EXPLANATORY MEMORANDUM TO

THE ANAESTHESIA ASSOCIATES AND PHYSICIAN ASSOCIATES ORDER 2024

2024 No. 374

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (DHSC) and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

2.1 This instrument will allow the statutory regulation of Anaesthesia Associates and Physician Associates ("associates") by the General Medical Council (GMC). It provides the framework for the regulation of associates and the powers and duties in relation to the GMC.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdictions which the instrument forms part of the law of) is England and Wales, Scotland and Northern Ireland.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales, Scotland and Northern Ireland.

5. European Convention on Human Rights

5.1 The Minister of State for Health and Secondary Care, Andrew Stephenson, has made the following statement regarding Human Rights:

"In my view, the provisions of the Anaesthesia Associates and Physician Associates Order 2024 are compatible with the Convention rights."

6. Legislative Context

6.1 This Order is made under the powers delegated by s.60 of the Health Act 1999, hereinafter 'the 1999 Act'. They give Parliament broad powers to make changes to regulatory legislation via secondary legislation. Prior to the 1999 Act, there had been growing public, parliamentary and professional concerns about the delivery of public and patient protection, as reform had been delayed by the need for primary legislation to overhaul a number of Acts dating back to the middle of the 19th century.

6.2 The delegated powers afforded by the 1999 Act allowed the Government to begin the large task of modernising and rationalising this legislation. These powers have facilitated some important changes and improvements to healthcare regulation including:

- The establishment of the Nursing and Midwifery Council and the introduction of regulation of nurses and midwives (2002)

- The establishment and creation of the Health and Care Professions Council and the introduction of the regulation of a number of health professions (2002)
- The establishment of the General Pharmaceutical Council and the introduction of the regulation of pharmacist and pharmacy technicians (2010)
- Giving the GMC responsibility for oversight of postgraduate regulation through the Postgraduate Medical Education and Training Board Order (2010)
- Introducing revalidation for doctors (2012)
- Introducing regulation of nursing associates in (2019)

6.3 Overall, the delegated powers have been operating effectively for over two decades, enabling significant improvements to public protection by the regulator.

6.4 The government has committed to reforming the legislative framework for regulated health and care professionals across the UK. The government has consulted on our proposed approach to modernising the legislation of the regulatory bodies and the policies that sit within the programme of reform. The regulators' current legislation will be replaced through a series of statutory instruments, giving each regulator near identical powers through broadly similar legislation.

6.5 The Order is the first step to deliver a large-scale programme of reform for all regulated healthcare professions, that will implement improvements to the system of professional regulation, to the health and care workforce and, most importantly, patient and public safety. As set out in the government's response to Regulating healthcare professionals, protecting the public, we are introducing regulation for associates to introduce a new regulatory framework without changing the GMC's regulatory framework for medical practitioners (doctors) at this stage. This means that the Order does not include some of the governance and operating reforms that we plan to introduce in a future GMC order, such as replacing the current 2-tier council with a unitary board structure. Therefore, the Order is not a complete template for the reforms that will be rolled out to the rest of the regulators. This means that the GMC's overall governance framework and regulation of doctors will continue to be legislated for under the Medical Act 1983 (c. 54) after the Order comes into effect.

6.6 We have committed to prioritising delivery of regulatory reform based on criteria including the size of registrant base, the need for reform, and regulators' readiness to implement the changes. Therefore, we will focus on the GMC (covering reform for doctors), the Nursing and Midwifery Council and the Health and Care Professions Council in the first instance which will enable us to implement reform for the majority of regulated healthcare professionals within the next few years. We will then move on to reform legislation for the rest of the regulators however no order in which regulators will receive their reforms, or estimated timetable, has yet been agreed. We plan that these future Orders will introduce similar reforms to those contained in the Order and also include the additional governance and operating reforms that were included in the broader policy consultations.

6.7 While we intend to move at pace, we will undertake 3-month consultations, as required by the legislative powers under s.60 of the 1999 Act, for every regulator to ensure that those who wish to contribute to the shaping and development of the legislation have the opportunity to do so. Although we anticipate that having the

framework of the Order will quicken the process for reforming future legislation, we recognise that there will be some areas where specific provisions are required for specific regulators and the professions they regulate. For example, premises regulation and protected functions are areas that will need to be considered in relation to some of the other healthcare regulators where they apply. We are unable to provide a more definitive timetable for reforming all of the professional regulators' legislation at this stage.

6.8 Our intention is to draft and publish a further instrument for consultation in due course which will cover reforms for doctors and further governance and operating framework reforms for the GMC.

7. Policy background

What is being done and why?

7.1 The current UK model of regulation for healthcare professionals is rigid, complex and needs to change to better protect patients, support our health services and to help the workforce meet future challenges. This is the first stage of a large-scale programme of reform that will implement improvements to the system of professional regulation, to the health and care workforce and to patient and public safety.

7.2 When considering reforms to the regulator's legislation, the government has followed a number of principles:

- Public safety is paramount and at the heart of professional regulation;
- Registrants' rights must remain protected;
- The system should be able to respond to changing workforce models and developments in health and social care delivery without the need for ongoing legislative change;
- Regulators should have broadly equivalent powers to maintain a level of consistency and effective public protection;
- Overly detailed legislation should be replaced; and
- Minimising the cost of regulation where possible, provided this is consistent with public protection.

7.3 In 2017, the consultation *Promoting professionalism, reforming regulation*[1] was published on options for reforming the regulation of healthcare professionals in the UK following publication of the Law Commission's report, *Regulation of healthcare professionals, regulation of social care professionals in England*[2]. In 2019, a response was published *Promoting professionalism, reforming regulation: government response*.

[1] https://assets.publishing.service.gov.uk/media/5a81d78ce5274a2e8ab561e7/Regulatory_Reform_Consultation_Document.pdf

[2] https://www.lawcom.gov.uk/project/regulation-of-health-and-social-care-professionals/

7.4 In 2017 a consultation was also published on *The regulation of Medical Associate Professions in the UK*[3]. This consultation sought views on proposals to introduce statutory regulation for associates.

7.5 Detailed proposals for the reform of the legislation underpinning healthcare regulation were set out in *Regulating healthcare professionals, protecting the public*[4], published in 2021. The response *Regulating healthcare professionals, protecting the public: consultation response*[5] was published in February 2023. A further consultation *Regulating anaesthesia associates and physician associates*[6] took place between February 2023 and May 2023 and sought views on the draft legislation that will enable the GMC to regulate associates in the UK.

7.6 Analysis of the responses to these consultations coupled with extensive stakeholder engagement has been carried out that has resulted in a set of finalised policy positions. We have engaged thoroughly with the regulators, the devolved governments, the Professional Standards Authority for Health and Social Care (PSA) and other key stakeholders across the health and care, employment, commercial and legal sectors to ensure that the instrument provides a legislative framework which can be adapted to future regulatory reform for all of the healthcare regulatory bodies.

7.7 The *Regulating anaesthesia associates and physician associates consultation response*[7] published on 11 December 2023 reflects the final positions that have been used as the basis for drafting this instrument, which will give the GMC the power to regulate associates under the new regulatory framework effectively.

7.8 The Anaesthesia Associates and Physician Associates Order 2024, was laid before the UK and Scottish Parliaments under the affirmative procedure on 13 December 2023. The GMC is proceeding to develop, consult on, and make rules to put in place the processes for regulating associates. This will include a consultation period where the GMC will seek views from patients, the professions and other key stakeholders on how regulation will be delivered.

7.9 The majority of provisions in the Order will commence on 13 December 2024. The offence relating to the use of the newly protected titles 'anaesthesia associate' and 'physician associate' will not take effect until 13 December 2026, to allow a further 2-year transition period for those who are already working as associates to register with the GMC.

7.10 The intention with the Order is to create a regulatory system whereby the GMC is able to set processes for regulation and to change them where necessary, without detailed granular Parliamentary oversight of these measures. Therefore, there is no requirement for Parliamentary approved rules in relation to the rule-setting powers in the Order. However, this increased flexibility is coupled with accountability

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3 https://assets.publishing.service.gov.uk/media/5a81d87440f0b62305b911d5/The_regulation_of_MAPs_in_the_UK.pdf

4 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/978833/Regulating_healthcare_professionals__protecting_the_public.pdf

5 https://www.gov.uk/government/consultations/regulating-healthcare-professionals-protecting-the-public/outcome/regulating-healthcare-professionals-protecting-the-public-consultation-response-executive-summary

6 https://www.gov.uk/government/consultations/regulating-anaesthesia-associates-and-physician-associates

7 https://www.gov.uk/government/consultations/regulating-anaesthesia-associates-and-physician-associates

mechanisms that are aimed at preventing the GMC from acting without taking appropriate account of relevant views on proposed measures. The new regulatory system clearly limits the areas that the GMC will have greater freedom to those which are relevant to its day-to-day functioning, and not wider questions about the professional regulation landscape which continue to be reserved to Parliament.

7.11 We have introduced a number of duties on the GMC (and, in future, for other regulators) to ensure that new powers are used reasonably and proportionately. This includes: (1) a duty to consult with relevant parties on changes to rules (including rules on fees); (2) a duty to co-operate with other parts of the healthcare sector as a means of preventing divergent practices that would negatively impact other stakeholders; and (3) a duty to produce annual reports to Parliament on the exercise the GMC's functions and how it has met its statutory duties.

7.12 We are also clear that the legislation does not give the GMC (or, in the future, any other regulators) carte blanche to introduce new regulatory functions where this would not be appropriate. For example, the GMC will not be able to create new registers for different AA or PA status (e.g. a student register). Similarly, the GMC will not be able to increase the number of professions that it regulates without additional legislation being approved by Parliament.

Regulatory Oversight

7.13 The Professional Standards Authority for Health and Social Care (PSA) is an independent organisation, accountable to the UK Parliament. The PSA oversees the 10 health and care regulators and carries out performance reviews on all of the regulators. This is a check on how well the regulators have been protecting the public and promoting confidence in health and care professionals and themselves.

7.14 For each review, the PSA will gather and analyse evidence for each regulator to see if they have met their Standards of Good Regulation. The Standards describe the outcomes it expects regulators to achieve for their four regulatory functions: guidance and standards, education and training, registration, and fitness to practise, as well as a set of general standards. The PSA publishes the reports that state how well the regulators are doing and helps the regulators improve, as the PSA identifies strengths and areas to improve and recommend changes.

7.15 The PSA operates an Escalation of performance review concerns policy[8] that allows it to escalate serious or intractable concerns to others, particularly Government and Parliament. This includes where a regulator has not met the same Standard for three years, or where it had concerns so significant that it considered they needed escalating even if they were new. There are several actions the PSA may take as part of the escalation process, including writing to the regulator's Chair, the Secretary of State for Health and Social Care, and/or the Chair of the Health and Social Care Committee. The PSA may also introduce closer monitoring of the issue with the regulator.

7.16 The Health and Care Select Committee can also hold regulators to account and has held hearings with the professional regulatory bodies on a number of occasions to oversee their work. Another of the accountability mechanisms requires the GMC to submit annual reports (a report on the exercise of its functions, a statistical report and a strategic plan) to the Privy Council who will lay copies of the reports and the plan

[8] https://www.professionalstandards.org.uk/docs/default-source/publications/performance-reviews/professional-standards-authority-process-for-escalating-performance-review-concerns.pdf?sfvrsn=82c34b20_2

before each House of Parliament which will enable Peers and MPs to scrutinise the regulator's activity and raise any issues in the House.

7.17 Finally, the Privy Council has a power to direct the GMC where it has failed to carry out its statutory functions, using what are called 'default powers'. While these powers have never been used, they provide a mechanism in extremis to ensure public protection by directing the regulator, or someone on behalf of the regulator.

Background to associate regulation

7.18 PAs work alongside doctors providing medical care as an integral part of the multi-disciplinary team. PAs can work autonomously, but always under the supervision of a fully trained and experienced doctor.

7.19 AAs are qualified to administer anaesthesia under the supervision of a consultant anaesthetist.

7.20 Like Allied Health Professionals, Advanced Clinical Practitioners, Health Care Scientists, and other healthcare roles, associates deliver specific aspects of patient care, increasing the capacity of clinical teams and reducing the workload of other clinicians, including doctors - increasing the capacity of the medical team to deliver care to patients.

7.21 PAs are trained to do clinical duties such as taking medical histories, carrying out physical examinations, and developing and delivering treatment and management plans.

7.22 AAs work within the anaesthetic team under the supervision of a consultant anaesthetist, with responsibilities such as reviewing patients before surgery, initiating and managing medications, administering fluid, and blood therapy during surgery and ensuring there is a plan for patients following their operation.

7.23 Typically, associates will undertake a two-year postgraduate degree (for example a Masters in Physician Associate Studies or a Postgraduate Diploma in Anaesthesia and Peri-Operative Sciences) with their first degree being bio-science related.

7.24 An integrated Master's degree is a four year programme which combines undergraduate and postgraduate study into a single course. Recently a limited number of Higher Education Institutions have introduced four-year undergraduate integrated Master of Physician Associate Studies programmes. These programmes offer a more direct route to qualification as a PA. The Faculty of Physician Associates at the Royal College of Physicians currently oversees and administers the running of a Managed Voluntary Register. This is a register of fully qualified PAs who have been declared fit to practise in the UK.

7.25 Similarly, following successful completion of an AA training programme, a qualified AA can register on the AA Managed Voluntary Register currently held by the Royal College of Anaesthetists.

7.26 The 2017 consultation, The regulation of medical associate professions in the UK[9], identified a level of risk in relation to the practise of associates that warranted the introduction of safeguards provided by statutory regulation and in 2019 the Government confirmed that the GMC would take on regulation of these roles. The

9 https://assets.publishing.service.gov.uk/media/5a81d87440f0b62305b911d5/The_regulation_of_MAPs_in_the_UK.pdf

majority of respondents to the public consultation were in favour of the GMC taking on regulation, including the professional bodies representing the roles and the medical royal colleges, including the Royal College of Anaesthetists, the Royal College of General Practitioners and the Royal College of Physicians. Regulation will give the GMC responsibility and oversight of AAs and PAs, in addition to doctors, allowing it to take a holistic approach to education, training and standards for these professions.

7.27 Regulation will provide a standardised framework of governance and assurance for clinical practice and professional conduct, to enable associates to make a greater contribution to patient care.

7.28 A quality assurance framework for associates' education will facilitate the future development and uptake in employment of these roles, ensuring these professions can work to their full potential as part of a multidisciplinary clinical team.

7.29 Regulation will also maintain patient safety as the two roles expand following commitments in the NHS Long Term Workforce Plan.

The GMC will:

- register associates it assesses to be appropriately qualified and competent
- set standards of practice, education and training, and requirements for continual professional development and conduct for associates
- approve associate education and training programmes
- operate fitness to practise procedures to investigate concerns and, if necessary, prevent or restrict an associate from practising

Effects of the Order

7.30 The Order sets out the Registrar's duty to record prescribed information in the register, with separate duties and powers on what information can then be published.

7.31 The proposed legislation requires the GMC to set the standards and requirements which associates from each profession must meet to be registered. To align with legislative requirements set out in the Health Care and Associated Professions (Indemnity Arrangements) Order 2014 (S.I. 2014/1887), the Order contains a requirement for associates to provide the Registrar with evidence to demonstrate that they hold adequate and appropriate cover in respect of their practice. This can be either through an indemnity arrangement, an insurance policy, or a combination of the two.

7.32 The Order mandates that associates who have previously been removed from the register due to a final measure being imposed at the outcome of fitness to practise proceedings must satisfy a Panel constituted under the Order that their fitness to practise is not impaired at the point of applying to return to the register. Appellants will accordingly have a right to appeal any decision not to readmit them to the register directly to the High Court in England and Wales, the High Court in Northern Ireland or the Court of Session in Scotland. Where the Order gives the GMC discretion to prescribe a decision-maker for the registration and fitness to practise elements of a restoration decision, the onward right of appeal will be dependent on whether or not a Panel is involved in either element of the initial decision. For cases decided by the GMC, appellants will have a right of appeal to a Panel before a further appeal to the

High Court in England and Wales, the High Court in Northern Ireland or the Court of Session in Scotland.

7.33 The government is clear that ensuring that professionals remain fit to practise is an essential component of public protection. The proposed legislation imposes a duty on the GMC to carry out a periodic assessment of whether an associate continues to meet standards determined by the GMC to remain on the register. The GMC has powers to remove associates who fail to meet these standards or who fail to comply with the procedural requirements of this assessment. An associate who is notified of a decision to remove their entry from the register has an onward right of appeal to a Panel and, subsequently, to a county court or, in Scotland, a sheriff.

7.34 The Order gives the GMC the power to set conditions on the registration of groups of associates who meet pre-determined criteria. These conditions will limit the scope of an associate's registration. This power is intended to allow the GMC to operate defined, different types of registration, for example provisional registration. The Order mandates that the GMC must publish this information to signal to the public and employers any restrictions on an associate's scope of registration. There is a complementary duty for the GMC to record information in the register relating to that person's practice as an associate where the Registrar is satisfied that its inclusion will aid the protection of the public. The Order also places a duty on the GMC to publish any information where it is satisfied that it serves the purpose of protection of the public. This enables the GMC to record and publish information in the register which it has identified has a legal effect that may either limit or enhance the scope of an associate's registration. For example, this mechanism could be used if a decision is made in the future to expand a form of prescribing responsibilities to either Anaesthesia Associates or Physician Associates.

7.35 The Order provides the GMC with a 3-stage fitness to practise process including an initial assessment stage, case examiner stage and Panel stage. Article 2(2)(a) sets out that there are two grounds for action; inability to provide care to a sufficient standard and misconduct. Grounds for action set out the reasons why the GMC might need to investigate and take action where there is a concern about an associate's fitness to practise.

7.36 Where a case examiner or Panel determines that an associate's fitness to practise is not impaired, no action will be taken against the associate unless it is deemed necessary to give the associate a warning. Where an associate's fitness to practise is found to be impaired, a case examiner or Panel will have a suite of final measures available to them, including applying conditions to registration, suspension of registration or removal of registration. The maximum period for which a final measure may be applied by a case examiner or Panel is 12 months, although this can be extended on review by the GMC, by no more than 12 months on each final measure review.

7.37 The GMC may review a final measure if an associate's entry in the register is subject to a condition or is suspended including where a question arises as to compliance with a condition on that associate's registration. On a review of a final measure, the GMC may revoke the measure if, in its opinion, the fitness to practise of the associate in respect of whom the final measure is imposed is no longer impaired. Where the GMC is of the opinion that the fitness to practise of the associate remains impaired, it may choose to make no changes to the final measure or it may choose to extend the period

specified in relation to the original final measure, vary a condition to which an associate's entry is subject, extend and vary a condition to which the associate's entry is subject to or substitute the final measure for another measure.

7.38 Interim measures are restrictions on an associate's practice that a Panel can put in place to address a public protection risk or if restrictions are otherwise in the interests of the public or associate while fitness to practise of the associate is under consideration. A Panel can put in place an interim measure for a maximum period of 18 months. In prescribed circumstances, the GMC may apply to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland to extend the interim measure beyond 18 months. The relevant court will be able to extend the interim measure for up to a further 12 months with further extensions possible subject to the GMC making further applications to the court.

7.39 A review of an interim measure by the GMC must take place before the end of a period of six months beginning with the date on which it first had effect. Subsequent reviews of the interim measure must take place within six months of the previous review or, where the duration of the interim measure has subsequently been extended by a court, within six months of that extension. An associate can request an early review of an interim measure at any time. However, such a review is at the GMC's discretion. Following a review of an interim measure the GMC may decide to make no changes to the interim measure, to extend the period specified, to vary a condition to which an associate's entry is subject, to extend and vary a condition to which an associate's entry is subject, or to substitute an interim measure for another measure if the interim measure remains necessary for the protection of the public or remains in the interests of the public or registrant. In addition, an interim measure may be revoked if the measure is no longer necessary for the protection of the public or is no longer in the interests of the public or associate.

7.40 The Order prohibits the GMC from being able to ask an associate, during fitness to practise proceedings, to provide it with any material the associate may have produced for the purposes of professional development or in the course of reflecting on their professional practice. This is in line with recommendation 5.3 of Professor Sir Norman Williams' review into gross negligence manslaughter in healthcare[10].

7.41 The GMC may revise decisions under the Order on the ground of error of fact or law or, except in relation to fitness to practise proceedings after the initial assessment stage, where there has been a material change of circumstances since the decision was made. The GMC must prescribe in rules the types of decisions it will revise using its revision powers.

7.42 Rights of appeal against registration and fitness to practise decisions made by the GMC and Panels are included within the Order. These are set out below.

7.43 Associates and applicants for registration will be able to seek permission from the GMC to appeal to a Panel against the following decisions:

- any decision not to grant registration

[10] https://assets.publishing.service.gov.uk/media/5b2a3634ed915d2cc8317662/Williams_Report.pdf

- where the GMC has placed a condition on the practice of a description of associates
- where the Registrar has determined that an entry should be removed from the register for a specific reason, examples include where registration was procured fraudulently or where a registrant no longer meets the prescribed standards

7.44 Applicants and associates who are granted permission to appeal against the above decisions will also have a subsequent right of appeal to a court specified in the Order.

7.45 Former associates who apply to re-join the GMC's register and have their applications for registration turned down will have a right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland.

7.46 Associates who wish to appeal against the following fitness to practise decisions will have a right of appeal to a Panel, subject to permission to appeal being granted:

- where a case examiner determines that an associate's fitness to practise is not impaired but issues a warning
- where a case examiner determines that an associate's fitness to practise is impaired and imposes a Final Measure
- where the GMC extends, varies or substitutes an interim measure for another interim measure following a review
- where the GMC extends, varies or substitutes a final measure for another final measure following a review

7.47 Associates who wish to appeal against the above fitness to practise decisions will have a subsequent right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland.

7.48 The Order permits the GMC to prescribe in rules additional persons who may appeal to a Panel. The GMC therefore has the flexibility to allow persons other than an associate to appeal against a case examiner's decision that an associate's fitness to practise is not impaired.

7.49 Furthermore, where a person who wishes to appeal to a Panel against a specified decision set out in article 16(1) of the Order and has their application for permission to appeal refused by the GMC, they will have a right of appeal to the relevant court. A direct right of appeal to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland will be available against the following decisions:

- where a Panel determines that an associate's fitness to practise is not impaired but issues a warning
- where a Panel determines that an associate's fitness to practise is impaired but takes no further action
- where a Panel determines that an associate's fitness to practise is impaired and imposes a final measure
- where a Panel imposes an interim measure on an associate
- where the Registrar has removed an associate's entry from the register, due to an associate receiving a custodial sentence, following a conviction for a listed offence set out within Schedule 2 of the Order.

7.50 The Order provides for the making of representations by education and training providers before a condition is attached to an education and training approval or the approval is varied or revoked. It also provides for the making of representations by associates before interim measures and final measures are imposed.

7.51 Introducing associates into statutory regulation will also mean that it will be an offence for someone, with intent to deceive to:

- use the title 'Anaesthesia Associate' or 'Physician Associate' if they are not registered as such with the GMC
- falsely represent anyone to have an approved qualification (which will cover associates' courses) or be registered
- make a false representation as to the content of the register
- procure, or attempt to procure, the inclusion or exclusion of information in the register

7.52 The offence relating to the use of the protected titles 'Anaesthesia Associate' and 'Physician Associate' will not take effect until December 2026, which allows for a 2-year transition period after regulation under the Order comes into force.

7.53 Consequential changes to other pieces of primary and secondary legislation have also been made to ensure that legislation relating to regulated healthcare professionals is updated to reflect the regulation of associates where appropriate.

7.54 The Order states that "rules must require the level of any fees to be set with a view to ensuring that, so far as is reasonably practicable and taking one year with another, the Regulator's fee income does not exceed its expenses, including amounts reasonably required to be set aside for reserves". It is recognised that it is difficult for the GMC to predict its annual income and expenditure given fluctuations in the number of registrants and fitness to practise cases, in addition to holding sufficient reserves and meeting its financial obligations. It is expected that the GMC will take a pragmatic approach by setting its fees at a level which allows for, and smooths out, year on year variations in its income and expenditure.

7.55 The objectives of the GMC and its duty to co-operate will be split across the Order and the Medical Act 1983. For completeness and to assist the reader, these are summarised below:

Objectives

7.56 The over-arching objective of the General Council in exercising their functions is the protection of the public.

7.57 The pursuit by the General Council of their over-arching objective involves the pursuit of the following objectives—

- to protect, promote and maintain the health, safety and well-being of the public,
- to promote and maintain public confidence in the medical profession and the anaesthesia associate and physician associate professions, and
- to promote and maintain proper professional standards and conduct for members of the medical profession and the anaesthesia associate and physician associate professions.

Duty to co-operate

7.58 In exercising their functions, the GMC has a limited duty to co-operate with public bodies or other persons concerned with:

- the employment (whether or not under a contract of service) of anaesthesia associates, physician associates and provisionally or fully registered medical practitioners,
- the education or training of anaesthesia associates, physician associates, 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.

Functions

7.59 The functions of the GMC are set out in both the Medical Act 1983 and the Order. The legislative framework provides for the GMC to carry out preventative actions to cover things such as setting standards and checking they are met, approvals of education and training, making administrative removals, disclosing information and compiling reports under s.52A of the Medical Act 1983.

Explanations

What did any law do before the changes to be made by this instrument?

7.60 Associates' roles exist within multi-disciplinary teams in the NHS workforce. However, the professionals in such roles are not subject to statutory regulation. Voluntary registers exist for each role, held for Anaesthesia Associates by the Royal College of Anaesthetists and for Physician Associates by the Faculty of Physician Associates.

Why is it being changed?

7.61 Strengthening the future NHS workforce is one of the Government's top priorities. The NHS has seen the emergence of new professional roles working within multi-disciplinary teams as part of a continuing drive to provide safe, accessible and high-quality care for patients across the UK. The growth of these professions, including these two new regulated associate roles, is central to the Government's commitment to develop a more effective, strong and expanding medical workforce to meet future need.

What will it now do?

7.62 Statutory regulation by the GMC will mean that anyone practising as an Anaesthesia Associate or Physician Associate must be registered with the GMC and will be subject to the relevant regulatory requirements. The GMC will be required to determine standards applicable to associates, these must relate to education and training, knowledge and skills, experience and performance, conduct and ethics, proficiency in the English language and such other matters as the GMC may prescribe in rules. Regulation is a significant step in embedding these associate roles in the multi-disciplinary healthcare workforce.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 This instrument forms part of the legislative framework for the GMC, alongside the Medical Act 1983. A second instrument will be drafted in due course that will bring in the remaining reforms, including those for medical practitioners, and amend the overall governance framework for the GMC.

10. Consultation outcome

10.1 All of the consultations mentioned in section 7 were subject to a statutory three month public consultation period. Overall, we have received nearly 5000 responses from individuals, organisations, healthcare professionals and members of the public. Responses to the consultations showed clear support for changes to the legislative structure that underpins the regulatory bodies and to the regulation of anaesthesia associates and physician associates. A copy of the final policy positions is included in the Regulating anaesthesia associates and physician associates consultation response published on 11 December 2023, following consultation on the draft legislation published in February 2023. A link to the consultation is here[11].

10.2 In 2017, the consultation *Promoting professionalism, reforming regulation*[12] was published on options for reforming the regulation of healthcare professionals in the UK following publication of the Law Commission's report, *Regulation of healthcare professionals, regulation of social care professionals in England*[13]. In 2019, a response was published *Promoting professionalism, reforming regulation: government response*. This response demonstrated clear support for reforming professional regulation of healthcare professionals, including 72% support for reform of fitness to practise processes, 74% support for regulators being enabled to support registrants' professionalism and a majority of respondents supporting proposals that would enable regulators to work closely with each other and other parts of the healthcare sector. There were mixed views on whether regulators should have great flexibility to set their own operating processes, with 42% agreeing and 34% disagreeing. We have worked with stakeholders subsequently to ensure that this flexibility is coupled with strengthened accountability and ensuring flexibility is provided where it is of benefit to registrants and patients.

10.3 In 2017 a consultation was also published on *The regulation of Medical Associate Professions in the UK*[14]. This consultation sought views on proposals to introduce statutory regulation for associates. The Government response[15] showed that there was clear support for regulation of Anaesthesia Associates (83%) and Physician

[11] https://www.gov.uk/government/consultations/regulating-anaesthesia-associates-and-physician-associates/regulating-anaesthesia-associates-and-physician-associates

[12] https://assets.publishing.service.gov.uk/media/5a81d78ce5274a2e8ab561e7/Regulatory_Reform_Consultation_Document.pdf

[13] https://www.lawcom.gov.uk/project/regulation-of-health-and-social-care-professionals/

[14] https://assets.publishing.service.gov.uk/media/5a81d87440f0b62305b911d5/The_regulation_of_MAPs_in_the_UK.pdf

[15] https://assets.publishing.service.gov.uk/media/5c5c053fe5274a318116c414/maps-consultation-report.pdf

Associates (95%). In addition, a majority of respondents (59%) agreed that the GMC was the most appropriate regulator.

10.4 Detailed proposals for the reform of the legislation underpinning healthcare regulation were set out in the *Regulating healthcare professionals, protecting the public*[16], published in 2021. The response *Regulating healthcare professionals, protecting the public: consultation response*[17] was published in February 2023. Respondents showed broad support for the proposals put forward although there was resistance to proposals on the number of grounds for action in fitness to practise cases and in respect of the freedom for regulators to set their own fees. In subsequent policy development we have sought to set out our rationale for these proposals. In respect of grounds for action, we have worked with regulators to ensure that the legislation is drafted in such a way that the grounds are sufficiently broad to enable them to consider and adjudicate on an appropriate range of fitness to practise concerns. In respect of fee setting powers, we have continued to ensure that any material changes to the rules as to fees are subject to consultation by the regulator and that any changes are accounted for in annual reporting duties.

10.5 A further consultation *Regulating anaesthesia associates and physician associates*[18] took place between February 2023 and May 2023 and sought views on the draft legislation that will enable the GMC to regulate associates in the UK.

10.6 The consultation sets out what powers and duties will be included in the Order to enable the GMC to operate a robust regulatory regime for associates, including in areas such as standards and approvals, the register, fitness to practise, and revisions and appeals.

10.7 Responses to that legislative consultation have necessitated changes to the legislation, such as in respect of the revisions and appeals provisions. The legislation now contains drafting that enjoys broad support from stakeholders and implements review and appeal mechanisms that will ensure that where a decision is challenged it can be considered and, where necessary, changed quickly without requiring escalation to a Court.

10.8 The UK Parliament is responsible for the regulation of healthcare professions in England and Wales. Regulation of health and care professionals is a transferred matter in Northern Ireland. In Scotland it is devolved for healthcare professionals who entered regulation after the passing of the Scotland Act 1998 (c. 46). The consultations and responses and the drafting of this instrument has been led jointly by the UK and the Devolved Governments of Northern Ireland, Scotland and Wales.

11. Guidance

11.1 Any guidance which may be required in relation to the powers and duties in this instrument will be issued by the GMC.

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16 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/978833/Regulating_healthcare_professionals__protecting_the_public.pdf

17 https://www.gov.uk/government/consultations/regulating-healthcare-professionals-protecting-the public/outcome/regulating-healthcare-professionals-protecting-the-public-consultation-response-executive-summary

18 https://www.gov.uk/government/consultations/regulating-anaesthesia-associates-and-physician-associates

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 The impact on the public sector is that there will be an initial impact on central government as the Department of Health and Social Care is providing funding for the initial set up costs of regulating Anaesthesia Associates and Physician Associates.

12.3 A full Impact Assessment has not been prepared for this instrument because of the low level of impact per business. The high-level assessment we carried out establishes that there is no significant impact on business, charities or voluntary bodies.

12.4 As part of developing the policy positions on reform and regulating associates, an Equalities Impact Assessment has been developed and updated. We don't anticipate that there will be any disproportionate impacts on protected characteristics from the regulation of associates as the GMC is under a legal obligation to consider the impact on protected characteristics, and the flexible framework the new legislation will give it will ensure it is able to adapt to the requirements of the professions' demographics.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is to keep it under review whilst developing the second instrument for the GMC and to carry out an internal review of the impact of the legislation on business after 5 years. The legislation may be amended accordingly.

15. Contact

15.1 Sean Marchesi-Denham, DHSC (Telephone: 020 7972 1422 or email: Sean.Marchesi-Denham@dhsc.gov.uk) can be contacted with any queries regarding the instrument.

15.2 Phil Harper, Deputy Director of Professional Regulation, DHSC can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Minister of State for Health and Secondary Care, Andrew Stephenson, DHSC can confirm that this Explanatory Memorandum meets the required standard.