IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
B E T W E E N :-

THE KING (on the application of)
(1) ANAESTHETISTS UNITED LTD
(2) MARION CHESTERTON
(3) BRENDAN CHESTERTON **Claimants**

-and-

THE GENERAL MEDICAL COUNCIL **Defendant**

-and-

(1) THE BRITISH MEDICAL ASSOCIATION[1]
(2) THE ASSOCIATION OF ANAESTHESIA ASSOCIATES[2]
(3) THE FACULTY OF PHYSICIAN ASSOCIATES[3]
(4) THE ROYAL COLLEGE OF ANAESTHETISTS[4]

Interested Parties

CLAIMANTS' SKELETON ARGUMENT

For Hearing listed 13-14 May 2025

References are as follows:

- **Hearing Bundles: [CB/Tab/Item/Page]** or **[SBX/Tab/Item/Page]** where CB is the core hearing bundle and SB is the supplementary hearing bundle and X is the hardcopy volume
- **Pleadings:** Claimants' Statement of Facts and Grounds (**"SFG"**) at **[CB/A/1/5-44];** Defendant's Summary Grounds of Defence (**"SGD"**) at **[CB/A/6/93-109];** Claimants' reply to the Defendants' SGD (**"Reply"**) at **[CB/A/7/110-120];** Defendant's Detailed Grounds of Defence (**"DGD"**) at **[CB/A/9/122-161]**
- **Claimant's Evidence:** First and Second Witness Statement of Richard Marks (**"Marks 1**", **"Marks 2"**) at **[CB/C/15/199-253; CB/C/18/272-320];** First, Second and Third Witness Statements of Marion Chesterton (**"Chesterton 1", "Chesterton 2", "Chesterton 3"**) at **[CB/C/13/171 – 187; [CB/C/19/321 - 329] [CB/F2/34/511-516];** Witness Statement of Roy Pollitt (**"Pollitt"**) at **[CB/C/14/188 - 198]**; Witness Statement of Dr Matthew Kneale (**"Kneale"**) of Doctors Association UK (**"DAUK"**) at **[CB/C/17/257 - 271]**
- **Defendant's Evidence:** First and Second Witness Statement of Professor Colin Melville (**"Melville 1", "Melville 2"**) at **[CB/F/31/389 - 463]; [CB/F/32/464 – 502]**
- **BMA's Evidence:** First and Second Witness Statement of Daniel McAlonan (**"McAlonan 1, McAlonan 2")** at **[CB/E/30/365 - 388]; [CB/F2/33/503 – 510]**.

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[1] The **"BMA"** is the trade union and professional body for doctors in the UK.
[2] The **"AAA"** is the representative body of the AA role in the UK.
[3] The **"FPA"** was the professional membership body for PAs in the UK. Until December 2024 it sat within the Royal College of Physicians (**"RCP"**) which is the leading representative body for physicians in the UK.
[4] The **"RCoA"** is the professional body responsible for anaesthesia in the UK.

INTRODUCTION

1. This claim is about the fundamental failure of the Defendant ("**GMC**") to regulate physician associates ("**PAs**") and anaesthetic associates ("**AAs**") (together, "**associates**") in a manner that protects the public, notwithstanding that being the Defendant's *"over-arching objective"* under ss 1(1A) of the Medical Act 1983 (**"1983 Act"**).

2. There have, so far, been three 'prevention of future deaths' ("**PFD**") reports and one record of inquest issued by coroners following detailed investigations into the tragic deaths of patients treated by associates: see **Annex 1**. Those reports reveal a common and deeply concerning story of deaths arising as a result of PAs acting as *de facto* doctors, without their patients being aware of their status (which is essential to them giving informed consent), without themselves or other members of the healthcare team being able to identify the limits of their competence (which is essential to ensuring safe delegation and supervision), failing to identify obvious red-flag symptoms, consequently misdiagnosing and not properly treating their patients, all whilst failing to identify the need to escalate the cases and without adequate supervision arrangements to prevent tragedies. Of course, only cases that resulted in deaths have resulted in coronial findings and these cases are thus the tip of a very well-documented iceberg.

3. The conclusions drawn by the coroners highlight systemic risks flowing from the deployment of associates. That is because those stark and shocking examples are part of a far broader evidence-base summarised in **Annex 2** that shows that these issues have long existed and have generated safety concerns amongst doctors and other interested parties for many years, concerns that only widen and deepen as the numbers of associates sharply rise. As that Annex explains, those concerns have been expressed vociferously and repeatedly by doctors, other healthcare staff, associates themselves, Royal Colleges and academics as well as coroners. They are also demonstrated in evidence from trusts about how they use associates, pushing the boundaries of what associates do and stretching associate supervision as thinly as they can.

4. It was these very concerns that led to the GMC being chosen as the regulator for associates in 2019 (when the number of working associates was materially lower) and thereafter in 2024 equipped with powers to create a system of regulation which Parliament intended would address the risks in question: see **Annex 3.** Those powers are set out in the Anaesthesia Associates and Physician Associates Order 2024 (**"the 2024 Order**"). Yet, the GMC has <u>not</u> created a system of regulation that addresses these associate-specific risks but rather one which is hollow. The only area in which the GMC has taken material action is in relation to the

standardisation of entry level training for associates. But that does not deal with the problems of post-qualification practice. There, the GMC's action is nugatory. In essence, the GMC's case that it has taken steps that will significantly address the risk posed by associates rests (beyond training harmonisation) in: (1) a general obligation on associates (and on the doctors delegating to or supervising them) to act within their competence (which remains undefined and difficult to ascertain – by both associates and those who work with them); (2) the process of revalidation of doctors (but with no operative standards to judge delegation or supervision of associates) and the prospect of future revalidation of associates (the timing and substance of which has yet to be determined); and (3) a GMC power to take *ex post* disciplinary action against associates or doctors who breaches those obligation (but only when a complaint or referral is made and raises concerns about current fitness to practice of a particular practitioner): see, in particular, Melville 2, at §§§14-16 **[CB/F/32/468-469]**.

5. The GMC's case (which has fundamentally changed between its SGR and DGD) is that it has acted rationally in extending to associates the same broad system of regulation it applies to doctors. In fact, it appears to have taken an undocumented and unattributed decision from the very outset of the process that using its new powers to regulate associates like doctors was the only appropriate way to proceed. Yet doctors and associates are profoundly different: see **Annex 4**. Most fundamentally: associates are dependent practitioners – i.e. they may *only* practise under supervision (although in practice that requirement has been ignored); to qualify, they complete only two years of post-graduate training following a normal undergraduate degree that need not be in a field related to practise or even a science degree (compared to doctors completing a 4 to 5 year medical degree and one year foundation training); and they do not have any formal post-qualification training, whereas most doctors complete another year of foundation training then 3 to 7 years of well-understood and embedded specialty training. Associates do not have the depth and breadth of learning and experience that is part and parcel of becoming a doctor, particularly as regards diagnosis and treatment decision-making, or the well-understood professional support structures and training paths that guide doctors.

6. All of this makes a fundamental difference not only to the actual competence of associates, but crucially to their ability to identify the limits of their competence and the ability of others working with them to do likewise (which is essential for safe delegation and supervision). Thus, the GMC's foundational premise (never consulted upon) – that the system for regulating doctors would be appropriate for regulating associates – was and is fundamentally flawed.

7. Moreover, the GMC now says that it would have taken "*compelling evidence*" to shake it from that starting point and that it discovered none. It is hard to understand why the 3 coroners' reports that predated the introduction of GMC regulation, all of which identified these issues, did not suffice. This is particularly so in the context of the widely expressed concerns: for there was already a plethora of other evidence demonstrating that the peculiar risks posed by associates, flowing in substantial part from the absence of scopes of practice (**"SoPs"**), required a particular regulatory response i.e. evidence from patients, practitioners, Royal Colleges, NHS trusts, academics and the press: see **Annex 2**. That evidence pointed again and again to the need: to safeguard patient safety by setting a ceiling on the practice of associates; to take robust action in relation to delegation and supervision; and to ensure that patients are giving informed consent to treatment by an associate. Yet the GMC appears to have ignored or sidelined all this evidence once the collective, "*corporate*" decision by the GMC (described at length in Melville 2) was taken that it would be inappropriate for it to regulate associates' SoP. This decision has led the GMC to, in effect, neither investigate nor take steps designed to address the public safety risks flowing from the very absence of authoritative guidance and practice on SoP. The result is that nothing of substance has changed and the risks that drove the case for regulation in the first place and that led to the tragedies already discussed continue to escalate unabated.

8. The GMC is thus failing to fulfil its regulatory role on an ongoing basis and this Court should find that that is unlawful.

THE CLAIMANTS' CASE AND THE GMC'S CHANGING RESPONSE TO IT

9. The Claimants challenge multiple ongoing failures by the GMC relating to its regulatory approach as regards associates, in particular, its failures to:

    (1) Produce guidance, policies or otherwise set standards (including, potentially, by adopting guidance or policies produced by others), whether for the doctors delegating to and supervising associates or for the associates themselves which (**Ground 1**):

        (a) set any or any adequate limits on the tasks associates may safely and lawfully undertake in practice post-qualification;

        (b) ensure informed patient consent is obtained to lawfully authorise any treatment provided by associates;

        (c) ensure associates are properly supervised by doctors after proper, considered delegation of tasks to them by an appropriate clinician exercising clinical judgement,

or at least ensure that decisions on delegation and supervision to particular associates are suitable for that associate's skills, clinically grounded, properly recorded and those with medical responsibility for such delegation and supervision identified; and

(d) meaningfully and transparently integrate (a), (b) and (c) above into the fitness to practise ("**FtP**") system proposed for associates which is already in place for doctors

(collectively '**the safe and lawful practise measures**'), thereby failing to act rationally in accordance with the statutory purpose for which it was given powers to regulate in the face of the known risks posed by associates; and

(2) Gather and consider sufficient information to address the question of how it should regulate associates, then lawfully address and answer that question (**Ground 2**).

10. When the claim was filed in October 2024, the 2024 Order had been passed but the GMC's regulatory scheme made pursuant to the Order was not due to enter into force until 13 December 2024 and remained under consultation via the GMC's 2024 consultation "*Regulating anaesthesia associates and physician associates: consultation on our proposed rules, standards and guidance*": Marks 1, §§142-3, 147, and the consultation document at **[SB2/J/69/566 - 1642]**. The GMC sought views on the proposed regulatory scheme, namely:

(1) Draft standards relating to education and training, including curriculum standards;

(2) Draft rules on: (i) regulating education and training (including transitional rules for courses that already existed); (ii) establishing and maintaining a register; (iii) procedures for registration and removal from the register; (iv) rules for FtP proceedings, including revising and appealing decisions; and (v) fees payable to the GMC by associates; and

(3) Draft high-level principles to inform the content of future FtP decision-making guidance (that would also apply to doctors);

but according to Melville 2, §§61 and 75-77 it maintained a deliberate, high-level position <u>of not</u> consulting on other matters including, critically, associates' SoP or whether there should be any other "*limits on the types of work that associates could undertake*".

11. At this time, there also already existed several guidance documents which the GMC relied on as forming part of its regulatory approach, the most notable being:

(1) *Good Medical Practice* ("**GMP**"). This is a high-level ethical code of practice that applies to all medical professionals: Marks 1, §96. In October 2021, the GMC published an interim

GMP that applied only to associates ("**Interim GMP**") **[SB1/G/3/65-95]**. In August 2023, the GMC published a new edition of GMP ("**2023 GMP**") **[SB1/G/5/124-153]** that initially applied to doctors but states in footnote 1 that from 13 December 2024, it also applies to associates (and thus replaced the Interim GMP which never in fact came into effect due to delays in regulation: Melville 2, §103). No version of GMP sets out the safe and lawful practise measures as explained further below.

(2) Three other guidance documents, all of which had been in existence for some time, which did not say anything direct about associates and which were pitched at a very high level (as demonstrated by the relevant excerpts collected on the list of essential reading), providing generic and abstract guidance, namely: (i) *Leadership and Management* (2012) **[SB1/G/1/20-40]**, (ii) *Decision-making and Consent* (November 2020) **[SB1/G/2/41-64]** and (iii) *Delegation and Referral* (published January 2024) **[SB1/G/8/244-254]**: Marks 1, §170.

(3) GMC website guidance on its "*PA and AA regulation hub*" **[SB1/G/14/332-335]**, which also contained high-level advice that did not go beyond GMP aside from some examples: Marks 2, §122.

12. In its SGD of 4 November 2024, the GMC said:

(1) <u>In relation to limits on practise in Ground 1</u>: that (a) it was not a purpose of the 2024 Order to protect the public by imposing 'ceilings' on AAs and PAs ever undertaking particular work (§35); (b) the 2024 Order required only the setting of 'standards', which did not include restrictions on SoP (§37); (c) there was no duty to set such limits and it was "*questionable*" whether the GMC even had the power to do so (§42); (d) the GMC lacked the expertise to set limits (§42); (e) it was rational for the GMC to take the approach of requiring associates not to work outside their competence with a case-by-case *post hoc* assessment of whether they have done so (§43); and (f) it would fetter its discretion always to accept guidance from a Royal College (§43).

(2) <u>In relation to informed consent in Ground 1</u>: that (a) the GMC's *Decision Making and Consent* applied to associates from 13 December 2024 (§46); (b) there is no duty to give guidance on the law on informed consent (§49); and (c) the law does not require patients to be informed that they are being treated by an associate (§51).

(3) <u>In relation to supervision in Ground 1</u>: that (a) this was a complaint about the GMC's regulation of doctors (§54) and (b) it has published guidance to doctors on its website and was under no duty to publish more granular advice (§§55-56).

(4) In relation to Ground 2: that (a) the *Tameside* duty has no application because it only arises where there is a duty to answer a particular question (§59); (b) it was for the GMC to decide what was relevant to its decision as to how to regulate associates (§60); and (c) its approach was reasonable (§60).

13. The Claimants filed a reply to the SGD, permission was granted by Chamberlain J on 13 January 2025 and the GMC filed its DGD on 17 February 2025. By this point, the GMC had published the final results of its 2024 consultation **[SB2/J/73/1659-1897]** and the regulatory scheme had come into effect on 13 December 2024. The key changes since the claim was filed (leaving aside a development of last week: §15 below) are addressed in Marks 2, §§109-125 and are in summary that:

(1) The rules and standards discussed above concerning training and education, the register of associates, FtP procedure and fees are now in force (with no material changes since the consultation drafts).

(2) GMP 2024 now applies to associates. It was amended in December 2024 to add that "*You should introduce yourself to patients and explain your role in their care*" **[SB1/G/18/379]**, and to include a requirement to "*practise under the level of supervision appropriate to your role, knowledge, skills and training, and task you are carrying out*" **[SB1/G/18/363]** (not materially different to the provision in Interim GMP, and making no mention of "named supervisors" or their role): Marks 2, §§116-118.

(3) The documents at §11(2) above were also amended in December 2024 to apply to associates: *Leadership and Management* **[SB1/G/20/412-432]**, *Decision-making and Consent* **[SB1/G/19/385-411]** and *Delegation and Referral* **[SB1/G/21/433-443]** but are otherwise materially unchanged: Marks 2, §121.

(4) The GMC's website was updated in December 2024 **[SB1/G/23/460-463]**, but the advice given is high level (and previous examples given have been omitted): Marks 2, §124.

(5) The GMC has announced an intention to create a system of associate revalidation in the future and to put further guidance on its website: Marks 2, §§112, 125. This is going to apply presumptively five yearly: see pp,8-9 of GMC Leng Review Response **[SB6/M/254/4919]**.

14. The DGD represents a fundamentally changed case from the SGD. The GMC now says that the question of whether it has the power to set limits on associates is "*academic*" because it took a rational and reasoned decision not to do so; and it is not appropriate for the Court to say

otherwise (§102). In particular, it says that its approach was rational because eg.: (1) it is not possible to craft meaningful limits (§§99; 103(4)); setting limits would itself have the potential to cause harm to patients because waiting lists might be longer and because associates might not have experience to act in an emergency (§§4; 100; 103(3)); and the patient safety concerns and issues around delegation/supervision and informed consent have been addressed (§§109-122). None of these reasons were identified in pre-action correspondence or the SGD.

15. Finally, on Thursday 24 April 2025, very shortly before this skeleton was due, the GMC launched an advice page on its "ethical hub", headed "*Supervision of physician associates and anaesthesia associates: Good practice advice for doctors who supervise and work with physician associates and anaesthesia associates*". This document (**"Supervision Practice Advice"**)**[SB1/G/24/464–473]**, which is advice for doctors produced outside the suite of materials consulted upon as part of the changes to GMP (which documents included changes to the general guidance on delegation induced by the GMC's new AA/PA regulatory duties), appears to be the second piece of 'AA/PA Bespoke Guidance', after the entirely generic *PAs and AAs in Practice* document, updated in December 2024 **[SB1/G/23/460-463]** (**"Associates in Practice 2024"**) which it updates or replaces. Given that in multiple respects it is advice directed at and addressed to doctors, the GMC did not need new powers to produce it. Moreover, materials disclosed with Melville 2 (on 22 April 2025) show that the potential need for such guidance was first recognised by the GMC as long ago as 2020 (see §10 of the Council Minutes at **[SB3/M/98/2486-2487]**) but no such guidance was produced, even in the teeth of complaints about the dangers of confused supervision, apparently because such arrangements should be settled locally: Melville 1, §95 **[CB/F/31/426-427]**.

16. The reason for and history of the Supervision Practice Advice is unexplained in Melville 1 or 2. As such, the inference must be that this guidance has been prompted by this challenge, and has been produced in an attempt to head off allegations of irrational regulatory inactivity, an inference also supported (beyond the timing of the Supervision Practice Advice) by: (i) its deployment on the ethical hub (when it is little or nothing to do with ethics) rather than by amendment or adjunct to the GMC's delegation guidance; (ii) its replacement of the Associates in Practice document amended in December 2024; and (ii) the failure to consult upon it as part of either of two consultations conducted on associates (see e.g. Melville 2, §56 **[CB/F/32/482]**).

FACTUAL BACKGROUND

17. Associates first began working in the NHS in very small numbers in 2002-2004, the idea being they would assist doctors in delivering specific aspects of patient care, always under doctor supervision: Marks 1, §§15-17. PAs work in general medicine, including in general practice, and AAs work specifically in anaesthesia. They are, therefore, a very recent profession compared to that of doctor and far less well understood by other healthcare practitioners and the public. They are also a fundamentally different profession: §§5-6 above and **Annex 4**.

18. Initially associates practised in low numbers, but their numbers have steadily increased: in 2023 there were 73 full-time equivalent AAs and 1,500 PAs working in secondary care and 1,700 PAs working in GP and other primary care settings: Marks 1, §17. The total number of associates at the end of 2024 according to the GMC is c. 6,000, a trebling since it was announced the GMC would their regulator in 2019): see the Chart at **[SB4/M/151/3817]**. The current GMC projection (subject now to the Leng Review) is that there be c.16,000 associates (that is a further 10,000) by 2030.

19. For many years now, and even when present in lower numbers, the deployment of associates has given rise to problems and the expression of concern. **Annex 2** sets out the evidence that demonstrates the problems that have been recognised in a wide variety of quarters about serious risks to patient safety: problems caused by the lack of limits on associates' practice, difficulties with delegation and supervision and concerns related to informed consent. **Annex 1** provides the context to the coronial evidence that demonstrates how serious these risks are.

20. Prior to December 2024, associates were not a regulated profession. The drive to regulate associates began with a series of consultations: see **Annex 3**. There were four (2017, 2018, 2021 and 2023) prior to the making of the 2024 Order. These progressed from: (1) a recognition that there were problems which created serious risks to patients and a compelling case for statutory regulation (2017 and 2018); to (2) a decision in 2019 by the DHSC that the GMC would be the chosen regulator; to (3) deciding the contours of the powers that would be given to the GMC (2021) and finally (4) deciding upon the specific drafting of the 2024 Order (2023). Throughout, the consultations recognised that the *status quo* was dangerously wanting and emphasised that regulation must respond proportionately to the degree of risk to patient safety (e.g. **[SB/J/65/1397**). Yet, according to Melville 2, throughout this process and beyond, the GMC consistently assumed that: (a) associates should have the same broad regulatory system and standards as doctors; and (b) it was not appropriate for the GMC to address the lack of SoP.

21. Regardless of the GMC's assumptions, the 2024 Order was intended to confer wide-ranging and effective powers to rectify these shortcomings: §§31-34 below. It permits a range of approaches and required the GMC to decide how to exercise the powers conferred. So, the GMC was expected and required to conduct a broad inquiry into the potential ways of regulating associates and alight upon a regime that rationally responded to the identified risks in a precautionary way. But instead, the evidence filed now shows that the GMC began the process with the fixed idea that it would regulate associates in the way it regulates doctors, only departing from that approach if there were "*compelling reasons*" to do so: DGD, §30; Melville 1, §§57. As part of this process, it reached the settled position (without any form of deliberative process or identifiable decision-making) that it would not address the topic of SoP: see Melville 2, §§53-56 in particular. In effect, the GMC shut its mind from the outset to the possibility of imposing on associates a different type of regulation, tailored to the distinct risks they presented (including the setting of safe and lawful practise measures), and defaulted instead to that imposed upon doctors, despite compelling evidence of the need for the contrary: **Annexes 1 and 2**.

22. This led to a regulatory scheme that effectively mirrors the approach the GMC has long taken to regulating doctors, set out in the documents described at §§10-11 and 13 above, notwithstanding the critical differences between the roles.

23. As for what the GMC's regulatory scheme comprises in substance, <u>in relation to limits</u>:

    (1) <u>First</u>, the GMC requires associates (like doctors) to act within their competence (via such a requirement in GMP): DGD, §§52-55), but in circumstances where there are (by stark contrast to doctors) no professional or other material guiderails for associates, there being no settled SoP and no regulatory requirement to have a bespoke or local SoP agreed. At least until the Supervision Practice Advice, this is a matter about which the GMC expected associates to exercise independent judgement, unassisted by any concrete professional structure or guidance or even advance plan: DGD, §59(3). And yet the risks materialised even when Interim GMP was published, guiding associates to act within their competence: Marks 2, §117. Critically, this approach assumes that associates *can* satisfactorily reach a judgement on such issues.

    (2) <u>Second</u>, decisions about SoP are primarily "*to be decided locally between the associate and their employer*": DGD, §59. The GMC's stance is that variance across the NHS is not itself a risk to patient safety and it is, in any event, a problem for those that oversee trusts: notably, the Secretary of State, NHS England and local Integrated Care Boards, as well

as NHS providers and their regulator, the Care Quality Commission: DGD, §60. Indeed, the GMC's latest position in the Supervision Practice Advice seems to be that, rather than being for associates' judgement or trust employers, SoPs are to be agreed with named supervising doctors: see §62 below.

(3) Third, the requirements of GMP will be backed up by FtP processes, although only in cases of "*serious or persistent breach*": DGD, §56. This will only be where FtP issues cannot be "*addressed locally*", are referred to the GMC and progress through the FtP procedure, which most do not: Marks 2, §38; Melville 2, §15. In deciding upon FtP proceedings, the GMC will take into account guidance given by the Royal Colleges as a factor in determining whether an associate has acted outside their competence: DGD, §58. It will obtain expert evidence if needed: DGD, §59(4). Notably, no mention is made by Professor Melville of the very recent development of the scope of practice to be agreed with the named supervisor, as set out in the Supervision Practice Advice.

24. As for supervision and delegation, there are no associate-specific requirements: DGD, §§62-67. Rather, the GMC considers that it has addressed any concerns via: (1) the generic obligation on all practitioners to practice under an appropriate level of supervision in GMP (which contains no material change to the Interim GMP in this regard: Marks 2, §119); (2) the high-level principles of *Leadership and Management* and *Delegation and Referral*, neither of which specifically address delegation to/supervision of associates (and which have also not materially changed: Marks 2, §121); and (3) the website publication described at §13(4) above which contains no material detail addressing the concerns (Marks 2, §§122-124). There is no recognition that as uncertainty and risk arising from the absence of SoPs and dependent associates' lack of insight into their competence rises, so too must the importance of rigorous controls over delegation and supervision which are bespoke to associates. Again, no mention is made in the DGD of the Supervision Practice Advice or the requirements it contains.

25. As for informed consent, the GMC relies on (1) the requirement in GMP that practitioners "*must be satisfied that they have consent*" (DGD, §69) and (2)) the guidance on *Decision Making and Consent*, while accepting it does not require associates to "*provide information about their level of skills, qualifications or experience as a condition of informed consent*" (DGD, §§70). The GMC asserts that the Claimants are wrong to say that it does not consider patients have a right to know they are being treated by an associate, because GMP states "*You must always be honest about your experience, qualifications, and current role*" (DGD, §71) (which provision was also present in the Interim GMP). But evidently this is not a proactive duty to inform a patient that

the party treating is an associate. The GMC also places emphasis on an amendment made in December 2024 (i.e. after this claim was filed), which added "*You should introduce yourself to patients and explain your role in their care*",[5] as well as information on the GMC's website (DGD, §72). This approach is deeply problematic and does not address the concerns raised: see Marks 2, §116 and §56 below.

26. As for the Royal Colleges, the only SoPs at the point of filing the claim were:

    (1) The RCoA 2016 SoP drawn up for AAs at qualification: Marks 1, §§38-42.

    (2) Royal College of GPs ("**RCGP**") October 2024 SoP for PAs already working in general practice (although its UK Council voted to oppose a role for PAs working in general practice going forwards), which sets out a list of matters within scope and those without: Marks 1, §§166-8; Marks 2, §130.

27. Since the claim was filed:

    (1) The RCoA has published an *Anaesthesia Associate Interim Scope of Practice* in December 2024 to replace the 2016 RCoA publication **[SB1/I/55/860 - 881]**: see Marks 2, §§43, 132. This states that AAs have been practising beyond the 2016 SoP, which has led to concerns about patient safety (p.2). It provides a new SoP for AAs post-qualification in year 1, years 2-4 and year 5 and beyond, each of which identifies included (green) and excluded (red) activities as well as extended roles which can be considered for development (amber), all under defined levels of supervision.

    (2) The RCP has published an *Interim guidance on scope of practice (general internal medicine)* in December 2024 **[SB1/I/54/855 - 859]**: see Marks 2, §131. This sets indicative tasks suitable for PAs and ceilings on practice (e.g. the instruction never to function as a senior decision-maker – p.3).

28. There are 24 Royal Colleges in the UK; the remaining 21 have not issued guidance. Nor have the three SoPs described above been adopted by the GMC into its regulatory regime; rather the GMC has been critical of the granular approach adopted by the Royal Colleges in responding to their consultations (**[SB5/M/226/4410-4418]** (GMC response to RCGP draft); **[SB5/M/235/4470 - 4473]** (GMC response to RCoA consultation). Those criticisms have been voiced despite the GMC's claim that it lacks the expertise to decide on SoPs (Melville 1, §98); a claim also belied by its ability to set detailed training curricula.

[5] N.b. this is misquoted in §111 of the DGD.

29. These recent documents are described as 'interim' because they have been issued pending the findings of the independent review of associates by Professor Gillian Leng CBE ("**Leng Review**") announced by the Secretary of State in January 2025. The Review not relevant to the issue of whether the GMC has acted lawfully (and the GMC does not suggest it is). However, on any sensible view, its existence reaffirms that there are very real/disruptive problems giving rise to increasing concern, although the GMC does not accept this (Melville 2, §35).

LEGAL FRAMEWORK

30. The 1983 Act defines the GMC's statutory purposes, including its s.1(1A) "*over-arching objective*" of "*the protection of the public*", which involves the pursuit of its s.1(1B) objectives "*to protect, promote and maintain the health, safety and well-being of the public.*" The 1983 Act empowers (and sometimes requires) the GMC to produce guidance and policies or otherwise to set standards for doctors, and to enforce those standards: SFG, §§75-85. In particular, s. 35 of the 1983 Act empowers the GMC to advise doctors on standards of professional conduct, professional performance or medical ethics.

31. The 2024 Order is made under s.60(1)(b) of the Health Act 1999 (**"1999 Act"**). Section 60 of the 1999 Act empowers ministers to make Orders in Council to regulate *"health professions"*. It provides *inter alia* for Orders to be made regulating or deregulating professions which require it for the protection of the public (emphasis added):

> "*(1) His Majesty may by Order in Council make provision –*
>
> *…(b) regulating any other profession which appears to Him to be concerned (wholly or partly) with the physical or mental health of individuals and to require regulation in pursuance of this section…*
>
> *(bza) deregulating a profession regulated by an enactment to which subsection (2) applies if the profession does not appear to Him to require regulation for the protection of the public,…"*

32. In brief summary, the 2024 Order works as follows:

    (1) Article 3(1) gives the GMC two new objectives in addition to those imposed by the 1983 Act: to promote and maintain "*public confidence in, and… proper professional standards and conduct for members of, the anaesthesia associate and physician associate professions*".

    (2) Article 3(1) also imposes a duty on the GMC to (emphasis added) determine the "*standards applicable to associates*". *The standards "must relate to…(a) education and training, (b) knowledge and skills, (c) experience and performance, (d) conduct and ethics, (e) proficiency in the English language, and (f) such other matters as the Regulator may prescribe in rules made under paragraph 2(2)(a) of Schedule 4.*" Article 3(2) requires the GMC to consult before

determining a standard. §5(1)(b) of Schedule 3 requires the GMC to publish its standards.

(3) Article 4 permits the GMC to approve education training and qualifications for the purposes of enabling a person to attain the standards determined under Article 3.

(4) Articles 5 and 6 set out requirements for a register of associates (and Article 9 deals with removals from the register).

(5) Article 7 requires the GMC to carry out a periodic assessment as to whether a registrant "*continues to meet the standards determined under article 3(1)*".

(6) Article 8 allows the GMC to impose "*conditions on the practice of such descriptions of associate as may be prescribed in rules [made under powers in Schedule 4]*" eg. provisional or conditional registration for newly qualified associates.

(7) Schedule 3, §5(1)(e) requires the GMC to publish guidance on what amounts to impairment of fitness to practice and §7 then requires it to "*take such steps as it considers necessary for the purpose of assessing whether – standards determined under Article 3(1) are met at any point in time, or a person's fitness to practise as an associate is impaired*".

(8) Articles 10 to 14 deal with questions of fitness to practise, defined in Article 2(2)(a) to include *"impairment by reason of…inability to provide care to a sufficient standard or…misconduct"* and Articles 15 to 17 deal with revisions and appeals arising out of fitness to practise decisions.

33. A clear purpose of the 2024 Order was to require the GMC to create a national system of regulation for associates (and doctors when they interact with the former) to ensure patient safety and public confidence, both at the point of an associate's entry into the profession *and* thereafter. This appears to be largely common ground, in that the GMC accepts that one, if not 'the', purpose of the 2024 Order is "*to protect the public*" (DGD, §88). For completeness, this is supported by:

(1) The consultation materials: see **Annex 3**.

(2) The enabling legislation (see the provisions of the 1999 Act at §31 above), as well as the structure and wording of the 2024 Order itself read as a whole (see the references to "*public confidence*" and "*the interests of those using or needing the services*" in paragraphs 3(1)(a)(i) and 3(1)(b)(2) of Schedule 1 to the Order) and in that context.

(3) The Explanatory Memorandum to the 2024 Order, which refers to "*the need for reform*" (§6.6), associates' delivery of "*specific aspects of patient care*" (§7.20), the existence

(identified in the 2017 Consultation) of *"a level of risk in relation to the practise of associates that warranted the introduction of safeguards provided by statutory regulation"* (§7.26) and that "*Regulation will provide a standardised framework"* (§7.27) and *"maintain patient safety as the two roles expand"* (§7.29).

34. While the 2024 Order was not intended to prescribe precisely how the GMC should achieve the legislative aim of ensuring patient safety, the fact that it was permissive of a range of approaches required the GMC to determine how to exercise the powers conferred. And it required the GMC, in the face of any identified serious systemic risks to patients arising from how associates work, to take regulatory action capable of meeting or mitigating such risk.

35. In light of the way the GMC's case has changed, its acceptance of the purpose of the 2024 Order and its defence that it was not "*appropriate*" to impose limits on associates' SoP (DGD, §4), the focus is no longer on the proper construction of that Order as to the scope of powers conferred. But see SFG, §§106-110; 116(1) and (4) and Reply, §§17-21 for the Claimants' case on this (which it is inferred is now accepted).

36. Notwithstanding this, the GMC continues to rely upon the DHSC's subjective intentions for the 2024 Order to guide to how its powers, once conferred in broad terms, were intended to be exercised (see DGD, §§16-23) ie. to support the notion that associates are to be regulated the way doctors are (DFD, §96). As to this:

    (1) The consultation documents are admissible as to the purpose of statutory interpretation as they inform the context in which Parliament was legislating, help to identify the *Padfield* purpose (*Coughlan v Cabinet Office* [2022] 1 WLR 2389 at §§58-75 and §77) and assist with a purposive interpretation of the scope of the 2024 Order (*R (Project for the Registration of Children as British Citizens/O (A Child)) v SSHD* [2022] 2 WLR 343 at §30, cited in *Coughlan* at §13). But they are not admissible to determine or limit how precisely the DHSC intended the powers in the 2024 Order to be exercised.

    (2) The commentary of the draft of the 2024 Order (DGD, §21; §96) is not admissible at all. Not only is the DHSC not before the court to give evidence (having declined to participate **[CB/A/8/121]**), such evidence is not a useful aid to ascertaining the legislative purpose or assisting with a purposive interpretation: "*what is relevant is the notional intention of the legislature not the intention of those who prepared the Act*", whereas evidence "*relating to the effect that officials or even ministers thought they were producing when preparing a Bill are wholly irrelevant when it comes to determining the legal meaning of the eventual Act*"

(Bennion Bailey and Norbury on Statutory Interpretation (8th Ed.), §24.10, approved in *Re Bowden* [2024] NICA 56, at §§32-33*)*.

(3) Private communications between DHSC and the GMC such as the commentary (see also Melville 1, §§67; 75), also breach the "*overarching principle running through the case law…that material ought not to be admitted as an aid to construction unless it is publicly available*": "*Views expressed by the drafter and others in private while preparing legislation are not admissible as an aid to construction*" (Bennion, §§24.2 and 24.10).

GROUNDS OF CHALLENGE

Ground 1: Irrationality and Abdication/Frustration of the Statutory Purpose

37. As explained, the 2024 Order conferred broad powers on the GMC but did not prescribe the precise manner in which they were to be exercised. However, the GMC was obliged to exercise those powers in accordance with the purpose for which they were conferred (i.e. the *Padfield* purpose), namely to protect patient safety and public confidence by creating a system of regulation that responded in a precautionary and rational way to the risks that were apparent. The GMC's attempt to sideline the *Padfield* principle as irrelevant ignores that if a regulatory scheme (viewed holistically) fails to operate in a way which discharges the underlying statutory purpose for creating the scheme, including because of features such a scheme of regulation lacks, that is an "*important factor*" when assessing the rationality of the choices made by the regulator: see *Johnson v SSWP* [2020] EWCA Civ 778; PTSR 1872 at §§105-107.

38. In reaching its judgement about how to exercise its powers under the 2024 Order rationally, the GMC was required to consider and assess the potential risks to patient safety and to take rational precautions to mitigate or avoid them. This accords with the 'precautionary principle', pursuant to which a public body, faced with a known/suspected serious risk to e.g. public health, takes preventative action to prevent that risk from eventuating by erring on the side of caution, in particular by not relying on uncertainty about the risk eventuating as a reason not to act (see e.g. *R (TransActual CIC) v SSHSC* [2025] PTSR 1 at §§177-180 and *R (Plan B Earth) v Secretary of State for Transport* [2020] EWCA Civ 214 [2020] PTSR 1446 at §§258-261).

39. There is no merit in the GMC's suggestion that the Court cannot properly decide this claim because it involves deciding complex policy issues (e.g. DGD, §§99, 101, 122). First, there was in reality no meaningful polycentric balancing conducted because of the GMC's settled approach as to its appropriate role, adopted by collective assumption as Melville 2 explains (see §§54-80) aligned with its then professed view as to its lack of powers. Second, the

Claimants' case is that the GMC's approach is irrational and wholly fails to secure the underlying statutory purpose given the risks in play, not that it has failed to take the 'best' approach to regulation (cf. DGD, §97; §101). That can be shown, in particular, if a specific risk (e.g. systemic failures in delegation and supervision; systemic confusion of associates with doctors leading to a lack of informed consent) receives no material or additional response (i.e. additional to the standards or rules prevailing when the risk arose). The Court is well able to decide such issues without opining on the 'best' approach: *Re McAleenon* [2024] 3 WLR 803 at §44.

40. There are, then, two overarching points relevant to Ground 1:

    (1) The GMC's approach was fundamentally flawed from the outset because it began from the irrational collective assumption that the same approach should be taken to regulating associates as had been taken to regulating doctors (§§5-7, 17, 21-22 above), i.e. that they presented materially the same form of 'risk profile' (both in risk type and scale). It then failed to depart from this approach even when its own test of "*compelling evidence*" to do so was met. This error then infected every subsequent step and the resulting regulatory scheme.

    (2) The GMC's regulatory model has, in practice, even once the risks have materialised, made no material change to the level of risk to patients posed by associates in the post-regulation world (see §§7; 23-25 above) beyond the possibility of *post hoc* FtP proceedings which is patently insufficient to control the risk, particularly given: (a) the systemic nature of the risks; and (b) the absence of, or the open texture of, the guidance in play. This is so even when the PFDs have identified, as either the source of or insufficient response to systemic risks, the very features of regulation that are continued without material change.[6]

41. The next three sections set out why the GMC could not lawfully conclude that it was not necessary to introduce each of the three facets of the safe and lawful practise measures.

(1)(a) Setting limits on the tasks AAs and PAs may undertake

42. There are limits, or ceilings, beyond which it would never be appropriate for an AA or PA to act instead of a qualified doctor (save in a genuine emergency: see §49(2) below). There is

[6] It also illustrates why it is no answer to say (c.f. Melville 1, §178) that much of the evidence upon which the Claimants rely predates the start of regulation whereas matters will be different going forward, as the GMC regulated the doctors involved at the relevant time.

compelling evidence that without such limits being set by the GMC, patient safety is at risk: see **Annexes 1 and 2** (and **Annex 3**, as the risks of associates acting without such limits was a key feature of the consultations). Unqualified reliance upon NHS Trusts, GP practices and other employers to set limits absent national standards is perverse, as the financial pressures they face was and is a critical source of the risk of associates being expected to act beyond their skills without proper delegation or supervision. So setting meaningful limits on the tasks that associates may undertake was necessary in order rationally to fulfil the statutory purpose.

43. Despite maintaining in passing the suggestion from the SGD that it is "*questionable*" whether it has the power to set limits (DGD, §102), the GMC does not appear seriously to maintain that it could not have done so. Any such reading of the 2024 Order would be without merit because the duty to impose 'standards' on e.g. experience and performance clearly includes a power to impose limits on practise; some of the regulation the GMC has put in place (e.g. registration requirements) operates as *de facto* limits (see SFG, §§116(1) and Reply to SGD, §§20-21).

44. So the focus of the GMC's case is now on why it was rational for it not to include direct limits on associates' practise as part of its regulatory scheme. Its answers, whilst convenient since provided against a backdrop where at the time it viewed itself as having no such powers/appropriate to follow the doctors model, are deeply flawed.

45. The primary and overriding reason the GMC gives is that it does not set limits on the practise of doctors (see e.g. DGD, §§9, 103(1)). That is factually wrong: the GMC <u>does</u> impose limits on doctors, both via the standards it sets in GMP, but even more obviously through provisional registration and restricted specialty registers: Marks 2, §§28-35. Melville 2's supposed answer (at §38) is incomplete: the fact that the limits on doctors are primarily "*ethical*" or detached from SoP does not detract from the fact that standards are set. But, in any event, the supposed answer reveals the lack of rationality in the GMC's approach, because it erroneously conflates two professions which are fundamentally different in aspects highly material to the question of limits: **Annex 4**. Doctors do not need scope controls because their structured training pathways present material different risks: such pathways make it far easier for all concerned to understand their likely competence at any given stage of training, and thus to engage in safe and predictable delegation and supervision, and doctors (through their greater training) are far more aware of their own limits: Marks 2, §§46-47, 49.

46. The GMC suggests that it has rationally responded to the patient safety concerns regarding limits by imposing a requirement on associates to remain within their competence (DGD, §§52-

55, 88, 104). But this does not begin to safeguard patients in the way that ceilings on practise would. The evidence repeatedly demonstrates that associates, given their short and limited training, experience difficulties identifying and remaining within their competence, particularly in the face of employer pressures to work outwith, resulting in patients coming to harm, sometimes with tragic consequences: see the Coronial evidence at **Annex** 1, other evidence at **Annex 2**, and, especially, Marks 2, §§50-54. Throughout this time, it ought to have been obvious to doctors involved in delegation and supervision that they should only delegate those tasks and functions associates are competent to undertake. And yet this has done nothing to prevent the problems and tragedies. Simply continuing the *status quo* – but formalising and extending it to associates - is therefore not a rational nor a precautionary response to the identified risks, particularly once recurring in PFDs.

47. The GMC seeks to bolster its position by relying on further mechanisms it has to ensure compliance with the requirement to remain within competence (DGD, §56), but these do not rationally address the core of the concern:

    (1) The fact that pre-qualification associate training is now regulated does not mean that associates will now be able to stay within the bounds of their competence in a way they were not able to do previously (c.f. DGD, §59(3); Melville 1, §180). It does not alter the extremely limited nature of that training, or deal with the thousands of associates already practising without such training, who are 'grandfathered' into the registration system: Marks 2, §111.

    (2) The fact that the GMC can take FtP proceedings if an associate persistently and seriously breaches the requirement to act within their competence (when the GMC may take into account the guidance from Royal Colleges as to safe SoP (DGD, §§10, 56(2), 58, 89, 104)), does not logically address the issue of whether associates can safely identify *ex ante* the limits of their competence – or, critically, whether the doctors delegating and supervising them can do so. FtP proceedings are, by their nature, likely to be reactionary to harm that has already arisen (a death, an avoidable failure of treatment etc), so relying on this mechanism as addressing the risks is the opposite of taking a precautionary approach. Such proceedings are also unlikely to be much use (for the very reasons Melville 2 explains at §21) in relation to systemic failings made possible by confusion and lack of certainty that cannot be attributed to a single practitioner, particularly absent clear procedures on delegation and supervision. The availability of the FtP powers is even less reassuring given that, to date, there is little or no evidence of action taken against any of the doctors (who have always been in regulatory scope) responsible for delegating to

and supervising associates involved in serious harm or deaths, particularly those that led to the PFDs.

(3) Indeed, the evidence in Melville 2, §§11-29 about the absence of FtP process (even an investigation) even in relation to the stark facts of the PFDs only demonstrates the total inadequacy of FtP processes as a patient safety safeguard in a context where: there is no national SoP; there is no enforceable obligation to have a local SoP; and doctors/PAs are working in a world of confused delegation and supervision where there is no chain of responsibility for key decisions on the appropriateness of PA/AA use and the supervision required therefor. In Emily Chesterton's case this is even when concerns were raised directly with the GMC: Chesterton 3, §17. It is therefore irrational to conclude that a FTP process is a sufficient precautionary response to the identified risks, particularly those in the PFDs, let alone one that justifies the cost of regulation; such liminal action cannot have been Parliament's intent: Marks 2, §183.

(4) The suggestion that there may in the future be a system of associate revalidation does not shore up the lawfulness of the current system and, in any event, cannot be meaningful without a baseline against which an associate's skillset can be measured: Marks 2, §112.

48. Beyond these points, the GMC raises a number of supposed disadvantages to imposing limits on associates' practise. These are addressed in turn, but the overarching point is that it is clear that the GMC did not <u>in fact</u> assess and weigh these supposed downsides against the benefits of imposing ceilings on practise as it never gave proper consideration to the latter (see Ground 2). These considerations appear to be all after the event rationalisations of its failure to act (given that it had earlier concluded either that it had no power, or that associates should as a default be treated like doctors). Absent exceptional circumstances, this is not permissible: *R v Westminster City Council ex p Ermakov* [1996] 2 All ER 302; <u>*R(Lanner PC) v Cornwall DC*</u> [2013] EWCA 1290, at [63]-[64] per Jackson LJ,.

49. The novel suggestion that patient safety might positively be <u>harmed</u> by the imposition of ceilings on the practice of associates (introduced in DGD, §100, not present in SGD or the LBA Response, still less in contemporaneous documents), is without substance: it is proffered to bolster the unmeritorious suggestion that the GMC has made a polycentric policy judgement with which the Court should not interfere (DGD, §§99, 101). The GMC makes two points; both are bad:

(1) The first suggestion is that ceilings might mean patients wait longer for operations or treatment (Melville 1, §99). First, the GMC has presented no evidence or assessment of the supposed effect of limits on waiting lists, which would need to take account of doctors' evidence that associates are in fact increasing their workload via the additional supervision burden. Second, the GMC's point depends on associates being "*so limited in the assistance they can provide*" that they exacerbate the waiting list issues, which depends on how low the ceilings/limits are calibrated. If limits are set sensibly then there is no reason to think they would have that effect: Marks 2, §134. Third, even if the point were evidentially sound, systemic issues with NHS waiting lists could not possibly justify permitting associates to act beyond safe limits, just as they could not justify permitting eg. a doctor with a provisional registration to practice beyond their permitted scope.

(2) The second point is that ceilings may mean that associates have not trained in a given task which they then have to perform in a 'genuine emergency' (DGD, §100). Again, there is no evidence of this occurring in practice, nor any evidence that this is actually a factor that the Defendant took into account. That is not surprising because it is not a good point. What is being envisaged is action being taken under the truly extraordinary 'Good Samaritan' exception that exists to any limitation on a healthcare professional's practise, including to that of eg. provisionally registered or retired doctors. Such an exceptionally unlikely possibility cannot possibly drive a rational approach to systemic risk-based regulation. It is similarly illogical (but telling) that the GMC suggests that an associate who exceptionally carries out a Good Samaritan act to a successful outcome should then be permitted to carry out that activity routinely (DGD, §100).

50. The GMC relies on the fact that other regulators have not adopted SoPs (DGD, §§12-14 and 103(2)) but appears to have made limited inquiries and does not explain whether they regulate analogously dependent practitioners with the same risk-profile: see Marks 2, §101. In any event, the GMC's approach is at odds with approach of the General Dental Council ("**GDC**"), an analogous regulator with similar powers, which has introduced a SoP document for various forms of dental professional which allows for professional development but also includes outer limits on practise for certain categories of practitioner: Marks 1, §37. The GMC seeks to sideline this evidence on the basis that the GDC supposedly regrets its approach and is in the process of changing it (DGD, §§5, 14, 103(3)). But whilst the GDC is consulting on changes, it does not propose to move away from its basic approach: see Marks 2, §§95-100. Melville 2, §§98-102 rationalises the *status quo* on the basis of the PSA's satisfaction with the GDC

interpreting its SoP flexibly. This simply reflects a need to regularly review SoPs so they are kept up to date.

51. The GMC claims that, even if it was appropriate to put limits in place, it is not the body best placed to do so because it does not have the expertise to give guidance about the work associates should or should not undertake (DGD, §38; Melville 1, §98), a submission that sits in uneasy tension with its suggestion it has made an expert, polycentric decision with which the Court should not interfere. That is contradicted by the GMC's own description of its attributes, experience and prowess (Melville 1, §§55-56) and by the facts that: the GMC felt itself fully able to be vocal in its criticism of the interim SoPs issued by the Royal Colleges (see §§27-28 above); was able to prescribe detailed curricula for associate training; and is able to police SoP in FfP proceedings. Relatedly, it says that there are bodies better placed to consider the question of limits, ie. (1) employers, and (2) Royal Colleges (DGD, §§59, 103(4)), 105, 107). Yet, given its express regulatory duty it was not lawful or rational entirely to leave the obvious scope-related safety issues arising to these bodies, particularly when there is no evidence that they had acted to control scope-related risk:

    (1) As for employers, a locally-determined SoP is not a mutually exclusive alternative to national ceilings on practice: see Marks 2, §152. And there is no evidence to show whether and how many employers have even adopted local SoPs, still less committed the resources required to implement them effectively. Further, the evidence categorically demonstrates that employers have not in the past imposed and are not imposing safe limits: see the coronial and other evidence in **Annexes 1 and 2** and Marks 2, §§154-158. The result is that at present NHS employers appear, in fact, to be the *problem*, not the *cure*. That is because they are financially and otherwise motivated (e.g. to reduce waiting lists) to push the boundaries of what associates can do and there is clear evidence that this has already caused serious harm. Most fundamentally there is no evidence of *any* NHS Trust taking action to control associate-related risks once they have manifested (e.g. through altering its delegation practices, local revalidation or competence evaluation etc) still less of a satisfactory pattern of such. The GMC can present no such evidence because it has made no systematic enquiries on this topic. Continuing the *status quo* in this regard is therefore to permit these risks to continue, leaving unaddressed the core statutory purpose. The fact that trusts are overseen in various ways by other bodies is irrelevant: such oversight existed before regulation and is not designed to, and did not, deal with these associate-specific issues: see Marks 2, §§158-160, c.f. DGD, §60. Put shortly,

problems arising from NHS Trust misuse of associates trigger the GMC's regulatory duties.

(2) As for Royal Colleges, most have not issued guidance, and the guidance that has been produced lacks teeth because it is not binding in the way that ceilings set by the GMC would be. Indeed, the evidence demonstrates that, in the past, employers have either ignored or sought to bypass limits on practice imposed by Royal Colleges (*viz.* the RCoA 2016 guidance: see **Annex 2**). And rather than endorse and adopt such guidance, either in specific or broad terms, the GMC has criticised it (without suggesting alternatives), at least until the Supervision Practice Advice, which is the first GMC document to draw upon Royal College SoPs with approval. The GMC also argues that it cannot adopt contradictory Royal College guidance: Melville 1, §155 **[CB/F/31/446]**. This does not explain why it cannot chose not to adopt guidance it disagrees with, or indicate it is adopting particular parties or guidance, or craft its own (as it has done with the Supervision Practice Advice).

(3) Even if such bodies are better placed to set granular rules, in the absence of them doing so the GMC was and is able and should address conspicuous cases of action beyond competence (e.g. unsupervised diagnosis in an emergency medicine context).

52. The GMC suggests that any SoP it produced would not be useful as it would either need to be so high-level and caveated as to be useless, or would be so detailed as to be impractical and risk defensive medicine (Melville 1, §§39-40). But this is belied by the scopes of practice produced by other bodies (*viz.* the GDC and Royal Colleges: see §§26-27 and §50 above) which are not flawed in this way; there is therefore no reason why the GMC could not have produced a similarly useful list of limits: Marks 2, §§129-132, 167. Indeed, the GMC's stance is also contradicted by its earlier position, which was that it would seek to adopt or draw upon SoPs once finalised by Royal Colleges, a stance it would not have taken if those SoPs were not useful: see Marks 2, §128.

53. For the same reason, there is no inherent reason why limits would inhibit the career development of associates (c.f. Melville 1, §97): that all depends on how such limits are calibrated. In any event, associates are not on a pathway to becoming *de facto* doctors. The whole reason for imposing ceilings is to recognise that there are limits to what it is appropriate that they do, in light of the fundamental difference in their selection, training and status and the unique patient safety concerns they generate: Marks 2, §133.

54. The GMC also seeks to suggest that there is no need or space for it to set limits because Parliament has indirectly imposed some limits on what associates may do via a matrix of unconnected piecemeal statutes that restrict certain tasks to particular professions (DGD, §§15, 80, 95, 98, 102). Not only is there no evidence that this was actually considered by the GMC as a reason not to set ceilings (again, the argument smacks of after the event legal rationalisation), it ignores that legislation and regulation have different roles to play: the existence of legislative limits in a given space (here, limits that relate largely to specific or extreme situations) does not constrain a regulator from setting further tighter general limits when charged with regulating that space notwithstanding those limits: Marks 2, §§27, 36. Indeed, that is the whole point in the conferral of discretionary powers. Parliament empowered the GMC to use its judgement to regulate associates because it identified a regulatory gap notwithstanding these enactments. Just as they do not exhaustively describe the boundaries of what doctors can and cannot do, it is nonsensical to suggest that they represent the exclusive means by which the activities of associates might be restrained or that they exhaustively regulate the issue of ceilings on practice within the space given to the GMC by the 2024 Order.

1(b) Failure to publish policies or guidance which ensures informed patient consent is obtained to lawfully authorise any treatment by AAs and PAs

55. Giving informed consent to treatment by an associate is not just a technical legal requirement; it is of profound practical importance to patients, not least because it affects their autonomy and judgement about whether or not to ask for a second opinion. The case of Emily Chesterton demonstrates particularly starkly how important this is because, had she and her family known she had never seen a doctor, they would have insisted that she did: Chesterton 1, §25. The coronial evidence and PFDs demonstrate the consistent and serious concern that patients are not able to give proper consent to being treated by an associate; either because they are not even aware that the person in question is an associate at all, or because they do not know what that role means: **Annex 1**.

56. The GMC's precise position on informed consent is difficult to pin down. What is clear is that it does not consider it to be a condition of such consent that the patient must be expressly told that they are being treated by an associate rather than a doctor (DGD, §§70, 112-119). The GMC seeks to disguise this by saying informed consent does not require patients to know the "*qualifications*", "*skills*" or *level of experience*" of the person treating them. But what this really means is that patients do not need to be told that the treating party is not a doctor.

57. The GMC seeks to derive support for its position from *Montgomery v Lanarkshire Health Board* [2015] AC 1430, where it was held that doctors are under a duty to take reasonable care to ensure that patients are aware of any material risks involved in recommended treatment. The GMC relies on this case as the court did not suggest that practitioners must inform patients of their qualifications or experience (DGD, §116). However, properly read *Montgomery* in fact assists the Claimants:

(1) The test of materiality is "*whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it*" (Montgomery at §87). Those considerations apply equally when the risk arises from the fact that the patient is being treated by an associate (who is far more lightly trained, and requires supervision, which they may not be getting) rather than a doctor.

(2) The GMC says it is not <u>always</u> material because treatment by an associate is not <u>necessarily</u> more risky, and materiality of risk depends on context (DGD, §§117-8).

(3) The Claimants agree, to a point: Marks 2, §145. What matters is that patients must not be misled, actively or passively, into believing they have seen a doctor. The key, therefore, is whether, in any particular context, the patient would reasonably expect the practitioner in question to be a doctor. This is context-specific, considering factors such as the setting and the task to be undertaken. E.g.:

(a) A patient would not have a reasonable expectation that certain minor matters, e.g. those routinely performed by nurses, would be performed by a doctor, especially if they are performed in a clinic where many different categories of healthcare staff practise. Examples include giving injections, vaccinations, taking notes, performing a PAP smear, performing other minor tests such as dipping urine, drawing blood, placing a cannula and triage: Marks 2, §145.

(b) But when an associate decides to and/or undertakes a task that the patient would reasonably expect to be ordinarily determined and/or undertaken by a doctor, especially where the setting contributes to the impression, then informed consent does require it to be made clear to them that the practitioner is not a doctor. Key examples are (i) inherently high-risk procedures such as administrating anaesthesia or performing surgery, and (ii) diagnosis, in both primary and secondary care settings, especially in an emergency care context. A patient like Emily Chesterton, seeing her GP with alarming symptoms, is clearly likely to believe that the clinician

in their 'GP appointment' is a doctor unless told otherwise. So too a person like Pamela Marking, diagnosed, treated and discharged from A&E by one practitioner.

(4) Any reasonable patient in such circumstances would think it material to know that they have seen an associate, rather than a doctor, in particular given the relevance of that to the question of whether to seek a second opinion or follow-up care and from e.g. if the medication given does not work or causes unexpected side effects; and in particular in the context of multiple visits.

(5) It is, accordingly, entirely irrelevant that doctors are not required to inform patients of their qualifications or experience. There is a type difference between the two professions, so no equivalent danger of mistaken identity (doctors are not mistaken for doctors). The public are also far more familiar with doctors as a profession and the differing levels of seniority and experience and types of specialism within that profession.

(6) The GMC is wrong to suggest that the Claimants' arguments go against *R(A) v SSHD* [2021] UKSC 37 (DGD, §113). The Claimants are not saying that the GMC is under a duty to provide a comprehensive statement of the law, as found in a textbook or court judgement. They are simply saying that the GMC must ensure that its regulatory regime protects patients from being misled into believing they have seen a doctor when they have not. The GMC's contrary approach does not therefore represent a rational or precautionary response to the evidence with which it was faced, which demonstrated that confusion was repeatedly occurring and so would reoccur in the future, absent intervention, with further consequences for patient safety.

58. At the same time as denying that informed consent is an issue at all, the GMC seeks to side-step concerns about it by relying on its amendment to GMP in December 2024, (which, as explained at §13(2) above, added in "*You should introduce yourself to patients and explain your role in their care*"). The GMC claims that this highly ambiguous or vague change responds to the Claimants' assertion (as characterised by the GMC) that "*the GMC does not consider that patients have a right to know that they are being treated by an associate*", which it says (confusingly, given the above) is not its position (DGD, §71). Professor Melville also says that the concerns raised by the Claimants that patients such as Emily Chesterton and Susan Pollitt believed they were being treated by a doctor are "*squarely addressed*" by the (post-claim) change to GMP (Melville 1, §196). Yet examination of the amendment shows this is not the case:

(1) First, the new wording does not require associates to do anything, but instead advises that they should introduce themselves. It is telling that the new wording is misquoted in

the DGD, which state (at §111, underlining in original) "*AAs and PAs must 'introduce [themselves]…*" etc. (cf. the actual "*should*"). This lack of precision on the part of the GMC is concerning, particularly when the same paragraph mentions the possibility of disciplinary action vs. associates for breach of this standard.

(2) In any event, what does it mean to "*introduce yourself to patients and explain your role in their care*"? GMP does not require that associates state their job title, let alone explain that the title means that they are not a doctor. The GMC tacitly recognises this because it says the amendment "*puts…beyond doubt*" only the fact that "*associates are required to explain their role to patients*" (DGD, §71), and not that patients must know they are not being treated by a doctor when they might reasonably assume otherwise. Indeed, the recommendation to "*introduce yourself*" could be met by giving your name, while you could "*explain your role in [the patient's] care*" by explaining the task you are going to perform (e.g. "I am going to treat you in A&E today", "I am responsible for your anaesthesia today"): Marks 2, §§142. This change does not therefore meet the concerns expressed in the evidence (see **Annexes 1 and 2**), or mean that the wrongful assumptions made by patients in the cases highlighted could not happen again. In fact, even if the amendment was interpreted as meaning associates should tell the patient their job title, i.e. that they are a PA or AA, that in itself is highly unlikely to be sufficient to ensure that the patient understands that they are not seeing a doctor. There is an inherent confusion in the title, which is liable to mislead patients unless clearly explained: **Annexes 1 and 2** and Marks 2, §§143.

(3) The GMC could easily have inserted a requirement that, where a patient would reasonably expect that the practitioner in question is a doctor, associates must clearly explain that they are not a doctor but work under the supervision of one. This is what is suggested by other bodies eg. the FPA: Marks 1, §113, but the GMC has chosen not to require this in its scheme.

(4) The GMC also relies on the guidance it has issued in the form of *Decision Making and Consent* and its webpage *More information on PAs and AAs* **[SB5/M/164/3881-3893]**. But the guidance remains at such a high level, without specific references to either associates or the particular consent issues to which their role gives rise, that it adds nothing meaningful to the requirements. The same is true of the webpage **[SB5/M/164/3881-3888]**, which simply repeats the GMP requirement that associates must clearly communicate who they are and "*welcomes*" the FPA guidance without formally adopting it (which anyway applies only to PAs, not AAs).

1(c) Failure to publish policies or guidance which ensure AAs and PAs are properly supervised

59. There is abundant evidence that there is a serious problem in relation to delegation and supervision which poses serious risks to patient safety: in particular, doctors have repeatedly told the GMC that they are unable safely to delegate to, and determine safe supervision levels for, associates because they cannot easily determine their competence (see **Annex 2**), and the result of that has been multiple unnecessary deaths (see **Annex 1**). Such problems are thus intimately linked to the absence of a SoP. This puts associates in a fundamentally different position to doctors, whose capabilities are relatively easier to benchmark (e.g. 'is this a task that it would ordinarily be appropriate to expect an F2 to undertake?'), as the GMC itself in effect admits in other contexts: see, e.g. in the context of revalidation, the Executive Board Paper of 18 December 2022 **[SB4/M/139/3566]** which states:

> *PAs and Aas are trained to work under the supervision of doctors, to a greater or lesser extent, and therefore adequate supervision is an essential element of safe practice, especially for newly qualified professionals. In addition to the assurances in the previous paragraph, we therefore propose to seek confirmation that a PA or AA is working within a locally agreed framework of clinical governance that includes a requirement for supervision appropriate to their role and experience. This proposal was supported by 96% of respondents to our survey. Further explanation of what is meant by appropriate supervision will be included in guidance.*

60. Faced with this serious risk, the GMC's decision, at least until the last-minute production of the Supervision Practice Advice, to make no material change to its supervision requirements upon regulating associates is irrational. As set out at §13(3) and §24 above, the amendment to GMP changed nothing from the Interim GMP, and the other generic guidance in place relating to delegation and supervision for doctors (*Leadership and Management* and *Delegation and Referral* **[SB1/G/20/412–432; SB1/G/21/433-443]**) long pre-dated the GMC's regulation of associates and were thus clearly inadequate. These documents are so vague as to be meaningless in substance (c.f. DGD, §§62-67) and do not grapple with the problems posed by delegating to and supervising associates. They contrast starkly with the strict guidance on supervision that can be seen in the Royal College guidance e.g. the guiding principles on AA clinical supervision and the 3 defined levels of supervision (direct, close and local), in the RCoA's *Anaesthesia Associate Interim Scope of Practice*, with all roles/activities to take place under one of those levels of supervision. The fundamental problem with them is that they rely on the supervising doctor being able to identify an associate's competence, which is, as already explained, extremely difficult, particularly given the realities of NHS working patterns which mean that doctors may frequently need to delegate to an associate they have never worked with before under significant time pressure: Marks 2, §§40, 138. The supervising doctor may

not even be in the hospital where the associate is working; the depth of training and experience of doctors also means that they are inherently better able to identify for themselves when they require senior input, whereas the evidence is that associates are less likely to be able to do so: **Annex 2**.

61. Until last week's production of the Supervision Practice Advice the GMC's stated concluded view was that issues of safe delegation and supervision were best addressed "*locally*", i.e. by employers, (Melville 1, §§95, 167, 192). This is untenable for the same reasons as it was in relation to safe limits on practice: see §51(1) above. It again confuses the problem with the cure.

62. It is worth noting that this issue relates just as sharply to the GMC's regulation of doctors, as they are the ones delegating and supervising. Thus, any concerns about the scope of the 2024 Order (unmeritorious as they are) do not arise. It also bears repeating that the GMC has not provided any evidence to suggest that it has *ever* subjected a doctor to FtP proceedings for inappropriate delegation to, or inadequate supervision of, an associate in breach of guidance. The First Claimant identified just one such case, that of Dr Stephen Zaw, where importantly, the case was determined on the basis of another doctor's expert evidence, *not* by reference to the breach of extant delegation and supervision guidance: Marks 2, §39. The Supervision Practice Advice appears designed to attempt to plug this gap, by providing clearer guidance to doctors and introducing (through advice rather than guidance) the idea of a "named supervising doctor", a term that first began to surface in GMC external/internal publications in November/December 2024 (after proceedings) and the idea that the SoP for a particular associate would be set by that named supervising doctor in consultation with the associate. But unless this is embedded in local policies and processes, of which there is no evidence, these new requirements (which shift all the burden on scope to individual doctors) are likely to be unworkable for those actually supervising. How this last-minute change is all to work, and why this solution was alighted upon (without consultation) is all unaddressed by Melville.

63. Finally, even if no detailed substantive guidance was required to be given by the GMC in relation to delegation and supervision, the GMC has never addressed why it was rational not to introduce, at the very least, process-based guidance that required clear *documenting* of the clinical judgements that sit behind decisions to delegate and supervisory arrangements. None of the GMC's objections would apply to, for example, a requirement that the doctor (now the "named supervising doctor") should identify the relevant delegation/supervision policy being applied and document their decision to delegate, including what task they delegated, to whom, at what level of supervision and why, in their clinical judgement, this was appropriate

and adequately resourced/workable (and the corollary judgements from associates). Decisions to delegate cannot and should not be made solely by NHS managers, as these are professional judgements. Such a requirement would assuage at least some of the concerns raised in the evidence: e.g. it would operate as a safeguard against associates being delegated to generically, such as when they are simply substituted for doctors on the rota (see e.g. the PFD report concerning Pamela Marking: **Annex 1**).

Ground 2: Insufficient Inquiry

64. The *Tameside* duty requires a decision-maker to take reasonable steps to acquaint itself with the relevant information to enable it to answer the question which it has to answer: *R (Campaign Against Arms Trade) v SSIT* [2019] 1 WLR 5765 ("***CAAT***") at §58 citing *SSES v Tameside Metropolitan Borough Council* [1977] AC 1014, 1065. The duty is a branch of the principles pertaining to rational exercise of discretionary powers, and a close adjunct to the rational control of relevant/irrelevant considerations. Rational use of such powers requires first that sufficient factual enquiries are made as to the topics relevant to the purpose of the power in the context of the problem in hand. Thus, in *R (Plantagenet Alliance) v SSfJ* [2014] EWHC 1662 (Admin), the Divisional Court summarised the authorities (at §§99-100) and formulated the point as follows "*Could a rational decision-maker, in this statutory context, take this decision without considering these particular facts or factors?*" (at §139). It is clear from that case and others (including *Tameside* itself (p.1064G - 1065B) and *R (Law Society) v Lord Chancellor* [2024] 1 WLR 3097, §§208, 210) that the duty does not require the question to be answered to have any express statutory footing. As a result the GMC is wrong to suggest that the *Tameside* duty did not apply (DGD, §125) because there was no question to be answered; it is a misreading of *CAAT* to suggest that the *Tameside* duty only arises where the question is set out in legislation.

65. But, in any event, the enactment of the 2024 Order clearly gave rise to a question which the GMC had to answer about the use of its discretionary regulatory powers i.e. what regulatory approach was it going to adopt to address the various risks posed by associates in order to safeguard public safety (and would this include the safe and lawful practise measures)? That was and is the central question facing the GMC when it first assumed the regulatory powers conferred by the Order. As explained above, the 2024 Order did not prescribe the approach to be taken by the GMC; it was intended that the GMC would make appropriate inquiries to establish how it should exercise the powers that had been conferred. But central in that statutory landscape, for any rational regulator, was the topic of the risk posed by associates and the source or nature of that risk, and the GMC had to undertake sufficient enquiries on

such topics. In any event, the GMC appears to recognise (DGD, §128) that there was a question for it inherent in the 2024 Order, namely "*what standards should be set for AAs and PAs*"? That question is a direct function of the risks presented by AAs and PAs without those standards.

66. Yet the GMC did not make the inquiries on the topics of risks and their source, as reasonably required to inform its exercise of the powers conferred by the 2024 Order. As explained above (see, especially, Marks 2, §§57-108), the GMC began the exercise by taking a flawed decision in principle that it ought to replicate for associates its regulatory approach to doctors. This error of approach tainted everything thereafter, because the GMC viewed such evidence as it gathered through the lens of that strongly-held belief, rather than identifying and investigating the risks associates posed or might pose because of their differences from doctors. The exercise it conducted does not therefore satisfy the *Tameside* duty.

67. Particular examples of the GMC's unreasonable approach to its inquiries include:

    (1) Failing to make adequate focused inquiries into the serious problems and harm to which the existing system had given rise and, on the contrary, assuming that the longstanding nature of the problems supported essentially continuing the *status quo*: Marks 2, §61. Rather than explore the differences between associates and doctors, and investigating the particular patient risks posed thereby, the GMC started from the premise that they could be regulated just like doctors, such that nothing further needed to be done.

    (2) Failing to investigate the risks posed by the absence of any or any consistent employer approach to associates' SoP (e.g. how is safe delegation possible when little is known about the skills of a particular associate and there is no training path against which to benchmark them?). Instead of considering the risks posed by the absence of such a SoP, the GMC decided that fixing such an SoP was not for it and so did not consider the systemic risks posed by its absence or whether there was anything it could do to mitigate or control such risks. Its internal decision-making documents are striking: "*[S]cope of practice or other matters… intersect with our role but are not for us to lead*": Melville 2, §75.

    (3) Failing to gather adequate evidence about the risks posed by the differential approaches being taken by NHS Trusts and other employers in order: (a) to understand whether, how and why they were creating a problem of associates acting beyond competence (as the PFD Reports indicated); and (b) to inform any conclusion as to whether such employers could be trusted, absent further regulation from the GMC, to empower delegating and supervising doctors to set safe limits on associate practise. The matter is worse than a bare failure to make inquiries: the GMC apparently ignored evidence that

could easily have been obtained about trusts pushing the boundaries of safe practise, such as was obtained by the Claimants: **Annex 2**, Marks 1, §§46-60 and Marks 2, §64.

(4) Even after receipt of the PFDs (the two PFD reports and one record of inquest which existed at the time and raised serious concerns: **Annex 1)**, failing to gather and consider further information on serious harm, including deaths, caused by the lack of safeguards. Such failure of investigation is particularly striking in the context of informed consent. For instance, notwithstanding the common fact pattern, the GMC did no research into whether or not patients were confused or had any expectation in certain clinical contexts that they were being treated by a doctor.

(5) Viewing its 'Community of Interest' survey results as supportive of its approach, when they should have raised a red flag as to the need to consider taking a different approach, in particular by considering introducing the safe and lawful practise measures; then claiming to have addressed relevant concerns when in reality they were ignored or dismissed: Marks 2, §§59, 67-87, 126-147, c.f. DGD, §38.

(6) Dismissing concerns raised in workshops, other meetings and responses to consultations, rather than further investigating them, where they did not suit the GMC's settled approach, and/or claiming to have addressed the problems raised when in fact they had not eg. concerns raised (i) at the March 2020 interactive forum (Marks 2, §65); (ii) in the External Advisory Group (Marks 2, §§88-90) (despite the GMC having brought its settled approach to that meeting and then claiming that no dissent was expressed: DGD, §35; Melville 1, §109), (iii) in the survey of key stakeholders before the GMP review (Marks 2, §103), (iv) in the 2022 consultation on the draft revised GMP (Marks 2, §104), and (v) in the responses to the 2024 consultation (Marks 2, §§105-106, c.f. DGD, §§47-50).

68. Accordingly, the limited nature of inquiries made by the GMC prior to deciding upon its regulatory model was irrational.

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