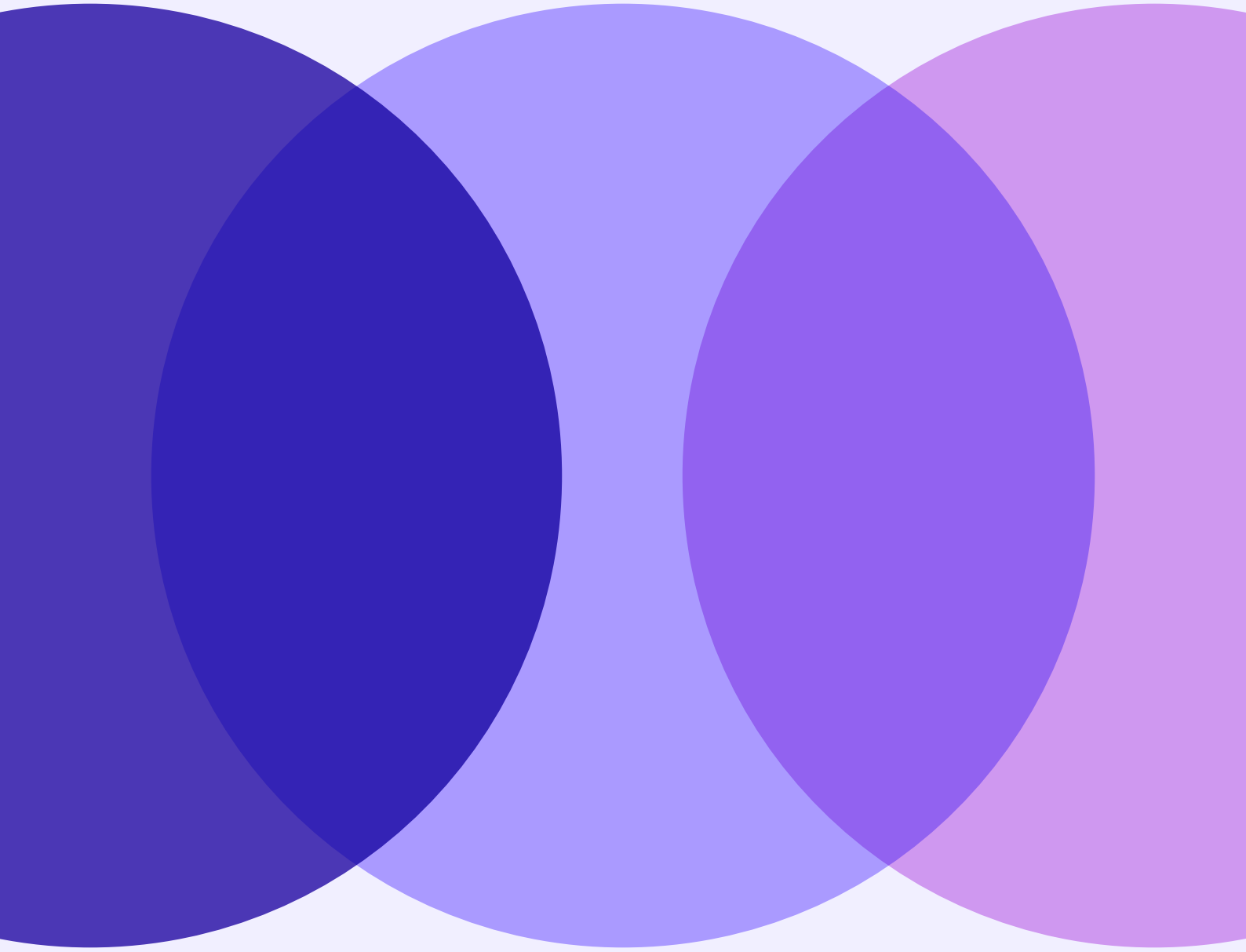
Guidance

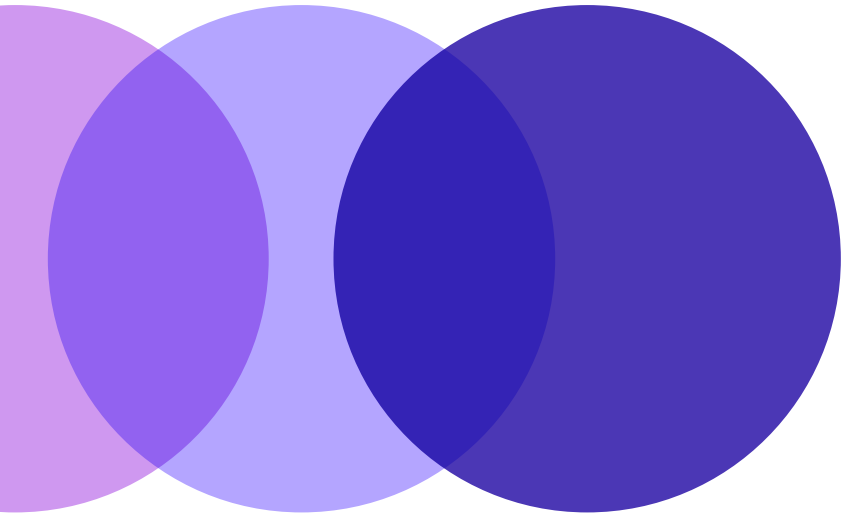
professional standards authority
for Health and Social Care

Rulemaking

Good practice guidance for regulators

2025





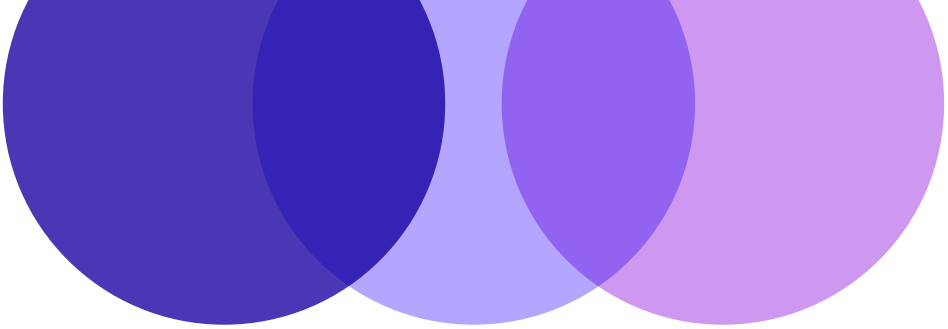
About the Professional Standards Authority

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

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

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

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



Why we produced this guidance

The Government is currently in the process of reforming the legislation for nine out of the 10 healthcare professional regulators we oversee, giving them a range of new powers and allowing them to operate in a very different way.

The reforms will introduce fundamental changes to how regulators handle fitness to practise concerns (the process by which concerns about healthcare professionals are dealt with) as well as giving them more flexibility around rulemaking (how regulators develop their operational processes).

We support the reforms to healthcare professional regulation but have also identified certain risks that may arise from the new ways of working, particularly in relation to the introduction of accepted outcomes in fitness to practise, and to rulemaking. We have therefore developed guidance on these two areas to aid the regulators to implement their new powers in a way that prioritises public protection. This is in line with our core functions, which include promoting best practice and formulating principles relating to good professional regulation, and our overarching objective; the protection of the public. This guidance focuses on rulemaking.

About this guidance

The Government's legislative reform programme to modernise healthcare professional regulators' legislation will result in regulators receiving new powers to make and amend their own operational rules. This will include removing the current requirement for the Privy Council to approve rules.

We have produced this good practice guidance to help regulators make effective use of their new rulemaking powers. This guidance is based on the best evidence on a good practice approach to rulemaking available to us at the time of writing.

As the rulemaking powers laid out in the Anaesthesia Associates and Physician Associates Order (AAPA Order) are currently only being used by the GMC (and only for the regulation of Anaesthesia Associates and Physician Associates, not for doctors), the guidance is currently high level. We intend to keep this guidance under regular review to incorporate the latest information on good practice as the new approach is rolled out.

This guidance has been developed in parallel with the AAPA Order and with work being undertaken by some regulators to develop their rules. In producing this guidance, we have drawn on:

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

How regulators should use this guidance

This guidance is intended for healthcare professional regulators and relates to the rulemaking powers laid out in the AAPA Order 2024. It sets out principles and guidance for regulators on developing, making and amending rules.

This Order 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.

Our purpose in producing this document is to provide good practice guidance to regulators to help them make the best use of their new powers. These powers will include powers 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.

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 process and may take this guidance into account in assessing their approach. We may ask regulators to provide a rationale for the approach they have taken and to explain how they have assured themselves that it maintains public protection.

Our purpose in producing this document is to provide good practice guidance to regulators to help them make the best use of their new powers.

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.

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

What are rules?

Rules describe the processes and procedures that will deliver the legislative duties and powers in the regulators' legislation. They are quasi-legislative documents, the formality of which provides a degree of certainty to others about how the regulators will carry out their various processes, and supports a consistent approach by a regulator for as long as the rules are in operation. The proposed new legislation will give greater autonomy to regulators to set out the details of their individual regulatory procedures in two ways:

1. They will have powers to set out in rules areas that currently sit in legislation.

2. Where currently rules have to be approved by the Privy Council, regulators will be able to sign off their own rules.

The legislative framework

The AAPA Order will form the legislative template for new powers for all healthcare professional regulators.

General legislative requirements

In common with current legislation, the overarching objective for regulators will remain the protection of the public.[1] This objective includes the following three sub-objectives:

1. to protect, promote and maintain the health, safety and wellbeing of the public,
2. to promote and maintain public confidence in the [named] profession, and
3. to promote and maintain proper professional standards and conduct for members of that profession.[2]

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.

There are a number of new wider provisions referenced in the AAPA Order which regulators with similar legislation would need to take into account when developing rules and processes. These include:

- The duty to discharge functions in a way that 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][3]
- The principle that regulatory activity should be targeted.

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

Rulemaking requirements

In contrast to current legislation, the AAPA Order grants regulators considerable discretion to define in rules how they exercise their regulatory functions.

Schedule 4 of the Order outlines the rulemaking powers that regulators with similar legislation would 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 (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.'

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 interests of persons using or needing the services of provisionally or fully registered medical practitioners in the United Kingdom, and

(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 or prospective associates.' [4]

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

Find out more/futher reading

- *Right-touch regulation*
- Anaesthesia Associates and Physician Associates Order
- Consultation outcome report

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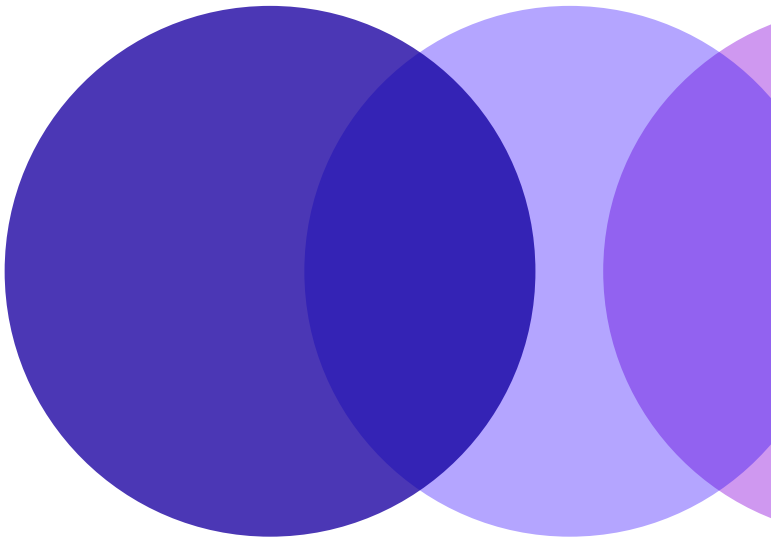


1. Part 1: Principles for good rulemaking

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.

Good rules and a good rulemaking process should result in regulation which is, first and foremost, consistent with the regulator's legislative duties and statutory remit of public protection, along with other requirements such as equalities legislation and Welsh language standards.

In addition, they should:

- **Be consistent with the principles of right-touch regulation (proportionate to the risk of harm, accountable, consistent, targeted, transparent, and agile)**
- **Promote equality, diversity and inclusion (EDI)**
- **Be fair to those it regulates and third parties who are affected by the rules**
- **Support consistency of regulatory practice between regulators, justifying disparity where appropriate**
- **Be agile, allowing regulators to swiftly respond to changes in the external environment**
- **Avoid ambiguity in the drafting**
- **Facilitate multi-disciplinary team working and innovative practice.**

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.**

2. Further information to support a good practice approach to rulemaking

This section provides more informaiton on consistency, consultation and governance as well as our right-touch regulation approach.

Right-touch regulation

The PSA developed its right-touch regulation principles building on the better regulation principles by adding 'agility'.

The aim is to make sure that the level of regulation is proportionate to the level of risk to the public.

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.

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
- **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.

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

1. **Identify the problem before the solution**
2. **Quantify and qualify the risks**
3. **Get as close to the problem as possible**
4. **Focus on the outcome**
5. **Use regulation only when necessary**
6. **Keep it simple**
7. **Check for unintended consequences**
8. **Review and respond to change.**

Consistency across regulators

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 review by the Law Commissions in 2015. The Government's response to the consultation published in 2023 was clear that there was an expectation of greater consistency across regulators, with appropriate variation where necessary.

The AAPA Order, as the template for reformed legislation, includes duties for regulators to discharge functions in a way which is 'transparent, accountable, proportionate and consistent'.

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 practise outcomes arising from the Dr. Bawa Garba case. On the back of the Williams Review, the PSA commissioned University College London (UCL), on behalf of the Secretary of State for Health and Social Care, 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**'.

In 2021 the PSA commissioned **research** into patient, carer, public and professional perspectives on the principle of consistency in health and care professional regulation.

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.

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.

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:

1. Establishing relevant arguments for making things the same (in relation to a specific rule change or policy development):

Our table at annex A sets out key arguments for sameness mapped out against particular role(s) regulators may be carrying out. A regulator might be playing more than one role when carrying out its functions and therefore numerous arguments for consistency could be relevant.

2. Identifying moderating factors

Variation between regulators is not necessarily 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.

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 judgement. This should be a transparent, discursive process.

Weighing up the arguments for consistency

Some examples of areas where regulators may wish to weigh up the arguments for consistency or difference as part of their rule development process are set out below:

Development of standards of practice for professionals.	**Standards in relation to education and training and the approach to assessing providers.**	**Continuing Professional Development (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.**

Overall, this approach recognises that there will be many legitimate differences in the way regulators operate, relating for example to public protection and fairness. It supports regulators to decide what these are, and conversely, where consistency is important.

> **We want to highlight the importance of collaboration in the consultation process. Regulators should pay particular attention to engagement with other regulators, who are likely to be able to share valuable insights.**

Consultation

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.

While 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.'

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

In the AAPA 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 or prospective associates.'

It is important to consult a wide range of stakeholders when exercising rulemaking powers to ensure that well informed decisions are being made. In addition to the requirements to consult above, regulators with similar legislation may wish to consider consulting with the following stakeholders, where relevant:

- Any groups at risk of experiencing disproportionate outcomes
- Professional associations
- The wider education sector
- Sole practitioners working in private practices
- Trainees
- Students.

We want to highlight the importance of collaboration in the consultation process. Regulators should pay particular attention to engagement with other regulators, who are likely to be able to share valuable insights.

Consultation will be an increasingly important accountability mechanism for rulemaking with the removal of the Privy Council approval stage. Regulators subject to the new legislation should have their own guidance in place on how and when they consult.

As there is little detail in the AAPA Order to guide regulators with similar legislation on when and how they should consult, we have outlined some considerations for regulators to consider when developing their approach.

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.

Find out more/further reading

- *Regulating healthcare professionals, protecting the public* 2021
- Anaesthesia Associates and Physician Associates Order
- *Gross negligence manslaughter in healthcare: The report of a rapid policy review*
- *Developing a methodology to assess the consistency of fitness to practise outcomes*
- *Patient, carer, public and professional perspectives on the principle of consistency in health and care professional regulation*

When and how to consult

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,**
- **would 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 equality, diversity and inclusion 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?[5]**

Types of consultation and wider engagement activity

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 consultation is needed is likely to be influenced by the scale and significance of the change in question, the best way to get the input from relevant stakeholders, and the need to foster public confidence in the process and proposed changes.

Formal public consultation would involve publishing a consultation document and enabling responses from anyone. It can also involve face-to-face discussions, workshops etc, which can be a valuable way of getting meaningful engagement with people who might not otherwise respond. It would result in changes being made on the basis of the feedback received, with a published report setting out what people said and how they responded.

Informal consultation would involve the regulator approaching chosen stakeholders in a more private way, and there would not necessarily be a published account of these interactions and their impacts on the proposals. This approach can lack the transparency of a formal public consultation.

Who to consult/engage with – identifying the groups regulators wish to consult will be an important part of deciding what type of consultation is required, alongside planning any additional engagement activity. This should consider 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 particular characteristics.

Length of consultation – decisions about how long a consultation should last should be informed by the scale and complexity of the changes proposed, and what is most likely to yield meaningful engagement from relevant stakeholders.

Whichever mode of consultation is chosen, the regulator should ensure that it takes a transparent approach to reporting on the outcomes of the exercise, how the feedback it received has been taken into account, and how it has assessed and plans to address any equality, diversity and inclusion impacts on particular groups.

Consultation good practice and wider considerations

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.

Although there may be limited scope for regulators to stagger consultations as there may be external or internal time pressures, it will be an important factor for regulators

when considering how best to engage stakeholders in consultations.

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.

Governance

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

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.[6]

Regulators working on new rules in advance of these changes will need to account for the transition between current and future governance arrangements.

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.**

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.

Annex A: Inter-regulator consistency tool – Step 1 table – establishing relevant arguments for making things the same

		(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

Endnotes

1 This is currently the overarching objective for all regulators under the PSA's oversight with the exception of the Pharmaceutical Society of Northern Ireland (PSNI) 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.

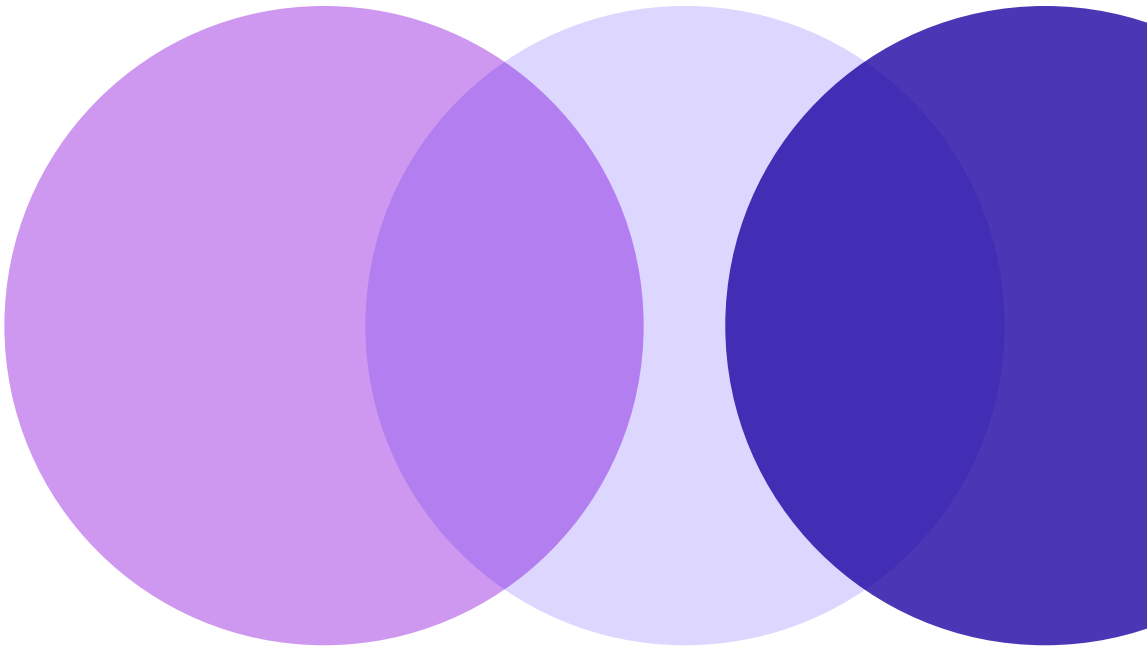
2 To note: as the Anaesthesia Associate Physician Associate Order forms an addition to the Medical Act 1983, the provisions within it specific to the regulation of Anaesthesia Associates and Physician Associates should be read alongside the general pre-existing legislative requirements for the General 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

3 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—
In exercising their functions, the General Council shall—
have proper regard for—
the interests of persons using or needing the services of provisionally or fully registered medical practitioners in the United Kingdom, and
any differing interests of different categories of provisionally or fully registered medical practitioners; (
co-operate, in so far as is appropriate and reasonably practicable, with public bodies or other persons concerned with—
the employment (whether or not under a contract of service) of provisionally or fully registered medical practitioners,
the education or training of medical practitioners or other health care professionals,
the regulation of, or the co-ordination of the regulation of, other health or social care professionals,
the regulation of health services, and
the provision, supervision or management of health services.

4 References to 'associates' reflect the wording of the AAPA Order, but this will be amended to refer to other professions as the reforms are rolled out across regulators.

5 Minor or non-substantive changes would primarily be limited changes to internal processes that have little or no impact on any third parties.

6 Department of Health and Social Care described 'unitary boards' as follows: 'boards which comprise of executive and non-executive directors, appointed on the basis that they have the skills, knowledge and expertise to ensure the regulator discharges its functions effectively'. See: Regulating healthcare professionals, protecting the public: consultation response - analysis (publishing.service.gov.uk)



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