SMOKING, HEALTH AND SOCIAL CARE (SCOTLAND) ACT 2005

EXPLANATORY NOTES

THE ACT

3. The main provisions of the Act are set out below.

Part 1– makes provision for a ban on smoking in certain wholly or substantially enclosed places:

- creating an offence of permitting others to smoke in and on no-smoking premises;
- creating an offence of smoking in no-smoking premises;
- creating an offence of failing to display warning notices in no-smoking premises;
- setting out the powers of enforcement officers to enter no-smoking premises;
- creating an offence of failing without reasonable excuse to give one's name and address on request by an authorised officer;

Part 1 also enables Scottish Ministers to raise by order the ages specified (currently age 16) in section 18 of the Children and Young Persons (Scotland) Act 1937, which includes the legal age for tobacco purchase.

Part 2 – provides for various matters concerning general dental services, personal dental services and general ophthalmic services:

- detection of vision problems in children
- free oral health assessments and dental examinations;
- free eye examinations and sight tests;
- assistance and support in the provision of general dental services;
- NHS provision of certain dental services;
- listing of those persons undertaking to provide or approved to assist in the provision of general ophthalmic services;
- listing of those persons undertaking to provide or approved to assist in the provision of general dental services and those persons performing personal dental services under section 17C arrangements and pilot schemes.

Part 3 – makes a series of provisions regarding pharmaceutical care services:

 requirements on Health Boards to plan provision of pharmaceutical care services;

- contracts for provision of pharmaceutical care services;
- listing of persons performing pharmaceutical care services;
- provision of assistance and support for pharmaceutical care services.

Part 4 – makes provisions for certain services to be treated as an NHS contract.

Part 5 – makes provisions for strengthening the powers of the NHS Tribunal, extending its jurisdiction and giving effect to corresponding provision made in England or Wales or Northern Ireland.

Part 6 – makes provisions for a number of miscellaneous issues:

- payments to certain persons infected with hepatitis C;
- amendment of the Regulation of Care (Scotland) Act 2001;
- registration of child care agencies and housing support services;
- amendment of the Adults with Incapacity (Scotland) Act 2000;
- appeals against certain orders under the Public Health (Scotland) Act 1897;
- the ability of Scottish Ministers and health bodies to enter into joint ventures;
- the Scottish Hospital Endowments Research Trust.

Part 7 – makes general provisions.

Schedule 1 – Fixed penalty for offences under sections 1, 2 and 3.

Schedule 2 – Minor and consequential amendments:

• including clarification of Scottish Ministers' powers under National Health Service (Scotland) Act 1978.

Schedule 3 – Repeals.

• including repeal of the age limit for serving on Mental Health Tribunal.

Part 1: Smoking: Prohibition and Control

Section 1 – Offence of permitting others to smoke in no-smoking premises

- 4. Subsections (1) and (2) make it an offence for the person who is in charge of no-smoking premises, having the management or control of those premises, to knowingly permit others to smoke there. The person in charge will be regarded as having permitted that other person to smoke if he or she knew, or ought to have known, that the other person was smoking there.
- 5. Two defences are provided under subsection (3). The first defence open to the accused person is to prove that they, or anyone working for them, had taken all reasonable precautions and had tried to the best of their ability to stop any other person from smoking in their premises. The second defence open to the accused is to prove that there were no lawful and reasonably practicable means by which they could prevent the other person from smoking in their premises.
- 6. Subsection (4) provides that the offence of permitting others to smoke in no-smoking premises is subject to a maximum penalty, on summary conviction, of a fine not exceeding level 4 on the standard scale (currently £2500).

Section 2 – Offence of smoking in no-smoking premises

- 7. Subsection (1) makes it an offence for a person to smoke in no-smoking premises.
- 8. Subsection (2) provides that it is a defence if the person accused of smoking can prove that they did not know, and could not reasonably be expected to have known, that the premises in which they were smoking were no-smoking premises. This might arise in instances where, for example, no-smoking signs had been removed or had failed to be displayed. The onus is however on the accused to prove this.
- 9. Subsection (3) provides that the offence of smoking in no-smoking premises is subject to a maximum penalty on summary conviction of a fine not exceeding level 3 on the standard scale (currently £1000).

Section 3 – Display of warning notices in and on no-smoking premises

- 10. Subsection (1) requires "no-smoking" signs to be conspicuously displayed in, on or near, and so as to be visible and legible from outside, no-smoking premises. The person who is in charge of those no-smoking premises, having the management or control of the premises, is liable for any failure to display such signs. Failure to display signs is an offence. The signs to be displayed must state that the premises are no-smoking premises and that it is an offence to smoke there or knowingly to permit smoking there.
- 11. Under subsection (2) it is a defence for anyone accused of failing to display "no-smoking" signs to prove that they or anyone working for them or representing them as an agent took all reasonable precautions and exercised all due diligence to ensure that signs were in place as required.
- 12. Subsection (3) gives the Scottish Ministers powers to make regulations which will provide further details as to the manner of display, form and content of the no-smoking signs. Regulations under this provision will be made under the affirmative resolution procedure, so that they cannot be made until the Parliament has approved a draft.
- 13. Subsection (4) provides that the offence of failing to display warning notices in and on no-smoking premises is subject to a maximum penalty on summary conviction of a fine not exceeding level 3 on the standard scale (currently £1000).

Section 4 – Meaning of "smoke" and "no-smoking premises"

- 14. Subsection (1) provides the meaning of "smoke" which in the context of Part 1 of the Act means to smoke tobacco or any other substance or mixture which can be smoked. This subsection further clarifies that a person is to be taken as smoking if the person holds or is otherwise in possession or control of lit tobacco or any other lit substance or mixture which can be smoked.
- 15. Subsection (2) provides for "no-smoking premises" to be defined as such premises or classes of premises of a kind mentioned in subsection (4), which will be prescribed by the Scottish Ministers under regulations. Subsection (3) allows the Scottish Ministers to exclude, by means of those regulations, certain premises, or parts of premises, or classes or premises or parts of premises, from the definition of "no-smoking premises". Regulations made under subsection (2) are to be made by affirmative procedure.
- 16. Subsection (4) lists the kinds of premises which are to be prescribed as "no-smoking premises" under subsection (2), being premises which are wholly or substantially enclosed and (a) to which the public or a section of the public have access, (b) which are used wholly or mainly as a place of work, (c) which are being used for the purposes of a club or an other unincorporated association and (d) which provide education, health or care services.

- 17. Subsection (5) clarifies that those premises described in subsection (4)(b) as a place used for work include those premises where people work for no financial advantage such as, for example, voluntary workers.
- 18. Subsection (6) gives a further power to the Scottish Ministers to define or elaborate by means of regulations on the meaning of certain expressions used under subsection (2).
- 19. Similarly, and as above, subsection (7)(a) empowers the Scottish Ministers to define or elaborate by means of regulations the meaning of "premises" by reference to the person or class of person who owns or occupies the premises, whilst subsection (7) (b) allows the Scottish Ministers to define or elaborate the meaning of "premises" to include specific forms of public transport as they see fit.
- 20. Subsection (8) allows the Scottish Ministers to make regulations to modify subsection (4) by adding to or removing from the kinds of premises listed there. Again, any such regulations will require to be made by affirmative resolution.
- 21. Subsection (9) relates to the "no-smoking" notices which are to be displayed under section 3(1). Subsection (9) provides that where regulations are made under subsection (2) which define or elaborate the meaning of "premises" to cover certain forms of transport, those regulations may provide how the "no-smoking" sign in relation to each form of transport is to be expressed, thus enabling bespoke "no-smoking" signs for the various forms of transport.

Section 5 – Proceeding for offences under sections 1 to 3

- 22. Subsection (1) links the start of the time limit for summary proceedings in pursuance of sections 1, 2 or 3 to the point at which the Crown is passed sufficient evidence on the offence to justify bringing a prosecution. This will prevent any lengthy or extended hearing processes consequential to the issuing of a fixed penalty notice under Part 1 of the Act resulting in a subsequent prosecution for that offence being time barred.
- 23. Subsection (2) provides that section 136(3) of the Criminal Procedure (Scotland) Act 1995 (c.46) applies to section 5(1) as it does to that section. Section 136(3) of the 1995 Act provides that summary proceedings are deemed to commence when a warrant is granted, if it is executed without undue delay. Subsection (3) clarifies that a certificate from the Crown as to the date that evidence came to the knowledge of the Crown is conclusive evidence of that date.

Section 6 – Fixed penalties

- 24. Subsection (1) provides for a fixed penalty scheme under Schedule 1 to have effect. Schedule 1 sets out the details of how the fixed penalty system will work for offences committed under sections 1, 2 and 3 of the Act. An explanation of the provisions in the Schedule is given at the end of these notes.
- 25. Subsection (2) provides that the fixed penalty system will not extend to offences under section 1 (permitting others to smoke in no-smoking premises) or section 3 (failure to display warning notices in or on no-smoking premises) committed otherwise than by a natural person.

Section 7 – Powers to enter and require identification

26. Subsection (1) empowers an officer of a council to enter no-smoking premises in order to check whether an offence under sections 1, 2 or 3 has taken place or is being committed. The council which authorises the officer under this subsection will be the council in the area where the premises are situated. Officers of the council will, in general terms, have access to premises to which the public has access; this additional power is therefore a back-up power.

- 27. A council officer exercising a power of entry under subsection (1), may use force to gain entry if necessary under subsection (2) and may, under subsection (1) search the premises.
- 28. An offence is committed under subsection (3) if a person who an authorised officer of a council reasonably believes is committing or has committed an offence under sections 1, 2 or 3, or has information relating to the offence fails without reasonable excuse to give their name and address when requested to do so by the enforcing officer. The penalty for a person guilty of an offence under this subsection is on summary conviction a fine not exceeding level 3.

Section 8 – Bodies corporate etc.

29. Section 8 provides that officers of companies and other corporations and members of partnerships can be held personally liable, in certain circumstances, for offences under Part 1 of the Act that their companies or partnerships commit.

Section 9 – Sale of tobacco to under-age persons: variation of age limit

- 30. Subsection (1) enables Scottish Ministers to raise by order the age in section 18 of the Children and Young Persons (Scotland) Act 1937 (c.37) (offence of selling tobacco etc. to under-age persons and other preventative measures). This allows them to raise the age from the current one of 16 years for the purchase of tobacco.
- 31. Subsection (2) requires that Scottish Ministers only make an order under subsection (1) after they have consulted on a draft with persons as they see as appropriate, for example local authorities and police bodies.

Section 10 - Crown application

- 32. Many enclosed public places will be operated and controlled by the Crown. Section 10 provides that Part 1 of the Act and any regulations made under it shall bind the Crown. Subsection (2) ensures that instead of making the Crown criminally liable for any contravention under this Part of the Act, the Court of Session may declare unlawful any act or omission of the Crown which constitutes a contravention.
- 33. Although the Crown itself cannot be prosecuted, subsection (3) ensures that the provisions in Part 1 apply to people in the public service of the Crown.

Part 2: General Dental Services, General Ophthalmic Services and Personal Dental Services

Section 11 – Detection of vision problems in children

34. Section 11 makes provision in relation to the detection of vision problems in children. It does so by placing a duty on Scottish Ministers, inserted at section 38B of the National Health Service (Scotland) Act 1978, to provide for the detection of vision problems in children, to such an extent as they consider necessary to meet all reasonable requirements.

Section 12 – Free oral health assessments and dental examinations

35. The provisions discussed in paragraphs 35 to 38 introduce free oral health assessments and dental examinations for all. In subsection (2) of section 70A of the National Health Service (Scotland) Act 1978 new wording is substituted, creating new paragraphs (a) and (b). Subsection (2) defines the dental treatment provided in accordance with section 17C arrangements for which regulations made under subsection (1) may prescribe the manner of making and recovering patient charges. New paragraph (a) excludes oral health assessments and dental examinations undertaken on or after 1 April 2006 from that definition.

- 36. In subsection (1) of section 71 of the 1978 Act, a new paragraph (a) is inserted. This excludes oral health assessments and dental examinations undertaken on or after 1 April 2006 from the Part II general dental services for which regulations may provide for the making of charges.
- 37. In subsection (2) of section 71 of the 1978 Act, new wording is substituted. This again excludes oral health assessments and dental examinations made on or after 1 April 2006 from the prescribed special dental treatment provided under general dental services for which regulations may provide for the making of charges.
- 38. In subsection (1) of section 20 of the National Health Service (Primary Care) Act 1997, new wording is substituted creating new paragraphs (a) and (b). New paragraph (a) replaces subsection (2) of section 20 which is repealed. Section 20 empowers regulations to be made to prescribe the manner of making and recovering patient charges for personal dental services under a pilot scheme. New paragraph (b) excludes oral health assessments and dental examinations undertaken on or after 1 April 2006 from these powers.

Section 13 – Free eye examinations and sight tests

- 39. Section 13 makes provision in relation to free eye examinations and sight tests. It does so by extending the meaning of general ophthalmic services, the provision of which must be secured under section 26 of the 1978 Act. At present, general ophthalmic services to be provided free of charge are limited to the testing of sight, which would determine whether or not a person requires an optical appliance (e.g. spectacles), of certain categories of person. This section extends the duty in section 26(1) of the 1978 Act both to include eye examinations, tailored to meet the needs of the individual patient and which may, or may not, include a sight test, and to apply to all.
- 40. In subsection (1) of section 26 of the 1978 Act, new wording is substituted in order to provide that Health Boards are placed under a duty to make arrangements with ophthalmic opticians and ophthalmic medical practitioners for the carrying out of eye examinations which will include the testing of the patient's sight where this is considered necessary in the clinical opinion of the ophthalmic optician or medical practitioner who is undertaking the eye examination.
- 41. Subsections (1A) to (1E) of section 26 of the 1978 Act are repealed. These set out the categories of patient who are currently entitled to have their sight tested free of charge under general ophthalmic services and are therefore otiose.
- 42. Sub-paragraph (3)(a) of paragraph 2A of Schedule 11 to the 1978 Act is repealed. This provides for Scottish Ministers or a Health Board to contribute towards the cost of sight tests for those persons whose income/capital does not exceed their requirements as calculated in accordance with regulations but falls within the regulatory parameters for help with costs.

Section 14 - Charges for certain dental appliances and general dental services

- 43. In section 70 of the 1978 Act, new wording is substituted in order to provide, by regulations, more flexibility for the way in which dental charges are made or recovered. In section 70, wording is expanded to add the category of dental appliances to allow for more flexibility in the charging system. Section 70(1A) is repealed as dental appliances are now included in subsection 1. Similarly, in section 70(2) the reference to subsection (1A), is amended to refer to subsection (1).
- 44. In section 70A(2) new wording is substituted to take account of the repeal of section 70 subsection (1A) and to refer to section 70(1) for the making and recovery of charges for dental appliances.
- 45. In section 71 of the 1978 Act new wording is substituted to reflect that section 71A is repealed.

46. In paragraph 2 of schedule 11 of the 1978 Act new wording is substituted. A new subparagraph (1A) is introduced to provide by regulations charges for dental appliances which are defined as dentures, bridges, crowns and orthodontic appliances. The wording in sub-paragraph (2) (a) is also amended to include dental appliance. In sub-paragraph 3 the reference to section 1A is repealed and the wording in sub-paragraph (4) is amended to reflect that section 70(1A) is repealed.

Section 15 – Arrangements for provision of general dental services

47. In section 25 of the 1978 Act, new wording is substituted to expand the categories of persons with whom Health Boards can make arrangements for the provision of dental services. In subsection (1), new wording is substituted to allow arrangements to be made with bodies corporate as defined in section 43 of the Dentists Act 1984 (the 1984 Act).

Section 16 – Assistance and support: general dental services

- 48. After section 28C of the 1978 Act a new section 28D is inserted to enable a Health Board to provide assistance, including financial assistance, to providers of general dental services in a way that the Board thinks fit.
- 49. A new subsection (1) is introduced which enables a Health Board to provide assistance and support to any person providing, or proposing to provide, general dental services under section 25 of the 1978 Act.
- 50. New subsection (2) enables the Health Board to provide such assistance and support in a way that it thinks fit, and new subsection (3) enables the assistance to include financial assistance.

Section 17 – Lists of persons undertaking to provide or approved to assist in the provision of general dental services

- 51. A new subsection (2) is substituted in section 25 of the 1978 Act for the existing subsection (2). The new subsection (2) provides a regulation-making power as to arrangements for the provision of general dental services (GDS).
- 52. The regulations as to arrangements shall provide for the listing of those who are approved to assist in the provision of GDS in the area of the Health Board for the first time. The subsection sets out those persons who will be listed on each part of a list to be prepared, maintained and published by each Health Board. Under paragraph (a), those persons who have undertaken to provide GDS will be named on the first part of the list. The second part will include those persons who are approved by the Health Board to assist in the provision of GDS and this is provided for in paragraph (b).
- A new subsection (2A) is substituted for existing subsection (2A) of section 25. Paragraphs (a) to (j) of subsection (2A) set out issues that may be included in the regulations as to the preparation, maintenance and publication of the list.
- 54. Paragraph (a) provides that the first or second part of the list or both parts may be divided into further sub-parts to enable different categories of persons undertaking to provide or assisting with the provision of GDS to be distinguished as necessary for example, those who provide domiciliary visits to nursing homes and similar establishments.
- 55. Paragraphs (b) to (j) provide that the regulation making powers may include provision as to: eligibility and applications for inclusion in a list; the grounds on which an application must be granted or refused, or a removal made and the consequences of removal; requirements with which a person included in a list must comply; circumstances in which a listed person may not withdraw from that list; the grounds under which a Health Board may suspend a person from its list; provision as to payments while subject to suspension by a Health Board; and disclosure of information about applications, refusal of applications, or suspensions, removal or references to the Tribunal.

56. A new subsection (2B) is substituted for existing subsection (2B) of section 25. Under this, regulations may specify that a person who acts as practitioner in a Health Board area may not provide GDS unless named on the first part of the Board's list and a person who acts only as an assistant practitioner in a Health Board area may not assist with GDS provision unless named on the second part of the Board's list.

Section 18 – Lists of persons performing personal dental services under section 17C arrangements or pilot schemes

- 57. A new section 17F is inserted into the 1978 Act. This provides an enabling power so that regulations may be made to establish lists of persons performing personal dental services (PDS) under pilot schemes or section 17C arrangements, that is, permanent schemes.
- 58. New subsection (1) provides that no person may perform PDS in an area unless that person's name is included in a list maintained by the Health Board.
- 59. Paragraphs (a) to (j) of new subsection (2) set out issues that may be included in the regulations and provide that the regulation making powers may in particular include provision as to: the preparation, maintenance and publication of a list by a Health Board, eligibility and applications for inclusion in such a list; the grounds on which an application must be granted, or refused, or a removal made and the consequences of removal; requirements with which a person included in a list must comply; circumstances in which a listed person may not withdraw from that list; the grounds under which a Health Board may suspend a person from its list; provision as to payments while subject to suspension by a Board; and disclosure of information about applications, refusal of applications, or suspensions, removal or references to the Tribunal.

Section 19 – Lists of persons undertaking to provide or approved to assist in the provision of general ophthalmic services

- 60. A new subsection (2) is substituted in section 26 of the 1978 Act for the existing subsection (2). As with existing subsection (2) this provides a regulation-making power as to arrangements made by medical practitioners and ophthalmic opticians undertaking to provide general ophthalmic services (GOS). The regulations as to arrangements shall provide for the listing of those who are approved to assist in the provision of GOS in the area of the Health Board for the first time. Paragraph (a) sets out those persons who will be listed on each part of a list to be prepared, maintained and published by each Health Board. Under (2)(a)(i), ophthalmic contractors, i.e. those persons who undertake to provide GOS, will be named on the first part of the list. The second part will include those persons who are approved by the Board to assist in the provision of GOS and this is provided for in (2)(a)(ii).
- 61. A new, expanded subsection (2)(b) replaces the former subsection (2)(c). Regulations will also provide for the procedure by which patients will have a right to choose the person that examines their eyes as well as the person that tests their sight or gives a prescription. Previously, the right to choose related only to the person by whom a patient's sight would be tested or from whom any prescription could be obtained but the Act now proposes that GOS should include eye examinations.
- 62. A new subsection (2A) is inserted into section 26. Paragraphs (a) to (j) of subsection (2A) set out issues that may be included in the regulations as to the preparation, maintenance and publication of the list.
- 63. Paragraph (a) provides that the first or second part of the list or both parts may be divided into further sub-parts to enable different categories of persons undertaking to provide or assist with GOS provision to be distinguished as necessary for example, those who provide domiciliary visits to nursing homes and similar establishments.

- 64. Paragraphs (b) to (j) provide that the regulating making powers may include: particular provision as to eligibility and applications for inclusion in a list; the grounds on which an application must be granted or refused or a removal made and the consequences of removal; requirements with which a person included in a list must comply; circumstances in which a listed person may not withdraw from that list; the grounds under which a Health Board may suspend a person from its list; provision as to payments while subject to suspension by a Board; and disclosure of information about applications, refusal of applications, or suspensions, removal or references to the Tribunal.
- 65. A new subsection (2B) is inserted into section 26 of the 1978 Act. Under this, regulations may provide that a person who acts as practitioner in a Health Board area may not provide GOS unless named on the first part of the Board's list and a person who acts only as an assistant practitioner in a Health Board area may not assist with GOS provision unless named on the second part of the Board's list.

Part 3: Pharmaceutical Care Services Etc.

Section 20 – Health Boards' functions: provision and planning of pharmaceutical care services

66. This inserts two new sections, 2CA and 2CB, into the 1978 Act.

New section 2CA – Functions of Health Boards: pharmaceutical care services

- 67. Subsection (1) of the new section 2CA requires Health Boards to provide pharmaceutical care services or to secure the provision of those services by others. This gives Health Boards a new obligation to provide services themselves, in contrast to current legislation that only permits them to secure provision by others.
- 68. The subsection also creates a power for Health Boards to provide or secure the provision of pharmaceutical care services for persons for whom they would not be under a duty to provide. This makes it possible for Health Boards to deliver pharmaceutical care services in a location that is outwith the area they cover.
- 69. Subsection (2) of the new section enables a Health Board securing the provision of pharmaceutical care services by others to do so by means of such arrangements as they think fit. The main arrangement available will be a pharmaceutical care service contract under new section 17Q, which replaces the current section 27 pharmaceutical services arrangements.
- 70. Subsection (3) of the new section places a duty on Health Boards to publish prescribed information about the pharmaceutical care services that they secure the provision of by others, or provide themselves. The information that can be prescribed is in relation to the provision of pharmaceutical care services under Part 1 of the 1978 Act and not just section 2CA.
- 71. Subsection (4) of the new section creates an obligation on Health Boards to co-operate with each other in discharging their functions connected with every aspect of the provision of pharmaceutical care services. This will be relevant where Health Boards choose to deliver pharmaceutical services in a location outwith their geographical area as described above. This specific duty of co-operation is in addition to the existing general duty on Health Boards and others under section 13 of the 1978 Act to co-operate with one another in exercising their functions in order to secure and advance the health of people in Scotland.
- 72. Subsection (5) of the new section allows regulations to be made that will define "pharmaceutical care services" for the purposes of the 1978 Act. The regulation will set out types of services that are and are not pharmaceutical care services for this purpose.

- 73. Subsection (6) of the new section allows the regulations made under subsection (5) to classify what services are to be regarded as essential or additional pharmaceutical care services and under paragraph (b) the manner or circumstances in which they will be provided. This would include, for example, categorising the type of premises from which different services are to be provided and the time of day during which services should be available. Subsections (c) and (d) provide that where the service provided involves dispensing it is undertaken in accordance with directions that list drugs, medicines and appliances (i.e. the current Drug Tariff) and the circumstances in which they may be prescribed, and against orders raised by prescribed persons, for example appropriately registered medical and dental practitioners.
- 74. Subsection (7) provides that any directions to be issued by Scottish Ministers (by virtue of their regulation powers at subsection (5)) must be published in the 'Drug Tariff', or other such other manner as they consider appropriate. The Drug Tariff already exists and, *inter alia*, lists or details the drugs, medicines and appliances that can be ordered and dispensed as part of the provision of pharmaceutical care services.
- 75. Subsection (8) makes it clear that arrangements which a Health Board may make for the provision of pharmaceutical care services may provide for the delivery of those services at a location outside Scotland. For instance, this would allow a Health Board to make arrangements that would enable persons to receive pharmaceutical care services outside Scotland where it was more practical or convenient for them to do so.
- 76. Subsection (9) of the new section provides that while Health Boards are exercising their own statutory functions to provide or secure the provision of pharmaceutical care services, they are to be regarded in law as exercising functions of the Scottish Ministers conferred on the Health Boards.

New section 2CB – Functions of Health Boards: planning of pharmaceutical care services

- 77. Subsection (1) provides the Scottish Ministers with broad regulation and direction-making powers that will prescribe the arrangements by which Health Boards will prepare, publish and keep under review plans that will enable them to discharge their duty under new section 2CB(1).
- 78. Subsection (2) gives examples of what the regulations under subsection (1) may cover and includes identification of what pharmaceutical care services are required in a Health Board's area, whether there is convenient access and where provision of those services is considered inadequate. It also includes the periods in which Health Boards are to prepare, publish and review their pharmaceutical care services (PCS) plan; and the consultation process by which the PCS plan is prepared and ultimately made available to public.
- 79. Subsection (3) gives the Scottish Ministers power to publish in directions what criteria ought to be considered in the identification by the Health Boards of the matters in subsection (2)(a) in preparing a PCS plan. For example, the directions might require Health Boards to compare the locations of NHS community pharmacies and GP surgeries relative to and the size and proximity of populations they serve and their pharmaceutical care service needs.

Section 21 – Pharmaceutical care services contracts

- 80. This section inserts new sections 17Q to 17V into the 1978 Act (in place of existing sections on pharmaceutical services). The new sections govern the terms and content of the new pharmaceutical care services (PCS) contracts and who may provide or perform PCS under the contracts. They contain regulation-making powers that will be used to set out the detail of the rights and obligations under the new contracts.
- 81. New **section 17Q** refers to the general content of the contract.

- 82. Subsection (1) allows a Health Board to enter into a PCS contract with a contractor to provide pharmaceutical care services in accordance with the provisions of Part I of the 1978 Act.
- 83. Subsection (3) sets out parameters for services to be provided under the contract, the remuneration for their provision and other matters. Health Boards and contractors are free to agree the terms of the contract subject to any restrictions on this freedom contained in Part I of the 1978 Act (restrictions set out in new sections 17R to 17V and in regulations under new section 17Q and those sections).
- 84. Subsection (4) allows the contract to cover a range of services, such as those that are provided in other primary and acute care settings and for the services to be delivered at a location outside the Health Board's geographical area.
- 85. New **section 17R** makes it compulsory for a PCS contract to require the contractor to provide pharmaceutical care services of such descriptions as may be set out in regulations under the section. The regulations may describe services by reference to the manner or circumstances in which they are to be provided. The intention is to set out in regulations that providers must provide certain essential services.
- 86. New **section 17S** sets out the persons with whom a Health Board may enter into a PCS contract. Subsection (1) allows a Health Board to enter into a PCS contract with a registered pharmacist or, where the statutory conditions are satisfied, a person or business lawfully conducting a retail pharmacy business (in accordance with section 69 of the Medicines Act 1968) provided that the contractor undertakes that the pharmaceutical care services are provided by, or under the supervision of, a registered pharmacist.
- 87. Subsection (2) enables regulations to set out the effect on the contract of a change in the membership of a partnership contracted to provide pharmaceutical care services. The intention is to allow the membership of a partnership to change without requiring a new contract to be entered into merely because such a change in partnership has taken place.
- 88. New **section 17T** deals with payments to be made under PCS contracts.
- 89. Subsection (1) enables Scottish Ministers to give directions as to payments to be made under the contracts. This follows the practice of using direction-making powers to ensure that Health Boards make payments that adhere to Scotland-wide rates and levels.
- 90. Subsection (2) makes it compulsory for a PCS contract to require payments to be made in accordance with the directions then in force.
- 91. Subsection (3) gives examples of the matters for which directions may provide.
- 92. Subsection (4) requires Scottish Ministers to consult before giving any direction under subsection (1)
- 93. Subsection (5) requires Scottish Ministers to publish directions under subsection (1) in the Drug Tariff or in such other manner as they consider appropriate, for example, a Health Department Letter of Circular.
- 94. New **section 17U** allows regulations to be made identifying those requirements that must be included in all PCS contracts.
- 95. Subsection (2) gives examples of the issues that the regulations under subsection (1) may cover, such as: the manner in which and standards to which services are to be provided; the persons who may perform services; contract variation and enforcement; and the adjudication of disputes. Subsection (2)(b) provides that the regulations may give the Scottish Ministers power to issue directions with regard to the manner and standards to which services under a PCS contract must be provided. The use of directions recognises the clinical nature of the services that will be provided and the need for them to be reviewed and revised on a regular basis.

- 96. Subsection (3) provides for regulations made under subsection (2)(c)(iii) to set out prescribed circumstances in which a contractor must accept a person to whom services are to be provided and in which a contractor may decline to accept such a person or may terminate responsibility under the PCS contract for the person.
- 97. Subsection (4) provides that regulations varying the contract terms (by virtue of subsection (2)(c)(v)) may include provision as to the circumstances in which a Health Board may so vary the terms or to suspend or terminate any duty under the contract to provide services of a prescribed description.
- 98. Subsection (6) provides that all PCS contracts must include a requirement that the contractors comply with any directions given by the Scottish Ministers under the regulation powers at subsection (1).
- 99. New **section 17V** essentially provides for two things.
- 100. Subsection (1) creates a regulation-making power to set national procedures for internal dispute resolution for the terms of proposed PCS contracts. The regulations may provide for the proposed terms to be referred to the Scottish Ministers and for the Scottish Ministers, or a person or panel of persons appointed by them, to determine what the terms of contract should be.
- 101. Subsection (2) creates a regulation making power to enable the parties to a PCS contract and parties who are already providing pharmaceutical care services under a PCS contract to opt to be treated as a health service body for any purposes in the existing section 17A of the 1978 Act. Section 17A allows health service bodies to enter into contracts with other health service bodies for the supply of goods and services. Such contracts are health service contracts, and are not regarded for any purpose as giving rise to contractual rights and liabilities, and they are not enforceable in courts. Section 17A instead provides for either party to a NHS contract to refer any matter in dispute to the Scottish Ministers for determination. It also provides for any determination made by the Scottish Ministers to contain directions (including directions about payments) and places a duty on the parties to the NHS contract to comply with any such directions.
- 102. Subsection (3) provides that if a PCS contractor or potential provider elects to become a health service body under subsection (2), section 17A of the 1978 Act applies with appropriate modifications. Where a business opts for its PCS contract to be an ordinary contract at law, it will have the option of asking the courts to resolve any resultant contractual disputes.

Section 22 – Drug Tariff

- 103. This section inserts a new **section 17W** into the 1978 Act.
- 104. New **section 17W** provides that Scottish Ministers must prepare, maintain and publish a document to be referred to as the Drug Tariff, and provides for what it must or may contain. As stated above (paragraph 74), the Drug Tariff already exists for the purposes of pharmaceutical services. However, its requirement in primary legislation terms is only implicit and for limited purposes. This new provision makes clear the status and purposes for which the Drug Tariff must or may be used.

Section 23 – Persons performing pharmaceutical care services

- 105. This section inserts a new **section 17X** into the 1978 Act.
- 106. Subsection (1) provides for regulation-making powers governing the ways in which persons performing pharmaceutical care services are listed. The regulations may prevent registered pharmacists from performing pharmaceutical care services for Health Boards unless their name appears on a list held by the Health Board that has the duty to secure or provide those services. An obligation to be on the list of a Health Board before performing services in that Health Board's area remains even if the services are

carried out as part of a contract with a neighbouring Health Board that is using its powers under section 2CA(1) of the Act to provide or secure the provision of pharmaceutical care services in the area of another Health Board.

- 107. Section 17X ends the current arrangements whereby the Health Board's pharmaceutical list contains the names of persons or businesses with whom the Health Board has made an arrangement to provide pharmaceutical services, and under which only the principal providers of those services are listed, and thereby subject to 'terms of service' requirements. The need to list contractors for 'terms of service' requirements is no longer necessary as arrangements will be governed by the terms of arrangements which Health Boards enter into with persons to secure the provisions of pharmaceutical care services under section 2CA.
- 108. The new listing arrangements will apply to all registered pharmacists wishing to perform pharmaceutical care services, i.e. whether contractors or employed or engaged by contractors.
- 109. Subsection (2) of section 17X sets out the particular issues that may be included in the regulations. These include, for example: how the list will be drawn up and maintained; what criteria an individual will have to meet to qualify to be on the list; the process by which decision on applications will be made; and mandatory grounds under which a Health Board would have to reject an application.

Section 24 – Assistance and support: primary medical services and pharmaceutical care services

- 110. This section inserts a new section 17Y into the 1978 Act, which makes new provision in relation to PCS and does this by replacing the existing section 17Q, which is an existing provision for Primary Medical Services (PMS). The existing PMS provision (replicated in new section 17Y) enables a Health Board to provide assistance and support (including financial assistance) to those providing, or proposing to provide, PMS. The new section 17Y extends the provision of assistance and support to PCS. The terms on which such assistance and support are given, including terms as to payment, are a matter for the Health Board.
- 111. Further provision relating to financial matters are made by amendments listed in Schedule 2 (paragraphs 2(17) and (18)).

Part 4: Provision of Services under Nhs Contracts

112. This part amends the 1978 Act to reflect the provisions in this Act in so far as this affects arrangements for provision of certain services to be treated as an NHS contract. The part also amends the 1978 Act to reflect the new pharmaceutical care services contract arrangements set out in part 3 of this Act in relation to NHS contracts.

Section 25 – Provision of certain services under NHS contracts

- 113. In section 17AA of the 1978 Act new wording is substituted to make provision regarding certain arrangements between dentists and Health Boards. This will facilitate the participation of dentists in co-management schemes whereby Health Boards may make arrangements with dentists to undertake functions complementary to the work of hospital departments.
- 114. In subsection (1) new wording is substituted to treat arrangements between a Health Board and persons on a dental list as NHS contracts. An NHS contract is an arrangement where disputes with respect to it or its proposed terms may be determined by the Scottish Ministers. New wording is inserted at subsection (3) to define a dental list and repeal the otiose reference to pharmaceutical list. Subsection (3)(b) repeals the reference to pharmaceutical lists; the reference to pharmaceutical lists at subsection (1) of section 17AA is also repealed. These are because the provisions in Part 3 of the Act

introduce new contract arrangements for the provision of pharmaceutical care services which, at new section 17V, provide for the service contracts in certain circumstances are to be classed as NHS Contracts. Section 17AA currently makes a similar provision and is, therefore, redundant.

Part 5: Discipline

115. This part makes a number of changes to those sections of the 1978 Act relating to the NHS Tribunal. The Tribunal is the principal NHS disciplinary body for family health service practitioners. It is an independent body comprising a Chair appointed by the Lord President of the Court of Session, a member of the relevant profession and a lay member both appointed by the Scottish Ministers.

Section 26 – Disqualification by the NHS Tribunal

- 116. A new subsection (2) is substituted in section 29 of the 1978 Act for the existing subsection. The substitution, taken together with the repeal of the words "the representations are that the second condition for disqualification is met and" in subsection (4)(b), enables the Tribunal to inquire into any case referred by a Health Board or other person within prescribed time limits and involving an applicant to any Health Board lists or a person who is already listed who meets any condition for disqualification.
- 117. Subsection (6) of section 29 sets out the first condition for disqualification by the Tribunal. In subsection (6), the words "inclusion or continued" are substituted for "continued" so that the first condition of disqualification may be satisfied by those applying to be included in a list. Subsection (6)(a) is expanded to cover the list of persons performing personal dental services described in section (8)(cc) and performing pharmaceutical services described in subsection (8)(e).
- 118. Subsection (6)(b) of section 29 is inserted to make similar provision for the list of persons described in subsection (8)(c) or (d) who provide, and assist in the provision of, services.
- 119. The new subsection (7A) inserted into section 29 adds a third condition of disqualification unsuitability (by virtue of professional or personal conduct) to the existing 2 disqualification conditions of fraud and prejudice to the efficiency of the relevant service. It enables disqualification of both list applicants and listed persons who meet this condition.
- 120. Subsection (8) of section 29 is amended as follows. The reference to the list of medical practitioners providing general ophthalmic services in paragraph (8)(b) is deleted. The existing paragraphs (8)(c) to (e) are replaced with references to the lists of those who provide, and assist in providing, general dental or general ophthalmic services and perform personal dental or pharmaceutical care services.
- 121. In subsection (11) of section 29, the insertion of the words "and cases in which representations are made that the third condition for disqualification is met are referred to below as unsuitability cases", taken together with the repeal of the word "and", provides for the categorisation of cases referred by Health Boards or other persons which meet the third condition of disqualification as "unsuitability cases" and adds this category to the other 2 categories of cases regarding the 2 existing disqualification conditions.
- 122. In section 29A, subsection (1) is amended so that the new third condition of disqualification can be met by any body corporate carrying on business as ophthalmic opticians if a director meets that condition. A new subsection, (1A), is inserted to make similar provision to subsection (1) for any body corporate which carries out dentistry as a business. The Tribunal may direct disqualification of the body corporate on ground of fraud or unsuitability if any director meets those conditions. Subsection (3) is amended

to provide that those who assist in the provision of services, as with those who provide or perform services currently, will be treated as meeting the disqualification condition of fraud if someone acting on their behalf meets that condition and they failed to take reasonable steps to prevent that happening. Subsection (5) is amended so that this may be done in efficiency and unsuitability cases also. In subsection (6) the circumstances in which a fraud or efficiency case is finally concluded are set out. It is amended so that it also applies to an unsuitability case.

- 123. A new paragraph (c) is inserted into section 29B(1). This adds the new third condition of disqualification to the grounds on which the Tribunal shall make a disqualification.
- 124. A new subsection (2) is substituted in section 29B for the existing subsection. The effect is that the Tribunal shall disqualify a person from all lists of persons delivering those services where it determines a condition of disqualification is met, unless it would be unjust to do so. In the case of dental services, the disqualification is from all lists of persons undertaking to provide and approved to assist in providing general dental services and of persons performing personal dental services.
- 125. A new paragraph (c) is added to subsection 29C(2) dealing with conditional disqualification which extends the scope of the conditions which the Tribunal may place on those who are permitted to practice conditionally.
- 126. Subsection (5)(aa) is amended to refer to section 17F, 17P or 17X or Part II of the 1978 Act. This allows the Tribunal, for the purpose of or in connection with the imposition of conditions, to vary any requirements to which a person subject to the inquiry is subject. This is in addition to the Tribunal's power under subsection (5)(a) to vary any terms of service the person is subject to by virtue of subsection (5)(a).
- 127. In section 32(2) the words "both an efficiency case and a fraud case" are replaced by "an efficiency case and a fraud case or an unsuitability case or any other combination of more than one such category of case". Section 32(2) provides that where representations are made to the Tribunal against the same person on grounds of efficiency and fraud, regulations may provide that it may inquire into one or other matter and, when then matter is finally disposed off, it may decide to adjourn the other matter indefinitely. This allows regulations to provide, for example, for situations such as where the Tribunal has decided that a condition for disqualification was met for, say, proven fraud and there would be nothing to be gained by considering other allegations. The amendment extends the regulation-making power to take account of the new ground of unsuitability.
- 128. Subsection (2) of section 32A is amended so that directions by the Tribunal for suspension of a person as respects services applies, in the case of dental services to both general and personal dental services. A new paragraph (b) is substituted in subsection 32A(2A). This widens the second ground on which the Tribunal may direct interim suspension from one only related to the further perpetration of fraud/ the prejudicing of investigation of a fraud case or review to a public interest ground. This includes cases where suspension is intended to ensure that further fraud is not perpetrated or evidence/witnesses in a fraud case are not interfered with. It will also enable the Tribunal to direct the interim suspension where it is otherwise in the public interest. It could include, for example, interim suspension to prevent serious disruption to the efficiency of services.
- 129. Subsection 6(a) is amended so that the definition of "relevant list" now covers persons providing services, and persons performing, undertaking to provide and approved to assist in providing services.
- 130. A new subsection (7) is inserted into section 32A. This will enable regulations to provide for the continuation of the suspension of a person whom a Health Board has suspended from one of its lists in terms of regulations under sections 17F, 17P, 17X, 25(2) or 26(2) of the 1978 Act and referred to the Tribunal until such time as the Tribunal has decided whether or not to suspend the person.

Section 27 – Corresponding provision in England or Wales or Northern Ireland

131. Section 27 substitutes a new section 32D of the 1978 Act. At present section 31 governs the effect in Scotland of decisions under provisions in force in England or Wales or Northern Ireland which correspond to provisions in force in Scotland regarding disqualification, and section 32D governs the effect in Scotland of decisions under provisions in force in England and Wales or Northern Ireland which correspond to provisions in force in Scotland regarding suspension by the Tribunal. However provisions in other parts of the UK may not correspond exactly to the provisions in force in Scotland. This new section replaces section 31 and 32D and allows regulations to provide for the effect of such decisions in Scotland, by providing for the effect that is to be given in Scotland to decisions made in other parts of the UK which correspond (whether or not exactly) with decisions made by the Tribunal.

Part 6: Miscellaneous

Infection With Hepatitis C as a Result of Nhs Treatment Etc.

Section 28 – Payments to certain persons infected with hepatitis C as a result of NHS treatment etc.

- 132. Subsection (1) provides for the Scottish Ministers to make a scheme for making payments to, or in respect of, persons who have been infected with the hepatitis C virus in certain circumstances.
- 133. Subsection (2) defines the relationships of persons covered by subsection (1) where the infection is acquired by transmission from a person infected as a result of NHS treatment.
- 134. Subsection (3) prescribes certain matters which must be included in a scheme such as the procedure to be followed in making a claim under the scheme and how claims are to be determined. This subsection also provides for a right of appeal against a decision refusing a claim under the scheme.
- 135. Subsection (4) provides that a scheme may include certain matters such as conditions for eligibility and the subsection also allows the Scottish Ministers to make provision in the scheme for other persons to undertake functions or manage the scheme on their behalf.
- 136. Subsection (5) provides that, where a scheme provides that it is to be managed, or functions are to be undertaken, on behalf of the Scottish Ministers, the Scottish Ministers remain responsible for those functions or the management of the scheme.