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# Professional, legal and ethical dimensions of prescribing. Part 2: legal and ethical

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## Abstract

Prescribing by nurses and midwives continues to expand and has consistently been evaluated as safe and effective. This article is part one of two exploring the core professional, legal and ethical dimensions of prescribing. Reference is made to a contemporary prescribing model, RAPID-CASE, devised by the authors to demonstrate the application of key prescribing practice principles. The importance of a structured approach is demonstrated with reference to the Royal Pharmaceutical Society competency framework for all prescribers, applicable legislation and underpinning ethical principles. This first article identifies the main professional dimensions of prescribing practice, while the second article focuses on the legal and ethical aspects.

## Keywords

Clinical, Duty of care, Ethical issues, Ethical practice, Legal issues, Medicines, Mental capacity act, Nurse prescribing, Prescribing, Prescription medicines, Professional

The prescribing practice of a range of healthcare practitioners has developed over the years through a series of amendments to medicines law. These amendments have resulted in an incremental expansion of prescribing rights and, by implication, the scope for which the practitioner owes a duty of care. Spanning the professional, legal and ethical dimensions of prescribing, duty of care is integral to professional standards and is a recognised legal concept that underpins common ethical principles (Beauchamp and Childress 2013, Griffith 2019). There is potential for overlap or conflict among these areas, for example there may be an ethical imperative to treat the person, but questions may arise about whether the situation is within the prescriber's current scope of practice. Being able to justify or explain decisions as part of a duty of care is supported through application of a prescribing model such as RAPID-CASE, which was devised by the authors and was presented in part one (Gould and Bain 2022a, 2022b).

This second article examines selected legal and ethical dimensions of prescribing decision-making to prompt consideration of these when nurses are faced with practical challenges. Critical consideration of the professional, legal and ethical dimensions of prescribing is highly pertinent when the scope of practice boundaries are uncertain or variable, such as during the coronavirus disease 2019 (COVID-19) pandemic.

## Legal dimensions

The Nursing and Midwifery Council (NMC), the General Pharmaceutical Council and the Health and Care Professions Council (HCPC) each hold the legal authority to admit qualified practitioners to their registers, annotate their records with additional qualifications and suspend or remove registrants, as well as set the educational standards for identified qualifications. To prescribe professionally involves being responsible for and understanding the ethical and legal implications of prescribing, while acting within legal and regulatory frameworks that affect prescribing practice (Royal Pharmaceutical Society (RPS) 2021). Practising professionally includes an awareness of laws underpinning prescribing, such as the legal authority to prescribe, mechanisms for prescription writing, controlled drug laws, off-label versus unlicensed medicines, supplementary prescribing, consent, capacity and the legal duty of care (NMC 2018, General Medical Council (GMC) 2021, HCPC 2021, RPS 2021).

Medicines law has been endorsed across numerous acts of parliament, European Union (EU) legislation and secondary legislation. It is useful for nurses to understand key reference points underpinning the legal authority to prescribe, the limits to that legal authority and the mechanisms by which prescriptions can be issued or medicines supplied. The four UK countries do not have the same legislation, due to devolved legislatures, although laws for England and Wales tend to be similar, while there are some marked differences for Scotland and Northern Ireland. Part of a prescriber's duty is to be aware of pertinent legislation and any updates to this for their respective countries. Table 1 shows the three main sources of law in the UK.

Table 1. Three main sources of law in the UK		
Legislation	Judicial decisions	Human rights laws and European Union (EU) law
<ul style="list-style-type: none"> <li>» Primary: acts of parliament (statute law)</li> <li>» Secondary: statutory instruments</li> </ul>	<ul style="list-style-type: none"> <li>» 'Common law': outcomes from court cases become common or case law and set the standard for how the law is applied</li> <li>» Decisions made in a higher court overrule lower courts</li> <li>» The hierarchy of courts is:               <ul style="list-style-type: none"> <li>– Lower courts (for example, crown or magistrates' court)</li> <li>– High Court</li> <li>– Court of Appeal</li> <li>– UK Supreme Court</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>» Embedded in UK law through acts of parliament</li> <li>» Human rights laws: incorporated through the Human Rights Act 1998</li> <li>» EU law: incorporated through the European Communities Act 1972. Since 31 December 2020, EU legislation is part of UK domestic legislation. Some types of EU legislation are directly applicable as law in an EU member state and are published on legislation.gov.uk as 'legislation originating from the EU'</li> </ul>

(Griffith and Tengnah 2020, legislation.gov.uk 2022)

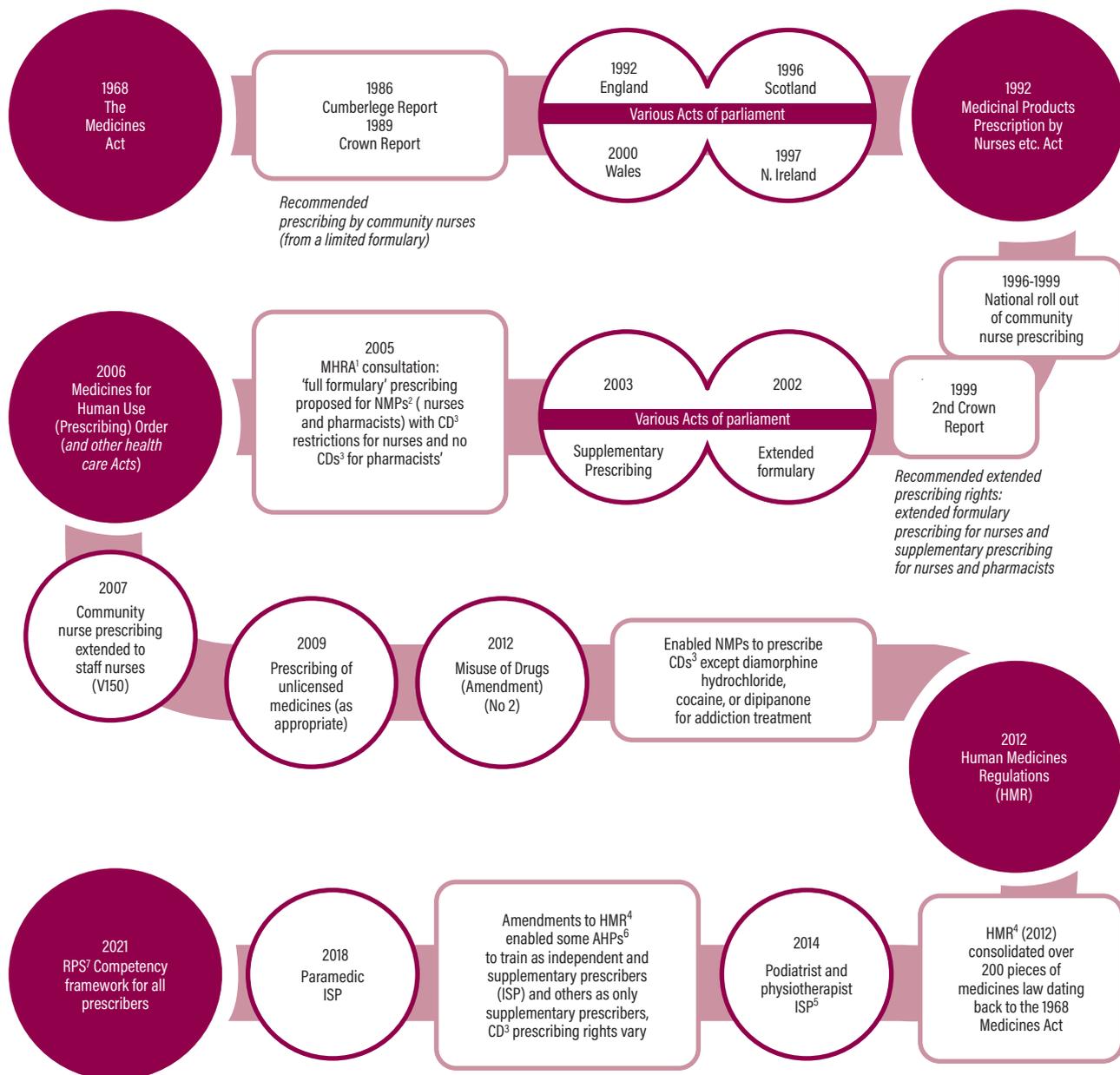
The main sources of legislation underpinning prescribing derive from acts of parliament (statute law) and secondary legislation (for example statutory instruments), along with EU law. Regulations are not laws but they affect what can legally be prescribed or sold.

Laws aim to safeguard the public; for example the Medicines Act 1968 was prompted by the off-label use of thalidomide. This 1968 act, which covered prescribing by doctors and dentists, has not entirely been repealed but most of its content has been replaced or superseded. For example, it was amended by the Medicinal Products: Prescription by Nurses etc. Act 1992 in response to reports by Baroness Julia Cumberlege (Department of Health (DH) and Social Security 1986) and June Crown (DH 1989) that proposed nurse prescribing would improve the efficiency and quality of community nursing care. While this amendment only allowed prescribing by health visitors or district nurses from a limited formulary for nurse prescribers, it was well- evaluated and paved the way for a series of extensions to prescribing rights.

Community practitioner nurse or midwife prescribers (denoted by the NMC as V100 or V150) continue to be limited to a specific number and type of products from the Nurse Prescribers' Formulary for Community Practitioners, as well as being subject to other restrictions such as the strength of certain products; they are also generally unable to prescribe 'off-licence' and unlicensed medicines (National Institute for Health and Care Excellence (NICE) and Nurse Prescribers' Advisory Group 2022, Pharmaceutical Services Negotiating Committee 2022).

A timeline of key prescribing legislation is shown in Figure 1.

Figure 1. A timeline of key prescribing legislation



<sup>1</sup>Medicines and Healthcare products Regulatory Agency <sup>2</sup>Non-medical prescribers <sup>3</sup>Controlled drugs

<sup>4</sup>Human Medicines Regulations <sup>5</sup>Independent and supplementary prescriber <sup>6</sup>Allied health professionals <sup>7</sup>Royal Pharmaceutical Society

(Adapted from Gould and Bain 2022c)

The second Crown Report (DH 1999) led to the establishment of 'extended formulary prescribing' (The Prescription Only Medicines (Human Use) Amendment Order 2002), ten years after the initial 1992 legislation. This was quickly followed by 'dependent' or supplementary prescribing (The National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc.) (England) Regulations 2003). A national consultation by the Medicines and Healthcare products Regulatory Agency (MHRA) resulted in much wider prescribing rights for nurse and pharmacist prescribers through The Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2006 (MHRA 2005a, 2005b). While that legislation opened most of the British National Formulary (BNF) (Joint Formulary Committee 2022) to nurses and pharmacists who undertook a recognised educational programme, there were still tight restrictions on controlled drugs. The Human Medicines Regulations 2012 consolidated more than 200 separate pieces of law, orders, regulations, statutory instruments or EU directives that had built up over the years, including those concerning prescribing by healthcare professionals other than medics (Griffith 2012).

Prescribing also concerns legislation for controlled substances (Misuse of Drugs Act 1971 and The Misuse of Drugs Regulations 2001), with amendments in 2012 for nurses and pharmacists, and at later dates for allied health professionals. Working within their scope of practice, nurses, midwives (denoted by the NMC as V300) and pharmacists can legally prescribe any item from the BNF, apart from three specific controlled drugs for treating addiction (NICE 2022). Allied health professionals have further differences in terms of restrictions on controlled drugs and only some HCPC registrants can train to prescribe (HCPC 2021). For nurses, knowing what prescribers can legally prescribe is necessary, while familiarity with common controlled drugs is useful (Home Office 2019). These drugs are listed by class in the Misuse of Drugs Act 1971 or a schedule in The Misuse of Drugs Regulations 2001.

## **Duty of care**

Safety is linked to professional practice but is also implicated in fulfilling the prescriber's legal duty of care. In the legal context, this refers to the obligation to act in a person's best interests, to ensure no act or omission results in harm, to act safely within areas of competence and to provide advice about the risks and benefits of treatment (Griffith 2018, 2019). Meeting this standard involves a comprehensive assessment and consideration of evidence-based treatment options. Clinical negligence occurs when the duty of care is breached causing physical or mental harm. It needs to be proved that the care or treatment was below the expected standard and that harm resulted from this. An example would be in leg ulcer care where a Doppler assessment was performed inaccurately and failed to detect arterial disease, resulting in compression damage leading to amputation. In cases where harm has occurred, a claim of negligence through civil or tort law could be brought by the person who was harmed (or their family) to compensate for the harm. Court rulings have established that successful negligence cases require three key features (Griffith 2019):

- » A duty of care was owed by the practitioner to the patient.
- » This duty of care was breached.
- » This breach of the duty of care caused loss or harm recognised by the courts.

The seminal legal case determining judgements about whether a breach of duty occurred was *Bolam v Friern Hospital Management Committee* [1957], often referred to as the 'Bolam test'. This ruling suggested that the professional is not negligent if their actions are aligned with the accepted practice of their peers. While the Bolam test was the benchmark for many years, it was seen to extend beyond its intended limits and risk subjectivity. The *Bolitho* ruling (*Bolitho v City and Hackney Health Authority* [1997]) suggested a need for a logical basis underpinning the standard of care and is now more likely to be used (Samanta et al 2003). The implication of this change for professionals and prescribers is the ability to show clear reasoning for decision-making in healthcare. This reflects a greater emphasis on evidence-based care, guidelines and support for informed decision-making. Using a prescribing model such as RAPID-CASE can guide the justification and rationale for decisions (Gould and Bain 2022a, 2022b).

A less-discussed allegation in the Bolam case was the failure of the doctor to inform Mr Bolam of the risks of the procedure. The UK Supreme Court ruling in *Montgomery v Lanarkshire Health Board* [2015] addressed duty of care in relation to the disclosure of information about the risks of treatment or alternatives.

Interpreting the Montgomery decision's practical significance, Chan et al (2017) stated 'the Montgomery decision redefined the standard for informed consent and disclosure'. The ruling reiterated the person's right to make their own decisions while asserting that professionals must provide information about 'the material risks inherent in the treatment' (*Montgomery v Lanarkshire Health Board* [2015]).

Clinical judgement is implied in determining which risks are material, for example if the person being prescribed for would consider the risk significant, or whether communicating the risk could be detrimental.

Key information needs to be communicated in a sensitive and understandable way, but this may be challenging with more complex conditions or management regimens, particularly where they span a range of specialisms. The Montgomery decision has strengthened the policy commitment to a person-centred approach, while the RPS (2021) competency framework unambiguously includes shared decision-making and providing information as core competencies for prescribers.

## **Consent**

While the key aim in assessing and managing care is to facilitate informed choice, NICE (2019) identified barriers including: professionals' belief that they already practise in this way, a lack of decision aids, the belief that people do not want to be involved in decisions about their care, and time or priority pressures. Practical influences on informed choice include communication barriers, the person's capacity and understanding of the health issue. Consent for assessment, treatment, advice or for using a person's information is required (GMC 2020).

Clinically, consent increases the likelihood of confidence in and cooperation with the treatment. Legally, without consent a practitioner can be charged with 'ill-treatment', 'assault' or 'trespass to the person' (Griffith and Tengnah 2011). Valid consent needs to be full, free and informed (Griffith and Tengnah 2011). These requirements imply that the person being treated comprehends the information being provided.

Having the mental capacity to consent means demonstrating an understanding of information given and using it to support decisions (Department for Constitutional Affairs (DCA) 2007). Although someone may be assessed as having mental capacity, it is not unusual to prescribe treatments for people whose health declines, who have fluctuating mental capacity or who may not fully understand the treatment. Duty of care extends beyond the prescription, so when capacity is compromised it is important to consider harm that may occur. Examples include people with chronic obstructive pulmonary disease who are prescribed anticipatory medicines to take when their condition deteriorates and there is a risk that their oxygen levels can cause them confusion; or people with deteriorating infections developing sepsis or delirium.

In cases where people are unable to give or express consent, legal frameworks in the UK enable practitioners to act and make decisions on their behalf (Mental Capacity Act 2005, Mental Capacity Act (Northern Ireland) 2016, Adults with Incapacity (Scotland) Act 2000). As these acts vary between the four countries of the UK, it is important for the nurse to access associated guidelines or codes that explain how they are applied in practice. In England and Wales, the Mental Capacity Act 2005 code of practice (DCA 2007) aims to ensure that decisions taken on behalf of someone who lacks capacity are made in their best interests. In practice this can be challenging because although there is an assumption of mental capacity, assessment can be affected by communication issues such as hearing loss or language barriers, or there may be undiagnosed or fluctuating dementia. Even where mental capacity is compromised, appropriate support must be given to facilitate people in making their own decisions or to optimise their involvement in decision-making processes (DCA 2007).

Fulfilling the legal duty of care involves being aware of risks, making justifiable decisions and recording these coherently. There may also be ethical aspects, such as the balance between paternalism with an overly authoritative approach, weighed against the risks of promoting autonomy (the ability to make one's own decisions) where people may be vulnerable.

## **Ethical dimensions**

Ethics or 'moral philosophy' involves considering fundamental questions about what is right and wrong. For healthcare professionals this includes their moral code and the need to be aware of their value system, as it can consciously or unconsciously influence their decisions. Östman et al (2019) described ethics as universal rules of conduct that guide actions, intentions and motives. Familiarity with professional and ethical principles supports practitioners to examine decisions and unpick the complex challenges of clinical practice. When making clinical decisions, moral analysis can be prompted by confusion about competing alternatives for action, or when healthcare professionals' values and those of the family are in conflict about what is in the best interests of the patient, or in dilemmas where none of the alternatives are fully adequate.

## Four principles of biomedical ethics

Beauchamp and Childress (2013) identified four core principles of biomedical ethics of pertinence to healthcare settings:

- » Beneficence (providing benefit).
- » Non-maleficence (avoiding harm).
- » Respect for autonomy (respecting decision-making).
- » Justice (fair distribution of risks and benefits).

Beneficence or providing benefit entails doing 'good' for patients and is fundamental to practice and integral to professional codes. While it appears straightforward it can become complicated when balancing benefits and risks, or when considering whose perception of good is given more credence. For example, it may be clear to community nurses that the significant benefits of compression bandaging outweigh the risks of discomfort or harm for patients, and in terms of evidence-based practice compression bandaging is considered the 'gold standard' (NICE 2021a). However, for the person in receipt of compression therapy, the discomfort may eclipse the benefits, particularly when it is impeding other aspects of their life. Beneficence can involve considering others' views, alongside the risks, benefits, costs and varying perspectives of diagnosis or treatment options.

While the principle of non-maleficence may seem to be the same as beneficence, it is more specifically about avoiding or minimizing the risk of harm. Following this principle means the person receiving care does not experience injury caused by the treatment, although it is recognised that most medicines involve potential for harm, even if minimal. For example, vaccinations hold potential for anaphylaxis, leading to death, but the risk of this occurring is quantitatively negligible.

Where people are apprised of the risks of treatment this should be balanced with an explanation of the risks of no treatment. For example, prescribing an antibiotic for a suspected infected laceration should show benefit in reducing pain, redness, swelling and exudate as well as preventing sepsis, but it risks allergic reaction or microbial resistance (NICE 2017, 2021b). Conversely, not treating with antibiotics may lead to wound deterioration, damage to surrounding skin and potential cellulitis leading to sepsis (NICE 2021b, 2021c).

The key principle of non-maleficence is that the harm is not disproportionate to the benefits of treatment. Because some harm is unpredictable, previous experience may influence clinical decision-making and perception of risk. If a prescriber has witnessed a significant adverse effect, this could influence their choice of treatment in the future. For example, the prescriber may have witnessed a relatively young woman experiencing a life-changing stroke as a side effect of the combined oral contraceptive (Joint Formulary Committee 2022), which might influence their subsequent contraception advice. With the example of compression bandaging, most nurses using this treatment will have seen the damage to skin and tissues caused by uncontrolled exudate levels, making it challenging to agree with the person's decision to decline this therapy.

As a prescriber it is also important to note that harm can be caused by error (Elliott et al 2018), side effects or interactions. With more than 50% of older people having two or more long-term conditions (Kingston et al 2018), prescribing is rarely undertaken in isolation.

The Hippocratic Oath places the philosophy of 'do no harm' above all else (Smith 2005). Similarly, Nightingale (1863) suggested do no harm should be the first requirement of a hospital, and research by Page (2012) found non-maleficence to be unambiguously the most important ethical principle to practitioners. However, in law a person's autonomy is seen as paramount (British Medical Association 2020) and Gillon (2003) suggested that autonomy 'trumps' all other principles. NICE (2019) stated that there is an ethical imperative for shared decision-making, based on the fundamental moral principles of respecting the person's autonomy. Promoting autonomy means respecting decision-making for people assessed as having mental capacity and enabling individuals as far as possible to make reasoned and informed choices.

However, conflict between non-maleficence and autonomy can pose a moral dilemma for practitioners, particularly when it involves choices likely to be harmful. A stark example is when someone assessed as having mental capacity refuses a potentially life-saving intervention, such as mechanical ventilation, or requests a potentially life-ending intervention, for example withdrawing a feeding tube. Varkey (2021) identified this type of conflict between the principles of beneficence (or non-maleficence) and autonomy to be highly significant and that in such cases clear communication is imperative. Autonomy requires active listening and providing the opportunity for the person to have views and choices heard and considered. Autonomy can be partial, for example if a person has been legally deemed as not having the mental capacity for certain treatment decisions (DCA 2007). From an ethical perspective, people lacking capacity should be regarded as central to decision-making, with their views respected as far as possible (Griffith and Tegnah 2012, NICE 2018).

## Deontology versus utilitarianism

A prescriber also needs to consider deontology (doing one's duty) versus utilitarianism (doing the greatest good for the greatest number). Deontology is based on rights and duty and involves 'doing the right thing' without regard to whether the end consequences are good or bad ('the means justify the ends') (Mandal et al 2016). Conversely, utilitarianism is 'ends based' and involves the practitioner acting without regard to whether the way they achieve a 'good thing' is right or wrong ('the ends justify the means').

A practical example of how these contrasting theories can be applied to prescribing is when considering the principles underpinning NICE guidance (NICE 2014). When developing guidelines, best practice is considered alongside an economic analysis to show the cost-

effectiveness of treatments (NICE 2014). This could be seen as utilitarian, because the purpose is to fairly distribute resources and enable the greatest number of people to be treated (Marseille and Kahn 2019). However, such a method of developing guidelines can come into conflict with duty-based care when a particular treatment is not approved by NICE or a local formulary, but represents the best treatment for the individual patient to whom the prescriber owes a duty of care. In this scenario, part of the prescriber's duty to individual patients involves advocating on their behalf to change the guidelines and formularies as appropriate. This links to the 'cost-effective' consideration in the RAPID-CASE prescribing model (Gould and Bain 2022a, 2022b), where part of this advocacy may involve collecting data to provide evidence of a potential cost benefit.

## Conclusion

As practice demand for safe and effective prescribers grows, it is important for prescribing healthcare professionals to continually update and critically reflect on legal and ethical dimensions of prescribing decision-making. The use of professional frameworks and prescribing models can support prescribing practice. Critical consideration of the professional, legal and ethical dimensions of prescribing is especially relevant when scope of practice boundaries are uncertain or variable, such as during the COVID-19 pandemic.

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