HOUSE OF LORDS

Secondary Legislation Scrutiny Committee

10th Report of Session 2023–24

Drawn to the special attention of the House:

Draft Anaesthesia Associates and Physician Associates Order 2024

Includes information paragraphs on:

Draft Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024

Draft Reporting on Payment Practices and Performance (Amendment) Regulations 2024

Draft Pensions Regulator General Code of Practice 2024

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Secondary Legislation Scrutiny Committee

The Committee's terms of reference, as agreed on 8 November 2023, are set out on the website but are, in summary:

To report on draft instruments and memoranda laid before Parliament under section 23(1) of the European Union (Withdrawal) Act 2018 and sections 11, 12 and 14 of the Retained EU Law (Revocation and Reform) Act 2023.

And, to scrutinise –

> (a) every instrument (whether or not a statutory instrument), or draft of an instrument, which is laid before each House of Parliament and upon which proceedings may be, or might have been, taken in either House of Parliament under an Act of Parliament;
>
> (b) every proposal which is in the form of a draft of such an instrument and is laid before each House of Parliament under an Act of Parliament,

with a view to determining whether or not the special attention of the House should be drawn to it on any of the grounds specified in the terms of reference.

The Committee may also consider such other general matters relating to the effective scrutiny of secondary legislation as the Committee considers appropriate, except matters within the orders of reference of the Joint Committee on Statutory Instruments.

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Registered interests

Information about interests of Committee Members can be found in the last Appendix to this report.

Publications

The Committee's Reports are published on the internet at https://committees.parliament.uk/committee/255/secondary-legislation-scrutiny-committee/publications/

Committee Staff

The staff of the Committee are Jen Mills (Clerk), Philipp Mende (Adviser), Chris Smith (Adviser), Jane White (Adviser) and Riona Millar (Committee Operations Officer).

Further Information

Further information about the Committee is available at https://committees.parliament.uk/committee/255/secondary-legislation-scrutiny-committee/

The progress of statutory instruments can be followed at https://statutoryinstruments.parliament.uk/

The National Archives publish statutory instruments with a plain English explanatory memorandum on the internet at http://www.legislation.gov.uk/uksi

Contacts

Any query about the Committee or its work, or opinions on any new item of secondary legislation, should be directed to the Clerk to the Secondary Legislation Scrutiny Committee, Legislation Office, House of Lords, London SW1A 0PW. The telephone number is 020 7219 8821 and the email address is hlseclegscrutiny@parliament.uk.

Tenth Report

INSTRUMENTS DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

Draft Anaesthesia Associates and Physician Associates Order 2024

Date laid: 13 December 2024

Parliamentary procedure: affirmative

This Order would require Anaesthesia Associates and Physician Associates to be registered and regulated in the same way as doctors are regulated. Regrettably, the Department for Health and Social Care's Explanatory Memorandum (EM) did not explain the role of such associates, and additional information from the Department is included in this report. The proposal has been subject to extensive consultation and there is general support for the move, including from the General Medical Council (GMC), which is an experienced regulator.

The Order makes the first use of powers inserted into the parent Act by the Health and Care Act 2022 to give the GMC direct powers to make and amend standards and procedures for these associates, ***removing the process from Parliamentary oversight. The Explanatory Memorandum should have been more explicit on this point and on what safeguards remain.***

The Department of Health and Social Care states that this Order is a first step in the reform of the way all the medical professions are regulated: this Report provides further information on the wider programme.

This Order is drawn to the special attention of the House on the ground that it is politically or legally important or gives rise to issues of public policy likely to be of interest to the House.

1. This Order would require Anaesthesia Associates (AAs) and Physician Associates (PAs) to be registered and regulated in the same way as doctors are regulated. Currently their registration is voluntary, and it is thought that there are about 3,500 PAs and 180 AAs currently in practice in the UK. Further explanation of their role and qualifications is set out below.

2. The proposal will apply to all parts of the UK and has been laid as a draft Order in Council simultaneously before the Westminster and the Scottish Parliaments. Most of its requirements would come into effect on 13 December 2024, with a two-year transitional period. The General Medical Council (GMC) has been publishing information on the proposed system,[1] and fully supports the change.[2]

3. The draft Order gives the GMC the power to set rules on the registration of groups of associates who meet pre-determined criteria. The GMC may also limit the scope of an associate's registration, for example by making

1 GMC, 'PA and AA regulation' (December 2023): https://www.gmc-uk.org/pa-and-aa-regulation-hub [accessed 23 January 2024].

2 GMC, 'GMC welcomes upcoming laying of AA and PA Order' (11 December 2023): https://www.gmc-uk.org/news/news-archive/gmc-welcomes-upcoming-laying-of--aa-and-pa-order [accessed 23 January 2024].

it provisional or subject to conditions and may sanction them for non-compliance.

4. The draft Order would provide the GMC with a three-stage fitness to practise process, comprising an initial assessment stage, case examiner stage and Panel stage. Appeals mechanisms are included for each decision including the imposition of conditions.

What AAs and PAs do

5. Unfortunately, the Explanatory Memorandum (EM) assumed that the role of these associates is generally known. The Department of Health and Social Care (DHSC) has therefore had to provide us with supplementary information:

> "Physician Associates (PAs), who work alongside doctors, provide medical care as an integral part of the multi-disciplinary team. PAs carry out clinical tasks autonomously but work under the supervision of a fully trained and experienced doctor. More specifically, PAs are trained to undertake a number of day to day tasks, including:
>
> - taking medical histories from patients;
> - performing physical examinations;
> - diagnosing illnesses;
> - seeing patients with long-term chronic conditions;
> - performing diagnostic and therapeutic procedures;
> - analysing test results;
> - developing management plans; and
> - providing health promotion and disease prevention advice for patients.
>
> In a similar way, Anaesthesia Associates (AAs) work under the supervision of a consultant anaesthetist in the anaesthesia team and work with the wider theatre and critical care teams including anaesthetists, surgeons, operating department practitioners (and other Allied Healthcare Professionals), nurses and intensive care and emergency medicine doctors. AAs have a number of responsibilities and duties including:
>
> - reviewing patients before surgery and assessing them for anaesthesia;
> - taking a medical history and clinical assessment allowing for an anaesthesia plan to be created;
> - inducing, maintaining and waking up patients from anaesthesia under appropriate supervision;
> - using anaesthesia techniques/agents, medications and specialist equipment;

- interpreting and monitoring clinical readings and patients' parameters during anaesthesia and responding appropriately;
- initiating and managing medications, fluid, and blood therapy during surgery;
- identifying potential issues during surgery and anaesthesia, taking action and seeking appropriate support when required;
- ensuring that there is a plan for patients following their operation and that it's carried out;
- being involved in the teaching, supervising and assessing of other team members; and
- supporting innovation, audit, and research within the anaesthetic department."

6. DHSC also provided additional background on the education and standards AAs and PAs currently meet and their plans to amend them:

> "AAs and PAs are healthcare professionals, trained to the medical model. Typically, AAs and PAs 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.
>
> 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.
>
> Furthermore, to become a qualified PA in the UK, the Faculty of Physician Associates (FPA) requires all PA students who have completed a postgraduate programme to take the Physician Associate National Examination (PANE). The PANE is developed and delivered by the Assessment Unit on behalf of the Royal College of Physicians (RCP), of which the FPA is part. The PANE is open to any candidate who has completed the requirements of the Competence and Curriculum Framework for the Physician Assistant within a UK university postgraduate programme in Physician Associate Studies (either as a Postgraduate Diploma or a Master's course) and had completion signed off by their relevant university exam board.
>
> There are plans to introduce a similar national examination for AAs in 2025.
>
> Education and training standards for AAs and PAs will be set by the General Medical Council (GMC) once the professions are regulated. The GMC will also be responsible for approving Higher Education Institutions to develop and teach the curricula content which is designed to enable students to meet the desired education and training standards. Once the professions are regulated, only students who have undertaken

> approved GMC education and training programmes will be able to work as an AA or PA in the UK."

7. We sought confirmation that the relevant universities and medical schools were content with these requirements and competent to deliver them. DHSC said:

> "Since January 2021, the GMC has had regular direct engagement with each Higher Education Institution (HEI) that provides a PA or AA course for the purposes of quality assurance. The course providers are engaging well and the GMC has had positive feedback from them about its processes.
>
> The GMC is confident that all HEIs are on track to meet the GMC's standards by the start of regulation."

Removal of Parliamentary oversight

8. Paragraph 5(1)(a) of Schedule 3 to the draft Order contains a duty to publish the rules that would apply to associates. They would be published on the GMC's website "as they will be GMC owned and approved rules".

9. We are pleased to note that the proposal has been subject to extensive consultation with the professions and regulators, and DHSC has made clarifications and amendments in response to obtain broad support. We note, however, that there were mixed views on whether regulators should have "great flexibility to set their own operating processes", with 42% of respondents agreeing and 34% disagreeing.

10. The EM refers obliquely to giving regulators "greater flexibility" and to "reforming the legislative framework" on the grounds that the current requirement for an Order in Council is cumbersome. The Order in Council mechanism has two stages: first, a draft of the legislation is considered by Parliament; then, if approved, it goes forward to the Privy Council for approval by the King. The EM did not make it obvious that, rather than using a simpler legislative mechanism such as a statutory instrument, the GMC would be given complete regulatory autonomy in these areas. (Further explanation of how this will work is published at Appendix 1.)

11. Article 3(2)(f) of this draft Order would permit the GMC to set standards on such other matters as the GMC may prescribe in rules made under paragraph 2(2)(a) of Schedule 4 of the draft Order. Paragraph 5(1)(a) of Schedule 3 contains a duty to publish those rules. In supplementary information, DHSC told us:

> "It is GMC's intention to fulfil that duty by publishing all rules on its website as they will be GMC owned and approved rules. Drafts of the rules will also be published alongside the consultation on the rules and supporting material."

12. DHSC confirmed that, when this Order takes effect, "changes in registration processes etc will no longer be laid before Parliament in any form, they will just be posted on the GMC's website … however members of either House can respond to consultations if they wish." **The supplementary information states more clearly than the EM the Government's**

intention to remove the making and changing of such rules from all Parliamentary oversight.

13. We raised several questions about what checks there would be on the GMC's autonomy; in particular, who would have oversight of the fairness of GMC registration rules if future changes to them could simply be posted to its website. DHSC replied:

> "The Professional Standards Authority for Health and Social Care (PSA) oversees the 10 health and care regulators. The PSA are an independent organisation, accountable to the UK Parliament.
>
> The PSA carries out performance reviews on all of the regulators and is a check on how well the regulators have been protecting the public and promoting confidence in health and care professionals and themselves.
>
> 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.
>
> In 2020 the PSA introduced an escalation policy that would allow it to escalate serious or intractable concerns to others, particularly Government and Parliament.[3] 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."

First step in wider reform programme

14. The EM also states that this Order is the first step in a wider programme of reform for the regulation of medical professions across the UK, which responds to the Law Commission's report, *Regulation of healthcare professionals, regulation of social care professionals in England*.[4] The EM states it is DHSC's intention 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.

15. In supplementary information, DHSC provided more detail about the scope of the project:

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3 Professional Standards Authority, 'Process for escalating performance review concerns' (June 2022): https://www.professionalstandards.org.uk/docs/default-source/publications/performance-reviews/professional-standards-authority-process-for-escalating-performance-review-concerns.pdf?sfvrsn=82c34b20_2 [accessed 23 January 2024].

4 Law Commission, 'Regulation of Health and Social Care Professionals': (April 2014): https://lawcom.gov.uk/project/regulation-of-health-and-social-care-professionals/ [accessed 23 January 2024].

> "As set out in *Regulating Healthcare Professionals, Protecting the Public,*[5] one of the main aims of our programme of reform is to give regulators greater flexibility to determine how they set standards. This flexibility will allow regulators to adapt to changes in the healthcare environment and to the changing needs of service users and the general public more quickly.
>
> The standards for AAs and PAs will be set by the GMC using the standard setting powers in the draft Order. The powers are broad to provide the GMC with flexibility.
>
> For example, article 3(2)(f) of the draft Order permits the GMC to set standards on other matters as the GMC may prescribe in rules made under paragraph 2(2)(a) of Schedule 4 of the draft Order.
>
> Furthermore, regulators often need to seek approval from the Privy Council for rule changes, including those relating to operational procedures. This limits their ability to respond to changes in the healthcare environment. As part of our programme of reform we intend to provide all regulators with broadly equivalent powers to change their operational procedures and to make or amend their rules without having to seek Privy Council approval; the Order confers such powers on the GMC in respect of rules relating to AAs and PAs."

Timetable for wider reform

16. Changing the way the medical professions are regulated is a long-term project. DHSC went on to say (and further detail is included in Appendix 1):

> "The draft 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 AAs and PAs to introduce a new regulatory framework without changing the GMC's regulatory framework for medical practitioners (doctors) at this stage. This means that draft 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 draft 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 after the draft [Order] comes into effect.
>
> While it is our intention to work as swiftly as possible to deliver reform for each regulator and profession, we plan to prioritise delivery based on criteria including the size of registrant base, the need for reform, and our assessment of the regulators' readiness to implement the changes. We are currently in the early stages of the work to develop reformed legislation for the Nursing and Midwifery Council (NMC) and the

5 DHSC, 'Regulating healthcare professionals, protecting the public' (2021): https://assets.publishing.service.gov.uk/media/607daac6d3bf7f0132941916/Regulating_healthcare_professionals__protecting_the_public.pdf [accessed 23 January 2024].

> Health and Care Professions Council (HCPC) for their professions, and further legislation for doctors regulated by the GMC over the next couple of years.
>
> We plan that these future Orders will introduce similar reforms to those contained in [this Order] and also include the additional governance and operating reforms.
>
> While we intend to move at pace, we will undertake 3-month consultations, as required by the legislative powers under s.60 of the Health Act 1999, 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 [this 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."

Conclusion

17. The proposal to register and regulate Associate Physicians and Anaesthetists is entirely in line with previous practice, and the GMC is experienced in that role. Hence, we have no concerns about the policy intention. However, this Order also represents a significant constitutional change in the way that system of regulation is to be delivered by removing direct Parliamentary oversight. **The Explanatory Memorandum should, therefore, have been more explicit on this point and on what safeguards remain.**

INSTRUMENTS OF INTEREST

Draft Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024

18. These Regulations would extend, for a further two years, certain provisions which facilitate a large scale COVID-19 or influenza vaccination programme. They allow non-registered healthcare workers and those registered but who cannot ordinarily vaccinate to administer a COVID-19 or influenza vaccine (but no others) under the supervision of a registered healthcare worker.

19. They would also continue the current relaxations that allow the assembly of COVID-19 vaccines to be undertaken by or under the supervision of a healthcare professional, without requiring additional marketing authorisations or manufacturer's licence, and the ability to move COVID-19 and influenza vaccines between premises without a wholesale dealer's licence. The Department for Health and Social Care states that these provisions played a key role in the safe and effective delivery of these vaccines at speed and scale, whilst maintaining patient safety. The Regulations would extend the provisions to April 2026 to maintain the pace of the vaccination programme, which in turn helps to prevent NHS services from being overwhelmed. **It is understood that this system has worked very well and the House may wish to ask the Minister why it is not made permanent to deal with future pandemics and even epidemics**.

Draft Reporting on Payment Practices and Performance (Amendment) Regulations 2024

20. These draft Regulations propose to strengthen the requirement on large companies and limited liability partnerships to publish information about their practices, policies and performance in relation to paying suppliers. According to the Department for Business and Trade (DBT), late payments remain a significant issue, particularly for small businesses that may find it difficult to challenge larger customers. DBT says that, in 2022, small and medium-sized enterprises were owed on average an estimated £22,000 in late payments.

21. The current requirement on large businesses to report payment practices and performance twice per financial year was introduced in 2017 to increase transparency. A review of the arrangements in November 2023[6] found that there "have been improvements in recent years": for example, the percentage of payments not paid within the agreed terms fell from 28% in December 2019 to 25% in December 2022, while, over the same period, average payment times reduced marginally from 36 days to 35.6 days. The review concluded, however, that late payment and long payment terms "remain persistent in key areas of the economy, with 40% of invoices still not being paid according to agreed terms". DBT says that respondents to a consultation on the changes

6 Department for Business and Trade, 'Publication of the Prompt Payment and Cash Flow Review' (22 November 2023): https://www.gov.uk/government/publications/publication-of-the-prompt-payment-and-cash-flow-review [accessed 23 January 2024].

proposed in this instrument in 2023 "provided positive feedback" on the impact of the arrangements to date and wanted to see them extended.[7]

22. This instrument proposes to extend the sunset date of the reporting requirement from 6 April 2024 to 6 April 2031. The instrument also proposes additional reporting requirements, including on the monetary value of the invoices not paid within the agreed payment period. The Department says that it monitors company reports to identify large businesses that fail to publish the required information and that, while it can prosecute and fine non-compliant businesses, it has not yet had to do so because once non-compliant businesses are contacted, they typically begin reporting.

Draft Pensions Regulator General Code of Practice 2024

23. Following a review by the Pensions Regulator, this draft Code combines ten previous codes of practice relating to the governance and administration of all types of pension schemes. It also updates the text to incorporate recent legislative changes: it does not itself make changes to the law but restates existing expectations more clearly. Restructured into 51 shorter topic-based modules, the draft Code is intended to assist trustees, scheme managers and their advisers in understanding their task and complying with the law. Topics in the draft Code include:

- Selecting and appointing members of the governing body;
- Knowledge and understanding;
- Risk management;
- Using service providers; and
- Investment governance.

24. The draft Code must lie before the House for 40 days to allow for comment before it can be made and brought into effect.

25. **This Committee has, in the past, been critical of the cumulative burden on both pension schemes and trustees from frequent changes of regulation.[8] We therefore welcome this move to consolidate the requirements and make them more accessible to the user. However, as this Code comprises 170 pages of tightly packed instructions, the Department for Work and Pensions still has some way to go in easing the overall burden on trustees.**

7 Department for Business and Trade/Department for Business, Energy and Industrial Strategy, 'Government response to the Amendments to the Payment Practices and Performance Regulations 2017' (22 November 2023): https://www.gov.uk/government/consultations/amendments-to-the-payment-practices-and-performance-regulations-2017/outcome/government-response-to-the-amendments-to-the-payment-practices-and-performance-regulations-2017 [accessed 24 January 2024].

8 See for example item on the Draft Occupational Pension Schemes (Governance and Registration) (Amendment) Regulations 2022 in our *6th Report* (Session 2022–23, HL Paper 31).

INSTRUMENTS NOT DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

Instruments subject to affirmative approval

Draft	Economic Crime and Corporate Transparency Act 2023 (Consequential, Supplementary and Incidental Provisions) Regulations 2024
Draft	Human Medicines (Amendments Relating to Coronavirus and Influenza) (England and Wales and Scotland) Regulations 2024
Draft	Local Elections (Northern Ireland) (Amendment) Order 2024
Draft	Representation of the People (Postal Vote Handling etc.) (Northern Ireland) (Amendment) Regulations 2024
Draft	Mesothelioma Lump Sum Payments (Conditions and Amounts) (Amendment) Regulations 2024
Draft	Paternity Leave (Amendment) Regulations 2024
Draft	Pneumoconiosis etc. (Workers' Compensation) (Payment of Claims) (Amendment) Regulations 2024
Draft	Reporting on Payment Practices and Performance (Amendment) Regulations 2024

Draft instruments subject to annulment

Draft	Pensions Regulator General Code of Practice 2024

Instruments subject to annulment

SI 2024/8	Railways and Freight Transport etc (Revocation) Regulations 2024
SI 2024/11	Rent Officers (Housing Benefit and Universal Credit Functions) (Amendment) Order 2024
SI 2024/15	National Health Service (Notifiable Reconfigurations and Transitional Provision) Regulations 2024
SI 2024/16	Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) (Amendment and Saving Provision) Regulations 2024
SI 2024/29	Council Tax Reduction Schemes (Prescribed Requirements) (England) (Amendment) Regulations 2024
SI 2024/30	Agricultural Holdings (Units of Production) (England) Order 2024

APPENDIX 1: DRAFT ANAESTHESIA ASSOCIATES AND PHYSICIAN ASSOCIATES ORDER 2024

Further material from the Department of Health and Social Care in response to questions

General background of s.60 Orders for healthcare regulation

Parliament has agreed to the delegated legislation arrangements in s.60 of the Health Act 1999. They give Parliament broad powers to make changes to regulatory legislation via secondary legislation. These powers were broadened further by the Health and Care Act 2022 to provide Parliament with the powers to: (1) close healthcare regulators down; (2) remove professions from regulation where it is no longer deemed to be necessary; (3) regulate groups that are not traditionally considered to be a profession e.g. senior managers/leaders; and (4) delegate functions of regulators to other regulatory bodies.

Since the coming into force of s.60 provisions in the Health Act 1999 (15 March 2000), there have been in excess of 30 Section 60 orders passed by Parliament since 15 March 2000, when the Act came into force. These orders have enabled the professional regulatory system to be updated with each statutory instrument approved by both Houses, and Scottish Parliament where appropriate.

There is precedent for s.60 orders making wide-ranging and fundamental changes to the regulatory landscape, similar in scope to the AAPA Order the SLSC is currently considering. Such major changes to the regulatory system include establishing the Nursing and Midwifery Council (NMC), the Health and Care Professions Council (HCPC) and the General Pharmaceutical Council and bringing new professions into regulation, such as Nursing Associates regulated by the NMC and operating department practitioners, practitioner psychologists and hearing aid dispensers regulated by the HCPC.

The orders have also made amendments to the framework legislation for the regulation of dentists, dental care practitioners, pharmacists, pharmacy technicians and the professions regulated by the Health Professions Council (now known as the HCPC) and has, for example, made amendments targeted at improving protection of children and vulnerable adults for all registered health care professionals.

General Medical Council (GMC) current and future powers

Previous Orders mean that the GMC already has a reasonable degree of autonomy. For example, the GMC already has the power to set its registration fees and to change them without Parliamentary oversight. Similarly, the GMC is able to set out its rules and guidance for Fitness to Practise processes without agreement from Parliament. The duties of consultation on such changes and the understanding of the regulators of their accountability to Parliament means that to date the regulators have discharged their functions in a way that has not been a cause of concern in either Houses.

The AAPA Order delegates further following principles recommended by the Law Commissions in 2014. At present, for a majority of healthcare regulators, the requirement for Parliamentary approval of changes to rules means that they are less able to respond quickly to amend their processes to reflect emerging workforce trends or concerns.

The AAPA Order seeks to increase the number of areas that the GMC has autonomy over in respect of its day-to-day functions. Whilst there are new powers and duties to make rules, some of these are necessary in light of the new way in which regulation will function e.g. a new three part fitness to practise process that requires new rule making powers for processes that don't currently exist. In addition, we have increased the rule-making powers that the GMC will have to include setting rules for registration processes, reflecting the expertise of the GMC in running these processes and allowing for proactive improvement of them where the GMC considers it necessary to do so.

Importantly, recognising that there needs to be a system of checks and balances in place to ensure regulators continue to act in accordance with the needs of their registrants, patients and the wider healthcare sector, 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.

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 PA or AA 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.

The intention with the AAPA Order has been to create a regulatory system whereby the regulator is able to set processes for regulation and to change them where necessary, without detailed granular Parliamentary oversight of these measures. This is coupled however with accountability mechanisms that are aimed at preventing regulators from acting without taking appropriate account of relevant views on proposed measures. And finally, 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 rightly continue to be reserved to Parliament.

SLSC questions

Q1. Who regulates the regulator? Does any other body have oversight of the GMC's actions or decisions?

A1: The Professional Standards Authority for Health and Social Care (PSA) oversees the 10 health and care regulators. The PSA are an independent organisation, accountable to the UK Parliament.

The PSA carries out performance reviews on all of the regulators and is a check on how well the regulators have been protecting the public and promoting confidence in health and care professionals and themselves.

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.

In 2020 the PSA introduced an escalation policy that would allow 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. A copy of the PSA's Escalation of performance review concerns is in this link.[9]

Q2. What is the DHSC's relationship with the GMC—can the government give it directions?

A2: DHSC works very closely with the General Medical Council (GMC) and has regular meetings with colleagues at every level of the organisation. The GMC is independent of Government and operates autonomously in order to deliver confidence to patients and the public, its professionals and stakeholders.

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.

Q3. What Parliamentary oversight is there left of the GMC's actions—presumably the Commons' Health Committee but are there any means for the House of Lords to discuss the way the GMC operates–apart from individual Peers putting down questions?

A3: The Health and Care Select Committee can hold regulators to account and has held hearings with the professional regulatory bodies on a number of occasions to oversee their work. One 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 before each House of Parliament which will enable Peers and MPs to scrutinise the regulator's activity and raise any issues in the House.

There is also the PSA's performance review process outlined above in question 1.

Q4. Are the relevant Universities content with the changes to the academic qualifications proposed for AAs and PAs and competent to deliver the courses?

A4: As set out below, the GMC has undertaken extensive engagement with [Higher Education Institutions] HEIs to ensure that there is broad support for the new education and training standards and that the HEIs are able to offer relevant qualifications to facilitate the meeting of those standards:

- Since January 2021, the GMC has had regular direct engagement with each HEI that provides a PA or AA course for the purposes of quality assurance. The course providers are engaging well and the GMC has had positive feedback from them about its processes.

9 Professional Standards Authority, 'Process for escalating performance review concerns' (June 2022): https://www.professionalstandards.org.uk/docs/default-source/publications/performance-reviews/professional-standards-authority-process-for-escalating-performance-review-concerns.pdf?sfvrsn=82c34b20_2 [accessed 23 January 2024].

- The GMC is confident that all HEIs are on track to meet the GMC's standards by the start of regulation.
- The GMC also has regular dialogue with the body that represents PA course providers, the PA Schools Council (PASC). The PASC provided representatives to sit on the GMCs PA curriculum development group (2020–2023). AA course providers contributed to the development of the AA curriculum via the Royal College of Anaesthetists.
- Many individual course providers also gave feedback on the GMC's overall education framework for PAs and AAs through an engagement exercise its ran in summer 2022 and their feedback was considered in the development of the final drafts of the curricula and outcomes. A report on the engagement exercise is available on the GMC's website.[10]

In addition, the GMC has a duty to consult with relevant persons where changes are proposed.

Q5. Is there any clearer statement of the DHSC's plans for extending these devolved powers to the GMC and the other health regulators?

A5: The Government has consulted (see details in response to question 6) on our proposed approach to modernising the legislation of the regulatory bodies and the policies that sit within the programme of reform. We intend to replace the regulators' current legislation giving each regulator near identical powers through broadly similar legislation. We will prioritise 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.

Q6. Can you give a clearer statement of the policy objective than "improving flexibility"?

A6: When considering reforms to the regulator's legislation, we have 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.

10 GMC, 'Physician associate and anaesthesia associate pre-qualification education framework: engagement report': https://www.gmc-uk.org/-/media/documents/pa-and-aa-pre-qualification-education-framework-engagement-report_pdf-93475349.pdf [accessed 24 January 2024].

History of regulatory reform

We have set out the case for reform below (referencing the various documents that have informed our policies) which has also been included in various documents including Regulating healthcare professionals, protecting the public (March 2021) and the government response (February 2023); and Regulating anaesthesia associates and physician associates consultation (February 2023) and the government response (December 2023).

The case for reforming professional regulation has long been acknowledged. The 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. In doing so, it needs to be faster, more flexible and minimise costs to registrants.

In 2014, the Law Commissions of England and Wales, Scotland and Northern Ireland published a comprehensive review of the legal framework for professional regulation in the UK. The reforms recommended by the Law Commissions aimed to consolidate and simplify the existing legal framework and introduce greater consistency across the regulatory bodies. In addition, they recommended that the regulators should be given powers to make rules concerning their procedures and processes which are not subject to approval by Government or any Parliamentary procedure.

In 2017, the UK Government and devolved administrations consulted on options for reforming the regulation of healthcare professionals in the UK. Promoting professionalism; reforming regulation set out five objectives for the regulatory system to:

- improve public protection from the risk of harm due to poor professional practice;
- support the development of a flexible workforce that is better able to meet the challenges of delivering healthcare in the future;
- address concerns about the performance of professionals in a more proportionate and responsive fashion;
- provide greater support to regulated professionals in delivering high quality care; and
- increase the efficiency of the system.

In July 2019 the Government published its response to this consultation. This built on the Law Commissions' recommendations and outlined our planned programme of work to provide all UK healthcare regulators with broadly consistent powers.

A number of reports have been published in recent years that have had a particular bearing on proposals for the future of professional regulation of healthcare professionals in the UK. The recommendations from these reports have been considered and reflected in our proposed reforms.

The Francis inquiry report—Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (Feb 2013)[11] which looked into the serious failings at the Mid Staffordshire NHS Foundation Trust. This inquiry examined the operation of

11 The Mid Staffordshire NHS Foundation Trust Public Inquiry, 'Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry' (February 2013): https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf [accessed 24 January 2024].

the commissioning, supervisory and regulatory organisations and other agencies, including the culture and systems of those organisations in relation to their monitoring role at Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009, and examined why problems at the Trust were not identified sooner and appropriate actions taken. One of the issues that the inquiry highlighted was that the regulatory regime allowed for overlap of functions that led to a tendency for regulators to assume that the identification and resolution of issues was the responsibility of someone else. Effective accountability to the public demands a simpler regime of regulation.

Lessons Learned Review into the Nursing and Midwifery Council's (NMC) handling of concerns about midwives' fitness to practise at Furness General Hospital (May 2018)[12] is an independent Investigation conducted by Dr Bill Kirkup CBE found serious concerns about the clinical competence and integrity of the midwifery unit at Furness General Hospital. In February 2017, the Secretary of State for Health asked the Professional Standards Authority for Health and Social Care (PSA) to undertake a 'lessons learned' review of the Nursing and Midwifery Council's (NMC) handling of concerns about midwives at the University Hospitals of Morecambe Bay NHS Foundation Trust. To identify lessons for the NMC (and other regulators) about its handling of these cases and its approach to relationships with witnesses and other stakeholders, the PSA looked at:

- the NMC's approach to managing the complaints;
- the administration of the cases; and
- the relationship with witnesses, registrants and other key stakeholders.

Williams review—Gross negligence manslaughter in healthcare (June 2018)[13] In February 2018 the Secretary of State for Health announced a rapid policy review into gross negligence manslaughter in healthcare. The review was set up to consider the wider patient safety impact resulting from concerns among healthcare professionals that simple errors could result in prosecution for gross negligence manslaughter, even if they occur in the context of broader organisation and system failings. In particular, there was concern that these concerns had had a negative impact on healthcare professionals being open and transparent should they be involved in an untoward event, as well as on their reflective practice, both of which are vital to learning and improving patient care.

Paterson Inquiry—Report of the Independent Inquiry into the Issues raised by Paterson (Feb 2020)[14] The Government commissioned this independent Inquiry to investigate the malpractice of surgeon Ian Paterson.

The inquiry looked at a number of key issues including:

- how and when information is shared between the NHS, independent sector, and others, including concerns raised about performance and patient 4 safety; and

12 Professional Standards Authority, 'Lessons Learned Review: The Nursing and Midwifery Council's handling of concerns about midwives' fitness to practise at the Furness General Hospital May 2018': nmc-lessons-learned-review-may-2018b2851bf761926971a151ff000072e7a6.pdf [accessed 24 January 2024].

13 Williams Review, 'Gross negligence manslaughter in healthcare The report of a rapid policy review' (June 2018): https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/717946/Williams_Report.pdf [accessed 24 January 2024].

14 'Report of the Independent Inquiry into the Issues raised by Paterson' (February 2020): https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/863211/issues-raised-by-paterson-independent-inquiry-report-web-accessible.pdf [accessed 24 January 2024].

- the arrangements for assuring that healthcare professionals maintain appropriate professional standards and competence, including appraisal, revalidation, scope of practice, and the role of hospital providers, professional and quality regulators, and other oversight bodies.

The report recommended that the Government should ensure that the current system of regulation and the collaboration of the regulators serves patient safety as the top priority, given the ineffectiveness of the system identified in this Inquiry.

IMMDSR (Cumberlege) Review—July 2020 First Do No Harm, The report of the Independent Medicines and Medical Devices Safety Review[15] This Review examined how the healthcare system in England responds to reports about harmful side effects from medicines and medical devices and considered how to respond to them more quickly and effectively in the future.

There are approximately 1.5 million people registered to practise in the healthcare professions regulated by statute in the UK. The system we have today is a historical patchwork, periodically mended and amended, with different aspects of the resulting regulatory regime reflecting the particular concerns and constraints of the time they were reformed. As a result there is inconsistency, in both practice and legislation.

While the healthcare regulators are generally effective in protecting the public from serious harm, there has been criticism, not least from the regulators themselves, that the system is slow, expensive, complicated, reactive, overly adversarial and confusing for patients, professionals and employers. This complexity makes it difficult for the regulators to operate as effectively and efficiently as they would wish. It also makes it difficult for patients to know when and how to raise concerns about the care provided by a healthcare professional.

Better and more responsive healthcare professional regulation is a shared ambition for both the regulators and all four UK governments.

DHSC

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15 IMDDS Review: 'First Do No Harm: The report of the Independent Medicines and Medical Devices Safety Review': https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf [accessed 24 January 2024].

APPENDIX 2: INTERESTS AND ATTENDANCE

Committee Members' registered interests may be examined in the online Register of Lords' Interests at https://members.parliament.uk/members/lords/interests/register-of-lords-interests. The Register may also be inspected in the Parliamentary Archives.

For the business taken at the meeting on 23 January 2024 and included in this report, Members declared the following interests:

Draft Anaesthesia Associates and Physician Associates Order 2024

Baroness Randerson

Chancellor of Cardiff University (which has a medical school)

Attendance:

The meeting was attended by Baroness Harris of Richmond, Lord Hunt of Wirral, Lord Hutton of Furness, Baroness Lea of Lymm, Lord de Mauley, Lord Powell of Bayswater, Baroness Randerson, Baroness Ritchie of Downpatrick, Lord Rowlands, Lord Russell of Liverpool and Lord Thomas of Cwmgiedd.