DRAFT - Good practice in rulemaking – Principles and guidance for regulators on developing, making and amending rules

January 2024

1. About the Professional Standards Authority

1.1 The Professional Standards Authority for Health and Social Care (PSA) promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and voluntary registration of people working in health and care. We are an independent body, accountable to the UK Parliament.

1.2 We oversee the work of 10 statutory bodies that regulate health professionals in the UK and social workers in England. We review the regulators' performance and audit and scrutinise their decisions about whether people on their registers are fit to practise.

1.3 We also set standards for organisations holding voluntary registers for people in unregulated health and care occupations and accredit those organisations that meet our standards. To encourage improvement we share good practice and knowledge, conduct research and introduce new ideas including our concept of right-touch regulation. We monitor policy developments in the UK and internationally and provide advice to governments and others on matters relating to people working in health and care.

1.4 Our organisational values are: integrity, transparency, respect, fairness and teamwork. We strive to ensure that our values are at the core of our work. More information about our work and the approach we take is available at www.professionalstandards.org.uk.

2. Introduction

2.1 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 will include the removal of the requirement for Privy Council approval of rules which is currently in place.

2.2 We have produced this good practice guidance to help regulators make effective use of their new rulemaking powers.

2.3 This guidance has been developed in parallel with the development of the Anaesthesia Associates and Physician Associates Order[1] and with work being undertaken by some regulators to develop their rules. We have drawn on

[1] The Anaesthesia Associates and Physician Associates Order 2024: https://www.legislation.gov.uk/ukdsi/2024/9780348255195

existing good practice, our own evidence base, information from other sectors and research, especially about regulatory consistency.

Status of guidance

2.4 This document provides good practice guidance to regulators to help them make best use of the new powers they will receive to develop, make and amend their operational rules. This guidance is advisory and intended to support and guide regulators in developing their own guidance and approach.

2.5 The PSA will not have any formal role within the rulemaking process. This guidance will therefore not have any official status or be binding on regulators. However, in the future, we may choose to look at how regulators are making use of their new rulemaking powers under our performance review and may take this guidance into account in assessing their approach. We may ask regulators to provide a rationale for the approach that they have taken and to explain how they have assured themselves that it maintains public protection.

Scope of guidance

2.6 This guidance relates to the rulemaking powers laid out in the Anaesthesia Associates and Physician Associate Order 2024 (AAPA Order)[2] which is expected to act as the template for reform across the healthcare professional regulators. It does not apply to any regulator until and unless its powers are reformed to bring them into line with those set out in the AAPA Order. It will not apply in the same way to Social Work England, which already operates a rulemaking process in line with its legislative powers, although the principles and information provided may be of relevance.

2.7 This guidance is based on the best available evidence we have at this time to support a good practice approach to rulemaking. As no regulators are yet using the rulemaking powers as laid out in the AAPA Order, the guidance is currently high level. However, it is likely that as the new approach is rolled out, further information will become available on good practice in this area. It is our intention to keep this guidance under review to reflect the roll out of these powers more widely and to incorporate further good practice as it emerges.

2.8 The focus of the guidance is primarily on the rulemaking process - the process of creating the rule framework that outlines how the regulator will operate. However, as rules themselves are usually an expression of an agreed policy approach, the principles and further information in the document are also intended to help regulators in taking account of key considerations when developing policy as well as the formal rule development process.

2.9 Whilst the main focus of the guidance is producing rules, we recognise that regulators are also likely to produce significant pieces of guidance and policy documents which are central to a particular regulatory function – for example standards of practice and associated guidance. Whilst these aren't the direct

[2] The Anaesthesia Associates and Physician Associates Order 2024: https://www.legislation.gov.uk/ukdsi/2024/9780348255195

focus of our guidance, we expect the principles and information outlined to also support regulators in these areas.

2.10 This document includes:

- Part 1
  - A summary of the legislative framework underpinning the powers that professional regulators will receive to make and amend operational rules
  - Principles to guide a good practice approach to rulemaking by regulators following the roll out of new rulemaking powers
- Part 2
  - Further information on key areas to support regulators in putting our principles into practice.

Part 1 – Legislative Framework and good practice principles

3. The legislative framework

3.1 The Anaesthesia Associates and Physician Associates Order (AAPA Order) will form the legislative template for new powers for all healthcare professional regulators.[3]

General legislative requirements

3.2 In common with current legislation, the overarching objective for regulators will remain the protection of the public.[4] This objective includes the following three sub-objectives:

- to protect, promote and maintain the health, safety and well-being of the public,
- to promote and maintain public confidence in the [named] profession, and
- to promote and maintain proper professional standards and conduct for members of that profession.[5]

3.3 This overarching objective and sub-objectives will remain the primary touchstone for regulators in carrying out their statutory responsibilities, including the development and implementation of rules.

3.4 There are a number of new wider provisions referenced in the AA PA Order which regulators will need to take into account when developing rules and processes. These include:

- The duty to discharge functions in a way which is transparent, accountable, proportionate and consistent
- The duty to co-operate [insofar as is appropriate and practicable, with persons concerned with the employment (whether or not under a contract of service), education or training of associates or the services they provide][6]

[3] The Anaesthesia Associates and Physician Associates Order 2024: https://www.legislation.gov.uk/ukdsi/2024/9780348255195

[4] This is currently the overarching objective for all regulators under the PSA's oversight with the exception of the Pharmaceutical Society of Northern Ireland whose overarching mission is the protection of the public as agreed by Council in their mission statement Page 7 'Safeguard Patients and Public through High Quality Pharmacy'. which is supported by the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2012.

[5] To note: as the Anaesthesia Associate Physician Associate Order will form an addition to the Medical Act 1983, the provisions within it specific to the regulation of Anaesthesia Associates and Physician Associates should be read alongside the general pre-existing legislative requirements for the General Medical Council within the Medical Act 1983 – this includes the overarching objective of public protection. When reforms are rolled out more widely for the General Medical Council to cover doctors, the Medical Act will also be replaced with updated legislation.

[6] This duty as outlined in the AAPAO is in addition to the GMC's pre-existing duties of co-operation under para 9A of Schedule 1 to the Medical Act 1983:-

- The principle that regulatory activity should be targeted.

3.5 They will also be required to comply with wider public law principles.

Rulemaking requirements

3.6 In contrast to current legislation, the Anaesthesia Associates and Physician Associates Order leaves a considerable discretion to be defined in rules how regulators will exercise their regulatory functions.

3.7 Schedule 4 of the draft Order outlines the rulemaking powers that regulators will have over different areas - this broadly includes rules relating to:

- The register and registration processes
- Procedural rules including for education and training
- Panels, including constitution and appointment process
- Non-compliance
- Fees
- Notifications (covering notifications as part of a wide range of regulatory processes)
- Fitness to practise (FtP rules will cover procedures for decision making)
- Revisions and appeals
- When Panel decisions take effect
- Evidence gathering
- General provisions allowing regulators to make rules which: 'may contain such incidental, consequential, transitional, transitory, saving or supplementary provisions as appear to the Regulator to be necessary or expedient.'

3.8 The General provisions about rules also require that the regulator, before making rules: 'must consult, to the extent it considers proportionate, representatives of any group of persons which appear to the Regulator likely to be affected by the rules, including representatives of -

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In exercising their functions, the General Council shall—
have proper regard for—
(i)the interests of persons using or needing the services of provisionally or fully registered medical practitioners in the United Kingdom, and
(ii)any differing interests of different categories of provisionally or fully registered medical practitioners;
(b)co-operate, in so far as is appropriate and reasonably practicable, with public bodies or other persons concerned with—
(i)the employment (whether or not under a contract of service) of provisionally or fully registered medical practitioners,
(ii)the education or training of medical practitioners or other health care professionals,
(iii)the regulation of, or the co-ordination of the regulation of, other health or social care professionals,
(iv)the regulation of health services, and
(v)the provision, supervision or management of health services.

- (a) associates;
- (b) employers of associates;
- (c) users of the services of associates;
- and (d) persons providing, assessing or funding education or training for associates of prospective associates.'[7]

3.9 These legislative provisions should underpin regulators' approach to rulemaking once they are rolled out more widely.

4. Principles for good rulemaking

4.1 We have outlined some principles to guide what good rules should aim to do or be, and the process. Where relevant, we have provided further information in section 2 of this document to support regulators in putting the principles into practice.

4.2 Good rules and a good rulemaking process should result in regulation which:

- Is consistent with the regulator's legislative duties and statutory remit of public protection
- Is consistent with the principles of right-touch regulation (proportionate to the risk of harm, accountable, consistent, targeted, transparent, and agile)
- Promotes equality, diversity and inclusion
- Supports consistency of regulatory practice between regulators, justifying disparity where appropriate
- Is agile, allowing regulators to swiftly respond to changes in the external environment
- Facilitates multi-disciplinary team working and innovative practice.

4.3 The process should be:

- Based on evidence of risks, benefits and impacts
- Underpinned by robust internal governance
- Built on meaningful consultation, collaboration and engagement with a wide variety of stakeholders, including patients and the public.

[7] References to 'associates' reflect the wording of the AA PA Order, but this will be amended to refer to other professions as the reforms are rolled out across regulators.

Part 2 - Further information to support a good practice approach to rulemaking

5. Right-touch regulation principles

5.1 The PSA developed its right-touch regulation principles building on the better regulation principles by adding 'agility'.[8] The aim is to make sure that the level of regulation is proportionate to the level of risk to the public.

5.2 Whilst right-touch regulation is likely to be more relevant at the policy development stage which generally sits before the development of rules, we recommend it as a useful framework for regulators and therefore have included an overview here.

5.3 The principles state that regulation should aim to be:

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

5.4 There are eight elements that underpin applying a right-touch regulation approach to a policy problem:

- Identify the problem before the solution
- Quantify and qualify the risks
- Get as close to the problem as possible
- Focus on the outcome
- Use regulation only when necessary
- Keep it simple
- Check for unintended consequences
- Review and respond to change.

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

6. Consistency between regulators

6.1 The Government's policy consultation on reforming the legislation of the healthcare professional regulators outlined its intention to 'provide all UK healthcare regulators with broadly consistent powers', building on the simplification review of the Law Commissions in 2015.[9] The Government's response to the consultation published in 2023 was clear that there was an expectation of greater consistency between regulators, with appropriate variation where necessary.

6.2 The Anaesthesia Associates and Physician Associates Order, as the template for reformed legislation, includes duties for regulators to discharge functions in a way which is 'transparent, accountable, proportionate and consistent'.[10]

6.3 Multiple inquiries and reviews have highlighted the need for greater regulatory consistency, including the Williams Review into gross negligence manslaughter which identified concerns about inconsistent fitness to practice (FtP) outcomes arising from the Bawa Garba case. On the back of the Williams Review, the PSA commissioned UCL (on behalf of DHSC) to produce a structured approach to understanding the factors influencing consistency and to propose a methodology that could take this work forward. A key recommendation was to refocus research towards avoiding "unjustifiable disparity".[11]

6.4 In 2021 the Authority commissioned research into patient, carer, public and professional perspectives on the principle of consistency in health and care professional regulation.[12] The research uncovered five arguments for 'sameness', which usually mapped to four roles that regulators were perceived to play when carrying out their functions (arbiter, assurer, service provider and team enabler). The arguments for sameness included – correct, fair, adequate, simple and coherent. Five arguments for difference were also identified. These were – risk, scope, expectation, narrative and team.

6.5 A key finding from this research was that the public, patients and registrants expect regulators to work in dialogue with one another, to ensure consistency of approach and transparency about why variation exists.

6.6 We have used the findings from the research to develop a three-step process for establishing whether inter-regulatory consistency is desirable across the regulatory functions. The steps are:

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[9] *Regulating healthcare professionals, protecting the public*, 2021. Available at: https://assets.publishing.service.gov.uk/media/607daac6d3bf7f0132941916/Regulating_healthcare_professionals__protecting_the_public.pdf

[10] The Anaesthesia Associates and Physician Associates Order 2024: https://www.legislation.gov.uk/ukdsi/2024/9780348255195

[11] *Developing a methodology to assess the consistency of fitness to practise outcomes*, 2019. Available at: 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

[12] Christmas S., et al. (2021) *Patient, carer, public and professional perspectives on the principle of consistency in health and care professional regulation*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/does-consistency-between-regulators-matter.pdf?sfvrsn=fbcc4920_4

1. Establishing relevant arguments for making things the same (in relation to a specific rule change or policy development)
2. Identifying moderating factors
3. Balancing arguments for sameness against moderating factors.

6.7 These steps are outlined in full in Annex A. These are intended to help regulators consider how to avoid unjustifiable disparities and aim for appropriate consistency where possible. This is in line with ambitions for the reforms that regulators should have broadly equivalent powers to maintain a level of consistency and effective public protection.

6.8 The consistency steps outlined are intended to support discussions about where consistency across regulators is valuable and should be pursued, or conversely, where disparity is justified and why. As highlighted previously, these steps may also be relevant at an earlier stage of the process when the policy underlying rule changes is being developed. They may also be relevant when developing significant pieces of guidance or standards for professionals.

6.9 Some examples of areas where regulators may wish to weigh up the arguments for maintaining consistency or pursuing a different approach as part of their rule development process may include:

- Development of standards of practice for professionals
- Standards in relation to education and training and the approach to assessing providers
- CPD and revalidation requirements
- Publishing data about their registrants beyond the minimum required by legislation
- Registration processes, including removal and readmittance processes to the register for administrative reasons, and appeals procedures
- Information published on the register
- Deciding whether to and how best to investigate a fitness to practise concern
- The details of how the fitness to practise panel stage operates
- Processes for restoration to the register in relation to fitness to practise cases.

6.10 Inevitably, those regulators that are first to receive reformed legislation will effectively create a template for other regulators to consider as they themselves receive reformed legislation and develop rules.

6.11 However, this guidance is intended to be relevant not just during the initial rule creation stage but also during future iterations and rule amendments with the hope that, over time, regulatory approaches will achieve a greater level of coherence.

7. Consultation

7.1 Consultation is generally acknowledged as an important part of the policy making process. It allows a government, public body or organisation to seek input from its stakeholders on a particular policy proposal or range of proposals. It can be a way of strengthening policy by seeking relevant views and information from those with particular knowledge, expertise or interest.

7.2 Whilst definitions of consultation and its purpose vary, the Scottish Government, in its overview of how consultation is used in government policy making outlines that: 'A good consultation should be accessible for people. The consultation should clearly outline what it is seeking people's views on and make sure that people are able to respond.'[13]

7.3 The 2018 Cabinet Office consultation principles also provide useful guidance to all organisations in formulating and carrying out effective and meaningful consultation.[14]

7.4 In the Anaesthesia Associates and Physician Associates Order the general provisions about rules require that the regulator, before making rules: *'must consult, to the extent it considers proportionate, representatives of any group of persons which appear to the Regulator likely to be affected by the rules, including representatives of -*

- *(a) associates;*
- *(b) employers of associates;*
- *(c) users of the services of associates;*
- *and (d) persons providing, assessing or funding education or training for associates of prospective associates.'*

7.5 Consultation will be an increasingly important accountability mechanism for rulemaking with the removal of the Privy Council approval stage. Although we recognise that regulators may well have their own guidance in place on how and when they consult, we suggest that regulators will need to review this in light of the new importance it will take on following the roll out of the reforms as a means of balancing out enhanced autonomy with accountability.

7.6 As there is little detail in the AA/PA Order to guide regulators on when and how they should consult, we have outlined some considerations for regulators to consider when developing their approach.

7.7 In doing so we have drawn on good practice already in use by the regulators we oversee, good practice and requirements in place in other sectors including those in place for regulators in the legal services sector and general good practice available on consultation, including that published by the Government.

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[13] Consultations in the Scottish Government: guidance: https://www.gov.scot/publications/consultations-in-the-scottish-government-guidance/

[14] Cabinet Office 2018, *Consultation principles: guidance*: https://www.gov.uk/government/publications/consultation-principles-guidance

When to consult

7.8 Factors which regulators may want to consider when deciding whether consultation is appropriate include:

- Legal requirement/legitimate expectation of a consultation – is there a legal requirement to consult or a legitimate expectation by stakeholders that a consultation will be held?
- Nature of the rule change – are there public protection implications, does it bring about major changes to the regulatory process?
- Who is affected – is there likely to be a particular impact on patients, service users, registrants, wider stakeholders?
- Does the rule change have human rights or EDI implications or opportunities?
- Potential for regulatory duplication or conflict – is there the potential for rule changes to duplicate or conflict with activity by any other regulatory bodies, including other professional regulators?
- Scale of change/complexity of change – is the change significant or is it largely a minor or non-substantive change?

Type of consultation and wider engagement activity

7.9 If a regulator concludes that a consultation is required, they may also want to consider the nature of the consultation, including whether to carry out formal or informal consultation, who to consult with and whether to plan any additional consultation activities to ensure participation from under-represented groups.

- Formal or informal consultation – considering whether a formal public consultation or informal engagement or consultation is needed is likely to be influenced by the scale and significance of the change in question as well as the best way to get the input needed from relevant stakeholders
- Who to consult/engage with – identifying the groups that regulators wish to consult with will be an important part of deciding on the type of consultation required, alongside planning any additional engagement activity. This should take into account the challenges that some groups may face in participating in different ways
- Ensuring participation from under-represented groups – regulators may wish to consider developing tailored plans around engagement and consultation with under-represented groups likely to be impacted by any changes, including those who share protected characteristics. This may include consideration of any Welsh language requirements.

Consultation good practice and wider considerations

7.10 Regulators may wish to consider the cumulative burden on stakeholders of responding to multiple consultations at once. This is particularly relevant to stakeholders who might have an interest in providing input to rule changes by

multiple regulators, for example patient organisations, if consultations are carried out in parallel or very close together.

7.11 Although there may be limited scope for regulators to stagger consultations as there may be external or internal time pressures, it will be a relevant consideration for regulators when considering how best to engage stakeholders in consultations.

7.12 As consultation is an important element of demonstrating accountability to stakeholders, it is good practice to keep a record of decisions made on whether to consult and how consultation responses were evaluated. It is also good practice to provide a report back to those who took part in a public consultation.

8. Governance

8.1 As the Privy Council will no longer approve rules and rule changes, regulators should establish appropriate internal governance for developing, making and amending rules.

8.2 Regulators' internal governance structures will change following the roll out of the new legislation. This includes the introduction of Unitary Boards to replace the existing Councils. Regulators undertaking rulemaking in advance of these changes will need to account for the transition between current and future governance arrangements.

8.3 Areas that regulators should consider when defining the governance pathway for rule changes include:

- Scale/significance of the rule change
- The role that the Council/Unitary Board will play
- Documenting decisions made about the approach taken including the governance pathway and decisions made on whether to consult.

8.4 We have previously produced guidance on governance in the public interest. Although largely focused on Board competencies and operation, it provides useful pointers for regulators when considering how to develop an appropriate governance process for the new approach to rulemaking.

professional standards authority

Annex A – Inter-regulator consistency tool

Step 1. Establishing relevant arguments for making things the same

- The following table sets out key arguments for sameness mapped out against particular role(s) regulators may be carrying out (reflecting the findings in Christmas et al.). A regulator might be playing more than one role when carrying out its functions and therefore numerous arguments for consistency could be relevant.

		(2) What arguments for consistency are most relevant to decision-making?				
		'Correct'	**'Fair'**	**'Adequate'**	**'Simple'**	**'Coherent'**
(1) What role are regulators playing?	**Arbiter** – Decides appropriate response to cases	Consistency is required by legal obligations, e.g., Equality duties	Consistency is required to ensure fair treatment and outcomes			
	Assurer – Ensures professionals maintain standards		Consistency is required to ensure fair treatment and outcomes	Consistency helps to ensure a minimum standard is met across professions		
	Service provider – Meets the needs of users of its services			Consistency helps to ensure a minimum standard for how the public and registrants experience engaging with regulators and the regulatory system	Consistency reduces complexity and potential for confusion for the public and registrants in their engagement with regulators and the regulatory system	
	Team enabler – Supports functioning of a team around a patient				Consistency provides clarity for professionals working at the edge of or across professional boundaries	Consistency supports a joined-up, coherent system necessary for public and professional confidence and to facilitate multi-professional working

Step 2. Identifying moderating factors

- Variation between regulators is not a bad thing, but divergence should be clearly explained to ensure trust and confidence in regulation. Moderating factors that might lead regulators to adopt different approaches include:
    - The risks associated with professional practice, including the extent of harm and benefit that can potentially be caused, and its context
    - The level of interaction and nature of the relationship between the profession and patients/ service users
    - The roles which professionals take within teams involving members of other professions
    - The speed of change in areas of professional practice and expertise (particularly with regards to fitness to practise and education and training)
- Any moderating factors should be identified and catalogued.

Step 3. Balancing arguments for sameness against moderating factors

- The final stage of the process involves weighing the arguments for sameness against the identified moderating factors and making a value judgment. This should be a transparent, discursive process.

Annex B – Further information and references

- The Anaesthesia Associates and Physician Associates Order 2024: https://www.legislation.gov.uk/ukdsi/2024/9780348255195Christmas S., et al. (2021) *Patient, carer, public and professional perspectives on the principle of consistency in health and care professional regulation*. Available at: https://www.professionalstandards.org.uk/docs/default-source/publications/research-paper/does-consistency-between-regulators-matter.pdf?sfvrsn=fbcc4920_4
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