ALTERNATIVE LOCAL ARRANGEMENTS FOR THE PROVISION OF APPLIANCES BY PRIMARY CARE TRUSTS

OPINION

Executive summary

1 I am instructed by the British Healthcare Trades Association (BHTA) to advise on the powers of NHS primary care trusts (PCTs) to implement "alternative local arrangements". The legal issues could arise in any pharmaceutical context, but in practice have been prompted by arrangements or proposed arrangements for the provision to NHS outpatients of stoma/continence appliances and related products and services.

2 A summary of the main questions I have to consider, and my conclusions on those questions, is as follows:

(a) Can PCTs lawfully enter into alternative local arrangements?

No.

In summary, this is because a PCT has *no power* to make alternative local arrangements. It can only make arrangements which comply with the requirements of the pharmaceutical list scheme under s. 126 of the NHS Act 2006, or which comply with the requirements for one of the expressly-defined statutory alternatives, namely, LPS schemes or pilot schemes.[1]

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[1] I address this topic at paragraph 21ff. below, after analysing the structure of the legislation at paragraphs 9-20. My reasons for reaching this conclusion are at paragraphs 25-27, 35-38 and 41 of this Opinion.

(b) Can alternative arrangements be justified as LPS schemes?

In the cases I have seen, no.

Any LPS scheme must require each contractor to dispense drugs. An agreement which only involves appliances cannot form part of an LPS scheme.

(c) Can a PCT engage a supplier on terms that it offers rebates or discounts below the Drug Tariff price?

In general, no. Reduced prices can be required from suppliers only if the arrangements form part of a valid LPS scheme.

In summary, this is because a PCT has *no power* to engage providers to meet prescription needs at prices below Drug Tariff rates (including by the use of rebates, discounts, or the provision of uncharged extra product), unless it can lawfully do so as part of an LPS scheme, complying with the LPS Regulations. At a minimum, this would require the agreement between the PCT and each LPS contractor to include the dispensing of drugs and the engagement of a registered pharmacist by the contractor (as well as compliance with the procedural requirements for an LPS scheme).[2]

Further factual background

3 There is a significant need for the provision of permanent or temporary stoma bags and other urological appliances to assist outpatients. The traditional way in which the NHS has met this need is by the use of dispensing appliance contractors (DACs), and also community pharmacists, whose names are on PCTs' pharmaceutical lists. This is a national regime under the NHS legislation and described in more detail below. Just as with prescription medicines, the regime for appliances involves fixed

[2] I address this topic at paragraphs 42-52 of this Opinion.

terms of service for the retailer, and a fixed price set under the Drug Tariff determined by the Department of Health.

4 Over recent years a number of PCTs have sought to engage contractors for alternative local arrangements. This is a convenient phrase, not found in the legislation, to describe arrangements which are not expressly authorised by the NHS legislation. Whether they are authorised under the general terms of that legislation is the key issue which I have to address.

5 The most recent example concerns Rotherham PCT, which has invited tenders for a home delivery service for urology consumables. It appears that the NHS in Rotherham has set up a Continence Service which is exclusively responsible for generating prescriptions on behalf of local GPs for patients who require urology consumables for home use. The GPs themselves no longer issue the prescription directly to the patient although they order it in the first place. Patients can then choose where the prescription is dispensed, either through a pharmacy, or a DAC, or by home delivery. If patients express no preference, then the intention is to offer the successful tenderer to them.[3]

6 The tender is to be assessed partly on price and therefore necessarily implies that bids below the Drug Tariff level are being sought. Indeed the tender expressly invites innovative pricing structures outside the FP10 route (as I understand it, FP10 is industry shorthand for remuneration under the Drug Tariff).

7 BHTA and many of its members are concerned about such alternative arrangements and their inconsistency, as they see it, with the general regime. In at least one previous case, the arrangement has been justified by the NHS as ancillary to the delegated duty of PCTs to provide medical and nursing services. It has been said that this primary duty of direct service provision is separate from a PCT's commissioning role. In so far as appliances are purchased by a PCT exclusively for

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[3] See NHS Rotherham's Invitation to Tender, 2.9.11, section 1.

inpatient use, rather than in response to prescriptions for outpatients, that is outside the scope of this Opinion.[4] In so far as appliances are procured for outpatient needs, this Opinion addresses the legality of those arrangements.

8 NHS Rotherham have not suggested that their procurement relates to inpatient supplies, nor have they made a general argument based on their delegated duties. They have however suggested that an arrangement of the type they envisage could be lawful as an LPS scheme, a variant of the main regime which I also consider below.

Overview of the powers and duties of PCTs

9 It is indisputable that because a PCT is a statutory corporation, its powers to act are therefore limited to what is expressly or impliedly conferred on it by legislation: *Hazell v LB Hammersmith & Fulham* [1992] 1 AC 1. I see no scope for implication in this case. The issue therefore is the scope of the powers expressly conferred.

10 It is appropriate to start with the overall structure of the National Health Services Act 2006 (the Act), so far as it relates to PCTs.[5] S. 1 sets out the general duty of the Secretary of State (the SoS) to promote a comprehensive English health service, and s. 3(1) requires him to provide (among other things) (c) medical, dental and ophthalmic services and (e) after-care and preventative services. The extent to which the SoS must provide those services in order to meet reasonable requirements is for him to judge. S. 2 gives the SoS power do anything which is incidental to his duties.

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[4] See NHS Southampton's letters to providers of 2.12.08 and 17.12.09. At least the first of these letters appears to have been accepted, on this issue, by the provider concerned in its reply of 23.2.09 (which was copied to BHTA). This may well have been on the basis that the supply was for inpatient needs.

[5] What follows is not intended to be absolutely comprehensive but to focus on the relevant features for present purposes.

11 The functions of the SoS under s. 3(1)(c) and (e) are delegated[6] to PCTs by the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002 (the 2002 Regulations). At the same time, under Parts 4, 5 and 6 of the Act, PCTs are also directly assigned the express function of providing, respectively, primary medical, primary dental and primary ophthalmic services. S. 3(2) states that services so provided must be regarded as provided by the SoS, *i.e.* they count towards performance of the SoS's general duty. There is a very high degree of overlap between Parts 4-6 and the relevant parts of s. 3(1).

12 Part 7 of the Act is headed "Pharmaceutical Services and Local Pharmaceutical Services", and confers express functions on PCTs to make arrangements for the provision of drugs and appliances to meet the NHS outpatient prescription needs of their area's population. In particular, Chapter 1 of Part 7 contains a specific duty to that effect, primarily embodied in s. 126. Subsequent chapters of Part 7 contain related powers; in particular, Chapters 3 and 4 permit PCTs to provide, and lay down a framework for the regulation of, local pharmaceutical services.

13 In contrast with Parts 4, 5 and 6 of the Act, PCTs' Part 7 functions do not overlap with any duty of the SoS. There is no provision of the Act imposing a duty on the SoS to make arrangements for pharmaceutical services. Indeed, the only explicit power which the SoS has to provide such services is the reserve power in s. 133, which is limited to the case where he considers that the PCT is failing to meet its duty. Pharmaceutical services are of course different from medical etc. services because they involve the supply of items (under supervision), rather than the provision of advice and medical care.

14 Moreover, and in clear contrast with s. 3(2) (under which performance of the PCT's duty to provide *e.g.* primary medical services counts towards the SoS's performance

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[6] I use this term broadly. What the relevant regulations provide is that those functions are "exercisable by" PCTs. This may not be identical to the traditional legal meaning of delegation, but the precise differences (if any) are not material for the purposes of this advice.

of his own like duty), s. 3(3) provides: *"This section does not affect Chapter 1 of Part 7."* A similar provision is contained in s. 2(2)(b). Thus, so far from there being a statutory overlap, the Act appears to "ring-fence" the functions under Chapter 1 of Part 7.

The detailed statutory dispensing scheme

15 S. 126(1) of the Act states that each PCT *"must, in accordance with regulations, make the arrangements mentioned in subsection (3)."* Services provided under s. 126 are referred to in the Act as *"pharmaceutical services"*.

16 The arrangements which s. 126(3) then requires to be made are *"for the provision to persons who are in [the PCT's] area of (a) proper and sufficient drugs and medicines and listed appliances which are ordered for those persons by a medical practitioner in pursuance of his functions in the health service, (b) [ditto for dental practitioners]... and (d) such drugs and medicines and listed appliances as may be determined by the Secretary of State for the purposes of this paragraph and which are ordered for those persons by a prescribed description of person... in pursuance of functions in the health service..."* Thus wherever doctors and other prescribers order medicines and appliances for NHS outpatients, the PCT must make arrangements *"in accordance with regulations"* for those items to be provided.

17 S. 129 then spells out detailed requirements for the regulations in accordance with which a PCT must make its arrangements. S. 129(2)(a) requires the creation of a list for each PCT of persons undertaking to provide pharmaceutical services from premises in that area. S. 129(2)(c) requires that applications to go onto the list *"may be granted only if the [PCT] is satisfied... that it is necessary or expedient to grant the application in order to secure in the neighbourhood in which the premises are located the adequate provision by persons included in the list of the services... specified in the application"*. S. 128A requires PCTs to carry out a general needs assessment. S. 130 requires the regulations to include a right of appeal.

18 The regulations made for the purposes of s. 126 are the National Health Service (Pharmaceutical Services) Regulations 2005 (the main regulations).[7] They contain an immensely detailed regime governing pharmaceutical services and needs assessments. I draw attention to the following features:

18.1 By regs. 12(2)(d) and 23, a PCT must notify potentially affected existing suppliers on the list (as well as others) of new applications, and must consider their representations when applying the "necessary or expedient" test".

18.2 By reg. 4(1)(b), the pharmaceutical lists published by the PCT must include those who undertake to provide pharmaceutical services by way of the provision of appliances. There are elaborate provisions governing the procedures and criteria for decisions as to admission to the list, suspension, withdrawal, etc.

18.3 By reg. 3, *"the arrangements for the provision of pharmaceutical services which it is the duty of a [PCT] to make under [(now) s. 126] shall incorporate... (c) in the case of arrangements with a supplier of appliances, the terms of service in Sched. 3."* Sched. 3 sets out detailed terms for DACs (termed suppliers of appliances by the regulations) which include, for example, a minimum of 30 opening hours per week (para. 10), the provision of appropriate advice to patients (para. 8), and the right to refuse to provide an appliance ordered on a prescription form if, among other things, this would be contrary to the supplier's clinical judgment.

18.4 By s. 164 of the Act and reg. 56[8], the remuneration paid to persons providing pharmaceutical services must be determined by the SoS, the aggregate of

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[7] They were made under the predecessor legislation, *i.e.* s. 41 of the National Health Service Act 1977. As amended by the Health and Social Care Act 2001, s. 41 was in materially identical terms to the current s. 126.

[8] Part 4 of the Regulations is headed "Payments to chemists" but by reg. 2, this term includes a supplier of appliances who is on the pharmaceutical list.

whose determinations is known as the Drug Tariff, and paid by the PCT under reg. 56(i). The Tariff can refer the determination to a PCT, in which case reg. 56(h) prescribes consultative procedures.

19 A feature of the legislation is that it refers to, and specifically defines the relationship that s. 126 has with, certain means of pharmaceutical provision other than pharmaceutical services under s. 126.

19.1 Sched. 12 (applied by s. 144) makes provision for local pharmaceutical services governed by schemes. Sched. 12 para. 1(7) defines local pharmaceutical services as *"such services of a kind which may be provided under s. 126... (other than [medical] practitioner dispensing services) as may be prescribed for the purposes of this Schedule"*.

19.2 An LPS scheme is defined as one or more agreements made by a PCT under which local pharmaceutical services will be provided, as also may be other NHS non-medical services. All such "LP services" are then subject to further regulations, although the mandatory content of such regulations is much less prescriptive than under s. 129. Likewise, the fixed price regime under s. 164 applies only to "pharmaceutical services" and so not to LPS schemes.

19.3 Significantly, in my judgment, Sched. 12 para. 1(5) states that *"In determining the arrangements it needs to make in order to comply with s. 126, a [PCT] may take into account arrangements under an LPS scheme made by it."*

19.4 S. 134 provides that PCTs may establish pilot schemes for the provision of local pharmaceutical services. Here again, s. 134(5) states that a PCT may take pilot schemes into account in determining what arrangements it needs to make to comply with s. 126.

19.5 S. 133 applies where the SoS considers that there is inadequate provision of pharmaceutical services in an area. He can then *"(2)(a) ...authorise the [PCT] to make such other arrangements as he may approve, or may himself make such other arrangements"*, or authorise dispensation of the requirements of the regulations under s. 126.

20 Thus in summary:

20.1 The legislation imposes not merely a power, but a duty, on PCTs to meet their local population's need for prescription drugs and appliances.

20.2 That duty is to be performed in a particular way: by making arrangements under s. 126.

20.3 Such arrangements are highly defined and include not only a high degree of procedural protection for suppliers once approved, but also fixed prices, and a gateway for entry into the system which by its very nature protects existing suppliers unless (to paraphrase very generally) there is a shortage of supply relative to demand.

20.4 There are specific derogations expressly permitted from the s. 126 duty which thereby cater for other, specified, forms of pharmaceutical supply by the NHS to the population. The mechanism of that derogation (adjustment of the s. 126 duty) enables those other forms of supply to be arranged without conflict with the s. 126 duty.

Availability of a PCT's auxiliary power

21 I now turn to the general auxiliary powers of PCTs. A PCT has power to do *"anything"* which *"appears to it to be necessary or expedient for the purposes of, or in connection with, its functions"*: see the Act, Sched. 3, para. 15(1). By para. 15(2)(b), this expressly includes *"enter[ing] into contracts"*. Para. 15 therefore directs attention to the (other) functions of a PCT, and provides a general auxiliary

power. It is an alternative to the form of ancillary power found in s. 2 of the Act and also in many other public sector contexts (most notably s. 111 of the Local Government Act 1972, which codifies the common law), which is a power to carry out actions which are "incidental" to the main function.

22 It can be accepted that Sched. 3, para. 15(2) is only a particularisation of para. 15(1) and therefore entry into contracts must fall within the general ambit of exercise of powers defined in para. 15(1). Moreover, because para. 15 generally is only an auxiliary power, and does not confer primary functions, it is self-evident that there must be some link between the act in question, and one or more primary function.

23 Nonetheless, I think it well arguable that the language of para. 15(1) goes beyond the concept of *incidental* powers. First, there is power to do anything which is not only necessary, but merely *expedient*, for the purposes of the PCT's functions. Expediency is a broad concept and connotes or includes any sort of action which might assist the function or make its performance better.[9] Second, this applies to actions not only for the purposes of the functions, but *in connection with* those functions. Third, it is for the PCT and not the court to judge (in contrast with the objective test for incidental powers), although of course the public body's judgment must remain a *Wednesbury*-reasonable one. Fourth, whereas s. 111 of the Local Government Act 1972 is expressly subject to other enactments, para. 15 is not.

24 Despite the width of para. 15, I do not consider that it can reasonably extend to justifying alternative local arrangements by reference to a PCT's Part 7 functions. As set out above, the exact mode of performance of the Part 7 functions, and the conditions under which they may (and therefore may not) be exercised, are specified in a very detailed way. It is clear that where detailed duties and powers of that kind are laid down in legislation, with specific limits and restrictions, the court will not readily interpret generally-worded powers as permitting the body to enter into other

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[9] Contrast the authorities on what is "incidental" summarised in *Risk Management Partners v Brent LBC* [2010] LGR 99, [165]-[166], and [169] where the linkage between what is incidental and what is necessary is brought out.

arrangements which may have a similar ultimate objective, or be of a generally similar nature, but lacking the detailed requirements, limits and restrictions.[10]

25 Although this principle has been recognised in cases involving "incidental" powers, I think the logic must apply equally to an auxiliary power of the kind in para. 15(1), notwithstanding the difference in wording. Where there is a duty to meet a need by making purchasing arrangements of one very specific kind, it cannot be necessary or expedient for the purposes *of that duty*, or connected with that duty's performance, to meet the need by making purchasing arrangements of a different kind.[11]

26 The next question is whether the auxiliary powers of PCTs can justify alternative local arrangements by reference to PCTs' generally-delegated functions, or their overlapping primary functions under Parts 4-6 of the Act. At first sight, it might seem simple to say that pharmaceutical services are sufficiently linked to the functions of, for example, providing a primary medical service. But there are a number of difficulties with that proposition:

(a) The provision of a medical, dental or ophthalmic service is about ensuring that medical practitioners can advise and treat. It is not the same as paying for drugs and devices which have been ordered for patients, or setting up the retail infrastructure for their provision. That appears to me to be an essentially separate activity.

(b) Of course, a prescription may well result from a visit to the GP, but so too may a hospital visit. No-one could suggest that providing hospitals was therefore necessary or expedient in connection with the performance of the duty to provide primary medical services.

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[10] *Dundee Harbour Trustees v D&J Nicol* [1915] AC 550.

[11] Indeed, from the correspondence I have seen, it does not appear that PCTs have ever sought to justify alternative local arrangements by such reasoning.

(c) The structure of the Act itself appears to draw that distinction by the different treatment of Parts 4-6 and Part 7. The SoS has no function to provide pharmaceutical services (except under s. 133 as a stand-in for a failing PCT). Moreover, s. 3(3) and s. 2(2)(b) specifically provide that those sections do not affect a PCT's duty to arrange pharmaceutical services under s. 126.

(d) Moreover, given that there is detailed treatment of pharmaceutical services functions in Part 7, it would be odd if there was a purely ancillary power to do the same kind of thing. Put more analytically, it would be surprising for an activity which is the subject of a detailed code of primary functions to be equally justified as a mere ancillary power. The very fact that Parliament has treated pharmaceutical services as the subject-matter for a separate primary function suggests that they are not something which can reasonably be regarded as merely subordinate to another primary function.

27 On balance, my conclusion is therefore that the factual and the legal separation of pharmaceutical services from the non-pharmaceutical primary functions conferred on PCTs by or under the Act have the consequence that arrangements for pharmaceutical services cannot be regarded as an ancillary activity to those primary functions.

28 However, for the sake of argument I will assume that my conclusion above is incorrect, and that it is *prima facie* ancillary to a PCT's functions under Parts 4-6 of the Act and/or the 2002 Regulations for it to make arrangements for the supply to the public of NHS prescriptions. The question then is in my view whether such *prima facie* power if conferred by para. 15 is displaced by the presence of a detailed and restricted statutory scheme covering the same ground. I will refer to this contention as "the displacement argument".

The displacement argument

29 The short point in favour of the displacement argument is: what is the purpose in having the elaborate national scheme in s. 126, if it can be displaced at any time by

PCTs making *ad hoc* arrangements for themselves? This point has obvious force and, on that basis alone, the BHTA would have an arguable case that alternative arrangements of the kind under consideration are unlawful. However, further analysis is required to arrive at a final conclusion.

30 I consider that three separate questions arise. First, are alternative arrangements within the auxiliary powers of the PCT if taken in isolation? I have already answered this in the negative but for the purposes of this part of my advice am assuming that there is an affirmative answer, to be found by reference to Parts 4-6 of the Act, the general delegation of the SoS's s. 3 functions, and the broad auxiliary power in Sched. 3 para. 15(1). Second, is that auxiliary power impliedly limited or cut down by the detailed statutory regime for dispensing? Third, if the auxiliary power is not cut down, would alternative arrangements nonethless be an unlawful exercise of the power?

31 In the recent PPI litigation, *R (British Bankers Association) v Financial Services Authority* [2011] Bus LR 1531, the Administrative Court considered whether the FSA's general power to issue guidance requiring firms to give active consideration to schemes of redress for PPI mis-selling was cut down by a specific statutory provision which empowered the FSA to make schemes of redress compulsory, but only with the consent of the Treasury, which had not been sought or obtained.

32 The judge subjected the earlier case of *R v Liverpool CC, ex p. Baby Products* [2000] LGR 171 to what I consider well-founded criticism (see [215]). He held at [248] that the correct question was not whether the specific provision exclusively occupied its field, and then to define that field and ask whether the use of the general powers came within it. Instead, it was whether the general power was limited by necessary implication from the specific provision. That is a fairly high hurdle to meet.

33 In the *BBA* case, although holding at [229] that the specific power was exercisable in the particular circumstances, the judge nonetheless concluded that the general power

remained intact, even though there were similarities in scope and aim [258]. In doing so, he distinguished a number of cases under s. 111 of the Local Government Act [259]. As he pointed out, in the legislation he was considering, both the general and the specific powers were aspects of a remedial code, whereas in the earlier cases, a general ancillary power was cut down by more specific provision. The present case is in the latter not the former category.

34 Despite that distinction, I am not convinced that the general power conferred by Sched. 3 para. 15 (again, assuming against myself that it is *prima facie* available) is necessarily limited by implication from s. 126. In the local government cases, the courts were considering whether councils had powers available under s. 111 of the Local Government Act which provides that incidental powers are conferred *"subject to the provisions of this Act or any other enactment"*. Lord Templeman in *Hazell v LB Hammersmith & Fulham* [1992] 1 AC 1, 31, said that a power was not incidental merely because it was convenient, desirable or profitable. But by contrast, Sched. 3 of the Act expressly deploys the word "expedient". Likewise, Lord Ackner at p. 45 emphasised that the incidental power was subject to the detailed provision for borrowing made in another part of the relevant legislation.

35 Although I consider that the arguments on the second question identified in para. 29 above are finely-balanced, there are much clearer arguments in relation to the third question which I identified, namely whether making alternative arrangements would be contrary to the purpose or policy of the Act. It is a well-established principle of public law that a statutory power may not be exercised for a purpose contrary to the policy of the relevant legislation: *cf. Padfield v Minister of Agriculture* [1968] AC 997; *R v Braintree DC, ex p. Hall* (2000) 32 HLR 770.

36 Unlike most of the previous cases, the present situation involves not a comparison of two *powers*, one specific and one general, but a power and a duty. Moreover, and for the reasons summarised at paragraphs 18 to 20 above, the duty in s. 126 and its associated provisions embodies a clear legislative policy as to how local pharmaceutical needs are to be met. That policy is to *require* use of a specific and

detailed statutory regime. The regime contains provisions which by their very nature strike an economic and social balance between the interests of suppliers in business stability, and the interests of the NHS in achieving economy and efficiency. The balance is one which must have been set by Parliament in the public interest.

37 By s. 126(3)(a), the duty to use this specific regime applies to *"the provision...of...proper and sufficient drugs, medicines and listed appliances which are ordered for [the local population] by a medical practitioner"*. It seems to me inescapable that the policy of the Act – namely, not merely to meet prescription needs, but to do so by using the specific regime of the pharmaceutical list, with all its checks and balances - would be frustrated if PCTs could make alternative arrangements for the supply of medicines or devices to local residents in response to NHS doctors' prescription of those items but which bypassed the pharmaceutical list.

38 Indeed, since prescription needs must be met by making s. 126 arrangements (subject only to the expressly permitted alternatives), the alternative arrangement necessarily involves a failure to comply with that duty. Where a statutory duty exists in a certain situation, the performance of which carries certain consequences which (intentionally) impose further responsibilities on the public body concerned, I do not see how it can be lawful for that public body to exercise a general auxiliary power so as to prevent that duty arising in the first place. Even if, contrary to my conclusions earlier, the alternative arrangements could *prima facie* be justified as ancillary to the duties under Parts 4-6 and the generally-delegated functions of PCTs, the exercise of a power in aid of those duties could not by any known legal doctrine disapply the specific duty under s. 126.

39 Moreover, in so far as PCTs have attempted to justify the alternative arrangements as meeting their "operational needs", I consider that this is a distinction without any legal substance, unless the PCT is using the appliances in a situation which falls outside s. 126(3). That is certainly not the case in the Rotherham situation, which concerns provision of the relevant categories of appliance generally within the

PCT's area in response to prescriptions issued by NHS doctors, *i.e.* the prime example of the situation for which arrangements must be made under s. 126. If a PCT is purchasing appliances solely for use by inpatients, without a prescription, that is outside the scope of s. 126, and of this Opinion.

40 Finally, I do not think that it makes any difference that the appointment of a contractor under alternative arrangements is not exclusive but only a "preferred provider". The critical point is that the terms are not those of a s. 126 arrangement. That being so, there is no general power available to sanction the arrangement.

Conclusion on alternative local arrangements under PCTs' general powers

41 Accordingly I consider that the alternative arrangements are unlawful, unless they can be brought within one of the expressly-defined statutory alternatives to s. 126 under Part 7 of the Act.

Local pharmaceutical services (LPS) schemes

42 The next question is whether the local alternatives are LPS schemes, or at least are capable of being LPS schemes. Such schemes are governed by Sched. 12 of the Act and by the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 (the LPS Regulations). They were introduced first as pilot schemes under primary legislation in 2001 and then generalised in the LPS Regulations five years later.

43 As a preliminary point, it does not appear that any of the alternatives have so far been introduced as LPS schemes. If they were, then the PCT would need to have specifically directed its mind to use of that statutory regime, and would also need to follow the separate rules which apply to (for example) the permissible range of candidates under LPS reg. 7. Reg. 14A also requires notification of schemes "selected for development" to interested persons, which procedure does not appear to have been followed in any of the examples I have seen. However, the question has been raised in correspondence with the Department of Health, and so needs to be addressed even if, so far, it is hypothetical.

44 There is no doubt that an LPS scheme can *include* the supply of appliances. By the LPS Regulations, Sched. 2 para 2(2)(a): *"where the local pharmaceutical services to be provided include the supply of appliances (i) the only appliances which may be supplied are listed appliances, and (ii) those appliances must be supplied in accordance with the provisions of the Notes, and the List of Technical Specifications, which appear at the beginning of Part IX of the Drug Tariff..."*

45 Sched. 2 para. 2(1) provides: *"Where an LPS scheme is limited to the provision of specified drugs or appliances..."*. I can only read this as meaning that a scheme may be limited to, for example, specified appliances only.

46 On the other hand, by reg. 14(1), *"An LPS scheme must specify (a) the services to be provided, which must include the dispensing of drugs"*. It is notable that this language was inserted by amendment in 2007. Before that, the LPS Regulations provided that an LPS scheme must specify *"the dispensing and other services to be provided"*, which therefore left open the content of those services.

47 In my view, reg. 14 overrides what would otherwise be the ordinary meaning of the Regulations, buttressed by Sched. 2 para. 2(1), that an LPS scheme could be limited to appliances only. Moreover, this construction of reg. 14 is supported by Sched. 2, para. 1(4), which states that where the Regulations impose a duty to do something which a human being would normally perform, then (a) *"if the contractor is a registered pharmacist"*, certain rules apply, or (b) a corporate contractor *"must secure compliance with that requirement by the registered pharmacists it employs or engages"*. This provision undoubtedly assumes that the contractor will be or employ registered pharmacists and in turn, therefore, assumes that LPS schemes will involve dispensing drugs, for which a registered pharmacist is required under the Medicines Act 1968. A company which is an LPS contractor would be unable to comply with para. 1(4)(b) if it did not employ a registered pharmacist.

48 The Department of Health have argued that an LPS scheme need not use contractors all of whom engage pharmacists. They rely on para. 1(2) of Sched. 12 of the Act,

which states that an LPS scheme contains one or more agreements. As a preliminary point, I note that this does not apply to the Rotherham example, or indeed any of the earlier examples I have been shown. In none of these instances was there any suggestion that the tender was for a contract which in some way was linked to a service for dispensing drugs. Absent a genuine link, there could be nothing constituting a "scheme".

49 In any event, in my view the DH argument is a misreading of LPS reg. 14(1). It is the *services to be provided* which must include drugs, not the scheme as a whole. Thus any service provision, *i.e.* by *any* contractor, must include drug dispensing.

50 This interpretation is supported by Sched. 2 para. 1(4) which, as noted, makes plain that a contractor must be, or employ or engage, a pharmacist. By contrast, Sched. 3 para. 2(1)(b) of the main regulations, which undoubtedly does apply to appliance-only suppliers, is worded simply so as to require a corporate contractor to secure compliance by *"a person whom he employs or engages"*. A court would be bound to regard this change in wording between the 2006 LPS Regulations and the 2005 main regulations as a deliberate departure from the more neutral template of the earlier wording.

51 Thus I am satisfied that the correct linguistic interpretation is that LPS schemes must involve drug dispensing, as well as the use by a contractor of a registered pharmacist. This reading is also supported by the DH's March 2008 guidance (Chap. 1 para. 7, Chap. 2 paras. 25 and 33). The fact that DACs can be and regularly are appointed to pharmaceutical lists under the main regulations shows that there is no general public policy requirement to have a pharmacist involved in dispensing appliances. Nonetheless the guidance supports the view that an intentional policy choice was made for LPS (to require drug dispensing as a "core service"), although the precise rationale behind that choice is not clear.

52 The extent to which any particular scheme must involve drug dispensing is, in my view, one which would depend on the precise circumstances of each case. I note the following:

52.1 I can see that if an element of drug dispensing were included purely to bring a scheme within the scope of LPS, without any operational justification, questions might arise about an improper or extraneous purpose. The artificiality might in any event be *Wednesbury*-unreasonable.

52.2 I note that in the *BBA* case, the FSA was challenged on the basis that it had adopted its preferred solution in order to avoid cumbersome restrictions under the more specific statutory route, but the judge held that this was not the FSA's main purpose (see [227]). If a particular component of a scheme was adopted solely or mainly to avoid the legal consequences which would otherwise exist, there might be grounds to bring a challenge.

Product rebates and preferred providers

53 Two further questions are raised. First, whether a PCT can seek rebates on the price when operating its pharmaceutical list, *i.e.* arrangements under s. 126. I have not seen any specific examples so can only advise in general. Second, whether a PCT can make preferred provider arrangements to the *de facto* exclusion of undertakings on the pharmaceutical list.

54 In my view, a rebate – by which I mean a return by the supplier of part of the price, or a reduction in the amount otherwise payable by the PCT - would be inconsistent with reg. 56(i), which requires a PCT to pay at the rates determined under s. 164. The same principles would apply to an arrangement in which the PCT required a discount, or extra products to be supplied for no extra remuneration with the purpose of using those extras to meet the local population's NHS prescription needs: this would simply constitute an alternative form of price reduction. In each of these cases, the arrangement would be inconsistent with the duty to make arrangements compliant with the regulations enacted under s. 126. Furthermore, for the reasons

explained above, there is no general power to make arrangements outside s. 126 or the other specific and limited regimes available under Part 7 of the Act.

55 A rebate (or discount or requirement for "free" extra products) could be agreed as part of an LPS scheme, if that scheme were otherwise valid. This is because the LPS Regulations are careful not to include the Drug Tariff in the mandatory conditions of an LPS scheme, except to the limited extent required under LPS Regs, Sched. 2, para. 2(2)(a) (cited in paragraph 44 above). That does not incorporate the price provisions. (I have reached this view independently based on the narrow scope of para. 2(2), but note that the DH's 2008 guidance at Chap. 1 para. 12 and Chap. 4 para. 27 is to the same effect.)

56 Remuneration paid by PCTs to those providing pharmaceutical services (*i.e.* under s. 126 arrangements) may be in respect of the costs of medicines and appliances, or in respect of other aspects of pharmaceutical services: *cf.* Sched. 14 to the Act. However, the principles concerning the validity of rebates etc. apply equally to all forms of remuneration under s. 126 arrangements. That is to say, a PCT may not seek to obtain a rebate etc. in respect of any matter for which it makes payment under such arrangements. The only way in which a price or rebate etc. can be set which diverges from a Drug Tariff price is if the agreement forms part of a valid LPS scheme.

57 As to preferred providers, the same overall point applies: there is no general or auxiliary power to make *ad hoc* local arrangements. I have not considered whether s. 126 arrangements would be necessarily inconsistent with a term conferring preferred provider status (*i.e.* for a supplier on the pharmaceutical list) because, given that the price of such arrangements is fixed, I can see no reason why a PCT would wish to make one supplier its preferred choice. Whether a PCT could in principle agree preferred provider status as part of an LPS scheme is a more difficult question.

58 The concept of a preferred provider is not mentioned in Sched. 12 of the Act nor in the LPS Regulations. However, although any contractors would need to be engaged on terms which included those which Sched. 2 sets out: see reg. 14(2), I do not read that requirement as being exhaustive of all the terms which may be required. Nor are the terms in Sched. 2 so comprehensive that they imply such an outcome. And in general, an LPS scheme does not inherently involve inconsistency with the s. 126 duty because, under Sched. 12 of the Act, a PCT is expressly authorised to take its LPS arrangements into account when deciding what it needs to do to comply with s. 126.

59 However, to agree a preferred provider for (say) an entire class of product by way of an LPS scheme for the whole of the PCT's area would seem to undercut the general statutory regime of the pharmaceutical list and its carefully-controlled price and inclusion criteria. Questions might arise whether such an agreement, even if otherwise satisfying the criteria for an LPS scheme, was a lawful exercise of a PCT's power to make such schemes, where it inevitably undermined the type of arrangement which it was the PCT's basic duty to make. Any such inquiry would be highly fact-specific and I therefore do not comment further.

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