included:

> ***"We strongly recommend that the use of one registrant and one lay case examiner, for every case, should be an explicit recommendation within the PSA guidance. Any deviation from this should automatically trigger a greater scrutiny at every monitoring or performance review of the regulator." [Professional defence organisation]***
>
> ***"There are strong arguments for there being a professional component in a final decision, not least because that provides both an important professional perspective and considerable assurance to the subjects of fitness to practise proceedings... there should be considerable caution in moving away from approaches in which both [lay and registrant] perspectives are represented." [Healthcare professional regulator]***
>
> ***"I (and I suspect most registrants) would be strongly opposed to case examiners being lay in circumstances where they are acting alone." [Registrant of a health or care professional regulator]***

3.78 The great majority of respondents who commented on the number of decision-makers used to resolve a case agreed that more than one may be required in some circumstances. There was a high level of concern amongst some respondents at the idea of a single decision-maker being used, with many feeling that the risk of bias was too high, and others being concerned about a decision of such significance sitting with one individual. Some respondents felt that the fact that case examiners are not independent of regulators compounded the risk of using a single decision-maker. Comments included:

"Given the huge responsibility of case examiners, having a single decision maker carries a significant degree of risk. We agree having more than one decision maker will help mitigate bias and lead to more balanced decision making, particularly when the view of lay and professional representatives are included." [Professional association]

"There is a potential for unfairness to the registrant and an increased risk of bias in there being a single decision maker for initial decisions, particularly in relation to consensual disposal." [NHS body]

"Having a single decision maker is likely to reduce the fairness of the fitness to practise process because of the risk of bias (including unconscious bias) influencing decision making." [Professional association]

3.79 While our guidance recommends that more than one decision-maker may be required for certain cases (for example those that are complex or involve significant ambiguity), a number of respondents thought multiple decision-makers should be used in *every* case. Comments included:

"We do not agree that it is only in situations described in 7.26 that two case examiners should be used, it should be all cases... There is never a situation in which it is appropriate for a case to be decided by one case examiner." [Professional association]

"We disagree that some fitness to practise cases may benefit from more than one decision-maker because we consider that all cases should have at least two decision-makers." [Legal firm representing registrants]

"[We do] not agree that consensual disposal cases should ever be decided by single decision-makers. Such decisions are far more

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susceptible to individual errors and prejudices." [Professional association]

3.80 Of those who disagreed that more than one decision-maker may be necessary, a number questioned the idea that panels would be less biased than a single case examiner, or pointed to evidence suggesting that panel decisions are susceptible to different biases. One respondent felt that we had misrepresented the evidence in relation to bias and that the findings were not presented in a balanced way:

"You state that having more than one decision-maker may help to counteract bias and lead to more balanced decisions. However, the advice you commissioned on bias in fitness to practise decision-making models sets out that cognitive biases may affect the quality of accepted outcome or tribunal decisions... We do not consider you have represented the findings of the advice you commissioned on biases in the guidance in a balanced way." [Healthcare professional regulator]

3.81 Some respondents felt that instead of seeking to mandate a certain number of decision-makers our focus should be on other safeguards against bias. Others pointed out that the AAPA Order does not mandate a minimum number of case examiners and therefore felt that the PSA should not make recommendations in this regard.

3.82 A few respondents objected to the statement in the guidance that there may be merit in using more than one decision-maker in particularly high profile or controversial cases. It was asserted that all cases should be undertaken with the assumption that they could be subject to significant scrutiny at any time.

3.83 Finally, some respondents questioned the assertion in the guidance that where a single decision-maker is used they should have 'relevant cultural competence'. Some respondents felt insufficiently clear about what this meant or unsure about how this could be assessed.

How we've responded

3.84 We remain of the view that lay representation in decision-making must remain a feature of the fitness to practise process. It is important that regulatory decisions are not just fair, robust and independent, but are seen to be so; the responses to our consultation show that there remains concern amongst patient groups and the public about the perceived closeness of regulators to the professions they regulate. A number of regulators also reported that they valued lay involvement in fitness to practise and felt it assisted with decision-making.

3.85 Given the importance to public protection of upholding trust and confidence in regulators, we intend to retain in the guidance the recommendation that lay people be involved in fitness to practise decision-making. We do not agree that this fetters the discretion of regulators and nor do we think it is in contravention of the AAPA Order. The Order does not say anything to prevent regulators from arranging lay input into decision-making; it does say they have an overarching duty to protect the public, including maintaining public confidence, and responses to our consultation indicated that lay input makes a significant contribution to this. We are not seeking to prescribe how regulators should incorporate lay people into the process; it is for regulators to formulate an approach that works for them.

3.86 We acknowledge the strong feeling amongst many respondents that registrants should also be involved in decision-making. We agree that there may be benefits to this approach, particularly in terms of maintaining the confidence of the profession in the regulators. As our primary objective is public protection, we do not intend to include registrant representation within our guidance. However, we hope that regulators will consider the feedback we have received in this regard when they are developing their fitness to practise processes.

3.87 In terms of the number of case examiners used to resolve a case, there was a great deal of concern from respondents about the use of single decision-makers, especially from organisations representing registrants. We remain of the view that using more than one decision maker may bring a wider perspective to decision-making, help to counteract bias, and lead to more balanced decisions. While we believe that many cases may be safely and fairly disposed of using a single decision-maker, others may benefit from the involvement of more than one person. We therefore intend to retain the recommendation to consider using more than one decision-maker if the case involves large amounts of evidence, particular complexities, or there is significant ambiguity as to what occurred.

3.88 Whilst we acknowledge that both the case examiner and panel models of decision-making are subject to bias, we do not agree with the feedback from one respondent that we have misrepresented the evidence in this regard. The guidance acknowledges that all decision-making processes are affected by bias. Amongst the research cited in our guidance, the report 'Advice on biases in fitness to practise decision-making in accepted outcome versus panel models' (Cuthbert, 2021) outlines characteristics of cases that might be better resolved through accepted outcomes or panels. Amongst the cases which are suggested to be more appropriate for the panel route are those that are 'paper heavy', cases involving different cultural considerations, and cases with substantial ambiguity as to what occurred. This is in line with the recommendations in our guidance.

3.89 We have carefully considered the point raised by some respondents that whether a case is high profile or controversial should not be a factor in determining the number of decision-makers to use. We agree that all cases should be assessed in a fair and robust way and all decisions should be capable of standing up to scrutiny. We believe this element of the guidance risks conveying the message

that the quality of decision-making is more important in high profile cases. This is not our intention, and we are persuaded that it should not feature in the guidance.

3.90 Based on the feedback received:

- we will remove from the guidance the suggestion that whether a case is high profile or controversial should be a factor in deciding whether to refer it to a hearing.

Question 16. Factor 7: publishing case examiner decisions. Do you agree that the bullet points in the guidance under this factor are the right ones? [Yes/no/don't know]

What people said

3.91 Question 16 was answered by 66 respondents, with 72.7% agreeing that regulators should publish case examiner decisions in the way we set out in the guidance (including giving clear reasons for regulatory decisions and providing sufficient detail about cases and how they are resolved). 10.6% disagreed and 16.7% didn't know.

Question 17. Do you have any comments on the bullet points listed in the guidance under this factor? [Free text box]

The bullet points listed in our guidance under this factor were:

- *Is the decision published in a place that is easy for the public to access?*
- *Is the decision sufficiently detailed that a third party with no prior knowledge of the case would be able to fully understand both the basis of the concern and the rationale for the decision?*

What people said

3.92 Most respondents agreed that the factors to consider on publishing case examiner decisions were the right ones. A number highlighted the importance to public confidence of decisions being transparent and accessible to the public. Publishing decisions was also felt by many to be an important part of upholding the confidence of registrants in their regulator. Comments included:

"The bullet points on publishing case examiner decisions emphasise transparency, accountability, and maintaining public confidence in the professions. These principles are fundamental for ensuring that the outcomes of fitness to practise processes are understood by the public and the profession, thereby supporting the overarching goal of public protection." [Patient body]

"Publishing decisions is an important part of transparency of processes. This matters for public confidence and also registrant confidence in their own regulator and its ability to follow due process and reach a fair reasonable decision about professional conduct." [Professional association]

"We believe that it is essential to publish the allegations, the acceptance of those allegations by the registrant and the outcome from the panel. This marks the seriousness of the concern and allows the public to understand how the regulator has dealt with the concern. It also allows for learning from the wider professions." [Healthcare professional regulator]

3.93 A number of respondents stated that published decisions should be written in a way that is accessible and easy to understand. Some felt that the guidance should be more robust in this regard.

3.94 Several responses, particularly from organisations representing registrants, stated that the guidance should do more to protect the privacy of registrants. Some felt that we should include more information on the circumstances in which decisions should remain confidential with reference to the relevant case law. Comments included:

"We would like to see a reference in the bullet points to safeguarding the registrant and their personal information ensuring that the publication does not provide more information than it needs to." [Professional Association]

"The disclosure of information should be reasonable and proportionate to achieve the regulatory purpose without unnecessarily infringing on an individual's right to privacy, including the registrant." [Professional defence organisation]

"The PSA's proposed guidance does not include sufficient detail regarding the circumstances where decisions should remain confidential." [Professional Association]

3.95 Of those respondents who disagreed that the factors to consider on publishing case examiner decisions were the right ones, one thought that no information on cases should be published at all, or if it was it should only be available for a short period of time. Others thought that publishing such detailed information would not be necessary where the facts had been accepted.

How we've responded

3.96 The introduction of accepted outcomes has the potential to reduce the transparency of decision-making since many cases that would previously have been heard in public will now be considered and agreed in private. Ensuring that decisions are transparent and accessible is a key means by which confidence in regulators, and regulatory processes, is maintained. Central to achieving this is ensuring that regulators publish sufficient detail about cases and how they are resolved. We therefore remain of the view all fitness to practise decisions should be publicly available and include enough detail so that a third party with no prior knowledge of the case would be able to fully understand both the basis of the concern and the rationale for the decision. The public must be able to have confidence in both the accepted outcomes process and the final outcome.

3.97 We conclude that the guidance should include a recommendation that regulators should publish the full details of the regulatory concern(s), grounds for actions, reasoning behind any decision-making, and final sanction.

3.98 We have considered the feedback regarding the lack of detail about what information should remain confidential, and believe that this can be addressed by adding a reference to relevant case law.

3.99 Based on the feedback received:

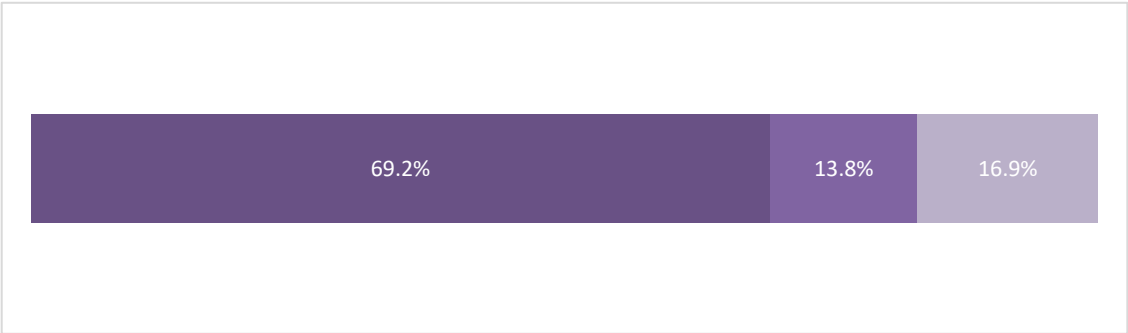
- we will update this section of our guidance to include reference to relevant case law regarding confidentiality.

Question 18. Factor 8: Promoting a fair and effective accepted outcomes process. Do you agree that the bullet points listed

under this factor in the guidance are the right ones? [Yes/no/don't know]

What people said

3.100 Question 18 was answered by 65 respondents, with 69.2% agreeing that the factor set out in our guidance to promote a fair and effective accepted outcomes process were the right ones. 13.8% disagreed and 16.9% didn't know.



Question 19. Do you have any comments on the bullet points listed in the guidance under this factor? [Free text box]
The bullet points listed in our guidance under this factor were:

- *Has due consideration been given to ensuring that complainants are treated with dignity and respect, feel heard, and are kept informed within the accepted outcomes process?*
- *Have steps been taken to protect the independence of decision-makers and ensure that they are able to make impartial and fair decisions, free from undue pressure to meet targets or save costs?*
- *Have steps been taken to identify any differential impacts of accepted outcomes on people who hold shared protected characteristics? Where the process may impact negatively on certain groups, have steps been taken to mitigate this?*
- *Are accepted outcomes monitored and recorded in such a way that it is possible to assess any differentials in sanction by protected characteristic?*

What people said

3.101 This section of the guidance covers 'complainant voice in accepted outcomes', 'the role of case examiners in proposing fair and proportionate accepted outcomes' and 'equality, diversity and inclusion considerations'. There was strong support for the inclusion of these factors in the guidance overall but a divergence of views on some aspects of the detail. Most comments focused on how the individual elements would work in practice, rather than the section as a whole. Of those that did provide feedback on this section in more general terms, comments included:

> ***"The guidance is helpful in that it highlights potential areas where the reforms may lead to unintentional negative impacts as a result of decisions based on limited or insufficient evidence. The 'key questions' and 'points for consideration' for regulators are all useful for helping regulators mitigate against unintentional impacts." [Professional association]***

> ***"safeguarding against bias and ensuring decisions are made impartially are crucial for effectiveness. These bullet points, align well with promoting fairness and effectiveness in the accepted outcomes process." [Patient body]***

The complainant voice in accepted outcomes

3.102 This section of the guidance outlines that patients and service users who are witnesses in proceedings should be treated with dignity and respect, feel heard, and kept informed throughout each stage of the accepted outcomes process. It also states that they should be able to make representations within the accepted outcomes process before a decision is made.

3.103 There was a divergence of views amongst respondents about this part of the guidance. Some responses, particularly those from patient groups or who were acting as patient representatives, felt that the guidance should go further and be more prescriptive in terms of the rights of complainants. Suggestions included that complainants should be able see the evidence and update their statements, have the right to make a complainant/witness impact statement, and be informed what aspects of their complaint had been taken into account in reaching a final decision. Some respondents pointed out that the initial account or complaint may have been given a long time before the investigation stage and the final allegations

may differ substantially from the initial complaint. New or different allegations may prompt the complainant to wish to provide additional information. Comments included:

"Certainty of facts cannot be achieved if the complainant has not seen the evidence... the guidance should include the regulator inviting the complainant or public witness to receive a copy of the most recent factual evidence including the most recent statement of the registrant and the allegations, in order for them to provide any further factual information relevant to the allegations before the case goes to the CE [case examiner]." [Patient representative]

"We agree that the complainant's voice is important when dealing with accepted outcomes. We agree that they should be able to make representations before a decision is made, and the published decision should refer to what the complainant has said." [Healthcare professional regulator]

"need more prescriptive guidance ensuring the complainant's story is included and they are able to provide updated statements against the final allegations before decisions are taken." [Patient representative]

3.104 We heard similar views from those who attended our patient and service user roundtable. Participants at the roundtable suggested a number of ways in which complainants should be involved in the accepted outcomes process including that they should be able to give video evidence, revise their statement before it is sent to case examiners, provide an impact statement, and be afforded a choice over whether the case is resolved by an accepted outcome or a panel. Concern was also raised that the voice of vulnerable people may be diminished without a panel hearing.

3.105 In contrast, a number of responses, most notably from healthcare professional regulators, did not support the recommendation that complainants should be able to make representations before a decision is made, or were unsure what this would mean in practice. Some were concerned that this could result in a negotiation between complainants and registrants. Others felt that as complainants have no official status it was unclear what representations they might make. Comments included:

"the suggestion that a complainant should be "able to make representations within the accepted outcomes process before a decision is made" as proposed at paragraph 7.37 of the guidance

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would also require a registrant to be able to do the same, turning the accepted outcomes into a negotiation between complainants and registrants which would undermine the regulator's role in assessing evidence based on risk to uphold public protection." [Healthcare professional regulator]

"It is unclear how the complainant will 'make representations within the accepted outcomes process before a decision is made'... For a complainant to make informed representations, it would be fair and reasonable for them to have sight of all documentation gathered in an investigation together with the registrant's response. We consider that this may be unworkable and may dissuade registrants and witnesses from engaging in the process." [NHS body]

"We agree with everything in paragraphs 13.3 and 13.4 to the effect that referrers should be kept informed of the progress of the matter and the critical importance of ensuring their concerns are properly understood before we reach a decision... This is not the same as seeking their representations or views before we reach a decision. This is also not the same as "giving them an opportunity to respond to evidence". [Healthcare professional regulator]

3.106 A number of respondents also felt that the guidance should reference the importance of the registrant's voice being heard.

The role of case examiners in proposing fair and proportionate accepted outcomes

3.107 This section of the guidance outlines that, unlike panel members, case examiners are not independent of regulators. It highlights the risk that case examiners may be subject to pressure or targets that affect the objectivity of their decision-making and recommends that regulators ensure that quality assurance processes are in place to mitigate such risks.

3.108 A number of respondents were concerned about the (lack of) independence of case examiners, perceiving this to be a risk to fairness. Some recommended particular controls or mitigations that could be put in place such as prohibiting case examiners from speaking to other employees and introducing robust quality assurance processes. Comments included:

"we are concerned about the independence of the decision-maker and the risks around their level of objectivity that may come with this. The level of independence afforded to panel members mean that

decisions can be made confidently without influence and internal pressures from the regulator." [Registrant body]

"Regulators should not only be alive to the risk of case examiners being impacted by targets they should also put into place robust and auditable quality and assurance processes to mitigate such risks... We strongly recommend that PSA guidance should make clear that regulators must have in place clear (and published) guidelines on how information is handled to prevent any conflict (or potential conflict) of interest." [Professional defence organisation]

"The question of the independence of the examiners is extremely important - these changes make much of the process internal and only open to scrutiny after the fact. Organisations should be regularly assessed on their performance in this regard and a review of the process should be carried out once it has been in place for an appropriate length of time" [Professional association]

3.109 In contrast, some respondents did not agree that case examiners were more likely than panel members to be subject to pressure that may affect their decision making:

"we do not agree with how you have articulated this consideration at paragraph 7.38 of the guidance. There is no evidence to suggest case examiners are more likely than other decision makers to 'be subject to pressure or targets that affect the objectivity of their decisions'. Working cultures should support decision making integrity for all decision makers..." [Healthcare professional regulator]

Equality, diversity and inclusion considerations

3.110 This section of the guidance outlines that the move to a paper-based approach in fitness to practise may have differential impacts, both positive and negative, on people with shared protected characteristics. It outlines our expectation that regulators should conduct an equality impact assessment as part of the development of their accepted outcomes process and take steps to mitigate negative impacts on people with shared protected characteristics or other needs and/or vulnerabilities.

3.111 Most respondents who commented on this aspect of the guidance were concerned to ensure that EDI considerations were taken into account by regulators and that any differential outcomes were monitored. There was also

concern expressed about the possibility of some registrants (particularly those without legal representation) feeling pressured into accepting an accepted outcome. Comments included:

"It is critical that outcomes are measured against protected characteristics" [Professional association]

"there should be a requirement in the guidance for regulators to demonstrate how they have promoted fair and effective accepted outcomes process. This would include providing comprehensive datasets which includes full and comprehensive EDI data" [Professional defence organisation]

3.112 One respondent objected to the part of the guidance stating that no participants should be disadvantaged by the accepted outcomes process due to a protected characteristic that they hold or other specific needs that are not met:

"we do not agree with your statement at paragraph 7.43 of the guidance "it is important that no participants are disadvantaged by the accepted outcomes process" because this is not something that can ever be guaranteed for any process or policy." [Healthcare professional regulator].

Other considerations

3.113 Finally, a number of respondents thought that regulators should seek feedback from people who have participated in a fitness to practise process in order to aid learning and improvement:

"The draft PSA guidance should also mandate seeking feedback from everyone that has taken part in that FtP process (complainants, registrants, witnesses, legal representatives etc). This feedback loop is critical to establish the veracity of any claims made by the regulator that their processes are fair. This feedback should be collated and any learning form part of the annual FtP report that regulators should publish." [Professional defence organisation]

"There should be a system of asking all people raising concerns and the registrants to give feedback on the experience regarding Fitness to

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Practice. From this feedback it would help in making improvements to the process." [Patient representative]

How we've responded

The complainant voice in accepted outcomes

3.114 We remain of the view that that ensuring patients and service users who are witnesses in proceedings are treated with dignity and respect, feel heard, and are kept informed, is vital to ensuring confidence in the regulatory process.

3.115 For some complainants, the paper-based nature of the accepted outcomes process may feel less transparent than a public hearing. This has the potential to undermine their trust and confidence in accepted outcomes. Further, the nature of the process, whereby agreement needs to be reached between the regulator and the registrant, but not the complainant, has the potential to appear unbalanced from the complainant's perspective. It is therefore important that regulators take steps to demonstrate that they have heard and considered the complainants' concerns in full.

3.116 The responses we have received, in particular from patient representatives, have highlighted that complainants who are patients or service users sometimes feel marginalised by the fitness to practise process. A number of such respondents felt strongly that complainants should have the opportunity to see the evidence (particularly any statement submitted by the registrant) and be afforded the opportunity to update their statement or submit further evidence if necessary.

3.117 We acknowledge that this view is not shared by a number of the regulators we oversee. However, we also note that Social Work England, which uses accepted disposals, does make provision for complainants to comment on written submissions by the registrant.[6] We have also sought a legal opinion on the objections raised by some respondents in respect of sharing the evidence of the registrant with the complainant. We have been advised that it would be appropriate for this evidence to be shared, and that doing so would not require full disclosure of all the supporting information, nor would it open the door to a prolonged process of negotiation. Were the complainant to provide new evidence which indicated an additional regulatory concern, this may require further investigation by the regulator. While this would present additional work for regulators, it is in the interests of public protection that all regulatory concerns are heard and understood in full.

[6] Social Work England's case examiner guidance outlines that during the investigation stage investigators may 'provide the complainant with a copy of the social worker's response and seek further submissions from the complainant. They may do this if (one or more of the following): they feel it is appropriate and relevant; the social worker's response has revealed new or conflicting evidence.' See: Social Work England, 2022, Case Examiner Guidance: Case examiner guidance - Social Work England

3.118 In light of the concerns raised by patient representatives, the example of Social Work England's accepted disposal process, and the legal advice we have received, we have decided to both clarify and strengthen the guidance by recommending that complainants are afforded the opportunity to provide further evidence where appropriate. This may involve providing the complainant with a copy of the registrant's response and seeking further submissions from them.

3.119 More broadly, we believe that that the role of the complainant in the accepted outcomes process may require further consideration by us and regulators when the practical implications of the new process are better understood. We will monitor and assess regulators use accepted outcomes in practice, including how they are ensuring that the concerns of complainants are fully understood and considered. We may revise the guidance in future to further advise on best practise in this area.

3.120 Based on the feedback received:

- we will amend the guidance to make clear that complainants should be afforded the opportunity to provide further evidence where appropriate.
- we will explain that this may involve providing the complainant with a copy of the registrant's response and seeking further submissions from them.

The role of case examiners in proposing fair and proportionate accepted outcomes

3.121 We remain of the view that the fact that case examiners are less independent of the regulator than panel members may present some regulatory risks in terms of the objectivity of decision-making. Our guidance seeks to ensure that regulators are alive to this risk and ensure that internal quality assurance processes mitigate it where possible. We do not seek to be prescriptive in terms of how regulators should design this process or assure themselves of its effectiveness. We believe this strikes the right balance between public protection and flexibility, and intend to retain this section of our guidance in its current form.

3.122 Based on the feedback received, we will not be making any changes to this part of the guidance.

Equality, diversity and inclusion considerations

3.123 We remain of the view that the introduction of accepted outcomes may have differential impacts, both positive and negative, on people with shared protected characteristics. We think it is important that regulators take steps to identify these and mitigate negative impacts, as well as ensuring that data is collected and recorded in such a way that it is possible to assess differentials in sanction by protected characteristic.

3.124 Having carefully considered the feedback received in response to this question, we agree that it would be beneficial to change the wording in respect of those who

may be disadvantaged by the accepted outcome process. We acknowledge that it is not always possible to ensure that no one is disadvantaged by any policy change.

3.125 Based on the feedback received, we will:

- remove the requirement for 'no participants' to be disadvantaged and focus instead on the need for impacts to be identified and for negative impacts to be mitigated where possible.
- continue to monitor regulators' performance in relation to equality, diversity and inclusion through our performance review function.

Other considerations

3.126 We agree with the respondents who suggested that regulators should routinely seek feedback from people who have participated in a fitness to practise process.

3.127 Based on the feedback received, we will include a recommendation for regulators to consider routinely seeking feedback from people who have participated in a fitness to practise process.

Question 20. Please set out any impacts that the guidance would be likely to have on you and/or your organisation, or considerations that we should take into account when assessing the impact of our proposals. [Free text box]

What people said

3.128 Responses to this question were varied and several focused on the impacts of the reforms to fitness to practise and the introduction of accepted outcomes, rather the impact of the guidance itself. Responses which fell into this category highlighted the perceived positives of the reforms, including more timely resolution of cases, as well as some perceived negatives, including large quantities of written evidence being required at early stages.

3.129 Of the respondents that focused on the impact of the guidance, two felt that it may cause confusion about the legislative framework or did not align with the aims of regulatory reform. One highlighted the risk that publishing the guidance may result in the expectation that it would be implemented, when in fact regulators may choose not to do so. Comments included:

> ***"by proceeding to issue guidance with no formal status, there is the potential to raise the expectations of registrants and members of the public that regulators will implement the new accepted outcome***

powers in the way the PSA is advocating for and.. the way the guidance is drafted is likely to cause confusion about the legislative framework and the powers that the legislation confers on regulators." [Healthcare professional regulator]

"We are concerned that some aspects of this guidance will create confusion and have misconstrued the aims for regulatory reform or misrepresented how the legislation is expected to operate." [Healthcare professional regulator]

3.130 Other responses were more positive, with one suggesting that the guidance might help to increase transparency and engagement:

"[We] anticipate that we might see the following impacts from the guidance: Increased transparency and engagement: Improved public understanding of the regulatory processes might lead to increased engagement with [us] from people seeking support or more information." [Patient body]

3.131 One respondent stated that it was not clear how the guidance supported consistent decision-making.

How we've responded

3.132 We hope that the guidance on the use of accepted outcomes in fitness to practise will assist regulators to develop their own guidance in a way that maximises the benefits of the reforms whilst ensuring public protection.

3.133 We do not agree that issuing guidance that is not mandatory is likely to cause confusion. Our statutory remit includes the requirement that we: promote the interests of users of health and care in relation to the regulators we oversee; promote best practice; and formulate principles relating to good regulation and encourage regulatory bodies to conform to them.[7] We believe that issuing this guidance is in alignment with that remit. We make clear in the guidance that it is not binding and has no formal status. This is the case for all guidance that we issue; its purpose is to promote good practice and enhance public protection, but it is for regulators to decide whether and how they implement it.

3.134 In terms of the concerns raised about the alignment of the guidance with the regulatory framework, these have been addressed in response to the questions

[7] National Health Service Reform and Health Care Professions Act 2002: National Health Service Reform and Health Care Professions Act 2002 (legislation.gov.uk)

above, and changes have been made where appropriate. The responses to this question do not suggest that further changes are necessary.

3.135 Based on the feedback received, we will issue the guidance as planned.

Question 21. Are there any aspects of our proposals that you feel could result in different treatment of, or impact on, groups or individuals based on the following characteristics as defined under the Equality Act 2010 [Yes/no/don't know]:
Age
Disability
Gender reassignment
Marriage and civil partnership
Pregnancy and maternity
Race
Religion or belief
Sex
Sexual orientation
Other (please specify)

If you have responded 'yes' about any of the above, please provide further details, explain why and what could be done to change this [Free text box].

What people said

3.136 Most responses to this question focused on the potential impacts of the introduction of accepted outcomes, rather than the impact of our guidance itself. Respondents identified a number of ways that accepted outcomes may impact on people with shared protected characteristics. These included concerns that certain groups may be more likely to lack representation which may result in differential outcomes; that registrants with certain health concerns may be more likely to agree to an accepted outcome to avoid the stress of a hearing; that a paper-based system may disadvantage those with learning needs or for whom English is not their first language; and that the use of single case examiners may increase the risk of bias which may impact more on certain groups. Of those that made suggestions about how negative impacts could be mitigated, a number recommended that outcomes for different groups should be recorded and monitored.

3.137 Of those who did comment specifically on the impact of our guidance, one felt that there might be negative impacts for people with shared protected characteristics due to the potential for higher levels of referral to panel hearings:

> ***"If strictly followed, then these proposals may result in more cases being referred to a panel hearing process than necessary... with a higher proportion of certain protected groups within that cohort."***
> ***[Healthcare professional regulator]***

3.138 Another respondent was concerned that the inclusion of the need to assess insight as a factor may be more likely to impact on people with different cultural or faith backgrounds:

> ***"We are concerned by the impact of your proposal in the guidance that cases should be referred for a hearing where there are significant doubts over a registrant's insight. We are aware that individuals involved in the fitness to practise process may think, feel or behave differently because of their cultural background or faith... These factors can be relevant to how evidence of insight is provided and the way in which it is expressed. Your proposal... may discourage decision makers from carefully and fully considering the impact of how culture, faith or other differences have affected the evidence provided."***
> ***[Healthcare professional regulator]***

3.139 Other responses suggested that the guidance should do more to address the training of decision-makers to ensure discriminatory practices are not perpetuated through the process; recommend annual monitoring of EDI trends in the use of accepted outcomes; and outline what adjustments could be made to the process for those with additional needs. It was also suggested that the guidance should be made more accessible including to people with disabilities.

How we've responded

3.140 We agree that the accepted outcomes process may have differential impacts on some groups with shared protected characteristics and we have outlined some of these in our guidance.

3.141 The guidance recommends that regulators take steps to identify any differential impacts and mitigate any that are negative. It also recommends that regulators monitor and record accepted outcomes in such a way that it is possible to assess any differentials in sanction by protected characteristic. We believe that these

recommendations will help regulators to consider, monitor, and respond to any differential impacts.

3.142 We agree that the result of our guidance may be that more cases are referred to a panel than would be had we not issued guidance. However, we believe that our guidance should only result in cases being referred to a panel where to do so would aid public protection. In such circumstances, referral to a panel would not be a negative impact, but a necessary step to ensure the public is protected.

3.143 Based on the feedback received, we will retain this section of the guidance in its current form.

Other issues raised in response to the consultation

3.144 Some respondents raised issues which do not naturally fall under any of the questions above. One of these, which was raised both at our roundtable event with patient and service user groups and in response to the public consultation, was an objection to the phrase 'case disposal'. This wording was felt to be insensitive as it has connotations of 'throwing away'. It was felt that this may be particularly offensive to those who had suffered the loss of a loved one.

3.145 A number of the healthcare professional regulators we oversee raised queries or concerns about the impact of the guidance on the assessments we carry out of their performance. It was pointed out that although we state that the guidance is non-binding, we also say that we may look at how regulators are making use of accepted outcomes under our performance review process. Some felt this to be contradictory.

3.146 Some respondents also commented that the guidance should apply to non-responding registrants; where a registrant does not respond to a case examiner's offer of an accepted outcome within the prescribed period, a case examiner can impose a final measure without their agreement.

3.147 Finally, one respondent felt that the guidance should be clearer about how the factors to consider should be used. It was felt that the bullet point factors might suggest that a case where any of the bullet points applied should be referred to a hearing.

How we've responded

3.148 The term 'case disposal' is widely used within the health and care professional regulatory sector. However, we acknowledge that that the term 'disposal' may have negative connotations and apologise to anyone who has been offended or upset by this. We will remove references to case 'disposal' from the guidance.[8]

3.149 In relation to the concerns raised about the impact of our guidance on our reviews of regulators' performance, we will seek to make this clearer to regulators in our

[8] Note that the guidance will retain a reference to Social Work England's 'accepted disposal' process as this is the term used by Social Work England to describe the resolution of cases without a hearing.

communications with them about the guidance. Our position remains that regulators are not bound to follow our guidance and departure from the guidance will not count against a regulator unless the approach they take to rulemaking or accepted outcomes causes concern. Where this is the case, we may ask regulators to provide a rationale for the approach they have taken and to explain how they have assured themselves that it maintains public protection. It will be important to keep the guidance under review, particularly once the practical implications of the reforms become better understood. We will work with regulators to understand whether and how they are using the guidance and how it could be improved. This may mean that we amend the guidance to accord with examples of good practice and/or to change sections of the guidance that do not work as intended or cause practical difficulties.

3.150 We will keep the guidance under review and may revise it when the practical implications of the reforms become better understood.

3.151 With regards to the application of the guidance to final measures that are imposed on a non-responding registrant, we have stated that that many of the factors to consider will be relevant to both accepted outcomes and imposed measures. The guidance is intended to guide and inform the process that leads to the offering (or not) of an accepted outcome. This part of the process occurs prior to the registrant responding to the case examiner's findings and will therefore be the same whether the registrant ultimately accepts the outcome or not. The guidance should be clearer on this point. In cases where a registrant does not respond, the case examiner will face a further decision point in terms of whether or not to refer to a panel. Our guidance may be relevant to that decision, but equally there may be other factors that a case examiner should take into account. We conclude that this decision point should be explicitly covered by the guidance.

3.152 We will amend the guidance to make clearer how it would and wouldn't apply to imposed measures.

3.153 Finally, in response to the concern that the guidance is not clear enough about how the factors to consider should be used. Our position is that the factors to consider listed in the bullet points under each section are simply that – factors that a case examiner may wish to have regard to when making their decision. They are not intended to be binding or to imply that should any single bullet point apply a case should be referred to a hearing.

3.154 We will amend the guidance to clarify how the factors to consider should be used.

Rule-making guidance: what people said and how we've responded

4. As part of the legislative reform programme being undertaken by the government to modernise the legislation for the healthcare professional regulators, regulators will receive new powers to make and amend their own operational rules. This includes the removal of the requirement for Privy Council approval of rules which is currently in place.

4.1 We support the reform programme, including the introduction of new rulemaking powers and intend to issue this guidance to aid regulators in exercising these powers effectively. We hope that it will be helpful for regulators with these new changes but accept that there may be areas for improvement in our guidance. We intend to keep the guidance under review as legislative reform is rolled out across the regulators and the practical implication of the reforms become better understood. We will assess how regulators are making use of their new powers and use this information to update our guidance as necessary. This may mean we revise the guidance to accord with examples of good practice and/or to amend sections of the guidance that do not work as intended or cause practical difficulties.

Question 22. Do you think our guidance will help regulators exercise their rulemaking powers effectively? (free text)

What people said

4.2 Most respondents to this question agreed that the guidance would help regulators exercise their rulemaking powers effectively. Those who agreed often commented on its potential to promote consistency across health and social care regulation.

4.3 Comments included:

"Yes. It is vital that registrants and the public can have clarity on the processes of regulators, to ensure safe, fair and equitable treatment." [Professional association]

"The PSA guidance covers the important principles at stake and should support transparency in rule making that is fair, proportionate and agile enough to enable timely action as well as accommodation change based on best evidence. The eight elements that underpin a right-touch regulation approach are particularly helpful – being to the point and easy to review" [Professional association]

"Yes – this will free up regulators to be more agile, and give greater flexibility to develop rules that meet the needs of their registrants [...] suggest that a dialogue between the PSA and the regulators to be maintained to ensure appropriate scrutiny and oversight of the regulator's process is maintained." [Professional association]

4.4 Respondents generally agreed that the guidance provides the public and registrants with clarity on the process with regulators.

4.5 A significant minority of respondents felt that the guidance would not help. Reasons for this included the PSA's limited statutory powers in enforcing rules, raising concerns around the non-binding nature of the guidance.

"The [Organisation] is concerned that the PSA's guidance will "not have any official status or be binding on regulators". The [Organisation] feels that the PSA's guidance should be binding upon regulators, to ensure consistency and high standards in regulation. The [Organisation] has seen examples of regulators not adhering to other non-binding PSA guidance" [Professional association]

"We acknowledge that the PSA has limited powers and is unable to mandate this guidance or enforce consistence standards of rulemaking across the regulatory bodies. For this reason, the [organisation] supports the suggested steps outlined in Annex 1 – inter-regulator consistency tool, and the rulemaking guidance 2.5, whereby regulators could be asked to explain any divergence, and assessed on their rulemaking approach within their review." [Professional association]

"The PSA needs more powers to ensure regulators stick to the rule" [Registrant of a health or care statutory body]

4.6 Respondents also raised concerns around what constitutes proportionate and who determines the threshold for proportionality.

4.7 Respondents highlighted the need to consult widely with a range of stakeholders. One respondent felt that the guidance required stronger reference to the education sector as well as inclusion of students, trainees and the sector itself in a list of stakeholders that regulators should consult with when holding a consultation.

"We would recommend that the guidance developed by the PSA strengthens references to the education sector, students, and trainees within a list of stakeholders that regulators should engage and consult with when making, developing, or amending rules which may have

implications for the workforce pipeline. This will support the development of a more systematic and collaborative approach to managing interdependencies in regulatory policy and workforce planning." [Other health or care body]

4.8 To improve the readability of the document, two respondents suggested including an introductory section outlining the importance of defining the 'purpose' of the rules and guidance. Additionally, one respondent also recommended clearer distinction between the types of principles (i.e. statutory requirements as opposed to guiding principles or good practice).

"It would be helpful for the guidance to be clear at the outset about the overarching purpose of any set of rules as this will determine the ingredients for good rulemaking" [Health or care statutory regulator]

"In terms of how the guidance could be improved, we think it would be helpful if there is more clarity in the following areas:

- *The purpose and aim of the guidance should be clear and reflected in the context, for example, the rule making guidance could be read as policy development guidance and good practice*
- *The guidance needs to be clear on which principles are statutory requirements (under the AAPA Order), and which are guiding principles or areas of good practice*
- *The guidance lacks detail on the rule making process itself for example, what is a rule and what is its purpose/status alongside primary legislation, and what does good rule-making look like and how do you achieve that." [Health or care statutory regulator]*

4.9 One respondent emphasised the importance of collaboration between key internal teams as well as engagement with other regulators. The benefit of regulators developing clear initial policy instructions was also highlighted.

"The guidance does not cover practicalities for developing and amending rules. It should, for example highlight the importance of policy colleagues developing clear initial policy instructions, and of policy and legal colleagues working collaboratively to refine draft rules. It could also reference the importance of early engagement with other regulators to encourage cross-sector consistency." [Health or care statutory regulator]

4.10 One respondent also suggested that the PSA create a 'rule bank' for regulators to use to ensure rules are sufficiently similar.

> ***"We also see a role for the PSA here in ensuring consistency by coordinating across regulators and creating a "rule bank" for use where rules are sufficiently similar." [Health or care statutory regulator]***

How we've responded

4.11 We acknowledge the concerns of some respondents that as our guidance is not mandatory it may not be followed. However, as regulators are independent bodies it is not our role (and nor do we have the power) to direct them to carry out their functions in a certain way. We hope that regulators will take our guidance into account and that this will promote a fair and consistent approach between regulators. Additionally, we acknowledge some respondents' concerns that 'proportionality of consultation' is at the discretion of the individual regulator. As the guidance is of a non-binding nature, 'proportionality' is considered at the discretion of the regulators. However, we will explore areas within the guidance that we can strengthen to support consistent decisions that fulfil the proportionality objective.

4.12 We agree that it will be helpful for regulators to include an introductory section setting out the 'purpose' of rules. We acknowledge that some differentiation between the various types of principles could provide greater clarity. We will also expand the stakeholder list under section 7.4 of our guidance to include the education sector, trainees and students when regulators undertake consultations. We recognise the importance of regulators consulting a wide range of stakeholders to ensure they are making well informed decisions when creating new rules, and of collaborating with other regulators.

4.13 Based on the feedback received, we will:

- Issue our rulemaking guidance as planned, subject to the revisions detailed in this report
- Include an introductory section on the purpose of rules

Question 23. Do you think that the principles outlined are the right principles?

What people said

4.14 Question 23 was answered by 62 respondents, with 80.6% agreeing that the principles outlined in the guidance are the right ones. 11.3% disagreed and 8.1% responded that they didn't know.

Question 24. Do you have any comments to make on the principles listed or any additional principles to suggest?

What people said

4.15 Most respondents supported the principles we listed. Comments included:

"We broadly support the principle listed in the guidance document. We particularly welcome the focus in the principles on developing rules which facilitates multi-disciplinary team working and innovative practice." [Other health or care body]

"We agree with the PSA that rulemaking should be based on robust evidence and good practice, however, in the context of workforce planning and education and training this can sometimes be more complex and difficult when planning over a longer-term period and preparing for the future workforce and needs of patients, service and employers." [Other health or care body]

"The depth to which this area appears to have been researched and historical matters seem to have been taken into account is welcomed in light of the well-publicised miscarriages of justice affecting registrants. Consideration of the principles of inter-regulatory consistency must be paramount." [Individual respondent]

4.16 Some respondents indicated that it is unclear how regulators will be assessed against the principles outlined in the guidance, and one respondent also suggested producing a framework outlining possible repercussions for nonadherence. Comments included:

"Produce a framework which groups possible infractions and possible repercussions where possible" [Other]

"It is not clear how regulators will be assessed against these principles, or how they may be challenged on the way they set rules" [Professional association]

4.17 We received a suggestion to provide extra clarification on the different types of principles.

"S.4.2 of the guidance is a mixture of statutory requirements, regulatory reform aims, PSA principles, and other factors. We would question how these principles sit together with the implication being that they are all equal in weight." [Health or care statutory regulator]

4.18 Several concerns were also raised that the principles we outlined supported consistency of regulatory practice, when some regulators and associations believed that consistency is inappropriate due to differing regulatory contexts.

"Concerned about the principles that good rules and a good rulemaking process should result in regulation which supports consistency of regulatory practice between regulators, justifying disparity where appropriate" [Health or care statutory regulator]

4.19 Some respondents suggested changes to the principles, including recognising fairness as a standalone principle as well as emphasising the need for collaboration and consultation with stakeholders.

"Principles should reflect the centrality of fairness to rulemaking. It is essential that we engage with the question for what is fair throughout the rules development process to strike the balance between efficient and effective regulatory processes and the legitimate interests of registrants and third parties who will be affected by those rules" [Health or care statutory regulator]

"Principles emphasising the need for collaboration and consultation with stakeholders, including healthcare professionals and their organisations, should be incorporated. This approach is more balanced and ensures that the guidance effectively addresses the needs and perspectives within the healthcare community." [Professional association]

4.20 One respondent highlighted situations where an individual registrant may be subject to conflicting rules from more than one regulator, particularly with regulators from outside the health and social care sectors.

> ***"We would suggest that the regulated individual should never be put in the position where two regulators (to which they are accountable) disagree with each other. This requires understanding the wider regulatory environment surrounding the regulated individual or entity – not just health and social care regulators. We must recognise that registrants are also regulated by other bodies such as the Information Commissioners Office (ICO), the Advertising Standards Authority (ASA), the Competition and Markets Authority (CMA) and Medicines and Healthcare Products Regulation Authority (MHRA)." [Health or care statutory regulator]***

How we've responded

4.21 We acknowledge the concern of some respondents that it is not clear how regulators will be assessed against our guidance and that we have not explained the possible consequences of nonadherence. However, as regulators are independent bodies it is not our role (and nor do we have the power) to direct them to carry out their functions in a certain way. The guidance is advisory in nature and is intended to be used as a tool to aid regulators in making rules with their new legislative powers.

4.22 We agree that there should be clearer distinctions between the different types of principles outlined in the guidance.

4.23 We agree that fairness should be included as a standalone principle. Fairness should be a key consideration for all regulators when undertaking the rulemaking process, including in support of equality, diversity and inclusion. We will therefore include fairness as a standalone principle within our guidance.

4.24 Based on the feedback received, we will:

- Make clear the difference between compliance with statutory and other duties, and good practice in the principles
- Include fairness as a standalone principle and expand on what fairness means in practice.

Question 25. Do you think that that the guidance on consistency between regulators (avoiding unjustifiable difference) is helpful?

What people said

4.25 Question 25 was answered by 62 respondents, with 79% agreeing that the guidance on consistency between regulators is helpful. 6.5% disagreed and 14.5% responded that they didn't know.

Question 26. Do you have any comments to make on this section of the guidance?

What people said

4.26 Many respondents agreed that the guidance on consistency between regulators is helpful, noting that consistency will promote fairness and aid regulators in balancing flexible rulemaking powers effectively.

4.27 Comments included:

"We agree the guidance on consistency will help professional regulators to balance their flexible rulemaking powers effectively. Healthcare professionals are increasingly working in new and different ways, in more integrated settings and often across organisational boundaries that require a greater level of regulator standardisation across the different regulated professional groups. [...] We agree that variation between regulators may sometimes be warranted [...].In addition, we welcome the inclusion of an argument in the inter-regulator tool for regulators to consider that consistency provides clarity for professionals working at the edge or across professional boundaries. [...] A failure to adopt a consistent approach could lead to variation and lack of understanding of the roles for patients and the public." [Other health or care body]

"The [organisation] supports the enablement of the regulators to have profession specific standards, particularly in relation to the HCPC's Standards of Education and Training (SET)." [Professional association]

"Ensuring consistency between regulators is achieved and maintained is of vital importance to protecting the public. Not only does this ensure all health and care professionals are to work to the same underlying

principles but it also allows for an easier transition to fewer regulators in the future if this is desired." [Individual respondent]

4.28 Several respondents raised concerns over the principles of consistency, noting that in certain occupations and contexts (particularly dentistry), departure from consistency is necessary. Comments included:

"The profession [of dentistry] and the systems in which it operates, as well as the way in which the General Dental Council (GDC) operates because of the profession's 'configuration', are very different to the other regulated professions and their regulators. There are areas in the current legislation which need to be kept to avoid significant increases in illegal practice of dentistry, for example, but these parts of the legislation do not appear in the same way in the legislation of other regulators" [Professional association]

"Despite the recognition of justifiable differences in regulatory practice, we consider that the guidance on consistency between regulators could have the unintended effect of hindering right-touch rulemaking approaches that lead to fair and proportionate regulatory outcomes which are appropriate to particular professional contexts. [...] The specific contexts in which the different healthcare professions work pose different sets of risks and thus have implications for how each profession is regulated." [Health or care statutory regulator]

4.29 Some respondents agreed that the guidance on consistency is useful in promoting collaboration and consistency across regulators. However, these responses also highlighted that there may be justifiable and necessary departures from consistency in certain contexts. Some also noted that the inter-regulatory consistency tool that we provided in Annex A was confusing. Comments included:

"We suggest the table in Annex A requires further thought if it is to be a useful tool for regulators as proposed. As it stands, we find the terminology and structure confusing." [Health or care statutory regulator]

"We found this tool confusing and inaccessible. The three-step approach outlined at paragraph 6.6 works well and more helpfully outlines the PSA's expectations on how regulators should approach the question of consistency." [Health or care statutory regulator]

4.30 One respondent agreed that the guidance was useful but highlighted the absence of a mechanism by which stakeholders can challenge regulators if rules/the rulemaking process are deemed to be unfair:

> ***"This guidance is useful, however it does not highlight a mechanism through which the rulemaking process and consistency between regulators can be challenged if it is thought to be unfair and/or if stakeholders identify unintended consequences of initial iterations or future amendments of changes to regulatory processes that require addressing. We would welcome this being included in any final documentation. Consistency and parity across healthcare is desirable and this guidance will ensure some cohesion across regulators." [Professional association]***

4.31 Another noted that the steps to achieving consistency were unclear:

> ***"The guidance is helpful to a point and lists areas for consideration but isn't particularly clear on how this consistency will be achieved or determined." [Other health or care body]***

How we've responded

4.32 We acknowledge concerns from organisations that a consistent approach may not always be beneficial, and that differences in approach may be beneficial or even essential to public protection. The guidance will reflect this.

4.33 We acknowledge the feedback that there are no mechanisms outlined within our guidance through which regulators can be challenged if rules or the rulemaking process are thought to be unfair or produce unintended consequences. Whilst the PSA does not have the remit to supervise regulators' rulemaking, we are required to review their performance. If in the course of this work, we find evidence that regulator's rules are producing outcomes that do not protect the public effectively, we would raise the issue and expect regulators to take appropriate actions in response.

4.34 Additionally, the PSA will always encourage third party feedback if stakeholders feel that regulator rules are producing outcomes that do not protect the public. This feedback will be taken into account during the performance review process.

4.35 We accept, on review, that the wording and layout of the inter-regulatory consistency tool in Annex A could be more accessible.

4.36 Based on the feedback received, we will:

- Reinforce that regulators may need to take different approaches in their rules for the benefit of public protection

- Make parts of the guidance about the consistency tool clearer

Question 27. Do you think that the guidance on consultation is helpful?

What people said

4.37 Question 27 was answered by 62 respondents, with 79% agreeing that the guidance on consultation is helpful. 9.7% disagreed and 11.3% responded that they didn't know.

Question 28. Do you have any comments to make on this section of the guidance?

What people said

4.38 Many respondents agreed that our guidance on consultation was helpful and that consultations were an essential step to the rulemaking process. Comments included:

"We agree that consultations will be an essential mechanism for balancing regulators' autonomy with effective accountability and transparency. The PSA's guidance may want to provide further detail on who regulators should consult with." [Other health or care body]

"It is clear and helpful guidance." [Professional association]

"This provides fairly comprehensive advice for the regulator." [Professional association]

"Knowing when to consult, who to consult and how to consult is notoriously complex and challenging, so guidance setting this out is helpful in offering clarity and reassurance." [Accredited register]

4.39 One respondent suggested that regulators should be required to publish reports on changes consulted on once an impact assessment has been undertaken.

"Regulators should be required to assess the impact of proposed changes to their rules, processes, and systems before they are introduced. However, once the impact assessment has been undertaken, a report should be published by the regulator and any changes consulted on within a specified time frame. An established time frame as to when this will apply, in terms of regulators setting their own rules and standards, needs to be made explicit." [Professional association]

4.40 One respondent commented on the ambiguity of proportionality and included suggestions on how to strengthen our guidance:

"The [organisation] does not support the ambiguity of regulators only being required to consult on rules "to the extent they consider proportionate". It is the [organisation's] experience that different regulators interpret the necessity for consultation in very different ways. The [organisation] would like the PSA's proposed guidance to include:

• much greater detail on the low bar for consultation to be necessary;

• examples of circumstances in which failure to consult has been deemed unlawful; and

• strong encouragement for regulators to proactively engage with and consult registrants and other stakeholders in accordance with Standard Five." [Professional association]

4.41 One respondent suggested the inclusion of professional associations in the stakeholder list.

4.42 One respondent proposed that the PSA create a set of pre-consulted rules that regulators could use as their starting point to reduce the risk of consultation fatigue:

"We view the risk of "consultation fatigue" identified in 7.10 as being a considerable risk – particularly over the time period of creating the first set of rules as each regulator undergoes regulatory reform. We suggest that the PSA could have a role in creating a standard set of "pre-consulted" rules that all regulators could adopt as their starting point – this would be consulted in one go, widely, across all regulators and all stakeholders – preventing the need for repeat consultation (and the risk of alternative interpretation of the same viewpoint). This would meet the goals of consistency across all regulators and ensure that only the rules

that a regulator considers should differ from the core rules would require consultation." [Health or care statutory regulator]

4.43 One respondent sought clarification on section 7.8, noting that duplication between regulators is rare.

4.44 Some respondents sought clarification on the difference between 'formal' and 'informal' consultation and how the guidance would be used to support these types of consultation:

"We consider that it is important to clarify what is meant by 'formal' and 'informal' consultation and how this guidance is envisaged to support regulators in enacting these types of wider engagement activities." [Health or care statutory regulator]

"We would comment that the point about the 'scale or complexity' of a potential change about which may or may not be consulted might be viewed differently by the stakeholders of a regulator than the regulator itself. There might be a need to add information to that section to reflect what might be meant by 'minor' or 'non-substantive' in case the interpretation is more subjective than expected." [Professional association]

4.45 One respondent provided suggestions on areas that the guidance could expand on, including further clarification on proportionality and reference to other resources that would be useful when undertaking consultations.

How we've responded

4.46 We remain of the view that consultation forms a key part of the rulemaking process.

4.47 Again, we acknowledge some respondents' concerns that 'proportionality of consultation' is at the discretion of the individual regulator. As the guidance is of a non-binding nature, 'proportionality' is considered at the discretion of the regulators. However, in future we may look at how regulators are making use of rulemaking guidance under our performance review process and may take this guidance into account in assessing their approach.

4.48 We agree that professional associations can provide valuable insights during the consultation process, and will reflect this in the guidance.

4.49 We acknowledge that a clearer distinction can also be drawn between informal engagement and formal consultation.

4.50 The feedback highlights an important point about the need for regulators to be transparent throughout the process. We will reinforce messages about the

importance of transparency, and specifically the need for transparent reporting of the outcomes of any consultation.

4.51 We acknowledge the recommendation that the PSA should publish a list of pre-consulted rules to aid regulators in exercising their new rulemaking powers. A bank of rules could be helpful for the future, and we will consider whether this is something we could encourage the regulators to work together on.

4.52 Based on the feedback received, we will:

- Include a clearer statement about the importance of transparent reporting on consultation outcomes
- Expand the stakeholder list under section 7.4 of our guidance to reflect the feedback.
- Amend our guidance to provide greater clarity on what is meant by 'minor and substantive', and to explain the differences between different types of consultation.

Question 29. Do you think that the guidance on governance is helpful?

What people said

4.53 Question 29 was answered by 55 respondents, with 69.1% agreeing that the guidance on governance is helpful. 10.9% disagreed and 20% responded that they didn't know.

Question 30. Do you have any comments to make on this section of the guidance?

What people said

4.54 Most respondents agreed that our guidance on governance was helpful. Comments included:

> ***"We recognise the importance of regulatory internal governance, since the Privy Council will no longer approve rules or rule changes."***
> ***[Professional association]***

"Again, this guidance is important in maintaining accountability – good governance processes will be necessary in replacing the function of the Privy Council, in approving new or changed rules." [Professional association]

"New legislation will alter the governance pathway of statutory regulators, so guidance is helpful." [Accredited register]

4.55 Many respondents commented on the significance that the new legislation will have on governance arrangements. One respondent commented that the implications of regulatory reform are still unknown:

"The approval process for making rules will change with the current final decision-making body replaced in the future with a unitary board. Therefore, the route to approve and adopt rules will change as the decisions will be made by the unitary board for approval (rather than council and exec) so there are still some unknowns on the impact of regulatory reform on rulemaking by regulators." [Professional association]

4.56 Greater involvement of registrants in Council decision making to strengthen governance guidance was supported by one respondent.

4.57 One respondent highlighted the importance of accountability and the transparency of decision making:

"The constitution of the 'Board' as to unitary or council is less important than the principle of accountability." [Health or care statutory body]

4.58 There was a suggestion that specific frameworks should be set up to enable professionals to scrutinise their regulatory body. One respondent raised concerns that section 8.3 makes room for divergence rather than consistency across regulators.

4.59 Another respondent also sought clarification of section 8.3, noting that the wording is unclear, particularly in relation to governance decisions:

"Section 8.3 of the guidance implies there may be discretion around the role of the Council/Unitary Board and the governance pathway for rulemaking. Taking the AAPA Order 2024 as the template for future reform, the delegation of rulemaking powers is forbidden under Schedule 1 Paragraph 2(2). In light of that legal requirement, it is unclear

what the guidance is suggesting here with regards to governance decisions." [Health or care statutory body]

4.60 One respondent suggested providing explanations on the difference between Councils and Unitary Boards.

4.61 There was a further suggestion that the PSA requires more legal powers to hold regulators accountable.

How we've responded

4.62 We will take on board the various suggestions to refine our guidance in places where it is unclear.

4.63 We agree that it is helpful for registrants to be involved in decision making athough would not prescribe that this should be achieved through the membership of registrants on the Board, not least because this runs counter to the principle of the unitary board.

4.64 The fact that the changes in rulemaking powers will be happening alongside changes in the governance of regulators creates significant levels of uncertainty about how this will all work in practice. We will keep our guidance under review and make changes where necessary.

4.65 Based on the feedback received, we will:

- Clarify some of the wording of this section
- Include a definition of a unitary board.

Question 31. Please set out any impacts that our guidance would be likely to have on you and/or your organisation, or considerations that we should take into account when assessing the impacts of the proposals.

4.66 Several respondents noted that it was too early to indicate whether or not the guidance would impact their organisation and work.

"It is hard to measure impacts without noting the effect on the regulatory body, as it is there is little prospect of change in current practices." [Other]

4.67 Some respondents have reiterated that the guidance may be useful in assisting regulators to navigate their new rulemaking powers. As developing rules may be resource intensive and open new areas of learning, our guidance provides an effective starting point.

"If required to develop Rules, the [organisation] would see their development as a significant and resource-intensive undertaking. We doubt that we have the capacity to manage in-house. That said, Council have been consistently appraised of the possibilities and would wish to invest in any approach. This is likely to include a mixed model of outsourcing and partnership working alongside other regulators. The guidance will provide a particularly useful foundation to that endeavour." [Health or care statutory regulator]

4.68 One respondent highlighted the importance of flexible rules to ensure regulations do not restrict healthcare providers in providing essential services.

"Clear, proportional, and independent professional regulation is critical to safeguard patients, clinicians, and public trust in the healthcare system. However, excessive and rigid regulations can create bureaucratic obstacles that discourage GPs from entering or remaining in the profession, limit clinical flexibility, increase non-clinical workload, and compromise the quality of healthcare services. While targeted regulation is necessary, it is essential to minimise excessive and inflexible regulations that can restrict GPs' ability to provide essential services to the public." [Professional association]

4.69 Additionally, some respondents have highlighted the need for our guidance to remain flexible and evolve with changes that may result as regulator's rulemaking powers change.

"Currently, it is difficult to comment in depth about the guidance and its effect. It seems reasonable for now as a document providing pointers on what regulators should think about, but also seems to be a document that in itself will need to evolve as more reform takes place and questions around these new powers are clarified." [Professional association]

"Keeping guidance flexible so developments in modern healthcare can be assessed and supported in a timely manner is vital. [...] it is important that guidance is enabling whilst maintaining the safety of the public." [Individual respondent]

4.70 One respondent highlighted the risk of potential confusion with the new rulemaking powers:

"As a healthcare provider we need parity and clarity for our patients and employees. These changes have the opportunity to cause confusion and uncertainty for practitioners if the regulatory bodies undertake to change their rules." [Individual respondent]

"When considering the impact of decisions made on registrants, and the specific context within which care is delivered, there must be an acknowledgement that the private practice, sole practitioner environment is distinctly different from that of the NHS and community-based care." [Professional association]

4.71 One respondent raised doubts about the impact that the guidance would have on our reviews of regulators' performance:

"We have not identified any impact. That said, and as we have identified in our response to question 4, the PSA needs to clarify the status of the guidance as we note that paragraph 2.5 states it will not be binding on regulators yet may be taken into account in performance reviews. It is important that the guidance does not fetter our and other regulators' agility in rulemaking" [Health or care statutory regulator]

How we've responded

4.72 We will ensure that our guidance is updated as rulemaking continues to change and evolve. We understand that it may be difficult to comment on the substantive impact that our guidance may have at this stage. The AAPA Order has opened doors to new powers for regulators, which will naturally introduce new learnings for all parties involved, including the PSA. We endeavour to remain agile and will continuously evaluate our guidance to make changes we believe are necessary and proportionate.

4.73 We acknowledge that the independent practice, sole practitioner environment is distinct from that of the NHS and community-based care. As such we will incorporate sole practitioners working in private practice into the list of stakeholders that regulators should seek to consult.

4.74 In relation to the concerns raised about the impact of our guidance on our reviews of regulators' performance, we will seek to make this clearer to regulators in our communications with them about the guidance. We will continue to make clear that our guidance is not binding on regulators and that they may take a different approach as long as that approach remains compatible with the legislative framework and regulators' overarching duty to protect the public.

4.75 As explained above, we intend to keep the guidance under review as legislative reform is rolled out across the regulators and the practical implication of the

reforms become better understood. We will assess how regulators are making use of their new powers and use this information to update our guidance as necessary. This may mean that we revise guidance to accord with examples of good rulemaking and/or to amend sections of the guidance that do not work as intended or cause practical difficulties.

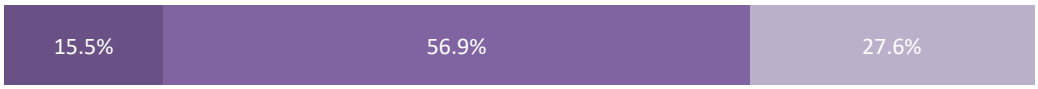
4.76 Based on the feedback received, we will:

- Include reference to independent practice and sole practitioners

Question 32. Are there any aspects of these proposals that you feel could result in different treatment of, or impact on, groups or individuals based on the following characteristics as defined under the Equality Act 2010?

What people said

4.77 Question 32 was answered by 58 respondents, with 15.5% agreeing that there are aspects of these proposals that they felt would result in differing treatment of, or impact on, groups or individuals based on the following characteristics as defined under the Equality Act. 56.9% disagreed and 27.6% responded that they didn't know.



If you have responded 'yes' about any of the above, please provide further details, explain why and what could be done to change this.

What people said

4.78 Of the respondents who did provide a written response, many agreed that those with protected characteristics under the Equality Act 2010 must be taken into account within our guidance.

"While we are not at this stage flagging up any specific concerns, it is essential to conduct thorough assessments to identify and mitigate any potential disparities or differential treatment that may arise from the proposal and may impact on individuals with protected characteristics." [Other health or care body]

"We have not identified any negative or specific differential impacts on groups who share protected characteristics. We endorse the emphasis the guidance places on the importance of consulting stakeholders, including patients and the public, who share protected characteristics, and of ensuring we and other regulators think about barriers that prevent them from participating effectively. We have suggested within our response the importance of ensuring fairness in rulemaking is explicit within PSA guidance, ensuring we and others implement rulemaking fairly, and in an accessible and flexible way to meet the needs of groups who share protected characteristics." [Health or care statutory body]

4.79 One respondent suggested that the PSA conduct regular Equality Impact Assessments with direct engagement with protected groups.

"Regulators should ensure continuous evaluation to understand their impact on groups with protected characteristics. The PSA may wish to undertake regular Equality Impact Assessments and engage directly with affected groups." [Other health or care body]

4.80 One respondent highlighted the need for reasonable adjustments to be taken into consideration for those with disabilities.

"People with disability may not be able to comply with tight schedules to read and respond, especially if they have no parents/family to assist and rely on the ephemeral case manager (Social worker/mental health) for support. Perhaps if such people are identified and then provided longer time-lines, assistance with reading/writing their response via face to face interview would mitigate the detriment." [Other]

How we've responded

4.81 As set out above, we agree that fairness should be a key consideration for regulators when making rules under their new legislative powers and we will amend the guidance to reflect the importance of this. In addition, both the PSA and regulators must comply with equalities legislation. We are keen use this guidance to help eliminate bias and disproportionate outcomes for registrants, as well as service users. As such we will ensure that our guidance encourages regulators to take the steps that are needed to assess and address any disproportionate impacts. During the consultation process, regulators should also seek to include any groups at risk of experiencing disproportionate outcomes.

4.82 In relation to the role the PSA can play to improve regulators' performance in relation to EDI, this is something that we already consider through our performance reviews. We recently revised our application of the standards in this area, and this will remain a key area of focus.[9]

4.83 Based on the feedback received, we will:

- Strengthen the references in the guidance related to assessing and addressing EDI impacts on particular groups

[9] Assessing performance against Standard 3 - guidance for regulators

Annex A: data tables

Accepted outcomes guidance

Q5 Factor 1

Row Labels	Don't know	No	Yes	Grand Total
Accredited Register			1	1
Accredited Register practitioner		1		1
Health or care statutory regulator		2	8	10
Member of the public	5	1	6	12
Other	1		5	6
Other health or care body			4	4
Patient representative body			2	2
Professional Association	1	1	22	24
Registrant of a health or care statutory body		3	4	7
Grand Total	**7**	**8**	**52**	**67**
%	10.4	11.9	77.6	100

Q7 Factor 2

Row Labels	Don't know	No	Yes	Grand Total
Accredited Register			1	1
Accredited Register practitioner			1	1
Health or care statutory regulator		2	8	10
Member of the public	3	2	7	12
Other	1		6	7
Other health or care body			4	4
Patient representative body			2	2
Professional Association	1	1	22	24
Registrant of a health or care statutory body		2	4	6
Grand Total	**5**	**7**	**55**	**67**
%	7.5	10.4	82.1	100

Q9 Factor 3

Row Labels	Don't know	No	Yes	Grand Total
Accredited Register			1	1
Accredited Register practitioner			1	1
Health or care statutory regulator		3	7	10
Member of the public	3	1	8	12
Other	2		5	7
Other health or care body			4	4
Patient representative body			2	2
Professional Association	2	2	18	22
Registrant of a health or care statutory body		1	6	7
Grand Total	**7**	**7**	**52**	**66**
	10.6	10.6	78.8	100.0

Q11 Factor 4

Row Labels	Don't know	No	Yes	Grand Total
Accredited Register			1	1
Accredited Register practitioner		1		1
Health or care statutory regulator		4	6	10
Member of the public	3	2	7	12
Other	2		5	7
Other health or care body			4	4
Patient representative body			2	2
Professional Association	2	2	18	22
Registrant of a health or care statutory body		2	5	7
Grand Total	**7**	**11**	**48**	**66**
%	10.6	16.7	72.7	100

Q13 Factor 5

Row Labels	Don't know	No	Yes	Grand Total
Accredited Register	1			1
Accredited Register practitioner			1	1
Health or care statutory regulator	1	1	8	10
Member of the public	2	1	8	11
Other		1	7	8
Other health or care body			5	5
Patient representative body			2	2
Professional Association	2	1	21	24
Registrant of a health or care statutory body	2	3	2	7
Grand Total	**8**	**7**	**54**	**69**
%	11.6	10.1	78.3	100

Q14 Factor 6

Row Labels	Don't know	No	Yes	Grand Total
Accredited Register			1	1
Accredited Register practitioner		1		1
Health or care statutory regulator	1	2	7	10
Member of the public	1	3	8	12
Other			8	8
Other health or care body	1		5	6
Patient representative body			2	2
Professional Association	1	2	22	25
Registrant of a health or care statutory body			7	7
Grand Total	**4**	**8**	**60**	**72**
% total	5.6	11.1	83.3	100.0

Q16 Factor 7

Row Labels	Don't know	No	Yes	Grand Total
Accredited Register			1	1
Accredited Register practitioner	1			1
Health or care statutory regulator	1	1	8	10
Member of the public	4		7	11
Other	2		5	7
Other health or care body			4	4
Patient representative body			2	2
Professional Association	3	2	19	24
Registrant of a health or care statutory body		4	2	6
Grand Total	**11**	**7**	**48**	**66**
% total	16.7	10.6	72.7	100.0

Q18 Factor 8

Row Labels	Don't know	No	Yes	Grand Total
Accredited Register	1			1
Accredited Register practitioner	1			1
Health or care statutory regulator	1	1	7	9
Member of the public	3	1	8	12
Other	1	1	5	7
Other health or care body			4	4
Patient representative body			2	2
Professional Association	1	4	17	22
Registrant of a health or care statutory body	3	2	2	7
Grand Total	**11**	**9**	**45**	**65**
% total	16.9	13.8	69.2	100.0

Rulemaking guidance

Q22

Count of ID	Column Labels			
Row Labels	Don't know	No	Yes	Grand Total
Accredited register			1	1
Accredited register practitioner		1		1
Health or care statutory regulator	1	1	5	7
Member of the public		1	6	7
Other	1	2	2	5
Other health or care body	1		3	4
Patient representative body			2	2
Professional Association	3	1	19	23
Registrant of a health and care statutory body		3		3
Grand Total	**6**	**9**	**38**	**53**
% total	11.3	17.0	71.7	100.0

Q23

Count of ID	Column Labels			
Row Labels	**Don't know**	**No**	**Yes**	**Grand Total**
Accredited register			1	1
Accredited register practitioner			1	1
Health or care statutory regulator	1	1	6	8
Member of the public	3	1	7	11
Other	1		4	5
Other health or care body			5	5
Patient representative body			2	2
Professional Association		1	23	24
Registrant			1	1
Registrant of a health and care statutory body		4		4
Grand Total	**5**	**7**	**50**	**62**
% total	8.1	11.3	80.6	100.0

Q25

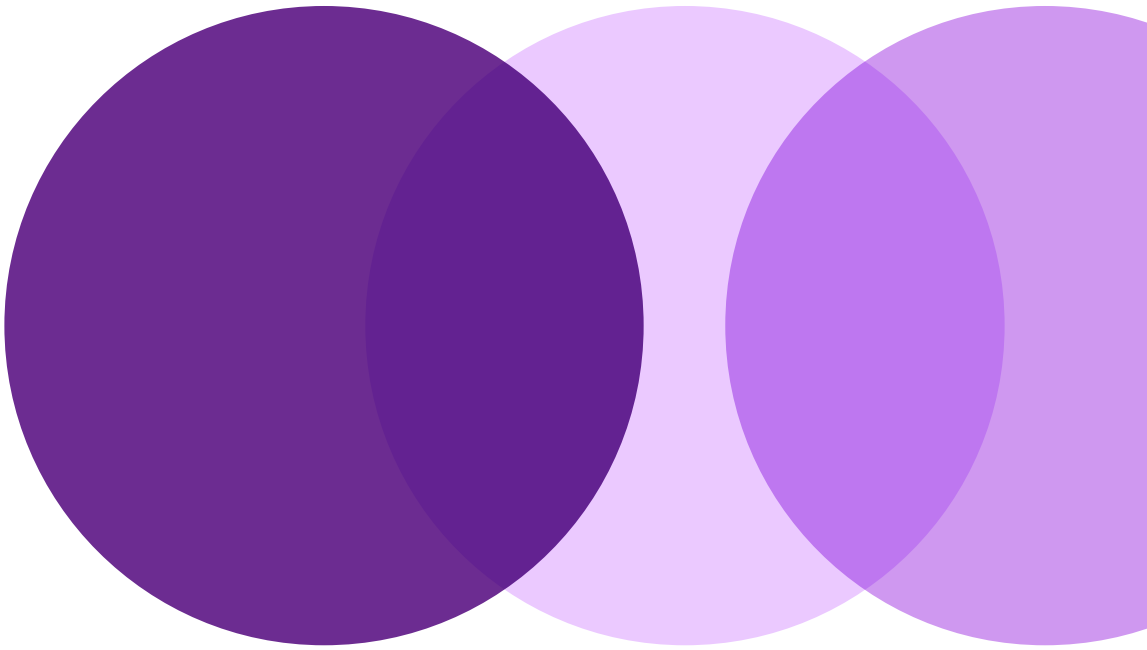
Count of ID	Column Labels			
Row Labels	**Don’t know**	**No**	**Yes**	**Grand Total**
Accredited register			1	1
Accredited register practitioner			1	1
Health or care statutory regulator	1	2	5	8
Member of the public	1	1	9	11
Other	1		4	5
Other health or care body			5	5
Patient representative body			2	2
Professional Association	4	1	19	24
Registrant			1	1
Registrant of a health and care statutory body	2		2	4
Grand Total	**9**	**4**	**49**	**62**
% total	14.5	6.5	79.0	100.0

Q27

Count of ID	Column Labels			
Row Labels	Don’t know	No	Yes	Grand Total
Accredited register			1	1
Accredited register practitioner		1		1
Health or care statutory regulator	2		6	8
Member of the public	2	2	7	11
Other			5	5
Other health or care body			4	4
Patient representative body			2	2
Professional Association	3	2	20	25
Registrant			1	1
Registrant of a health and care statutory body		1	3	4
Grand Total	**7**	**6**	**49**	**62**
% total	11.3	9.7	79.0	100.0

Q32

Count of ID	Column Labels			
Row Labels	Don't know	No	Yes	Grand Total
Accredited register	1			1
Accredited register practitioner		1		1
Health or care statutory regulator	3	5		8
Member of the public		8	3	11
Other		1	3	4
Other health or care body	1	2		3
Patient representative body	1		1	2
Professional Association	8	14	1	23
Registrant		1		1
Registrant of a health and care statutory body	2	1	1	4
(blank)				
Grand Total	**16**	**33**	**9**	**58**
% total	27.6	56.9	15.5	100



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