HEALTH (TOBACCO, NICOTINE ETC. AND CARE) (SCOTLAND) BILL

EXPLANATORY NOTES

(AND OTHER ACCOMPANYING DOCUMENTS)

CONTENTS

As required under Rule 9.3 of the Parliament's Standing Orders, the following documents are published to accompany the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill introduced in the Scottish Parliament on 4 June 2015:

- Explanatory Notes;
- a Financial Memorandum;
- a Scottish Government statement on legislative competence; and
- the Presiding Officer's statement on legislative competence.

A Policy Memorandum is published separately as SP Bill 73–PM.

SP Bill 73–EN 1 Session 4 (2015)

EXPLANATORY NOTES

INTRODUCTION

- 1. These Explanatory Notes have been prepared by the Scottish Government 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.
- 2. 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 a part of a section, does not seem to require any explanation or comment, none is given.

PART 1 – TOBACCO, NICOTINE VAPOUR PRODUCTS AND SMOKING

THE BILL - OVERVIEW

- 3. Part 1 of the Bill includes a number of new controls on the sale of tobacco, the sale and promotion of a nicotine vapour product ("NVP") and on smoking outside hospital buildings. Chapter 1 contains provision which puts a prohibition on selling NVPs to persons under the age of 18, a power to ban the sale of NVPs from vending machines, a prohibition on the purchase of NVPs on behalf of a person under the age of 18 and a requirement for retailers of NVPs to be on a Register and related provision about banning orders. It also includes controls which apply to the sale of both NVPs and tobacco products: a requirement on retailers to operate an age verification policy, a prohibition on unauthorised sales by persons under the age of 18 and a statutory due diligence defence. Chapter 2 contains regulation-making powers which enable certain forms of advertising and promotion of NVPs to be prohibited or restricted. Chapter 3 contains provision related to prohibiting smoking in designated smoke-free outdoor areas on NHS hospital grounds.
- 4. In summary, Part 1 of the Bill:
 - introduces the offence of selling a NVP to a person under the age of 18,
 - introduces the offence of failing to operate an age verification policy at premises where tobacco products and NVPs are offered for sale,
 - introduces the offence of allowing a tobacco product, cigarette papers or a NVP to be sold by a person under the age of 18 without authorisation,
 - provides powers to introduce the offence of selling a NVP from a vending machine,
 - introduces the offence of carrying on a NVP business whilst unregistered or from unregistered premises,
 - provides for a due diligence defence against certain tobacco product and NVP related offences.
 - makes it an offence for a person aged over 18 to purchase a NVP for a person under the age of 18 (commonly known as "proxy purchase"),

- provides powers to make regulations containing prohibitions or restrictions on NVP advertisements and brand-sharing and to make related offences,
- provides powers to make regulations prohibiting or restricting giving away a NVP or a coupon for a NVP and to make related offences,
- provides powers to make regulations prohibiting or restricting a sponsorship agreement which promotes NVPs and to make related offences,
- makes it an offence to smoke outside a NHS hospital building within an area designated by regulations and makes related offences as well as powers to make regulations on the detail.

PART 1 – TOBACCO, NICOTINE VAPOUR PRODUCTS AND SMOKING

CHAPTER 1 – SALE OF TOBACCO AND NICOTINE VAPOUR PRODUCTS

Nicotine vapour products

Section 1 – Nicotine vapour products

- 5. Section 1 of the Bill amends the Tobacco and Primary Medical Services (Scotland) Act 2010 ("the 2010 Act") by including a definition of "nicotine vapour product" at section 35A (meaning of "nicotine vapour product"). Other amendments made by the Bill to the 2010 Act depend on this definition.
- 6. The first part of the definition (section 35A(1)(a)) covers devices intended to enable the inhalation of nicotine-containing vapour by an individual. The kinds of devices caught include those which contain nicotine and typically mimic conventional smoking behaviour e.g. devices commonly known as "e-cigarettes", "e-cigars" and "e-shisha". However, the definition is not limited to these kinds of devices. Vapour does not need to be visibly inhaled or exhaled. A hand-to-mouth action is not required.
- 7. The second part of the definition (section 35A(1)(b)) covers devices which are intended to enable the inhalation of vapour by an individual which do not contain nicotine. These devices are identified by reference to the devices in the first part of the definition: they must be intended to resemble (e.g. by shape, colour or texture) and be operated in a similar way (e.g. the method of inhalation or the way the device is activated or powered). This part of the definition is, therefore, reliant on the first part.
- 8. The third part of the definition (section 35A(1)(c)) covers items which are intended to form part of a device within the first or second parts of the definition e.g. a cartridge, a mechanical part or an electrical component. Accordingly, an item which is not intended to be used as part of a device caught by the definition does not fall within this part of the definition.
- 9. The fourth part of the definition (section 35A(1)(d)) covers substances intended to be vaporised by a device caught by the definition and any item containing such a substance. This can include, amongst other things, liquids (e.g. those commonly known as "e-liquid") and refill containers which hold liquid. It covers substances which contain nicotine as well as those which

do not. It covers substances which are intended to be mixed together to form a new substance where the intention is that the substances are to be vaporised in a device caught by the definition.

10. Finally, there are some exclusions from the definition (section 35A(2)). Tobacco and smoking related products (within the meaning of section 35(2) of the 2010 Act) are excluded. Medicinal products and medical devices are excluded by reference to the meaning of those expressions in the Human Medicines Regulations 2012 and the Medical Devices Regulations 2002, respectively. It should also be noted that nicotine at very high concentrations is already subject to regulation by the Poisons Act 1972 by virtue of the Poisons Rules 1982.

Sale and purchase of tobacco and nicotine vapour products

Section 2 – Sale of nicotine vapour products to persons under 18

- 11. Section 2(1) inserts a section 4A (sale of nicotine vapour products to persons under 18) into the 2010 Act.
- 12. Section 4A(1) makes it an offence for a person to sell an NVP to a person under the age of 18. The person who sells can be an individual (e.g. an employee) or a legal person (e.g. a body corporate) or both depending on the circumstances; where it is a legal person then section 34 (offences by bodies corporate etc.) of the 2010 Act may be relevant.
- 13. Section 4A(2) provides a defence for a person accused of an offence under section 4(1) where that person believed the customer was aged 18 or over and took reasonable steps to establish the customer's age. The reasonable steps are those provided for in section 4A(3). This includes being shown identification such as a passport, a driving licence or such other identification as may be prescribed in regulations made subject to negative procedure (by virtue of section 40(3) of the 2010 Act) by the Scottish Ministers (section 4A(4)). Section 4(5) provides that the penalty for committing the offence in section 4A(1) is, on summary conviction, a fine not exceeding level 4 on the standard scale (currently £2,500).

Section 3 – Age verification policy

- 14. Section 3(1) of the Bill inserts section 4B (age verification policy) into the 2010 Act.
- 15. Section 4B(1) and (2) require a person who carries on a tobacco or NVP business to operate an age verification policy at every premises where such a business is being carried on, but is does not include distance sales (for example, it does not apply to premises, such as a warehouse used to service internet sales, which are used only to despatch tobacco or NVPs). Section 35 (interpretation) of the 2010 Act contains a definition of "tobacco business". Section 8(2) of the Bill inserts into section 35 of the 2010 Act definitions of "nicotine vapour product business" and "tobacco or nicotine vapour product business". The businesses referred to by these definitions only involve the sale of products by retail.
- 16. Section 4B(3) defines an "age verification policy". It involves the person selling taking steps to challenge the age of a customer buying a tobacco product or an NVP who appears to that person to be under the age of 25 or such older age as may be specified in the policy. Section

- 4A(4) provides the Scottish Ministers with a power to make regulations to amend the age (up or down) referred to in subsection (3).
- 17. Section 4B(5) provides that the Scottish Ministers may issue guidance on matters relating to age verification policies. It sets out a number of things which, in particular, the guidance may contain. The guidance is intended to assist retailers to operate an age verification policy e.g. by setting out appropriate identification which young-looking customers should be asked to produce. Guidance can also cover related matters e.g. training. Section 4B(6) requires a person operating a policy to have regard to the guidance; this means a person must have regard to the guidance when establishing a policy and thereafter during the operation of the policy.
- 18. Section 4B(7) provides that a person who commits an offence under subsection (1) is liable on summary conviction to a fine not exceeding level 2 on the standard scale (currently £500).
- 19. Section 3(2) of the Bill amends section 40(4) (orders and regulations) of the 2010 Act to make any regulations made under section 4B(4) subject to affirmative procedure.

Section 4 – Sale by persons under 18

- 20. Section 4(1) of the Bill inserts section 4C (sale of tobacco or nicotine vapour products by persons under 18) into the 2010 Act.
- 21. Section 4C(1) makes it an offence for a responsible person to allow the unauthorised sale of tobacco products or NVPs by a person under the age of 18. In accordance with section 4C(2) the "responsible person" is the registered person, where premises from which the sale is made is noted in the Register against that person's name, or where the premises is unregistered it is the employer of the person who made the sale and/or a person having management and control of the premises. Section 4C(3) provides an exception to the offence, which allows persons under 18 to make sales where a registered person has authorised a person under 18 to make sales at the premises noted in the Register against that registered person's name.
- 22. Section 4C(4) requires the authorisation to be recorded and kept at premises where a person under 18 has been authorised to make sales. Section 4C(5) enables the Scottish Ministers by regulations to prescribe the form and content of authorisations, and the method of how authorisations must be recorded.
- 23. If an authorisation is not recorded and kept in accordance with section 4C(4) and regulations made under section 4C(5), then section 4C(6) provides that the authorisation is deemed not to have been made. That means the person under 18 is not authorised and the responsible person is liable for the offence under section 4C(1) if the responsible person allows the person under 18 to make a sale.
- 24. Section 4C(7) provides that a responsible person who commits an offence under section 4C(1) is liable on summary conviction to a fine not exceeding level 1 on the standard scale (currently £200).

Section 5 – Defence of due diligence for certain offences

- 25. Section 5(1) of the Bill inserts section 4D (defence of due diligence for certain offences) into the 2010 Act.
- 26. Section 4D(1) and (2) provides a due diligence defence for a person (or any employee or agent of that person) charged with the offence of—
 - selling a tobacco product to a person under the age of 18 (in section 4(1) of the 2010 Act),
 - selling a NVP to someone under the age of 18 (in section 4A(1) of the 2010 Act, inserted by section 2 of the Bill), or
 - allowing the sale of a tobacco product or NVP by an unauthorised person under 18 (in section 4C(1) of the 2010 Act, inserted by section 4 of the Bill).
- 27. The defence is that the accused (or the employee or agent of that person, as the case may be) took all reasonable precautions and exercised all due diligence to prevent the offence from being committed.

Section 6 – Purchase of nicotine vapour products on behalf of persons under 18

- 28. Section 6(1) of the Bill inserts section 6A (purchase of nicotine vapour products on behalf of persons under 18) into the 2010 Act.
- 29. Section 6A(1) makes it an offence for a person aged 18 or over to buy or attempt to buy a NVP on behalf of a person aged under 18. This is commonly known as a 'proxy purchase' offence. Section 6A(2) provides that a person who commits this offence is liable on summary conviction to a fine not exceeding level 5 on the standard scale (currently £5,000).

Section 7 – Extension of vending machine prohibition

30. Section 7 of the Bill contains an enabling power for the Scottish Ministers to make regulations to amend section 9 (prohibition of vending machines for the sale of tobacco products) of the 2010 Act so that it includes vending machines for the sale of NVP. The effect of such an amendment would be to make a person who has the management or control of premises on which a vending machine for the sale of NVPs is available commit an offence and be liable to the penalty set out in section 9(2) of the 2010 Act (on summary conviction a fine not exceeding level 4 on the standard scale, currently £2,500).

Register of tobacco and nicotine vapour product retailers

Section 8 – Register of tobacco and nicotine vapour product retailers

31. Section 8(1) of the Bill amends section 10(1) (Register of tobacco retailers) of the 2010 Act to require that the Scottish Ministers keep a Register of persons carrying on a NVP business. This is in addition to the existing requirement in section 10 which requires the Scottish Ministers to keep a Register of persons carrying on a tobacco business. As amended, section 8(1) means

that the Scottish Ministers must keep a single Register covering: tobacco businesses and NVP businesses, and consequently, businesses which are both tobacco and NVP businesses.

32. Section 8(2) of the Bill inserts into section 35 of the 2010 Act definitions of "nicotine vapour product business" and "tobacco or nicotine vapour product business". The businesses referred to by these definitions only involve the sale of products by retail.

Section 9 – Registration and changes to the Register

- 33. Section 9 of the Bill amends sections 11 to 14 of the 2010 Act to make changes to registration and the Register (as established by section 10 of the 2010 Act).
- 34. Section 11 of the 2010 Act concerns the application for registration and addition of premises etc. on the Register. Section 9(1)(a) amends section 11(2) so that persons carrying on a NVP business can apply for registration and persons carrying on a tobacco business can update their registration if they also retail NVPs. Under section 20 of the 2010 Act (as amended by section 11 of the Bill) it is an offence for an unregistered person to carry on a tobacco or NVP business.
- 35. Section 9(1)(b) inserts subsection (2A) into section 11 which requires an applicant, in relation to each premises, to state whether the applicant proposes to carry on a tobacco business, a NVP business or both. Under section 11(3)(a) of the 2010 Act the Scottish Ministers cannot grant an application if required information is missing or the application is not made in the correct form and manner, as set out by section 11(2).
- 36. Section 11(3)(b) of the 2010 Act bars the Scottish Ministers from granting an application if an applicant is banned, under a tobacco retailing banning order, from carrying on a tobacco business at any premises specified in the application. Section 9(1)(c) amends this provision to refer to a "tobacco and nicotine vapour product banning order" to account for the changes made to banning orders by section 10 of the Bill.
- 37. When an application meets the requirements, the Scottish Ministers must grant the registration and update the Register in accordance with section 11(4) (for new applicants) or (5) (for updates) of the 2010 Act. Section 9(1)(d) and (e) of the Bill amends section 11(4) and (5) to require the Scottish Ministers to enter information in the Register on NVP businesses and businesses which are both tobacco and NVP businesses. Section 9(2) of the Bill amends section 12 (certificates of registration) of the 2010 Act. Certificates of registration issued by the Scottish Ministers under section 12 must now state whether the premises noted against a person's entry in the Register are premises at which the person carries on a tobacco business, a NVP business or both.
- 38. Section 9(3) of the Bill amends section 13(1) (duty to notify certain changes) of the 2010 Act so that a registered person is under a duty to inform the Scottish Ministers if that person is no longer carrying on a NVP business at the address noted in the person's entry in the Register. Section 13(2) of the 2010 Act continues to require notice to be given within three months of the date of the change to which it relates. A failure to comply with this duty is an offence under section 20 of the 2010 Act (as amended by section 11 of the Bill).

39. Section 9(4) of the Bill amends section 14 (changes to and removal from Register) of the 2010 Act. This requires the Scottish Ministers to amend the Register if a tobacco and NVP banning order is made against a registered person. The Scottish Ministers may remove a person from the Register if they are not satisfied that the person is carrying on a tobacco or NVP business; they must notify the person and re-instate the entry where that person notifies them no later than 28 days after notice of the removal is given under section 14(4)(a) that the person is still carrying on a tobacco or NVP business. Note that there is no automatic reinstatement once a tobacco and NVP banning order expires – a fresh application is required under section 11 of the 2010 Act.

Section 10 – Tobacco and nicotine vapour product banning orders

- 40. Section 10(1) of the Bill amends section 15 (tobacco retailing banning orders) of the 2010 Act to allow a person carrying on a tobacco or NVP business to be the subject of an application for a retailing banning order, now renamed a "tobacco and nicotine vapour product banning order". Applications are made by a local authority to the sheriff. Where an order is made a person is banned from carrying on a tobacco business and a NVP business at the premises specified in the order for the period of time stated in the order (which cannot exceed 24 months). A sheriff may make an order where, in addition to other prerequisites in section 15(3), there have been three or more "relevant enforcement actions" in respect of each premises specified in the order. At present, section 15(3) requires the person who is the subject of the application for an order to have been the subject of the relevant enforcement actions. Now, as amended, a relevant enforcement action can relate to an offence committed by, or fixed penalty notice issued to, an employee or agent of the person who is the subject of the application to that person.
- 41. Section 10(2) of the Bill amends section 16 (tobacco retailing banning orders: ancillary orders) of the 2010 Act so that reference is now made to a tobacco and NVP banning order. Section 16 as amended allows local authorities to apply to the sheriff for an ancillary order in respect of NVP businesses as well as tobacco businesses.
- 42. The application for an ancillary order can be made along with an application for a tobacco and NVP banning order or it can be made at a later date once a banning order is in place. The order can be sought against "P" who is the person against whom the banning order is being sought or has already been made. An ancillary order can be sought by the local authority banning P from being connected to or seeking to control another person carrying on a NVP or tobacco business at the premises to which the banning order relates.
- 43. In addition, where P is not an individual (e.g. where P is a company or partnership), an ancillary order can be sought to ban any person connected to P from carrying on a tobacco or NVP business at the premises or from being connected to a person who carries on such a business at those premises.
- 44. Section 10(3) of the Bill amends section 17 (tobacco retailing banning orders etc.: appeals) of the 2010 Act to change references from "tobacco retailing banning order" to "tobacco and nicotine vapour product banning order". This allows for an appeal to be made against such an order to the sheriff principal (or when established, the Sheriff Appeal Court).

- 45. Section 10(4) of the Bill amends section 18 (tobacco retailing banning orders etc.: notification to Scottish Ministers) of the 2010 Act to change the reference from "tobacco retailing banning order" to "tobacco and nicotine vapour product banning order". Section 18 requires the sheriff to notify the Scottish Ministers on making a tobacco and NVP banning order or an ancillary order. The sheriff principal must notify the Scottish Ministers of the outcome of any appeal (or when established, the Sheriff Appeal Court).
- 46. Section 10(5) of the Bill amends section 19 (tobacco retailing banning orders: display of notices) of the 2010 Act to change references from "tobacco retailing banning order" to "tobacco and nicotine vapour product banning order" and adjust the signage requirements so that they include reference to the point of sale of NVPs. Section 19 requires retailers of tobacco or NVPs, in respect of whom a tobacco and NVP banning order has been granted, to display a notice in the premises specified in the order if the person continues to carry on a retail business at those premises. Section 19 sets out specific requirements of the notice, including its content, where it must be displayed on the premises (it must be readily visible to persons at every relevant point of sale) and the period of time it must be displayed.

Section 11 – Offences relating to the Register

47. Section 11 of the Bill amends section 20 (offences relating to the Register) of the 2010 Act to extend the existing offences as a consequence of the Register being revised to include NVP businesses. Unregistered persons commit an offence. It is an offence for a person to carry on a tobacco or NVP business from premises other than those noted in that person's entry in the Register. It is an offence for a person to fail to notify changes to that person's entry in the Register. It is an offence for a person to breach a tobacco and NVP banning order or an ancillary order. Section 11(4) of the 2010 Act continues to set out the different levels of penalty for these offences. The Bill does not change the penalty levels.

Section 12 – Public inspection of the Register

48. Section 12 of the Bill amends section 21 (public inspection of Register) of the 2010 Act. The Scottish Ministers must continue to make available for public inspection, and free of charge at all reasonable times, a list of all premises on the Register. Rather than the list comprising only premises at which tobacco businesses are carried on or proposed to be carried on, it now in addition must list premises where persons carry on or propose to carry on NVP businesses and businesses which are both tobacco and NVP businesses.

The 2010 Act: miscellaneous

Section 13 – Power to exclude certain premises

49. Section 13 of the Bill amends section 35 (interpretation of Part 1) of the 2010 Act to define "vehicle" and to include a regulation-making power for the Scottish Ministers enabling them to exclude specified kinds of aircraft or ship, boat or other water-going vessel.

Section 14 – Presumption as to contents of container

- 50. Section 14 of the Bill amends section 33 (presumption as to contents of container) of the 2010 Act. This section of the 2010 Act currently contains a presumption in prosecutions for displaying tobacco products (and smoking related products) or for selling tobacco to persons under 18. The presumption is that the contents of a container are what would be expected given the packaging. The presumption can be rebutted by the accused or another party in a trial. As amended by the Bill, the presumption now applies in the case of the following offences—
 - selling a tobacco product to a person under the age of 18 (section 4),
 - selling a NVP to a person under the age of 18 (section 4A),
 - failing to operate an age verification policy (section 4B),
 - allowing the sale of a tobacco product or NVP by an unauthorised person under 18 (section 4C),
 - purchasing of tobacco by a person under 18 (section 5),
 - purchasing a tobacco product or NVP on behalf of a person under 18 (section 6 and 6A),
 - managing or controlling premises on which a tobacco vending machine is available for use (section 9).

Section 15 - Part 1 of the 2010 Act: miscellaneous

51. Section 15 of the Bill makes a number of amendments to the titles and headings of provisions in the 2010 Act to reflect the amendments made by sections 1 to 14 of the Bill.

Interpretation

Section 16 – Meaning of "the 2010 Act"

52. Section 16 of the Bill defines references in Part 1 of the Bill to "the 2010 Act" as being to the Tobacco and Primary Medical Services (Scotland) Act 2010.

CHAPTER 2 – ADVERTISING AND PROMOTION OF NICOTINE VAPOUR PRODUCTS

Section 17 – Advertising and brand sharing

53. Section 17(1) of the Bill contains a wide power for the Scottish Ministers to make regulations to prohibit or restrict advertising and brand-sharing of NVPs. The powers could, for example, be used to prohibit or restrict the advertising of NVPs on billboards, product displays, bus stops, posters, leaflets, banners, brochures and certain published material in Scotland. Regulations could also prohibit or restrict unrelated branded products or services being used in NVP branding, and vice versa. The regulations can only apply to an activity in the course of a business. Section 17(2) contains a non-exhaustive list of the kind of provision which may also be made in regulations, covering enforcement, offences, penalties, defences and exceptions e.g.

there could be an exception made for specialist trade shops and an exception allowing certain forms of advertising and promotion at point of sale.

- 54. Section 17(3) specifies the maximum penalty which regulations may prescribe for offences as, on summary proceedings, imprisonment not exceeding 12 months or a fine not exceeding the statutory maximum (currently £10,000) or both and, on conviction on indictment, imprisonment not exceeding two years or an unlimited fine or both.
- 55. Section 17(4) defines certain expressions used in section 17. In particular, the definition of "nicotine vapour product advert" concerns a "published advertisement" whose purpose or effect is to promote a NVP, but it also includes a product "display" whose purpose or effect is to promote a NVP. The word "advertisement" is not defined and bears its ordinary meaning. A wide definition of "published" is provided to make clear that this term covers any way of making an advertisement available to the public in Scotland; it is, for example, not limited to print media and can cover electronic and audio-visual media.

Section 18 – Free distribution and nominal pricing

- 56. Section 18(1) of the Bill contains a power for the Scottish Ministers to make regulations to prohibit or restrict in the course of a business the giving away of NVPs (and coupons for those products) for free including retailing them for a nominal sum. Section 18(2) contains a non-exhaustive list of the kind of provision which may also be made in regulations, covering enforcement, offences, and penalties, defences and exceptions. It also makes clear that regulations can make further provision about the circumstances in which a product or coupon is to be treated as being made available for a nominal sum.
- 57. Section 18(3) specifies the maximum penalty which regulations may prescribe for offences as, on summary proceedings, imprisonment not exceeding 12 months or a fine not exceeding the statutory maximum (currently £10,000) or both and, on conviction on indictment, imprisonment not exceeding two years or an unlimited fine or both.

Section 19 – Sponsorship

- 58. Section 19(1) of the Bill contains a power for the Scottish Ministers to make regulations to prohibit or restrict a person in the course of a business entering into a sponsorship agreement where the purpose or effect of anything done as a result of the agreement promotes a NVP. Subsection (4) defines "sponsorship agreement". It can include the sponsorship of an event, activity or person in, or connected to, Scotland. Section 19(2) contains a non-exhaustive list of the kind of provision which may also be made in regulations, covering enforcement, offences, and penalties, defences and exceptions.
- 59. Section 19(3) specifies the maximum penalty which regulations may prescribe for offences as, on summary proceedings, imprisonment not exceeding 12 months or a fine not exceeding the statutory maximum (currently £10,000) or both, and on conviction on indictment, imprisonment not exceeding two years or an unlimited fine or both.

CHAPTER 3 – SMOKING OUTSIDE HOSPITALS

Section 20 – Smoking outside hospitals

60. Section 20 of the Bill amends Part 1 of the Smoking, Health and Social Care (Scotland) Act 2005 ("the 2005 Act").

Section 20(2)

61. Section 20(2) inserts new sections 4A, 4B, 4C and 4D into the 2010 Act. The new sections contain powers for the Scottish Ministers to designate no-smoking areas around certain buildings on certain NHS hospital grounds and provide for related duties, offences and penalties. Each new section is considered in turn below.

Section 4A: Offence of permitting others to smoke outside hospital building

- 62. Subsection (1) makes it an offence for a person who has management and control of a nosmoking area to knowingly permit smoking there.
- 63. Subsection (2) provides that a person knowingly permits smoking if the person should have known that someone was smoking in the no-smoking area.
- 64. Subsection (3) provides that it is a defence for an accused to show that the accused (or an employee or agent of the accused) took all reasonable precautions and exercised all due diligence to avoid committing the offence, or that there were no lawful and reasonably practicable means by which the accused could have prevented the smoking in the no-smoking area. The onus is, however, on the accused to prove this.
- 65. Subsection (4) provides that a person who commits the offence under this section is liable on summary conviction to a fine not exceeding level 4 on the standard scale (currently £2,500).

Section 4B: Offence of smoking outside hospital building

- 66. Subsection (1) makes it an offence for a person to smoke within the no-smoking area outside a hospital building.
- 67. Subsection (2) provides that it is a defence if the accused can prove that the accused did not know, and could not reasonably be expected to have known, that the area in which the accused was smoking was a no-smoking area. 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.
- 68. Subsection (3) provides that a person who commits the offence of smoking in a nosmoking area is liable on summary conviction to a fine not exceeding level 3 on the standard scale (currently £1,000).

Section 4C: Display of warning notices in hospital buildings and on hospital grounds

- 69. Subsection (1) places a duty on Health Boards to prominently display signs at every entrance to the hospital grounds.
- 70. Subsection (2) requires the person in management and control of each building on a hospital ground to prominently display signs at the entrance to each building. Subsection (5) makes it an offence for a person to fail to comply with this requirement. It also makes it an offence to fail to comply with requirements which may be set out in regulations made under subsection (4).
- 71. Subsection (3) provides that a sign must state that it is an offence to smoke in the nosmoking area outside a hospital building or knowingly permit smoking there.
- 72. Subsection (4) gives the Scottish Ministers a power to make regulations which may provide further detail as to the manner of display, form and content of the no-smoking signs.
- 73. Subsection (5) provides that a person who commits an offence of failing to display signage at the entrance to hospital buildings in compliance with this section is liable to a fine not exceeding level 3 on the standard scale (currently £1,000).

Section 4D: Meaning of "no-smoking area outside a hospital building" and related expressions

- 74. Subsection (1) defines the meaning of "no-smoking area outside a hospital building". It is an area lying immediately outside the hospital building. It is bounded by a perimeter of a specified distance from the building. However, the area is limited to being within, and thereby cannot fall outside of, hospital grounds. Subsection (2) gives a power to the Scottish Ministers to make regulations prescribing the specified distance. The regulations can also make further provision about determining the perimeter around a building, for example they could make detailed provision on how to determine the starting point outside a building from which the specified distance is to be measured.
- 75. Subsection (3) defines "hospital", "hospital building" and "hospital grounds" for the purposes of this section. A hospital means a health service hospital as defined in section 108(1) of the National Health Service (Scotland) Act 1978. A hospital building is simply a building on hospital grounds. Hospital grounds covers land in the vicinity of a hospital which is associated with it.
- 76. Subsection (4) allows the Scottish Ministers to make regulations which can—
 - (a) exclude certain hospitals altogether from the ban on smoking outside hospitals,
 - (b) include certain land within the meaning of hospital grounds e.g. land which might not necessarily be in the vicinity of, or associated with, a hospital, so that it can be caught by a no-smoking area,

- (c) exclude certain land from the meaning of hospital grounds e.g. land which despite being in the vicinity of, and associated with, a hospital, is not to be caught by a nosmoking area,
- (d) make further provision to elaborate on the meaning of "hospital grounds" e.g. criteria could be set out for determining whether land is to be regarded as associated with a hospital or not,
- (e) provide that certain buildings on hospital grounds are not to be regarded as hospital buildings for the purposes of the ban on smoking outside hospitals, and thereby, remove these buildings from having a perimeter applied from them, and
- (f) provide that certain land within a no-smoking area is to be exempt from that area so that it is not an offence to smoke there or permit others to do so.
- 77. Subsection (5) allows regulations made under subsection (4) by the Scottish Ministers to make provision modifying the application of section 4C so that, for example, signage requirements can be adjusted, as appropriate, to take account of exceptions and other provision made by those regulations.

Section 20(3) to (8) of the Bill

- 78. Section 20(3) of the Bill amends section 5(1) (proceeding for offences under sections 1 to 3) of the 2005 Act to include the offences contained in new sections 4A, 4B and 4C(5) within section 5; and section 20(4) amends the title of section 5 to reflect this change This links the start of the time limit for summary proceedings to the point at which the Crown is passed sufficient evidence on the offence to justify bringing a prosecution. This will prevent any lengthy or extended hearing processes consequential to the issuing of a fixed penalty notice under Part 1 of the 2010 Act resulting in a subsequent prosecution for that offence being time barred.
- 79. Section 20(5) amends section 6(2) (fixed penalties) of the 2005 Act to include the offences contained in new sections 4A, 4B and 4C(5) within section 6(2). This means that only an individual (or, put another way, a "natural person") can be issued with a fixed penalty notice in relation to these offences i.e. fixed penalty notices cannot be issued to bodies corporate etc. who may be accused of committing these offences.
- 80. Section 20(6) amends section 7 (powers to enter and require identification) of the 2005 Act to apply it appropriately in relation to the offences contained in new sections 4A, 4B and 4C(5). It provides an authorised officer of a local authority, for the area in which the hospitals falls, with powers to enter and search hospital grounds and to require identification (name and address) from an accused or a person with information about the offences.
- 81. Section 20(7) amends section 40 (regulations or orders) of the 2005 Act so that regulations made under new section 4D(2)(a) and (4)(a) are subject to the affirmative procedure.
- 82. Section 20(8) amends, and renames, schedule 1 (fixed penalty for offences under sections 1, 2 and 3) to the 2005 Act to account for the new offences in sections 4A, 4B and 4C(5) for which fixed penalty notices may be issued.

PART 2 – DUTY OF CANDOUR

- 83. Part 2 of the Bill introduces a duty of candour in health and social care settings.
- 84. Part 2 of the Bill creates a legal requirement for health and social care organisations to inform people (and their families) when they have been harmed (either physically or psychologically) as a result of the care or treatment they have received. There will also be requirements for organisations to prepare and publish reports in relation to the duty of candour.

Duty of candour procedure

Section 21 – Incident which activates duty of candour procedure

- 85. Section 21 describes incidents which give rise to the duty of candour procedure. The responsible person (defined in section 25) is required to follow the duty of candour procedure where the person has provided someone with a health service, a care service, or a social work service, and in the course of providing that service an unintended or unexpected incident has occurred which has resulted in certain outcomes. The outcomes need to relate to the incident rather than being attributable to the person's illness or condition. The decision as to whether the outcome relates to the incident is to be made by a registered health professional who was not involved in the incident itself.
- 86. The outcomes are set out in subsection (4) and cover a range of physical and psychological effects as well as death.
- 87. Subsection (5) provides the Scottish Ministers with the power to make regulations to amend the list of outcomes in subsection (4). Under section 32(2), any such regulations would be subject to the affirmative procedure.

Section 22 – Duty of candour procedure

- 88. The duty of candour procedure, which covers actions to be taken by responsible persons, will be set out in regulations made using the power in subsection (1). Those regulations will be subject to negative procedure. Responsible persons are defined in section 25 and include Health Boards (both territorial and Special Health Boards), the Common Services Agency (which operates under the name of NHS National Services Scotland), independent health care services, local authorities and other providers of care services and social work services. Individuals providing health, care or social work services are not included in the "responsible person" definition.
- 89. Subsection (2) gives detail as to what the regulations may, in particular, make provision about. This includes taking actions to meet with and apologise to the "relevant person" (see paragraph 92 below) and provide support to them. Subsection (2) also includes detail on recording and monitoring incidents and providing training and support to those carrying out the duty of candour procedure.

90. Subsection (3) gives a definition of 'relevant person' for the purposes of the section and the duty of candour procedure, which is the person who has received the health service, care service, or social work service, or a person acting on behalf of that person where that person has died or lacks capacity, or for other reasons cannot make decisions about the service provided to them.

Section 23 – Apologies

91. Section 23 defines 'apology' in relation to the duty of candour provisions and subsection (2) provides that any apology or other steps taken which are in accordance with the duty of candour procedure set out in regulations made under section 22 cannot be taken by itself to be an admission of negligence or a breach of a statutory duty. This means that there is not to be taken to be a link between giving an apology (or otherwise following the duty of candour procedure) in relation to an incident and acknowledgment of any wrong-doing. This does not prevent individuals affected from taking further action in relation to an incident.

Section 24 – Reporting and monitoring

- 92. Responsible persons who provide health services, care services or social work services in a financial year are required to prepare and publish reports. These reports are not to identify individuals. The reports must include the following information (but responsible persons can also include other information if they wish)—
 - details about the incidents that have occurred,
 - information on the organisation's compliance with the duty of candour procedure,
 - information about policies and procedures and whether there have been changes to these policies and procedures resulting from incidents that have occurred.
- 93. In order to assist with monitoring the extent to which the duty of candour procedure has been followed, there is a power for certain bodies to require responsible persons to provide them with information. These same bodies are to be notified when the annual reports are published. The particular bodies with the power to require information (and who are to be notified) vary depending on the responsible person. So, for example, Health Boards are linked to the Scottish Ministers, independent health service providers are linked to Healthcare Improvement Scotland, while providers of care services or social work services are linked to Social Care and Social Work Improvement Scotland (SCSWIS, which operates under the name of the Care Inspectorate).

Interpretation

Section 25 – Interpretation of Part 2

- 94. Section 25 defines certain terms used in Part 2.
- 95. "Care service" is defined by reference to section 47(1) of the Public Services Reform (Scotland) Act 2010 ("the PSR Act") and covers the following: support services, care home services, school care accommodation services, nurse agencies, child care agencies, secure

accommodation services, offender accommodation services, adoption services, fostering services, adult placement services, day care of children and housing support services. Each of those services is further defined in Schedule 12 to the PSR Act.

- 96. "Health service" is defined to cover services under the national health service continued under section 1 of the National Health Service (Scotland) Act 1978 and also independent health care services. Independent health care services are independent hospitals, private psychiatric hospitals, independent clinics, independent medical agencies and independent ambulance services (section 10F(1) of the 1978 Act).
- 97. "Social work service" is defined by reference to section 48 of the PSR Act. Section 48 defines such services by reference to local authority social work services functions (whether the services are provided by the local authority or by other persons that the local authority has entered into an arrangement with). Social work services functions are then listed in schedule 13 to the PSR Act which lists a range of statutory functions.
- 98. "Registered health professional" is defined by reference to section 60(2) of the Health Act 1999. Section 60(2) covers professions regulated under various enactments and also professions that might be regulated in the future by an Order in Council made using the powers in section 60. Those professions are: doctors, dentists, professions complementary to dentistry, optometrists, dispensing opticians, osteopaths, chiropractors, pharmacists, pharmacy technicians, nurses, midwives, arts therapists, biomedical scientists, chiropodists, podiatrists, dietitians, hearing aid dispensers, occupational therapists, operating department practitioners, orthoptists, paramedics, physiotherapists, practitioner psychologists, prosthetists, orthotists, radiographers, speech and language therapists.

PART 3 — ILL-TREATMENT AND WILFUL NEGLECT

99. Part 3 of the Bill establishes offences relating to the wilful neglect or ill-treatment of adults receiving health care or social care. There are two main offences in this part: an offence that applies to care workers, and an offence that applies to care providers.

Offences by care workers and care providers

Section 26 – Care worker offence

100. Section 26 sets out the care worker offence and the penalty for conviction. "Care worker" is defined in section 28(1) and covers care workers (employees and volunteers), their managers and supervisors, and directors or similar officers of organisations. The offence is committed where a care worker is providing care for another person and ill-treats or wilfully neglects that person. If providing that care is only incidental to the worker's other activities (for example, where the worker is a cleaner) then such a person would not fall within the "care worker" definition (and the same principle applies in relation to care by a "care provider") (section 28(4)). Section 26(2) provides the penalties for those convicted of the care worker offence: on summary conviction, to imprisonment for a term not exceeding 12 months or a fine not exceeding the statutory maximum (or both); and, on conviction on indictment, to imprisonment for a term not exceeding five years or a fine (or both).

Section 27 – Care provider offence

- 101. Section 27 sets out the care provider offence that will apply to providers of health or social care services. Care provider is defined in section 28(3) and covers both legal persons (corporate bodies, partnerships and unincorporated associations) and individuals who have others working for them. The care provider offence is committed if a three-stage test is met:
 - an individual is ill-treated or wilfully neglected by someone providing health care or social care on behalf of the care provider,
 - the care provider's activities are organised in such a way as to be a gross breach of the duty of care owed to the individual, and
 - were it not for that gross breach, the ill-treatment or wilful neglect would not have occurred (or would have been less likely to occur)
- 102. Section 27(3) defines "relevant duty of care" for the purposes of this offence and provides further detail on what is meant by a "gross" breach of that duty. Section 27(4) provides the penalties for those convicted of the care provider offence: on summary conviction, to a fine not exceeding the statutory maximum; and, on conviction on indictment, to a fine.

Section 28 – Meaning of "care worker" and "care provider"

- 103. Section 28 sets out various definitions.
- 104. Subsection (5) defines "adult health care" and "adult social care". "Adult health care" is defined as services provided to individuals aged 18 or over and is described by reference to the National Health Service (Scotland) Act 1978 to include services provided under the national health service and services from independent providers. "Adult social care" is defined by reference to certain services listed in section 47(1) of the Public Services Reform (Scotland) Act 2010. Those services are support services, care home services, nurse agencies and housing support services (where provided to those aged 18 or over) and offender accommodation services and adult placement services (where provided to those aged 16 or over).

Remedial orders and publicity orders

Section 29 – Power to order offence to be remedied or publicised

105. Section 29 makes provision for the court to make a remedial order or a publicity order in respect of a care provider where that care provider has been convicted of an offence under section 27(1) (the "care provider offence"). A remedial order will require the care provider to take steps (specified in the order itself) to remedy matters relating to the gross breach (described in paragraph 103 above). Any order made must specify a compliance period within which requirements made in the order must be complied with. Where a care provider fails to comply with either a remedial order or a publicity order, the care provider commits an offence (subsection (10)). Subsection (11) sets out the penalties for non-compliance with an order: on summary conviction, to a fine not exceeding the statutory maximum; and, on conviction on indictment, to a fine.

Section 30 – Remedial and publicity orders: prosecutor's right of appeal

106. Section 30 makes amendments to the Criminal Procedure (Scotland) Act 1995 to enable the prosecutor, in both solemn and summary proceedings, to appeal against a decision of the court not to make a publicity order or a remedial order.

Ill-treatment and wilful neglect of mentally disordered person

Section 31 – Penalty for ill-treatment and wilful neglect of mentally disordered person

107. Section 31 makes amendments to the existing offence in section 315 of the Mental Health (Care and Treatment) (Scotland) Act 2003. The amendments change the penalty for an offence under section 315 from a maximum of two years imprisonment on indictment to a maximum of five years imprisonment. This section also amends section 315 to update the definitions of "provides care services" and "care services". "Care services" are defined by reference to section 47(1) of the Public Services Reform (Scotland) Act 2010 and cover support services, care home services, nurse agencies, secure accommodation services, offender accommodation services, adult placement services and housing support services.

PART 4 — FINAL PROVISIONS

Section 32 – Regulations

108. This section provides that regulation-making powers in the Bill also include the power to make different provision for different purposes and can make certain ancillary provision, for example, transitional provision. It also provides for which parliamentary procedure applies to each power in the Bill.

Section 33 – Ancillary provision

109. This section gives the Scottish Ministers the power by regulations to make incidental, consequential, transitional, transitory and savings provision. This power allows free-standing ancillary provision to be made, which aids the implementation of the Bill.

Section 34 – Commencement

110. This section provides that the Scottish Ministers can commence the provisions of the Bill by regulations, with the exception of this section and sections 32, 33, and 35, which will come into force the day after Royal Assent.

Section 35 – Short title

111. This section describes the short title of the Bill as it is enacted as the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016.

FINANCIAL MEMORANDUM

INTRODUCTION

- 1. This document relates to the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill introduced in the Scottish Parliament on 4 June 2015. It has been prepared by the Scottish Government to satisfy Rule 9.3.2 of the Parliament's Standing Orders. It does not form part of the Bill and has not been endorsed by the Parliament.
- 2. The Policy Memorandum, which is published separately, explains in detail the background to the Bill and the policy intention behind the Bill. The purpose of this Financial Memorandum is to set out the costs associated with the measures introduced by the Bill, and as such it should be read in conjunction with the Bill and the other accompanying documents.
- 3. The Bill covers three distinct policy areas: controlling non-medicinal nicotine vapour products (NVPs)¹, tobacco and smoking on hospital grounds; ill-treatment and wilful neglect; and duty of candour. This document sets out the details of consultation, policy objectives, and alternative approaches for each element of the Bill as follows:
 - Minimum age of 18 for the sale of NVPs,
 - Prohibition of sales of NVPs from vending machines,
 - The purchase of NVPs on behalf of an under 18 ("proxy purchase"),
 - Mandatory registration for the sale of NVPs,
 - Banning certain forms of domestic advertising and promotion of NVPs,
 - An age verification policy for sales of tobacco products and NVPs,
 - Banning unauthorised sales of tobacco and NVPs by under 18s,
 - A smoke-free perimeter around buildings on NHS hospital sites,
 - An organisational duty of candour,
 - An offence of ill-treatment and wilful neglect.
- 4. Alongside the Scottish Government's latest Tobacco Control Strategy, Creating a Tobacco-Free Generation², this Bill supports the Scottish Government's objective to support longer healthier lives and to tackle the significant inequalities in Scottish society. It will do this by restricting the accessibility of NVPs to young people; reducing their visibility and appeal to young people and non-smokers; reinforcing the age restriction on tobacco products to further protect young people; and introducing statutory smoke-free perimeters around buildings on NHS hospital sites.
- 5. The duty of candour provisions support the implementation of a legal requirement for health and social care organisations to inform people, and their families, when they have been

¹ References to NVPs throughout this document refer to non-medicinal NVPs, e-liquids and associated devices.

² www.gov.scot/tobaccofreegeneration

accidentally harmed (either physically or psychologically) as a result of the care or treatment they have received.

6. The provisions on ill-treatment or wilful neglect will establish a new criminal offence which will apply to individual care workers, managers and supervisors, either employed or volunteering on behalf of a voluntary organisation, who provide care or treatment. An offence is also established that will apply to organisations. The Bill provides courts with additional penalty options in respect of organisations that are convicted of wilful neglect or ill-treatment.

Approach to costing

- 7. A formal written consultation was undertaken for each of the three topics. Each consultation paper requested specific information about the impacts on business or organisations as a result of each of the policy proposals. The Scottish Government met with a number of organisations including local authorities, industry, retailers, pharmacies, and a wide range of health and social care providers. Discussions with such organisations have informed the development of the costs associated with the Bill.
- 8. Costs associated with Part 1 of the Bill primarily fall to local authorities as the anticipated enforcement agency. These are ongoing costs. There are costs to the NHS associated with raising awareness of, and compliance with, the new offences relating to smoking outside hospitals. These are expected to be short term. The Scottish Government envisages the legislation becoming self-enforcing. To a lesser extent, there are one-off costs to the Scottish Administration associated with awareness-raising and minor ongoing costs associated with maintaining the Register and criminal proceeding costs. There are likely to be modest one-off costs to retailers associated with familiarisation with the legislation. There will almost certainly be a loss of profit to industry and business but the Scottish Government has been unable to quantify this, despite efforts to extract this information during the consultation and the purchasing of NVP market intelligence data.
- 9. Costs associated with Part 2 of the Bill cover four main areas: disclosure, apology and review; training and implementation; monitoring and publication of reports. Costs for disclosure, apology and review are divided into those modest short-term costs for the Scottish Administration to support smaller organisations with costs for implementation of the duty and ongoing modest costs for provision of support which will fall on the NHS, local authorities and other bodies. For training and implementation, modest non-recurrent costs will fall to the Scottish Administration to provide a tailored package of training to implement the duty of candour along with some very small recurrent costs to ensure the training package is kept up-to-date. Non-recurrent costs will also fall to other organisations outwith the NHS and the social care sector to ensure staff are trained and supported appropriately to fulfil the duty, along with some very small recurrent costs to ensure new staff are trained as they are employed. No additional costs are anticipated for monitoring or publication of reports.
- 10. Modest ongoing costs are associated with Part 3 of the Bill. These will fall to the Scottish Administration and are associated with the investigation and prosecution of offences of wilful neglect and ill-treatment.

PART 1 — TOBACCO, NICOTINE VAPOUR PRODUCTS AND SMOKING

COSTS ON THE SCOTTISH ADMINISTRATION

Communications and awareness raising for all proposals on the sale and advertising of tobacco and nicotine vapour products

- 11. There will be initial set-up costs to inform retailers about the requirement to comply with the tobacco and NVPs sales and marketing legislation. Communications and awareness raising will take the form of information packs being sent in hard copy to retailers and an update of the Scottish Government website and the existing Scottish Tobacco Retailers Register website. Estimated one-off costs for this activity are in the region of £47,000 and will be met from within existing public health programme budgets. This is subject to a fairly high degree of certainty since it is based on a recent comparable exercise to provide a letter, guidance document, a poster and flyer to alert 31,500 businesses in Scotland that they would need to comply with legislation that required all retailers (food and non-food) to charge for each new single-use carrier bag.
- 12. There will be costs on the Scottish Government associated with developing guidance. The preparation of the guidance will be a matter for the Scottish Government as part of the normal business of the Directorate of Population Health Improvement.

Communications and awareness raising of smoke-free areas on hospital grounds

- 13. In order to inform the public of the forthcoming legislation to make it an offence to smoke within a defined area of hospital grounds around buildings, the Scottish Ministers will establish a communications programme in advance of the regulations coming into force. A one off cost at implementation is anticipated to be in the region of £300,000. This is subject to a fairly high degree of certainty as it is based on recent media campaigns on changes to the law on the drink driving limit and a campaign run by the NHS to raise awareness of their smoke-free grounds policy.
- 14. Provisions on the age of sale for NVPs; domestic advertising; unauthorised sales by under 18s tobacco and NVPs; and age verification policy (challenge 25) tobacco and NVPs. There are no significant costs to the Scottish Government associated with these measures. The cost of ensuring that retailers and business are aware of these measures is covered under communication and awareness raising.

Vending machines

15. The Scottish Government is not aware of any NVPs currently being sold from vending machines in Scotland. It does not envisage any cost to the Scottish Government as a result of banning such sales.

Proxy purchase

16. In order to raise awareness of the new offence to purchase NVPs on behalf of someone under the age of 18, communication and awareness-raising costs set out above include the cost of a poster that could be displayed by retailers. The poster could also cover the proxy purchasing of

tobacco products which is already an offence in the Tobacco and Primary Medical Services (Scotland) Act 2010.

Registration scheme

- 17. There will be initial set up costs to extend the remit of the existing Retailer Register to enable it to hold new national level information. This is estimated to be in the region of £15,000 in the first year only. This is subject to a fair degree of certainty as it is based on a quote from the provider ranging from £10,000 to £20,000. £15,000 takes the mid-range of the quote. The Register was built and continues to be maintained externally. For the continuing administration and maintenance of the registration scheme and database, it is estimated that additional ongoing yearly maintenance costs will be in the region on £13,200 per annum. This is based on the requirement for a 0.5 FTE administrative officer. This is subject to a high degree of certainty as staff costs as staff costs are highly predictable.
- 18. There will be ongoing costs on the Scottish Government to deal with the additional enquiries and updates to retailer information generated by extending the Register to include retailers of NVPs. This maintenance of the Register will be a matter for the Scottish Government as part of the normal business of the Directorate of Population Health Improvement. The ongoing maintenance of the register will require 0.5 FTE time of a Scottish Government administrative officer, in addition to the external costs described in paragraph 16.
- 19. Therefore, the cost associated with extending, and additional maintenance of, the Register in the first year is estimated to be around £28,200 in the first year with running costs of £13,200 every year thereafter.
- 20. The cost of ensuring that retailers are aware of these measures is covered under communication and awareness raising.

Smoke-free areas on NHS hospital grounds

21. The legislation requires signage to be displayed on entry to NHS hospital grounds and buildings on the grounds to ensure staff, visitors and patients are aware that is an offence to smoke within areas of the grounds. The Scottish Government will be responsible for providing signage to all health boards. The Scottish Ministers expect the total national costs for signage to be in the range of £99,000 to £198,000. This is an approximate cost based on the amount paid by Greater Glasgow and Clyde NHS Board for signage (£70 per 1 x 1 metre outdoor sign and £10 per A3 poster with case for indoors). There are 149 hospitals listed on the Scottish Government Estates and Asset Management System (excluding mental health hospitals and specialist hospitals). The lower estimate assumes that, on average, five outdoor and 20 indoor signs are required per hospital. The higher estimate assumes that 10 outdoor signs and 40 indoor signs are required. In addition, the indoor signs will be available to print.

Costs to the criminal justice system

22. The costs in this section are based on assumptions using previous tobacco and smoking legislation as a comparator.

Table 1 – Court proceedings under the Tobacco and Primary Medical Services (Scotland) Act 2010

Proceedings- Tobacco and Primary				
Medical Services (Scotland) Act 2010				
		2011-12	2012-13	2013-14
Purchase of tobacco products on behalf of an	Plea Not Guilty			
under 18	accepted	1	-	
	Fine	1	3	(
	Admonished	-	1	2
	Total	2	4	5
Sale of tobacco products to persons under 18	Fine	1	-	3
	Total	1	-	3
An unregistered person who carries on a	Plea Not Guilty			
tobacco business	accepted	-	2	-
	Fine	-	1	
	Total	-	3	
Prohibition of vending machines for the sale of				
tobacco	Fine	-	-	1
	Total	-	-	1
D. P. CODEG P. 4				
Police or COPFS direct measure		2011 12	2012.12	2012 14
D 1 0 1 1 10 0	D.I. E. 1	2011-12	2012-13	2013-14
Purchase of tobacco products on behalf of an	Police Formal	1		
under 18	Adult Warning	1	-	
	Fiscal Fine	6	3	3
	Total	7	3	4
0.1. ()	Police Formal			
Sale of tobacco products to persons under 18	Adult Warning	-	-	
	Other Police			
	Warning	-	-	
	Total	-	-	

Source: Scottish Government Criminal Proceedings Database.

Table 2 - Court proceedings under the Smoking, Health and Social Care (Scotland) Act 2005

Proceedings - Smoking, Health and Social Care (Scotland) Act 2005							
							2013
		2007-08	2009-10	2010-11	2011-12	2012-13	-14
Offence of permitting others to smoke in no-							
smoking premises	Fine	-	-	-	-	1	-
	Total	-		-	-	1	-
Offence of smoking in no-smoking premises	Plea Not Guilty accepted	_	_		1		

1	i	i i	1	i i	Ī	•	
	Acquitted						
	not guilty	1	-	1	-	1	-
	Fine	ı	1	8	2	1	4
	Admonished	1	-	1	i	1	1
	Total	1	1	8	3	3	4
Police or COPFS							
direct measure							
							2013
		2008-09	2009-10	2010-11	2011-12	2012-13	-14
Offence of							
smoking in no-							
smoking premises	Fiscal Fine	2	5	14	26	18	3
failing to supply							
the officer with							
the person's name							
and address on							
being so required							
by the officer	Fiscal Fine	-	2	1	Т	-	-

Source: Scottish Government Criminal Proceedings Database.

Nicotine vapour products and tobacco sales and advertising offences

- 23. Trading standards services have a proven track record of taking a measured approach to enforcement of tobacco regulation. They aim primarily to provide advice and support to businesses and retailers, only taking enforcement action when needed. When enforcement action is required, this is largely dealt with using their powers to issue fixed penalty notices. The level of offences referred to the procurator fiscal is low, with only the most serious offences referred for prosecution. This is demonstrated by the table above which shows that, over a three-year period, only 11 cases proceeded to court, with a further 16 cases dealt with by direct measures. The Scottish Government would expect trading standards services to continue to provide advice, support and assistance and, where necessary, manage the majority of enforcement using fixed penalty notices. The Scottish Ministers would expect court proceedings to remain at the same level. If the number of retailers which are subject to the legislation increases by approximately 76%, there could be an increase in the number of cases proceeding to court to around 20 over three years.
- 24. The new offences created by or under the Bill largely mirror those already in existence for tobacco products under the Tobacco and Primary Medical Services (Scotland) Act 2010 and the Tobacco Advertising and Promotion Act 2002. There has been a high level of compliance with the Tobacco Advertising and Promotion Act 2002. There have been no cases referred for prosecution in Scotland since its introduction. The offences associated with the requirement to operate an age verification policy and to prohibit unauthorised sales by under 18s are new policies for both NVPs and tobacco products. As such it is not possible to make a comparison but it is reasonable to assume that the number of criminal proceedings would be small.

Smoke-free areas on NHS hospital grounds

25. The smoking ban created by the Smoking, Health and Social Care (Scotland) Act 2005 was introduced in Scotland in 2006. There has been a high level of compliance and the

legislation is now largely self-enforcing. This is demonstrated with only 21 offences proceeding to court over the six year period after the legislation was introduced in 2006 (there were no cases proceeding to court in 2006). Since the provisions in the Bill will only extend to NHS hospital grounds, the numbers proceeding to court are expected to be negligible.

Table 3 — Unit cost of criminal procedures

	Average prosecution costs per procedure (COPFS)	Average court costs per procedure (SCTS)	TOTAL (excluding legal aid costs)	Average legal assistance costs per procedure (SLAB)	TOTAL (including legal aid costs)
Sheriff Court Summary Procedure	£342	£357	£699	£612	£1311

Source: Costs of the Criminal Justice System in Scotland Dataset (2013)

Table 4 — Total criminal justice costs*

Procedure	Number of cases	Cost per case	TOTAL*
Sheriff Court Summary Procedure	20 (over three years)	£699 - £1311	£23,160 - £26,220
		Average total each year	£7720 - £8,740

^{*}Ranges illustrate the differences in costs between 75% and 100% of defendants receiving legal aid

Fixed penalties and banning orders

26. Trading standards officers are responsible for reporting cases to the procurator fiscal, which in some cases can be complex and take anything up to two days to complete. The Bill will ensure that fixed penalty notices are available for breaches of offences in Part 1 of the Bill (with the exception of offences at sections 17-19). Fixed penalty notices will be payable to the local authority in order to offset some costs.

Total cost on the Scottish Administration from Part 1 of the Bill

27. The total cost of Part 1 of the Bill on the Scottish Government in the first year using the range of estimations for hospital signage is between £461,000 and £560,000 (using the lowest and highest estimation for hospital signage) and £21,940 in each year after implementation of the legislation.

Table 5 — Total costs to the Scottish Administration from part 1 of the Bill

Costs associated with:	Implementation	Each year following implementation
Extending the remit of the existing Retailers Register to include NVPs.	£28,200	£13,200
Communication and awareness raising of all of the provisions in Part 1 of the Bill	£347,000	Nil
Providing smoke-free signage for NHS hospitals.	between £99,000 and £198,000	
Costs to the criminal justice system (the lower figure assumes only 75% of cases receive legal aid).		£7720 - £8,740
Total	Between £474,200 - £573,200	£20,920 - £21,940

COSTS ON THE NHS

Compliance with smoke-free areas in NHS hospital grounds

- 28. All Health Boards now have smoke-free grounds policies in place. Health Boards have called for legislation to support this approach. Modest costs are anticipated to inform staff, patients and visitors about the new legislation through existing communication channels for example, through staff communication and induction packs and also as part of routine information to patients alongside appointment and admission letters. It is expected that the need for such activity will decrease as the legislation becomes embedded and people are more aware of the law and comply.
- 29. Health Boards have opted for a number of varying approaches in seeking compliance with their current policies. These range from employing enforcement wardens or all staff challenging smoking on the grounds. The legislation provides flexibility for Health Boards to continue with their preferred approach. However, some may opt to add additional measures, particularly in the early days of enforcement and may, therefore, incur additional costs. As with current measures to secure compliance, it is anticipated that this cost will be met from existing NHS budgets. Enforcement will be provided by local authority environmental health officers. If Health Boards opt to add additional measures, based on previous NHS tender exercises from large hospital sites, the additional costs could range from £10,260 to £41,064 per annum at each site.

Fixed penalty notice scheme for smoke-free building perimeters in NHS hospital grounds

30. The fixed penalty notice scheme set out in the Smoking, Health and Social Care (Scotland) Act 2005 is to be extended. A fixed penalty notice will only be issued if an offence inserted into the 2005 Act by the Bill is thought by an enforcement officer to have been committed. The level of fixed penalty notices is £150 as set by the *Prohibition of Smoking in Certain Premises*

(Scotland) Regulations 2006. The intention is for the same level to apply to an offence under the Bill. This fixed penalty applies to the offence of smoking, allowing others to smoke in a no-smoking area and a failure to display signage at the entrances to buildings. As with the Smoking, Health and Social Care (Scotland) Act 2005, fixed penalty notices can be issued to persons having management and control of no-smoking areas who may be employed by the NHS, but this is expected this to be rare.

COST ON LOCAL AUTHORITIES

Nicotine vapour products and tobacco sales enforcement

- 31. Trading standards services would have an essential role in advising businesses on how to comply with legislation. Trading standards services already visit 10% per annum of tobacco retailers to undertake test purchasing and a minimum 20% per annum of tobacco retailers to provide advice and support.
- 32. The NVP market is relatively new and still maturing. The Scottish Government does not have robust data on the number of retailers of NVPs as there is no mechanism for identifying such businesses. During a two-week period in March 2015, 21 out of the 31 trading standards authorities took part in a survey on NVPs retailers which was a snapshot in time of the high streets in Scotland. Trading standards staff visited premises in the main thoroughfares to determine if they sold NVPs, tobacco or both. They visited a total of 1190 retailers: of these 53 premises sold tobacco only, 181 sold NVPs only, and 186 sold both tobacco products and NVPs. If this sample is representative of the combined tobacco and NVP retail sector in Scotland, this means that approximately 13% sell only tobacco, 43% sell only NVPs, and the remaining 44% sell both types of product. Based on this data, and the current level of enforcement, it could be assumed that the number of retailers which trading standards will need to visit to provide advice, support and undertake test purchasing will increase by 76%.
- 33. As highlighted above, the Scottish Government will fund national awareness raising and communication to help trading standards officers inform retailers of the implementation of this new legislation and avoid costs falling on local government. Nevertheless, there would be an increased and ongoing demand for advice to businesses from trading standards resulting from new measures.
- 34. The Scottish Government already funds local authorities for the enforcement of tobacco products. Funding of £1.5 million is provided each year in their baseline General Revenue Grant as part of their annual local government finance settlement (not ring fenced). If trading standards services enforce the new provisions for NVPs at the same level as currently agreed for tobacco products (10% of NVP retailers visited for test purchasing purposes, a further 20% of NVP retailers visited for business advice and support), COSLA estimates that the additional ongoing cost of enforcing the new provisions will be an additional £2 million per year. This figure is based on the number of additional retailers, resource required to enforce the extension of the register and inflation (since the introduction of the Tobacco and Primary Medical Services (Scotland) Act 2010). Taking into account inflation since 2010 (when this funding commenced) on the current funding of £1.5 million per annum, this would bring the figure to £1.68 million per year. However, using the data provided by trading standards services, the additional number of retailers expected to be supported is 24% less for NVP-only retailers when compared to the

number of retailers selling tobacco products which trading standards services are currently funded for. This brings the additional cost per year to £1.22 million per annum. The level of enforcement requires further consideration and could be set a lower rate than currently in place for tobacco. The Scottish Government, therefore, anticipates that the new additional ongoing cost will be in the region of £1 million to £1.5 million per year. The market is relatively new and subject to swift change. The Scottish Government will continue to monitor the number and variety of retailers and continue dialogue with COSLA to assess and refine additional costs.

35. There will be some initial set up costs associated with updating fixed penalty notice books and staff training. Based on funding currently provided to trading standards services, this is likely to be in the region of £15,000 in the first year only.

Smoke-free areas in NHS hospital grounds enforcement

- 36. Enforcement of smoke-free areas on NHS hospital grounds will be undertaken by local authority environmental health officers. This new measure largely reflects the smoking ban that was introduced by the Smoking, Health and Social Care (Scotland) Act 2005. It is anticipated that the enforcement of this measure will operate in largely the same way. Local authority officers can be contacted by anyone (including the Health Board) who believes that there is an issue on particular hospital grounds either with an individual smoking in the smoke-free area, someone in management or control of the no-smoking area knowingly permitting smoking or a failure to display signage.
- 37. There are 149 hospitals listed on the Scottish Government Estates and Asset Management System (excluding mental health hospitals and specialist hospitals). All buildings on an NHS hospital site will need to comply with the legislation unless excepted. The Scottish Government already funds local authorities for the enforcement of smoke-free legislation. Funding of £2.5 million is provided each year in their baseline General Revenue Grant as part of their annual local government finance settlement (not ring fenced). It is expected that there will be an increase in demand for enforcement activity from environmental health services following the introduction of the legislation. This would require a reprioritisation of duties and resources. However, it is expected that the need for such activity will decrease as the legislation becomes embedded and people are more aware of the law and comply. The Scottish Government does not expect additional costs to local authority environmental health services associated with this measure. Dialogue will continue with local authorities and COSLA to assess the impact of this proposal.

Fixed penalties notices

38. Trading standards officers and environmental health officers are responsible for reporting cases to the procurator fiscal. The Bill will ensure that fixed penalty notices are available for breaches of offences in Part 1 of the Bill (with the exception of offences at sections 17-19). Fixed penalty notices will be payable to the local authority in order to offset some of the costs incurred by the administration of the scheme.

Total costs on local authorities

39. The total cost of Part 1 of the Bill on local authorities in the first year using the highest estimation for enforcement is estimated to be £1,515,000 and using the lowest estimation for enforcement is £1,015,000. There will be an ongoing cost of between £1,000,000 and £1,500,000 per annum. These costs are explored in more detail at paragraphs 30 to 437.

Costs on other bodies, businesses and individuals

- 40. During the consultation, retailers and industry were clear that they implemented voluntary measures to prevent access to NVPs by young people. Nonetheless, evidence demonstrates that young people are accessing the products either by themselves or by other adults.
- 41. To estimate the direct costs to businesses, a top-down approach, estimating the size of the NVP market attributable to under 18s in Scotland, has been taken. This is based on the value of the retail market for NVPs in Scotland, which has been estimated at £36 million in 2015. This figure includes an estimation of on-line sales in Scotland. The population in Scotland between 11 and 17 years of age was 405,625 in 2013. SALSUS data show that less than 1% of 13 and 15 years olds in Scotland use NVPs once a week or more. This means that, in Scotland, approximately 4,056 under-18 year olds may use NVPs more than once a week and that under-18s potentially represent 2% of the market with a value of approximately £700,000 per annum. Assuming a 40% profit margin it is estimated, using the mid-range of estimations provided by 'EcigIntelligence' that the total cost of banning sales of NVPs to under-18s in Scotland could lead to approximately £280,000 of profit loss in the first year to Scottish businesses. This assumes 100% compliance with the policy.
- 42. There will be a minimal cost to businesses and retailers in understanding the new legislation. The Scottish Government has agreed to fund awareness raising and communications to help inform retailers of the new legislation which will reduce the burden on them.

Registration scheme to retail nicotine vapour products

43. Costs to the industry will be minimal to cover the administrative requirement of completing a simple registration form (on paper or online) and to update any changes to registration if the retailer stops selling NVPs or changes premises. There is no registration fee associated with the proposal.

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 $^{^3}$ This is based on estimates provided to the Scottish Government in February 2015 by ECigIntelligence, using IRi data, where the estimated value of the Scottish market in 2015 was between £30m and £40m.

⁴ Data from the Young People in Scotland Survey in late 2014 showed that 2% of 11 to 18 years old in secondary schools reported using e-cigarettes at least once a week The Scottish Government will publish a summary analysis of these data in summer 2015.

⁵ A 40% profit margin for e-cigarettes was noted in, 'High margin options and growing fast, *Scottish Grocer*, March 2013: http://www.scottishgrocer.co.uk/2013/03/high-margin-options-and-growing-fast/

An estimated 40% profit margin figure was also provided to the Scottish Government by the National Federation of Retail Newsagents in a consultation meeting on 02/12/14. The minutes are available on the Scottish Government website.

Banning orders

44. Businesses will incur costs from banning orders only in the event that they fail to comply with NVP and tobacco sales law.

Fixed penalty notice scheme for the sale of tobacco and nicotine vapour products

45. Businesses will incur costs from a fixed penalty notice scheme only in the event that they fail to comply with Part 1 of the Bill. The level at which fixed penalties are set is provided in the Sale of Tobacco (Registration of Moveable Structures and Fixed Penalty Notices) (Scotland) Regulations 2010⁶. This scheme will be extended to cover these new offences.

Ban on sale of nicotine vapour products from vending machines

46. The Scottish Government is not aware of any NVPs currently being sold from vending machines in Scotland. It does not, therefore, envisage any cost to businesses or retailers as a result of banning such sales.

Banning the domestic advertising and promotion of nicotine vapour products

47. It is extremely difficult to isolate the value that domestic advertising brings to retailers within a whole marketing and promotion budget and the Scottish Government is unable to estimate the loss of profits that this might bring to businesses. The Scottish Government has sought to estimate impacts from NVP businesses and retailers but has been unable to obtain data. It is inevitable that there will be a loss of revenue to the NVP industry and retailers, but this is unquantifiable.

Fixed penalty notice scheme for smoke-free areas on NHS hospital grounds

48. It is possible that fixed penalty notices could be issued to businesses operating on NHS hospital grounds. The fixed penalty notice scheme set out in the Smoking, Health and Social Care (Scotland) Act 2005 is to be extended. The level of fixed penalty notices is £150, as set by the Prohibition of Smoking in Certain Premises (Scotland) Regulations 2006⁷. This fixed penalty applies to the offence of permitting others to smoke on a no-smoking premises and failure to display signage on buildings.

Total cost to other bodies, businesses and individuals

49. There will be minimal costs associated with registration and familiarisation with the legislation. There will inevitably be a loss to business revenue associated with a prohibition on domestic advertising, but this is unquantifiable. It is estimated that the total cost of banning sales of NVPs to under-18s in Scotland could lead to approximately £280,000 of profit loss in the first year to Scottish businesses.

32

⁶ http://www.legislation.gov.uk/sdsi/2010/9780111011270/contents

⁷ http://www.legislation.gov.uk/ssi/2006/90/contents/made

Total cost associated with Part 1

Table 6 — Summary of additional costs arising from Part 1 of the Bill

Policy area	Sale of NVPs, tobacco, advertising and smoke-free legislation
Costs on Scottish	Between £474,200 -£573,200in the first year and between
Administration	£20,920 and £21,946 in each year after implementation of the
	legislation
Costs on local	Between £1,515,000 and £1,015,000 in the first year and between
authorities	£1,500,000 and £1,000,000 each year after implementation of the
	legislation
Costs on NHS	Modest costs associated with updating existing training and
	materials.
Costs on other bodies,	Minimal costs to retailers associated with familiarisation with the
businesses and	legislation. An estimated £280,000 loss per annum associated
individuals	with implementing an age restriction. Unquantifiable costs
	associated with implementing a ban on domestic advertising.

PART 2 — DUTY OF CANDOUR

INTRODUCTION

- 50. The provisions to introduce a duty of candour on organisations providing health and social care will require that organisations implement procedures (which will be set out in regulations made using powers in the Bill) to ensure that, when there has been an unintended or unexpected event resulting in death or harm, people are notified of this, that an apology is provided and that actions are taken to meet with people, ensure that they are provided with an account of the incident and information about further steps to be taken and that there is a review of the events.
- 51. It is intended that regulations will impose a requirement for training, and organisations will be required to make available, or provide information about and facilitate access to, support to persons affected by the incident. Training, supervision and support will be required for the staff who are to be involved in carrying out the duty of candour procedure.
- 52. The financial impacts of the Bill have been summarised in table 7. All figures are given in full, though the tables that follow outline the costs for each element of the procedure for the Scottish Administration, NHSScotland, local authorities and for other bodies, individuals and businesses. For the purpose of outlining the financial implications of the provisions in respect of the duty of candour, the main elements are: apology and review, followed by support, training and implementation, monitoring and finally publication of reports.

Table 7 — Summary of costs of the duty of candour provisions

	2016-17		201	7-18	2018-19 onwards	
	Recurring costs	Non- recurring costs	Recurring costs	Non- recurring costs	Eventual recurring costs	Total non- recurring costs
Disclosure, apology and review	_	£100,000	_	£75,000	_	£50,000
Support	£456,000		£460,560		£465,965	
Training & implementation	_	£307,000	_	£60,000	_	£40,000
Total	£456,000	£407,000	£460,560	£135,000	£465,965	£90,000
TOTAL COSTS	£863,000		£595,560		£555,965	

Disclosure, apology and review

53. The Bill and regulations that the Scottish Government intends to make using powers in the Bill will require organisations to make arrangements to disclose that an unexpected or unintended incident resulting in harm has occurred, to make arrangements to apologise and arrange for a review to be undertaken in order to identify learning arising from the event.

Table 8 — Costs of disclosure, apology and review

	2016-17		201′	7-18	2018-19 onwards	
	Recurring costs	Non- recurring costs	Recurring costs	Non- recurring costs	Recurring costs	Non- recurring costs
Scottish Administration	_	£100,000	_	£75,000		£50,000
NHS	_	_	_	_	_	
Local authorities	_	_	_	_	_	
Other bodies	_	_	_	_	_	
Total	_	£100,000	_	£75,000	_	£50,000

Costs on the Scottish Administration

54. The principles and approach that will be made explicit through the duty of candour provisions of the Bill, and regulations that the Scottish Government intends to make under those provisions, are consistent with current policy and strategies reflected through work in support of improvements in complaint handling, reporting and learning from adverse events and the professional requirements reflected in statutory regulatory requirements of the regulated health and care professionals. Work in support of these programmes is already established and in progress, meaning that there is no additional cost. As part of the training and implementation requirements of the new provisions, additional funding will be made available. This is outlined in the section on Training.

Costs on the NHS in Scotland

55. The Scottish Government does not anticipate any additional direct costs arising from the disclosure, apology and review elements of the duty of candour for the NHS in Scotland. These dimensions of the provisions are already reflected in guidance issued by Healthcare Improvement Scotland through its framework 'Learning from Adverse Events through reporting and review'.

Costs on local authorities

56. The Scottish Government does not anticipate any additional costs arising for local authorities as a result the duty of candour provisions of the Bill as local authorities already have mechanisms in place to support disclosure, apology and case review where there have been unintended or unexpected incidents that result in harm.

Costs on other bodies, individuals and businesses

57. The Scottish Government anticipates that some indirect costs may occur for smaller organisations which do not have existing systems and processes to support disclosure, apology and review of events that have resulted in harm. The Scottish Government will work with stakeholders to develop a suite of resources and guidance which is intended to support organisations through this process. Where organisations identify direct costs relating to their plans for implementation of the duty of candour procedures, they will be able to seek implementation support through the Healthcare Quality and Strategy Directorate, Scottish Government. This will include access to funding to release staff for meetings and work to support introduction. These have been listed as costs to the Scottish Administration above. These have been calculated on the basis of 100 organisations requiring support in Year 1, 75 in Year 2 and 50 in Year 3, using a figure of £1000 per organisation which covers the provision of bespoke advice, mentoring and dedicated adverse event and system review resources as part of work to establish effective disclosure, apology and review processes. Funding for these costs has been factored into future budgets.

Savings

58. It is possible that there are some incidents that result in harm that would traditionally have been subject to complaints or claims procedures. Significant numbers of people embark upon actions through these processes as they have not been able to participate in processes or receive information on the learning and improvement actions that are focused on reducing a risk of recurrence in the future.

Support

59. The Bill, and regulations that the Scottish Government intends to make using the powers in the Bill, will require organisations to ensure that support is provided to people who have been affected by unexpected incidents or events that result in harm. In many cases, this support will be provided through existing support mechanisms and services and will, therefore, not result in direct costs as a result of this procedure. There are likely to be some incidents where direct costs of providing tailored support will require specific sessional provision to clinical and care support staff. The nature and extent of costs will depend upon the existing staff support services and range of specialist psychological care provision already in place.

Table 9 — Costs of support

	2016-17		201	2017-18		2018-19 onwards	
	Recurring costs	Non- recurring costs	Recurring costs	Non- recurring costs	Recurring costs	Non- recurring costs	
Scottish Administration	_	_	_	_	_	_	
NHS	£228,000	_	£230,280	_	£232,583	_	
Local authorities	£114,000	_	£115,140,	_	£116,691	_	
Other bodies	£114,000	_	£115,140	_	£116,691	_	
Total	£456,000		£460,560	_	£465,965		

60. Table 9 is based on the requirement for 10 whole time equivalent Band 6 staff (a grade within the Agenda for Change pay scales in operation for all NHS Scotland staff except medical, dental staff and senior managers) who would be a counsellor, mental health nurse or therapist, allocated in a ratio of 50% to NHSScotland, 25% to local authorities and 25% to other organisations - the ratio being determined by a review of the balance of incidents likely to fall within the duty of candour procedure. The costs are at the mid-point of the salary scale and include national insurance and superannuation costs (calculated at 20%). There is a high margin of uncertainty for these estimates given the range of counselling and support services available and the unpredictable nature of the levels of support that will be required following the introduction of the new duty of candour procedure. However, the overall estimated resource is likely to be sufficient to ensure an effective national response to ensure that the support and care needs of all those affected by unexpected or unintended events resulting in harm will be met.

COSTS ON THE SCOTTISH ADMINISTRATION

61. The Scottish Government does not anticipate any additional direct costs arising from the duty of candour provisions as a result of the requirement to provide support. Organisations will require advice and training to implement the support elements of the provisions – this advice and guidance will be developed as part of wider guidance, training and implementation support costs.

COSTS ON THE NHS IN SCOTLAND

62. The Scottish Government anticipates that, in most cases, the existing resources for support services through staff support and counselling, psychological care and specialist mental health services will be sufficient to ensure that people who require support will access this through existing services. However, there may be some incidents which will require specialised, tailored sessional support to clinical and care support staff. The nature and extent of costs will depend upon the existing staff support services and range of specialist psychological care provision already in place. In most cases, the clinical teams who were involved with the unexpected or unintended event are best placed to provide ongoing support for patients and families affected, support that is provided as part of currently resourced services.

COSTS ON LOCAL AUTHORITIES

63. The Scottish Government anticipates that, in most cases, existing resources for support services through staff support, social care and specialist mental health services will be sufficient to ensure that people who require support will access this through existing services. In most cases, the care teams who were involved with the unexpected or unintended event are best placed to provide ongoing support for patients and families affected, support that is provided as part of currently resourced services. However, as with the NHS, the Scottish Government anticipates that there will be some incidents requiring additional specialist support provision and Table 9 reflects these costs.

COSTS ON OTHER BODIES, INDIVIDUALS AND BUSINESSES

64. The Scottish Government anticipates that, in most cases, there will no direct costs for other organisations in respect of the provision of support for people affected. These organisations will make use of existing support services provided by the NHS in Scotland or local community support organisations. However, in recognition of the importance of ensuring that there is adequate specialist resource available and that this does not negatively impact on the responses of services to meet demands that are already being identified, estimates have been made on the basis of a national requirement to employ the equivalent of 10.0 WTE counsellors, nurses or therapists that could provide support as required as reflected in Table 9.

SAVINGS

65. It is likely that the early identification of support needs for staff and people affected by unexpected or unintended incidents resulting in harm will reduce the likelihood of more clinically significant emotional and psychological reactions developing, reactions which would otherwise have required more intensive clinical and care responses through the provision of specialist interventions and support.

TRAINING AND IMPLEMENTATION

66. The duty of candour provisions of this Bill (and regulations that the Scottish Government intends to make using the powers in the Bill) will require organisations to ensure that training and support for implementation is available for staff who will be involved in the application of all requirements of the statutory duty of candour.

Table 10 — Costs of training and implementation

	2016-17		2017-18		2018-19 onwards	
	Recurring costs	Non- recurring costs	Recurring costs	Non- recurring costs	Recurring costs	Non- recurring costs
Scottish Administration	_	£182,000	£45,000	_	£25,000	_
NHS	_	_	_	_	_	_
Local authorities	_	_	_	_		_
Other bodies	_	£125,000	£15,000	_	£15,000	_
Total		£307,000	£60,000	_	£40,000	_

COSTS ON THE SCOTTISH ADMINISTRATION

67. The Scottish Government recognises the importance of ensuring that all organisations which will be required to implement the duty of candour procedure have access to training and implementation support. Training and implementation support resources will be developed for use by all organisations which have to implement the duty. The costs of providing this training are based on training that was developed by NHS Education for Scotland on complaints handling and the power of apology training (delivered through workshops and DVDs) (£32,000 per annum in 2016-17 and 2017-18, and reducing to £15,000 in 2018-19)). Government has also previously commissioned training entitled Compassionate Connections. Compassionate Connections is an implementation of the Refreshed Framework for Maternity Care in Scotland (Scottish Government 2011a) and Improving Maternal and Infant Nutrition: a Framework for Action (Scottish Government 2011b) (£150,000 in 2016-17, reducing to £13,000 in 2017-18 and £10,000 in 2018-19 to cover reprinting and updating costs of national training and implementation resources). The costs listed are the maximum costs likely. There is a low margin of uncertainty as they are determined by the costs of similar work on related Scottish Government programmes.

COSTS ON THE NHS IN SCOTLAND

68. The Scottish Government anticipates that Health Boards will be able to incorporate the requirements for the duty of candour procedure within their existing processes to support staff training and induction programmes.

COSTS ON LOCAL AUTHORITIES

69. The Scottish Government anticipates that local authorities will be able to incorporate the requirements for the duty of candour procedure within their existing processes to support staff training and induction programmes.

COSTS ON OTHER BODIES, INDIVIDUALS AND BUSINESSES

- 70. The Scottish Government anticipates that smaller organisations are likely to have additional costs in relation to the requirement for training to be provided to those staff required to implement the duty of candour procedure. The development of national training and implementation resources for these organisations will remove the requirement for organisations to deliver bespoke training. Independent providers of health and social care will be able to integrate the duty of candour provisions within their existing programmes to train staff on the management of complaints or adverse events. However, some organisations may need support to ensure that staff can be released to act as trainers within their organisations. £50,000 has been set aside for organisations who may require this support, though, given a high margin of uncertainty associated with the training requirements for other bodies, it is possible that this could be greater. This has been calculated on the basis of approximately 200 organisations requiring to cover backfill for clinical sessions of staff to undertake training in respect of the duty of candour procedure.
- 71. In keeping with existing custom and practice when there are new policies or requirements, partnership working arrangements with the Care Inspectorate, Scottish Care and Community Care Providers Scotland Limited mean that they would collectively develop training and implementation support materials for their staff. Healthcare Improvement Scotland would use existing community of practice and clinical engagement networks. mechanisms, support and training would be provided. The Scottish Government would work jointly with the Care Inspectorate and Healthcare Improvement Scotland to ensure that jointly branded information and literature on the expectations for organisations was developed using a range of formats. This will be an important element for other bodies, individuals and businesses which, unlike the NHS and local authorities, may be less familiar with the requirements of a duty of candour procedure. It would be anticipated that this would cost £75,000 initially with recurring costs of £15,000 per annum. These costs are based on design, print and distribution costs and venue hire. Time for staff to attend meetings would be costs within existing staff requirements for ongoing professional development and training. The costs listed are the maximum costs likely. There is a low margin of uncertainty for these estimates as they are based on current costs of developing similar materials for other Scottish Government programmes.

MONITORING

72. The duty of candour procedure will require that Healthcare Improvement Scotland, the Care Inspectorate and the Scottish Government implement arrangements to monitor the implementation of the duty of candour procedure.

COSTS ON THE SCOTTISH ADMINISTRATION

73. The Scottish Government does not anticipate any additional costs associated with monitoring of the implementation of the duty of candour provisions of the Bill. The existing programmes and processes in place to monitor performance and consider reviews of provider organisations will be developed to incorporate the monitoring of the duty of candour implementation as required.

COSTS ON THE NHS IN SCOTLAND AND LOCAL AUTHORITIES

74. The Scottish Government does not anticipate any additional costs for the NHS in Scotland or on local authorities of the monitoring of the duty of candour. Health Boards are already required to collate and report information on specified incidents and events as part of procedures already in place as part of requirements such as the NHS complaints procedure and the framework 'Learning from adverse events through reporting and review'. Local authorities already collate and report information on specified incidents and events as part of their public protection responsibilities.

COSTS ON OTHER BODIES, INDIVIDUALS AND BUSINESSES

75. The Scottish Government anticipates that there will be not be additional costs of monitoring of the duty of candour, as this will be incorporated within existing processes of organisations such as Healthcare Improvement Scotland and the Care Inspectorate. Organisations that are not currently subject to regulation by Healthcare Improvement Scotland or the Care Inspectorate (e.g. GP practices, dental surgeries, optometry practices and community pharmacies) are required to collate information for accreditation or contractual purposes and would, therefore, be expected to integrate any monitoring requirements within their existing administrative procedures.

PUBLICATION OF REPORTS

76. The duty of candour provisions of the Bill would require organisations subject to the duty to submit and publish an annual report outlining how their organisational procedures and processes support the implementation of the duty of candour procedure.

COSTS ON THE SCOTTISH ADMINISTRATION

77. The Scottish Government does not anticipate that there would be additional costs associated with the consideration of reports in relation to the implementation of the organisational duty of candour, as such consideration would be integrated with existing mechanisms for the review of performance of organisations or receipt of reports from

organisations and scrutiny organisations who currently routinely share reports with the Scottish Ministers.

COSTS ON THE NHS IN SCOTLAND AND ON LOCAL AUTHORITIES

78. The Scottish Government does not anticipate that there would be any additional costs associated the requirement for Health Boards and local authorities to produce reports on the implementation of the duty of candour procedure. Health Boards and local authorities are already required to produce reports for a range of monitoring, review and accreditation processes and will be expected to integrate duty of candour reporting within those processes.

COSTS ON OTHER BODIES, INDIVIDUALS AND BUSINESSES

79. Other organisations that are covered by the duty of candour procedure are regulated by Healthcare Improvement Scotland or the Care Inspectorate and are already required to collate and report information in respect of incidents and complaints as part of the requirements of their registration. The Care Inspectorate collects annual data and information from organisations such as care homes as well as requiring them to notify it of any incidents that occur with service users. The Care Inspectorate has indicated that it could collate this information and provide this to the Scottish Government as part of its statutory responsibilities with no additional cost. Embedding reporting within existing notification schemes that are already in place would not result in significant additional costs.

PART 3 – WILFUL NEGLECT/ILL TREATMENT

COSTS ON THE SCOTTISH ADMINISTRATION

Criminal justice system

- 80. The provisions relating to wilful neglect or ill-treatment will have a resource impact on Police Scotland, the Crown Office and Procurator Fiscal Service (COPFS), the Scottish Courts and Tribunals Service (SCTS), the Scottish Legal Aid Board (SLAB), and the Scottish Prison Service (SPS).
- 81. The police will be responsible for the investigation and charging of individuals and organisations, and the subsequent preparation of reports to COPFS for review and a decision on whether to proceed with prosecution.
- 82. In terms of the costs of the police investigation, and the required time required to help build the case and evaluate the evidence to assist COPFS in making a decision on whether and who to prosecute, it is not possible to know how much time would be needed and so it is not possible to quantify these potential costs. Furthermore it is not possible to isolate current police expenditure on adult criminal justice. There is currently no information about the average amount of time that would be required to investigate such an offence, and this is likely to vary considerably depending on the specific case in question. It is anticipated that any such investigations could be managed within existing resources.

83. It is difficult to provide an estimate of how many cases there will be as a result of the new offence. The Scottish Government has based its assumptions on costs relating to the existing offence in relation to people receiving mental health care or treatment. Tables 11 and 12 summarise the number of prosecutions for wilful neglect or ill-treatment under mental health and adults with incapacity legislation.

Table 11 — Prosecutions for wilful neglect/ill-treatment under the Adults with Incapacity (Scotland) Act 2000 (where main offence)⁸

	Adults with Incapacity (Scotland) Act 2000, section 83				
Financial Year	Prosecutions	Guilty	Not Guilty		
2013-14	1	1	0		

Source: Scottish Government Court Proceedings Database

Table 12 — Prosecutions for wilful neglect/ill-treatment under mental health legislation (where main offence)

	Mental Health (Care and Treatment) (Scotland) Act 2003, section 315			Mental Hea 1984, section	•	,
Financial Year	Prosecutions	Guilty	Not Guilty	Prosecutions	Guilty	Not Guilty
2004-05				1	1	0
2005-06				0	0	0
2006-07				2	1	1
2007-08	1	1	0			
2008-09	1 0 1					
2009-10	2	2	0			
2010-11	1	1	0			
2011-12	3	2	1			
2012-13	8	4	4			
2013-14	4	1	3			

Source: Scottish Government Court Proceedings Database

84. The rate of prosecutions for the existing mental health offence has been used in producing an estimate for the number of prosecutions for the new offence. Taking an average of two prosecutions per year for the section 105 and 315 offences, per 15,401 patients receiving mental health care or treatment, and then applying this rate to an estimated 884,000 additional users of health and social care services in Scotland who would be covered by extending the legislation, gives an estimate of a potential 100 prosecutions per year. However, this is likely to be a high estimate as those receiving mental health care or treatment are likely to be more vulnerable and, therefore, at greater risk of suffering ill-treatment or wilful neglect. There are also possible differences in reporting rates, and other factors which are not taken into account in this calculation.

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 $^{^{\}rm 8}$ There were no prosecutions under this section prior to 2013

- 85. Table 13 sets out the average costs of criminal procedures. Table 14 provides the number of prosecutions for the existing offences of wilful neglect or ill-treatment, split by court type. For the new offence, based on calculations of an additional 100 cases per year, and assuming the same split between summary and solemn procedure, the additional cost to the criminal justice system would be around £300,000 per year (as set out in tables 15 and 16). This figure does not include costs relating to imprisonment. The figures provided in tables 15 and 16 give ranges to illustrate the difference in costs where 75% of defendants receive legal aid compared to all defendants.
- 86. The care worker offence will carry a maximum sentence of five years imprisonment on indictment. There has been only two cases, so far, under existing legislation which have resulted in a sentence of imprisonment. It currently costs £33,153 per year to keep a person in custody⁹. It is difficult to usefully predict how many people will be imprisoned as a result of the new offences, but if one person is held in custody for a period of three years then this would cost £100,000. While sentencing will be for the courts, it is expected that more minor offences will not attract a prison sentence and so the overall impact on prisons will be minimal.

Table 13 — Unit cost of criminal procedures

	Average prosecution costs per procedure (COPFS)	Average court costs per procedure (SCTS)	TOTAL (excluding legal aid costs)	Average legal assistance costs per procedure (SLAB)	TOTAL (including legal aid costs)
Sheriff Court Solemn Procedure	£5158	£1743	£6901	£1892	£8793
Sheriff Court Summary Procedure	£342	£357	£699	£612	£1311

Source: Costs of the Criminal Justice System in Scotland Dataset (2013)

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⁹ Source: Scottish Prison Service

Table 14 — Prosecutions for existing offences of wilful neglect/ill-treatment, by court type

	Court Type		
	Sheriff Solemn	Sheriff Summary	
2004-05	0	1	
2005-06	0	0	
2006-07	1	1	
2007-08	0	1	
2008-09	0	1	
2009-10	0	2	
2010-11	0	1	
2011-12	0	3	
2012-13	1	7	
2013-14	3	2	
TOTAL	5	19	
TOTAL %	21%	79%	

Source: Scottish Government Court Proceedings Database

Table 15 — Costs of estimated 100 cases per year

Procedure	Number of cases	Cost per case*	TOTAL*
Sheriff Court Solemn Procedure	21	£6901 - £8793	£173,301 - £184,653
Sheriff Court Summary Procedure	79	£699 - £1311	£91,329 - £103,569
		TOTAL COST	£264,630 - £288,222

^{*}Ranges illustrate the differences in costs between 75% and 100% of defendants receiving legal aid. Totals may not add up due to rounding.

Table 16 — Breakdown of estimated costs by organisation

	Sheriff Solemn*	Sheriff Summary*	TOTAL*
Number of cases	21	79	100
COPFS	£108,318	£27,018	£135,336
SCTS	£36,603	£28,203	£64,806
SLAB	£28,380 - £39,732	£36,108 - £48,348	£88,080
Total	£173,301 - £184,653	£91,329 - £103,569	£264,630 - £288,222
Totals (rounded)	£173,000 - £185,000	£91,000 - £104,000	£265,000 - £288,000

^{*}Ranges illustrate the differences in costs between 75% and 100% of defendants receiving legal aid. Totals may not add up due to rounding.

Costs on local authorities

87. There will be no new costs falling on local authorities as a consequence of these specific sections.

Costs on other bodies, individuals and businesses

88. There will be no new costs falling on other bodies, individuals and businesses as a consequence of these sections.

TOTAL COSTS OF THE BILL

	Year 1	Year 2	Year 3
Part 1*	£1.48m – £20.1m	£1m -£1.5m	£1m -£1.5m
Part 2	£863,000	£595,560	£555,965
Part 3	£265,000-£288,000	£265,000-£288,000	£265,000-£288,000
Total**	£2.6m-£3.2m	£1.9m - £2.4m	£1.8m-2.4m

^{*}rounded to the nearest £10,000

^{**} rounded to the nearest £100,000

[SCOTTISH GOVERNMENT] [MEMBER'S] [PROMOTER'S] STATEMENT ON LEGISLATIVE COMPETENCE

On 4 June 2015, the Cabinet Secretary for Health, Wellbeing and Sport (Shona Robison MSP) made the following statement:

"In my view, the provisions of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill would be within the legislative competence of the Scottish Parliament."

PRESIDING OFFICER'S STATEMENT ON LEGISLATIVE COMPETENCE

On 4 June 2015, the Presiding Officer (Rt. Hon Tricia Marwick MSP) made the following statement:

"In my view, the provisions of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill would be within the legislative competence of the Scottish Parliament."

HEALTH (TOBACCO, NICOTINE ETC. AND CARE) (SCOTLAND) BILL

EXPLANATORY NOTES (AND OTHER ACCOMPANYING DOCUMENTS)

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