# Primary care groups and the right to prescribe

Christopher Newdick

Department of Law, University of Reading, Reading, Berkshire RG6 6AH
Christopher Newdick, *reader in health law*
c.newdick@reading.ac.uk

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## Summary points

- Since the NHS began, general practitioners have had a duty under their terms of service to prescribe medicines to their patients
- New drugs to treat hitherto intractable conditions will increase the overall cost of medicines
- Despite promises that the NHS will treat patients on the basis of "need and need alone," primary care groups will have to operate within cash limits
- What is the nature of the general practitioner's duty to prescribe expensive medicines when the cost of doing so exceeds the cash limits imposed on primary care groups?
- Is this duty to prescribe dependent on the needs of individual patients or on the overall level of funding in the system?
- If the historic commitment of the NHS has legal force, will doctors be blamed when patients are denied access to expensive medicines?

In matters of NHS funding, politicians tend to say one thing and health economists another. Governments commit themselves to the Hippocratic ethic that patients should be treated solely on the basis of need. But economic reality has always required us to make hard choices between deserving patients. Today we require a legal dimension to this tension. This article examines the general practitioner's legal duty to prescribe medicines.

The terms of service of general practitioners impose a duty to prescribe on the basis of need. Yet, primary care groups will be expected to operate within a "cash limited envelope." Is this duty to prescribe dependent on patients' needs or limited by available resources? Will it be lawful to deny access to effective but expensive medicine on grounds of cost? As patients litigate for NHS resources, general practitioners need to know who is to blame when patients are denied access to expensive medicines.

What are the rights and duties of general practitioners to prescribe medicines to their patients? Since the start of the NHS doctors have been assured that the principle of legitimate clinical freedom will be preserved. In 1948, Ernest Bevan promised doctors "all the facilities, resources, apparatus and help I can, and then to leave you alone as professional men and women to use your skills and judgment without hindrance."[1] And in the new white paper, the present government "has committed itself to the historic principle of the NHS: that if you are ill or injured there will be a national health service there to help; and access to it will be based on need and need alone."[2]

But the pressure imposed by scarce resources is not always consistent with political rhetoric. In addition, the proposals to create primary care groups will require general practitioners to manage NHS resources "within [a] single cash limited envelope"[2] and to make hard choices between deserving cases.[3] We are familiar with health authorities being challenged before the courts in this regard.[4–6] General practitioners, however, have a very different and more intimate legal relationship with patients, which is governed, among other things, by their terms of service. If primary care groups require general practitioners to undertake some of the resource management functions of health authorities, what becomes of the right to prescribe? To what extent, if any, can the "historic" commitment of the NHS survive in primary care?

In this article, I consider the problem of expensive medicines; the duty to prescribe and the terms of service; what patients' "needs" are; and primary care groups and the National Health Service (Primary Care) Act 1997.

## Expensive medicines

Expensive medicines present doctors with the dilemma of choosing between clinical and economic efficacy in health care. Doctors who take a "macroeconomic" approach to their obligations may give weight to studies showing the economic efficiency, or the "opportunity costs," of medicines.[7] How much benefit does treatment contribute to patients overall? An expensive medicine might not be prescribed, particularly if its advantages are marginal, if the cost of doing so would deprive others of treatment. Alternatively, those who practise with the individual patient as the dominant, perhaps the only, consideration in mind will react to individual clinical needs first, on the ground that their Hippocratic commitment precludes their denying any treatment to those who can benefit from it.

The General Medical Council has taken a rather ambivalent view of the problem. Although it "endorses the principle that a doctor should always seek to give priority to the investigation and treatment of patients solely on the basis of clinical need," it also acknowledges that "doctors have to work within resource constraints … they must make best use of resources available for their patients, recognising the effect their decisions may have on the resources and choices available to others."[8]

One solution to this difficulty is the introduction of a "fourth hurdle" in the drugs' licensing process. For example, the Department of Health could demand evidence that new medicines have economic advantages over others before issuing a product licence under the Medicines Act 1968.[9] For the present, however, looking at the relative efficacy of a drug by comparing it with others is expressly excluded from consideration by the licensing authority.[10] The Department of Health proposes to create a National Institute for Clinical Excellence to advise doctors on the clinical and cost

efficacy of drugs.[11] However, in the absence of clear current guidance from the General Medical Council and the Medicines Act, what approach to this problem is taken by the general practitioners' terms of service?

## Duty to prescribe and the terms of service

Ernest Bevan's promise not to interfere with medical discretion was given legal effect in the original terms of service between health authorities and general practitioners in 1948. The duty to prescribe stated that "a practitioner is required to issue to his patients … free of charge any certificates reasonably required by them."[12] The modern terms of service have changed little in this regard. The current equivalent of the 1948 regulations is contained in paragraph 43 of the current terms of service. This provides that, with the exception of "black listed" medicines, "a doctor shall order any drugs or appliances which are needed for the treatment of any patient for whom he is providing treatment under these terms of service."[13]

Notice that, consistent with its 1948 meaning, the word is "shall," rather than "may" or "subject to available resources." Prima facie, therefore, the matter is expressed in terms of a duty. A duty to do what? The duty is to prescribe what patients need. But the word "need" is notoriously imprecise.[14] It certainly does not require doctors to prescribe on the basis of patients' "wants." Indeed, were a doctor to prescribe on such a basis, contrary to his clinical judgment, and the patient suffered damage, it would be impossible to defend his action in negligence since such a practice could not be consistent with a responsible and logical body of medical opinion.[15 16] (For this reason the practice of defensive medicine is ill advised.) Given this qualification, what interpretation should be given to the duty imposed by paragraph 43 to prescribe on the basis of need?

JANE SMITH

## What are patients' needs?

The courts have never considered the meaning of paragraph 43, so we must balance the arguments about its interpretation. There are a number of ways in which the word need may be analysed.

### Restrictive view of the right to prescribe

The argument in favour of a restrictive interpretation of the duty is as follows. The duty to supervise the terms of service is imposed on the health authority. Ironically, this is precisely the body on which there is a statutory duty to ensure that health service spending remains within budgetary limits. Under the National Health Service Act 1977 "it is the duty of each Health Authority … to secure that the expenditure of the Health Authority … does not exceed [its income]."[17]

There is an obvious inconsistency in requiring a health authority to encourage doctors to prescribe all the drugs that their patients need and, at the same time, manage their resources in a way that ensures expenditure does not exceed income. Arguably, this suggests that the notion of clinical freedom within paragraph 43 must depend on available resources.

In 1980, Lord Denning considered the duty of the secretary of state to provide "a comprehensive health service" under sections 1 and 3 of the National Health Service Act 1997. He decided that the duty must be read subject to the implied qualification that it was "to meet all reasonable requirements such as can be provided within the resources available … . That includes the numerous pills that people take nowadays: it cannot be said that he has to provide all these free for everybody."[18] Although the terms of service were not raised as matters for consideration in this case, if this implication is read into paragraph 43, the duty to prescribe could be limited in the same way. Health authorities and primary care groups could insist that access to some expensive medicines was made subject to waiting lists or withheld from patients altogether.

Further support for this restrictive view of paragraph 43 is also available from a recent judgment of the House of Lords. The matter arose under the Chronically Sick and Disabled Persons Act 1970, which imposes on local authorities a duty to "meet the needs" of its residents. The question arose as to the meaning of the word "needs." Is it a patient led (or absolute) duty; or a resources led (and relative) duty? By a bare majority of 3:2, the Law Lords said that, in the context of the 1970 act, the word should be interpreted as being resources led. Therefore, the standard of the duty required by the act was made relative to the funds available to the authority. Surprisingly, clients with recognised needs in one year could, under the 1970 act, cease to have needs thereafter, notwithstanding that their circumstances remained unchanged or even if they deteriorated.[19] It also means that national standards of social services are extremely difficult to achieve because the level of resources differs from region to region.

If this approach to the resource problems faced by health authorities were adopted, general practitioners would find that the freedom to prescribe could be restricted on the grounds that the drugs and appliances that patients "need" will fluctuate according to the resources made available to the authority. In

**NHS Executive's view of excessive prescribing**

The executive gives four examples of excessive prescribing:

- Where it seems that far too much of a drug is prescribed for the condition under treatment
- Where two drugs with the same apparent mode of action are prescribed when beneficial synergy is not to be expected
- Where treatment is begun or drugs are added without stopping the previous treatment
- Where additional drugs are prescribed prophylactically to meet infrequent side effects

other words, the concept of clinical need would have to be replaced by that of resource dependent need in which managerial, not clinical, considerations would predominate.

**Unrestricted view of the right to prescribe**

There is an alternative way of analysing paragraph 43. Words of statutes have to be interpreted in their context and in a manner that gives effect to the intentions of parliament. The words "shall order" in paragraph 43 have to be read in harmony with other regulations governing general practitioners in the NHS. A number of other statutory and non-statutory provisions have a bearing on this matter. For example, general practitioners who waste resources may rightly be punished by the health authority where their prescribing cost is "in excess of that which was reasonably necessary for the proper treatment of [a] patient."[20] In this context, "reasonably necessary" and "proper treatment" certainly do not suggest that those who could obtain benefit from medicines should be denied access to them.

The NHS Executive seems to share this view of the sanction against excessive prescribing. It advises that "there are several types of prescribing which may give rise to a perception … that there may have been excessive prescribing." The box gives four examples of this.[21 22] Notice, however, that they do not seek to restrict the responsible exercise of clinical discretion in the choice of medicine, nor do they place any particular emphasis on the burdens imposed by expensive medicines.

The attention of the NHS Executive is clearly focused on waste and irresponsible behaviour. There is no intention to inhibit the responsible exercise of clinical discretion. This same view may be taken of the indicative prescribing scheme, which introduced targets for those general practitioners who remained non-fundholders. Accordingly, section 18 of the National Health Service and Community Care Act 1990 provides that general practitioners "shall seek to ensure that except with the consent of the Health Authority, or for good cause, the [cost of prescriptions] does not exceed the indicative amount." Note, however, that the target is "indicative," it is not set in stone. To put it the other way, doctors have a duty to husband public resources; nevertheless a "good cause" permits the practice to exceed the indicative amount.

Precisely such an approach was recently adopted by the House of Lords in R v East Sussex CC, ex p Tandy[23] with respect to the duty of a local authority to provide "suitable education" to disabled children under section 298 of the Education Act 1993. Notwithstanding the unenviable position of local authorities, who are both rate capped and subject to limitations of funding from central government, Lord Browne-Wilkinson held that the duty to provide sufficient resources for this purpose was absolute. He said that "there is nothing in the Act of 1993 to suggest that resource considerations are relevant to the question of what is a 'suitable education'."

Thus, the child in question established her right of access to proper education at home. The Education Act imposed a needs based duty on local authorities which was entirely different to the resource based discretion of the Chronically Sick and Disabled Persons Act 1970, discussed in the case of ex p Barry above.[19] Importantly, Lord Browne-Wilkinson continued: "If Parliament wishes to reduce public expenditure on meeting the needs of sick children, then it is up to Parliament so to provide. It is not for the courts to adjust the order of priorities as between statutory duties and statutory discretions."

*"The doctor's duty to prescribe under a service agreement … is left unresolved."*

After the ex p Tandy judgment,[23] therefore, paragraph 43 can be interpreted as needs led. Examined in the context of the other regulations pertaining to general practitioners, and interpreted in a way that emphasises responsible rather than wasteful prescribing, it seems to preserve the principle of discretion to prescribe on the basis of clinical effectiveness (as opposed to cost effectiveness). In this case, medicines should be prescribed on the basis of clinical need, notwithstanding that the costs of doing so may exceed the target budget. If this is correct, reserves would have to be held within the health authority to support those general practitioners who exceed their targets, for good cause.

Of course, whenever possible, sound evidence should be the basis for responsible decision making.[24 25] No doubt, much can be done to improve clinical effectiveness by outcome indicators. In addition, as the Audit Commission has suggested, it may sometimes be reasonable for doctors to consider a policy of using "second best" medicines first, when they will probably be equally effective for most patients—always conscious of the duty to transfer patients to the "best" medicine, irrespective of cost, if the patient's condition so requires.[26] However, the extent to which this would generate savings in practice is not clear, and the policy could not apply to many new medicines that treat previously intractable and chronic illnesses.

## Primary care groups and the 1997 act

Throughout the evolution of the NHS there has been no suggestion that the historic commitment to patients should change. On the contrary, as has been noted above, the very idea runs counter to the assertions of successive governments that the NHS will continue to treat patients on the basis of clinical need. On the other hand, institutions have been created within the NHS that place immense strain on the ideals of

paragraph 43. This process began with fundholding, although the proportion of total spending generated by practices that was allotted for them to manage for themselves was relatively small.

The reforms proposed by the Labour government, however, invite general practitioners to involve themselves far more extensively in the allocation process. Primary care groups, staffed by health professionals and members of social services departments, will extend the idea of fundholding and the philosophy of enhancing the influence of primary care. Necessarily, they will engage doctors in the business of managing resources. How exactly will paragraph 43 impinge on the practitioner who in the morning attends a subcommittee of the health authority considering how to manage scarcity,[27] and in the afternoon returns to his surgery to treat patients with expensive requirements within the framework of the terms of service? This question, which goes to the root of general practitioners' duties to patients and health authorities, is not addressed in the white paper.

*"Rationing may have to be accepted as a fact of life."*

A related problem arises under the National Health Service (Primary Care) Act 1997. Traditionally, health authorities have been responsible for providing general medical services to patients. They have done this by engaging doctors under the terms of service. However, under the 1997 act, general medical services may now be provided "otherwise than by the authority,"[28] by primary care pilots under "service agreements," rather than the terms of service, with health authorities. What is the doctor's duty to prescribe under a service agreement? Again, the matter is left unresolved. In addition, primary care pilots may engage general practitioners as employees, and they too will work independently of the terms of service. Employees owe a duty of loyalty and fidelity to their employers. When a doctor is faced with a conflict between the clinical duty to his patient and the targets and bonuses laid down by his employer within his contract of employment, which will take precedence?

## Conclusion

As pharmaceutical and medical technology advances, general practitioners will increasingly need to be clear about their rights and duties in respect of their patients. Assuming that substantially more resources will not be committed to the NHS, cash limited primary care groups will force general practitioners to make choices which put intolerable strain on paragraph 43 of the terms of service and the duty to prescribe.

Of course, the relative view of the duty to prescribe may be inevitable. Rationing may have to be accepted as a fact of life, and, if so, who better to do it than well informed doctors? In this case we may have to accept that primary care groups in the NHS will begin to resemble health maintenance organisations in the United States.[29] If this is correct, however, we should embark on a very different debate about the duty to prescribe. To what extent, for example, should doctors benefit from incentives to save money or be penalised for exceeding targets?[30] Should patients be told of the treatments which the NHS cannot afford? How can the national character of the NHS be preserved? And, more profoundly, we will have to reassess the "historic principle of the NHS" and develop procedures for protecting both doctors and patients when care is denied.[31 32]

Alternatively, this view may be mistaken because the absolute or historic principle remains intact. In this case, however, when care is not made available to needy patients, governments may look to general practitioners for explanations as to why. Indeed, it may be primary care groups that will be blamed for failing to provide the care that patients are permitted to expect. Either the duty is relative or absolute, but it cannot be both. In the interests of the national character of the NHS and for the guidance to which they are entitled, primary care doctors should press for an answer.

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# Commentary: Bevan's covenant continues intact

Brian Hurwitz

Prescribing by general practitioners now accounts for 80% of total NHS expenditure on drugs, and continues to grow faster than overall health service costs.[1] Since the inception of the NHS, successive governments have sought to curb this cost. They have used a variety of macroeconomic measures that have targeted patients (prescription charges), the pharmaceutical industry (profit control), community pharmacists (clawback of discounts), health authorities (statutory duty to remain within budget), and general practitioners (penalties for excess prescribing and exclusion of schedule 10, "black listed" drugs).

This medley of measures has been supplemented by initiatives such as the distribution of high quality appraisals of drug efficacy to general practitioners and regular feedback of data on prescribing costs that aim to promote more rational prescribing decisions and to minimise drug costs. The Audit Commission concluded that most drugs in general practice should be prescribed generically (as they are in hospitals) rather than by brand name; prescriptions should be selected from preferred lists within drug groupings (as is now encouraged by many prescribing incentive schemes); and drugs with limited therapeutic efficacy should not be prescribed at all.[2]

Prescribing budgets combined with incentives to underspend have been introduced for fundholders, and subsequently matched by target prescribing budgets and incentive schemes for non-fundholders. Both have probably resulted in overall savings.[3 4] However, the true extent of savings is difficult to estimate because many other factors also influence prescribing. These factors include introduction of new drugs, ageing of the population, advertising activities of pharmaceutical companies, substitution of pharmacological for surgical treatments, and moves to declassify medicines from prescription only status.[5]

Newdick has suggested that there could be a conflict of statutory duties between a general practitioner's obligations "to order any drugs and appliances that are needed"[6] and stay within budget—responsibility for which will be devolved from health authorities to primary care groups next April. He focuses on how disciplinary panels (or courts) are likely to interpret such a conflict, but takes no account of the many prescribing initiatives that have been undertaken within the NHS over past decades. Excluding the creation of the "black" and "grey" lists of medicines (schedules 10 and 11 of the general practitioner contract), all these initiatives—and even fundholding itself—have been introduced without making changes to the terms of service of general practitioners. Through all these changes, the formulation of the general practitioner's duty to prescribe (paragraph 43) has remained remarkably stable.

Strong historical and moral grounds exist, therefore, for believing that Bevan's covenant with doctors (and ultimately with patients) to provide doctors with the resources to enable them to exercise professional discretion "without hindrance" continues intact as far as prescribing is concerned. This would mean that if the type and quantity of medication prescribed by general practitioners are rational responses to clinical need, overspending on drug budgets will not in itself constitute a breach of the general practitioner contract. Difficulties might arise from the tendency of some general practitioners to interpret clinical situations within a broad conceptual framework that allows aspects of patients' wants and interests to be taken into account when assessing how best to respond to their medical needs. However, tailoring medication to individual circumstances lies at the heart of the general practitioner's role; expenses so incurred will be difficult to characterise as unreasonable.

Newdick points to the budgetary difficulties that expensive new treatments pose for primary care groups. However, general practitioners already face similar prescribing problems over prescribing statins for prevention of coronary disease or in deciding when to switch from thiazide drugs to angiotensin converting enzyme inhibition as first line treatment for hypertension.

Primary care groups will need mechanisms for deciding prescribing policies in the light of good evidence about the needs of local populations, relative drug efficacy, safety, and cost. It is hoped that the National Institute for Clinical Excellence will be able to supply authoritative guidance on these matters.[7] In addition, primary care groups will be empowered to monitor and investigate the prescribing patterns of their general practice members and will be able to set up prescribing incentive schemes.

The latest guidance from the NHS Executive indicates that moving money between budgets is to be allowed. It states that primary care groups are expected "to extend indicative budgets to individual practices for the full range of services, but no individual element will be capped."[8] There are to be clear lines of financial accountability between primary care groups and health authorities, but on how such accountability is to operate between individual general practitioners and primary care groups the guidance is silent. The BMA has reminded us of ministerial assurances that under the new arrangements "freedom to refer and prescribe remains unchanged."[9] In the last analysis, provision will presumably be made for overspending by primary care groups to be rolled forward as a charge on next year's budget as currently occurs for general practice fundholders and health authorities; ministerial confirmation of this is awaited.

Department of Primary Health Care and General Practice, Imperial College School of Medicine, London W2 1PG

Brian Hurwitz, *senior lecturer*

b.hurwitz@ic.ac.uk

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