SMOKING, HEALTH AND SOCIAL CARE (SCOTLAND) BILL

EXPLANATORY NOTES

(AND OTHER ACCOMPANYING DOCUMENTS)

CONTENTS

1. As required under Rule 9.3 of the Parliament’s Standing Orders, the following documents are published to accompany the Smoking, Health and Social Care (Scotland) Bill introduced in the Scottish Parliament on 16 December 2004:

   • Explanatory Notes;
   • a Financial Memorandum;
   • an Executive Statement on legislative competence; and
   • the Presiding Officer’s Statement on legislative competence.

A Policy Memorandum is printed separately as SP Bill 33–PM.
EXPLANATORY NOTES

INTRODUCTION

2. These Explanatory Notes have been prepared by the Executive in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by the Parliament.

3. The Notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a section or schedule, or a part of a section or schedule, does not seem to require any explanation or comment, none is given.

THE BILL – AN OVERVIEW

4. The main provisions of the Bill are set out below.

Part 1 – makes provision for a ban on smoking in certain wholly 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 2 – provides for various matters concerning general dental services, personal dental services and general ophthalmic services:
- 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;
These documents relate to the Smoking, Health and Social Care (Scotland) Bill (SP Bill 33) as introduced in the Scottish Parliament on 16 December 2004

- provision of assistance and support for pharmaceutical care services.

Part 4 – 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 5 – 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;
- the ability of Scottish Ministers and health bodies to enter into joint ventures;
- the Scottish Hospital Endowments Research Trust.

Part 6 – makes general provisions.

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

Schedule 2 – Minor and consequential amendments.

Schedule 3 – Repeals.

PART 1: PROHIBITION OF SMOKING IN CERTAIN WHOLLY ENCLOSED PLACES

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

5. 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.

6. 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.

7. 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

8. Subsection (1) makes it an offence for a person to smoke in no-smoking premises.
9. 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.

10. 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

11. Subsection (1) requires “no-smoking” signs to be conspicuously displayed inside and 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.

12. 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.

13. 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.

14. 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”

15. Subsection (1) provides the meaning of “smoke” which in the context of Part 1 of the Bill means to smoke tobacco or any substance or mixture which includes it. 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 lit substance or mixture which includes tobacco.

16. 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 of premises or parts of premises, from the definition of “no-smoking premises”. Regulations made under subsection (2) are to be made by affirmative procedure.

17. Subsection (4) lists the kinds of premises which are to be prescribed as “no-smoking premises” under subsection (2), being premises which are wholly enclosed and (a) to which the
18. Subsection (5) 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 (6)(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 (6)(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 (7) 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 (8) relates to the “no-smoking” notices which are to be displayed under section 3(1). Subsection (8) 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 – Fixed penalties

22. 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 Bill. An explanation of the provisions in the Schedule is given at the end of these notes.

23. 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 6 – Powers to enter and require identification

24. 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.

25. 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.
26. 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 7 – Bodies corporate etc.

27. Section 7 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 Bill that their companies or partnerships commit.

Section 8 – Crown application

28. Many enclosed public places will be operated and controlled by the Crown. Section 8 provides that Part 1 of the Bill 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 Bill, the Court of Session may declare unlawful any act or omission of the Crown which constitutes a contravention.

29. 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 9 – Free oral health assessments and dental examinations

30. The provisions discussed in paragraphs 30 to 33 fulfil the partnership agreement of introducing free dental checks for all before 2007. 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.

31. 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.

32. 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.

33. 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 10 – Free eye examinations and sight tests**

34. Section 10 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.

35. 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.

36. 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.

37. 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 11 – Charges for certain dental appliances and general dental services**

38. 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).

39. 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.

40. In section 71 of the 1978 Act new wording is substituted to reflect that section 71A is repealed.

41. In paragraph 2 of schedule 11 of the 1978 Act new wording is substituted. A new sub-paragraph (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 12 – Arrangements for provision of general dental services

42. 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).

43. A new subsection (3) is introduced to further define the bodies corporate as being ones
which carry on the business of dentistry in terms of section 40 of the 1984.

Section 13 – Assistance and support: general dental services

44. 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.

45. 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.

46. 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 14 – Provision of certain dental services under NHS contracts

47. 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.

48. 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.

Section 15 – Lists of persons undertaking to provide or approved to assist in the provision of
general dental services

49. 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).
50. 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. 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).

51. 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.

52. Paragraph (a) provides that the first part of the list may be divided into further sub-parts to enable different categories of persons undertaking to provide GDS to be distinguished as necessary – for example, those who provide domiciliary visits to nursing homes and similar establishments.

53. 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.

54. A new subsection (2B) is substituted for existing subsection (2B) of section 25. Under this, regulations may specify that 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 16 – Lists of persons performing personal dental services under section 17C arrangements or pilot schemes

55. 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.

56. 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.

57. 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 17 – Lists of persons undertaking to provide or approved to assist in the provision of general ophthalmic services

58. 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).

59. 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 Bill now proposes that GOS should include eye examinations.

60. 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.

61. Paragraph (a) provides that the first part of the list may be divided into further sub-parts to enable different categories of ophthalmic opticians to be distinguished as necessary – for example, those who provide domiciliary visits to nursing homes and similar establishments.

62. 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.

63. A new subsection (2B) is inserted into section 26 of the 1978 Act. Under this, regulations may provide that 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 18 – Health Boards’ functions: provision and planning of pharmaceutical care services

64. This inserts two new sections, 2D and 2E, into the 1978 Act.

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

65. Subsection (1) of the new section 2D 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.

66. 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.

67. 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.

68. 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 2D.

69. 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.

70. 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.

71. 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.

72. 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.

73. 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.

74. 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 2E – Functions of Health Boards: planning of pharmaceutical care services**

75. 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 2D(1).

76. 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.

77. 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 19 – Pharmaceutical care services contracts**

78. 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.
79. New section 17Q refers to the general content of the contract.

80. 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.

81. 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).

82. 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.

83. 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.

84. 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.

85. 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.

86. New section 17T deals with payments to be made under PCS contracts.

87. 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.

88. Subsection (2) makes it compulsory for a PCS contract to require payments to be made in accordance with the directions then in force.

89. Subsection (3) gives examples of the matters for which directions may provide.
90. Subsection (4) requires Scottish Ministers to consult before giving any direction under subsection (1).

91. New section 17U allows regulations to be made identifying those requirements that must be included in all PCS contracts.

92. Subsection (2) gives examples of the issues that the regulations 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.

93. Subsection (3) provides for regulations made under subsection (2)(d) 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.

94. Subsection (4) provides that regulations varying the contract terms (by virtue of subsection (2)(f)) 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.

95. Subsection (6) provides that all PCS contracts include a requirement that the contractors must comply with any directions given by the Scottish Ministers as to the drugs, medicines or other substances that may or may not be ordered.

96. New section 17V essentially provides for two things.

97. 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.

98. 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.

99. 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 20 – Persons performing pharmaceutical care services

100. This section inserts a new section 17W into the 1978 Act.

101. 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 2D(1) of the Act to provide or secure the provision of pharmaceutical care services in the area of another Health Board.

102. Section 17W 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 2D.

103. 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.

104. Subsection (2) of section 17W 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 21 – Assistance and support: primary medical services and pharmaceutical care services

105. This section inserts a new section 17X 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 17X) enables a Health Board to provide assistance and support (including financial assistance) to those providing, or proposing to provide, PMS. The new section 17X 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.

106. Further provision relating to financial matters are made by amendments listed in Schedule 2 (paragraphs 1(10) and (11)).
PART 4: DISCIPLINE

107. 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 22 – Disqualification by the NHS Tribunal

108. 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.

109. Subsection (6) sets out the first condition for disqualification by the Tribunal. In subsection (6) of section 29, 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).

110. Subsection (6)(b) 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.

111. 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.

112. Subsection (8) 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.

113. 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.

114. 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 (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.

115. 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.

116. 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.

117. 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.

118. Subsection (5)(aa) is amended to refer to section 17F, 17W and 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).

119. 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.

120. 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.

121. 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.
122. 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, 17W, 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 23 – Corresponding provision in England or Wales or Northern Ireland

123. Section 23 substitutes a new section 32D. 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 5: MISCELLANEOUS

INFECTION WITH HEPATITIS C AS A RESULT OF NHS TREATMENT

Section 24 – Payments to certain persons infected with hepatitis C as a result of NHS treatment

124. 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.

125. Subsection (2) 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.

126. Subsection (3) 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.

127. Subsection (4) 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.

AMENDMENT OF REGULATION OF CARE (SCOTLAND) ACT 2001

Section 25 – Independent health care services

128. Under the Regulation of Care (Scotland) Act 2001 (the 2001 Act) the Care Commission registers and inspects a range of care services, deals with complaints and, where necessary, takes
enforcement action. Section 2 of the 2001 Act lists and defines care services which are regulated by the Scottish Commission for the Regulation of Care (the Care Commission). This section of the Bill amends section 2(5) of the 2001 Act which defines “an independent healthcare service” as: an independent hospital; a private psychiatric hospital; an independent clinic; and an independent medical agency. This amendment gives Scottish Ministers the power to except services from this definition by regulations, bringing it into line with other relevant care service definitions.

Section 26 – Implementation of certain decisions under the 2001 Act

129. This section amends sections 16(2), 48(2) and 51(1) of the 2001 Act.

130. The Care Commission has powers under the 2001 Act to issue a condition notice to service providers already registered and those applying to register as providers of care services (for example to require a care home provider to keep a door closed at all times to prevent residents from having access to a busy road). When such a notice is issued the 2001 Act allows a person receiving to make representation to the Care Commission. Subsection (2) amends section 16(2) to make further provision regarding representations. In particular it ensures that where representations are made to the Care Commission about a notice given under 16(2)(a) these will be considered by the Care Commission before it decides whether or not to do the thing proposed in the notice.

131. The Scottish Social Services Council (the Council) has the power under section 46 of the 2001 Act to grant registration to a social service worker either unconditionally or give notice to the worker that registration will be granted subject to certain conditions (for example to require a worker to complete a specific training requirement within a specified period of time). Section 48 allows the person who has received notice to make representations to the Council. Subsection (3) amends section 48 to make further provision about representations. In particular it ensures that where representations are made these will be considered by the Council in deciding whether or not to do the thing proposed.

132. Subsection (4) amends section 51 to ensure that there is a right of appeal against all decisions of the Council and not just an appeal against the implementation of a proposal.

Section 27 – Provision of information to the Scottish Social Services Council

133. This section inserts new sections 57A and 57B into the Regulation of Care (Scotland) Act 2001.

134. The new section 57A requires the employer of a social service worker to inform the Scottish Social Services Council where the social service worker has been dismissed on grounds of misconduct or has resigned or abandoned their position in circumstances where there would have been grounds for their dismissal. The employer must also provide the Council with an account of the circumstances.

135. The new section 57B requires that the employer of a social service worker will provide to the Council any information as respects that worker that the Council requires in the pursuit of its functions.
CHILD CARE AGENCIES AND HOUSING SUPPORT SERVICES

Section 28 – Registration of child care agencies and housing support services

136. This section is concerned with persons providing certain child care agencies and housing support services on 1 April 2003 who were deemed to have their service registered with the Care Commission until 30 September 2003. Where a provider did not make an application to the Care Commission for registration before 1 October 2003 or did not have their application granted by 1 April 2004 their deemed registration lapsed and continuation of the service was unlawful. The effect of this provision is that where such a person applied for registration by 30 September 2004, they are to be treated as if their deemed registration had not lapsed and, subject to the earlier occurrence of certain events, they are deemed to be registered until 1 April 2006. It also provides that, where, before 1 April 2006, the application for registration is granted or refused, registration is cancelled, or if the provider ceases providing the service, the deemed registration ceases on the date that happens.

137. Subsection (1) provides that subsections (2) to (4) apply where:
   • from 1 April 2003, a person was providing a housing support service or a previously unregulated child care agency which was deemed to be registered with the Care Commission under Part 1 of the 2001 Act by virtue of transitional provisions contained in subordinate legislation;
   • that deemed registration lapsed, either on 1 October 2003 because the provider had not submitted an application for registration before that date, or on 1 April 2004 because registration had not been granted; and
   • the provider continued to provide the service when it was no longer deemed registered.

138. Subsection (2) provides that, where the circumstances described in subsection (3) apply, such a service is to be treated as if it was registered, from the date deemed registration ran out and for the period during which the service continued to be provided until one of the events in subsection (4) occurs.

139. Subsection (3) provides that the circumstances referred to in subsection (2) are where an application for registration has been made before 30 September 2004 or no such application was made before that date and the person ceased providing the service before then.

140. Subsection (4) provides that the service ceases to be treated as if it were registered on the earliest of the following events:
   • the date that the Commission refuses an application where no appeal is made under section 20(1) of the 2001 Act;
   • the date that the sheriff confirms the Commission’s decision after a timeous appeal has been made;
   • where an appeal is made under section 20(1) but is later abandoned, the date on which that is intimated to the sheriff clerk or, where there is no intimation, the date on which it is deemed by the Sheriff to be abandoned;
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- the date the Care Commission decides (other than in the case of an application from the provider) to cancel the registration effected by subsection (2);
- where there is no appeal under section 17(3) of the 2001 Act from the provider against the Care Commission’s decision to cancel the registration effected by subsection (2), the fifteenth day after the day the Care Commission gave notice of that intention;
- where there is such appeal and the sheriff decides to grant it, the day the sheriff decides to do so;
- the day the sheriff grants an application by the Care Commission under section 18 of the 2001 Act for cancellation of registration;
- where an appeal under section 17(3) is made and later abandoned, the date on which that is intimated to the sheriff clerk or, where there is no intimation, the date on which it is deemed by the court to be abandoned.
- the day the person ceases to provide the service; or
- 1 April 2006 – unless this date has been changed to a later one in an order made by Scottish Ministers.

**Section 29 – Grants in respect of housing support services**

141. This section provides that payments to providers of regulated housing support services which were not registered with the Care Commission, by local authorities out of money they had received from Scottish Ministers under the Housing (Scotland) Act 2001, were made lawfully.

**AUTHORISATION OF MEDICAL TREATMENT**

**Section 30 – Amendment of Adults with Incapacity (Scotland) Act 2000: authorisation of medical treatment**

142. This section provides for two substantive changes, and consequent amendments, to Part 5 of the Adults with Incapacity (Scotland) Act 2000. First an extension to the range of health professionals who can sign certificates of incapacity and second extending the length of certificates from one to three years in certain prescribed circumstances.

143. Subsection (1) signposts the two main amendments to the 2000 Act.

144. Subsection (2)(a) widens the scope of who can issue a certificate under section 47 of the 2000 Act from the ‘medical practitioner primarily responsible’ for the treatment of an adult, to include other named healthcare professionals as listed in subsection 2(b) and other who meet various requirements set out by the Scottish Ministers. A certificate under section 47 of the Act confers a general authority to treat an adult with incapacity, where the medical practitioner primarily responsible for the medical treatment of the adult is of the opinion that the adult is incapable in relation to a decision about the medical treatment in question. Only a ‘registered medical practitioner’ currently has the power to complete and sign a certificate.

145. Subsection (2)(b) lists the persons who will be able to issue a certificate, they are: the medical practitioner primarily responsible for the medical treatment of the adult; a dental
practitioner; an ophthalmic optician; a registered nurse. This section also makes provision for others to be added by regulation as and when appropriate. The additional ‘healthcare professionals’ (dentists, ophthalmic options and registered nurses) will only be allowed to certify for treatment in respect of their own specialist area.

146. Subsection (2)(c)(i) makes consequential amendments to the references in section 47(2) of the 2000 Act to the medical practitioner primarily responsible for the health of the adult.

147. Subsection (2)(c)(ii) sets out that a healthcare professional who is competent to sign a certificate of incapacity can only do so within his or her own professional area.

148. Subsection (2)(d) clarifies that treatment can be delegated to any other person authorised by the certificate signatory and acting on his or her behalf, under instructions, or with his or her approval and agreement.

149. Subsection (2)(e)(i) amends section 47(5)(a) of the 2000 Act as to who can issue the certificate from ‘medical practitioner primarily responsible for the medical treatment of the adult’ to ‘person who issues the certificate’.

150. Subsection (2)(e)(ii) sets out that a healthcare professional who is competent to sign a certificate of incapacity can only do so within his or her own professional area.

151. Subsection (2)(f)(i) amends section 47(5)(b) of the 2000 Act so that, in certain circumstances and in relation to certain conditions to be prescribed by the Scottish Ministers the maximum duration of the certificate is 3 years.

152. Subsection (2)(f)(ii) amends section 47(6)(b) of the 2000 Act so that, in certain circumstances to be prescribed by Scottish Ministers the maximum duration of the certificate is 3 years.

153. Subsection (3) widens the scope of subsection 49(1) of the 2000 Act to ensure that health professionals do not treat a patient where they know that an application for an intervention order or guardianship order has been made to the sheriff and has not been determined.

154. Subsection (4) widens the scope of section 50 of the 2000 Act to include all health professionals who are empowered to sign certificates of incapacity.

JOINT VENTURES

Section 31 – Joint ventures

155. Subsection (1) inserts a new section 84B after section 84A of the National Health Service (Scotland) Act 1978 and gives new powers for Scottish Ministers to form or participate in forming joint ventures for the provision of facilities or services. This will provide the basis for the long term
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delivery of facilities that meet the needs of local communities, as well as encouraging more joint working, for example between the NHS, local authorities and the voluntary sector.

156. Subsection (1) of 84B defines the nature and extent of the involvement of Scottish Ministers in such companies.

157. Subsection (2) of 84B allows facilities and services to be provided to those persons or bodies exercising functions under the 1978 Act.

158. Subsection (3) of 84B provides the definitions of “companies” and “facilities” as applied under section 31(1).

159. Subsection (2) amends section 7 of the Health and Medicines Act 1988 to give Scottish Ministers powers to exploit intellectual property. The amendment inserts a new subsection (7C) to allow Scottish Ministers to form or participate in forming companies, or to participate in companies. It also allows Ministers to make financial provision to or in respect of companies, including by means of loans, guarantees and investments.

160. Subsection (2) also introduces a new subsection (7D) to the 1988 Act to provide a definition of “companies” for the purpose of subsection (7C), and provides that the new subsection (7C) is without prejudice to the powers already made available in subsection (2).

SCOTTISH HOSPITAL ENDOWMENTS RESEARCH TRUST

Section 32 – Scottish Hospital Endowments Research Trust

161. The Scottish Hospital Endowments Research Trust is a self-financing Non Departmental Public Body and a registered charity established, in 1953 by Act of Parliament, to receive and hold endowments, donations and bequests and to make grants from these funds to support medical research in Scotland. Subsection (2) repeals the Scottish Ministers’ responsibility for the Research Trust.

162. Subsection (3) substitutes paragraphs concerning the membership of the Research Trust.

163. New paragraph 3A provides for the continuation of existing members of the Research Trust, and makes them subject to the new terms and conditions of appointment of members determined by the Research Trust when those new terms and conditions are determined, or after a period of 90 days, whichever occurs first. This provision seeks to provide sufficient time within which the Research Trust can draft and agree its new terms and conditions.

164. New paragraph 3B sets out the terms of office of the membership of the Research Trust, the tenure of office - specifying that a single term of appointment shall not exceed 4 years - and vacation from office.

165. New paragraph 3C provides for single term of reappointment.
166. New paragraph 3D replaces section 12 (3(d)) of the National Health Service (Scotland) Act 1978 with new provisions for the reimbursement of expenses of the membership of the Research Trust.

167. New paragraph 3E provides for the Research Trust to appoint staff on such terms and conditions as they think appropriate.

168. New 3F provides the necessary provisions for the self regulation of the Research Trust, and requires standing orders to be made within a 90 day period.

169. New 3G provides for the Research Trust to be able to do anything necessary or expedient to enable them to exercise their functions.

PART 6: GENERAL

Section 33 – Ancillary provisions

170. This section enables the Scottish Ministers to make further provision, by order, which is incidental to or consequent on the Bill and to allow transitional or savings provisions as required in implementing the Bills’ provisions.

Section 34 – Regulations or orders

171. This section provides that powers to make orders or regulations in the Bill shall be exercisable by statutory instrument. Subsection (2) provides that except where otherwise provided, the statutory instruments containing such orders or regulations shall be subject to negative procedure in the Scottish Parliament. Subsection (3) provides that the following orders or regulations shall be the subject of affirmative resolution:

(a) regulations under sections 3(3) or 4(2) or (7) or paragraph 2, 4(1), 5(2), 12 or 13 of Schedule 1;
(b) an order under section 28(4)(e); and
(c) an order under section 33 which contains provisions which alter the text of an Act.

Subsection (4) provides that Scottish Ministers must consult such persons as they consider appropriate before laying a draft of a statutory instrument containing regulations under sections 3(3) or 4(2) or (7).

Section 35 – Interpretation

172. This section defines terms used throughout the Bill and is self-explanatory.

Section 36 – Minor and consequential amendments and repeals

173. Section 36 introduces schedule 2 (which makes minor and consequential amendments) and schedule 3 (which contains consequential repeals).
Sub-paragraphs (10) and (11) of paragraph 1 to schedule 2 lists amendments to section 85AA of the 1978 Act that have the effect of placing the financial resources for meeting the remuneration element of providing pharmaceutical care services (PCS) with Health Boards, as part of their unified budgets. Currently the cost of the national contract is paid by Health Boards but funded centrally; additional services are funded locally. Given the intention to make Health Boards responsible in future for planning and securing or providing all PCS requirements (under both national and local contract arrangements) it is appropriate to make them responsible for the financial management of the process too.

**Section 37 – Short title and commencement**

This section provides for the short title of the Bill. Further, the section allows the Scottish Ministers to bring the provisions of the Bill into force by order, except for sections 1 to 8, 28, 29 and 35 and Schedule 1 which will come into force on the day after Royal Assent, and sections 33, 34 and 37 which will come into force on Royal Assent by order. Different days may be appointed in the order for different provisions.

**SCHEDULE 1 - FIXED PENALTY FOR OFFENCES UNDER SECTIONS 1, 2 AND 3**

Paragraph 1(1) and (2) provides power for an authorised officer of a council or a constable to issue a fixed penalty notice, whilst paragraph 1(3) provides the definition of a “fixed penalty notice” for the purposes of Schedule 1.

Paragraph 2 provides the Scottish Ministers with the power to set via regulations a time limit between an offence being committed and an authorised officer being able to give a fixed penalty notice.

Paragraph 3 sets out the contents of the fixed penalty notice. It must identify the offence to which it relates and give reasonable particulars of the circumstances alleged to commit that offence. It must also state: the amount of the penalty and the period within which it may be paid; the discounted amount and the period within which it may be paid; the person to whom and the address at which payment may be made; the method or methods by which payment may be made; the person to whom and the address at which any representations relating to the notice may be made; and the consequences of not making a payment at which any representations relating to the notice may be made.

Paragraph 4 provides for the level of the fixed penalty notice to be prescribed and the period within which payment of the notice should be made. The council has a discretionary power to extend the period of payment.

Paragraph 5 enables offenders to pay a lesser amount in respect of the fixed penalty notice if they make an earlier payment.

Paragraph 6 sets out the effect of a fixed penalty notice, providing that no proceedings may be commenced before the end of the period for payment of the penalty, or if payment of the penalty is made before the end of that period or is accepted by the council after that time. Payment of the
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discounted amount will only count in that regard if it is made before the end of the period for payment for that discounted amount.

182. Paragraph 7 enables a person in receipt of a fixed penalty notice to request a hearing in respect of the offence for which they have been given notice provided that that request is made within 29 days of receipt of the notice. The request must be made in writing to the designated person at the address shown on the fixed penalty notice. The council will hold the meeting and the procurator fiscal will be notified that a hearing is to be held. The period between a person requesting a hearing and being notified of the hearing’s decision will not count towards the 29 days for the payment of the penalty.

183. Paragraph 8 provides for a power of the council to withdraw notices, in cases where they have been erroneously issued or consider if there are extenuating circumstances. Sub-paragraph 3 provides that a council is bound to consider any representations made by or on behalf of a person given a notice, and that they must decide in all circumstances whether to withdraw the notice.

184. Paragraph 9 provides for the withdrawal of a fixed penalty notice where proceedings for an offence are commenced.

185. Paragraph 10 provides for the recovery of unpaid fixed penalty fines. After the expiry of 29 days the council is able to enforce the unpaid penalty as if it were an extract registered decree arbitral. In practice this means that the unpaid penalty can be recovered in the same way as a sum of money due under a civil court decree.

186. Paragraph 11 provides a mechanism under which disputes as to whether or not a fixed penalty has been paid or a hearing sought within the period for paying can be resolved by the courts. Subparagraph (1) enables a person who is in dispute with a council to apply to the sheriff by summary application for a declaration that the fixed penalty cannot be enforced under paragraph 10 either because the fixed penalty has been paid or a request for a hearing has been made within the period for paying.

187. Paragraph 11(2) provides that the sheriff may declare that the person has or has not paid the penalty or requested a hearing within the period for paying and that the fixed penalty is or is not enforceable under paragraph 10.

188. Paragraph 12 allows the Scottish Ministers to make regulations about the application by councils of fixed penalties under Schedule 1 and also about the keeping of accounts and the preparation and publication of statements of account, relating to fixed penalties under Schedule 1.

189. Paragraphs 13(a) and (c) provide the Scottish Ministers with powers to make regulations prescribing the circumstances in which a fixed penalty notice may not be given and the methods for the payment of penalties.
INTRODUCTION

190. As the Bill covers a number of discrete policy areas, this document sets the details of costs on the Scottish Administration, costs on local authorities, and costs on other bodies, individuals and businesses for each main policy area that appears in the Bill. The order of the subjects covered within this document is as follows:

- prohibition of smoking in certain wholly enclosed places (sections 1 - 8);
- free eye and dental examinations (sections 9 - 10);
- provision of General Dental Services (sections 11 - 14);
- listing of additional categories of General Dental Practitioners, optometrists and Ophthalmic Medical Practitioners (sections 15 - 17);
- pharmaceutical care services (sections 18 - 21);
- discipline (sections 22 - 23);
- payments to certain persons developing hepatitis C as a result of NHS treatment (section 24);
- amendment of Regulation of Care (Scotland) Act 2001, and child care agencies and housing support services (sections 25 - 29);
- authorisation of medical treatment (section 30);
- joint ventures (section 31); and
- Scottish Hospital Endowments Research Trust (Section 32).

191. A table summarising the additional costs arising from the Bill appears at the end of the document.

PROHIBITION OF SMOKING IN CERTAIN WHOLLY ENCLOSED PLACES

Introduction

192. The Bill is the means by which the Executive will take measures to prohibit smoking in certain wholly enclosed places.

Costs on the Scottish Administration

193. In order to inform the public and businesses of the forthcoming legislation and the steps that should be taken, Scottish Ministers will establish a communications programme in advance of the regulations coming into force. Costs are anticipated to be in the region of £2 million in 2005/06 leading up to the regulations coming into force with a further £1 million per year and for the next 3 years 2006/07 - 2008/09 following introduction of smoke-free public places.

194. Options are currently being explored on enforcement of the regulations. Evidence from New York and Ireland suggests that compliance rates will be high at around 97%. If similar
compliance rates were achieved in Scotland we would expect that there would be relatively few prosecutions and therefore costs to the criminal justice system would be low and could reasonably be absorbed within existing budgets.

195. The further costs that may be incurred in enforcing smoke-free public places would be dependent on the complexity of the approach chosen for enforcement of the provisions, and the general acceptance and compliance levels by the public and Scottish businesses. In Ireland a Smoke-free Compliance Help-line was established which allows the public to phone and report alleged breaches of the ban. The line logged 1,524 calls in the first month, of which 827 (54%) occurred in the first week and 104 calls were logged in week 5. A broad estimate would suggest a cost of £50,000 to £100,000 to establish a Scottish compliance line, if one was established. Ongoing costs will be dependent on the level of compliance in future years which mean that these costs are not measurable at present but it is anticipated that they will diminish to a lower constant rate over time.

196. International experience has shown that introduction of smoking bans leads to significant numbers of smokers quitting with consequential increasing demand for smoking cessation services. For example, in the first month (April 2003) following the ban on smoking in the workplace in New York 18,821 people contacted the NYC smoking cessation help line seeking assistance to quit smoking. This compares with a call rate of 420 calls for the month of January 2003. Scottish Ministers have already increased funding for smoking cessation services in 2005-06 by £4 million, making the total funds available for smoking cessation services £7 million per annum. This will enable Health Boards to expand smoking cessation services in a wide range of settings, using best practices which include one-to-one counselling and group cessation services to help smokers quit. Since 2002, nicotine replacement therapy and Zyban have been available on prescription to help smokers with their attempts to give up smoking. Consideration will be given as to whether any additional funding from 2006-07 may be required in order to meet the additional demand which a ban on smoking in public places is likely to stimulate for assistance from the Scottish Smoke-line and for smoking cessation services but at this stage the presumption is that any increase in demand can be funded from existing planned provision.

Costs on local authorities

197. It is intended that authorised officers of the Council will have principal responsibly for enforcement. The precise details of this approach are still to be determined, but it is anticipated that costs of enforcement will diminish over time as the smoking prohibition becomes established and self-enforcing. It is likely that there will be high levels of inspections initially and these will fall to a lower constant rate over time. Ministers will discuss with CoSLA the options for, and practicalities of, enforcement. The details of these are required to obtain a meaningful estimate of the costs of enforcement. Full details of the anticipated costs will be produced and included in the regulatory impact assessment. However, whichever of the enforcement options are chosen, there is likely to be some additional cost in the early years.

Costs on other bodies, individuals and businesses

198. A full regulatory impact assessment will be prepared in support of the detailed regulations, which will be subject to affirmative resolution.
199. As part of the consultation process the Executive engaged the University of Aberdeen’s Health Economic Research Unit to consider the international evidence on the health and economic impact of controls on second-hand smoke and the potential impact of such controls in Scotland. In addition Ministers commissioned research by David Hole, Professor of Epidemiology and Biostatistics at the University of Glasgow, to estimate the number of deaths of Scottish adults from smoking related diseases which can be attributed to passive smoking. These reports, along with the research on workplace smoking policies in Scotland undertaken by BMRB Social Research, are available on the Executive website1.

Number of deaths amongst “never smokers associated with” environmental tobacco smoke

200. The research by Glasgow University suggests that environmental tobacco smoke (ETS) is associated with 865 deaths per year amongst lifelong non-smokers in Scotland. Further modelling by Aberdeen University based on this research suggests that, of the 865 deaths, 120 are attributable to exposure in public places. This is a conservative estimate as it is based only on the four main causes of death for which there is the most evidence and assumes that the person never smoked, rather than including (former smokers) non-smokers.

201. The benefits from reduced exposure to ETS accrue over time. The University of Aberdeen estimate that by 2034 the number of lives saved due to a ban on smoking in public places will be 186 per year. This is a worst case scenario and only looks at the deaths attributable to lung disease and ischaemic heart disease, which have the greatest amount of evidence available.

Savings to NHS Scotland

202. The Wanless Report2, which was published earlier in 2004, estimated that if a workplace smoking ban were introduced, up to 4% of all smokers would quit smoking. Although this Bill relates to a ban on smoking in public places, many public places are also workplaces and we would expect a similar reduction in the smoking rates to occur over time. Stopping smoking has almost instant benefits to improving health, for example after 1 year’s cessation the risk of heart attack falls to about half that of a smoker. In 1999 it was estimated that Scotland spent up to £140 million every year on treating 35,000 people for smoking-related disease – at current prices this would amount to over £200 million per year.

203. A reduction in the number of smokers will lead to significant savings for NHS Scotland over time in the treatment of smoking related disease and reduce the number of smoking related deaths. The University of Aberdeen estimate that reducing exposure to ETS would reduce mortality from lung cancer by 0.64%, mortality from stroke by 2.24%, mortality from respiratory disease by 0.68% and mortality from ischaemic heart disease by 1.77%. This would equate to gross savings to NHS Scotland of between £5.7 million and £15.7 million per annum based on best and worst case outcomes.

Costs to business

204. The majority of workplaces which allow different types of general public access have specific smoking policies for these areas. 55% of small to medium sized enterprises (SMEs) and

1 http://www.scotland.gov.uk/Topics/Health/health/smoking/Publications
2 http://www.hm-treasury.gov.uk/consultations_and_legislation/wanless/consult_wanless03_index.cfm
These documents relate to the Smoking, Health and Social Care (Scotland) Bill (SP Bill 33) as introduced in the Scottish Parliament on 16 December 2004

64% of large enterprises do not permit smoking anywhere, while 21% of SMEs and 23% of large enterprises restrict smoking for the public to smoking rooms or designated areas. A ban on smoking in public places is likely to have the greatest impact in the hospitality sector where the highest number of businesses without existing smoking policies are found. It is currently estimated that six in ten workplaces in the leisure and hospitality sector require employees to work in areas where smoking is permitted and seven out of ten public houses allow smoking throughout.

205. The hospitality sector in Scotland in 2003 employed 150,000 and had an annual turnover of £5,113 million. Of the 13,015 enterprises in the sector 43% are restaurants, 31% are bars and 18% are hotels. Each sector accounts for about 30% of the total turnover.

206. The hospitality sector is not the only sector where the Bill will have a potential impact. However this analysis will primarily focus on the hospitality sector as it is the largest. The other sector that could be affected is the recreational, cultural and sporting sector which accounts for less than 3% of employment or turnover. The majority of the enterprises in this sub-sector already have smoking restrictions in place.

207. The table below, based on research from the University of Aberdeen shows the potential economic impact upon the hospitality sector per annum. Central estimates represent a conservative estimate of the most likely impact whilst low and high estimates show a range of possible impacts. However, the figures quoted in the table below incorporate more conservative assumptions on the estimate of the impact on the pub sector than that contained in the published paper.

<table>
<thead>
<tr>
<th></th>
<th>Central estimate £ million</th>
<th>Low estimate £ million</th>
<th>High estimate £ million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hotels</td>
<td>-10</td>
<td>-26</td>
<td>5</td>
</tr>
<tr>
<td>Restaurants</td>
<td>4</td>
<td>-21</td>
<td>28</td>
</tr>
<tr>
<td>Bars</td>
<td>0</td>
<td>-58</td>
<td>104</td>
</tr>
<tr>
<td>Total*</td>
<td>-6</td>
<td>-104</td>
<td>137</td>
</tr>
</tbody>
</table>

*Totals vary due to rounding

208. The range reflects the uncertainty and limitations around some of the data available. The best case estimate is a £137 million benefit to the hospitality sector, but the range of possible benefits could be either positive or negative. It is important to note however that any potential gains or losses in this sector will not entirely be gains or losses to the Scottish economy as a whole as expenditure diverted from one sector of the economy may be taken up in others.

209. Signatories to the Scottish Voluntary Charter on Smoking in Public Places, who include the Scottish Licensed Trade Association, Scottish Beer and Pub Association, Scottish Tourism Forum and the British Hospitality Association, recognise the need for acceleration in standards and non-smoking provision in pubs and the hospitality industry. They have expressed a fear that a ban on smoking in public places that extends to pubs will mean that a quarter of licensed premises will cease trading with a loss of 30,000 jobs.
Estimated business savings

The research undertaken by the University of Aberdeen suggests that the most likely economic impact of a ban will be a net gain for Scottish society, with conservative estimates of savings in Scottish workplaces through reduced absenteeism, a reduction in smoking breaks, reduced fire damage and reduced redecoration costs. Additional financial gains would come from the health improvements. As these health benefits and potential costs will accrue over a long time period the Executive is undertaking research to calculate the net present value for each of the potential outcomes.

FREE EYE AND DENTAL EXAMINATIONS

Introduction

These provisions of the Bill provide for the introduction of free eye and dental checks for all after 1 April 2006.

Costs on the Scottish Administration

The costs of implementing free NHS eye and dental checks will be funded from the General Ophthalmic Services budget and General Dental Services budget respectively. The current cost of providing free NHS eye and dental checks is £15.2 million and £7.7 million respectively. The cost of extending free NHS eye and dental checks would be £7.5 - £17.9 million for eye checks and £9.1 - £12.4 million for dental checks, based on the fees paid to optometrists/ophthalmic medical practitioners and to dentists. These figures are based on the costs of £16.72 for an NHS sight test and £6.80 for a dental check and on an increase of up to 25% on the numbers of people who currently pay for checks (currently 450,000 eye checks and approximately 2 million dental checks). The Executive would provide NHS National Services Scotland with the additional funding to pay for the free eye and dental checks.

Costs on local authorities

The free eye and dental checks have no financial implications for local authorities.

Costs on other bodies, individuals and businesses

Costs on Health Boards

There will be no additional cost for Health Boards who draw down the expenditure from the centrally held budgets.

Costs on NHS National Services Scotland (NSS)

NSS process and pay general dental and ophthalmic service fees for Scotland as a whole. Some amendments would be required to claim forms submitted to NSS by dentists and optometrists/ophthalmic medical practitioners and adjustments made to the relevant NSS payment systems to deal with the partnership commitment. Discussions with the professional bodies will have to be concluded in order for meaningful costs to be established.
PROVISION OF GENERAL DENTAL SERVICES

Introduction

216. This Bill is the vehicle through which the Executive will implement the new General Dental Services (GDS) arrangements for providers of primary dental services. The proposed new arrangements follow a comprehensive consultation on the future of NHS dental services in Scotland.

Costs on the Scottish Administration

Current arrangements for funding General Dental Services

217. Nearly all general dental practitioners (GDPs) are paid by the NHS as independent, self-employed contractors. They are entitled to payments in respect of patients registered and work carried out. The payments they receive cover both their expenses in providing GDS and a net income for doing so.

218. Expenditure on GDS is non-discretionary, that is, demand led and met by Health Boards. The Scottish Executive Health Department issues allocations to Health Boards, based on indicative spend.

New arrangements

219. Under the new arrangements as implemented by the Bill and its consequential regulations, funding will continue to flow from the Executive to GDPs via the Health Boards. But, in addition, Health Boards will be able to make arrangements with groups of dentists and dental corporations for the provision of NHS Dental Services. The new arrangements assume a redistribution of existing resources.

220. Current financial expenditure on general dental services in Scotland is around £200 million per year, mainly in respect of item of service fees, capitation and allowances. It is planned to simplify the item of service fee structure from over 400 items to a smaller number of items. It is proposed that the new payment arrangements would comprise a mixture of: capitation, allowances (building on existing allowances), item of service fees, and a new scheme of reimbursements to support infrastructure costs and payments to support quality. Consequently some reordering of the overall financial provision will be required, but the simplification should be cost neutral.

221. It is also anticipated that the new arrangements would be nationally agreed and would be supplemented by local arrangements for services outwith the national framework.

222. The provisions of the Bill in section 11(4) are also intended to simplify the patient charging system which raises around £50 million in patients’ contributions. The current system links the patient charge to the dentist’s item of service. To provide more flexibility for patient charges it is proposed to de-link the patient charge from the dentist’s item of service, while still generating the current level of funding achieved by the current patient charge.
These documents relate to the Smoking, Health and Social Care (Scotland) Bill (SP Bill 33) as introduced in the Scottish Parliament on 16 December 2004

Costs on local authorities

223. The general dental services provisions of the Bill have no financial implications for local authorities.

Costs on other bodies, individuals and businesses

Cost to Health Boards for administering ‘new contract’ arrangements

224. The aim of giving greater responsibility to Health Boards for the delivery of NHS dental services will result in a higher level of administration cost than at present. It is estimated that additional support staffing (administrative and professional) in Health Boards would cost some £500,000 per annum across Scotland based on an additional 10 whole time equivalents at a cost of £50,000 each. This would be funded out of existing Health Board allocations.

Costs on NHS National Services Scotland for payment processing

225. Nothing in the new arrangements is expected to impact substantially on the current expenditure levels for payment processing in NSS (£3.3 million).

LISTING OF ADDITIONAL CATEGORIES OF GENERAL DENTAL PRACTITIONERS, OPTOMETRISTS AND OPHTHALMIC MEDICAL PRACTITIONERS

Introduction

226. The Bill extends the categories of persons who are to be named on lists held by Health Boards in relation to general dental services (GDS) and general ophthalmic services (GOS).

Costs on the Scottish Administration

227. The listing provisions of the Bill will have no financial implications for the Executive.

Costs on local authorities

228. The listing provisions of the Bill will have no financial implications for local authorities.

Costs on other bodies, individuals and businesses

Costs on Health Boards

229. It is estimated that less than 200 additional dentists and less than 100 additional optometrists/ophthalmic medical practitioners will be listed. Health Boards will incur limited additional costs as a result of listing these groups. These will be subsumed within their overall resources.

Costs on NSS

230. NSS will be commissioned to maintain up to date databases of all those who are listed to provide or assist with the provision of GDS or GOS or to perform personal dental services, i.e. national “virtual” lists. It is the policy intention that no-one may perform personal dental services.
or provide or assist with the provision of GDS or GOS unless they are named on a list and have therefore undergone the various eligibility checks. Since locums will be listed, this will be of help to practice owners seeking locum cover. NSS has estimated that initial development costs will be in the order of £10,000-£20,000.

**PHARMACEUTICAL CARE SERVICES**

**Introduction**

231. The Bill is the means by which the Executive will implement new arrangements for modernising NHS community pharmacy in Scotland

**Costs on the Scottish Administration**

232. The pharmaceutical care services (PCS) provisions of the Bill do not have financial implications for the Executive.

**Costs on local authorities**

233. The pharmaceutical care services provisions of the Bill have no financial implications for local authorities.

**Costs on other bodies, individuals and businesses**

*Cost to Health Boards for new planning and administrative processes*

234. Based on financial data provided by Health Boards, the cost for administering the current control of entry and service delivery arrangements across Scotland as a whole is less than £200,000 per annum. Under the new arrangements detailed in the Bill there will be an enhanced role for Health Boards in terms of planning and monitoring service delivery, and financial management. Whilst in part some of the administrative arrangements associated with the current regime will disappear, overall it is estimated that a further £500,000 per annum will be required across Scotland, that is an additional 10 whole time equivalents of staff (at £50,000 per head) spread across the larger Health Boards. This would be funded out of existing Health Board allocations.

*Cost to facilitate change and support new provision in service gap sites*

235. The identification of locations where new or enhanced service provision is required will be an outcome of Health Boards’ new planning responsibilities and consequently the overall requirement cannot be estimated at present. However, based on current contractor numbers and remuneration costs, the required revenue provision would be in the region of £85,000 per location per annum if a full range of pharmaceutical services were to be delivered, which may not always be necessary. In some cases it may be necessary to fund ‘set up’ costs, for example for the provision or upgrading of premises. The cost of acquiring suitable premises will be dependent on a range of factors, for example location; new or existing; build, purchase or lease which, again, cannot be estimated at present. Fitting premises to provide pharmaceutical services can range from £30,000 to £80,000 for a small to medium size site (estimate provided by Scottish Pharmaceutical General Council).
236. The 2003-04 NSS Practitioner Services Division (PSD) cost for administering community pharmacy contractor payments on behalf of Health Boards was £12.3 million. This included staff, rent, rate and information management and technology costs, and all support and maintenance costs. The number of whole time equivalent employees was 365.

237. Nothing in the new contract arrangements as such is expected to impact significantly on the current expenditure levels for NSS payment processing.

Costs on NSS for maintenance of ‘virtual’ pharmaceutical list

238. Under the arrangements contained in the Bill, Health Boards will be required to maintain a list of all registered pharmacists who wish to perform PCS in their respective areas. In order to reduce the administration requirements on Health Boards and individual pharmacists alike, the intention is that applicants would apply to one Health Board indicating any other Health Boards they wish to be listed with. The “host” Health Board would then pass copies of any relevant documentation to each relevant Health Board for their decision on listing for their area. To facilitate the process, NSS will be commissioned to maintain an all-Scotland pharmaceutical list that Health Boards and contractors will be able to access to check and confirm individual PCS performer status. Such a list is already held and maintained by NSS for Primary Medical Services performers. NSS estimate that the addition of PCS performers to the existing system would have an initial development cost of £10,000.

Costs on NSS National Appeal Panel (NAP) for revised appeal role (national dispute resolution)

239. Over the last three full financial years the NAP costs have averaged a total of £85,000 per annum comprising £6,000 for training, £39,000 for administration and £40,000 for NAP and legal costs (including judicial reviews). Under the new planning and contract arrangements, the need for appeal procedures on control of entry decisions will no longer be required as control of entry will be managed through the contractual procedure. However, there will be a need for a panel to consider contract dispute cases that are not resolved at local Health Board level. The proposal is to meet this requirement by a change in NAP’s current role. Its activity requirements cannot be predicted at this stage but the working assumption is that the budget will fall within NAP’s current expenditure levels.

DISCIPLINE

Introduction

240. The Bill introduces measures which will help to improve the protection of patients and of NHS resources. These include strengthening the powers of the NHS Tribunal.

Costs on the Scottish Administration

241. Referrals to the NHS Tribunal are a rare event. They concern only the most serious actions or lack of action and this is expected to continue to be the case. The Executive pays fees to the Tribunal members for the case hearings they attend. The total fees paid depend on the number of days which each hearing lasts, which is variable.
Costs on local authorities

242. The discipline provisions of the Bill have no financial implications for local authorities.

Costs on other bodies, individuals and businesses

Costs on Health Boards

243. It is generally Health Boards which refer cases involving family health service practitioners to the NHS Tribunal. In many cases, they approach the Central Legal Office of NHS National Services Scotland (NSS) to prepare the case and represent the Board at the Tribunal hearing. Recent maximum administrative costs to NSS of a Tribunal case have been around £10,000. These costs are met currently from the unified budget and it is expected that they will continue to do so.

244. Generally Health Boards will be required to make payments to suspended practitioners in accordance with any determination by Scottish Ministers.

Costs on NHS National Services Scotland (NSS)

245. NSS will be commissioned to maintain an up to date database of all suspensions and disqualifications from lists, refusals of entry to lists and list removals which take place in Scotland and elsewhere in the UK. Health Boards will be able to access this when checking whether an applicant should be on the list for their area. NSS estimate that additional set-up costs would be in the order of £15,000.

PAYMENTS TO CERTAIN PERSONS INFECTED WITH HEPATITIS C AS A RESULT OF NHS TREATMENT

Introduction

246. The Bill provides a statutory basis for making continuing payments into the UK scheme for making ex gratia payments to patients who have contracted the hepatitis C virus from NHS treatment.

Costs on the Scottish Administration

247. The UK scheme for making ex gratia payments to patients who have contracted the hepatitis C virus from NHS blood treatment prior to September 1991 states basic eligibility criteria expressed in terms of the route and nature of the infection. Claimants who satisfy these eligibility criteria receive a basic payment and are eligible for a further payment if the disease progresses to a more advanced stage. There is no time limit as to when claims can be made.

248. Estimates of the numbers of people likely to be eligible for the payments have been made for Scotland, based on predictions of the number of people infected across the UK. These make allowances for the proportion of those estimated to have died between infection and the time when a claim could be submitted and for the fact that current statistics suggest that twenty per cent of those infected with the hepatitis C virus develop cirrhosis, liver cancer or liver failure within twenty to forty years of the original infection.
249. Based on these estimates, as outlined by the Minister for Health and Community Care to the Health Committee on 9 September 2003, the Scottish Executive Health Department has made a provision of £15 million to fund payments to Scottish claimants over the life of the scheme.

250. The hepatitis C provisions of the Bill do not increase the existing costs to the Executive.

**Costs on local authorities**

251. The hepatitis C provisions of the Bill have no financial implications for local authorities.

**Costs on other bodies, individuals and businesses**

252. The hepatitis C provisions of the Bill have no financial implications for other bodies, individuals or businesses.

**AMENDMENT OF REGULATION OF CARE (SCOTLAND) ACT 2001, AND CHILD CARE AGENCIES AND HOUSING SUPPORT SERVICES**

**Introduction**

253. The Bill makes a number of small amendments to the Regulation of Care (Scotland) Act 2001.

**Costs on the Scottish Administration**

254. The regulation of care (RoC) provisions of the Bill have no financial implications for the Executive.

**Costs on local authorities**

255. The regulation of care provisions of the Bill have no financial implications for local authorities.

**Costs on other bodies, individuals and businesses**

256. **RoC (Scotland) Act 2001 Section 2(5):** The use of the power to except services from the definition of independent healthcare (IHC) services in the Regulation of Care (Scotland) Act 2001 (the 2001 Act) will restrict the current scope of IHC services which would be subject to regulation by the Scottish Commission for the Regulation of Care (Care Commission) under the 2001 Act (were the definition to be commenced fully now). Services which are excepted by regulations are not required to register with the Care Commission. The services to which this exception is likely to be applied are not currently regulated by the Care Commission and are therefore not generating any income for the Care Commission. The current policy is that for those services where the provisions of the 2001 Act have commenced, the fees are charged at full cost recovery.

257. **RoC (Scotland) Act Section 16(2):** Both the Care Commission and service providers are already considering and making representations. This change formalises a process which the Care
Commission and providers are already carrying out, therefore, there will be no additional costs incurred.

258. **RoC (Scotland) Act Section 2**: Care Commission fees for these services are at full cost recovery levels, therefore there will be no net effect on the Care Commission.

259. **RoC Act Sections 48, 51 & 53**: These are technical amendments which clarify the original intent of the Act. There is no extra work or expense involved as a result of these amendments. The Scottish Social Services Council has always taken account of any representations made in the registration process. From its initiation, the Council has included in its annual budget a provision for legal expenses which covers any legal expense incurred by the Council in relation to its functions. This amount includes any expense incurred where an appeal is made by an applicant to the Sheriff. This amendment does not mean that there will be an increase in appeals and will not, thereby, increase the original costs associated with the 2001 Act.

260. **Child care agencies and housing support services**: The provisions of the Bill which ensure that housing support services and child care agencies were deemed to be registered from 1 April 2003 and that registration does not cease until 1 April 2006 if necessary have no financial implications other than ensuring that certain payments made by local authorities to housing support services are made lawfully.

**AUTHORISATION OF MEDICAL TREATMENT**

Introduction

261. Since Part 5 of the Adults with Incapacity (Scotland) Act 2000 (the 2000 Act) came into effect it has been possible, in some circumstances, for a medical practitioner primarily responsible for treatment to charge another health professional (for example a dentist) for producing a certificate under section 47 of the 2000 Act. The proposed changes are likely to reduce this expenditure, as described below.

Costs on the Scottish Administration

262. The authorisation of medical treatment provisions of the Bill have no financial implications for the Executive.

Costs on local authorities

263. The authorisation of medical treatment provisions of the Bill have no financial implications for local authorities.

Costs on other bodies, individuals and businesses

*General Practitioners*

264. Certificates issued under section 47 of the 2000 Act in general attract no fee. Where, however, a GP has not yet issued a certificate and one is requested by an independent health professional in order to treat a patient under the NHS, or in the unlikely event that a GP is required
to undertake a second assessment and produce an additional certificate for an independent health professional, having already issued a certificate which enabled the GP to treat his own patient, then in both cases a fee can be claimed. The fee is currently set at £92.60. Where a fee is properly payable under these arrangements it is for the GP concerned to make an application for payment to the local NSS Practitioner Services Division (PSD). Since Part 5 of the 2000 Act came into force on 1 July 2002, PSD has paid approximately £80,000.

265. It has been estimated that the number of certificates required which would incur a fee would reduce over time as the provisions of the Bill, which will allow other healthcare professionals to sign certificates, take effect. There should also be a reduction in certificates required as a result of the increase in duration in some cases. These effects should lead to a decrease in the costs of certification.

JOINT VENTURES

Introduction

266. The Bill makes provision to allow Scottish Ministers and NHS bodies to form or participate in joint venture companies. It is intended that this will be for two purposes. Firstly for the provision of facilities and services and, secondly, for the exploitation of intellectual property.

Facilities and services

Costs on the Scottish Administration

267. An option being explored is for Scottish Ministers to take a direct equity stake in each joint venture in order to provide stability, co-ordination and support at national level. We would expect that equity investment would be a maximum of £0.5 million per joint venture, which is already included within the existing capital budget which has a provision for 7 projects (£3.5 million) during 2006-07 and 2007-08. There would not, therefore, be any additional expenditure as a result of using this approach. The joint venture approach is an additional tool for health boards to use, but is not mandatory. It is not possible, therefore, to estimate how many projects may use it.

268. Given the experience and costs of development of NHS LIFT in England, the development costs for the joint venture model are estimated at £300,000. This would cover the development of appropriate documentation together with technical and legal advice and is a one-off cost. Again provision has been made within existing baselines to support such a development.

Costs on local authorities

269. The Executive is of the view that there will be no impact on local authorities as a result of the creation of joint ventures. Whether public or private bodies are investors or tenants within facilities developed under the joint venture model, procedures will be in place on which value for money can be assessed and tested on an ongoing basis.
These documents relate to the Smoking, Health and Social Care (Scotland) Bill (SP Bill 33) as introduced in the Scottish Parliament on 16 December 2004

Costs on other bodies, individuals and businesses

270. The Executive is of the view that there will be no impact on other aspects of public expenditure or on the costs of the voluntary or private sectors or individuals, as a result of the creation of joint ventures.

Intellectual property

Costs on the Scottish Administration

271. The intellectual property provisions of the Bill allow Scottish Ministers to invest, or provide loans or guarantees etc.. However, the policy intention is that the powers will not be exercised in such a way. No new duties or obligations are imposed; the power will allow the Scottish Ministers an additional way to progress innovations within the NHS. It will therefore be applied in two circumstances:

- where the innovation cannot be exploited currently because participation with companies is not allowed; or
- where the innovation could be exploited other than through a company but that method of exploitation is less beneficial to the NHS.

272. In both these circumstances, where the use of the new power is authorised by the Scottish Ministers through a direction to NHS bodies, the direction will ensure that the power is only used where an evaluation of the value and viability of the proposal has been carried out to confirm that this is the most appropriate means of exploitation.

Costs on local authorities

273. The intellectual property provisions of the Bill have no financial implications for local authorities.

Costs on other bodies, individuals and businesses

274. NHS expenditure through Health Boards in support of progressing innovative products or ideas is a very small element of the NHS research and development (R&D) budget. Only £150,000 of the £35 million NHS organisations receive annually from the Chief Scientist Office (CSO) of the Scottish Executive Health Department for research and related activities is designated centrally for this purpose to Scottish Health Innovations Ltd (SHIL) and, although this figure is supplemented by local expenditure of approximately the same order, it is still an extremely low proportion of the total research expenditure. As an illustration the Scottish National Blood Transfusion Service spends approximately £200,000 per year on intellectual property protection costs, for example patents and trade marks, this is closely linked to its well established commercial activities which have generated external income of £45 million over the last 9 years primarily through product sales, contract manufacture and consultancy and testing services.

275. The use of the limited funds available to progress innovative ideas beyond their research stage and into product development is therefore very carefully considered with a view to maximising a health and financial benefit to the NHS. The introduction of this new power will therefore increase the range of ways in which these funds can be deployed, but not necessarily increase the funds themselves. It should not increase costs to the NHS as the use of this new power
is limited to circumstances where it will generate income for the NHS. The ability to transfer ownership of a technology to a spin-out company will not only increase the likelihood of investment by commercial partners, but also ensure that financial and other liabilities lie with and are limited to the liabilities of the company and not the NHS organisation. As such, the NHS risk will be both limited and circumscribed. The costs of establishing a spin-out company are minimal - £20 for registering the company. If Memorandum and Articles of Association are not already available they can be purchased from a law or legal stationers or formation agent for £20 to £30. Any legal costs between the NHS and commercial partner should be no more than that for negotiating a license deal with a third party for the same product. As at present this can be up to approximately £5,000 and in all likelihood less. Therefore, across all innovations using the company mechanism, there are no additional costs of going down this route.

276. The provisions of the Bill are intended to overcome the current difficulties in attracting capital and the willingness of academic partner organisations to participate in joint venture projects. Thus it is not possible to provide predictions of future benefits at present.

277. One measure of the anticipated economic and financial benefit from NHS innovation activities might be the willingness of non-NHS organisations to provide financial support. In addition to the £150,000 paid annually from the NHS R&D budget and £75,000 directly from CSO to support SHIL, Scottish Enterprise contributes £150,000 per year, Highland and Island Enterprise £50,000 per year and the UK Department of Trade and Industry a total of £425,000 to this initiative.

278. In terms of anticipated benefit from any individual innovation, that is impossible to estimate. One well advanced NHS product currently being developed through a spin-out company created by SHIL has already attracted £305,000 of external investment with a further £250,000 to follow if milestones are met. A further £0.5 million investment is also being pursued. Although this is unlikely to be typical, it does nonetheless demonstrate the potential for this new power to attract external funding in NHS innovations and to attract income.

**SCOTTISH HOSPITAL ENDOWMENTS RESEARCH TRUST**

**Introduction**

279. The Bill provides for the ending of the Scottish Hospital Endowments Research Trust’s (SHERT) status as a non-departmental public body while preserving its continuing status as a charitable trust.

**Costs on the Scottish Administration**

280. There are no financial consequences on the Executive as SHERT is self financing and receives no funding from the Executive. The repeal of public body status will result in minimal savings (approximately £10,000 per annum) in terms of sponsorship costs.

**Costs on local authorities**

281. The provisions relating to the Scottish Hospital Endowments Research Trust of the Bill have no financial implications for Local Authorities.
Costs on other bodies, individuals and businesses

Costs on SHERT

282. The policy of the proposed adjustment to the existing legislation has relatively minor cost implications for SHERT. This approach will require SHERT to take both legal advice and advice from accountants and auditors with anticipated professional costs being in the region of £5,000.

283. By contrast, the cost associated with the alternative of transferring the functions to a new charitable trust would be considerable. In addition to detailed legislation being required to ensure that all assets and liabilities are transferred to the new body, and that legacies left to SHERT would automatically transfer to “new SHERT”, existing royalty streams and intellectual property from past grants would need to be secured. In addition, land that SHERT owns would need to be transferred. In total, the costs associated with the combined accounting, audit and legal costs of such an approach would be in the region of £40,000.

284. The administration of SHERT is undertaken by a firm of Edinburgh solicitors. The associated management, support and staff costs of this arrangement are detailed in SHERT’s Annual Reports, and for the year ended 31 July 2003 amounted to £215,286. With independence will come the reduction in time spent by the Secretaries on liaising with the Chief Scientist Office, and vice versa, on public body related issues. At most, it is considered that the ongoing cost implications for SHERT will be neutral.
Table 2. Summary of additional costs arising from the Bill

<table>
<thead>
<tr>
<th>Policy Area</th>
<th>Cost on Scottish Administration</th>
<th>Health Boards</th>
<th>Local Authorities</th>
<th>Cost on Other Bodies</th>
<th>Paragraph reference(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>£2m for communications ahead of implementation and £1m p.a. for 3 years following implementation. £50,000 - £100,000 in first year for compliance line. Ongoing costs not known.</td>
<td></td>
<td></td>
<td>Enforcement costs to be developed in full RIA.</td>
<td>193, 195, 197, 203, 207</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Free Eye and Dental Checks</td>
<td>£7.5m - £17.9m p.a. for eye checks and £9.1m - £12.4m p.a. for dental checks</td>
<td>Nil</td>
<td></td>
<td>Nil</td>
<td>212</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dentistry</td>
<td>N/A</td>
<td>Nil</td>
<td></td>
<td>Nil</td>
<td>224</td>
</tr>
<tr>
<td>Listing</td>
<td>Nil</td>
<td>Nil</td>
<td></td>
<td>£10,000 - £20,000 one-off NSS database costs.</td>
<td>230</td>
</tr>
</tbody>
</table>
These documents relate to the Smoking, Health and Social Care (Scotland) Bill (SP Bill 33) as introduced in the Scottish Parliament on 16 December 2004

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>£500,000 p.a. for Health Board planning and monitoring activities.</th>
<th>Nil</th>
<th>£10,000 one-off NSS database cost.</th>
<th>234, 238</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discipline</td>
<td>Nil</td>
<td>Nil</td>
<td>£15,000 one-off NSS database cost.</td>
<td>245</td>
</tr>
<tr>
<td>Hep C</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>RoC Amendments and Child Care etc.</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>Authorisation of Treatment</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>Joint Ventures</td>
<td>£300,000 one-off cost of development of JV model.</td>
<td>Nil</td>
<td>Nil</td>
<td>268</td>
</tr>
<tr>
<td>SHERT</td>
<td>£10,000 p.a. saving</td>
<td>Nil</td>
<td>Nil</td>
<td>One-off £5,000 professional advice.</td>
</tr>
</tbody>
</table>
EXECUTIVE STATEMENT ON LEGISLATIVE COMPETENCE

285. On 16 December 2004, the Minister for Health and Community Care (Mr Andy Kerr MSP) made the following statement:

“In my view, the provisions of the Smoking, Health and Social Care (Scotland) Bill would be within the legislative competence of the Scottish Parliament.”

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PRESIDING OFFICER’S STATEMENT ON LEGISLATIVE COMPETENCE

286. On 15 December 2004, the Presiding Officer (Right Honourable George Reid MSP) made the following statement:

“In my view, the provisions of the Smoking, Health and Social Care (Scotland) Bill would be within the legislative competence of the Scottish Parliament.”
These documents relate to the Smoking, Health and Social Care (Scotland) Bill (SP Bill 33) as introduced in the Scottish Parliament on 16 December 2004

SMOKING, HEALTH AND SOCIAL CARE (SCOTLAND) BILL

EXPLANATORY NOTES

AND OTHER ACCOMPANYING DOCUMENTS