

LAW AND POLICY IN MEDICINE

Distinguishing legal duties, NHS policy, clinical judgment and commercial influence

An evidence-led framework for safe patient-clinician decision making, policy verification and non-destructive escalation

Research question

When a treatment, referral or investigation is restricted, how can a patient and clinician determine whether the restriction arises from law, clinical evidence, professional competence, NICE guidance, NHS commissioning, local policy, funding or administrative custom - and what lawful route remains when those layers conflict?

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Referencing: ISO 690:2021 author-date for documentary sources; standard neutral citations for UK cases and conventional citations for legislation.

Purpose, scope and evidential discipline

This paper is a research and decision-support document. It is not a substitute for individual legal advice or clinical assessment. It does not conclude that an NHS body, clinician, private provider or regulator has acted unlawfully or for improper financial reasons in any individual case. Its purpose is to create a reproducible method for testing those questions against primary law, case law, professional standards, NHS policy and evidence.

The paper arose from a practical patient-safety problem: a patient may be offered treatment that they consider harmful or unacceptable, may identify an alternative they wish to have assessed, and may encounter a refusal expressed simply as “the NHS does not allow that”. That phrase can conceal several very different propositions. The restriction may be statutory, clinical, professional, contractual, financial, local-policy based, or merely customary. Each category has a different legal effect and a different route of challenge or resolution.

The framework therefore treats the patient and clinician as potential collaborators rather than adversaries. The patient does not acquire a general legal right to compel a prescription. The clinician does not acquire immunity from individual professional judgment merely because an organisational policy exists. The goal is to identify the controlling rule, preserve safe clinical judgment, document reasons, recognise patient autonomy, and use independent verification before escalating to complaints or regulatory proceedings.

Executive findings

- **Law and policy must be separated.** Acts, regulations and binding case law differ from GMC professional standards, NICE guidance, commissioning rules, formularies and local administrative policy. A local policy cannot create a statutory prohibition simply by being described as “the rules”.
- **Patient autonomy is strong but not unlimited.** A competent patient may accept or refuse treatment and must receive information needed for informed decision making. However, the patient cannot ordinarily require a clinician to provide a treatment that the clinician reasonably concludes is not a clinically reasonable option. Montgomery [2015] UKSC 11 and McCulloch [2023] UKSC 26 together illustrate this balance.
- **Clinical inability and pathway inability are different.** A GP may properly conclude that a medicine requires specialist initiation or lies outside primary-care competence. That should not automatically end the pathway. PHSO Summary 695 found fault where a GP practice correctly declined specialist-only prescribing but failed to discuss the issue early, refer promptly and maintain continuity while specialist assessment was arranged.
- **NHS funding policies are reviewable.** NHS bodies may ration resources, but the policy and its application must be lawful and rational. In R (Rogers) v Swindon NHS PCT [2006] EWCA Civ 392, the Court of Appeal quashed an irrational Herceptin policy. Condliff demonstrates the counterpoint: not every refusal of requested NHS funding is unlawful.
- **Previous harm and patient knowledge matter.** Medication safety requires attention to prior adverse effects, monitoring, interactions and what the patient says has happened before. PHSO case studies document harm or increased risk where medication history, monitoring or patient warnings were inadequately handled.
- **Policy barriers can displace care.** NHS England’s 2019 review of cannabis-based medicines documented barriers, private prescribing and substantial financial burden reported by some families. A 2024 cross-sectional study estimated substantial illicit cannabis self-treatment of diagnosed conditions. These sources support investigation of displacement risk, but do not by themselves prove that NHS policy caused any individual person to use illicit or private markets.
- **Verification should precede accusation.** The preferred route is clinical review, structured medication review/pharmacist input, a second clinical opinion or specialist referral, and targeted verification from

bodies such as GMC, NICE or MHRA. Complaints and regulators should be reserved for evidence that actually warrants them.

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1. The problem: when policy is spoken as though it were law

Healthcare decisions are made inside several overlapping systems. Parliament and delegated legislation create legal powers and restrictions. Courts interpret those powers. Professional regulators set duties for registered clinicians. NICE evaluates evidence and cost effectiveness. NHS commissioners decide what services to fund. Trusts and GP practices create formularies, protocols and administrative pathways. Each layer can affect a patient, but they are not legally interchangeable.

A statement such as “we are not allowed to do that” is therefore incomplete until the source of the restriction is identified. For patient safety, the decision should be classified rather than merely accepted or contested.

Decision category	What it means	Typical next question
Clinical	The clinician considers the option unsafe, ineffective or not clinically appropriate for this patient.	What evidence, contraindication or risk-benefit reasoning supports that conclusion?
Competence	The clinician cannot safely initiate/manage the option.	Who is competent to assess it, and is referral/shared care appropriate?
Statutory/legal	Legislation or controlled-drug/medicines law constrains the action.	Which section/regulation applies, and what alternative lawful route exists?
NICE	National evidence/guidance or technology-appraisal requirements affect care.	Is this clinical guidance, a technology appraisal with funding consequences, or another NICE instrument?
Commissioning/funding	The NHS does not routinely commission/fund the intervention in this setting.	Is there an IFR/exception process, and what reasons must be given?
Local policy/formulary	An ICB, trust or practice limits use locally.	What is the policy, version, authority, exception clause and review route?
Administrative/custom	A pathway or customary practice has become treated as a rule.	Is there any binding source at all? Who has authority to reconsider it?

Core rule of the framework

Never infer “illegal” from “not routinely provided”. Never infer “clinically appropriate” from “lawfully possible”. The legal question and the clinical question must be answered separately.

2. The legal and professional hierarchy

The hierarchy below is a practical classification tool, not a claim that every instrument lower in the table is automatically overridden by everything above it. Different instruments regulate different subjects. The purpose is to identify the source and legal effect before deciding how conflicts should be resolved.

Layer	Examples	Legal/practical significance
Primary/secondary law	NHS Act 2006; Equality Act 2010; Human Medicines Regulations 2012; Misuse of Drugs legislation; Health and Social Care Act 2008 regulations.	Binding law. Policy must operate within statutory powers and duties.

Layer	Examples	Legal/practical significance
Case law	Montgomery; McCulloch; Rogers; Tracey; Condliff; Bolitho.	Interprets legal duties and limits. Binding effect depends on court/jurisdiction.
Professional regulation	GMC Good medical practice; Decision making and consent; prescribing; conflicts; raising concerns.	Regulates registered doctors. “Must” ordinarily denotes a legal/ethical duty expected to be met or justified.
National NHS/NICE framework	NHS Constitution; Standing Rules; NICE guidelines/appraisals; NHS England commissioning policies.	Can create enforceable rights or important duties in some settings, while other guidance remains advisory to clinical judgment.
Local commissioning/formulary	ICB policies, IFR criteria, trust medicines policies, shared-care protocols.	May validly organise/ration services, but must be within powers, rational, procedurally fair and compatible with higher duties.
Practice procedure/custom	Appointment rules, preferred referral route, local workflow.	Lowest evidential status unless anchored to a higher authority. Must not be misrepresented as law.

2.1 Patient-centred statutory standards

For regulated providers in England, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 provide a statutory floor. Regulation 9 requires person-centred care that is appropriate, meets needs and reflects preferences, with the person involved in decisions. Regulation 11 addresses consent. Regulation 12 requires safe care, risk assessment, mitigation, competent staff and safe medicines management. These duties do not create an entitlement to any requested medicine, but they constrain how care decisions are made and implemented (UK, 2014).

The Equality Act 2010 adds a separate duty to make reasonable adjustments where a provision, criterion or practice places a disabled person at substantial disadvantage. A “standard pathway” is not immune from adjustment simply because it is standard (UK, 2010).

2.2 Professional duties remain personal

GMC standards require doctors to make patient care their first concern, work within competence, communicate effectively, support informed decisions, prescribe safely, and act where patient safety or dignity is seriously compromised. GMC guidance expressly covers situations in which organisational systems, policies or procedures may be placing patients at risk; professional duties are not extinguished simply because an organisation has a policy (GMC, 2024/2026).

3. Patient-clinician decision rights and responsibilities

3.1 What the patient can require

- An opportunity to participate meaningfully in decisions about their care and to say what outcomes, risks and burdens matter to them.
- Information about the proposed option and reasonable alternatives, including material risks relevant to that person.
- The opportunity to refuse a proposed treatment if they have capacity, even where the clinician considers the refusal unwise.

- An explanation where a requested option is considered clinically inappropriate, and consideration of alternatives including a second opinion.
- Accurate recording of relevant adverse reactions, medication history and the reasoning behind major treatment decisions.
- Reasonable adjustments where disability creates substantial disadvantage in accessing or communicating about care.
- Reasons and appropriate routes of reconsideration where commissioning/funding decisions are made under applicable NHS rules.

3.2 What the patient cannot generally require

- A clinician to provide a treatment the clinician reasonably concludes is not a clinically reasonable option.
- A GP to practise outside their competence or to initiate a medicine that legislation or a specialist-prescribing rule reserves to another practitioner.
- An NHS commissioner to fund every treatment that is medically possible. Resource allocation remains lawful where the policy itself and the decision are lawful.
- A regulator such as the GMC to order a particular prescription or award compensation.

3.3 The combined Montgomery-McCulloch position

Montgomery v Lanarkshire Health Board [2015] UKSC 11 replaced a paternalistic approach to disclosure with a patient-centred duty to take reasonable care to ensure the patient is aware of material risks of recommended treatment and reasonable alternatives. McCulloch v Forth Valley Health Board [2023] UKSC 26 later clarified an important boundary: clinicians are not required to discuss every imaginable alternative. Whether an alternative is clinically reasonable is determined through professional judgment that can be supported by a responsible body of medical opinion. Read together, the cases support informed choice between reasonable clinical options, not a patient right to compel any preferred intervention.

Practical patient formulation

“I am not asking you to prescribe this simply because I prefer it. I am asking you to assess whether it is a clinically reasonable alternative in my circumstances, explain the comparative risks and benefits, and tell me whether any barrier is clinical, legal, competence-based, commissioning-based or local policy.”

4. Testing NHS policy against law

A patient or clinician questioning a policy should not begin by declaring it unlawful. The stronger method is to reconstruct the decision chain and test each link.

1. Obtain the exact policy title, issuing body, version and effective date.
2. Identify the statutory or contractual authority under which it was made.
3. Determine whether the wording is mandatory (“must”), presumptive (“normally”), advisory (“should/consider”), or simply descriptive.
4. Identify any exception, individual funding, appeal, second-opinion or specialist-referral route.
5. Check whether national guidance or statutory directions require the policy-maker to have regard to particular evidence.
6. Test compatibility with patient-centred care, consent, equality/reasonable-adjustment and safety duties.
7. Ask whether the individual facts were considered or the policy was applied mechanically.
8. Check whether reasons were given and relevant factors were considered while irrelevant factors were excluded.
9. Compare the treatment of materially similar patients and the rationale for distinctions.

10. If necessary, obtain independent clinical and legal advice before formal challenge.

4.1 Rogers: a policy can itself be unlawful

In *R (Rogers) v Swindon NHS Primary Care Trust* [2006] EWCA Civ 392, the PCT declined to fund Herceptin for early-stage HER2-positive breast cancer under an exceptionality policy. The Court of Appeal held the policy irrational because, after the PCT had decided not to rely on cost, it could not rationally identify clinical or personal circumstances distinguishing one eligible patient from another. The policy and decision were quashed. Crucially, the court did not itself order the treatment: it required the PCT to formulate and apply a lawful policy. Rogers therefore demonstrates both the power and the limit of judicial review.

4.2 Condliff: not every restrictive policy is unlawful

R (Condliff) v North Staffordshire PCT concerned refusal of an individual funding request for bariatric surgery. The litigation illustrates that NHS bodies may lawfully adopt resource-allocation criteria and that courts do not ordinarily substitute their own view of which treatment should be funded. The proper question is whether the public body acted within its powers and public-law duties, not whether a court or patient would have preferred a different allocation. This is an essential counterweight to Rogers.

4.3 Guidance is neither nothing nor always binding

Rogers itself distinguishes statutory directions from guidance and refers to earlier authority requiring relevant Secretary of State guidance to be properly taken into account. For the present framework, the key operational point is that “guidance” should not automatically be described as law, but it also cannot necessarily be ignored. The legal effect depends on the source, statutory framework and wording.

5. Treatment access when the first clinician cannot or will not provide it

A refusal should be converted into a route decision. The critical distinction is between “this treatment is inappropriate” and “I am not the appropriate person to initiate it”.

First response	What it may mean	Safe next step
“I cannot prescribe this.”	Specialist-only initiation, competence limit, controlled-drug rule, shared-care restriction.	Identify the competent specialist/service and referral criteria.
“It is not on our formulary.”	Local funding/formulary restriction.	Obtain policy; check exception/IFR and alternative formulary options.
“NICE says no.”	Could be a guideline recommendation, technology appraisal or overstatement.	Identify exact NICE document, population, indication and strength/type of recommendation.
“There is not enough evidence.”	Clinical evidence concern.	Ask which evidence threshold is being applied and whether specialist/research route exists.
“The NHS does not fund it.”	Commissioning decision rather than necessarily a clinical contraindication.	Ask for commissioning authority, exception route and whether private availability changes continuity/shared-care issues.
“I do not think it is safe for you.”	Individual clinical judgment.	Request explanation of specific risks, reasonable alternatives, monitoring and second opinion if disagreement persists.

5.1 PHSO case study: specialist medication was correctly outside primary care, but the pathway still failed

PHSO Summary 695 is unusually close to the problem this toolkit is designed to solve. A new GP practice correctly decided that the patient's specialist painkiller should not be prescribed in primary care. PHSO nevertheless found fault because the practice did not have an early discussion with the patient, did not promptly refer her for specialist assessment, and did not maintain continuity in the interim. The patient was left in pain and uncertainty. The lesson is not that a GP must prescribe outside competence; it is that “not mine to initiate” should not become “no route exists” (PHSO, 2014a).

6. Medication safety and prevention of repeat harm

The framework is intended to prevent a recurring patient-safety failure: an adverse or intolerable previous medicine experience is not accurately carried forward into later prescribing decisions. A safe process distinguishes allergy, adverse drug reaction, intolerance, contraindication, interaction, lack of efficacy and patient refusal. Those labels are not interchangeable.

6.1 Minimum medication safety loop

1. Confirm the indication and the intended outcome.
2. Review current medicines, previous trials and documented adverse effects.
3. Check interactions, contraindications, dose and monitoring requirements.
4. Explain material benefits and harms and reasonable alternatives.
5. Record what the patient says happened previously and what they are/are not willing to accept.
6. Agree monitoring, stopping criteria and a review date.
7. Where a serious suspected adverse reaction exists, consider/report through the MHRA Yellow Card system as appropriate.

6.2 Structured Medication Review as a non-adversarial tool

NHS England describes a Structured Medication Review (SMR) as an evidence-based, comprehensive review in which the clinician and patient work as equal partners to understand medicines, balance benefits and risks, and consider alternatives. This is particularly well suited to a patient who is not simply “refusing medication” but is trying to avoid repeating a harmful or unacceptable treatment experience (NHS England, n.d.-a).

6.3 PHSO case studies: listening and monitoring

In the PHSO case “Expert patient's requests for medication ignored”, a patient with a history of blood clots repeatedly raised concern about her anticoagulant medication. Communication failures and failure to respond to those requests increased her risk; she was later readmitted with blood clots. The Ombudsman highlighted the importance of listening to a knowledgeable patient and maintaining medication continuity (PHSO, 2011).

In PHSO Summary 669, a GP practice diagnosed lupus without sufficient indicators, prescribed medication requiring regular monitoring, failed to review it for 18 months and delayed specialist referral. PHSO found failures in diagnosis, medication management, records and referral; the practice later audited its medication policy and the GP undertook further learning (PHSO, 2014b). These are not binding precedents, but they provide practical examples of how medication-safety duties can fail even without malicious intent.

7. Private provision, corporate structure and conflicts of interest

Private participation in NHS care is not itself evidence of wrongdoing. The NHS has always included independent contractors in primary care, and legislation permits NHS commissioners to contract with non-NHS providers. The research question is narrower: when a patient cannot access a treatment through an NHS

pathway but can access related care privately, are the clinical, legal, commissioning and financial reasons transparent, and are conflicts of interest properly managed?

7.1 GMC conflict-of-interest safeguards

GMC conflict-of-interest standards require clinicians to prioritise patient care, disclose relevant interests, avoid exploiting patients' vulnerability, and not influence provider choice for improper financial benefit. Where a clinician stands to benefit financially, the rationale and available alternatives should be transparent. These standards provide a testable framework: the existence of private provision is not the problem; undisclosed or distorting financial influence would be.

7.2 Questions for a corporate/financial audit

- Who owns and controls the private provider, and what relevant NHS contracts does it hold?
- Who made the NHS commissioning decision and what conflicts were declared?
- Does the clinician, practice, trust or related body receive any financial or non-financial benefit from the referral route?
- Was a clinically reasonable NHS alternative or exception mechanism available and explained?
- What patient data is transferred, under what controller/processor relationship, lawful basis and confidentiality authority?
- Does the provider's advertising accurately distinguish licensed indications, off-label use, unlicensed products and NHS availability?

8. Care displacement: private, self-treatment and illicit-market exposure

Where substantial symptoms remain unresolved and acceptable treatment is unavailable, a patient may migrate to another route. This paper calls that phenomenon "care displacement". It is a risk model, not an assumption of causation.

Route after unmet need	Potential benefit	Principal risks
Regulated NHS alternative	Clinical oversight, continuity, regulated supply.	May remain unavailable or delayed.
Regulated private treatment	Lawful access and clinical oversight.	Cost, fragmented records/shared care, commercial incentives and inequality of access.
Self-treatment with lawful consumer products	Immediate patient control.	No clinical oversight, interactions, uncertain efficacy, delayed diagnosis.
Unregulated online/illicit supply	Accessibility where other routes fail.	Unknown composition/potency, contaminants/counterfeits, legal risk, no monitoring.
No treatment	Avoids medicine adverse effects.	Continuing pain/distress, functional loss, delayed diagnosis and loss of trust.

8.1 NHS England cannabis review: private burden and reported barriers

NHS England's 2019 review examined barriers to clinically appropriate prescribing of cannabis-based products for medicinal use after the 2018 legal rescheduling. It included case reviews, patient/family meetings, clinician interviews and commissioning surveys. The review recorded concerns about evidence, clinician confidence, commissioning and cost. Some families reported obtaining private prescriptions after NHS delay or uncertainty, with substantial and sometimes unsustainable financial burden. Patients/carers also reported frustration about

what they perceived as rigid application of guidance and inadequate explanation. These are reported experiences, not findings that clinicians acted unlawfully (NHS England, 2019).

8.2 Population evidence of self-treatment

Erridge, Troup and Sodergren (2024) surveyed 10,965 UK adults and modelled that approximately 1.77 million adults were using illicit cannabis to manage diagnosed health conditions, with chronic pain associated with increased likelihood of such use. The authors identify potential barriers to legal access and call for harm-reduction approaches because illicit products may contain contaminants and self-treatment occurs without clinical oversight. The study is cross-sectional and cannot establish that NHS policy caused illicit use. Its findings should therefore be used as evidence of the scale of a displacement-risk population, not proof of institutional causation. One author listed an affiliation with Curaleaf Clinic; the paper should be read alongside independent public-sector evidence rather than used alone.

Causation rule

“NHS refusal → private/illicit treatment” must not be asserted as a causal fact without individual evidence. The paper instead asks whether displacement was foreseeable, whether safer routes were considered, what information was given, and whether the actual later pathway can be evidenced.

9. Worked medicine examples: cannabis-based medicinal products and ketamine

These examples demonstrate the framework. They are not recommendations for any individual patient and do not imply that either medicine is clinically appropriate in a particular case.

9.1 Cannabis-based medicinal products (CBPMs)

Certain cannabis-based products for medicinal use were rescheduled from 1 November 2018, creating a lawful prescribing route subject to controlled-drug, medicines and specialist-prescribing requirements. NHS England states that unlicensed CBPMs generally require specialist-register involvement for initiation/direction; a GP may in some circumstances continue prescribing under appropriate specialist arrangements. This legal possibility is distinct from routine NHS commissioning and from NICE recommendations for particular indications (NHS England, 2026a).

NICE NG144 recommends against several cannabis products for chronic pain and limits CBD for that purpose to clinical trials, while giving different recommendations for certain other conditions. Therefore “medical cannabis is legal” does not mean “the NHS must provide it for chronic pain”, but “NICE does not routinely recommend it” is also not the same statement as “Parliament prohibits it”. The framework exists to preserve that distinction (NICE, 2019, updated).

9.2 Ketamine

Ketamine is a controlled medicine used in recognised medical settings. NICE NG193 recommends that clinicians do not initiate ketamine for chronic primary pain. That recommendation is population- and indication-specific: chronic primary pain is distinguished from chronic secondary pain and other specialist uses. A safe analysis therefore requires the actual diagnosis/indication, the proposed route, specialist competence, evidence, controlled-drug requirements, monitoring and local service availability. “NICE says no ketamine” would be an over-generalisation of NG193 (NICE, 2021, updated).

10. Historical “Factor Time” markers for NHS/private provision

The study uses “Factor Time” to mean a sourced point at which law or national policy materially altered who could provide NHS-funded care, how NHS purchasers/commissioners could use non-NHS providers, or how private activity could coexist with NHS structures. It avoids the inaccurate claim that private participation began on one single day.

Marker	Date / actor	What changed	Why it matters
FT-1	31 Jan 1989 - UK Government / Working for Patients	Proposed purchaser-provider separation and internal-market reforms.	Created architecture in which purchasing could be separated from provision.
FT-2	29 Jun 1990 - NHS and Community Care Act 1990	Legislated NHS trusts and internal-market arrangements.	Legal implementation of major structural reforms.
FT-3	27 Jul 2000, 1:14 pm - Prime Minister Tony Blair, House of Commons	NHS Plan explicitly endorsed a new framework with private-sector capacity where it could improve NHS care or fill gaps, while remaining free to NHS patients.	Clear national policy pivot towards continuing partnership rather than ad hoc purchasing.
FT-4	31 Oct 2000 - Department of Health / Independent Healthcare Association	Concordat formalised relationships with private and voluntary providers.	Commons Health Committee later characterised the opening as a significant policy shift.
FT-5	1 Oct 2012 - Health and Social Care Act 2012 reforms	Abolished the previous foundation-trust private-patient income cap, while retaining statutory constraints around NHS purpose/income.	Objective change in the permissible financial structure of NHS foundation-trust activity.
FT-6	1 Jan 2024 - Provider Selection Regime	New statutory regime for selecting providers of relevant NHS healthcare services in England.	Current route by which NHS healthcare-provider selection is structured.

These dates are not proof that private provision harmed patients or altered prescribing decisions. They are audit markers. For any alleged commercial influence, the investigation must identify the particular contract, policy, decision-maker, financial flow and patient effect rather than relying on the existence of a private market.

11. Case studies and precedent

The cases below do not all reach the same result. That is deliberate. Together they define the legal corridor within which the toolkit operates.

Authority / study	Problem	Finding	Use in this framework
Montgomery v Lanarkshire HB [2015] UKSC 11	Obstetric risk disclosure and alternative delivery method.	Patient must be made aware of material risks and reasonable alternatives; patient perspective matters.	Supports Tool 3 (patient legal standing) and Tool 4 (informed medication/treatment choice).
McCulloch v Forth Valley HB [2023] UKSC 26	Whether a non-recommended alternative had to be discussed.	Reasonable alternatives are bounded by clinical judgment supported by a responsible body of medical opinion.	Prevents the toolkit becoming a mechanism to compel clinically unreasonable treatment.
R (Rogers) v Swindon NHS PCT [2006] EWCA Civ 392	Herceptin funding under an exceptionality policy.	Funding policy was irrational and unlawful; court quashed policy/decision but did not prescribe treatment itself.	Core precedent for Tool 2: policy can be challenged against public law.
R (Condliff) v North Staffordshire PCT [2011] EWHC 872 (Admin), appeal [2011] EWCA Civ 910	IFR for bariatric surgery.	Shows legitimate limits of patient claims against resource-allocation policy.	Counterbalance: not every policy refusal is unlawful.
R (Tracey) v Cambridge University Hospitals NHS FT [2014] EWCA Civ 822	DNACPR decision without adequate patient involvement.	Article 8/autonomy required involvement absent appropriate reasons not to discuss; second-opinion issues formed part of the case.	Demonstrates that process, communication and patient involvement have legal significance.
PHSO Summary 695 (2014)	GP declined specialist pain medicine after patient changed practice.	Primary-care refusal was correct, but failure to discuss, refer promptly and maintain interim continuity was fault.	Near-direct operational match for Tool 1/Tool 4.
PHSO “Expert patient’s requests for medication ignored” (2011)	Patient warned about anticoagulant needs based on prior clotting history.	Communication and medication failures increased risk; subsequent thrombosis occurred.	Supports systematic recording/listening to previous treatment harm.
PHSO Summary 669 (2014)	Incorrect lupus diagnosis, long-term medicine with inadequate monitoring and delayed referral.	Medication management, diagnosis, records and referral were found deficient.	Shows why monitoring and escalation are separate safety duties.
NHS England CBPM barrier review (2019)	National review after medicinal cannabis rescheduling.	Found evidence/evidence-confidence, commissioning, supply and cost barriers; some families used private prescriptions and reported significant burden.	System-level support for policy-vs-law and displacement analysis.
Erridge et al. (2024)	UK survey of illicit cannabis self-treatment for diagnosed health conditions.	Estimated substantial self-treatment population; highlights access and harm-reduction issues, but cannot prove causation.	Supports the care-displacement research layer with explicit methodological caution.

11.1 Bolitho and the quality of clinical reasoning

Bolitho v City and Hackney Health Authority [1997] UKHL 46 is relevant to the quality of professional reasoning. Expert support for a clinical position does not automatically make that position immune from legal scrutiny

where the opinion is not capable of withstanding logical analysis. This does not permit patients to substitute their own medical judgment; it reinforces the need for a defensible risk-benefit rationale where clinical evidence is contested.

11.2 Convergent conclusion from the case material

The rough common conclusion is not “the patient wins over policy” or “the doctor wins over the patient”. It is more precise: clinical choices must be made through lawful, rational and professionally defensible processes; patients must be involved and informed; commissioning policies may ration access but cannot be irrational or misrepresented; competence limits should route care rather than silently terminate it; and adverse-treatment history must be taken seriously. Where those conditions are met, a patient may still lawfully be refused the treatment they prefer.

12. Non-destructive verification route

The framework intentionally separates verification from accusation. Many disagreements can be resolved by checking the standard before identifying any practitioner to a regulator.

Stage	Verifier	Purpose	Escalatory effect
1	Treating clinician	Clarify diagnosis, rationale, risks, alternatives and exact barrier.	None - ordinary clinical care.
2	Clinical pharmacist / SMR	Independent medication-risk, interaction, tolerability and alternatives review.	None - clinical safety support.
3	Second GP / specialist	Independent assessment of whether the preferred alternative is clinically reasonable and who should initiate it.	Low - normal second-opinion/referral process.
4	NICE / MHRA / NHS England source	Verify what guidance, licensing or commissioning material actually says.	None - documentary verification.
5	GMC standards enquiry	Ask an anonymised professional-standards question about doctor duties.	Normally none if no doctor is identified and no fitness-to-practise complaint is made.
6	Formal NHS complaint / ICB / provider governance	Challenge unresolved service, policy or commissioning failure.	Formal organisational process.
7	Regulator / Ombudsman / legal review	Use where evidence indicates professional, systemic or public-law failure.	Potentially significant; reserve for warranted cases.

The GMC is particularly useful for standards verification. Its public material explains what patients should expect and its professional-standards contact route can be used to ask how published standards apply. A standards enquiry is conceptually different from a fitness-to-practise referral. If serious public-protection information is formally disclosed, however, a regulator cannot necessarily promise that no action will follow.

13. Operational framework and supporting Tools 1-4

This paper is accompanied by four operational documents. The paper supplies the reasoning and evidence base; the tools are intended for real-world use before and during care decisions.

Tool	Primary user	Situation	Output
Tool 1 - Doctor Legal Abilities and Duties	Patient and clinician	Someone says “I cannot / I am not allowed”.	Classifies clinical, competence, legal and professional duties; identifies referral/escalation options.
Tool 2 - NHS Policy vs Law Assessment	Patient, clinician, advocate, investigator	A policy, formulary or commissioning rule is cited as the barrier.	Policy provenance, legal authority, exception route, rationality/equality/safety test.
Tool 3 - Patient Legal Standing Against NHS Policy	Patient / advocate	The patient needs to exercise consent, information, reconsideration, second-opinion, adjustment or complaints rights.	Rights-based request without falsely claiming a right to compel prescription.
Tool 4 - GP Obstruction, Treatment Access and Medication Safety	Patient and clinician	Previous harm, risky prescribing, blocked referral, competence issue or treatment substitution.	Medication-safety loop, pathway escalation and contemporaneous decision record.

13.1 Combined decision audit

1. What problem/outcome is the patient trying to address?
2. What happened with previous treatments, including benefit and harm?
3. What options are clinically reasonable?
4. What prevents the preferred option: individual clinical risk, competence, law, NICE, commissioning, local policy, funding or administration?
5. If the first route is unavailable, who can assess/provide the next lawful safe route?
6. What monitoring, stopping criteria and review are needed?
7. If disagreement persists, what independent verification can be obtained before complaint or regulatory escalation?

14. Research questions for a local or individual audit

The national legal framework is only the first layer. To investigate an individual pathway or locality, the following documents should be obtained for the relevant date, not merely the current version.

Evidence class	Documents/data to obtain	Question answered
Clinical record	Consultations, medication history, adverse reactions, referral decisions, letters, test results.	What was known, requested, offered and recorded at the time?

Evidence class	Documents/data to obtain	Question answered
Practice	Prescribing policy, significant-event policy, complaints policy, clinician roles, local pharmacist/SMR access.	Was the obstacle a practice rule or a clinical decision?
ICB/commissioner	Formulary, IFR policy, pathway criteria, medicines optimisation policy, contracts.	Was the treatment commissioned; what exception/appeal route existed?
Trust/specialist service	Referral criteria, shared-care agreement, controlled-drug/unlicensed-medicine policy.	Could a specialist assess/initiate; what monitoring was required?
Private provider	Ownership, CQC registration, advertising, pricing, clinician register status, NHS contracts.	What commercial route existed and who benefited financially?
Data governance	Privacy notice, DPIA, data-sharing agreement, processor contracts, lawful basis/confidentiality authority.	What patient information moved to private organisations and why?
Conflict registers	Declarations by decision-makers, gifts/hospitality, outside interests.	Were financial/non-financial conflicts disclosed and managed?
Outcome evidence	Subsequent treatment, adverse effects, private expenditure, self-treatment, delayed diagnosis.	What actually happened after the NHS decision, and can causation be responsibly assessed?

15. Conclusions and limitations

The evidence supports a route rather than a simple entitlement. A patient who considers the offered treatment harmful or unacceptable can refuse it, explain what matters to them, ask for reasonable alternatives to be assessed, request clarification of the exact barrier, seek medication review/second opinion/specialist assessment, and use the policy-law tools where commissioning or local policy is involved. The clinician retains responsibility for deciding what is clinically reasonable and for staying within competence and medicines law.

A policy can be lawful and still restrict access. A policy can also be irrational or unlawfully applied. The distinction cannot be resolved by slogans. It requires the policy text, statutory authority, evidence, reasons, individual facts and the correct standard of review. Rogers demonstrates that policies can fail that test; Condliff demonstrates that a patient preference does not itself defeat a lawful resource-allocation framework.

The paper also identifies a patient-safety consequence that deserves further study: unresolved treatment need may displace some people into private care, self-treatment, unregulated supply or no treatment. NHS England's cannabis review and recent survey evidence make that risk empirically plausible, but individual causation and improper financial motive must be proved rather than assumed.

The most constructive operational conclusion is therefore “verification before escalation”. A clinician and patient should first identify the clinical question and medicine-safety facts; then identify the legal/policy layer; then use targeted independent verification; and only then use complaints, regulation or litigation where the evidence warrants it. This preserves both patient safety and professional fairness.

The framework in one sentence

A patient cannot simply override NHS policy, and NHS policy cannot simply override law or professional duty: the decision must be classified, individually reasoned, safely managed, transparently documented and capable of lawful review.

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Referencing convention: ISO 690:2021 author-date for documentary sources. Legal cases are cited by standard UK neutral citation; legislation is cited by title/year and statutory instrument/chapter where applicable. Online sources accessed 27 September 2026 unless otherwise stated.

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- Montgomery v Lanarkshire Health Board [2015] UKSC 11; [2015] AC 1430.
- R (Condliff) v North Staffordshire Primary Care Trust [2011] EWHC 872 (Admin); appeal [2011] EWCA Civ 910.
- R (Rogers) v Swindon NHS Primary Care Trust [2006] EWCA Civ 392; [2006] 1 WLR 2649.
- R (Tracey) v Cambridge University Hospitals NHS Foundation Trust [2014] EWCA Civ 822; [2015] QB 543.

Key legislation and regulations

- Equality Act 2010, c.15, especially sections 20 and 29.
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, SI 2014/2936, especially regulations 9, 11, 12, 13, 17 and 20.
- Human Medicines Regulations 2012, SI 2012/1916.
- Misuse of Drugs Act 1971 and Misuse of Drugs Regulations 2001.
- Misuse of Drugs (Amendments) (Cannabis and Licence Fees) Regulations 2018, SI 2018/1055.
- National Health Service Act 2006, c.41.
- National Health Service and Community Care Act 1990, c.19.
- Health and Social Care Act 2012, c.7.
- Health and Care Act 2022, c.31.
- National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, SI 2012/2996, as amended.
- Health Care Services (Provider Selection Regime) Regulations 2023, SI 2023/1348.

Supporting documents supplied with this paper

- Tool 1 - Doctor Legal Abilities and Duties.
- Tool 2 - NHS Policy vs Law Assessment.
- Tool 3 - Patient Legal Standing Against NHS Policy.
- Tool 4 - GP Obstruction, Treatment Access and Medication Safety.

The supporting tools are practical implementation documents. This paper should be retained as the evidential rationale and source map behind them.