Response to the Government consultation on the draft Anaesthesia Associates and Physician Associates Order

May 2023

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care (the PSA) promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk.

1.2 As part of our work we:

- Oversee the ten health and care professional regulators and report annually to Parliament on their performance
- Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General Comments

2.1 We are grateful for the opportunity to comment on the draft Anaesthesia Associates and Physician Associates Order. We support these reforms, which herald a new era for professional regulation, and will bring much-needed change to the sector.

2.2 They will give regulators the flexibility to change the way they implement their legislation without having to go through a sometimes lengthy process of having these changes approved by the Privy Council. This will enable regulators to adapt more quickly to developments in healthcare and its delivery, and to improve their processes. We have called for them to have this agility, so they can deal with workforce pressures and risks emerging from new ways of treating patients and funding healthcare.

2.3 The Government's commitment to give all the regulators the same legislation – with some tailoring where needed – is a first step to making them more consistent. Consistency matters because it would help to simplify the complicated regulatory framework, making it easier for patients and employers

to navigate it, and for regulators to co-operate. This is all the more important in the wider context of multi-disciplinary team working, of which maternity services are one example. The second step will be for the regulators to work together to be consistent in how they put the legislation into practice.

2.4 The Government's proposal to use 'accepted outcomes' as an alternative to panel hearings will provide a quicker, less adversarial way to deal with concerns about professionals. The regulator would decide the outcome and put it to the registrant for agreement. It would cut out the step of a formal panel hearing – though panels would still be used for some cases. This change should help to reduce the impacts on all involved. The money saved could potentially be used for other things regulators do to help prevent harm, or to help keep fee increases manageable, at a time of acute financial pressure on health services.

2.5 We want to help make the most of what these reforms can offer, while being there to spot and address problems as they come up. In our response to the previous consultation, we recommended specific changes to our powers to counterbalance this greater freedom. We accept the Government's decision not to proceed with these changes. We support the aim of giving regulators more autonomy, but it remains important that this is appropriately balanced by effective accountability.

2.6 We are now considering how we can make best use of the other tools available to us to support these reforms. We will need to make some changes to what we look for in our performance reviews, and possibly also what we do to assess performance against our standards. Until the new model is brought in, we may not know exactly what this would look like, but we need to be prepared to adapt. We may need to make more use of policy advice and guidance to support the regulators to use their new powers effectively, and to guide our performance reviews. We provide some examples of this in our detailed answers below.

2.7 These reforms have the potential to be a significant improvement to the way things work now. It is important that they are rolled out to all the regulators we oversee as quickly as possible, not least to avoid having both the old and new models running at the same time for longer than necessary.

2.8 But there are still areas for improvement in the Government's proposals. Our detailed response to the consultation in the pages that follow sets out the improvements we have identified.

2.9 In response to the 2021 consultation *Regulating healthcare professionals, protecting the public*,[1] we developed a set of success and failure measures for

[1] https://www.gov.uk/government/consultations/regulating-healthcare-professionals-protecting-the-public

these reforms, building on the Government's own objectives.[2] We have amended them slightly to bring them up-to-date with the priorities we set out in *Safer care for all*, which themselves reflect the big patient and service user safety challenges in the health and care sectors. We have used these criteria to guide our response to the Government's proposals (see Annex A).

2.10 We encountered some challenges in responding to this consultation. We found the Order difficult to read and understand, with heavy use of cross-references throughout, and new concepts and umbrella terms that are not well defined (such as revision of decisions). In post-consultation redrafting, we would recommend some thought is given to how it could be made more accessible, as well as to how to eliminate some of the ambiguity created by these features of the current drafting.

2.11 Also, knowing that the intention is for much of the policy and legal drafting to be used across all the health professions, it would have been helpful if the consultation document had contained more information about how some of these approaches would apply to other professions and regulators. This is particularly the case where there has been a departure from what was set out in the 2021 consultation on policy.

2.12 The significance of this consultation may not have been apparent to some stakeholders, and even those who have understood its broader application may have found it difficult to respond meaningfully. This is a particular concern because wider stakeholders, and particularly patients, service users and the public, may have been insufficiently involved in the development of these reforms, in our view.

2.13 We are also concerned that the consultation itself did not include any meaningful assessment of the Equality Diversity and Inclusion (EDI) impacts (we discuss this in more detail in our response to the final question). It is evident that many of the changes being made will have impacts on protected groups, especially the fitness to practise framework – an area we know is problematic under the current model.

2.14 We trust that the Government will put in place robust evaluation mechanisms as part of the roll-out, to check whether policy objectives are being met, and help identify any unintended consequences – including EDI impacts and risks to public protection. Such an evaluation would also be a means of getting meaningful input from those affected by the reforms, including patients, service users and the public. Ideally such an evaluation would enable changes to be made, including retrospectively, where concerns have been identified, and need not interrupt the flow of implementation.

[2] These were to: 'improve the protection of the public from the risk of harm from poor professional practice; support the development of a flexible workforce that is better able to meet the challenges of delivering healthcare in the future; deal with concerns about the performance of professionals in a more proportionate and responsive fashion; provide greater support to regulated professionals in delivering high quality care; and increase the efficiency of the system.' From Regulatory_Reform_Consultation_Document.pdf (publishing.service.gov.uk).

2.15 This approach would help to mitigate:

- the risks of introducing sweeping reforms without piloting them first, and
- the challenges of assessing the risks and impacts pre-implementation resulting from the fact that this is 'framework' legislation, which delegates responsibility for implementation decisions to the regulators.

3. A note on our approach to this response

3.1 Most of the questions in this consultation relate to the regulatory model for Anaesthesia Associates (AAs) and Physician Associates (PAs). The Government has signalled that the policy direction, and drafting of the Order, determined by this consultation will set the direction for reform of other regulators.

3.2 Our response, therefore, considers the implications of the proposed legislation and underlying policy *across the range of healthcare professions and regulators*.

4. Consultation questions

Do you have any comments relating to 'part 1: general' of the consultation?

4.1 Our main comment on this part of the draft Order is nonetheless significant, as it relates to the interpretation of impaired fitness to practise.

4.2 The draft Order suggests that '*impaired fitness to practise should be defined as:*

'(i) inability to provide care to a sufficient standard; or
(ii) misconduct'

4.3 This is a change from the current approach, which specifies a range of possible grounds for taking action in fitness to practise. For most regulators this includes health, English language competency, criminal convictions, and findings by other bodies.

4.4 It will be important to make sure regulators can still take action in cases where harm has not yet occurred, but it is nonetheless necessary for a registrant's practice to be restricted for reasons of public safety. For example, this may be the case for certain health conditions that are known to present a risk if not properly managed.

4.5 Currently, to demonstrate deficient professional performance, regulators have to present a reasonable sample of work that demonstrates performance is deficient – typically several examples of deficient performance, and input from expert witnesses. This contrasts with the approach to health and English language in particular, where registrants can be required to undergo an assessment, the results of which are relied upon by panels to demonstrate

that the registrant's fitness to practise is impaired by reason of the relevant ground. If 'inability to provide care to a sufficient standard' is considered equivalent to deficient professional performance, regulators would be required to follow the former approach, which could make it harder for them to take action in these sorts of cases than currently.

4.6 When it comes to health, there will be cases where the condition has led to wider behavioural problems, or issues which have had an impact on public confidence, but that fall outside the direct delivery of care to a patient – it is hard to see how these would be dealt with under the new test. It is also unclear what impact the change would have on registrant's ability or willingness to self-refer.

4.7 We note that for health, this change would remove the procedural safeguards which go to creating a kinder, less adversarial environment – such as that health grounds should not result in removal from the register or should be determined in private. This could in part be replicated in rules, however regulators would need to ensure they were not fettering the discretion of panels and case examiners that is set out in the Order.

4.8 There is also a concern around criminal convictions and findings by other bodies, which are currently explicitly captured in grounds for impairment. It is unclear how these cases would be handled under the new regime. Removing these grounds would appear to introduce an additional step to establish whether a particular conviction or determination constitutes misconduct. This concern could perhaps be addressed in part though the Regulator's procedure rules. The current GMC fitness to practise rules, for example, state that production of a certificate of conviction "shall be conclusive evidence of the offence committed".[3] Similar provisions could be made under paragraph 10(3) of Schedule 4 to the Order with regard to proving the facts. Rules could potentially also be drafted to enable a more streamlined approach to proving misconduct in these cases.

4.9 More generally, the concerns we raised on this topic in our response to the 2021 consultation remain:

- The lack of information to explain the policy, its purpose, and evidence or analysis to support it
- The lack of definition of the problem this change is meant to address
- The potential for this change to redefine the meaning and purpose of key fitness to practise concepts, and lack of clarity over whether this is the policy intent
- The lack of support among some regulators for this policy change.

4.10 As we understand it, there is no intention to change the substance of what regulators can look at in fitness to practise. Changing the grounds appears

[3] General Medical Council Fitness to Practise Rules 2004, rule 34(3). Available at: https://www.mpts-uk.org/-/media/mpts-documents/ftp-rules---amended-november-2017-64002624.pdf

instead to be an attempt to describe the same things in a different way. We have identified some risks around that here, and there are likely to be other unintended consequences. It seems to us that giving all regulators the same, wider list of grounds would achieve the Government's objective of consistency, without running those risks.

4.11 A further point relates to the wording of the first ground of action. It is unclear how 'inability to provide care to a sufficient standard' would apply to registrants who are not providing care directly to patients or service users. This could be the case, say, for those working in research, health sciences, or senior management positions. We would welcome further clarity on this point.

4.12 To conclude on the grounds for action, the benefits of the proposed approach have not been well articulated, nor have the problems with the current one. Grounds for action will underpin decision-making at every step of the fitness to practise process. We consider that changing them in this way could introduce unjustified – and unacknowledged – risk and uncertainty, and lead to years of legal challenges, to develop the case law for the new framework.

4.13 We are not opposed to change, but would need to see stronger arguments in favour of this approach, to justify the risk, uncertainty and potential expense. We would also want to see a detailed EDI impact evaluation, as these changes will have direct impacts on individuals. This would be particularly important, given that we know that the current framework tends to disadvantage registrants from ethnic minority backgrounds.[4] [5]

4.14 Finally, on a different part of the 'Interpretation', we wanted to highlight the scope for confusion in the use of the term 'conditions' – which falls under the definition of 'final measure' here, but features as something else for the purposes of Article 7 – Conditions on Registration. We will return to this in more detail under the question on this article below.

Do you agree or disagree that the powers outlined in 'part 2: standards and approvals' are sufficient to enable the GMC to fulfil its role safely and effectively in relation to the education and training of AAs and PAs?

Note: This question does not relate to the GMC's powers for setting the standards for registration contained in Part 3.

4.15 Neither agree nor disagree.

4.16 We are pleased to note that, in line with our feedback on the previous consultation, the GMC would now be required to set standards for education and training. While we support the flexibility that Article 4(1) gives the GMC to

[4] Dr. Doyin Atewologun & Roger Kline, with Margaret Ochieng, 2019, Fair to refer? Reducing disproportionality in fitness to practise concerns reported to the GMC. Available at: https://www.gmc-uk.org/-/media/documents/fair-to-refer-report_pdf-79011677.pdf

[5] The University of Greenwich, 2017, The Progress and Outcomes of Black and Minority Ethnic (BME) Nurses and Midwives through the Nursing and Midwifery Council's Fitness to Practise Process. Available at: https://www.nmc.org.uk/globalassets/sitedocuments/other-publications/bme-nurses--midwives-ftp-research-report.pdf

undertake different types of approvals, we are concerned that it does not explicitly include a duty, rather than a power, for regulators to undertake some form of approvals process. In our view the GMC should be *required* to have a way of checking that education/training and assessments are sufficient to ensure that those qualifying are safe and effective AAs and PAs – with flexibility about how they do this.

4.17 This would provide greater clarity and certainty for both the regulator and regulated, and an unambiguous legal basis for conducting quality assurance activity.

4.18 We would also have liked to see an expectation that the regulator should consult patients and service users in both the development of standards for education and training, and the quality assurance of delivery.

4.19 We were unsure as to the significance of Article 4(3) – the power for the GMC to coordinate the stages of education and training, and would have welcomed more explanation of the meaning of this clause, and intention behind it.

Do you have any additional comments on 'part 2: standards and approvals' in relation to the drafting approach as it would apply to all regulated healthcare professionals?

4.20 See our answer to the previous question – these points would apply across all regulators and professions.

Do you agree or disagree that the draft order provides the GMC with the necessary powers to determine the standards and procedural requirements for registration?

4.21 Neither agree nor disagree.

4.22 We would like to be assured that across the regulators, the shift from renewal cycles to continuous registration would not have unintended consequences. Renewal of registration serves several purposes: collecting fees, periodic assurance that the basic registration requirements are met, and periodic assurance that registrants are up-to-date and fit to practise. We would have welcomed some acknowledgement of this, and explanation of how these mechanisms would be expected to operate under the new model – especially as the complex drafting makes this particularly challenging to ascertain.[6]

4.23 A policy decision seems to have been made not to give the GMC powers to register an individual, as opposed to a group, with conditions, aside from

[6] This part of the drafting is an example of the complex cross-referencing discussed in our general comments above. By our reading, the GMC's means of providing something approximate to the renewal process would be via: Article 8(2)(b)(ii)(aa), refers to Sched 4, 3(2)(b), refers to Sched 3, para 7, refers to Article 3(1) and is subject to Sched 3, para 7(2), which is subject to Article 7(3), refers to Sched 4, para 13; with Article 8(2)(b)(ii)(aa) being subject to Article 13(1), which is itself subject to Articles 13(2) and (5).

under emergency conditions.[7] As this option was suggested in the previous consultation, it would have been helpful for this to have been made clear.

4.24 We understand that in parallel with these reforms, the Government is looking at ways to improve the framework for appropriate clinical negligence cover, in particular to address issues arising for patients within the independent sector. This builds on work already underway, but links to the response to the failings relating to Ian Paterson, which resulted in many patients being unable to seek financial compensation because of the indemnity arrangements in place. We would therefore urge the Department to consider whether more can be done with the reform legislation to support this important agenda. We note that as it stands, the wording in the draft Order appears to replicate the current requirements for registrants with regard to indemnity requirements.

Do you agree or disagree that the draft order provides the GMC with proportionate powers for restoring AAs and PAs to the register where they have previously been removed due to a final measure?

4.25 Agree.

4.26 We strongly support the proposal for decisions about whether to restore an individual who has previously been removed through the fitness to practise processes to be made by a panel. We set out our reasons for this in our response to the previous consultation – the main point though is that these are people whose actions or behaviour were considered so egregious they were removed from the register, and as a result, restoration decisions are high-risk. Having the opportunity to question the applicant face-to-face is undoubtedly more effective than reviewing written submissions, when it comes to assessing insight and remediation – factors that are central to determining whether someone is fit to practise in these circumstances.

4.27 It is our understanding that the Government's policy is that the PSA should have rights to appeal restoration decisions about the registrants fitness to practise, which are to be made by panels. These are high-risk decisions, which currently fall under our section 29 (s.29) jurisdiction[8] – we therefore support this policy approach.[9]

4.28 We note however, that as currently proposed, our s.29 powers would only apply to panel restoration decisions following removal *by a fitness to practise panel*, and not removal by case examiners. The level of risk in restoring the registrant is the same, regardless of who imposed the final measure to remove them. We therefore strongly recommend that the drafting of s.29 is amended to include restoration decisions following removal by case examiners.

[7] See para 189 of Regulating healthcare professionals, protecting the public (publishing.service.gov.uk).
[8] Section 29 of the National Health Service Reform and Health Care Professions Act 2002.
[9] It is worth noting that s.29(2)(c) does not restrict our appeal powers to restoration decisions made by panels – it covers 'a decision of the regulatory body, or one of its committees or officers'.

4.29 We would be happy to work with DHSC to identify suitable wording for the legislation.

Do you agree or disagree that the draft order provides the GMC with proportionate powers for restoring AAs and PAs to the register where the regulator identifies in rules that it is necessary for the applicant to satisfy the regulator that their fitness to practise is not impaired?

4.30 Neither agree nor disagree.

4.31 We agree that the GMC and other regulators should have powers to determine whether a registrant is fit to return to the register where this may be in question. Currently at the GMC these decisions are not taken by panels, unlike restoration decisions post-fitness to practise removal – they can be made instead by the Registrar or case examiners if there are fitness to practise concerns. We support the decision to give regulators flexibility to deal with these cases as they see fit. Publishing rules about how and when they will make such decisions should help promote transparency and consistency.

Do you agree or disagree that the powers in the draft order relating to the content of the register and its publication will enable the GMC to effectively maintain a register of AAs and PAs who meet the standards required to practise in the UK?

4.32 Neither agree nor disagree.

4.33 We support the policy to grant regulators flexibility for registration of professionals in times of national emergency.

4.34 However, with respect to non-emergency registration, it would have been helpful to have more information on how the 'conditions' regime would be expected to function. This power is very broad, and there is little in the commentary to help understand it. For example, how would links be made between post-registration qualifications and conditions for a group of registrants? How would this work for the licence to practise regime operated by the GMC for doctors?

4.35 In addition, the use of the term 'conditions' on registration here seems unnecessarily confusing, given that it is also used elsewhere in the Order to describe a particular category of fitness to practise final measure, and is defined in the interpretation as such. This type of condition is a restriction on an individual's practice following a finding that their fitness to practise was impaired.

4.36 In contrast, one intended meaning of the term in Article 7 as we understand it, is what is currently referred to as 'annotations', which often denote a specialty, or other extension of practice – but could be used to differentiate between different categories of registrant or registration, such as temporary registration, or students. We therefore suggest a different term is used – 'annotations' could work – to avoid confusion with fitness to practise measures.

4.37 On the more general question of whether the GMC would be able effectively to maintain a register of AAs and PAs, it would be helpful to understand how the Order would enable the GMC to assure itself of the continuing fitness to practise (CFtP) of AAs and PAs – whether through revalidation or another model. As we explain in the footnote to 4.22 above, we found this part of the drafting particularly hard to follow.

Do you agree or disagree that the draft order provides the GMC with the necessary and proportionate powers to reflect different categories of registration and any conditions that apply to the registration of people in those categories?

4.38 See our answer to the previous question.

Do you agree or disagree that the draft order provides the GMC with proportionate and necessary powers in relation to the removal of AA and PA entries from the register which will enable it to operate a safe and fair system of regulation that protects the public?

4.39 Neither agree nor disagree.

4.40 There are a number of different provisions within this article. Perhaps the most complex – and risky – policy area relates to voluntary removal (VR) in 8(2)(b)(i). It is right that the regulator should have discretion about whether to grant voluntary removal – we note that there would be no restrictions on granting VR to registrants who are going through the fitness to practise process, which is where risks are likely to arise.

4.41 We welcome, alongside this, the provisions in Article 6(1)(b)(ii) that would allow regulators to check a registrant's fitness to practise before allowing them to return to the register following removal by means other than fitness to practise. This is an important part of the VR process, in that the biggest risks are likely to arise if former registrants about whom concerns have been raised but not established can return to the register with relatively little scrutiny of their fitness to practise.

4.42 More generally, we are not opposed to regulators having the ability to grant VR in these situations, but would want to see policies developed by the regulators that limited the circumstances of VR to the following:

- Where the concerns about the registrant's fitness to practise are limited to risks to the public that are not so serious as to require a public hearing or engage the public interest limbs of the overarching objective
- Where assurances that the registrant does not intend to practise again have been obtained; but at the same time there should be a clear process for any who do choose to apply to return to the register, and this should be done through a robust restoration process
- Where the investigation is sufficiently advanced to ensure that no significant aspects of the case have been overlooked, and there is enough

information about the concerns to inform a decision in the event of an application for restoration.

4.43 Another important safeguard is that these decisions should be published, so that there is a public record of any concerns that might be important for employers and the public to be aware of, should the person move to an unregulated role. We would therefore recommend that regulators are under a duty rather than a power to publish these decisions in Schedule 3, Art. 3, subject to the usual caveats about respecting confidentiality where concerns relate to health conditions or there are other overriding public interest reasons.

4.44 We accept that the Government has decided the legislation should be high-level and that the detail of implementation should be left to regulators to determine. As with other policy areas, the PSA may consider developing guidance on voluntary removal to help regulators develop their approach, and could choose to scrutinise implementation more closely through its Performance Review.

4.45 With respect to other types of administrative removal, it is unclear whether the GMC would have the powers to remove from the register a registrant who has technically complied with requirements for ongoing registration, but where there is clear evidence that they do not meet the standards – without having to go through fitness to practise. We understand that regulators who have this power now use it sparingly, but suggest it would be helpful for it to feature under the new framework.

Do you have any additional comments on 'part 3: the register' in relation to the drafting approach as it would apply to all regulated healthcare professionals?

4.46 See our answer to the previous question.

Do you agree or disagree that the draft order provides the necessary powers to enable the GMC to implement an efficient and safe system of temporary registration for AAs and PAs during a period of emergency as declared by the Secretary of State?

4.47 Agree.

4.48 We support inclusion of powers for emergency registration and do not have any particular concerns about these proposals.

4.49 In our review of the regulators' actions in response to COVID-19[10], we recommended an evaluation of the emergency registration arrangements that were used during the 2020 pandemic. As far as we are aware, this has not been done, making it difficult to comment on the effectiveness of those arrangements.

[10] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/learning-from-covid-19-a-case-study-review-of-the-initial-crisis-response-of-professional-regulators.pdf?sfvrsn=c6ad4920_6

4.50 That aside, we support the inclusion of broad powers for emergency registration of AAs and PAs, and do not have any particular concerns about what is proposed here.

Do you agree or disagree that the powers in the draft order enable the GMC to implement a 3-stage fitness to practise process for AAs and PAs proportionately and sufficiently?

4.51 Disagree.

4.52 The first stage of the fitness to practise process does not feature in the legislation, and contrary to what is stated in the consultation document, we are not of the view that regulators would be able to make rules in relation to this stage, because there are no rule-making powers that relate to this stage in the Order. Given that the Government intends all regulators to have a three-stage fitness to practise process, we recommend including all three stages in the legislation, rather than just two of the three.

4.53 We fully support the approach set out in the Government's own response to the previous consultation, that regulators should have a 'duty to consider a matter referred to them, and a discretion to determine whether or not there is a basis for onward referral'.[11] However, the main effect of not having this first stage in the draft is that it is not clear the regulator would have enough of either.

4.54 The Order, as currently drafted, does not include a clear duty on the GMC to consider all allegations. This is different to existing legislation which imposes explicit obligations on statutory healthcare regulators to investigate allegations (see, for example, the Medical Act 1983, s.35C(4)).

4.55 On an ordinary reading of the draft Order, (i) an officer of the regulator probably would have to determine whether any concerns brought to the regulator's attention (or arising internally) gave rise to a "question" as to whether an associate's fitness to practise was impaired; and (ii) if it did, they would be required to refer that matter to case examiners for them to consider exercising their powers under Article 9(1).

4.56 This would provide a limited filter, broadly equivalent to the role played by the Registrar at the rule 4 stage of GMC proceedings, where they are required to consider whether an allegation "falls within" section 35C(2) – i.e. whether it is capable of amounting to misconduct.[12]

4.57 In order to ensure that all allegations are considered, and enable a more extensive initial assessment (as envisaged in the Government's response to the 2021 consultation), we would recommend that the Order is amended to make explicit provision for initial assessment.

[11] P 134, Regulating healthcare professionals, protecting the public: consultation response - analysis (publishing.service.gov.uk)
[12] See R (Pal) v GMC [2009] EWHC 1061 (Admin)).

4.58 The absence of the initial assessment also means that there would be no mechanism for review of decisions made about a case at the early stages of the fitness to practise process. This would represent a backwards step for several of the regulators including the GMC, whose existing Rule 12 process allows for review, on request, of decisions made before the case is referred for adjudication.

4.59 A further problematic effect of this drafting decision is that it could give rise to unhelpful inconsistency. Each regulator could design a very different process, with different sifting stages for closing cases, using different criteria. This would be confusing to navigate and could result in inconsistent decisions between professions. The Williams Review shone a light on apparent differences between decisions made by the regulators, and the perceptions of unfairness that resulted from this.[13]

4.60 For the initial assessment stages, there is already inconsistency in the current system, and we have said that this should be fixed.[14] In our view, the Government should take this opportunity to require a minimum level of consistency between the regulators.

4.61 We therefore recommend that the Order is redrafted to include the initial assessment stage.

Do you agree or disagree that the powers in the draft order enable case examiners to carry out their roles appropriately and that the powers help to ensure the safe and effective regulation of AAs and PAs?

4.62 Neither agree nor disagree.

4.63 We support the move to expand the use of consensual disposals, and to give case examiners powers to dispose of cases in this way, to enable concerns to be dealt with more quickly, in a less adversarial way. This support has always been contingent on there being effective means of challenging these decisions for the purposes of public protection, and we will say more about this in our feedback on Article 11.

[13] We note the challenges of establishing or comparing fairness of decisions across regulators under existing arrangements, as highlighted both by the Williams review (https://www.gov.uk/government/publications/williams-review-into-gross-negligence-manslaughter-in-healthcare), and the related research we commissioned UCL to undertake, looking at possible methodologies to look into the question of consistency of fitness to practise outcomes (https://www.professionalstandards.org.uk/docs/default-source/publications/developing-a-methodology-to-assess-the-consistency-of-fitness-to-practise-outcomes-2019.pdf?sfvrsn=97c57420_0)

[14] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-reform-2017.pdf?sfvrsn=2e517320_7

4.64 We nonetheless have some comments on the proposed approach. We firstly would strongly recommend extending the maximum possible length of conditions from 12 months (Article 9(4)) to 3 years, which is what is available to the GMC and other regulators currently. Limiting conditions to a year is entirely unnecessary and would rule this measure out for many cases where a panel was not confident registrants could remediate in such a short time. This could lead to an increase in the number of review hearings – assuming the regulator had the ability to do this (see our comments on Article 11(2) below). In relation to both conditions and suspensions, Article 9(4) makes reference to the possibility of subsequent measures being imposed, based on the same evidence. We assume this is a reference to the framework that will supersede review hearings. If this is the case, it is important to note that review decisions are new decisions, rather than a revisiting of the original decision. New evidence must therefore be admissible, to enable a decision about whether the registrant's fitness to practise is still impaired, and what measure should be imposed if it is.

4.65 We expressed concern in our response to the 2021 consultation about the absence of a non-restrictive sanction – i.e. warnings, cautions, etc – for cases where the registrant is found to be impaired. Given the Government's stated intention to give case examiners and panels access to 'all measures', it is not clear why the options should be limited in this way. We are aware that Medical Practitioners Tribunals do not have an equivalent sanction, but other large regulators like the NMC do. In the spirit of giving the regulators all the tools they need to regulate effectively, we would recommend that such a measure is included.

4.66 We note that the legislation does not seem to provide for the registrant to simply request that their case is referred to a hearing. Instead, they would be required to provide a 'reasoned response' (Article 9(2)(b)) to the case and final measure put to them by case examiners. It would be helpful to understand what is intended by this requirement, and what assessment has been made of its fairness and possible impacts. For example, there is a risk that unrepresented registrants would be disadvantaged, which could have EDI implications.[15]

4.67 Specifically in relation to the use of case examiners, we note that there would be nothing prohibiting the regulator from using a single case examiner to make decisions – and we understand that the GMC has been considering the implications of this option.

4.68 Final decisions could be made by either a lay, or a registrant case examiner on their own. The former scenario could raise concerns about fairness to registrants, if the case examiner was not sufficiently well informed of professional and clinical matters. The latter could be a backward step, combining loss of transparency with the loss of the lay perspective in decision-making. This could affect public confidence in both the process and the decisions made.

4.69 This is a change from the current arrangements. Medical Practitioner Tribunal Service (MPTS) panels, which make all the adjudication decisions for the GMC, are made up of both lay and professional members. In fact, the GMC has had a requirement for adjudicating panels to include at least one lay member since 2000. The AAPA Order maintains this requirement for fitness to practise panels (Sched 4, 10(1)(b)), recognising its importance – it is unclear therefore, why this approach should not be applied to the proposed case examiner model.

4.70 Lay and professional involvement in final fitness to practise decision-making is something we are likely to take into account in our work looking at how regulators can make best use of their new powers to dispose of cases through accepted outcomes. We are planning to produce guidance for regulators to help them develop their own policies about how best to use the decision-making tools at their disposal, to maximise public protection under the new arrangements.

Do you agree or disagree that the powers in the draft order enable panels to carry out their roles appropriately and that the powers help to ensure the safe and effective regulation of AAs and PAs?

4.71 Neither agree nor disagree.

4.72 See our answer to the previous question, insofar as it relates to the length of conditions, review decisions, and the absence of a non-restrictive sanction post-impairment.

Do you agree or disagree that the powers in the draft order on reviewing interim measures are proportionate and sufficient for the safe and effective regulation of AAs and PAs?

4.73 Disagree.

4.74 It seems there may be an oversight in the drafting, as Article 10 gives case examiners no powers in relation to interim measures and therefore does not meet the policy intent here – any power to impose a new interim measure rests with the court only. The Order would need to give case examiners the power to renew, vary, revoke, or allow expiry of the interim measure in force before it expires. Without this, we cannot see how the interim measures scheme would operate.

4.75 Setting aside this drafting issue, we would recommend that the regulator is given the flexibility to use panels for these sorts of decisions. Interim measures are used only in high-risk cases, and while a decision to renew may be straightforward, decisions to vary, revoke, or allow to lapse may require a more robust decision-making mechanism.

[15] See for example: Overseas GPs lack representation at fitness-to-practise hearings and face 'harsher sanctions' - Pulse Today

Do you have any additional comments on 'part 4: fitness to practise' in relation to the drafting approach as it would apply to all regulated healthcare professionals?

4.76 See the answers to our previous questions.

Do you agree or disagree that the powers in the draft order provide the GMC with proportionate and sufficient powers in relation to the revision of decisions concerning the regulation of AAs and PAs?

4.77 Disagree.

4.78 We are concerned that Article 11 as drafted does not give the regulator adequate powers to protect the public: it is not clear how the power to revise decisions will operate, or that it will maintain the current level of public protection. It appears that some of the proposals will depart from the established hierarchy of decision-making. It also does not appear that regulators will have the power to carry out review hearings, which are a vital part of the current framework.

Article 11(1)

4.79 Article 11(1) would give the regulator powers to revise a range of decisions on the basis of an error of fact or law, or a material change of circumstances.

4.80 We recommend that the term 'revision' is defined, and that the legislation provides more clarity about what outcomes would be available in the event of a revision.

4.81 This applies to 11(1)(e), which gives the regulator powers to revise case examiner decisions. We had understood that an important aspect of this policy was that a case could be referred to a panel for a new decision – it is not clear that this would be an option as currently drafted.

4.82 More broadly, we would suggest two complementary changes to the mechanism for reviewing case examiner decisions, so that it might fulfil the public protection intent set out in the Government's 2021 consultation on the reforms.

Reintroduce a public protection test for reviewing case examiner decisions

4.83 According to the draft, case examiner decisions would be revised on the basis of an error of fact or law, or a material change of circumstances. This is a departure from the test that was consulted on in 2021, which, while not equivalent to the test of sufficiency for protection that is used for s.29 appeals, at least made reference to public protection. The current test more closely resembles an administrative challenge, and it is not clear that it is fit for the purpose of protecting the public.

4.84 We would therefore strongly recommend introducing a test for the review of case examiner decisions looking explicitly at whether they are sufficient for public protection.

4.85 Failing that, rules made under Schedule 4 would likely include further provisions as to the circumstances in which a decision may be revisited. This could include a public interest test equivalent to that in rule 12 of the GMC Fitness to Practise Rules, which specifies that decisions can be overturned where doing so is deemed necessary for the protection of the public.[16] This would not be equivalent to the s.29 public protection test though, as the grounds would still be limited to errors of fact or law and material changes of circumstances.

Reinstate the policy that regulators must refer a final decision onwards to a panel if the grounds for review are met

4.86 The 2021 consultation stated that '*where the registrar review results in a case being reopened which had been closed at the case examiner stage, it must be referred to the Fitness to Practise panel*.' It was our understanding that the proposed fitness to practise model was based on a hierarchy of decision-makers, in order of increasing authority: case examiners, then panels, followed by the Courts. The argument was made that referring case examiner decisions that were insufficient to protect the public to the Courts would be disproportionate, and that instead they should be referred to a panel.

4.87 The referral to panel requirement is not included in this draft. This is a concern both from a procedural and a public protection perspective. We would consider it anomalous for final decisions made by case examiners – with or without agreement from the registrant – to be capable of being revised by a member of regulator staff. While the case examiner process may not have the same trappings of formality as a panel hearing, these are none the less final fitness to practise decisions with the same legal status and effect as those made by a panel.

4.88 To grant 'the regulator' the ability to revise a case examiner decision appears to undermine the authority, specialist role, and formality of a case examiner decision. It would also seem to run counter to the Government's policy intention to remove the GMC's ability to appeal final fitness to practise decisions, by introducing an administrative process that would do just this – based on different grounds, but without the independence of the Courts.

4.89 The consultation went on to say: '*In all cases, the Fitness to Practise panel will make the final decision and the outcome will be published. As with all other decisions made by a Fitness Practise panel, these cases could be appealed by the PSA under its existing powers*.'

4.90 Losing the referral to panel element would also remove the ability for the PSA to challenge a new decision made by a panel under s.29, which was an integral part of the original policy. We therefore recommend that decisions that appear to the regulator to meet the criteria for revision – which we hope will be reframed as a public protection test – are referred to a panel for a new decision.

[16] Or the prevention of injustice to the practitioner or otherwise in the public interest (Rule.12(3)).

4.91 It is worth noting that under the Order, as currently drafted, identification of an error of law or fact would not *necessarily* lead to the decision being overturned: the Regulator would have discretion. This would constitute the first stage, meaning that under our proposal, not every request for a review would lead to referral to a panel. This two-stage decision would be similar to the current GMC rule 12 process.

4.92 To conclude, the approach set out in this consultation differs significantly from what was described in the 2021 consultation on the policies underpinning these reforms. We recognise that this is not an attempt to replicate s.29, but any proportionate alternative still needs to be capable of fulfilling a public protection role effectively – and in our view, the proposed process would not do so.

4.93 These changes, which have been introduced since the 2021 consultation,+ have been neither acknowledged nor explained in the published documents, which makes it difficult to engage meaningfully with the proposals, and to be assured that the policy making process is robust. The Government's response to the previous response suggests that stakeholder support for this approach was based at least in part on an assumption that appears not to be the case, namely that serious cases would be referred to panels. We would have liked to see any departures from the 2021 policy approach clearly explained to avoid further confusion, and to give stakeholders, and in particular patient groups, the chance to comment meaningfully on the new process.

Article 11(2)

4.94 This article would enable 'the regulator' to revise, among other things, decisions made by panels, on both interim measures and final measures, 'but not so as to increase the period specified in an Interim measure or Final Measure'. This revision can be made if there has been a material change of circumstances since the original decision was made.

4.95 The purpose of this article is not at all clear. If it is intended to replicate the review hearings regime, it is not fit for purpose, and we explore this in more detail in the next sub-section.

4.96 The arguments made above about the hierarchy of decision-makers apply here too, but more starkly. There would be nothing to prevent the regulator from making rules empowering a junior member of staff to revise a panel decision. While conditions and suspensions could not be extended, we see nothing in the drafting prohibiting the regulator from replacing a sanction with a lower or higher level sanction – e.g. replacing a suspension with a removal, or conditions. This seems highly anomalous, and we are not aware of any examples elsewhere in quasi-judicial or judicial systems of a regulator being given powers to amend decisions made by a quasi-independent decision-making body.

4.97 Currently, the most serious cases go to panels to ensure rigour, transparency, and independence in the decision; creating an administrative process with the

power to change the original panel decision, but without the procedural safeguards of the panel hearing, raises public protection concerns.

4.98 In addition, the PSA would have no powers to challenge these revised decisions on public protection grounds, despite our having the ability to challenge the original decision. This would seem to undermine the purpose and effect of s.29.

4.99 It would also create complexity by further upsetting the decision-making hierarchy. On a practical level, we would want clarity on how any revisions would interact with the PSA's statutory deadlines for referral of fitness to practise panel decisions to the Courts under s.29.[17]

4.100 Finally on this, as above, it would be helpful to understand how this policy sits with the Government's stated intention to remove the GMC's right to appeal FtP decisions made by the MPTS.

4.101 Overall, we would been keen to understand more about the policy thinking behind this proposal, in terms of both its utility and how it would work in practice. Granting regulators the ability to revise a panel decision was not, as far as we can see, proposed in the previous consultation, nor is it fully explained here. We are concerned that it could undermine both the fitness to practise panel framework, and the s.29 public protection safeguards that go with it.

4.102 We recommend the Government reconsider this approach. Should it decide to proceed with it, we would strongly recommend that the PSA is given powers to challenge a revised panel decision in the Courts, to avoid creating a public protection loophole.

Review hearings

4.103 Our reading is that the Order provides no effective mechanism to replace review hearings.

4.104 Under the current framework, when panels have imposed conditions on a registrant, or suspended their registration, the regulator can check whether the registrant is fit to practise unrestricted, before the sanction – or 'measure' under the new model – expires. The purpose of a review hearing is to i) consider whether existing concerns have been addressed, and ii) impose a further sanction to protect the public if they have not. In order to do this, review panels are able to consider new evidence (see our feedback on Art 9(4) above).

4.105 Regulators can trigger review hearings early, say if it is apparent that conditions are not working and need to be varied, or if the registrant has not complied. Conversely, the registrant can usually request an early review, if for

[17] For decisions against which the registrant can appeal we have 40 days to lodge an appeal starting on the last day on which the registrant can appeal; for non-appealable decisions, we have 56 days from when the registrant is notified of the decision.

example, they feel they have met the conditions and could safely return to practice.

4.106 The closest thing to this in the draft is article 11(2), which would give the regulator the ability to revise panel decisions, but there are significant problems with this:

- It would apply only to panel decisions and not to case examiner decisions, despite case examiners having the same ability to impose/agree conditions and suspensions as panels
- It would enable panel decisions to be 'revised' on the basis of a 'material change of circumstances' – so not a test relating to public protection
- It includes a restriction that the length of the measure could not be extended
- It assumes that these decisions are a revisiting of the original decision, rather than new decisions in their own right.

4.107 As mentioned above, the Order would also restrict the maximum period of conditions to 12 months, down from the three years currently available to the GMC and NMC, among others. Combining the shorter maximum period, with the inability to review fitness to practise decisions come the end of the conditions, risks creating a serious – and as far as we can see, unnecessary – public protection gap.

4.108 To add to this, it is not at all clear whether in future these decisions would be made by panels. This would mean that the PSA was unable to challenge under s.29 any outcomes that were insufficient to protect the public, because our powers would only cover panel decisions. At the moment, we carry out checks on decisions not to renew conditions or suspensions, and have successfully challenged several such decisions in the Courts for not protecting the public. Losing this ability would reduce the independent safeguards currently in place for fitness to practise decisions.

4.109 Review hearings – at which the full range of sanctions can be imposed – are necessary to ensure public protection.[18] A review decision that is insufficient to protect the public presents just as much risk to the public interest as an insufficient decision at a first substantive hearing. That said, we understand that in practice, not every review decision may need to be made by a panel – many are straightforward, and the risk of a decision, say to renew conditions or a suspension, is unlikely to be insufficient to protect the public. We would nonetheless want the regulators to be able to use panel hearings where

[18] The importance of an effective system of review of conditions and suspensions was underlined by Dame Janet Smith in her Fifth Report of the Shipman Inquiry, at para 25.328: '*Review hearings are extremely important, as they are the 'teeth' behind the sanctions other than erasure. If a doctor thinks that a period of suspension or conditional registration will simply expire and that s/he will automatically be allowed to return to unrestricted practice, there will be cases in which the remediation objective behind the imposition of suspension or conditions will not be achieved and patients will be put at risk*.' Available at: https://webarchive.nationalarchives.gov.uk/ukgwa/20090619150023/http://www.the-shipman-inquiry.org.uk/5r_page.asp

needed – and this option should be available irrespective of whether the original decision was made by case examiners or a panel.

4.110 The question of when to use panels for these sorts of decisions is likely to be relevant to our policy work on how regulators can make best use of their new powers to dispose of cases.

4.111 We therefore recommend that the Government:

- gives regulators clear powers to review conditions and suspensions to make sure a registrant is fit to return to unrestricted practice
- empowers regulators to use panel hearings for these decisions, and
- enables the PSA to challenge decisions made at these hearings under s.29.

Do you agree or disagree that the powers in the draft order provide individuals with proportionate and sufficient appeal rights in respect of decisions made by the GMC and its independent panels relating to the regulation of AAs and PAs?

4.112 Neither agree nor disagree.

4.113 We note that 12(1) would create a new internal appeal mechanism through panels for a range of decisions, including case examiner final decisions. No limits are placed on the circumstances in which such an appeal might be taken forward. As we understand it, registrants could also request that a case examiner final decision is reviewed under Article 11(1). It would be helpful to understand the different functions to be performed by these two mechanisms, and how they would work together in practice.

4.114 These panel appeals represent a new mechanism for appealing internal decisions. We note that the PSA would not have any means of challenging the outcome of a panel appeal of a case examiner final decision. We raise this because the most likely scenario, where a sanction is imposed because the practitioner fails to respond[19] and then seeks to challenge the outcome by way of an Article 12 appeal, the issue coming before the Panel would essentially be the same as if the practitioner had rejected the proposed sanction at an earlier stage and requested a hearing (the outcome of which could be appealed under section 29). While we have no particular wish to expand the PSA's remit, we cannot see the logic of having s.29 powers over a proposal rejected at an early stage, but not at a later one. We would welcome discussion with officials to work this through.

4.115 On Article 12(2), we would like to understand the rationale for fettering the grounds on which a registrant could appeal a fitness to practise decision of the Panel to the Courts. Currently there is no restriction on the grounds on which a registrant can appeal – the draft Order, however, limits them to errors of law, and the consultation documents provide no rationale for this.

[19] Using the case examiners' powers under 9(2)(b)

4.116 This change would make it difficult for a registrant to argue simply that a decision was wrong because it was too harsh – which is hard to reconcile with the aim of protecting registrants' rights stated in the previous reform consultation.[20] In our view, this would be unfair to registrants generally, could further disadvantage registrants from ethnic minority backgrounds who are already over-represented in the fitness to practise process, including by widening the inequality between registrants with representation and those without. We would recommend that this restriction is removed, and the current framework retained.

Do you have any additional comments on 'part 5: revision and appeals' in relation to the drafting approach as it would apply to all regulated healthcare professionals?

4.117 Our comments above apply across the regulators.

Do you agree or disagree that the offences set out in the draft order are sufficient to ensure public protection and to maintain public confidence in the integrity of the AA and PA professions?

4.118 Agree.

4.119 As we have outlined previously, we believe there is a need to review which titles are protected, and how regulators use their protection of title powers.

Do you have any additional comments on 'part 6: miscellaneous' in relation to the drafting approach as it would apply to any regulated healthcare professionals?

4.120 Our responses above are relevant across all professions and regulators.

Do you agree or disagree with the proposed powers and duties included in Schedule 1 'The Regulator' in relation to AAs and PAs?

4.121 Neither agree nor disagree.

Delegation

4.122 We support the introduction of powers for the regulator to delegate powers to other regulators overseen by the PSA. It could allow for some consolidation of the currently fragmented regulatory landscape. The PSA would encourage regulators to work together to explore the potential of this new provision.

Objective, matters to which the Regulator must have regard and co-operation

4.123 We understand that the governance reforms to the GMC are only partial, which explains, for example, the limited nature of the duty to co-operate in 3(1)(d), which will be sitting alongside the GMC's existing, broader duty to co-

[20] See para 8, page 5. Regulating healthcare professionals, protecting the public (publishing.service.gov.uk)

operate. It will be important for there to be a full public consultation on whichever legislation ends up acting as the complete template for reform, including the wider governance changes.

Default powers of the Privy Council

4.124 We agree that the default powers of the Privy Council should be retained. The PSA considers itself well placed to advise on whether these default powers should be invoked, insofar as they relate to regulator performance.

Do you have any additional comments on schedule 1, the regulator, in relation to the drafting approach as it would apply to all regulated healthcare professionals?

4.125 Our responses above are relevant across all professions and regulators.

Do you have any comments on schedule 2, listed offences?

4.126 We support this approach.

Do you agree or disagree that the powers in the draft order enabling the GMC to gather, hold, process, disclose and assure information in relation to the regulation of AAs and PAs are necessary and proportionate for meeting its overarching objective of protecting the public?

4.127 Neither agree nor disagree.

4.128 As mentioned above, we would want to see a requirement for the regulator to publish a decision to remove a registrant who was under investigation for fitness to practise concerns under the voluntary removal process, unless there was a compelling reason not to.

4.129 We continue to have concerns about the potential for unhelpful inconsistencies of approach to the publication of sanctions. We have long called for standardisation of sanction publication, and will continue to encourage this as regulators move to a model where they can decide on these policies without having to amend their legislation or rules.

Notifications to the PSA

4.130 We recommend that the GMC, and other regulators as they are reformed, are required to notify the PSA in a timely manner of any final fitness to practise decisions over which we will have s.29 jurisdiction, or that we could request are reviewed by the regulator under Article 11(1). We currently have good-faith arrangements with most regulators, and occasionally, we are not notified or are notified too late, of a decision. This can make it challenging to meet our statutory deadlines for lodging an appeal, which apply irrespective of when the regulator notifies us of a decision.

4.131 Having an express requirement in the regulator's legislation would put this matter beyond doubt and ensure certainty and prompt compliance.

Evidence gathering

4.132 As mentioned above, it is essential that the provisions set out in the Order give the GMC, and subsequently other regulators, powers to operate flexible continuing fitness to practise/revalidation/CPD, that could be linked to removal from the register.

Do you have any additional comments on schedule 3, evidence gathering, notifications, publication and data, in relation to the drafting approach as it would apply to any regulated healthcare professionals?

4.133 Our response to the previous question is relevant across all professions and regulators.

Do you agree or disagree that the draft order provides the GMC with sufficient and proportionate rule making powers to enable it to effectively maintain a register of AAs and PAs who are safe to practise?

4.134 We refer you to our feedback on other parts of the Order.

Do you agree or disagree that the draft order provides the GMC with proportionate and sufficient rule making powers to address non-compliance of AAs and PAs?

4.135 As mentioned above, we have concerns about the framework for reviewing conditions and suspension measures, and do not consider the Order is fit for purpose in this respect. We note that the rules relating to non-compliance add a further layer of complexity by giving the GMC powers to make rules allowing for the substitution of a different final measure when conditions or suspensions have not been complied with. This appears to sit outside the frameworks described in Articles 9 and 11, and would potentially circumvent the s.29 appeal mechanism.

4.136 The simplest and in our view most effective option would be to retain the existing review hearings model. It functions as a single mechanism for settling ongoing fitness to practise questions about a registrant under conditions or suspension measures – notwithstanding that we accept case examiners might be well placed to make certain review decisions.

4.137 We would also like to highlight that the PSA currently has powers to challenge decisions of the Medical Practitioners Tribunal made under the GMC's non-compliance powers. One effect of the change of approach to non-compliance is that we may be unable to challenge these decisions under s.29, if rules were made for panels to hear and determine non-compliance concerns as standalone cases.

4.138 It is hard to evaluate the impact of this. At the moment only the GMC has these powers, and we have not sought to challenge any such decisions to date. If the PSA were to lose the ability to challenge these decisions under the current framework, the impact could be minimal.

4.139 On the other hand, we are conscious that the changes to the fitness to practise framework are so extensive, they could lead to unforeseen departures from current ways of working. It is possible that the GMC could begin to rely on non-compliance provisions more than it has to date, and rolling these provisions out to all regulators would self-evidently also increase the impact of any loss of s.29 jurisdiction.

4.140 We are in discussions with DHSC officials about the boundaries of our s.29 jurisdiction. On balance, our preference would be for the PSA to have the ability to challenge these decisions through s.29 if considered necessary.

Do you agree or disagree with the provisions set out in the draft order for the setting and charging of fees in relation to the regulation of AAs and PAs?

4.141 Neither agree nor disagree.

4.142 We do not involve ourselves in the management of the regulators' finances, because this could then compromise our ability to comment on performance insofar as it relates to public protection.

4.143 That said, proper management of resources is essential to the smooth operation of regulation. It is therefore important that the GMC, and other regulators, have legislation that enables and supports them to manage their finances effectively. We are aware that some of the regulators have concerns about the workability of the drafting of the rules as to fees. As we understand it, the requirement to balance the books year-on-year does not reflect how some regulators currently manage their finances, for example to comply with charitable body status requirements.

4.144 There is also a concern that this requirement encroaches on regulatory independence. The principle that regulators should operate independently of Government is important – and any involvement in the management of their finances runs the risk of compromising this arrangement. The thrust of the reforms is to increase regulator autonomy, and setting prescriptive legislation about how they manage their finances would run counter to this. This looks to be an unintended consequence of the drafting.

4.145 We would therefore urge the Government to take the regulators' feedback into account, to avoid creating unnecessary complications, and to preserve the independence that they have now.

Do you agree or disagree that the rule-making powers set out in the draft order will enable the GMC to deliver the safe and effective regulation of AAs and PAs?

4.146 Neither agree nor disagree.

4.147 It seems to us that the Order would not enable the GMC to make rules relating to the initial assessment stage of the fitness to practise process. This appears to run counter to the stated intention for a three-stage process, and would be

of concern because this is an important and integral part of the fitness to practise framework.

Do you have any additional comments on schedule 4, rules in relation to the drafting approach, as it would apply to all regulated healthcare professionals?

4.148 The regulators are in a better position than us to comment on the extent to which the rule-making powers would enable them to regulate effectively. We note however that any rules would need to be within the boundaries of the powers set out in the Order (*intra vires*), and not fetter any discretion set out in the legislation. There is a risk, therefore, that they will not for example be able to replicate certain current statutory safeguards in their rules. This would be the case, for example, if prescribing in rules that allegations relating to ill-health could not result in the registrant being struck off, amounted to a fettering of the powers available to panels and case examiners under Article 9.

4.149 In our response to the previous consultation, we raised concerns about the approach to rule-making, focusing on the scope for unhelpful divergence between the regulators, and the risk of rules being developed that prioritise efficiency over public protection. These are things that are made possible by the 'framework legislation' approach chosen by the Government. At that time, we put forward a suggestion, which has not been taken up by Government, that the PSA be granted a power to oversee the process of rule-making, to guard against these outcomes.

4.150 In the absence of specific powers, we will use our existing functions to help mitigate any risks. More specifically, we are developing principles and guidance on rule-making under the proposed legislation. These could be used in our scrutiny of the regulators' performance, which we may wish to adapt to consider this kind of activity in more detail.

4.151 One area where we feel this would be particularly helpful is on the duty to consult on rules. We note that regulators would have discretion as to the level of consultation carried out, and who they consult with. We are aware that currently regulators take quite different approaches to what they consult on. Given that so much more of what they do will be set out in rules, it will be important to get the views of key stakeholders on the changes that affect them, and in ways that are transparent and help to maintain public confidence in regulation.

4.152 We hope that our work in this area will help to build on good practice in the making of rules, and the development of the policies that underpin them.

In relation to schedule 5, consequential amendments, do you have any comments on how the draft order delivers the policy intention in relation to AAs and PAs?

4.153 In addition to points made elsewhere in the draft relating to our jurisdiction, we have identified some gaps and anomalies in the draft relating to the categories

of decision that the PSA would be able to challenge, whether under s.29 or through requesting a review of a case examiner decision.

Include restoration decisions after a registrant has been struck off in s.29

4.154 We understand that it is the Government's intention for the PSA to retain its ability to challenge, through s.29, decisions to restore a registrant who had previously been struck off under the fitness to practise process.

4.155 We therefore recommend that the amendments to the PSA's legislation[21] are redrafted to enable the PSA to challenge the following decisions relating to the registrant's fitness to practise:

- Panel restoration decisions where the practitioner was removed under a final measure, by including 'panels' in the list of decision-making bodies whose restoration decisions the PSA can challenge under s.29(2)(c)
- Restoration decisions where the practitioner was removed under a final measure imposed by a case examiner(s) – these are excluded in the current draft of the Order, because s.29(2)(c) does not provide for restoration decisions following removal by case examiners.

4.156 Restoration cases of this type are some of the highest risk, by virtue of the fact that they relate to individuals who have departed so far from the standards expected of them that the regulator has seen fit to strike them off. A decision to return someone to the register under these circumstances is a complex one that should be underpinned by all the necessary public protection safeguards.

Amend s.26(4) of our legislation to enable the PSA to challenge a regulator review through Judicial Review

4.157 Other parties who are able to request a review of a case examiner decision would have recourse to Judicial Review if they felt the decision was wrong. However, the PSA's prohibition on 'doing anything' which relates to a fitness to practise case – aside from under s.29 and, in future, requesting a regulator review – would prevent the PSA from doing so. This would be a concern because of the PSA's public protection role, and the fact that a regulator has full discretion over whether to act on a request for a review by the PSA.

4.158 We therefore suggest that the exemptions in s.26(4) of our legislation are broadened to include the right to commence Judicial Review proceedings in respect of a regulator's decision under Article 11(1).

Exclude interim orders from s.29

4.159 As currently drafted, the amendment to s.29 would enable the PSA to challenge interim order decisions made by a panel. We do not have this power currently, and do not wish to, on the basis that it would interfere with the timely deployment of interim measures.

[21] The National Health Service Reform and Healthcare Professions Act 2002.

Include a right to request a review of a case examiner decision that fitness to practise is not impaired

4.160 With respect to the amendment to enable the PSA to exercise its right to request a review of case examiner final decision, the amendment to our s.26(4) would enable us to request a review of a decision to impose a final measure, but *not* a decision that the registrant's fitness to practise was not impaired (with or without a warning). We had understood that the policy intent was for the PSA to be able to challenge case examiner decisions equivalent to panel decisions of no impairment. These can be high risk, because they result in no restrictions on practice, despite the case having been considered sufficiently serious by the regulator to be referred to the adjudication – or case examiner equivalent – stage.

4.161 We therefore recommend that the draft legislation is amended to mirror our s.29 remit in relation to case examiner no impairment decisions. We would be willing to work with officials on the detail of this.

Would you like to provide any further comments on the draft order?

The PSA's future role and legislation

4.162 The PSA is going to need to consider how it uses its powers of oversight of the new regulatory model. Because these reforms will devolve decision-making to the regulators, there are many unknowns in the future of professional regulation. The reforms will change what the regulators do and how they do it, as well as the safety nets that sit beneath all this activity. The PSA is going to need to change how it monitors the performance of the regulators it oversees.

4.163 We do not know where regulators will perform well or where they may encounter challenges. We are very likely to have to change the way we look at their work to make sure we are focusing on the right things to spot any fluctuations in performance, or new risks. To do this, we will need to obtain information from the regulators.

4.164 Alongside this, there is the specific risk that without the ability to get case files from the regulators, our right to ask a regulator to review case examiner decisions may not work as it should. We will need to be able to obtain information from regulators, so we can decide whether or not to ask a regulator to review case examiner decisions. We could not properly undertake the role without this power.

4.165 Our observed experience is that regulators sometimes do not feel comfortable sharing the information we want to help us understand how they are performing, because they have concerns that the data protection legislation restricts them from doing so – especially if it is information they have not given us before. This happens, notwithstanding the statutory duties to co-operate contained in both the regulators' and our own legislation.

4.166 If we had an express statutory power to require the provision of information, a request to a regulator from the PSA would be significantly more straightforward and compelling than is currently the case (noting that regulators would still be under a duty to comply with the data protection principles when responding to the request).

4.167 Enacting such a power would not only benefit the PSA in discharging its functions, it would also promote efficiency, reducing the burden on the regulators in responding to information requests from the PSA. Crucially, it would enable us to be more flexible and adapt our oversight to the new model of regulation. This power would mirror the powers the GMC and other regulators will have to obtain the information they need to carry out their work.

4.168 We are also taking this opportunity to review our legislation for any outstanding technical amendments, and considering whether any changes need to be made to the sections relating to accredited registers.

Do you think there are any further impacts (including on protected characteristics covered by the public sector equality duty as set out in the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998) from the legislation as currently drafted?

4.169 We have commented throughout this response where we feel there may be impacts on people with protected characteristics.

4.170 We are concerned that no equality impact assessment has been published to accompany the current consultation. We know that the GMC is conducting impact assessments in relation to the implementation decisions that are within its gift to make, and of course in relation to AAs and PAs – and this approach will be replicated across the regulators and professions.

4.171 This will leave a gap though, because, to our knowledge, at no point up to and including this current consultation has there been a thorough assessment of the impacts – EDI or otherwise – of the template policies and legislation, across all the regulators and professions in scope of the reforms.

4.172 As we mentioned in our general comments at the start of the document, and in the light of the above observation, we trust that the Government will set up mechanisms to evaluate the success and impacts of these reforms, to include a focus on the EDI impacts.

5. Further information

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

Professional Standards Authority for Health and Social Care
16-18 New Bridge St, Blackfriars, London, EC4V 6AG
London SW1W 9SP

Email: policy@professionalstandards.org.uk
Website: www.professionalstandards.org.uk
Telephone: 020 7389 8030

6. Annex A: success and failure criteria for the legislative reforms of the healthcare professional regulators

6.1 The PSA believes that the proposed reforms will be a step forwards for professional regulation if they create:

- Greater coherence of the regulatory system to support modern, multi-disciplinary health and social care
- More interprofessional working, and flexibility between professions
- Greater agility for regulators so they can adapt to new risks
- A safe and appropriate balance of accountability and flexibility in the work of the professional regulators
- A proportionate, and less adversarial way of dealing with concerns about professionals with the necessary public protection safeguards
- A fair system of regulation that supports equality, diversity, and inclusion for registrants as well as patients and service users
- Overall, a more effective public protection framework, that listens to patients and responds to their concerns, and has the confidence of the public and professionals.

6.2 These reforms will have failed the public if they lead to:

- Lower levels of public protection, public confidence, or professional standards
- Less transparency or accountability for regulators
- The same or more complexity from the perspective of the public, employers, and professionals
- Continuing difficulties for regulators in working together
- Continuing challenges to closer working between professions
- Significantly increased costs that are not justified by public protection.