

SMOKING, HEALTH AND SOCIAL CARE (SCOTLAND) ACT 2005

EXPLANATORY NOTES

THE ACT

Part 3: Pharmaceutical Care Services Etc.

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

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

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

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

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

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

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

Section 21 – Pharmaceutical care services contracts

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

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

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

Section 22 – Drug Tariff

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

Section 23 – Persons performing pharmaceutical care services

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

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

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

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

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