Landmark CHAMBERS

GP PRACTICE MANAGEMENT

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Abbreviations

Accountable Care Organisation	ACO
The Alternative Provider Medical Services Directions 2016	APMS Directions
Care Quality Commission	CQC
Clinical Commissioning Group	CCG
Department for Work and Pensions	DWP
Department of Health and Social Care	DHSC
General Medical Council	GMC
General Practitioner	GP
National Health Service	NHS
National Health Service Act 2006	NHS Act
National Health Service (General Medical Services Contracts) Regulations 2015	GMS Regulations
National Health Service (Personal Medical Services Agreements) Regulations 2015	PMS Regulations
Out of hours	OOH

Introduction

1. General practice has always been at the front line in terms of providing essential medical care to the population. It is a vital component of the NHS as the gateway by which the majority of NHS secondary care services are accessed by NHS patients. In order to access such services, patients must register with an NHS GP Practice as a permanent or temporary patient in order to receive services from an NHS GP and to be referred by that GP to secondary care providers.

2. In what is a seemingly constantly changing policy context, GPs remain of central importance to the Department of Health and Social Care ("DHSC") and NHS England's[1] vision for an increasingly integrated health and social care system. As part of its General Practice Forward View published in April 2016, NHS England announced its intention, in conjunction with Clinical Commissioning Groups ("CCGs"), to commission extended access to primary care appointments and encourage new models of providing primary care. This includes integrating primary care with community, urgent and acute services. By way of example, from December 2017 patients all across London have been able to access GP services across extended hours on weeknights and Saturdays for the first time ever.

3. However, it is widely reported that general practice is "in crisis", with GPs complaining of growing pressures as a result of an increased demand and consequent work load, under-staffing and the burden of keeping up-to-date with constantly evolving models of care.[2] Part of the reason is that the management of patients with long term conditions has moved from hospital based services to GP services inexorably over the last 25 years as the number of patients with one or more long term conditions increases. This relieves pressure on NHS acute care but makes the role of GP more complex, particularly as the promised secondary care support is uneven across the country.

4. Against this background this chapter seeks to explain exactly **which** services GP practices are required to provide under their contracts (and what other services they can contract to provide), **when** they must provide those services, to **whom**, **how** they must manage the services provided to their patients, and when they can **charge** for services provided to patients.

5. It should be noted that, to the best of these authors' knowledge, this chapter represents the law at the time of writing. However, as stated above, the policy context within the NHS and the models of primary care proposed by NHS England and the DHSC are in constant flux. The legality of many of these models and their associated contracts is uncertain (particularly given the proposal to change the contracting structures entirely by creating the Accountable Care Organisations ("ACOs") model and draft ACO contract, concerning which there may be

[1] The legal title of NHS England is The National Health Service Commissioning Board. It refers to itself as "NHS England", although this has no bearing on its legal functions. Please see Chapter X on the powers and duties of NHS England for further information.
[2] See, for example, Beccy Baird, The King's Fund, "Is general practice in crisis?", 1 June 2017: https://www.kingsfund.org.uk/publications/articles/big-election-questions-gp-crisis.

clarification from the courts in future[3]). Changes to primary and secondary legislation may be forthcoming to address this. Readers should therefore ensure that they read this chapter along with any updates that may be issued.

Overview of the legal framework governing general practice management

6. The primary duty to commission primary care services rests with NHS England. Section 83(1) of the National Health Service Act 2006 ("the NHS Act") provides:

   > *"The Board must, to the extent that it considers necessary to meet all reasonable requirements, exercise its powers so as to secure the provision of primary medical services throughout England"*

7. The nature of this duty means that there is no absolute requirement on NHS England to ensure that every individual is able to register with a GP practice which is local to their home. The duty requires NHS England to set up a network of GP services to meet the "reasonable requirements" of patients. What is "reasonable" will depend on a number of things, in particular what the needs are of the local population for which NHS England is commissioning services, but it is axiomatic that one relevant factor will be the level of resources available. However, NHS England is also under duties to tackle health inequalities in exercising its commissioning functions, and this duty may affect the way it is required to commission primary care services[4].

8. Once NHS England has discharged its duty by ensuring such a network of primary care services is available, it is a matter of choice for individual patients as to whether to register themselves with a GP practice to receive such services or not to do so. There is no obligation on anyone living in England to register with an NHS GP Practice. As is explored below, however, there are limited circumstances in which a patient can receive primary care services if they do not register with a GP.

9. NHS England complies with the duty under section 83(1) of the NHS Act by "making arrangements" for the provision of primary medical services with GP practices or those running such practices. Section 83(2) of the NHS Act provides:

   > *"The Board may (in addition to any other power conferred on it) make such arrangements for the provision of primary medical services as it considers*

[3] At the time of writing there are 2 challenges proceeding against the DHSC/NHS England models concerning ACOs. One has been granted permission.

[4] Include cross reference to relevant part of NHS England chapter.

appropriate; and it may, in particular, make contractual arrangements with any person."

10. The way that NHS England discharges this duty in each area is to set up a series of contracts (either legally binding contracts or NHS contracts) with GP practices who agree to provide primary medical services to patients in that area.[5] It is becoming increasingly common for GP practices to join "federations" or "super partnerships", which broadly can be described as more than one practice working collaboratively to varying degrees legally and organisationally. That federation or partnership may hold a contract with NHS England rather than the individual practices.

11. In recent years, NHS England has moved to a model of primary care co-commissioning, whereby it either partially or wholly delegates its responsibility for primary care commissioning to local CCGs. NHS England, however, retains ultimate responsibility for primary care commissioning under the section 83 primary duty to meet reasonable requirements and is named as the commissioning party in any primary care contract.

12. As explained in the chapter on primary care contracting[6], under sections 83(2), 84 and 92 of the NHS Act, NHS England has created three types of contract, by which it discharges its duty to make arrangements to meet reasonable requirements throughout England:

    a. A **General Medical Services ("GMS") Contract**. This is a nationally negotiated contract which takes effect between NHS England and a GP practice. Its central features are (a) that it potentially exists in perpetuity for the practice (b) if it is a contract with a partnership, it exists with the partners as they exist from time to time and (c) the contractual fees payable are set by Directions made by the Secretary of State. The GMS contract is the default option for many GP practices since a PMS contractor has a statutory right to revert to a GM contract. Although APMS contracts became a popular method of contracting, for reasons that are explored in the chapter on primary care contracting, the majority of practice contracts are still GMS contracts and many PMS contracts are now being changed to operate far more like GMS contracts.

    b. A **Personal Medical Services ("PMS") Contract**. This is a local contract and some of the terms can be agreed between NHS England and the practice, including funding arrangements. However, many of the terms of the PMS contract are governed by the Regulations which require the contract to contain terms which replicate a GMS contract. PMS contracts are almost always time-limited contracts (but the practice can "convert" to a GMS contract which has no time limit).

    c. An **Alternative Provider Medical Services ("APMS") Contract**. This allows NHS England to contract with "any person" to provide primary care services under local

[5] Please see Chapter X on primary care contracting for further information.

[6] And thus the relevant statutory provisions are not intended to be addressed in detail here.

commissioning arrangements. APMS contracts are individually negotiated although some of the terms found in PMS contracts (themselves based on the GMS contract) are mandatory under Directions published by the Secretary of State for Health. They are time-limited.

13. The conditions and terms that are required to be in the various forms of contract are set out in regulations, in the case of GMS and PMS contracts, and directions, in the case of APMS contracts:

    a. GMS contracts are governed by the National Health Service (General Medical Services Contracts) Regulations 2015 ("the GMS Regulations");

    b. PMS contracts are governed by the National Health Service (Personal Medical Services Agreements) Regulations 2015 (the "PMS Regulations"); and

    c. APMS contracts are governed by The Alternative Provider Medical Services Directions 2016 (as amended by the Alternative Provider Medical (Amendment) Directions 2017).

14. Once the NHS commissioner and the practice have agreed the contract (which ought to comply with the statutory duties on NHS England as set out in the relevant regulations or directions), the terms of the agreement take effect as a normal commercial contract between the parties (see *Tomkins v Knowsley Primary Care Trust* [2010] EWHC 1194 (QB) per Hickinbottom J at paragraph 5). The GP practice will owe various duties under private law of negligence to patients, which will no doubt be informed by the services specified in the contract, but the duty to provide the services under the terms set out in the contract will be a separate contractual duty owed to the commissioner.

15. In addition to fulfilling their contractual obligations, as noted in the GMS and PMS Regulations, and remarked upon by Arnold J in *Generics (UK) Limited (Trading as Mylan) v Warner-Lambert Company LLC* [2016] R.P.C. 3 at para. 555, GPs are also required to have regard to guidance issued by NHS England, although they are not obliged to follow it if they have good reasons to depart from it.

16. In November 2017, NHS England published a comprehensive guidance document entitled, "**Primary Medical Care Policy and Guidance Manual (PGM)**". This document contains guidance on many of the issues discussed in this chapter and in the chapter on primary care contracting.

17. This chapter will explore which services GPs are contractually obliged to provide, when and under what terms; what types of other services they might provide; how a practice must manage its list of registered patients and deal with unregistered patients; and when it can charge for services. In doing so it will predominantly focus on the GMS regulations, since not

only do they direct the content of GMS contracts, but they also inform to a large extent the content of PMS contracts, and are the basis for some mandatory terms in APMS contracts.

The services provided by GP practices

What are primary medical services?

18. Sections 83(5) and (6) of the NHS Act provide:

> *"(5) Regulations may provide that services of a prescribed description must, or must not, be regarded as primary medical services for the purposes of this Act.*
>
> *(6) Regulations under this section may in particular describe services by reference to the manner or circumstances in which they are provided"*

19. The GMS Regulations contain a somewhat circular definition of "primary medical services", describing them in regulation 3 "*as medical services provided under or by virtue of a contract or agreement to which the provisions of Part 4 of the 2006 Act applies*". However, as set out above, section 83 of the 2006 Act states that regulations may provide that certain services are "primary medical services", which those delivering primary care within the NHS are obliged to or may provide.

20. Part 5 of the GMS Regulations contains a number of terms which must be included within practice contracts with NHS England held by GP practices. Some of these terms relate to services that must or may be provided under a contract. From these, it can be deduced that "primary medical services" include the following categories of service, which are explored below:

    a. essential services (including emergency services);
    b. additional services;
    c. enhanced services
    d. out of hours services; and
    e. other services provided for in the regulations.

Essential services

21. The current definition of "essential services" for primary care is set out at Regulation 17 of the GMS Regulations as follows:

    (1) Subject to paragraph (2), for the purposes of section 85(1) of the Act (requirement to provide certain medical services), the services which must be provided under a

contract ("essential services") are the services described in paragraphs (4), (6), (7) and (9).

(2) Essential services are not required to be provided by the contractor during any period in respect of which the Care Quality Commission has suspended the contractor as a service provider under section 18 of the Health and Social Care Act 2008 (suspension of registration).

(3) Subject to regulation 20(2)(b) and (c), a contractor must provide the services described in paragraphs (4) and (6) throughout the core hours.

(4) The services described in this paragraph are services required for the management of a contractor's registered patients and temporary residents who are, or believe themselves to be—

a) ill, with conditions from which recovery is generally expected;
b) terminally ill; or
c) suffering from chronic disease,
d) which are delivered in the manner determined by the contractor's practice in discussion with the patient.

(5) For the purposes of paragraph (4)—

"disease" means a disease included in the list of three-character categories contained in the tenth revision of the International Statistical Classification of Diseases and Related Health Problems 1…

22. This definition is incorporated into the PMS Regulations in its entirety by Regulation 3.

23. The above provisions, and the scope of "primary medical services", need to be interpreted in the light of the NHS Act as a whole, which divides healthcare services into different categories. Acute medical services come within Part 1 of the NHS Act and primary care services fall within Part 4 of the NHS Act. Other parts of the Act provide for dental and pharmaceutical services to be delivered as part of NHS funded care.[7]

24. Although there is an inevitable measure of overlap between acute services and primary care services, where services are classified as "acute services" under Part 1, they are generally not primary care services under Part 4. Acute services are widely defined in section 3(1) of the NHS Act as follows:

"(a) hospital accommodation,

(b) other accommodation for the purpose of any service provided under this Act,

[7] See chapters X, Y, Z

(c) medical, dental, ophthalmic, nursing and ambulance services,

(d) such other services or facilities for the care of pregnant women, women who are breastfeeding and young children [as the group considers] are appropriate as part of the health service,

(e) such other services or facilities for the prevention of illness, the care of persons suffering from illness and the after-care of persons who have suffered from illness [as the group considers] are appropriate as part of the health service,

(f) such other services or facilities as are required for the diagnosis and treatment of illness"

25. Where a CCG, which has responsibility for commissioning acute services, commissions relevant services under section 3(1) of the NHS Act, a GP can discharge his or her obligations as a provider of primary care by referring an NHS patient onto another NHS provider where his or her patient requires one of those acute services. The "essential services" that are required to be provided by GPs are therefore a much narrower group of services.

26. The core requirement on a GP who provides essential services to NHS patients is "*the management of*" such patients. Regulation 17(5) provides that, "management" of a patient includes:

"(a) offering consultation and, where appropriate, physical examination for the purposes of identifying the need, if any, for treatment or further investigation; and

(b) making available such treatment or further investigation as is necessary and appropriate, including the referral of the patient for other services under the Act and liaison with other health care professionals involved in the patient's treatment and care."

27. This is expanded by Regulation 17(6) which provides that management of the GP's patients includes the provision of appropriate ongoing treatment and care to all registered patients and temporary residents taking account of their specific needs including:

    a. the provision of advice in connection with the patient's health, including relevant health promotion advice; and

    b. the referral of the patient for other services under the NHS Act (which normally means referral for acute and community services under section 3 of the NHS Act).

To whom must GPs provide "essential services"?

28. The persons to whom the GP is obliged to offer this "management" service are:

    a. The patients on the list for the GP practice held by NHS England; and

    b. Temporary patients.

29. These are precisely defined terms under the GMS Regulations, and are explored below in the section on patient list management.

30. The GP practice is not obliged to offer "management services" to every patient on their list for every minute of the core hours (because that would be an impossible task to fulfil and would mean offering services where they were not needed). The contractual duty is to provide services to patients who are, or *believe* themselves to be:

    a. ill, with conditions from which recovery is generally expected;

    b. terminally ill; or

    c. suffering from chronic disease.

31. The expression "illness" is defined in section 275 of the NHS Act as follows:

    ""illness" includes any disorder or disability of the mind and any injury or disability requiring medical or dental treatment or nursing"

32. There are thus two important implications of the scope of this duty. The first is that the duty to provide management services to a patient is engaged by the patient's own *subjective* belief that they are ill. Thus, a GP practice is obliged to see and offer management services to a patient who believes himself or herself to be ill even if that person is not, in fact, suffering from any diagnosable illness. Of course, a patient who was suffering from hypochondria and continually believed themselves to be ill might indeed require treatment of some sort. Which leads into the second implication of the duty, which is that "illness" is defined extremely broadly. The wide definition means that, for example, a drug addiction is likely to be an "illness" because drug addiction changes the brain in fundamental ways, disturbing a person's normal hierarchy of needs and desires and substituting new priorities connected with procuring and using the drug. The resulting compulsive behaviours that override the ability to control impulses despite the consequences are similar to hallmarks of other mental illnesses. The behaviour can be classified as an illness in ICM 10 within the International Statistical Classification of Diseases and Related Health Problems and thus GP practices have the same management duty to such patients as they have to patients with any other illness.

33. A GP is obliged to provide a management service to a patient "*in the manner determined by the contractor's practice in discussion with the patient*" (Reg. 17(4) of the GMS Regulations). Thus, the patient is entitled to be consulted about the way in which general

medical services are provided to the patient but the final decision about the manner in which services should be provided (including the location at which the services should be provided) rests with the GP.

When are GPs obliged to provide essential services?

34. The GMS Contract (and virtually all PMS Contracts) provides that the contractual duty on the GP practice to provide the essential services is only operative during "core hours". These hours are defined in Regulations 3 of the GMS and PMS Regulations as follows:

> *"core hours" means the period beginning at 8.00am and ending at 6.30pm on any day from Monday to Friday except Good Friday, Christmas Day or bank holidays*"

35. However, the GMS Contract does not require the GP practice to make a GP available in person to provide routine services to patients throughout the core hours. Under Regulation 20 the duty to provide services within core hours has 2 parts, namely:

    a. to provide the essential services and additional services funded under the global sum[8] within core hours, "*as are appropriate to meet the reasonable needs*" of its patients; and

    b. to have in place arrangements for its patients to access such services throughout the core hours in case of emergency.

36. Thus, if GP practice premises are closed at any point during the core hours, the GP practice either must provide a means for patients to be able to access one of the practice GPs throughout that period or must make arrangements with an out of hours provider to provide emergency GP services to patients during that period. There are no set surgery hours within the GMS contract but the opening hours need to be sufficient to "*meet the reasonable needs of its patients*".

37. There has been considerable discussion in the professional press about practices which do not provide sufficient surgery slots to meet the needs of patients and thus patients find themselves having to wait for an appointment time. In the past, the Labour government had a policy that patients should have a maximum period of waiting of 48 hours before seeing a GP. However, that target was abandoned by the coalition government in 2010. The present position is that there is no specific time target but the NHS website states:

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[8] The "global sum" is defined in Regulation 3 of the GMS Regulations as "*having the meaning given in the GMS Statement of Financial Entitlements*", which are directions as to payments to be made under GMS contracts. The "global sum" is a contribution towards the contractor's costs in delivering essential and additional services, including its staff costs. It represents the core funding for GP practices and is calculated by reference to a formula. See primary care contracting chapter.

> *"Your surgery should be able to offer you an appointment to see a GP or other healthcare professional quickly if you need it. However, you should also be able to book appointments in advance if this is more convenient."*[9]

38. GP practices which fail to provide a sufficient number of surgery appointments to meet the reasonable needs of their patient populations are probably acting in breach of the contractual requirement to provide services to "*meet the reasonable needs of its patients*" and could find that NHS England/the CCG serve a Remedial Notice to require them to extend the number of surgery appointments. However, NHS England (or its delegate the CCG) is the only party that can enforce compliance with the contract. Patients can, however, seek to put pressure on NHS England to enforce the terms of the contract and could consider a judicial review action against NHS England if it failed to do so.

The duty on GP practices to provide emergency services

39. GPs are not paramedics and will not usually be called to a medical emergency within their practice area. However, under Regulation 17 of the GMS Regulations, as part of the "essential services" provided by the GP Practice, it must also provide a range of emergency services in defined circumstances. These are as a result of an accident or emergency in its practice area or constitute emergency care for certain patients who are not on its registered list. Given that the definition of "essential services" is incorporated into the PMS Regulations in its entirety, PMS contractors will also be obliged to provide emergency services in the core hours as defined in the contract.

Accident and emergency care

40. Regulations 17(7) and (8) of the GMS Regulations provide:

> *"(7) A contractor must provide primary medical services required in core hours for the immediately necessary treatment of any person to whom the contractor has been requested to provide treatment owing to an accident or emergency at any place in its practice area.*
>
> *(8) In paragraph (7), "emergency" includes any medical emergency whether or not related to services provided under the contract"*

41. This is an obligation to react to requests for assistance made at any time throughout the core hours. The contractual duty to provide services only comes into effect if the GP practice has been "requested" to provide emergency primary care services in the event of an accident or emergency taking place anywhere in the practice area. The identity of the person making the request is not specified in the Regulations and the request therefore could be made by the police, fire brigade, paramedics or a member of the public (whether a

[9] https://www.nhs.uk/chq/Pages/2555.aspx?CategoryID=68&SubCategoryID=158

patient on the practice list or not). The Regulation does not specify what sort of service the GP is required to provide beyond saying that the GP must provide primary medical services. Thus, the GP has to provide the same type of "management" services for the patient in an emergency situation as he or she would provide in the surgery. This includes:

a. physical examination for the purpose of identifying the need, if any, for treatment or further investigation; and

b. the making available of such treatment or further investigation as is necessary and appropriate, including the referral of the patient for other services under the Act and liaison with other health care professionals involved in the patient's treatment and care.

42. It seems clear that, in order to comply with the contractual obligation, the practice would have to send out a qualified GP who could administer such services as could be reasonably expected from a GP as opposed to a specialist in emergency medicine. The contractual obligation is likely to be fulfilled if the GP arrives at the scene of the accident or emergency reasonably promptly and provides a primary medical service whilst, at the same time, calling for help from specialist emergency practitioners.

Emergency care for certain patients who are not on the registered list

43. The second type of emergency service that a GP practice is required to provide is "immediately necessary treatment" to someone who is not on the list of patients for the practice and is not a temporary patient but who comes within certain specified categories. Regulation 17(9) to (11) provides the contractual duty is as follows:

"(9) A contractor must provide primary medical services required in core hours for the immediately necessary treatment of any person to whom paragraph (10) applies who requests such treatment for the period specified in paragraph (11).

(10) This paragraph applies to a person if—

a) that person's application for inclusion in the contractor's list of patients has been refused in accordance with paragraph 21 of Schedule 3, and that person is not registered with another provider of essential services (or their equivalent);

b) that person's application for acceptance as a temporary resident has been refused under paragraph 21 of Schedule 3; or

c) that person is present in the contractor's practice area for a period of less than 24 hours.

(11) The period specified in this paragraph is, in the case of a person to whom—

a) paragraph (10)(a) applies, 14 days beginning with the date on which that person's application was refused or until that person has been subsequently

registered elsewhere for the provision of essential services (or their equivalent), whichever occurs first;

b) paragraph (10)(b) applies, 14 days beginning with the date on which that person's application was rejected or until that person has been subsequently accepted elsewhere as a temporary resident, whichever occurs first; or

c) paragraph (10)(c) applies, 24 hours or such shorter period as the person is present in the contractor's practice area."

44. The contractual duty on a GP practice to provide emergency services is thus limited in 3 ways:

    a. It is not a duty to provide a full primary care service to these patients but only to provide immediately necessary treatment to such patients. There is clearly a measure of judgment that the GP practice will have to make as to what services are within this requirement and which services can be left for another GP to provide in due course;

    b. The duty is limited to those categories of patients set out in Regulation 17(10) namely individuals who have applied to join the practice list and been refused, who have been rejected as temporary residents or are in the practice area for less than 24 hours;

    c. The duty is time limited in that for patients who have been rejected from the practice list either as permanent or temporary patients, the duty only lasts for a maximum of 14 days but can come to an end if the patient secures another GP in that period and, in the case of a person only in the practice area for 24 hours, is limited to a maximum of 24 hours.

45. A person who has been accepted onto the practice list and is then removed from the list because, for example, the patient has been violent to staff members, does not come within Regulation 17(10) of the GMS Regulations unless that person applies to re-join the practice list and is refused. Equally, a person who has applied to join the practice list but has not yet been accepted or refused does not come with this provision. The GP practice is therefore under no contractual duty to provide services to such a patient.

46. The Regulations do not explain what happens if, at the end of the 14-day period, the rejected patient presents at the surgery seeking a further course of "immediately necessary treatment". It seems likely that the duty under Regulation 17(10) of the GMS Regulations is a "one off" duty to an individual and that, once the period specified in Regulation 17(11) has ended the GP practice has no further duty to provide medical services to that individual. If it were otherwise a patient who had been refused entry onto the practice list as a result of violence to staff could, for example, keep seeking services under this provision and thus remain a threat to staff.

Additional Services

47. Essential services are the range of services that GP practices are obliged to provide as a minimum to their practice patients and temporary residents. However, pursuant to Regulation 19 of the GMS Regulations, GP practices can contract to provide extra services to patients and thus avoid the need for the GP practice to refer patients who need such services elsewhere. Services which are extra to the essential services (as described above) are classified as "additional services" and "enhanced services". GP practices are not obliged to contract to provide additional services but they are paid additional sums (usually as part of the global sum) where they agree to do so.

48. "Additional services" are defined in Regulation 3 of the GMS Regulations as follows:

> *""additional services" means one or more of-*
>
> *a) cervical screening services;*
>
> *b) contraceptive services;*
>
> *c) vaccines and immunisations;*
>
> *d) childhood vaccines and immunisations;*
>
> *e) child health surveillance services;*
>
> *f) maternity medical services; and*
>
> *g) minor surgery"*

49. Under Regulation 19, where a GP practice opts to provide such a service, it must include, within its contract:

    a. a term which has the same effect as that specified in Schedule 1, paragraph 1 (i.e. that the contractor must provide, in relation to each additional service, such facilities as are necessary to enable the contractor to properly perform that service); and

    b. a term which has the same effect as that specified in in Schedule 1 in so far as they are relevant to the specific service which the practice is opting to provide

50. Schedule 1 of the GMS Regulations contains specific requirements when GP practices provide the defined "additional services". Hence, for example, GP practices that agree to provide contraceptive services are required to provide services in the following way (Schedule 1, para. 3):

"(1) A contractor whose contract includes the provision of contraceptive services must make the services described in sub-paragraph (2) available to all of its patients who request those services.

(2) The services described in this sub-paragraph are—

(a)the giving of advice about the full range of contraceptive methods;

(b) where appropriate, the medical examination of patients seeking such advice;

(c) the treatment of such patients for contraceptive purposes and the prescribing of contraceptive substances and appliances (excluding the fitting and implanting of intrauterine devices and implants);

(d) the giving of advice about emergency contraception and, where appropriate, the supplying or prescribing of emergency hormonal contraception or, where the contractor has a conscientious objection to emergency contraception, prompt referral to another provider of primary medical services who does not have such an objection;

(e) the giving of advice and referral in cases of unplanned pregnancy including advice about the availability of free pregnancy testing in the contractor's practice area and, where appropriate, where the contractor has a conscientious objection to the termination of pregnancy, prompt referral to another contractor who does not have such an objection;

(f) the giving of initial advice about sexual health promotion and sexually transmitted infections; and

(g) the referral as necessary to specialist sexual health services, including tests for sexually transmitted infections."

51. The contract can specify that the GP practice should provide additional services to the practice patients and persons accepted by the GP practice as temporary residents. However the GMS contract can also be extended so that such services are provided to a wider range of patients. Hence, for example, a GP practice could develop a specialism in minor surgery or be contracted to provide contraceptive services to a wider range of patients than just those on its practice list.

When are GPs obliged to provide additional services?

52. The same requirements as to providing essential services in the core hours apply to additional services that are funded under the global sum. Readers are asked to refer to the section above on essential services.

Enhanced Services

53. Enhanced services are defined in Regulation 3 of the GMS Regulations as follows:

> *““enhanced services” are-*
>
> *services other than essential services, additional services or out of hours services;*
>
> *or*
>
> *essential services, additional services or out of hours services or an element of such a service that a contractor agrees under a contract to provide in accordance with specifications set out in a plan, which requires of the contractor an enhanced level of service provision compared to that which it needs generally to provide in relation to that service or element of service”*

54. Enhanced services are therefore something that goes above and beyond the essential services, additional services, or out of hours services required by the regulations, be that the *type* of service altogether that is provided or the hours or intensity of service provision. There is no limit on the type of enhanced services that a commissioner and a GP practice can agree to be provided to NHS patients, provided that the service can properly be considered to be part of the health service. The terms fall to be agreed between the commissioner and the provider.

55. The archetypal “enhanced services” are extended hours. There is a present focus among commissioners on extending the hours during which GP practices provide routine primary care appointments, as a means to tackle the pressures on urgent and emergency services. This is not without controversy, however, in the professional GP press.

56. Certain enhanced services schemes are provided for nationally as “Directed Enhanced Services”. The nature of those services is set out in Directions, the most recent of which are the Primary Medical Services (Directed Enhanced Services) Directions 2017. They provide that NHS must operate the following enhanced services schemes to meet its reasonable requirements duty under section 83 of the NHS Act, which it must offer to GP Practices to be part of their GMS or PMS contract:

    a. An Extended Hours Access Scheme, the underlying purpose of which is to enable patients to consult a health care professional, face to face, by telephone or by other means at times other than during the core hours specified in the contractor’s

primary medical services contract, as agreed with the Board – these are not "out of hours" services, which are explained below, but are routine bookable appointments;

b. A Learning Disabilities Health Check Scheme;

c. A Childhood Immunisation Scheme;

d. An Influenza and Pneumococcal Immunisation Scheme;

e. A Violent Patients Scheme; and

f. A Minor Surgery Scheme.

57. These schemes apply on yearly basis, after which the terms might change. For example, in this year's Extended Hours Access Scheme, the Directions have introduced a requirement that a practice that closes for a half day on a weekly basis cannot join the scheme, unless by written prior agreement with NHS England. It is understood by these authors that this requirement is a reaction to the perception that (often single handed) practices that close for long periods during the day produce worse clinical outcomes for their patients.

58. Another example of enhanced services provision is the recent introduction in London of the London Extended GP Access Service, which allows all Londoners registered with a GP practice to book routine GP, and in some case nurse, appointments in the evenings, weekends and on bank holidays. This scheme was proposed in the GP Forward View. These services were commissioned by NHS England and CCGs working together under the Transforming Primary Care in London: A Strategic Commissioning Framework. As with the Directed Extended Hours Access Scheme, practices do not necessarily provide these services individually, but CCGs have typically contracted strategically with a number of practices so that they provide these services collectively. Therefore, a patient might have to go to a different practice to see a GP or see a GP other than their usual GP. These kind of enhanced services can "wrap around" a practice's GMS or PMS contract and are often procured by way of an APMS contract.

Out of Hours Services

59. Regulation 3 defines out of hours services as "*the services required to be provided in all or part of the out of hours period which (a) would be essential services if provided by a contractor to its registered patients in core hours; or (b) are included in the contract as additional services funded under the global sum.*" The out of hours period is the remainder of the time outside the core hours as defined by the GMS Regulations, so from 6.30pm on Monday to Thursday to 8am the following day, the weekend starting at 6.30pm on Friday and ending at 8am on Monday, and Good Friday, Christmas Day, and bank holidays.

60. Therefore, and as explained above, the out of hours period does not include any period where a GP practice closes during contracted hours, during which time the practice has a responsibility (including a financial responsibility) to provide cover.

61. If a GP has signed up to an extended access scheme, either the Directed Enhanced Services scheme, or a local scheme, it is likely that these appointments will be routine bookable appointments. Out of hours ("OOH") services therefore would co-exist with this enhanced provision, since there will still be patients who require urgent primary care in a community setting and have not booked an appointment in advance. However, in practice, patients will access these services via an Extended Hours scheme rather than through an OOH provider (which is likely to be different to the GP Practice).

62. Until 2004 GP practices were required to provide essential service to patients at all times of the day and night. Many practices used deputising services to provide services to patients outside of core hours. Thus, in practice, prior to 2004 many patients would not see their family doctor if they sought GP OOH services. However, from 2004 GP practices were entitled to opt-out of responsibility for providing OOH services. The vast majority of GP practices did so and accordingly the responsibility for OOH GP provision fell to primary care trusts (the predecessors of CCGs) to arrange.

63. The present duty to commission OOH primary care services for GP practices which have opted out of OOH responsibilities lies with the CCG and not NHS England. It follows that CCGs need to be careful to observe the rules on conflicts of interest in any contract process where one of the bidders includes GPs who work within a local GP practice (and are therefore connected to members of the CCG).[10]

64. The way OOH services are structured varies. CCGs typically arrange for the provision of OOH services by entering into contracts with specific OOH providers, including co-operatives of local GPs. There have been a series of scandals concerning OOH providers, such as Serco in Cornwall, which was issued with a warning notice by the CQC for failing to meet essential health and safety standards and subsequently gave notice to terminate the contract. It is becoming increasingly common for OOH providers to be GP-led social enterprises or community interest companies, such as Devon Doctors.

65. Despite the widely-reported problems with OOH providers, analysis by Urgent Health UK of data from approximately half of all GP urgent care providers found that they have an important role to play in reducing pressure on the acute system, ensuring that patients are cared for in the community when appropriate.[11] Nonetheless, worrying stories about understaffing of OOH provision continue to emerge. A freedom of information request by

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[10] Please see Chapter X on the Powers and Duties of CCGs, which explores how CCGs should manage conflicts of interest.

[11] http://www.pulsetoday.co.uk/news/commissioning/commissioning-topics/urgent-care/out-of-hours-gps-are-keeping-hundreds-of-thousands-of-patients-out-of-ae/20033831.article.

Pulse magazine, a major professional publication for GPs and healthcare professionals, found 10 areas where patients were left with no GP available during out of hours shifts in 2016.[12] Any failure by the OOH provider to fulfil its contractual obligations with the CCG could lead to enforcement action by the CCG. However that will not, of itself, inevitably leave the CCG in breach of the terms of its statutory obligation to make the appropriate OOH arrangements because the arrangements are in place, albeit not being performed. There may, however, come a time when the failure to provide a robust service will leave the CCG in breach of this duty.

Obligations on GPs who have not opted out of OOH

66. Regulation 18(2) of the GMS regulations provides that, where a GP practice has contracted to provide OOH services, it:

> *"(a) is only required to provide out of hours services to a patient if, in the contractor's reasonable opinion having regard to the patient's medical condition, it would not be reasonable in all the circumstances for the patient to wait to obtain those services; and*
>
> *(b) must, in the provision of out of hours services—*
>
> > *(i)meet the quality requirements set out in the document entitled "National Quality Requirements in the Delivery of Out of Hours Services" published on 20th July 2006 1, and*
> >
> > *(ii) comply with any requests for information which it receives from, or on behalf of, the Board about the provision by the contractor of out of hours services to its registered patients in such manner, and before the end of such period, as is specified in the request."*

67. A judgement call is therefore required by the contractor as to whether a patient presenting out of hours could wait until the morning to receive services. It is also a matter for the judgment of the GP whether advice given over the telephone is sufficient, whether the GP should visit the patient or whether the patient should be advised to attend a local A & E.

Obligations on GPs who have opted out of OOH

68. However, even where a GP practice has opted out of providing OOH services, it will have some responsibility relating to the OOH care that its patients receive, including quality

[12] http://www.pulsetoday.co.uk/your-practice/practice-topics/out-of-hours/revealed-why-out-of-hours-is-on-a-knife-edge/20033775.article

monitoring and reporting requirements. This is set out in Regulation 18(3) of the GMS Regulations:

> *"(3) Where a contractor is not required to provide out of hours services under a contract or, by virtue of Part 6, has opted out of the provision of such services under the contract, the contractor must—*
>
> *(a) monitor the quality of the out of hours services which are offered or provided to the contractor's registered patients having regard to the National Quality Standards referred to in paragraph (2)(b), and record, and act appropriately in relation to, any concerns arising;*
>
> *(b) record any patient feedback received, including any complaints;*
>
> *(c) report to the Board, either at the request of the Board or otherwise, any concerns arising about the quality of the out of hours services which are offered or provided to patients having regard to—*
>
> *(i) any patient feedback received, including any complaints, and*
> *(j) (ii) the quality requirements set out in the National Quality Standards referred to in sub-paragraph (2)(b)."*

69. It should be noted that, since 2013, the NHS has also been operating the NHS 111 telephone service. The NHS website describes the function of NHS 111 with respect to OOH care as follows:

> *"The NHS pledges to provide services at a time that's convenient for you. Outside normal surgery hours you can still phone your GP practice, but you'll usually be directed to an out-of-hours service. The out-of-hours period is from 6.30pm to 8.00am on weekdays and all day at weekends and on bank holidays.*
>
> *Consider calling NHS 111 if you urgently need medical help or advice, but it's not a life-threatening situation. You can also call NHS 111 if you're not sure which NHS service you need."*[13]

70. Thus, patients who need primary care support out of hours have the alternative of calling NHS 111 in order to find out and to be directed towards the appropriate service.

71. Following the Urgent and Emergency Care review led by Sir Bruce Keogh, which was announced in 2013, NHS England has set out in the GP Forward View its intention to move towards integrated 24/7 urgent care services, which includes the NHS 111 service as well as OOH and other urgent care services. NHS England has also published guidance for

[13] https://www.nhs.uk/NHSEngland/AboutNHSservices/Emergencyandurgentcareservices/Pages/NHS-111.aspx (accessed on 18 November 2017)

commissioners with responsibility for OOH and urgent care commissioning: Commissioning Standards Integrated Urgent Care.[14]

Where must GPs provide services to patients?

72. The default position is that a contractor must provide "premises", that is to say a GP practice building, from where services may be provided. Regulation 20(1)(b) of the GMS Regulations (and 13(1)(b) of the PMS Regulations) provides that the contract must specify the name of the premises. However, Regulation 20(4) of the GMS Regulations (and Regulation 13(3) of the PMS Regulations) provides that those premises do not include the homes of any patients or any other premises where services are provided on an emergency basis.

73. Patients who seek assistance from their GP are, by definition, ill (or at least consider themselves to be ill). Some of these patients will be too ill to be able to attend the surgery premises or, if they have an infectious condition, it may not be medically appropriate for them to attend the GP surgery because they may spread their condition to other patients. Thus treating patients at their own home has always been part of the work of a GP.

74. Schedule 3, paragraph 5 of the GMS Regulations and Schedule 2, paragraph 6 of the PMS Regulations have the following provision which sets out when a GP is obliged to treat a patient outside the surgery premises:

> *"(1) Where the medical condition of a patient is such that, in the reasonable opinion of the contractor—*
>
> *(a) attendance on the patient is required; and*
> *(b) it would be inappropriate for the patient to attend the contractor's practice premises,*
>
> *the contractor must provide services to the patient at whichever of the places described in sub-paragraph (2) is, in the contractor's judgement, the most appropriate.*
>
> *(1) The places described in this sub-paragraph are—*
>
> *(a) the place recorded in the patient's medical records as being the patient's last home address;*
> *(b) such other place as the contractor has informed the patient and the Board is the place where the contractor has agreed to visit and treat the patient; or*
> *(c) another place in the contractor's practice area.*

[14] https://www.england.nhs.uk/wp-content/uploads/2015/10/integrtd-urgnt-care-comms-standrds-oct15.pdf

(2) Nothing in this paragraph prevents the contractor from—

(a) arranging for the referral of the patient without first seeing the patient in any case where the patient's medical condition makes that course of action appropriate; or
(b) visiting the patient in circumstances where this paragraph does not place the contractor under an obligation to do so."

75. Thus a patient is entitled to medical treatment from home from a GP if, in the reasonable opinion of the GP practice, two conditions are satisfied, namely:

    a. attendance on the patient is required; and

    b. it would be inappropriate for him to attend at the practice premises.

76. At the stage that the GP is making this assessment, it is likely that the GP will not have seen the patient and therefore can only make this decision based upon the information that the patient has given to the GP practice (or has been provided on the patient's behalf) and on the medical history of the patient as set out in the notes. It seems clear however that the decision whether to make a home visit is a matter for the GP's judgement and is not something that could properly be left to reception staff or even the practice nurse, because the contract requires "the contractor" to make the assessment and accordingly this must be an assessment made by a qualified person. Assessments as to whether a person needed a home visit could be made by practice nurses provided there was a system to enable the nurse to seek guidance from a GP in cases of doubt.

77. The first test is whether the patient requires "attendance", which must mean that the patient has a need for the provision of the type of patient management services defined in the Regulations as being essential services.

78. The second test is whether it is inappropriate for the patient to attend at the practice premises. There is no limit to the reasons why a GP might consider that it could be inappropriate for the patient to attend at the practice premises. It may be that the patient is too ill to attend, has an infectious illness which makes it inappropriate to attend or has a medical condition such as agoraphobia which makes it difficult for the patient to attend the surgery. This provision could also be used to manage a violent patient who the GP practice does not wish to remove from its list but nonetheless wishes to treat in a location where there is a measure of protection for the GP (such as a room at a local police station if he police were to agree to that arrangement).

79. Once the GP practice has reached the opinion that the patient needs treatment (from a GP) outside the surgery, the place at which the GP must offer treatment is set out in the Regulations. It must be offered at the "most appropriate" of the following places:

a. at the patient's home;

b. at another place agreed between the GP practice and the patient; or

c. at some other place within the practice area.

80. The final provision appears to be a catch-all provision, but that place must still pass the test of being the most appropriate place to provide services to the patient.

81. A GP practice which asserted that it did not offer home visits under any circumstances or applied a requirement for a patient who sought a home visit which was different to those set out above would be acting in breach of contract and could, in an extreme case, have contract sanctions imposed or, in extremis, have the contract cancelled by NHS England (either through the Area Team or by the CCG under delegated powers).

Other services that a GP practice is obliged to provide

82. Part 1 of Schedule 3 to the GMS Regulations provide a list of other services that GMS contracts must specify all GMS practices must provide to their patients. There is a similar list in Part 1 of Schedule 2 to the PMS Regulations. The following paragraphs summarise these requirements.

83. **Premises**: The contract provides that the contractor shall ensure that the premises used for the provision of services under the contract are:

a. suitable for the delivery of those services; and

b. sufficient to meet the reasonable needs of the contractor's patients.

84. **Telephone lines:** NHS GP practices are prohibited from using premium rate telephone numbers which start with the digits 087, 090 or 091 or consists of a personal number, unless the service is provided free to the caller. There are also provisions to prevent NHS GP practices using other types of premium rate telephone services.

85. **Attendance by patients at the practice premises**: GP practices must take steps to ensure that any patient who has not previously made an appointment and attends at the practice premises during the normal hours for essential services is provided with such services by an appropriate health care professional during that surgery period. There is an exemption to this obligation if it is more appropriate for the patient to be referred elsewhere or if the patient is offered an appointment at another time, which is appropriate and reasonable, at the practice and the patient's health would not be jeopardised as a result.

86. **Newly registered patients:** Patients who are new to the practice list (but are not temporary residents) must also be offered a "consultation" with the GP practice within 6 months at

which the GP must make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances. This appointment is to enable the GP to conduct a baseline assessment of the patient's health and thus offer such advice and/or other services as are appropriate to that individual. It is pro-active requirement, and thus is an exception to the general approach of GP practices which is to be responsive to requests for services initiated by patients. The wording of this requirement (in paragraph 6 of Schedule 3 to the GMS Regulations) is as follows:

> *"(1) Where a patient has been—*
>
> *(a) accepted on a contractor's list of patients; or*
>
> *(b) assigned to that list by the Board,*
>
> *the contractor must invite the patient to participate in a consultation either at the contractor's practice premises or, if the patient's medical condition so warrants, at one of the places described in paragraph 5(2).*
>
> *(2) An invitation under sub-paragraph (1) must be issued by the contractor before the end of the period of six months beginning with the date of the acceptance of the patient on, or assignment of the patient to, the contractor's list of patients.*
>
> *(3) Where a patient (or, where appropriate, in the case of a patient who is a child, the patient's parent) agrees to participate in a consultation mentioned in sub-paragraph (1), the contractor must, during the course of that consultation, make such inquiries and undertake such examinations as appear to the contractor to be appropriate in all the circumstances.*
>
> *(4) This paragraph and does not affect the contractor's other obligations under the contract in respect of the patient."*

Either as part of this consultation, or separately, the practice is also required to offer an alcohol dependency assessment to newly registered patients over the age of 16. The practice must also in certain circumstances provide follow up services for alcohol dependency.

87. **Accountable GP:** Contractors must ensure that each of their patients, if they wish, is assigned a GP that is accountable for ensuring that necessary services to meet the needs of patients are coordinated and delivered. The requirements in relation to the accountable GP for those aged 75 and over is found in paragraph 11 of Part 1 of Schedule 3 of the GMS Regulations are more stringent, including an obligation on the GP to work cooperatively with other health and social care professionals to ensure the delivery of a multi disciplinary care package. Another significant difference is that all patients over the age of 75 must have an accountable GP.

88. **Patients who are not seen for 3 years**: Where a registered patient between the ages of 16 and 75 who has not attended the surgery for 3 years requests a consultation the GP practice must take advantage of the opportunity to this individual attending the surgery to "make

such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances". However there is no duty on the GP practice to seek out patients who have not attended for 3 years to offer them a check-up. The duty only arises if the patient requests a consultation.

89. **Patients over the age of 75**: The time period of non-attendance which needs to elapse before the GP practice has a duty to "make such inquiries and undertake such examinations as appear to it to be appropriate in all the circumstances" is reduced to 12 months. However once again, there is no duty on the GP practice to seek out patients over the age of 75 who have not attended the practice for 12 months to offer them a check-up. The duty only arises if such a patient requests a consultation with the GP practice.

90. **Patients living with frailty**: GP practices must take steps to identify any registered patient aged 65 years and over who is living with moderate to severe frailty. Such patients are to be identified by the use of the electronic Frailty Index (eFI) or another appropriate assessment tool.[15] Once identified, the practice must:

    a. undertake a clinical review in respect of the patient which includes—

        i. an annual review of the patient's medication, and
        ii. where appropriate, a discussion with the patient about whether the patient has fallen in the last 12 months;

    b. provide the patient with any other clinically appropriate interventions; and

    c. where the patient does not have an enriched Summary Care Record, advise the patient about the benefits of having an enriched Summary Care Record and activate that record at the patient's request.

91. Where an intervention is provided, any appropriate information relating to it must be recorded in the patient's Summary Care Record.

92. **Clinical Reports on patients on the list of another practice**: Where the GP practice provides any clinical services, other than under a private arrangement, to a patient who is not on its list of patients, it shall, as soon as reasonably practicable, provide a clinical report relating to the consultation, and any treatment provided, to NHS England. Thus every time medical care is provided to a temporary resident or emergency care is provided to a patient who is not registered with the practice, a report should be sent to NHS England explaining what care has been provided and the clinical findings. NHS England then has the task of sending the report to the patient's own practice so that it can form part of the clinical notes for that practice.

[15] More detail on the eFI can be found in the NHS Updated guidance on supporting routine frailty identification and frailty care through the GP Contract 2017/2018, https://www.england.nhs.uk/wp-content/uploads/2017/04/supporting-guidance-on-frailty-update-sept-2017.pdf (accessed 18 November 2017)

93. **Storage of vaccines:** GP practices must ensure that all vaccines are stored in accordance with the manufacturer's instructions and that all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken on all working days.

94. **Infection control:** Each GP practice must ensure that it has appropriate arrangements for infection control and decontamination. The content of Infection Control policies are a matter for each GP Surgery. However NICE has published Guidance about infection control in primary care.[16] Whilst there is a measure of discretion, GP practices would have to have good reasons for adopting policies which departed from the infection control guidance published by NICE. In addition, infection control is one of the Care Quality Commission's ("CQC") fundamental standards under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

95. The Medical Protection Society ("MPS") has identified the following as the most common breaches of infection control in GP practices, after having analysed data from more than 120 Clinical Risk Self Assessments of practices conducted in 2012[17]:

    a. The cleaning of premises was inadequate because no schedule of cleaning was available;
    b. Reception staff were handling specimens at the reception desk;
    c. Hand washing was not addressed within the practice;
    d. Risks associated with clinical waste and the management of sharps. For example not using pedal operated clinical waste bins, clinical waste bins not being provided in the consulting room and inappropriate storage of clinical waste awaiting collection;
    e. GP practices were not providing spillage kits, either purchased or made up in-house, for dealing with spillages such as body fluids, blood and mercury (if applicable);
    f. Failing to provide staff training on infection control;
    g. Waiting room toys that were not cleaned routinely. The Guidance observed that soft toys are hard to disinfect and tend to rapidly become re-contaminated after cleaning and that conversely, hard toys can be cleaned and disinfected easily.

96. Their headline finding was that 85% of those practices had some problems with infection control, which suggests that this an area of risk for many GP practices.

97. **Duty of Co-operation**: Paragraph 15 of Schedule 3 to the GMS Regulations provides that GP practices which do not provide additional services, enhanced services or OOH services, either at all or for some parts of the day or in relation to some services, must co-operate with those providers who do deliver those services for NHS patients. The GP practice must:

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[16] https://www.nice.org.uk/guidance/cg139 (accessed 18 November 2017)

[17] https://www.medicalprotection.org/uk/practice-matters-issue-4/risk-alert-infection-control (accessed 18 November 2017)

(a) co-operate, insofar as is reasonable, with any person responsible for the provision of that service or those services;

(b) comply in core hours with any reasonable request for information from such a person or from the Board relating to the provision of that service or those services; and

(c) in the case of out of hours services—

(i) take reasonable steps to ensure that any patient who contacts the contractor's practice premises during the out of hours period is provided with information about how to obtain services during that period,

(ii) ensure that the clinical details of all out of hours consultations received from the out of hours provider are reviewed by a clinician within the contractor's practice on the same working day as those details are received by the practice or, exceptionally, on the next working day,

(iii) ensure that any information requests received from the out of hours provider in respect of any out of hours consultations are responded to by a clinician within the contractor's practice on the same day as those requests are received by the contractor's practice, or on the next working day,

(iv) take all reasonable steps to comply with any systems which the out of hours provider has in place to ensure the rapid, secure and effective transmission of patient data in respect of out of hours consultations, and

(v) agree with the out of hours provider a system for the rapid, secure and effective transmission of information about registered patients who, due to chronic disease or terminal illness, are predicted as more likely to present themselves for treatment during the out of hours period.

98. **Handover requirements:** Where a contractor ceases to be required to provide a particular additional service, a particular enhanced service or out of hours services, either at all or in respect of some periods or some services, the GP practice is obliged to comply with any reasonable request for information relating to the provision of that service or those services made by NHS England or by any person with whom NHS England intends to enter into a contract for the provision of such services.

Management of the practice list of patients

99. As set out above, the primary statutory duty on NHS England is to make arrangements to meet the "reasonable requirements" of patients for primary care services throughout England. That does not mean that NHS England has a duty to ensure that every single person is registered with a GP practice, but does mean that everyone must have reasonable access to a GP practice which is reasonably local to their home. Thus NHS England is responsible for the overall "footprint" of GP practices but it is up to individual patients and GP practices to decide which patient is registered with which practice.

100. The GMS and PMS Regulations make provision for GP Practices to manage the admission of patients onto their list, either as a registered patient or temporary patient. The management of practice lists and patients wishing to be treated by practices is generally consigned to the domain of the GP Practice's contractual obligations, except, for example, in circumstances where there are no GP Practices accepting patients across a whole area, such that NHS England is in breach of its statutory duty to make arrangements for reasonable requirements.

101. GP Practice Lists may be "open" for applications, or "closed", meaning that the GP practice is not accepting applications for patients to join their list other than from immediate family members. As a general rule, GP Practices are allowed to refuse applications from patients who are not resident in a particular area.

102. This section explores the legal rules which apply to GP practices admitting patients to their lists, removing patients from their lists and the powers of NHS England to force an NHS GP practice to take a patient onto the practice list.

Who are the patients to whom a GP practice is obliged to provide primary care services?

103. The word "patient" is defined in Regulation 2 of the GMS Regulations and Regulation 3 of the PMS Regulations as:

> *(a) a registered patient;*
>
> *(b) a temporary resident;*
>
> *(c) persons to whom the contractor is required to provide immediately necessary treatment under regulation 17(7) or (9) respectively;*
>
> *(d) any other person to whom the contractor has agreed to provide services under the contract; and*

(e) any person in respect of whom the contractor is responsible for the provision of out of hours services.

104. The nature of the services set out in (c), (d), (e) are explored in the section above.

105. Regulation 20(1)(c) of the GMS Regulations and Regulation 13(1)(c) of the PMS Regulations require every GMS and PMS contract to specify "*the persons to whom such services are to be provided*". These must be the patients as defined in Regulation 2 of the GMS Regulations The obligations owed to the different types of patients are explored below.

The registered patients of the practice

106. Regulation 2 of the GMS Regulations and Regulation 3 of the PMS Regulations define a "registered patient" of a GP practice as follows:

(a) a person who is recorded by the Board[18] *as being on the contractor's list of patients;*
or
(b) a person whom the contractor has accepted for inclusion in its list of patients, whether or not notification of that acceptance has been received by the Board, and who has not been notified by the Board as having ceased to be on that list

107. There are 2 categories of patients or patients who are clearly included as registered patients with a GP practice, namely:

a. Patients who are on the GP practice list held by NHS England (because the practice has notified NHS England that the person is on the practice list and NHS England have put that name on the list); and

b. Patients who have been accepted by the practice into the practice list but where the practice has yet to pass their name on to NHS England.

108. A patient will remain on the practice list until their name is removed by NHS England. This will usually be because the patient has moved to another practice and thus is registered on the list of that other practice. A patient can only be on the list of one practice at a time (which can cause difficulties for students who have to decide whether to register at with a GP practice at their home or at their place of study). If a patient gives notice to the GP practice they are leaving the practice but then changes his or her mind before NHS England give effect to the removal, the patient will remain on the practice list.

[18] "The Board" is a reference to NHS England.

109. At the time of writing NHS England have sub-contracted the management of practice to a private company under a service contract. There are reports that service performance by this company is well below that which GPs find acceptable. This may well be an area for future litigation as GP practices become exasperated with the failure of NHS England's agents to deliver on the contractual obligations around the management of patient lists.

110. The Regulatory scheme is that persons who have been removed from the list of a practice, for whatever reason, can only regain their status as a practice patient by a separate decision being made by NHS England to include a person's name on the practice list. One consequence of this arrangement appears to be to ensure that disruptive or violent patients who are excluded from a practice list and are properly notified, cannot claim that the practice has accepted them back as a result of an informal agreement. Once a notified former patient is excluded, the patient can only regain their status as a practice patient by getting onto the list for the practice held by NHS England. In practice, this will mean that the practice has to forward the relevant name to NHS England and ask that the patient be restored to the list of registered patients.

Temporary residents

111. A person can only be permanently on the list of one NHS GP practice at a time. However, a person may be in need of primary care services when temporarily away from the area in which they are registered as a GP. Both the GMS and PMS contracts enable patients to access services in such circumstances by registering with a GP as a "temporary resident".

112. Paragraph 20 of Schedule 3 of the GMS Regulations and Paragraph 19 of Schedule 2 of the PMS Regulations set out the scheme for dealing with temporary residents and the clauses that must be included within the contracts:

> *"(1) The contractor may, if the contractor's list of patients is open, accept a person as a temporary resident provided the contractor is satisfied that the person is—*
>
> *(a) temporarily resident away from their normal place of residence and is not being provided with essential services (or their equivalent) under any other arrangement in the locality where that person is temporarily residing; or*
>
> *(b) moving from place to place and not for the time being resident in any place.*
>
> *(2) For the purposes of sub-paragraph (1), a person is to be regarded as temporarily resident in a place if, when that person arrives in that place, they intend to stay there for more than 24 hours but not for more than three months.*

113. It is irrelevant whether the proposed temporary resident is registered with another GP practice (either as part of the NHS or in another part of the world) or is someone who is not registered with any GP practice. A person can thus apply to be accepted by a practice as a temporary resident if they have a GP in another part of the country and if they have no other GP. In practice, temporary residents are often patients who fall ill whilst on holiday, away from home for work or are staying with relatives. They can also be patients who have never registered with a GP and present on a very occasional basis, but do not wish to become permanent patients of a GP practice for any reason.

114. The proposed temporary resident is not required to be living on a temporary basis in the GP practice area. However if the person is temporarily living outside the GP "practice area", the contractor has the right to refuse to register the person as a temporary resident. See below for a further discussion on the definition of a GP practice area.

115. If the person intends being resident in their present "temporary" home for more than 3 months, then the person cannot be registered as a temporary resident. The only option here would be for the GP practice to register the patient as a permanent patient (and thus for them to give up their existing GP practice registration).

116. Once a person is registered as a temporary resident, the GP practice has the same range of duties to that patient as the GP practice has to all its other patients, and the CCG has the same range of duties to the patients regarding secondary care. These duties last for three months or such shorter period as is agreed between the temporary resident and the practice. This could be, for example, a 2-week period during which a person is on holiday.

117. A GP Practice is not obliged to continue to provide services to a temporary resident for as long as the patient wants. It is entitled to terminate its responsibility for a person accepted as a temporary resident before the end of three months provided a shorter period was agreed between the Contractor and the patient has expired. Hence, a GP practice is entitled to say to a temporary patient that he or she can be accepted as a temporary patient for, say, 1 month only (as long as that is consistent with the GP's duty of care to the patient). At the end of that period the Contractor is entitled to give 7 days notice of that fact to the person either orally or in writing and the Contractor's responsibility for that person is to cease.

118. It is irrelevant whether the temporary resident is or is not usually, ordinarily or habitually resident in the UK at the time that they seek primary care services from a GP or is a UK citizen. A temporary resident will often be someone who is usually resident abroad. Although NHS services are provided primarily for the "*physical and mental health of the people of England*" (see section 1(1) of the NHS Act) there is nothing in the statutory scheme which requires a person to be a UK national or usually, ordinarily or habitually resident in the UK before that person can take advantage of NHS services. Hence it is highly likely to be unlawful to refuse to register someone as a temporary resident solely on the grounds that the person is not usually, ordinarily or habitually resident in the UK.

How can patients join the list of a GP Practice?

119. Before moving on to a discussion of the process by which patients may apply to become a permanent or temporary patient at a practice, it is necessary to discuss three concepts inherent to that issue.

What is the "list" of patients?

120. First, what is it that one is talking about when discussing the "list" of a GP Practice? Primarily the duty to keep a list of registered patients for each GP practice falls on NHS England. Under paragraph 17 of Part 2 of Schedule 3 of the GMS Regulations and paragraph 13 of Part 2 of Schedule 2 of the PMS Regulations, the practice contract must contain a term that requires NHS England to keep an up to date list of the patients who have been accepted by the contractor for inclusion in its list of patients and who have not subsequently been removed from that list or who have been assigned by NHS England to that contractor's list of patients.

121. This being said, in reality practices will keep their own lists of patients, which is an administrative necessity and thus GP practices manage the patients on that list accordingly. Applications to join a practice's list will be made to the practice, not NHS England. Under paragraph 18 of Schedule 3 of the GMS Regulations, a contractor must give notice to NHS England as soon as it has accepted a patient onto its list. Thereafter, NHS England is required to include the patient in the list from the date on which the notice was received and give notice to that applicant (or their representative, see below).

Open or closed list

122. Second is whether a GP Practice's list is "open" or "closed". Under the GMS and PMS Regulations, unless they are an immediate family member of an existing patient, people can only apply to become patients of a practice if its list is open. If a practice list is open, the GP practice has no absolute duty to accept the patient onto its list. However there are a defined list of grounds which must not be relied upon by a GP practice to refuse admission to its list and thus, in practice, a GP practice with an open list has little alternative but to accept virtually all applications from potential patients who live in the practice catchment area.

123. Whether, at the date on which the practice contract come into force, the Practice's list of patients is open or closed is something that the contract is required to specify under Regulation 20 of the GMS Regulations and Regulation 13 of the PMS Regulations.

124. The circumstances in which a GP practice list may be "closed" are discussed further below.

The "practice area"

125. Regulation 20 of the GMS Regulations and Regulation 13 of the PMS Regulations requires a GP primary care commissioning contract to specify the "practice area" for the GP practice.

126. The purpose of the practice area is to create a geographical area outside of which the GP practice are entitled, as of right, to refuse to register patients on the grounds that the patient lives outside the area that the practice is intended to serve. However, a contractor is not obliged to refuse to register someone who lives outside the practice area. The practice can register a patient with a GMS practice regardless as to whether that person lives within the practice area or not but, where the area is defined, the contractor is under no duty to do so. However, the practice retains the same obligations on providing home visits and so taking on patients that live far from the practice can impose additional obligations on the practice.

127. The GMS and PMS Regulations (under paragraph 21 of Schedule 3 and paragraph 20 of Schedule 2 respectively) provide that an application by the patient can be refused because living outside the area gives the contractor "*reasonable grounds*" to refuse to register the patient. However the fact that the patient does not live in the contractor's practice area is not a "reasonable ground" for a refusing an application to become a temporary resident.

128. The Regulations use the test as to whether a person "*lives*" in the contractor's practice area. There is no definition of the meaning of "*lives*" in the GMS or PMS Regulations but it seems likely that this refers to a person's place of ordinary residence. It is well established that a person can be ordinarily resident in more than one place at a time. However, the GMS and PMS schemes only permit an NHS patient to be registered with one GP practice at a time. Accordingly individuals who live in more than one place need to decide where to register for primary care services. For example, students regularly register with a GP practice near their university and thus can only be treated during the vacation by registering as a temporary resident on the practice list at place of vacation residence (which may be their parent's home). If they re-register at their home practice they will end up being removed from the practice list of their university residence.

129. GP practices will routinely identify their "catchment area" by way of a map on their website, or a list of street names, so prospective patients can determine if they live within the practice area.

The "outer-boundary area"

130. As well as the practice area, the GMS and PMS regulations have a separate concept of the "outer-boundary area".

131. There are instances of people who continue be registered with a practice, despite living outside its practice area. As explained above, a GP practice is entitled (but not obliged) to register a person who lives outside the practice area. However changes to the GMS contract in 2012 made provision for patients who were originally living inside the GP practice area but then move to live in an area which is reasonably proximate to the practice but is nonetheless outside the GP practice area.

132. Under Regulation 20(3) of the GMS Regulations and Regulation 13(2) of the PMS Regulations, a practice is not obliged to identify an outer practice area, but *may* identity one. If a patient who was living in the practice area moves into the outer-boundary area and would like to remain on the contractor's list of patients, they may remain on that list, if the contractor agrees. The Regulations then provide that, once a patient remains on the list because of this provision, the outer boundary area is to be treated as if it were the practice area for the purposes of the application of any other terms and conditions of the practice contract in relation to that patient; in other words, they are not to be treated any differently or be offered a lesser service as a result.

Applications to join a practice list

133. Applications to join a practice list are governed by paragraph 18 of Part 2 of Schedule 3 of the GMS Regulations and replicated in paragraph 17 of Part 2 of Schedule 2 of the PMS Regulations.

134. Anyone can apply to join the practice list either as a permanent or temporary resident by "*delivering to the practice premises a medical card or an application signed (in either case) by the applicant or a person authorised by the applicant to sign on his behalf*". The application is made by the patient themselves if the person is an adult and is capable of making the application.

135. For children and adults who lack capacity, the Regulations provide that:

> *"(4) An application may be made—*
>
> *(a) where the patient is a child, on behalf of the patient by—*
> *(i) either parent, or in the absence of both parents, the guardian or other adult who has care of the child,*
> *(ii) a person duly authorised by a local authority to whose care the child has been committed under the Children Act 1989, or*
> *(iii) a person duly authorised by a voluntary organisation by which the child is being accommodated under the provisions of the Children Act 1989; or*

(b) where the patient is an adult who lacks capacity to make such an application, or to authorise such an application to be made on their behalf, by—

(i) a relative of that person,

(ii) the primary carer of that person,

(iii) a donee of a lasting power of attorney granted by that person, or

(iv) a deputy appointed for that person by the court under the provisions of the Mental Capacity Act 2005."

136. A "medical card" under Regulation 3 of the GMS Regulations means "*means a card issued by the Board or a Local Health Board, Health Authority, Health Board or Health and Social Services Board to a person for the purpose of enabling that person to obtain, or to establish entitlement to receive, primary medical services*". However, the Regulations allow practices to use "an application" as an alternative to a medical card. Therefore, any document which can reasonably be taken by the contractor as being an application by a person to be registered at the practice and is signed by or on behalf of the patient is sufficient to constitute an application by the prospective patient.

137. Once the contractor receives the application the GP practice must decide whether to accept the patient onto the practice list as either a permanent patient or a temporary resident, or refuse to register the patient.

138. If the practice list is closed the only person who can be accepted onto the list is an "immediate family member" of a registered patient, which is defined in the Regulations as:

"(a) a spouse or civil partner;

(b) a person whose relationship with the registered patient has the characteristics of the relationship between spouses;

(c) a parent or step-parent;

(d) a son or daughter;

(e) a child of whom the registered patient is—

(i) the guardian, or

(ii) the carer duly authorised by the local authority to whose care the child has been committed under the Children Act 1989; or

(f) a grandparent;"

139. This provision prevents a GP practice from having a closed list but being selective about who is admitted to the practice in the period when the list is closed (so as to avoid a situation where, for example, only patients who are straightforward to manage are accepted onto the practice list). Only immediate family members can be added to a closed list regardless as to where that person lives. However, there is no obligation on a GMS contracting practice to take an immediate family member who lives outside the practice area onto the list. In the case of immediate family members who live in the practice area, the practice needs to have reasonable grounds for refusing to take the person onto the list. Although this is not expressly stated in the Regulations, the fact that the practice list is (depending on the circumstances) closed is capable of amounting to such a reason.

140. If the practice list is open then, by virtue of paragraph 21 of Schedule 3 of the GMS Regulations and paragraph 20 of Schedule 2 of the PMS Regulations:

> *"(1) The contractor may only refuse an application made under paragraph 18 or 20 if the contractor has reasonable grounds for doing so which do not relate to the applicant's age, appearance, disability or medical condition, gender or gender reassignment, marriage or civil partnership, pregnancy or maternity, race, religion or belief, sexual orientation or social class.*
>
> *(2) The reasonable grounds referred to in sub-paragraph (1) may, in the case of an application made under paragraph 18, include the ground that the applicant—*
>
> *(a) does not live in the contractor's practice area; or*
>
> *(b) lives in the outer boundary area (the area referred to in regulation 20(3)).*

141. It follows that an NHS practice cannot refuse to admit a patient to its list either on a permanent basis or as a temporary resident because the patient suffers from a medical condition which will be time consuming for the doctors working at the practice or will result in the practice having to prescribe expensive drugs or other treatment for the patient. Equally the patient cannot be refused admission to the practice list on grounds which might give rise to a free-standing discrimination claim under the Equality Act 2010, such as on the basis of race or sexual orientation. It should be noted, however, that although the grounds in subparagraph (1) of paragraph 21 of the GMS Regulations broadly correspond with the protected characteristics under the Equality Act, they are not identical.

142. This provision raises some interesting and potentially difficult questions as to whether GP practices can refuse to register patients with alcohol or drug problems. A GP practice would not be entitled to refuse to register a person because they suffered from such an addiction but may be entitled to refuse to register such a patient if their conduct (related to their addiction) makes it difficult or impossible for the GP to be able to provide primary care services to the patient. This can be a difficult area in practice and GP practices may well find it sensible to seek legal advice in borderline cases.

143. If a contractor refuses an application of a person to join the list, be that as a registered patient or temporary resident, then the contractor has 14 days to provide reasons in writing: "*the contractor must give notice in writing of that refusal and the reasons for it to the applicant (or, in the case of a child or an adult who lacks capacity, to the person who made the application on their behalf) before the end of the period of 14 days beginning with the date of its decision to refuse.*"

What options do patients have if their application to join a practice list has been refused?

Appeals to NHS England

144. A patient who has been refused admission to a practice list by a GMS or PMS contractor (either on a permanent or temporary basis) is entitled to apply to NHS England to be admitted to the practice list, even if that list is closed, after the contractor has made the decision to refuse to permit the patient to be admitted to the list. The fact that the decision was made by the GP practice for a good reason (as the GP practice sees matters) does not prevent the patient from having this right.

145. Paragraphs 38 to 43 of Schedule 3 of the GMS Regulations and paragraphs 37 to 42 of Schedule 2 of the PMS Regulations provide how the decision is to be made by NHS England when a patient appeals against the refusal by the practice to admit a patient to its list (either permanently or on a temporary basis).

146. The first step in this process is that the patient is required to approach the practice to apply to be admitted to the list, and the practice is required to make the initial decision. NHS England has no power to impose a patient on a practice unless the patient has first applied and been refused admission to the practice (either on a permanent basis or as a temporary patient).

147. If the practice list is closed there are only very limited circumstances in which NHS England are entitled to require a practice to take on a new patient. The scheme for requiring admission of a patient to a closed list is looked at in detail in the section of this chapter relating to closed practice lists.

148. If the practice list is open, NHS England has a discretion to decide whether to require a GMS contracting practice to accept a patient onto its list or to accept a patient as a temporary resident. The decision is generally made on paper by NHS England officials. Where the list is open, in making that decision, the terms of the contract (as mandated by the GMS Regulations) require NHS England to take account of the following factors:

a. *The preferences and circumstances of the person*. The "preferences" of the patient to be admitted to the practice list are a material factor but they are not

conclusive. NHS England is also required to take account of the "circumstances of the person", which in practice must mean such of the circumstances as are known to NHS England and the practice. There can be no duty on the patient to disclose all of their personal circumstances but clearly NHS England can only take account of circumstances that are known;

b. *The distance between the person's 's place of residence and the contractor's practice premises*. The usual significance of this will be that the nearer the patient lives to the practice premises (or one of the practice premises), the stronger case can be made for the patient being admitted to that particular practice;

c. *Any request made by any contractor to remove the person from its list of patients within the preceding period of 6 months starting on the date on which the application for assignment is received by the Board*. It is a relevant factor as to whether the practice has asked NHS England to remove the person from the list within the previous 6 months and the circumstances which led to that request being made (whether it was granted or not). The person may be applying to be re-admitted to the list after NHS England agreed to remove the patient from the list. Alternatively it is possible that the request was refused but that the patient had been removed from the practice list for a different reason and was now seeking to rejoin the list;

d. The wording under sub-paragraph (d) requires NHS England to take into account whether, during the preceding period of 6 months starting on the date on which the application for assignment is received by the Board, the patient has been removed from the list of patients of any NHS GP practice either at the request of the contractor or because the patient had been violent;

e. Sub-paragraph (e) requires NHS England to take into account whether, in a case where the patient has been removed from the list of patients of any NHS GP practice because the patient had been violent, the contractor has appropriate facilities to deal with such patients; and

f. NHS England is required to take such other matters into account as NHS England considers relevant.

149. There is no provision in the rules for an oral hearing, but NHS England is a public body making a decision which potentially affects the article 8 rights of the patient. It would be required to follow a fair process in reaching the decision. The procedural requirements of this decision have not been tested in the courts but are is likely to require:

a. giving the person the opportunity in writing (or with an NHS England official if writing is not appropriate for any reason) to explain why he or she wishes to be included on the practice list;

b. giving the practice the opportunity to explain why the person has been refused admission to the list;

c. giving both the practice and the patient the chance to see and comment on the observations made by the other before a decision is made; and

d. taking reasonable steps to consider any other relevant information provided by the patient or any third party; and

e. Although this is not expressly stated in the Regulations, it seems highly likely that a fair decision could only be given by NHS England if reasons are given for the decision. Those reasons should explain how the decision maker has taken account of the various factors set out above and the weight given to each factor. Some weight should be given by the decision maker to every factor because each factor is one which is required to be included by the GMS Regulations. However, provided some weight is attached to each factor, the decision maker is entitled to exercise a wide margin of discretionary decision making in reaching the view as to which factor or factors are more important than other factors in the particular circumstances of each case.

150. There is no appeal provided within the GMS or PMS Regulations by either the patient or the practice against the decision of NHS England to order or not to order a patient to be admitted to a GP practice list. If NHS England refused the patient's appeal, that decision may be the subject of a challenge by way of judicial review if the patient considered that the decision was made unlawfully. However this would not be an appeal on the merits because the relevant Regulations make NHS England the discretionary decision making body. It could only be a challenge asserting that the decision was made in an unlawful way by, for example, failing to take account of one of the mandatory factors, or was an irrational decision.

What can a practice do if it disagrees with NHS England's decision?

151. If NHS England decides in favour of the patient and the GP practice still disagrees with the decision it has 2 options. It may accept the decision but then exercise its power to remove the patient from the list. Removal of patients from the practice list is considered below. This is a high risk strategy which may well be successfully challenged by the patient (assuming that there are no new grounds to justify removal). Secondly, if the practice believed that the decision had been taken on an improper basis (as opposed to a decision on the merits with which they disagreed) it may be possible for the practice to refer the matter to the NHSLA under the contractual dispute resolution process. The details of the dispute resolution process are considered elsewhere in this guide. However, the NHSLA ought to recognise that decision making about this matter is given to NHS England and accordingly it will only look to see whether the decision has been properly taken by NHS England. The NHSLA ought not to attempt to reconsider the decision on its merits but only ask itself

whether NHS England have reached a proper decision. However, the patient would remain on the practice list and thus must be provided with general practice services until (at least) the NHSLA have reached a decision.

Other remedies or routes of challenge for patients

152. In theory, it is possible for a patient who feels their application has been refused on grounds which constitute discrimination under the Equality Act 2010 to commence a discrimination claim under that Act in the County Court. There is some overlap between the contractual obligations of the GP practice not to refuse a patient on specified grounds and the protected characteristics under the Equality Act. However the contractual grounds are wider because these include appearance or social class and any medical condition, whether it led to the patient being disabled or not.

153. It would be difficult for a patient to judicially review the decision of the GP practice to refuse his or her application if it had not appealed to NHS England because the patient would have an alternative remedy and thus it could be argued that permission should be refused because Judicial Review should only operate as a remedy of last resort.

154. The patient may feel aggrieved if he or she believes that the practice has turned down an application on grounds that are impermissible under the GP Contract (such as a refusal based on the patient's medical condition). However it is hard to see how a patient can enforce the terms of the contract because the practice's contractual obligations are owed to the commissioner, i.e. NHS England (and potentially also the CCG) but not to the patient. Further the standard form of contract excludes any right for a third party (such as a patient) to enforce the terms of the contract (thereby excluding any rights the patient may have claimed under the Contracts (Third Party Rights) Act 1999. However in making the decision as to whether a patient can join an NHS GP Practice, it is probable that the GP practice is acting as a public body and hence, if all other obstacles could be overcome, a claim to quash the refusal to admit the patient may be possible as a Judicial Review action.

155. However a patient who was refused admission to a practice list in a manner which amounted to a breach of the GMC Code of Conduct (which is likely to be rare) could report the doctors to the General Medical Council ("GMC"). The issue of reports to the GMC is considered in more detail below in relation to the removal of patients from a GP list but it could apply equally to a refusal to take a patient onto a list in the first place.

156. If NHS England considered that the practice had refused one or more patients access to the patient list in circumstances which amounted to a breach of contract (because the practice did not have good reasons for the refusal), NHS England would be obliged to enforce the contract by allowing an appeal. If the practice still refused to accept the patient entitled to serve a Remedial Notice on the practice. The consequences of such a notice are explored below.

Removal of patients from a practice list

157. The removal of patients from the lists of GP practices is a hugely contentious area. It is the subject of a specific paragraph in the GMC Code of Conduct and several bodies including the British Medical Association ("BMA") and the GMC have published guidance on this issue.[19] There can be particularly difficult issues arising from both violent patients and patients who make excessive demands upon limited practice resources by, for example, seeking a GP appointment several times a week without proper justification.

GMC professional standards

158. The GMC's Good Medical Practice code of conduct provides:

"*62. You should end a professional relationship with a patient only when the breakdown of trust between you and the patient means you cannot provide good clinical care to the patient*"[20]

159. Thus a doctor will thus potentially act in breach of the GMC Code of Practice by ending a relationship with a patient unless 2 things are present, namely:

a. There must be a breakdown of trust between the doctor and the patient; and

b. The doctor must be unable to provide good clinical care to the patient as a result of that breakdown.

160. Asking NHS England to remove a patient from a practice list because of one or more complaints is a breach of the professional standards unless the number and/or nature of the complaints means that there has been a breakdown of trust between the patient and the doctor. Examples given for situations where there may have been a breakdown of trust include where a patient has been violent, threatening or abusive to their GP or a member of practice staff, stolen from their GP or the premises, persistently acted inconsiderately or unreasonably, or made a sexual advance.

161. It is also clear, even in the face of such scenarios, that a doctor must work at a relationship with a patient and cannot seek to exclude the patient at the first sign of difficulties. A warning must usually be given and then the doctor must attempt to make the relationship work before concluding that it is the interests of both parties for medical care

[19] See the BMA guidance here: https://www.bma.org.uk/advice/employment/gp-practices/service-provision/removal-of-patients-from-gp-lists.

[20] The associated guidance is found here: https://www.gmc-uk.org/Ending_your_professional_relationship_with_a_patient.pdf_58834078.pdf

for the patient to be provided by someone else. A GP is also advised to discuss the decision with (a more senior) colleague. However there will be occasions where the patient has acted in a way that leads a doctor genuinely to conclude that trust and confidence has broken down to such a degree that the doctor cannot continue to provide medical services to the patient. In such circumstances it is in the interests of the doctors, the patient and the rest of the patients served by the practice for the patient to be moved to another practice or provided with primary care services in another way.

Grounds for removal of the practice list under the Regulations

162. The GMS and PMS Regulations, however, do provide for a number of special situations in which a patient can be removed from a practice list without there being a breakdown of trust between the doctor and the patient, including when patients are violent.

163. These grounds are fairly numerous and are set out in Part 2 Schedule 3 of the GMS Regulations and Part 2 of Schedule 2 of the PMS Regulations. The exact conditions and requirements of each ground are not explored in detail here, and readers should go to the Regulations for more information, but they include removal of a patient from the list:

a. On discretionary grounds by the practice (discussed in further detail below);

b. When their period as a temporary resident expires;

c. Following the death of a registered patient;

d. At the patient's request;

e. When a patient registers with another practice;

f. When a patient moves out of the practice area (although a practice is entitled to keep a patient on its list even if a patient moves out of the practice area);

g. When a patient's address is unknown to NHS England and a notice period of six months has expired;

h. When a patient is sentenced to more than 2 years in prison (the rationale being that specialist services for prisoners are commissioned by NHS England and thus to avoid double funding);

i. When a patient joins HM Forces (again the rationale for this is that specialist services for members of HM Forces can access services specially commissioned for them by NHS England);

j. When a patient is abroad for more than 3 months;

k. When a patient who has registered as a temporary resident elsewhere remains in that location for a long term basis and thus now "lives" in the practice area where they registered as a temporary resident;

l. If they were receiving services by virtue of being pupils at a (usually residential) school and are no longer on the roll of that school;

m. If the patient is violent

Removal of violent patients from GP lists

164. The last of these categories, violent patients, merits further consideration.

165. There is a specific scheme under Paragraph 25 of Schedule 3 of the GMS Regulations and replicated in Paragraph 24 of Schedule 2 of the PMS Regulations for removal from the list of patients who are violent "with immediate effect". It provides:

> *"(1) Where a contractor wants a person to be removed from its list of patients with immediate effect on the grounds that—*
>
> *(a) the person has committed an act of violence against any of the persons specified in sub-paragraph (2) or has behaved in such a way that any of those persons has feared for their safety; and*
>
> *(b) the contractor has reported the incident to the police,*
>
> *the contractor must give notice to the Board in accordance with sub-paragraph (3).*
>
> *(2) The persons specified in this sub-paragraph are—*
>
> *(a) the contractor, where the contractor is an individual medical practitioner;*
>
> *(b) in the case of a contract with two or more persons practising in partnership, a partner in the partnership;*
>
> *(c) in the case of a contract with a company limited by shares, a person who is both a legal and beneficial owner of shares in that company;*
>
> *(d) a member of the contractor's staff;*
>
> *(e) a person engaged by the contractor to perform or assist in the performance of services under the contract; or*
>
> *(f) any other person present—*
>
> *(i) on the contractor's practice premises, or*
>
> *(ii) in the place where services were provided to the person under the contract.*

(3) Notice under sub-paragraph (1) may be given by any means but, if not in writing, must subsequently be confirmed in writing before the end of a period of seven days beginning with the date on which notice was given.

(4) The Board must acknowledge in writing receipt of a request for removal from the contractor under sub-paragraph (1).

(5) A removal requested in accordance with sub-paragraph (1) takes effect at the time at which the contractor—

(a) makes a telephone call to the Board; or

(b) sends or delivers the notice to the Board.

(6) Where, under this paragraph, the contractor has given notice to the Board that it wants to have a person removed from its list of patients, the contractor must inform that person of that fact unless—

(a) it is not reasonably practicable for the contractor to do so; or
(b) the contractor has reasonable grounds for believing that to do so would—
(i) be harmful to that person's physical or mental health, or
(ii) put the safety of any person specified in sub-paragraph (2) at risk.

(7) Where a person is removed from the contractor's list of patients under this paragraph, the Board must give that person notice in writing of that removal.

(8) The contractor must record the removal of any person from its list of patients under this paragraph and the circumstances leading to that removal in the medical records of the person removed."

166. The notification can be given to NHS England orally or in writing but, if given orally, must be confirmed in writing within 7 days. Emails are sufficient to constitute written confirmation.

167. There is no precise definition in the contract of the phrase "*committed an act of violence*". However the World Health Organisation published a report on Violence and Health in 2002. This defines violence as follows:

"The intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation"

168. This seems an appropriate test against which to judge the act complained about. It can include a threat of violence if the threat, if carried out, would result in injury. The alternative formulation of conduct which can lead to a patient being removed instantly from

a practice list is that the patient must have "*behaved in such a way that any such person has feared for his safety*". This test has a potentially wider scope because it focuses on the reaction of the person to the actions of the patient and not just on the actions of the patient himself or herself.

169. It is important to note that in order to come within the terms of the immediate removal provisions in the contract, the incident must be reported to the police. The trigger, however, is a report to the police and not any defined action by the police themselves. Thus a police response which suggests that no criminal offence has been committed does not prevent the GP Practice from relying on the incident.

170. The Regulations provide that a removal shall take effect at the time the Contractor makes the telephone call to the Board, or sends or delivers the notification to the Board. It follows that the duty on the contractor to provide continuing medical care to the patient ceases immediately the contractor has made a report to NHS England of violence and made a "request" for the patient to be removed from the practice list. If the patient was in need of emergency care then the contractor would have a duty to continue to provide emergency care to the patient in the same way as emergency care is required for any other individual, whether a registered patient or not. However there is no contractual duty on the GP practice to take steps to ensure that the violent patient is able to access alternative primary medical services before the patient is removed from the list.

171. However, under the Primary Medical Services (Directed Enhanced Services) Directions 2017, NHS England is obligated to establish, operate and, as appropriate, revise a Violent Patients Scheme. The Violent Patient Scheme was introduced as a Directed Enhanced Service in 2004, with the aim of providing a secure environment in which patients who have been violent can still receive primary care services. Typically, NHS England commissions these services via APMS contracts with single providers for a geographical area. These services can include security escorts who accompany violent patients to appointments to protect the safety of GPs and other staff.

Discretionary removal of patients from a GP list

172. There are, of course, numerous reasons why a GP practice may wish to remove a patient from a practice list. The BMA Guidance and the GMC Code of Practice make it clear that this should be an exceptional and rare event.

173. Both GMS and PMS contracts are required to contain terms which prevent a GP practice applying to NHS England to remove a patient for any of the following reasons:

- Age
- Appearance
- Disability or medical condition
- Gender or gender reassignment

- Marriage or civil partnership
- Pregnancy or maternity
- Race
- Religion or belief
- Sexual orientation
- Social class

174. The approach of the GMS and PMS Regulations (paragraphs 24 of Schedule 3 and 23 of Schedule 2 respectively) is generally to permit a contractor to require NHS England to remove a patient from the practice list provided:

a. The contactor has a good reason for wanting to remove the patient (the reason cannot be a prohibited reason);

b. (Save in a specified set of cases) the patient has been warned about the conduct which led to the decision and has failed to heed the warning; and

c. The patient is generally entitled to know the reason that the GP wants to remove the patient from the practice list.

175. However a practice will continue to have clinical responsibility for a patient until the removal of the patient comes into effect in accordance with the contractual scheme described below. The practice has a full duty to provide services to the patient until the removal takes effect.

176. **The warning for the patient:** The first stage in the process of removing a patient from a GP practice list is that a warning should has to be given to the patient about the patient's conduct which is causing the practice concern and which may lead to the practice seeking to have the patient removed. The Regulations provide that:

(3) Except in the circumstances specified in sub-paragraph (4), a contractor may only request the removal of a person from its list of patients under sub-paragraph (1) if, before the end of the period of 12 months beginning with the date of the contractor's request to the Board, the contractor has—

(a) warned that person of the risk of being removed from that list; and
(b) explained to that person the reasons for this.

177. There are a limited number of exceptions to the need to warn the patient before a request is made to NHS England to remove the patient from the practice list:

(4) The circumstances specified in this sub-paragraph are that—

(a) the reason for the removal relates to a change of address;
(b) the contractor has reasonable grounds for believing that the giving of such a warning would—
(i) be harmful to the person's physical or mental health, or
(ii) put at risk the safety of one or more of the persons specified in sub-paragraph (5); or
(c) the contractor considers that it is not otherwise reasonable or practical for a warning to be given.

178. The persons specified in subparagraph (5) are as follows:

(a) the contractor, where the contractor is an individual medical practitioner;
(b) in the case of a contract with two or more persons practising in a partnership, a partner in the partnership;
(c) in the case of a contract with a company limited by shares, a person who is both a legal and beneficial owner of shares in that company;
(d) a member of the contractor's staff;
(e) a person engaged by the contractor to perform or assist in the performance of services under the contract; or
(f) any other person present—
(i) on the practice premises, or
(ii) in the place where services are being provided to the patient under the contract.

179. The contractor is then required to keep a written record of: (a) the date of any warning given in accordance with sub-paragraph (3) and the reasons for giving such a warning as explained to the person concerned; or (b) the reason why no such warning was given.

180. Once a warning has been given and the GP practice reaches the view that it has not been heeded or if the contractor considers that it is entitled to dispense with a warning in accordance with the above provisions, the Regulations provides that the contractor should write to NHS England saying that it "wants" to remove the patient. At the same time the GP practice is required to notify the patient of the *specific reasons* for requesting removal. Those reasons cannot be any of the prohibited reasons.

181. Subject to these specific limitations, there are a wide range of potential reasons why a practice could seek to have a patient removed from its list. The most obvious reasons are that the patient has moved out of the practice area or that the doctors do not feel able to continue to provide services to the patient. Some guidance on reasons is provided in paragraph 24(2) of the GMS Regulations (replicated in the PMS Regulations) which provides that "*where, in the reasonable opinion of the Contractor, the circumstances of the removal are such that it is not appropriate for a more specific reason to be given; and there has been*

an irrevocable breakdown in the relationship between the patient and the Contractor, the reason given under subparagraph (1) may consist of a statement that there has been such a breakdown".

182. This language echoes the grounds on which a doctor can terminate a relationship with a patient in the GMC Code. The NHS practice contract gives the patient no right to object to the proposed removal or to challenge the factual basis of the decision to remove him or her from the practice list. The provisions in the contract treat this mater as being solely to be decided between the practice and NHS England. Neither the GMS Regulations nor the GMS contract gives any legal right to the patient to object to being removed from a practice list.

183. Where notification is given to NHS England that a practice wishes to remove a patient from its list there is no provision for a separate decision to be made by NHS England as to whether the practice has properly made out a case to have the patient removed. The next step is that the removal takes effect automatically on the date when the patient is registered with another practice or 8 days after the notice is sent to NHS England, whichever is the sooner unless the patient is being treated at intervals of less than seven days. If the patient is in receipt of medical treatment at less than 7 day intervals, the removal does not take effect until the eighth day after NHS England receives notification from the Contractor that the person no longer needs such treatment, or on the date on which the person is registered with another provider of essential services, whichever is the sooner.

184. This scheme seeks to preserve the balance between the interests of the contractor who wishes to have the patient removed from the practice list and the interests of the patient who may have a need for on-going medical treatment. It however has the potential to cause a difficulty in the case of a patient who has a chronic condition which will require treatment at less than 7 days intervals indefinitely. The patient is under no obligation to seek out a new GP practice and cannot be registered with a new practice unless he or she makes an application to join the list of that practice. If the patient prefers to stay with their existing practice then the patient cannot be compelled to join another practice. The contractor continues to have a full duty to provide medical treatment to the patient until the removal notice takes effect, and cannot reduce the level of input for the patient because a removal has been requested. In these circumstances, a mediation may be the appropriate way forward if mutually agreed.

185. The GP is a contractor who seeks to discharge NHS England's statutory duty to make arrangements for patients to have access to primary care services. Accordingly any public law action by a patient who is left without access to GP services would have to be against NHS England and not the GP practice. However that could only be based on an overall alleged failure by NHS England to provide primary care services in a particular area, and so could be cured by NHS England offering to arrange for the patient to be registered at another practice or offering the GP services under arrangements for patients who are excluded from GP practices generally in an area. It is therefore difficult if not impossible to see how a patient could construct a cause of public law action arising out of the decision of a

GP practice to remove a patient from their list of registered patients (unless that left the patient with no possible alternative provision). The patient's only remedies appear to be to sue in defamation or to complain to the GMC.

186. If the patient is removed from the practice list pursuant to this scheme, NHS England has a duty to write to both the patient and the contractor to inform them that the patient has been removed and the date of removal. However, NHS England does not need to explain the reasons for the patient's removal since this will usually have already been explained by the contractor to the patient.

187. NHS England and the contracting GP are required to keep proper records relating to the removal of patients from a list of registered patients including, as stated above, in the case of the GP practice, proper records of any warnings that have been given in advance of any removal.

Closure and reopening of GP practice lists

188. GP practices list sizes vary enormously but it is not in the interests of patients or doctors for a GP practice to have too many patients and not enough doctors. A GP practice has a contractual and professional duty to deliver services of an acceptable quality for patients and this will not be possible if the GP practice does not have enough capacity. As referenced above, there is often talk of a "crisis" in general practice, with GPs struggling to cope with overwhelming demand for their services. This is particularly problematic where GPs retire and cannot be replaced, leaving the remaining partners with responsibility for a list that is too large for them to manage properly.

189. One way of managing demand is for a GP practice to close its list to new patients. However, a closure is assumed in the Regulations to be a strictly temporary measure whilst the GP practice takes the necessary steps to increase its capacity to deliver services to patient. The Regulations do not make provision for the present (possibly chronic) shortage of GPs which inevitably means that some practices are simply unable to recruit and thus are left with lists that are too large on a semi-permanent basis.

190. Lists are held by NHS England and not the individual practice and therefore the decision on any closure application is strictly a decision for NHS England and not the GP practice. Although it is becoming increasingly common for GP practices to make requests to NHS England/CCGs to close their lists, it is understood by these authors that a sizeable proportion of these requests are refused. It seems likely that this reluctance to allow GP practices to close their lists is a result of NHS England not wanting to prevent new patients having a practice with which they can register. However, that decision could be the subject of a challenge by a GP practice (probably to the NHSLA) that felt that it had done everything reasonable to be able to staff up the practice and had failed to recruit sufficient GPs.

How can practices apply to close their list?

191. The scheme for closure of GP practice lists is found in Part 3 of Schedule 3 of the GMS Regulations and Part 3 of Schedule 2 of the PMS Regulations.

192. The first step when a contractor wants to close its list of patients is to send a written application to that effect to NHS England.

193. The application must contain the following information:

(a) the options which the contractor has considered, rejected or implemented in an attempt to alleviate the difficulties which the contractor has encountered in respect of its open list and, if any of the options were implemented, the level of success in reducing or extinguishing such difficulties;

(b) details of any discussions between the contractor and its patients and a summary of those discussions including whether or not, in the opinion of those patients, the list of patients should be closed;

(c) details of any discussions between the contractor and the other contractors in the contractor's practice area and a summary of the opinion of the other contractors as to whether or not the list of patients should be closed;

(d) the period of time, being a period of not less than three months and not more than 12 months, during which the contractor wants its list of patients to be closed;

(e) any reasonable support from the Board which the contractor considers would enable its list of patients to remain open or would enable the period of the proposed closure to be minimised;

(f) any plans which the contractor may have to alleviate the difficulties mentioned in the application during the period of the proposed closure in order for that list to re-open at the end of that period without the existence of those difficulties; and

(g) any other information which the contractor considers ought to be drawn to the attention of the Board.

194. NHS England must acknowledge receipt of the application within seven days from when it receives the application. It must consider that application and make requests for any other information it requires to determine it.

195. NHS England must then enter into discussions with the practice, about what support it can provide or any changes that can be made, with both doing everything possible to keep the list open. The Local Medical Committee ("LMC") may be invited at any stage during these discussions to attend any meetings that have been arranged. Also, NHS England may

consult anyone who might be affected by the closure of the list, and if so, must provide the practice with a summary of any views expressed. NHS England must give the practice the opportunity to comment on all the information relating to the application before they make their decision. The practice may withdraw its application at any time before NHS England makes its decision. This must be made within 21 days from the date it received the application (or within a longer period if both parties agree). The decision will be either to:

a. Approve the application and set the dates of closure and reopening of the list; or
b. Reject the application.

196. A practice will not be able to make another application to close its list within 12 months of the date of this decision unless the application has been rejected (in which case different time limits apply) or there has been a change in circumstances affecting the ability of the practice to deliver services under its contract.

197. A decision by NHS England to give approval to an application to close a list of patients must be sent in writing to the practice as soon as possible. This should also be copied at the same time to others who were involved in this process such as the LMC and/or anyone affected by the list closure who was consulted.

198. The closure notice must include:

a. The period of time the list will be closed, which must be either the period stated in the practice's application, or a period agreed subsequently. In either case, this must be 3 months or over but cannot be longer then 12 months;

b. The date the list will close; and

c. The date the list will reopen (which may change should the practice and NHS England agree that the closure period will be extended or the list will reopen sooner).

199. A decision by NHS England to reject an application to close a list of patients must be sent in writing to the practice as soon as possible. This should also be copied at the same time to others who were involved in this process such as the LMC and/or anyone who was consulted. A practice will not be able to make another application to close its list within 3 months of the date of NHS England's decision to reject an application, or the date of any final determination in a dispute on this matter, whichever is the later. This time limit will not apply where there has been a change in circumstances affecting the ability of the practice to deliver services under its contract. Although the Regulations do not provide that NHS England has a duty to give reasons, there is probably a common law duty on NHS England to do so. A practice that disagrees with the rejection of its application to close its list could refer the matter to the NHSLA under the contractual dispute resolution provisions.

Extension of the closure period

200. During a period of closure, a practice may apply to have this extended. The application must be made in writing at least 8 weeks in advance of the date the list will reopen. The application to extend must include:

a. any options the practice has considered, rejected or implemented to try to relieve the difficulties it has encountered during the closure period and, if any of these options were implemented, the level of success in reducing or eliminating these difficulties;

b. the period of time during which the practice wishes its list to remain closed, which must not be more than 12 months;

c. any reasonable support from NHS England which the practice considers would enable its list to reopen or would enable the period of proposed extension of closure to be minimised;

d. details of any plans the practice may have to reduce or eliminate the difficulties mentioned in their application to extend the closure which would allow their list to reopen when this period elapses; and

e. any other information which the practice considers necessary to bring to the attention of NHS England.

201. NHS England must acknowledge receipt of the application within 7 days of receiving it. It must consider the application and may request any information from the practice to enable it to do so. NHS England may enter into discussions with the practice, about what support it can provide or any changes that can be made, with both doing everything possible to enable the list to reopen.

202. Within 14 days of the receipt of the application to extend the closure period, NHS England must make a decision either to approve or reject it. Where NHS England approves an application to extend the closure period, it must notify the practice in writing as soon as possible. A copy of the decision letter should be sent to others who were involved in discussions on the original list closure application. This can include the LMC and/or anyone affected by the list closure who was consulted.

203. The extended closure notice must include:

a. The period of time the list will be closed, which must be either the period stated in the practice's application to extend the closure period, or a period agreed in writing between NHS England and the practice subsequently. In either case, this must be 3 months or over but not longer than 12 months;

b. The date from when the closure period will be extended; and

c. The date the list will reopen.

204. GP practices which disagree with decisions made by NHS England on patient list matters can invoke the NHS Disputes Resolution process by registering a dispute with the Family Health Appeal Unit of the NHSLA, now called "NHS Resolution".

205. NHS England has published guidance on list closure entitled, "Managing Closed Lists".[21] This Guidance summarises the statutory provisions but provides little additional information about how the processes should be handled.

Assignment of patients to closed lists

206. Under the Regulations, there is a special procedure that NHS England must adopt (under Part 4 of Schedule 3 of the GMS Regulations and replicated under Part 4 of Schedule 2 of the PMS Regulations) if it wishes to assign patients to the list of a GP Practice that is closed. NHS England can only do this after having constituted a special assessment panel to determine whether new patients may be assigned to the GP Practice in question, and if that that determination has not been overturned by the Secretary of State, to whom a right of review lies. Finally, before doing so, NHS England must have entered into discussions with the GP Practice if required under the Regulations.

Services for which GPs can charge fees

Introduction

207. NHS services are generally free at the point of use for patients. However, the NHS has always imposed charges for some services which are not included within NHS

[21] https://www.england.nhs.uk/wp-content/uploads/2013/07/mng-close-list.pdf

commissioned care or where Regulations require charges to be imposed[22]. There are also other functions undertaken by NHS doctors which are outside their NHS duties and hence attract a fee. It follows that full legal position is somewhat more nuanced. The general requirement that services should generally be provided free of charge is set out in section 1(4) of the NHS Act which provides:

> *"The services provided as part of the health service in England must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed"*

208. There are a number of areas where Regulations provide that charges may be imposed for NHS services including:

   a. Prescriptions;
   b. Dental services;
   c. Optical services;
   d. Contraceptive services ;
   e. Hospital services for persons who are not usually ordinarily resident in the UK.

209. Primary care services provided under a GMS or PMS contract to patients on the practice list or temporary residents are required to be provided free of charge. As outlined above, the GMS and PMS contracts also provide that GP practices have a contractual obligation to provide a range of other services to patients. However, GP practices are (almost all) private sectors businesses that have contracted with NHS England to provide defined primary care services to a defined group of patients and to provide defined level of emergency medical services in limited circumstances. If a registered patient or temporary resident seeks primary care services from an NHS GP practice outside the terms of the contract held by that practice, the NHS GP practice has no obligation to provide services to that person. A GP may choose to do so; however, he or she may not charge for treatment provided outside the GP Practice contract unless the service falls within a limited categories of specific services.

The general prohibition on an NHS GP Practice charging fees to patients.

210. The general prohibition on an NHS GP Practice charging fees for services provided to patients is set out in Regulation 24 of the GMS Regulations which provides:

> *" (2)The contractor must not, either itself or through any other person, demand or accept from any of its patients a fee or other remuneration, for its own benefit or for the benefit of another person for—*

[22] Charges are and remain a hugely contentious area. The original Minister of Health, Rt Hon Hye Bevan, resigned from the government over the imposition of charges for prescription charges for drugs prescribed by GPs.

i. *the provision of any treatment whether under the contract or otherwise; or*

ii. *any prescription or repeatable prescription for any drug, medicine or appliance,*

(3) except in the circumstances set out in Regulation 25"

211. There is a like provision in Reg. 18 of the PMS Regulations.

212. The prohibition covers any charge which is made for the provision of treatment or any prescription to a patient, not just treatment that the GP is required to provide under the practice contract. A GP practice cannot therefore charge a third party, such as an employer or the parent of a child, for medical treatment provided to a patient.

213. A "patient" in these circumstances is defined as described above.

214. The general prohibition on imposing charges for treatment means that a GP with a GMS or PMS contract cannot charge a "patient" for the delivery of any form of medical treatment even if that treatment is not provided as part of NHS funded healthcare. Thus a GP who provides, for example, osteopathy, acupuncture or homeopathy outside of NHS funded care is prohibited from charging patients (as that term is defined above) for the provision of such a service. There is nothing to prevent a GP practice from offering such services on a commercial basis to persons who are not patients of the practice and do not otherwise come within the definition of being a "patient" under the GMS or PMS Regulations. However Regulation 24 provides that a GP practice which holds an NHS contract cannot charge for offering any form of medical treatment (even outside NHS services) to patients of an NHS practice.

Medical certificates

215. The GMS and PMS Regulations contain a list of statutory certificates that GP practices are required to provide without charge. Regulation 22 of the GMS Regulations provides:

"(1) Subject to paragraphs (2) and (3), a contract must contain a term which has the effect of requiring the contractor to issue any medical certificate of a description prescribed in column 1 of Schedule 2 under, or for the purposes of, the enactments specified in relation to that certificate in column 2 of that Schedule if that certificate is reasonably required under or for the purposes of the enactments specified in relation to that certificate.

(2) A certificate referred to in paragraph (1) must be issued free of charge to a patient or to a patient's personal representatives.

(3) A certificate must not be issued where, for the condition to which the certificate relates, the patient is—

(a) being attended by a medical practitioner who is not—

(i) engaged or employed by the contractor,

(ii) in the case of a contract with two or more persons practising in a partnership, one of those persons, or

(iii) in the case of a contract with a company limited by shares, one of the persons legally or beneficially owning shares in that company; or

(b) not being treated by or under the supervision of a health care professional."

216. The exception in paragraph (3)(a) does not apply where the certificate is issued in accordance with regulation 2(1) of the Social Security (Medical Evidence) Regulations 1976 (evidence of incapacity for work, limited capability for work and confinement) or regulation 2(1) of the Statutory Sick Pay (Medical Evidence) Regulations 1985 (medical information).

217. This provision is somewhat clumsily worded but it means that a GP must issue one or more statutory certificates without charge where the following apply:

a. The GP is asked to produce the certificate by a patient (as that term is defined, as to which see above) or his personal representative;

b. The certificate is of a description prescribed in column 1 of Schedule 2 to the GMS Regulations. These are listed below;

c. The certificate must be reasonably required under or for the purposes of the enactments specified in relation to the certificate in column 2 of Schedule 2 to the GMS Regulations;

d. The exemptions in Reg. 22(3)(a) and (b) do not apply (as to which see below); and

e. The exemption in Regulation 22(4) to the exception in Regulation 22(3)(a) applies.

218. Column 1 of Schedule 2 to the GMS Regulations lists the types of certificates which have to be provided free of charge and column 2 lists the Acts of Parliament under which the certificates have to be provided.

Column 1: Purpose of certificate	Column 2: Enactments
To support a claim or to obtain payment either personally or by proxy;	Naval and Marine Pay and Pensions Act 1865

to prove incapacity to work or for self-support for the purposes of an award by the Secretary of State; or to enable proxy to draw pensions etc	Air Force (Constitution) Act 1917 Pensions (Navy, Army, Air Force and Mercantile Marine) Act 1939 Personal Injuries (Emergency Provisions) Act 1939 Pensions (Mercantile Marine) Act 1942 Polish Resettlement Act 1947 Social Security Administration Act 1992 Social Security Contributions and Benefits Act 1992 Social Security Act 1998
To establish pregnancy for the purpose of obtaining welfare foods	Section 13 of the Social Security Act 1988 (Benefits under schemes for improving nutrition: pregnant women, mothers and children)
To secure registration of still-birth	Section 11 of the Births and Deaths Registration Act 1953 (special provision as to registration of still-birth)
To enable payment to be made to an institution or other person in case of mental disorder of persons entitled to payment from public funds	Section 142 of the Mental Health Act 1983 (pay, pensions etc of mentally disordered persons)
To establish unfitness for jury service	Juries Act 1974
To support late application for reinstatement in civil employment or notification of non-availability to take up employment owing to sickness	Reserve Forces (Safeguarding of Employment) Act 1985
To enable a person to be registered as an absent voter on grounds of physical incapacity	Representation of the People Act 1985
To support applications for certificates conferring exemption from charges in respect of drugs, medicines and appliances	National Health Service Act 2006
To support a claim by or on behalf of a severely mentally impaired person for exemption from liability to pay the Council Tax or eligibility for a discount in respect of the amount of Council Tax payable	Local Government Finance Act 1992

219. The wording of the exemption in Reg. 22(1) means that none of the above certificates have to be provided free of charge where the medical condition to which the certificate relates is being treated by a doctor or other healthcare professional who is not

either a partner of the practice (including a corporate partner) or is employed by the GP practice. In such a case the Regulations effectively signpost the patient to obtaining the certificate from the doctor or other healthcare professional who is treating the patient. This could be a private doctor or is more likely to be a consultant in secondary care. This exception does not apply where the certificate is sought in accordance with regulation 2(1) of the Social Security (Medical Evidence) Regulations 1976 (evidence of incapacity for work, limited capability for work and confinement) or regulation 2(1) of the Statutory Sick Pay (Medical Evidence) Regulations 1985 (medical information). In such cases the GP practice must issue the certificate free of charge even though the patient is being treated by another doctor or other healthcare professional.

220. The exemption in Reg. 22(3)(b) provides that where the medical condition to which the certificate relates is not being treated by a health care professional at all, the GP practice is not required to provide a certificate free of charge.

221. The BMA reports that it has clarified with the Department of Work and Pensions ("DWP") that it is not obligatory for GPs to fill in statements of incapacity when requested for the purposes of social security benefits by DWP. These forms attract a separate fee paid by the DWP.

222. Once a certificate has been issued to the DWP, the person to whom the certificate is sent is entitled to come back with follow up questions. The terms of the GMS and PMS contracts provide that the GP practice be satisfied that the patient has consented before any questions but, if consent is given, no charge can be made by the GP practice for answering questions which follow on from a report that must be provided free of charge. This is set out in Reg. 76 of the GMS Regulations which provides that GMS Contract must contain a term that:

> *(1) The contractor must, if satisfied that the patient consents—*
>
> *(a) supply in writing to a person specified in paragraph (3) (a "relevant person"), before the end of such reasonable period as that person may specify, such clinical information as a person specified in paragraph (3)(a) to (d) considers relevant about a patient to whom the contractor, or a person acting on behalf of the contractor, has issued or has refused to issue a medical certificate; and*
>
> *(b) answer any inquiries by a relevant person about—*
>
> > *(i) a prescription form or medical certificate issued or created by, or on behalf of, the contractor, or*
> > *(ii) any statement which the contractor, or a person acting on behalf of the contractor, has made in a report.*

223. For the purpose of being satisfied that a patient consents, a contractor may rely on an assurance in writing from a relevant person that the consent of the patient has been obtained, unless the contractor has reason to believe that the patient does not consent.

224. For the purposes of this regulation, *"a relevant person"* is—

a. a medical officer;
b. a nursing officer;
c. an occupational therapist;
d. a physiotherapist; or
e. an officer of the Department for Work and Pensions who is acting on behalf of, and at the direction of, any person specified in sub-paragraphs (a) to (d).

225. Paragraph (f)(ii) of Regulation 25 of the GMS Regulations provides that where a GP practice is asked by a commercial, educational or not-for-profit organisation to attend and/or examine (but not otherwise treat) a patient for the purpose of creating any other form of medical report or certificate the GP practice is entitled to charge a reasonable fee. This seems to cover virtually all types of reports that are requested concerning patients other than the certificates issued under the various statutes listed above.

Charges where the GP practice has reasonable doubts as to whether a patient is on the practice list

226. Regulation 24 of the GMS Regulations and Regulation 18 of the PMS Regulations contain a provision to cover situations where a person presents seeking treatment but where the GP has genuine doubts about whether the GP practice has a duty to provide services to that person. In such a case the GP practice may impose a charge. Regulation 24(3)-(4) of the GMS Regulations states as follows:

> *"(3) Subject to paragraph (4), where—*
> *(a) a person—*
> *(i) applies to a contractor for the provision of essential services,*
> *(ii) claims to be on that contractor's list of patients, and*
> *(iii) fails to produce a medical card relating to that person on request; and*
> *(b) the contractor has reasonable doubts about that person's claim,*
> *the contractor must give any necessary treatment to that person and may demand and accept from that person a reasonable fee in accordance with regulation 25(e).*
>
> *(4) Where—*
> *(a) a person from whom the contractor has received a fee under regulation 25(e) applies to the Board for a refund within 14 days from the date of payment of the fee (or within such longer period not exceeding one month as*

the Board may allow if it is satisfied that the failure to apply within 14 days was reasonable); and

(b) the Board is satisfied that that person was on the contractor's list of patients when the treatment was given,

the Board may recover the amount of the fee from the contractor, by deduction from the contractor's remuneration or otherwise, and must pay the amount recovered to the person who paid the fee."

227. This Regulation imposes a duty on the GP to provide "essential services" to the person notwithstanding the fact that the GP practice has "reasonable doubts" that the practice contract requires the GP practice to treat the person. However, in such a case the GP practice can impose a reasonable charge and recover this sum from the patient.

228. The reasonable fee will, of course, depend on the circumstances and the precise nature of the treatment provided. The Regulations provide that the individual can then claim the fee back from NHS England if that person can prove they were on the list of patients for the practice at the relevant time. NHS England will then claim the fee back from the GP practice if the patient was a "patient" of the practice.

229. The above provision only applies if a GP practice has "reasonable doubts" whether a person is on the practice list or not. If the GP practice knows (without any reasonable doubt) that the patient is not on the practice list, then there is no duty to provide essential services to that person. Hence if, for example, a patient has been removed from the practice list because they have moved away, registered with anther GP practice or have been violent, attends the surgery seeking treatment, the GP practice owes no duty to provide essential services to that person (unless there is a medical emergency) and can require the patient to leave the premises. The person will be a trespasser and thus, if they do not leave, the person may commit a civil wrong. If there is a suggestion of a breach of the peace the police can be called.

Charges permitted by Reg. 25 of the GMS Regulations and Reg. 19 of the PMS Regulations

230. The specific circumstances in which GP practices can impose charges on "patients" is set out in Reg. 25 of the GMS Regulations. There is a like provision in Regulation 19 of the PMS Regulations. The particular circumstances relating to each of these exemptions is set out below. APMS contractors are likely to have the same restrictions on charging and the same exemptions introduced through a contractual term (see paragraph 10 of Part 4 of the APMS Directions).

231. Regulation 25 of the GMS Regulations provides as follows:

The contractor may demand or accept (directly or indirectly) a fee or other remuneration—

(a) from a statutory body for services rendered for the purposes of that body's statutory functions;

(b) from a body, employer or school for—

(i) a routine medical examination of persons for whose welfare the body, employer or school is responsible, or

(ii) an examination of such persons for the purpose of advising the body, employer or school of any administration action that they might take;

(c) for treatment which is not primary medical services or is otherwise required under the contract and which is given—

(i) at accommodation made available in accordance with the provisions of paragraph 11 of Schedule 6 to the Act (accommodation and services for private patients), or

(ii) in a registered nursing home which is not providing services under the Act,

if, in either case, the person administering the treatment is serving on the staff of a hospital providing services under the Act as a specialist providing treatment of the kind the patient requires, and if, within seven days of giving the treatment, the contractor or the person giving the treatment supplies the Board, on a form provided by the Board for that purpose, with such information as the Board may require;

(d) under section 158 of the Road Traffic Act 1988 [1] (payment for emergency treatment of traffic casualties);

(e) when the contractor treats a patient under regulation 24(3), in which case the contractor is entitled to demand and accept a reasonable fee (recoverable in certain circumstances under regulation 24(4)) for any treatment given, if the contractor gives the patient a receipt;

(f) for attending and examining (but not otherwise treating) a patient—

(i) at a police station, at the patient's request, in connection with possible criminal proceedings against the patient,

(ii) for the purpose of creating a medical report or certificate, at the request of a commercial, educational or not for profit organisation,

(iii) for the purpose of creating a medical report required in connection with an actual or potential claim for compensation by the patient;

(g) for treatment consisting of an immunisation for which no remuneration is payable by the Board and which is requested in connection with travel abroad;

(h) for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines or appliances in the form of a travel kit) which a patient requires to have in their possession solely in anticipation of the onset of an ailment or occurrence of an injury while that patient is outside of the United Kingdom but for which that patient is not requiring treatment when the drug, medicine or appliance is prescribed;

(i) for a medical examination—

(i) to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear a seat belt, or

(ii) for the purpose of creating a report—

(aa) relating to a road traffic accident or criminal assault, or

(bb) that offers an opinion as to whether the patient is fit to travel;
(j) for testing the sight of a person to whom none of paragraphs (a) to (e) of section 115(2) of the Act (primary ophthalmic services) applies (including by reason of regulations made under section 115(7) of the Act) [2]*;*
(k) where the contractor is authorised or required in accordance with arrangements made with the Board under section 126 of the Act [3] *(arrangements for pharmaceutical services) and in accordance with regulations made under section 129 of the Act* [4]*(regulations as to pharmaceutical services) to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of dispensing services, any Scheduled drug; and*
(l) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.

Charges for meeting the requirements of other Statutory bodies

232. Under Regulation 25 of the GMS Regulations a GP practice may demand or accept (directly or indirectly) a fee or remuneration from a statutory body for services rendered for the purposes of that body's statutory functions.

233. GP practices are under contract to NHS England (and sometimes CCGs too). They are obliged to undertake the functions set out in the contract but are not obliged to spend time responding to requests from other statutory bodies including local authorities unless the request is based on another form of statutory authority including, for example, requests under the Freedom of Information Act 2000. In practice, it can often be difficult for GP practices to set out clear limits on what they are prepared to do because statutory bodies assume that GP practices have a duty to co-operate with them in the discharge of their public functions.

234. The right to charge for doing work in response to requests by other public bodies includes where a GP is asked to attend a Child Protection Conferences at the request of the local authority for a child who is a practice patient or the GP has seen. According to the BMA, some CCGs have suggested that, although GP contracts contain no provision requiring them to participate in the safeguarding process, GPs would nonetheless have to justify non-compliance, with regard to their statutory safeguarding duties, and that non-compliance could justify a referral to the GMC, with the implication that disciplinary action could be taken against defaulting GPs. Whilst the extent of GPs' safeguarding duties is outside of the scope of this chapter, it is clear that GPs are entitled to charge a fee for this work. The BMA recommends that such fees should be indicated in advance of the GP in advance of preparing reports or attending case conferences.[23]

235. If a GP is called to a Child Protection Conference by another statutory body (usually the local authority or the police) and no fee is agreed, the right course is probably for the GP

[23] https://www.bma.org.uk/advice/employment/fees/safeguarding-children-and-adults (accessed 18 November 2017).

to make it clear in advance that he or she is attending in response to the request and the GP practice expects to be remunerated for the GP's time, for the GP to attend the Child Protection Conference (in discharge of his or her duties as a doctor) and then for the GP Practice to send an invoice to the public body that called the GP seeking a reasonable fee. Although the authors are unaware of any case in which this issue has been tested in court, it seems likely that the GP Practice would be entitled to a reasonable fee in quasi-contract and thus ought to succeed in such a claim.

236. The BMA has also provided guidance on so-called 'collaborative arrangements'.[24] This term refers to work done by GPs on behalf of local authorities in the fields of education, social services and public health. With the exception of family planning, fees for collaborative arrangements are not agreed nationally. Instead they must be agreed at a local level in accordance with local needs. GP practices are advised to agree these fees in advance because this avoids difficult arguments over quasi-contract claims. The BMA reminds GPs that "basic health information provided by GPs for community care purposes does not attract a fee. [However] community care work that goes beyond the provision of basic health data…does attract a fee".[25]

237. If a GP practice is asked to undertake work for any other statutory agency, the GP practice is entitled to levy a reasonable fee. However no fee can be claimed if a GP is required to do something under a different statutory scheme (which may or may not give rise to a right to payment depending on that statutory scheme). Hence if a GP is summoned to court as a witness of fact by the Crown Prosecution Service, no fee is payable because the legal duty to attend arises from the summons. It is, of course, different if the GP is attending court as an expert where fees can be claimed.

Fees for conducting routine medical examinations

238. It is not part of the duties of a GP to undertake medical examinations of persons who are not and do not believe themselves to be ill. Hence, the second exemption to the rule against charges in Reg. 25 provides that if an employer, a school or any other body (including the patient themselves) asks a GP to do a medical examination of a well patient "for the purpose of advising the body, employer or school of any administrative action they might take", a fee can be charged. The request for such a service is outside the terms of the duty to provide "essential services" under a GMS or PMS contract and yet it is not in the interests of the patient for the GP to refuse to provide such a report. Hence the Regulations allow the GP practice to charge a fee for this work. A fee cannot be claimed for the health checks that are required for new patients or those over the age of 75.

239. If a patient of the practice asks for a medical examination to provide reassurance to an employer that they can undertake a physical job or a student wants a report to confirm

[24] https://www.bma.org.uk/advice/employment/fees/collaborative-arrangements (accessed 18 November 2017)
[25] Ibid.

he or she is fit to go on an expedition, the GP practice is entitled to charge a reasonable fee for this service.

Services provided by a specialist GP for private patients in hospitals or a care home

240. The third circumstance in which a GP practice can charge a fee in Reg. 25 needs a little explanation.

241. There is no difficulty in a GP practice charging a fee for providing services to a nursing home or receiving remuneration for working in an NHS hospital if the patients who are being treated are not "patients" of the GP practice within the above definition. However, there are only very limited circumstances in which a GP practice can charge for medical services provided in a hospital or care home to practice patients or others who come within the above definition. In order for the GP practice lawfully to be able to impose a charge under the above exemption:

a. The **location requirement** must be met. The services must be provided in either a registered care home or to a private patient in an NHS hospital. This exemption does not extend to providing services in a private hospital;

b. The **services requirement** must be met. The services provided to the patient must not be "primary care services" under this exemption. The meaning of "primary care services" is explored in above. The fact that a general management service for a resident patient in a care home or a private patient in an NHS hospital is provided in the home rather than requiring the patient to come to the surgery does not take the service outside being a primary care service. Thus charges can only be made if the service provided by the GP Practice is something which cannot properly be described as being a primary care service. It thus effectively means that the GP is contracted by the care home (or private wing in an NHS hospital) to provide a service that is different to the services that GPs usually provide in the surgery;

c. The **person requirement** must be met. The person from the GP practice who is providing the services must be employed by a hospital providing services under the NHS Act as a specialist providing treatment of the kind the patient requires; and

d. The **procedural requirement** must be met. Within 7 days of giving the treatment, the contractor or the person providing the treatment must supply the Board with such information about the treatment as the Board may require on a form provided by the Board for this purpose.

242. This is the provision which is used by some GP practices to charge for providing medical cover to nursing homes. If the patients at a nursing home are not registered patients of a GP practice (because they are registered with another practice) and do not come within the definition of "patients" as set out above, then there is no prohibition on a

GP practice providing medical cover for the care home and charging for that service. However, if the residents are registered patients of the GP practice, the right to charge is strictly limited by the above 4 provisions. This exemption probably only applies in practice to a partner or salaried doctor in a GP practice who is employed by a local NHS Trust to deliver a specialist skill and, as part of that work, finds himself or herself treating a patient from his or her own practice. It is thus a very limited exemption.

Payment for emergency treatment of traffic casualties

243. Section 158 of the Road Traffic Act 1988 provides for very modest payments to any doctor who treats a victim of a road traffic accident.

244. This exemption to the general rules against charging practice patients only applies if a GP attends on a road accident on a road or in some other public place (i.e. not in the doctor's surgery) and the victim happens to be a "patient" within the meaning of the above definition. In such a case, a GP who administers any treatment to such a patient is allowed to claim a fee of £21.30 from the accident victim and 41p per mile for any travelling over 2 miles. The fee must be claimed from the patient and it can then be reclaimed from whoever caused the accident in the first place (unless that was the person being so treated of course).

245. If the person who is treated by the GP is not a "patient" of the practice then the GP can still claim the fee under section 158. However this arrangement is entirely outside the contract and so there are no relevant restrictions on the GP.

Fees for attending a police station

246. Many GPs are under contract to the police service to attend police stations in order to provide healthcare services to those who are arrested or otherwise detained by the police. There will, of course, be occasions where the person who the GP is called upon by the police to treat is a patient of the practice where the GP is a partner or works as a salaried doctor. Exemption (f)(i) provides that a GP can still claim his fee (usually from the police) in such circumstances.

247. This exemption would also entitle a GP to claim a fee if he was asked to attend a police station by anyone else to see a patient of the practice (or any other person coming within the above definition of being a "patient") including for example a solicitor for the patient.

Fees for preparing a medical report or certificate

248. Regulation 25(f)(ii) of the GMS Regulations provides that where a GP practice is asked to attend and/or examine (but not otherwise treat) a patient for the purpose of

creating a medical report or certificate at the request of a commercial, educational or not for profit organisation, the GP practice is entitled to charge a reasonable fee.

Fees for preparing medico-legal reports

249. Regulation 25(f)(iii) of the GMS Regulations provides that where a GP practice is asked to attend and/or examine (but not otherwise treat) a patient for the purpose of creating a medical report required in connection with an actual or potential claim for compensation by the patient, the GP practice is entitled to charge a reasonable fee.

250. The fee can be payable by the patient or by the solicitor's firm who have made the request, depending on the circumstances.

Requests by patients who are about to travel abroad

251. Where a patient asked for treatment consisting of an immunisation for which no remuneration is payable by NHS England (because it is not usually provided as part of NHS funded treatment) and which is requested in connection with travel abroad, a fee can be charged.

252. Travellers also frequently request a prescription of drugs to prevent them from contracting a condition. The GP practice can also charge for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines or appliances in the form of a travel kit) which a patient requires to have in his possession solely in anticipation of the onset of an ailment or occurrence of an injury while he is outside the United Kingdom but for which he is not requiring treatment when the medicine is prescribed.

253. A fee can also be charged for prescribing or providing drugs or medicines for malaria chemoprophylaxis.

Fees for preparing reports for seat belt purposes, following a traffic accident, a criminal assault or for fitness to travel

254. A fee can be charged where a GP practice is asked to undertake a medical examination to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear a seat belt.

255. A fee can also be charged where a GP practice is asked to undertake a medical examination for the purpose of creating a report relating to a road traffic accident or criminal assault or that offers an opinion as to whether a patient is fit to travel.

Eye examinations by GPs

256. Part 6 of the NHS Act 2006 places a requirement on NHS England to arrange ophthalmic services for specific classes of people, notably those who are under 16, over 60, who are on state benefits or have defined medical conditions. These services are generally delivered by opticians and not by GPs. However, unlike other areas of NHS services, the ophthalmic service is not universal and there are individuals who are not included in NHS provision. If such persons come to a GP practice then a fee can be charged for undertaking an eye examination.

Dispensing doctors and scheduled drugs

257. The last exemption in Regulation 25 of the GMS Regulations only applies to dispensing GP practices. It permits dispensing practices to charge a fee to patients if a "scheduled drug" is prescribed to that patient. A "scheduled drug" means a drug which has been prohibited by the Secretary of State from being prescribed to NHS patients generally or has been prohibited for prescription as part of NHS funded treatment apart from a limited class of patients[26]. This is known as the "black list" or the "black/grey list".

[26] Reg. 3 of the GMS Regulations define a "scheduled drug" as follows:
"Scheduled drug" means—
(a) a drug, medicine or other substance specified in any directions given by the Secretary of State under section 88 of the Act (GMS contracts: prescription of drugs etc.) as being a drug, medicine or other substance which may not be ordered for patients in the provision of medical services under the contract; or
(b) except where the conditions in regulation 61(3) are satisfied, a drug, medicine or other substance which is specified in any directions given by the Secretary of State under section 88 of the Act as being a drug, medicine or other substance which can only be ordered for specified patients and specified purposes;