

Mark Drakeford AC / AM
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

Eich cyf/Your ref
Ein cyf/Our ref: LF/MD/0411/15

David Rees AM
Chair of the Health and Social Care Committee
National Assembly for Wales
Ty Hywel,
Cardiff Bay
Cardiff
CF99 1NA

11 June 2015

Dear David,

Public Health (Wales) Bill – Statement of Policy Intent

Following the introduction of the Public Health (Wales) Bill into the National Assembly for Wales on 8 June 2015, I am pleased to enclose the Statement of Policy Intent for the subordinate legislation and other delegated legislative powers contained in the Bill.

The statement provides further information on the policy intent for the subordinate legislation, which could be made under the Bill, if enacted.

I look forward to providing evidence before the Committee in due course.

A copy of this letter and the enclosed statement is also being sent to David Melding, Chair of the Constitutional and Legislative Affairs Committee.

*Best wishes,
Mark*

Mark Drakeford AC / AM
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



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Welsh Government

PUBLIC HEALTH (WALES) BILL

Statement of Policy Intent for Subordinate
Legislation

June 2015

PUBLIC HEALTH (WALES) BILL

STATEMENT OF POLICY INTENT FOR SUBORDINATE LEGISLATION

This document provides an indication of the current policy intention for the subordinate legislation that the Welsh Ministers would be empowered or required to make under the provisions of the Public Health (Wales) Bill ('the Bill'). It has been prepared in order to assist committees during the scrutiny of the Bill and should be read in conjunction with the Explanatory Memorandum and Explanatory Notes.

The key purpose of the Bill is to introduce changes that:

- Place restrictions on the use of tobacco and electronic cigarettes (nicotine inhaling devices) in enclosed and substantially enclosed public and work places, and give the Welsh Ministers a regulation-making power to extend the restrictions to open spaces;
- Provide for the creation of a national register of retailers of tobacco and nicotine products;
- Provide the Welsh Ministers a regulation-making power to add to the offences for which a Restricted Premises Order may be sought in Wales;
- Prohibit the handing over of tobacco and/or nicotine products to a person under the age of 18;
- Provide for the creation of a mandatory licensing scheme for businesses/practitioners carrying out "special procedures" (acupuncture, body piercing, electrolysis and tattooing);
- Introduce a prohibition on the intimate piercing of persons under the age of 16;
- Change the arrangements for determining applications for entry onto the pharmaceutical list of Local Health Boards (LHBs), to a system based on the pharmaceutical needs of local communities; and
- Require local authorities to prepare local toilets strategies to plan how they will meet the needs of their communities for accessing toilet facilities.

For ease of reference, this document includes separate information for each provision in the Bill which involves subordinate legislation. However, in reality a number of these areas would be likely to be combined and dealt with, for example, within a set of regulations. A number of these regulations will need to be passed by the Assembly before the corresponding sections of the Bill are brought into force.

Implementation of some parts of the Bill will not involve the production of subordinate legislation. These areas are referenced at relevant points within the document. The contents of this document correspond to the information provided in Chapter 5 of the Explanatory Memorandum.

In developing subordinate legislation, the Welsh Government will work closely with stakeholders in order to ensure the provisions are relevant, valid and proportionate.

PART 2: TOBACCO AND NICOTINE PRODUCTS

Chapter 1 – Smoking and use of nicotine inhaling devices

REGULATIONS RELATING TO	The exemption of a device, or description of a device, from the definition of a 'nicotine inhaling device'
BILL PART	Chapter 1 of Part 2
SECTION	2(2)(b)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This power enables the Welsh Ministers to make regulations to exempt a device, or description of a device, from the definition of a 'nicotine inhaling device' provided at Section 2(2). For the purpose of the Bill a 'nicotine inhaling device' is a device that enables the inhalation of nicotine via a mouth piece (whether or not the device also enables any other substance to be inhaled). A device that is intended to be used for the consumption of lit tobacco is already exempted from the definition by Section 2(2)(a).</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power allows the Welsh Ministers to make regulations to exempt devices that would otherwise fall within the definition of a nicotine inhaling device for the purpose of the Bill. This would enable devices or descriptions of devices that would otherwise be captured by the definition of a nicotine inhaling device to be used in smoke-free premises.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>This regulation-making power enables the Welsh Ministers to provide exemptions for devices that are not intended to be captured by the definition of a nicotine inhaling device. Regulations made under this power are subject to the negative procedure because such regulations will add technical detail to the definition of 'nicotine inhaling device' provided on the face of the Bill. This power may be used to provide clarity to the regime by exempting a device or description of a device from the definition of nicotine inhaling device at Section 2(2) where it is found that such a device is being captured by that definition but their use in public is not undermining the policy rationale behind the provisions.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Specifying further devices that enable the inhalation of a substance, or descriptions of such devices, to which provisions on smoking and the use of nicotine inhaling devices may apply
BILL PART	Chapter 1 of Part 2
SECTION	3(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations that provide for other devices, or descriptions of a device, to be covered by this Chapter where they are satisfied that this is likely to contribute towards the promotion of the health of the people of Wales. Such additional devices may or may not enable nicotine to be inhaled. This power enables the Welsh Ministers to modify how Chapter 1 applies in relation to any such other devices, or description of devices, as they consider necessary or expedient.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>The Welsh Ministers could use these powers, for example, should it become apparent that devices which are not currently captured by the definition of a NID are contributing to the renormalisation of smoking behaviours and/or are undermining enforcement of the smoke-free requirements and are therefore having a negative impact on the health of the people of Wales.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>It is possible that some inhaling devices not covered by the definition of 'nicotine inhaling device' in this Chapter may exist or are being/will be developed by industry in the future. This regulation-making power is required to enable the Welsh Ministers to react to any such developments, where they are satisfied that this is likely to contribute towards the promotion of the health of the people of Wales. The Welsh Ministers will need flexibility to respond to these changes in order to ensure the integrity of the provisions on smoking and the use of nicotine inhaling devices is maintained.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Duties regarding additional smoke-free premises and smoke-free vehicles
BILL PART	Chapter 1 of Part 2
SECTION	5(2)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>Section 5 (1) requires managers of smoke-free workplaces and public premises to take reasonable steps to prevent smoking or the use of nicotine inhaling devices in those premises.</p> <p>This power, in Section 5 (2), enables the Welsh Ministers to make regulations to place corresponding duties on a person or description of person in respect of any additional smoke-free premises (designated by virtue of Section 8 of the Bill) and smoke-free vehicles (designated by virtue of Section 9) designated by the Welsh Ministers.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power enables the Welsh Ministers to place a duty on managers of any additional smoke-free premises and those responsible for smoke-free vehicles in Wales to take reasonable steps to prevent smoking or the use of nicotine inhaling devices in their premises/vehicles. This would achieve consistency across the smoke-free regime in Wales for all managers of smoke-free premises.</p> <p>Such regulation-making powers are currently provided for in the Health Act 2006, but only in respect of smoking in additional smoke-free premises and smoke-free vehicles; not for the use of nicotine inhaling devices in such places, which would also be covered by these regulations.</p> <p>In relation to smoke-free vehicles, the Health Act 2006 and the Smoke-free Premises etc. (Wales) Regulations 2007 currently place the duty to take reasonable steps to prevent smoking on the operator, the driver and any person on a vehicle who is responsible for order and safety on it. The policy intention is to continue to make these persons responsible in any vehicles designated as smoke-free.</p> <p>In relation to any additional smoke-free premises designated under Section 8, it is intended to decide on a case by case basis whether or not to place the duty on the manager of those premises. So, for example, if hospital grounds in Wales were designated by the Welsh Ministers as additional smoke-free premises, consideration would be given to placing a duty on hospital managers in Wales to take reasonable steps to prevent smoking or the use of nicotine inhaling devices in the grounds of the hospital(s) for which they are responsible.</p>	
WHY THE REGULATIONS ARE REQUIRED	
<p>This power is required to create the offence of failing to prevent a person from smoking or using a nicotine inhaling device in any additional smoke-free premises and smoke-free vehicles designated by regulations. This will enable enforcement</p>	

authorities to prosecute persons they believe to have committed such an offence, so that they may be liable on summary conviction to a fine on the standard scale.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

Section 8(3) of the Health Act 2006 currently provides the Welsh Ministers with powers to make regulations that place a duty on managers of any additional smoke-free places (designated by virtue of Section 4 of the Health Act 2006), and those responsible for smoke-free vehicles in Wales (designated by virtue of Section 5) to cause a person smoking there to stop smoking. Regulations made under these powers in the Health Act 2006 are subject to the affirmative procedure. These powers are used in respect of smoke-free vehicles in regulation 7 of the Smoke-free Premises etc. (Wales) Regulations 2007.

REGULATIONS RELATING TO	The meaning of “enclosed” and “substantially enclosed” for designating smoke-free workplaces and public premises
BILL PART	Chapter 1 of Part 2
SECTION	6(7)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations to define what is meant by “enclosed” and “substantially enclosed” for the purposes of designating smoke-free workplaces and premises that are open to the public.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>The power enables the Welsh Ministers to clarify which areas of workplaces and premises open to the public are required to be smoke-free.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>The power is required to provide technical detail to the legislative scheme. The definitions provided in regulations will add precision to the meaning of the words ‘enclosed’ and ‘substantially enclosed’. This detail is relatively minor to the overall legislative scheme and therefore best achieved through regulations.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
<p>Section 2(5) of the Health Act 2006 provides the Welsh Ministers with powers to make regulations that specify what “enclosed” and “substantially enclosed” means. Regulations made under these powers in the Health Act 2006 are subject to the negative procedure. The current definitions of “enclosed” and “substantially enclosed”, for the purposes of smoke-free premises under the Health Act 2006, are set out at regulation 2 of the Smoke-free Premises etc. (Wales) Regulations 2007.</p>	

REGULATIONS RELATING TO	Additional smoke-free premises
BILL PART	Chapter 1 of Part 2
SECTION	8(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations to designate any place, or description of place, in Wales as smoke-free. The additional smoke-free places need not be enclosed or substantially enclosed and must not already be designated as smoke-free by the Bill. Being 'smoke-free' in these provisions means that smoking and use of nicotine inhaling devices is not permitted, unless an exemption applies. The regulations allow the Welsh Ministers to consider the circumstances, times, conditions and/or areas in which any additional premises should be smoke-free on a case by case basis.</p> <p>The regulations may also provide for exemptions to the smoke-free status of any additional smoke-free premises. The regulations may, for example, allow the person in charge of the additional smoke-free premises to designate areas in which smoking or the use of a nicotine inhaling device is to be permitted. The designation would have to be in accordance with any conditions set out in the regulations.</p> <p>Under this power, the additional smoke-free premises may not be a private dwelling (NB. private dwellings being used as a workplace or open to the public are covered by Sections 6 and 7.)</p> <p>The Welsh Ministers will only be able to designate additional smoke-free premises where they are satisfied that designating that place as smoke-free is likely to contribute towards the promotion of the health of the people of Wales.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power will allow the Welsh Ministers to create additional smoke-free premises where doing so is likely to contribute towards the promotion of the health of the people of Wales. The intention is to create additional smoke-free non-enclosed spaces which may include, but are not limited to, hospital grounds, school grounds and children's playgrounds. The regulation-making power will also enable the Welsh Ministers to allow for areas within those additional smoke-free premises to be exempt from the smoke-free requirements where they have been designated as such by the manager of those premises.</p> <p>It is the current policy intention that there will be no obligation on the person in charge of the additional smoke-free premises to designate areas within the premises where the smoke-free requirements do not apply, unless in specific circumstances as determined by the Welsh Ministers. So, for example, if the Welsh Ministers make regulations for smoke-free hospital grounds, the regulations could provide that the manager of those hospitals <u>may</u> designate areas within the grounds in which smoking and/or use of a nicotine inhaling device is permitted. Any designation would have to comply with specific requirements in the regulations.</p>	

The power allows for flexibility to make regulations on additional non-enclosed places in the future if the Welsh Ministers are satisfied that doing so is likely to contribute to the promotion of the health of the people of Wales.

WHY THE REGULATIONS ARE REQUIRED

This power is required to continue to ensure that smoking behaviours are not re-normalised, nor the use of nicotine inhaling devices normalised, by permitting smoking and the use of nicotine inhaling devices in certain non-enclosed places; particularly those where children and young people are commonly present.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

These powers differ to those under Section 4 of the Health Act 2006, whereby the Welsh Ministers may designate an additional smoke-free place (in relation to smoking, not to the use of nicotine inhaling devices) in Wales only if, in their opinion, there is significant risk that, without designation, persons present in the place would be exposed to significant quantities of smoke. Regulations made under Section 4 of the Health Act 2006 are subject to the affirmative procedure. The power for the Welsh Ministers to make such regulations has not yet been used.

REGULATIONS RELATING TO	Smoke-free vehicles
BILL PART	Chapter 1 of Part 2
SECTION	9(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations providing for vehicles to be smoke-free. It enables the Welsh Ministers to require certain types of vehicles to be smoke-free, to set the circumstances in which vehicles are smoke-free, to provide that the vehicle is to be smoke-free when located in specific areas, and to make exemptions to any of these requirements. The Welsh Ministers can only designate a vehicle as being smoke-free where they are satisfied that doing so is likely to contribute towards the promotion of the health of the people of Wales. Smoking and the use of a nicotine inhaling device is prohibited in a smoke-free vehicle, unless the Welsh Ministers make regulations to provide for exemptions (e.g. to allow the use of nicotine inhaling devices).</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power will allow the Welsh Ministers to establish a smoke-free regime for vehicles in Wales that is specific to certain types of vehicles, and details when and where they must be smoke-free. This allows for flexibility so that the regime for smoke-free vehicles can be adapted for specific scenarios.</p> <p>The policy intention is that all vehicles used for the transportation of the public or for work purposes by more than one person should be smoke-free all of the time.</p> <p>It is not the current policy intention to require private vehicles, including privately rented vehicles, to be smoke-free unless they are carrying persons under the age of 18, and unless the private rental includes a driver, in which case the rental is a workplace and so should be smoke-free.</p> <p>Being 'smoke-free' means that smoking and the use of nicotine inhaling devices is not permitted, unless an exemption applies.</p> <p>This regulation-making power could be used to extend the ban on smoking in cars carrying children, contained in the Smoke-free premises etc. (Wales) (Amendment) Regulations 2015, laid on 5th May 2015 and debated by the National Assembly for Wales 2nd June, to include a ban on the use of nicotine inhaling devices in those vehicles. The Welsh Ministers may only do so if they are satisfied that doing so is likely to contribute to the promotion of the health of the people of Wales.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>This power is required to enable Welsh Ministers to apply the smoke-free requirements to vehicles in a range of settings and scenarios. For example, the regulations may designate vehicles used for public transport as smoke-free (e.g. buses), vehicles that are workplaces (e.g. taxis), and private vehicles carrying persons under the age of 18.</p>	

The restatement of the Health Act 2006 and the extension of the meaning of smoke-free to include the use of a nicotine inhaling device as well as smoking creates a need to re-establish the smoke-free regime for vehicles. This power permits the Welsh Ministers to do this.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

The Smoke-free Premises etc. (Wales) Regulations 2007 continue to apply until such time as the Welsh Ministers use these regulation-making powers. Section 95 of the Children and Families Act 2014 amends Section 5 of the Health Act 2006 to provide enabling powers for the Welsh Ministers to make regulations to prohibit smoking in private vehicles carrying persons under the age of 18. Regulations made under these powers in the Health Act 2006 are subject to the affirmative procedure.

REGULATIONS RELATING TO	Making exemptions for premises from the smoke-free requirements
BILL PART	Chapter 1 of Part 2
SECTION	10(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>This power allows the Welsh Ministers to make regulations to exempt premises, or specified areas within premises in Wales, from the requirement to be smoke-free. Exemptions from the smoke-free requirements may be in respect of both smoking and the use of nicotine inhaling devices, smoking only, or the use of nicotine inhaling devices only.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power will enable the Welsh Ministers to allow smoking and/or the use of nicotine inhaling devices in certain public premises or workplaces, or specific areas within these premises (i.e. exempt them from the smoke-free requirements). This will achieve some flexibility in the application of the smoke-free regime in Wales.</p> <p>Exemptions from the existing smoke-free regime currently apply to specific rooms within care homes, adult hospices, mental health units, research or testing facilities, hotels, guesthouses, inns, hostels and members' clubs. These are provided for by regulation 3 of the Smoke-free Premises etc. (Wales) Regulations 2007.</p> <p>There is a commitment in the Tobacco Control Action Plan for Wales to review the exemption from the existing smoke-free requirements for mental health units that provide residential accommodation. It is the intention to review this exemption in respect of smoking when regulations are made under this power. It is also the intention to retain all other existing exemptions in respect of smoking, and to include the use of a nicotine inhaling device in these exemptions. It is intended to provide an exemption in mental health units that provide residential accommodation in respect of the use of a nicotine inhaling device.</p> <p>It is not currently intended to provide any further exemptions for workplaces and public premises to those already provided for by the Smoke-free Premises etc. (Wales) Regulations 2007 in respect of smoking. There are currently two judicial reviews being considered regarding smoking in prisons in England and Wales. The position in prisons relating to smoking and the use of nicotine inhaling devices will be considered following the outcome of these cases. There is no current intention to restrict entirely the use of nicotine inhaling devices in prisons in Wales.</p> <p>It is the intention to provide further exemptions in premises or specified areas of premises in respect of use of a nicotine inhaling device only – i.e. the use of nicotine inhaling devices would be permitted in such premises even though smoking is not permitted. Such additional exemptions could include, but are not limited to; use of a nicotine inhaling device in specific areas of pharmacies (for example, the pharmacy consulting room); or by performers where use of a nicotine inhaling device is required for the artistic integrity of their performance.</p>	

WHY THE REGULATIONS ARE REQUIRED?

This power is required to enable the Welsh Ministers to exclude from the smoke-free requirements settings which may be considered a person's dwelling for the time being. For example, this will be relevant in settings such as a room in a hotel or guesthouse, or where persons may be detained (such as mental health units). This is in line with the policy intention that the smoke-free requirements should not apply to private dwellings.

The power is also required to exclude the application of the smoke-free requirements in workplaces or public premises which have justifiable reasons for allowing smoking and/or the use of a nicotine inhaling device. For example, this may be appropriate in premises where research on smoking cessation or emission testing is being undertaken.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

An equivalent power to exempt premises from the current smoke-free requirements is included at Section 3 of the Health Act 2006. Regulations made under these powers in the Health Act 2006 are subject to the affirmative procedure. Regulation 3 of the Smoke-free Premises etc. (Wales) Regulations 2007, made under the Health Act 2006, sets out the premises within which managers may designate smoking rooms (i.e. may designate rooms as being exempt from the smoke-free requirements of the Health Act 2006).

The Smoke-free Premises etc (Wales) Regulations 2007 continue to apply until such time as the Welsh Ministers use these regulation-making powers.

REGULATIONS RELATING TO	Smoke-free signs
BILL PART	Chapter 1 of Part 2
SECTION	11(1)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This power permits the Welsh Ministers to make regulations that specify requirements for smoke-free signs. Such requirements may include how the signs should be displayed as well as specifications regarding the dimensions of the sign, the minimum text size and font, any graphic or symbol that must be included, and any mandatory warning message.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>Smoke-free signs will communicate the requirement to refrain from smoking and using a nicotine inhaling device in smoke-free premises, places and vehicles. This power will enable the Welsh Ministers to make regulations detailing the technical specification of smoke-free signs. This will ensure consistency in the signs displayed.</p> <p>The intention is to specify requirements for signs in respect of the requirement to refrain from smoking, and for signs in respect of the requirement to abstain from the use of a nicotine inhaling device. The requirements for each sign may differ depending on whether they are to be used in enclosed or substantially enclosed smoke-free premises, in smoke-free vehicles or on non-enclosed or non-substantially enclosed smoke-free premises (referred to as “additional smoke-free premises” in the Bill).</p> <p>For smoke-free enclosed or substantially enclosed premises, the intention is for occupiers/managers of such premises to retain their existing no-smoking signs for the purpose of communicating the requirement to refrain from smoking in enclosed or substantially enclosed smoke-free premises. The current specifications for no-smoking signs for enclosed or substantially enclosed premises are provided for in regulation 5 of the Smoke-free Premises etc. (Wales) Regulations 2007. The specifications for such signs will not change as a result of regulations being made using this new power. The existing no-smoking signs will therefore not need to be updated or replaced. This will reduce waste and enable the internationally recognised no-smoking symbol to be retained. The same will apply to no-smoking signs for smoke-free vehicles, the specifications for which are provided for in regulation 6 of the Smoke-free Premises etc. (Wales) Regulations 2007.</p> <p>To communicate the requirement to refrain from use of a nicotine inhaling device in enclosed or substantially enclosed smoke-free premises and vehicles, it is intended that regulations will specify requirements for separate signs to the existing no-smoking signs. It is intended that the specifications for this new sign will be very similar to those of the existing no-smoking signs, albeit that the graphic image and text will need to be slightly amended. The graphic image will depict a nicotine inhaling device in a circle with a red bar crossing through it, and the message will reflect the requirement to refrain from using a nicotine inhaling device in the premises. It is intended that such signs should be displayed alongside existing no-smoking signs.</p>	

A new distinctive sign to communicate the requirement to refrain from the use of a nicotine inhaling device in enclosed or substantially enclosed smoke-free premises and smoke-free vehicles will make it clear that the requirements in enclosed or substantially enclosed smoke-free premises have changed.

In addition, separate signs are required to enable exemptions from the smoke-free regime in respect of smoking, use of a nicotine inhaling device, or both. For example, if the Welsh Ministers make regulations to provide for an exemption from the smoke-free regime for pharmacy consulting rooms in respect of use of a nicotine inhaling device, such areas of the premises will require a sign to communicate the requirement to refrain from smoking only. Although it will not be a legal requirement, guidance will advise on the display of a sign to show that the use of nicotine inhaling devices is permitted.

The requirements for the signs to be displayed in non-enclosed or non-substantially enclosed smoke-free premises by virtue of regulations made under Section 8 will differ to those for smoke-free premises as outlined above. It is the current intention to use the same graphic image and message; however, other requirements such as the dimensions and where signs should be placed will differ to reflect the non-enclosed or non-substantially enclosed environment.

WHY THE REGULATIONS ARE REQUIRED?

The power is required to provide technical detail to the legislative scheme. The public need to be aware of which premises, places and vehicles are smoke-free as they will be committing an offence if they smoke or use a nicotine inhaling device in such smoke-free premises, places and vehicles. The negative procedure is used here because the regulations will be of a technical nature.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

Section 6 of the Health Act 2006 provides the Welsh Ministers with powers to specify the requirements for no-smoking signs in regulations. Regulations made under these powers in the Health Act 2006 are subject to the negative procedure. Regulation 5 of the Smoke-free Premises etc. (Wales) Regulations 2007 establishes the existing requirements for no-smoking signs for smoke-free premises, and regulation 6 provides the existing requirements for no-smoking signs for smoke-free vehicles.

The Smoke-free Premises etc. (Wales) Regulations 2007 will continue to apply until such time as the Welsh Ministers use these regulation-making powers.

It is likely that any regulations that utilise this power will have to be notified pursuant to Article 9(2) of Directive 98/34/EC ("the Technical Standards Directive"), as they will be setting technical standards for the smoke/nicotine inhaling device signs to be used.

REGULATIONS RELATING TO	Signs for additional smoke-free premises and smoke-free vehicles
BILL PART	Chapter 1 of Part 2
SECTION	11(3)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	
<p>Smoke-free signs will communicate the requirement to refrain from smoking and the use of a nicotine inhaling device in smoke-free premises in Wales. Section 11(1) requires those who occupy or manage smoke-free public premises or workplaces to display smoke-free signs. The power in Section 11(3) permits the Welsh Ministers to make regulations that place a corresponding duty on those who occupy or manage additional smoke-free premises (designated by virtue of Section 8) and smoke-free vehicles (designated by virtue of Section 9).</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>This power will enable the Welsh Ministers to require managers of additional smoke-free premises and smoke-free vehicles to display smoke-free signs.</p> <p>Regulation 6 of the Smoke-free Premises etc. (Wales) Regulations 2007 places a duty on the operator, driver and any person on a vehicle who is responsible for order or safety on it to ensure no-smoking signs are displayed. There is no intention to change this existing duty. Instead, it is the intention to make the same persons responsible for ensuring signs are displayed relating to refraining from use of a nicotine inhaling device in smoke-free vehicles.</p> <p>Should the Welsh Ministers make regulations under Section 8 to provide for additional smoke-free premises, it is intended to require the manager or occupier of the additional smoke-free premises to ensure appropriate smoke-free signs are displayed. For example, if the Welsh Ministers make regulations to provide for hospital grounds to be smoke-free, the manager of those hospitals will be responsible for ensuring that the required signs are displayed.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>This power is needed to enable the Welsh Ministers to require the managers/occupiers of additional smoke-free premises and smoke-free vehicles to display signs. The power is also required to ensure the public are aware, by way of appropriate signs, that the additional premises or vehicle in question should be smoke-free. The corresponding duty for managers of smoke-free public and work places is on the face of the Bill and therefore subject to full scrutiny by the Assembly. The affirmative procedure is used for regulations made under Section 11(3) to ensure a similar level of scrutiny by the Assembly because the regulations will place a duty on managers of additional smoke-free premises and smoke-free vehicles.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

Section 6(2) of the Health Act 2006 provides the Welsh Ministers with powers to require persons or descriptions of persons to display no-smoking signs in places that are smoke-free by virtue of Section 4 of that Act, and vehicles that are smoke-free by virtue of Section 5. Regulations made under these powers in the Health Act 2006 are subject to the affirmative procedure. Regulation 6 of the Smoke-free Premises etc. (Wales) Regulations 2007 provides the existing requirements for no-smoking signs for smoke-free vehicles. This includes a duty on the operator, driver and any person on a vehicle who is responsible for order or safety on it to ensure no-smoking signs are displayed.

REGULATIONS RELATING TO	Enforcement authorities
BILL PART	Chapter 1 of Part 2
SECTION	12(1)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This power requires the Welsh Ministers to make regulations to designate persons, or descriptions of person, as enforcement authorities for the purposes of this Chapter. The regulations must also specify the descriptions of premises, places or vehicles to which an enforcement authority is designated. An authorised officer is any person authorised by the enforcement authority to carry out its enforcement functions. An authorised officer may or may not be an officer of the enforcement authority.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>Regulations made under this power will establish who is responsible for enforcing the smoke-free requirements and descriptions of the premises, places or vehicle for which the enforcement authority is responsible. It is the intention that county and county borough councils in Wales (local authorities) shall be designated as enforcement authorities for the enforcement of the smoke-free requirements in public premises and workplaces, as well as any additional smoke-free premises. Section 12(4) permits the designated enforcement authority to make arrangements with another enforcement authority for a case dealt with it to be taken over by that authority. This is the same as the current enforcement arrangements under the Health Act 2006.</p>	
WHY THE REGULATIONS ARE REQUIRED?	
<p>This power is required as it adds technical detail to the smoke-free regime. This detail is relatively minor in the overall legislative scheme and therefore best achieved through regulations.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
<p>Section 10(1) of the Health Act 2006 provides the Welsh Ministers with powers to make regulations to designate the bodies or descriptions of body as enforcement authorities for the purpose of Chapter 1 of Part 1 of that Act. Regulations made under these powers in the Health Act 2006 are subject to the negative procedure. Regulation 8(1) of the Smoke-free Premises etc. (Wales) Regulations 2007 designates county and county borough councils in Wales to enforce the smoke-free provisions of the Health Act 2006 in relation to the premises and the vehicles that are within their area.</p> <p>For smoke-free private vehicles carrying persons under the age of 18, the intention, in draft Regulations laid on 5 May 2015, is to designate the Police in addition to county and county borough councils in Wales as the relevant enforcement authority.</p>	

Chapter 2 - Retailers of tobacco and nicotine products

REGULATIONS RELATING TO	Specifying the registration authority to maintain a register of retailers of tobacco and nicotine products
BILL PART	Chapter 2 of Part 2
SECTION	22(2)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>Section 22 of the Bill places a duty on the registration authority to maintain a register of retailers of tobacco and nicotine products.</p> <p>This power will allow the Welsh Ministers to make regulations to specify which organisation will undertake the role of the registration authority. Section 22(8) provides that the regulations can specify the Welsh Ministers as the registration authority. This may be required to ensure the register remains operational.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations will specify a local authority, or other statutory, voluntary, or private organisation, to act as the registration authority for the register of retailers of tobacco and nicotine products.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The Welsh Ministers require the ability to specify an organisation to maintain the register. The organisation specified within these regulations, referred to as the registration authority, will then be required to fulfil the duties required of the registration authority contained within Chapter 2 of Part 2 of the Bill.</p> <p>The Welsh Ministers will also need to be able to change the organisation which is nominated as the registration authority in certain circumstances. For example, the power will enable the Welsh Ministers to respond to a situation where the organisation nominated as the registration authority becomes unable to continue to perform the role. In addition, the ability to nominate the Welsh Ministers as the registration authority is intended to provide additional flexibility to ensure that the register will remain in operation if there are difficulties in finding a suitable organisation to fulfil this role.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	The application form for the register, information contained within the form and accompanying fee.
BILL PART	Chapter 2 of Part 2
SECTION	23(3)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>Section 23 of the Bill covers applications by retailers of tobacco and nicotine products for entry onto the register. This includes detail about the type of information an application for inclusion on the register must include.</p> <p>This power will enable the Welsh Ministers to provide for the form of an application, the way it is to be submitted, any other information which must be included, and for a fee to accompany the application.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations would provide details regarding how a retailer would be required to submit an application for entry onto the register. It is intended that applicants will be able to complete an application either electronically or in paper format. Engagement will take place with stakeholders (such as trading standards departments and retailers) in order to ensure the relevant information is collected and to keep the application process as straightforward as possible.</p> <p>In relation to other types of information to be included within the register, it is the current intention that additional information requested will only be that which could be useful in reducing access to tobacco products and nicotine products by persons under 18.</p> <p>The regulations will also outline if there is a fee required as part of an application. It is currently intended that applicants will have to pay a small fee as part of a registration application. The precise detail of the fee structure is yet to be determined, but the current intention is for there to be a £30 fee to cover the application and registration of one premises, with a further £10 for each additional initial premises. It is intended that the level of the fee will be kept to a reasonable level which would not be prohibitive for small retailers.</p>	
WHY THE REGULATION IS REQUIRED	
<p>This power is required in order to ensure that the information captured on the register is relevant, and that the registration process is not too burdensome for retailers who need to submit applications. The precise form of the application will need to be developed with input from stakeholders. In addition, following the launch of the register there may be a need to amend the form or format in which an application is submitted to the registration authority, for example to improve the process, or make it quicker and easier for retailers.. Regulation-making powers are considered the most effective way of achieving this as they will provide the required level of flexibility.</p>	

Similarly, there may be a need to set or change the level of the fee in the future. This will provide flexibility for the fee to be increased or reduced, based on variables such as inflation. Any future changes to the fee would need to take account of the need to ensure fees are proportionate and not prohibitive.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Charging a fee in connection with revising the register
BILL PART	Chapter 2 of Part 2
SECTION	26(6)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>Section 26 of the Bill places a duty on the registration authority to revise the register of retailers of tobacco and nicotine products under certain conditions such as;</p> <ol style="list-style-type: none"> 1. upon receiving notice from a registered person to revise the register, in respect of matters detailed in 25 (1); or 2. to correct any inaccuracies in the register of which it becomes aware, other than by notification by a registered person. <p>The Section outlines the process the registration authority must follow when revising the register. This power will enable the Welsh Ministers to make regulations to allow the registration authority to charge a fee in connection with making revisions to the register.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations will stipulate if the registration authority can charge a fee to make revisions to the register, as well as the level of the fee. It therefore provides limited further technical detail to the operation of the register.</p>	
WHY THE REGULATION IS REQUIRED	
<p>When the register initially becomes operational, it is intended that any revisions made to the register will not incur a fee. However, it may be necessary to review this position and consider providing for a fee in the future. This will provide flexibility to consider this issue, for example once it is known how many requests are being received to revise details on the register and the administrative burden this places on the registration authority.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Application of the register of retailers of tobacco and nicotine products to moveable structures
BILL PART	Chapter 2 of Part 2
SECTION	28
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>This power provides regulation-making powers to enable the Welsh Ministers to modify the provisions of Chapter 2 of Part 2, including its requirements, when applied to a vehicle, a stall, a tent or a moveable structure (for example, by requiring the application for registration for a stall to include additional information to that which is required for retail premises).</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>Regulations made under this power could specify specific information which must be included in an application for a moveable structure to be included on the register of retailers of tobacco and nicotine products. It is intended that this regulation-making power will only be used if the application process needs to be modified for moveable structures.</p>	
WHY THE REGULATION IS REQUIRED	
<p>Identifying moveable units, particularly stalls, is considered much more difficult than the other types of retail outlet captured by the register. The regulation-making power is therefore intended to enable the application process to be amended to capture specialist information which is unique to moveable structures, and which would assist enforcement agencies in dealing with this type of retail premises. For example, this may include some form of unique trading number for stalls (or other moveable units).</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Definition of 'nicotine product' in respect of the register of retailers of tobacco and nicotine products
BILL PART	Chapter 2 of Part 2
SECTION	39(2)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION	
<p>Section 39 of the Bill contains definitions of terms used within Chapter 2 of Part 2. This power will enable the Welsh Ministers to specify in regulations what is included within the definition of "nicotine product" in relation to the register of retailers of tobacco and nicotine products.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations will specify what constitutes a "nicotine product" in relation to the register of retailers of tobacco and nicotine products. These regulations would therefore indicate in relation to which products a retailer must register.</p> <p>It is currently intended that the regulations will define "nicotine product" to capture any nicotine product that is subject to an age restriction on sale. Nicotine products which do not have an age of sale restriction, or which are licensed as medicines, will not be included within the definition of "nicotine product" in relation to the register.</p>	
WHY THE REGULATION IS REQUIRED	
<p>Currently the Nicotine Inhaling Products (Age Of Sale and Proxy Purchase) Regulations 2015 provide detail about which nicotine products can only be sold to persons aged 18 or over. It is the intention that the definition of "nicotine product" in relation to the register of retailers of tobacco and nicotine products will mirror these regulations, and will therefore exclude medicinal products (for example nicotine inhaling products that are licensed medicines).</p> <p>In addition, it may be necessary to amend the definition of "nicotine product" in the future to respond to changing circumstances. This will ensure the register remains relevant and effective in the light of future developments in the area of nicotine products.</p> <p>Use of the power will provide appropriate clarity which would otherwise not be provided.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

Chapter 3 - Prohibition on sale of tobacco and nicotine products

REGULATIONS RELATING TO	Adding new tobacco or nicotine offences to the Restricted Premises Order regime
BILL PART	Chapter 3 of Part 2
SECTION	40(2)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION	
<p>Currently a local authority in Wales can apply to the magistrates' court to impose a Restricted Premises Order on a premises in relation to the following tobacco offences, where they have been committed on three separate occasions over a two year period;</p> <ol style="list-style-type: none"> 1. sale of any tobacco or cigarette papers to a person under the age of 18, whether for their own use or not, or 2. if it is proved to the satisfaction of the courts that an automatic machine for the sale of tobacco kept on premises has been used by any person under the age of eighteen. <p>A restricted premises order prohibits the sale of any tobacco or cigarette papers, to any person, for a set period of time, on the premises to which it relates.</p> <p>Section 40 of the Bill amends Section 12D of the Children and Young Persons Act 1933 to allow the Welsh Ministers to make regulations to amend the definition of tobacco or nicotine offences. This will enable the Welsh Ministers to include additional tobacco or nicotine offences for which a local authority can apply for a Restricted Premises Order for a retail premises in Wales.</p> <p>The Welsh Ministers will only be able to add new offences if they are satisfied that the offence is one that relates to the supply, sale, transport, display, offer for sale, advertising or possession of tobacco or nicotine, and is punishable by a level 4 fine on the standard scale or greater.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulations will allow the Welsh Ministers to add further tobacco and nicotine offences to those which can currently trigger a local authority requesting a Restricted Premises Order. The Welsh Ministers will only be able to add new offences if they are satisfied that the offence is one that relates to the supply, sale, transport, display, offer for sale, advertising or possession of tobacco or nicotine, and is punishable by a level 4 fine on the standard scale or greater.</p> <p>In considering this issue, engagement will take place with stakeholders such as Wales Heads of Trading Standards and HM Revenue and Customs to identify the relevant offences which should be included within the Restricted Premises Order regime.</p> <p>Potential offences which could be considered for inclusion, subject to consultation, could include those relating to the sale of illegal tobacco or infringements of the</p>	

display ban.

WHY THE REGULATION IS REQUIRED

Having the power to add new offences will ensure that any future offences which meet the criteria can be added to those for which a Restricted Premises Order can be sought.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

Chapter 4 – Handing over of tobacco etc. to persons under 18

There are no provisions in this Chapter which provide for the production of subordinate legislation.

PART 3 - SPECIAL PROCEDURES

REGULATIONS RELATING TO	Exemption from the requirement to be licensed
BILL PART	Part 3
SECTION	49(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION/DIRECTIONS/GUIDANCE	
<p>This power enables the Welsh Ministers to make regulations which provide that a special procedures licence is required by an individual who is a member of a profession set out in paragraphs (a) to (ga) of Section 25(3) of the National Health Service Reform and Health Care Professions Act 2002, and who would otherwise be exempted from the requirement to be licensed, in order for them to practice a specified special procedure. The list of special procedures is provided in Section 46 and comprises: acupuncture, body piercing, electrolysis and tattooing.</p> <p>The professions listed in Section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 are:</p> <ul style="list-style-type: none"> (a) the General Medical Council, (b) the General Dental Council, (c) the General Optical Council, (d) the General Osteopathic Council, (e) the General Chiropractic Council, (f) the General Pharmaceutical Council, (g) subject to Section 26(6), the Pharmaceutical Society of Northern Ireland, (ga) the Nursing and Midwifery Council. 	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The power enables the Welsh Ministers to require that members of a specified profession require a special procedures licence in order to practice one or more special procedures. It is the intention that the regulations are tailored to take account of the practices undertaken by individuals within each profession, and are developed in conjunction with the relevant regulatory bodies.</p> <p>For example, the regulations may provide that a member of a specified profession, (such as a chiropractor) may be required to obtain a special procedure licence in order to practice body piercing, electrolysis and tattooing, but will not be required to obtain a licence to practice acupuncture as the relevant regulatory body has determined that the practice of acupuncture is within the scope of practice of its members.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The Welsh Ministers will retain responsibility for the special procedures that exempt individuals can perform without a special procedure licence. As exempt individuals will perform special procedures without a licence, it is important to ensure they are only performed by individuals who are determined to be competent and acting within</p>	

their scope of practice as determined by their regulating body.

The regulations are also needed to provide flexibility and ensure that exemptions can be amended over time.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Exemption from the requirement to be licensed
BILL PART	Part 3
SECTION	49(3)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATION	
<p>This power enables the Welsh Ministers to make regulations specifying when a special procedures licence is not required by an individual in order for them to practice a specified special procedure. The list of special procedures is provided in Section 46 and comprises acupuncture, body piercing, electrolysis and tattooing.</p> <p>The Welsh Ministers will only be able to exempt an individual who is:</p> <p>(a) a member of a profession which is specified in or under regulations (but not a profession that is regulated by a body mentioned in paragraphs (a) to (ga) of Section 25(3) of the National Health Services Reform and Health Care Professions Act 2002) or who is a worker of a description specified in or under regulations; and</p> <p>(b) who is registered, in the capacity of a member of that profession or a worker of that description, in a qualifying register. A qualifying register is:</p> <ul style="list-style-type: none"> • a register maintained by the Health and Care Professions Council; or • a voluntary register that is accredited by the Professional Standards Authority for Health and Social Care under Section 25G of the National Health Service Reform and Health Care Professions Act 2002 or that is specified in or under regulations. 	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The regulations will enable the Welsh Ministers to provide that an individual, who is a member of a profession or is already registered with a qualifying register, is exempt from the requirement to obtain a special procedure licence in order to practice a specified special procedure.</p> <p>It is the intention that the regulations are tailored to take account of the practices undertaken by individuals within each profession and are developed in conjunction with the regulatory body/ registering authority. For example, it is the intention that a</p>	

physiotherapist who is a member of a register maintained by the Health and Care Professions Council will be exempt from the requirement to obtain a licence in order to practice acupuncture. It is also the intention for members of the British Acupuncture Council (BAcC) to be exempt from the requirement to obtain a licence to practice acupuncture (subject to the BAcC maintaining its accreditation with the Professional Standards Authority for Health and Social Care).

WHY THE REGULATION IS REQUIRED

The Welsh Ministers will retain responsibility for the special procedures that exempt individuals can perform without a special procedure licence. As exempt individuals will perform special procedures without a special procedures licence, it is important to ensure special procedures are only undertaken by individuals who are determined to be competent and acting within their scope of practice as determined by their regulating body or authority.

The regulations are also needed to provide flexibility and ensure that exemptions can be amended over time.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

Health and Care Professions Council: <http://www.hpc-uk.org/>
 Professional Standards Authority for Health and Social Care: <http://www.professionalstandards.org.uk/about-us>

REGULATIONS RELATING TO	Licensing criteria
BILL PART	Part 3
SECTION	51(1), 51(3), 51(4)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION/DIRECTIONS/GUIDANCE	
<p>These powers require the Welsh Ministers to prescribe in regulations the licensing criteria that must be met upon application for a special procedures licence in order for the application to be granted. The licensing criteria may relate to (among other things):</p> <ul style="list-style-type: none"> (a) an individual’s eligibility for a licence; (b) the premises or vehicle at or in which a special procedure is to be performed, or at or in which equipment or material used in the special procedure is to be stored or prepared (including, among other things, facilities available there and standards of hygiene); and (c) the equipment used in, or in connection with, the performance of a special procedure. <p>Regulations made under this Section may also require that the local authority undertakes an inspection of the premises or vehicle identified in the application before a licence is issued or renewed. This is to enable the local authority to determine the premises’ or vehicle’s compliance with the licensing criteria before a</p>	

licence is granted.

In addition, the regulations may make different provision for different descriptions of premises and vehicles, for different special procedures, and for the different circumstances in which a special procedure is performed. These circumstances may include the frequency, regularity or period during which a procedure is performed.

The licensing criteria may also address the basis upon which the special procedure will be performed (i.e. whether the special procedure is performed on a peripatetic basis, on a fixed site basis, on a mobile basis, on a temporary basis, or otherwise), and specify the requirements in relation to each practice. Further detail on the basis is provided in Section 77(3).

Before the regulations are made, Section 53 requires the Welsh Ministers to consider whether there are persons who appear to represent the interests of those likely to be affected by them, and if so to consult with them if appropriate. This will ensure that those who are affected by the regulations are consulted and have their views considered before they are put in place.

WHAT CAN THE REGULATION ACHIEVE?

The regulations will provide the Welsh Ministers with the ability to develop tailored and specific licensing criteria that relate to an individual special procedure, the location it is practiced from (i.e. a premises or vehicle), and the basis upon which it is performed. As the practice of special procedures varies significantly, the licensing criteria will be developed to take account of the variance. For example, it is expected that the licensing criteria will be different for an individual practicing tattooing from a single premises than those for a practitioner practicing acupuncture peripatetically.

It is the intention that the licensing criteria will specify the standards of competence that an individual must have in order to be granted a licence. For example, a requirement may be that the individual is able to demonstrate that they have specific knowledge or have undertaken training in relation to infection control in order to undertake the special procedure safely. The criteria may also relate to the equipment to be used in, or in connection with, the performance of a special procedure for example the presence of non-hand operated taps at the location from which special procedures will be performed.

It is therefore the intention to specify in these regulations the licensing criteria in relation to each type of practice. It is also the intention to address the licensing criteria required for performing special procedures during conventions in these regulations.

WHY THE REGULATION IS REQUIRED

In addition to the ability of the regulations to take account of the different special procedures and the different circumstances in which they are practiced, they will also provide consistency in relation to the licensing criteria and ensure that the same criteria are applied across Wales. The regulations will ensure that the requirements to be met by those applying for a special procedure licence are transparent and

obtainable.

The regulations are also needed to provide flexibility and ensure that the licensing criteria can be amended over time.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS	Mandatory licensing conditions
BILL PART	Part 3
SECTION	52(1), 52(3)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION/DIRECTIONS/GUIDANCE	
<p>Section 52 requires the Welsh Ministers to make regulations that set out the mandatory licensing conditions in relation to special procedure licences. The mandatory licensing conditions will detail the requirements that the holder of a special procedure licence must adhere to. The mandatory licensing conditions may relate to (among other things):</p> <ul style="list-style-type: none">(a) the premises or vehicle at or in which a special procedure is to be performed, or at or in which equipment or material used in a special procedure is to be stored or prepared;(b) the way in which a special procedure is to be performed (including, among other things, equipment used in connection with its performance, protective clothing etc.);(c) information to be provided by and to the licence holder, and consultation to be carried out before, and after a special procedure is performed;(d) record keeping;(e) displaying a licence;(f) circumstances in which an application for variation of a licence is to be made; and(g) the return of a licence, on its expiry, to the authority by which it was issued. <p>In addition, the regulations may make different provision for different descriptions of premises and vehicles, for different special procedures, and for the different circumstances in which a special procedure is performed. These circumstances may include the frequency, regularity or period during which a procedure is performed.</p> <p>Before the regulations are made, Section 53 requires the Welsh Ministers to consider whether there are persons who appear to represent the interests of those likely to be affected by them, and if so, to consult with them as appropriate. This will ensure that those who are affected by the regulations are consulted and have their views considered before the regulations are put in place.</p>	

WHAT CAN THE REGULATION ACHIEVE?

The policy intention is to ensure that the physical condition of the premises or vehicle used in connection with special procedures will not provide a risk of harm to human health. Details about how the licence holder must maintain their records, display their licence, the circumstances in which an application for variation of a licence is required, and how the licence must be returned on its expiry, will all be specified in the conditions.

The mandatory licensing conditions may also specify the way in which a specified special procedure is to be performed. This may include details about the equipment that should be used, how the procedure should be performed, and the requirements in relation to protective clothing to be worn by the licence holder. The provision of information by the licence holder to clients both before and after a special procedure is carried out may also be specified in the conditions.

It is the intention to specify in these regulations the mandatory licensing conditions in relation to each type of practice. It is also the intention to address the conditions governing practice of special procedures during conventions in these regulations.

WHY THE REGULATION IS REQUIRED

In addition to the ability of the regulations to take account of the different special procedures and the different circumstances in which they are practiced, the regulations will also provide consistency in relation to the mandatory licensing conditions and ensure that each local authority in Wales requires the same conditions in relation to specified special procedures. The regulations will also ensure that the requirements of those holding a special procedure licence are transparent and obtainable.

The regulations are also needed to provide flexibility and ensure that the licensing conditions can be amended over time.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Performance of special procedure In course of business: approval requirement
BILL PART	Part 3
SECTION	58(6)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>Section 58 establishes that a person carrying on a business, in the course of which a special procedure is performed, must comply with two approval requirements. The first requirement is that the procedure is performed at premises or in a vehicle that has been approved by the local authority under Section 59. The second requirement ensures that, once approved, a premises or vehicle complies with the applicable mandatory conditions of approval (provided for in secondary legislation - Section 59(3)(c)).</p> <p>This power provides the Welsh Ministers with the ability to make regulations to exempt certain premises or vehicles from the approval requirements.</p> <p>The premises or vehicle may be described in the regulations by way of reference to the persons by whom they are managed or controlled; the nature of activities carried on, at or in them; the different circumstances in which a special procedure is performed at or in them; or the number of individuals performing special procedures.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>This power will enable the Welsh Ministers to exempt specific premises or vehicles from either or both of the approval requirements. For example, the premises from which a special procedure is performed by an exempted individual may be exempt. The regulations may also provide that specific types of premises, such as GP surgeries or hospitals, are exempt from the requirement to be approved.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The Welsh Ministers will retain responsibility for determining which descriptions of premises and vehicles are exempt from the requirement to be approved. As the local authority will not be required to approve exempted premises or vehicles and will therefore have little or no role in overseeing the practice of special procedures from them, it is important to ensure special procedures are only undertaken in premises or vehicles that are deemed to be suitable.</p> <p>The regulations are also needed to provide flexibility and ensure that exemptions can be amended over time.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Approval of premises and vehicles in respect of performance of special procedure
BILL PART	Part 3
SECTION	59(3), 59(7), 59(8)
METHOD OF BRINGING INTO FORCE	59(3)- Affirmative 59(7), 59(8) - Negative
DESCRIPTION OF THE REGULATION	
<p>This Section requires the Welsh Ministers to make regulations in relation to the approval of premises and vehicles.</p> <p>Regulations made under Section 59(3) must cover the criteria to be met in order for the application to be granted, the circumstances in which an application for approval is to be granted, and the process for an applicant to appeal against a refusal of an application. In addition, the regulations will specify the conditions (the “mandatory approval conditions”) which must be complied with in order for an approval to be retained.</p> <p>Regulations made pursuant to Section 59(7) may also make provision about the way in which an application for approval is made and is dealt with (including the payment of a fee), the circumstances in which an application for approval must not be granted, or may be granted at the local authority’s discretion, and the process that will apply to the renewal of an approval.</p> <p>In addition, regulations made under Section 59 may make different provision for different descriptions of premises and vehicles; for different special procedures; and for the different circumstances in which a special procedure is performed.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The regulation-making power in Section 59(3) will allow the Welsh Ministers to make specific provision in relation to the performance of special procedures from premises and vehicles. As the regulations will enable the Welsh Ministers to take account of different descriptions of premises and vehicles, different descriptions of special procedures and different circumstances, the requirements specified by the regulations, including the criteria and mandatory approval conditions, may be tailored to the specific practice of special procedures. For example, the regulations may require that the premises has an adequate and constant supply of hot and cold running water, that there are suitable hand cleansing facilities (for example non-hand operated taps), and that any surface that may be contaminated with blood or other body fluids must be impermeable and suitable for effective cleaning.</p>	
WHY THE REGULATION IS REQUIRED	
<p>In addition to the ability of the regulations to take account of the different special procedures and the different circumstances in which they are practiced, the regulations will provide consistency in relation to approved premises and vehicles and ensure that each local authority in Wales has the same requirements in relation to specified special procedures. The regulations will also ensure that the</p>	

requirements in relation to approved premises and vehicles are transparent and obtainable.

The regulations are also needed to provide the flexibility required to respond to changing circumstances.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Adding or removing special procedures from the list
BILL PART	Part 3
SECTION	76(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATION	
<p>This power enables the Welsh Ministers to amend the list of special procedures in Section 46 by adding or removing a type or description of procedure to or from the list, or by varying a reference to a type or description of procedure.</p> <p>The procedure may be described by reference to (amongst other things) the individual who carries out the procedure, or the individual on whom it is carried out.</p> <p>In order for a procedure to be added to the list, the Welsh Ministers must consider that the procedure is capable of being performed for aesthetic or therapeutic purposes and the performance of the procedure for those purposes is capable of causing harm to human health. Harm to human health is defined in Section 77(4) and includes harm to an individual's physical or mental health.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>This power will enable the Welsh Ministers to amend the list of special procedures in future. The Welsh Ministers could use the power if it was clear that a specific procedure performed for aesthetic or therapeutic purposes was causing harm to human health. For example, due to the increase in popularity of tattooing, it may be the case that demand for tattoo removal procedures may soon increase. This power could therefore potentially be used to add tattoo removal to the list of special procedures in Section 46.</p>	
WHY THE REGULATION IS REQUIRED	
<p>It is possible that other procedures carried out for aesthetic or therapeutic purposes and with the potential to cause harm to human health exist or are being developed by the industry. The regulation-making power is required to enable the Welsh Ministers to react to developments within the special procedures sector, and ensure that the list of special procedures remains up to date and relevant. The power will</p>	

therefore ensure the licensing requirements take account of changing practices and trends, within a quickly evolving sector. It also therefore provides a mechanism for making appropriate amendments to the list more easily than amending primary legislation on each separate occasion.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

REGULATIONS RELATING TO	Interpretation of “body piercing”
BILL PART	Part 3
SECTION	77(1)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>This Section provides the Welsh Ministers with a power to amend the definition of “body piercing” by describing objects that may be implanted in an individual’s body.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The power will enable the Welsh Ministers to extend the definition of “body piercing” so that it captures the attachment of objects, other than jewellery to an individual’s body. Objects such as a “flesh plugs” may be inserted into the body to progressively stretch the skin, for example the ears. Therefore, the regulations may include “flesh plugs” so that these objects are included in the definition of “body piercing” in the future.</p>	
WHY THE REGULATION IS REQUIRED	
<p>There are a range of objects, other than jewellery, that may be attached to an individual’s body. In order for the definition of “body piercing” to remain effective and reflect the range of objects that may be implanted into the body, the regulation-making power is required to enable the Welsh Ministers to react to changing trends and ensure the definition remains up to date.</p> <p>The regulation-making power also therefore provides a mechanism for amending the definition more easily than by amending primary legislation, as this is a technical matter which may need updating from time to time.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

PART 4 - INTIMATE PIERCING

There are no provisions in this Part which provide for the production of subordinate legislation.

PART 5 - PHARMACEUTICAL SERVICES

REGULATIONS RELATING TO	The preparation and publication of an assessment of needs for pharmaceutical services in its area by a Local Health Board
BILL PART	Part 5
SECTION	89
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	
<p>This Section inserts Section 82A in to the National Health Service (Wales) Act 2006. Section 82A places a duty on Local Health Boards to prepare and publish an assessment of needs for pharmaceutical services in its area.</p> <p>Section 82A also includes a regulation-making power. The Welsh Ministers must by way of regulations, specify a date by which a Local Health Board is to prepare and publish its first assessment; make provision about the circumstances in which a Local Health Board should review and if appropriate revise its assessment; and make provision about the way in which an assessment is to be published.</p> <p>Regulations may make further provision about the preparation, publication, review and revision of an assessment, which could include things such as the information to be contained in the assessment, the extent to which the assessment should take account of future needs and of other matters, the requirements for consultation, and procedural requirements.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>The regulations will ensure that every Local Health Board has made and maintains an assessment of the needs for pharmaceutical services in its area.</p>	
WHY THE REGULATIONS ARE REQUIRED	
<p>The Welsh Ministers must make regulations that require each Local Health Board to make arrangements for the provision of pharmaceutical services to persons within its area by a specific date. In order to maximise the public health role of community pharmacies it is necessary for a Local Health Board to fully understand the need for pharmaceutical services within its area when making arrangements for their provision.</p> <p>The regulations will also provide consistency in relation to the pharmaceutical needs assessment and ensure that each Local Health Board in Wales provides the same level of information, and abide by the same procedural requirements.</p> <p>Providing further technical detail about the process surrounding the preparation of pharmaceutical needs assessment through regulations will provide appropriate flexibility for details of the process to be amended from time to time, without the need to amend primary legislation.</p>	

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)
N/A

REGULATIONS RELATING TO	The determination of applications by persons seeking to provide NHS pharmaceutical services within the area of a Local Health Board
BILL PART	Part 5
SECTION	90(3), (4), (5), (6), (7), (8), (10)
METHOD OF BRINGING INTO FORCE	Negative procedure
DESCRIPTION OF THE REGULATIONS	
<p>The powers within this Section relate to regulation-making powers currently located in Section 83 of the NHS (Wales) Act 2006. The provisions in this Section amend that existing regulation-making power.</p> <p>Section 90(3) inserts a new Section 2B in Section 83 of the National Health Service (Wales) Act 2006. Section 2B provides that unless specified otherwise in regulations, applications for inclusion on a pharmaceutical list by a person not already on a list, or applications by a person already included on a list for inclusion may only be granted if the Local Health Board is satisfied, if having regard to their most recent pharmaceutical needs assessment and to any matters specified in the regulations, that the granting the application would meet a need in its area for the services applied for.</p> <p>Section 90(7) gives the Welsh Ministers powers to make regulations which specify the circumstances in which a Local Health Board may invite persons to make an application for inclusion in a pharmaceutical list.</p> <p>Section 90(7) also enables the Welsh Ministers to make regulations that specify circumstances in which a Local Health Board may, or must, remove a person from its pharmaceutical list for breaches of a term or condition of arrangements made with the Local Health Board for the provision of pharmaceutical services. The regulations will place conditions on such a removal, in particular that before removing a person from the pharmaceutical list a Local Health Board must issue that person with a notice detailing the breach and the action required to remedy it, and that person has then failed to comply with that notice.</p> <p>Section 90(10) provides that if regulations made under Section 83 of the NHS (Wales) Act 2006 contain provisions about the removal or a person from a pharmaceutical list, the regulations must make provision about the giving of notice of a Local Health Board's intention to remove and the right to make representations.</p>	
WHAT CAN THE REGULATIONS ACHIEVE?	
<p>The regulations will ensure that the provision of pharmaceutical services is closely aligned to the needs of the citizens who use community pharmacies in Wales, in particular by ensuring that persons wishing to provide pharmaceutical services seek to do so in areas where a Local Health Board has identified a need for those services, and where necessary, by allowing Local Health Boards to issue invites to provide services in areas with unmet need.</p> <p>The regulations will also ensure that where, by breaching their terms of service,</p>	

persons providing pharmaceutical services fail to do so effectively, that the Local Health Board can take graduated action to improve the provision of pharmaceutical services. This will improve the consistency and quality of services.

WHY THE REGULATIONS ARE REQUIRED

The Welsh Ministers must make regulations that require each Local Health Boards to make arrangements for the provision of pharmaceutical services to persons within its area. In order to maximise the public health role of community pharmacies it is necessary for a Local Health Board to take account of the need for pharmaceutical services within its area when making arrangements for their provision, and for them to take action to remedy poor performance.

Providing further technical detail about the process for determining applications seeking to provide pharmaceutical services, and the process for removal from a pharmaceutical list, will provide appropriate flexibility for details of the process to be amended from time to time, without the need to amend primary legislation.

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

N/A

PART 6 - PROVISION OF TOILETS

There are no provisions in this Part that confer regulation-making powers on the Welsh Ministers.

PART 7 – GENERAL

REGULATIONS RELATING TO	Consequential and transitional provisions
BILL PART	7
SECTION	100(1)
METHOD OF BRINGING INTO FORCE	Negative or affirmative
DESCRIPTION OF THE REGULATION	
<p>Section 100(1) provides a regulation-making power to allow Welsh Ministers to make supplementary, incidental, or consequential provisions or any transitional, transitory or saving provisions as appropriate in connection with the Bill.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The regulations will permit the Welsh Ministers to make amendments to provisions as outlined above in order to give full effect to the provisions of the Bill</p>	
WHY THE REGULATION IS REQUIRED	
<p>These regulations are required to allow the Welsh Ministers to make supplementary, incidental, consequential, transitional or saving provisions if it is considered necessary for the purposes of giving full effect to the provisions of the Bill. Such changes would be relatively minor and making them through regulations will provide appropriate flexibility for such provisions to be made without the need to amend primary legislation.</p> <p>If the regulations amend or repeal any provision of an Act of Parliament or Measure or Act of the National Assembly for Wales, then they will be subject to the affirmative procedure. Otherwise, they will be subject to the negative procedure.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Commencement provisions
BILL PART	7
SECTION	101(2)
METHOD OF BRINGING INTO FORCE	No procedure applicable to commencement order
DESCRIPTION OF THE POWER	
<p>Section 101(2) provides that the Welsh Ministers may appoint by order that provisions not listed in Section 101(1) shall to come into force on a specified date.</p> <p>Section 101(1) provides that the following Sections will come into force on the day Royal Assent is received:</p> <ul style="list-style-type: none"> • Section 1; • Sections 96 to 100; • Section 101; and • Section 102. <p>The enforcement date for the remaining Sections will be determined by Welsh Ministers by statutory instrument.</p>	
WHAT CAN THE POWER ACHIEVE?	
<p>The power will enable the Welsh Ministers to appoint by order a date other than that of Royal Assent for some of the Bill's provisions to come into force.</p>	
WHY THE POWER IS REQUIRED	
<p>This power is required to allow the Welsh Ministers to set commencement dates by order, as noted above. Such orders will be confined to commencement and are technical in nature.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

SCHEDULE 1 – FIXED PENALTIES

REGULATIONS RELATING TO	Provisions on content and form of Fixed Penalty Notices
BILL PART	Schedule 1
SECTION	Paragraph 5
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>Schedule 1 makes provision about the fixed penalty notices that may be issued for offences under Chapter 1 of Part 2 (smoking and use of nicotine inhaling devices) and Chapter 2 of Part 2 (register of retailers of tobacco and nicotine products), including requirements relating to content. Paragraph 5 of Schedule 1 provides the Welsh Ministers with the power to make further provision in relation to the details that a fixed penalty notice must contain. The regulations will also state the form in which a fixed penalty notice must be issued.</p>	
WHAT CAN THE POWER ACHIEVE?	
<p>The regulations will state the form of a fixed penalty notice issued in relation to Part 2, Chapter 1 (Smoking and use of nicotine inhaling devices) and Part 2, Chapter 2 (Retailers of tobacco and nicotine products). The regulations can also make further provision about the content required on the fixed penalty notice.</p>	
WHY THE REGULATION IS REQUIRED	
<p>This power is required in order to ensure that the information included on the fixed penalty notice remains accurate. This will enable the Welsh Ministers to include additional information to be included on the fixed penalty notice if required.</p> <p>In addition, should it become necessary to include additional information on the fixed penalty notice, the penalty form will have to be amended. In order to achieve this, the Welsh Ministers will require regulation-making powers relating to the penalty form.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
<p>Schedule 1 to the Health Act 2006 makes provision about fixed penalty notices in relation to existing smoke-free offences. Paragraph 4 of that Schedule gives powers to the Welsh Ministers to specify the form of the penalty notice in regulations. The Schedule to the Smoke-free Premises etc. (Wales) Regulations 2007 sets out the fixed penalty notice forms for existing smoke-free offences.</p> <p>The Schedule to the Smoke-free Premises etc. (Wales) Regulations 2007 continues to apply until such time as the Welsh Ministers use these regulation-making powers.</p>	

REGULATIONS RELATING TO	Amount of penalty for fixed penalty notices
BILL PART	Schedule 1
SECTION	Paragraph 6
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION	
<p>Schedule 1 covers fixed penalty notices. Paragraph 6 of Schedule 1 provides the Welsh Ministers with the power to make regulations to prescribe the amount set for a fixed penalty notice issued for the offences below.</p> <p>Part 2, Chapter 1 (smoking and use of nicotine inhaling devices)</p> <ul style="list-style-type: none"> • Smoking or use of a nicotine inhaling device in smoke-free premises or a smoke-free vehicle. • Not displaying signs in smoke-free premises or a smoke-free vehicle. • Failing to take reasonable steps to cause a person to stop smoking or using a nicotine inhaling device in any smoke-free private vehicles. <p>Part 2, Chapter 2 (retailers of tobacco and nicotine products)</p> <ul style="list-style-type: none"> • A registered person carrying on a tobacco or nicotine business at premises in Wales other than those stated in the person's entry in the register. • A registered person carrying on a tobacco or nicotine business at premises consisting of a moveable structure, a stall, a tent or a vehicle in the area of a local authority other than one stated in the persons entry on the register. • A person who fails, without reasonable excuse, to comply with Section 25 (duty to notify certain changes). 	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulation-making power will allow the Welsh Ministers to set fixed penalty notice levels across the relevant offences in Part 1, Chapters 1 and 2 to ensure consistency across the requirements regarding smoking and use of nicotine inhaling devices, and to consider appropriate levels for all offences.</p>	
WHY THE REGULATION IS REQUIRED	
<p>This power is required as there could be a requirement in the future to alter the penalties linked to the offences above. Taking a regulation-making-power through an affirmative process is therefore the most appropriate way to meet this requirement, as this provides an appropriate level of flexibility whilst also providing additional security that the amount set for fixed penalty notices will not be determined without full consideration and opportunity for debate.</p> <p>.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

Schedule 1 to the Health Act 2006 makes provision about fixed penalty notices in relation to existing smoke-free offences. Paragraph 5 of that Schedule gives the Secretary of State powers to specify the amount of the penalty in regulations. Regulation 2 of the Smoke-free (Penalties and Discounted Amounts) Regulations 2007 sets out the penalty amounts for existing smoke-free offences. These are:

- £200 (discounted to £150) for offences relating to failure to display smoke-free signs; and,
- £50 (discounted to £30) for offences relating to smoking in a smoke-free place.

The Smoke-free (Penalties and Discounted Amounts) Regulations 2007 continue to apply in Wales until such time as the Welsh Ministers use these regulation-making powers.

REGULATIONS RELATING TO	Discounted amount of penalty for fixed penalty notices
BILL PART	Schedule 1
SECTION	Paragraph 9
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE POWER/REGULATION	
<p>Schedule 1 of the Public Health Bill covers fixed penalty notices. Paragraph 9 of Schedule 1 provides the Welsh Ministers with the power to make regulations to state the discounted penalty for a fixed penalty notice issued for the offences below.</p> <p>Part 2, Chapter 1 (smoking and use of nicotine inhaling devices)</p> <ul style="list-style-type: none"> • Smoking and use of a nicotine inhaling device in smoke-free premises or a smoke-free vehicle. • Not displaying signs in smoke-free premises or a smoke-free vehicle. • Failing to take reasonable steps to cause a person to stop smoking or using a nicotine inhaling device in any smoke-free private vehicles. <p>Part 2, Chapter 2 (retailers of tobacco and nicotine products)</p> <ul style="list-style-type: none"> • A registered person carrying on a tobacco or nicotine business at premises in Wales other than those stated in the person's entry in the register. • A registered person carrying on a tobacco or nicotine business at premises consisting of a moveable structure, a stall, a tent or a vehicle in the area of a local authority other than one stated in the persons entry on the register. • A person who fails, without reasonable excuse, to comply with Section 25 (duty to notify certain changes). <p>A discounted amount is payable if the penalty is paid within 15 days, beginning with the day the fixed penalty notice is issued.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulation-making power will allow Welsh Ministers to set fixed penalty notice levels across the relevant offences in Part 2, Chapters 1 and 2 to ensure consistency across the requirements regarding smoking and use of nicotine inhaling devices, and to consider appropriate levels for all offences.</p>	
WHY THE REGULATION IS REQUIRED	
<p>This power is required as there could be a requirement in the future to alter the penalties linked to the offences above. If the penalty amount is changed then there may be a requirement to alter the discounted amount as well. In addition, there may be a requirement to only change the discounted amount (for example if it is considered that the discounted amount is not sufficient to encourage prompt payment). Taking a regulation-making power through an affirmative process is the most appropriate way to meet this requirement, as this provides an appropriate level of flexibility whilst also providing additional security that the discounted amount set for fixed penalty notices will not be determined without full consideration and opportunity for debate.</p>	

Other relevant information (work done to date, policy documents, Ministerial Statements etc.)

Schedule 1 to the Health Act 2006 makes provision about fixed penalty notices in relation to existing smoke-free offences. Paragraph 8 of that Schedule gives the Secretary of State powers to specify the amount of the discounted penalty in regulations. Regulation 2 of the Smoke-free (Penalties and Discounted Amounts) Regulations 2007 sets out the penalty amounts for existing smoke-free offences. These are:

- £200 (discounted to £150) for offences relating to failure to display smoke-free signs; and,
- £50 (discounted to £30) for offences relating to smoking in a smoke-free place.

The Smoke-free (Penalties and Discounted Amounts) Regulations 2007 continue to apply in Wales until such time as the Welsh Ministers use these regulation-making powers.

**SCHEDULE 2 – SMOKING AND NICOTINE INHALING DEVICES:
CONSEQUENTIAL AMENDMENTS**

REGULATIONS RELATING TO	Fixed penalty notices
BILL PART	Schedule 2
SECTION	Paragraph 17(2)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	
<p>Section 91 of the Children and Families Act 2014 makes Schedule 1 to the Health Act 2006, which covers fixed penalty notices (FPNs), applicable in relation to the offence of the purchase of tobacco etc. on behalf of persons under 18 (the so called “proxy purchase” offence).</p> <p>However, paragraph 15 of Schedule 2 to the Public Health (Wales) Bill amends paragraph 4 of Schedule 1 to the Health Act 2006, such that the reference to “appropriate national authority” is changed to “Secretary of State”. Thus the power in the Health Act 2006 to specify in regulations the form of the FPNs becomes applicable to England only.</p> <p>The consequential amendment at Paragraph 17(2) of Schedule 2 further amends Schedule 1 to the Health Act 2006 so as to retain the Welsh Ministers’ powers to specify in regulations the form of the FPN in relation to the proxy purchase offence.</p>	
WHAT CAN THE REGULATION POWER ACHIEVE?	
<p>The regulation-making power enables the Welsh Ministers to prescribe in regulations the form of the FPN in relation to the proxy purchase offence.</p>	
WHY THE REGULATION IS REQUIRED	
<p>Without this regulation-making power, the repeal of Part 1 of Chapter 1 of the Health Act 2006 in relation to Wales would remove the power for the Welsh Ministers to prescribe in regulations the form of the FPN in relation to the proxy purchase offence, powers for which are provided by Section 91 of the Children and Families Act 2014.</p> <p>Whilst the proxy purchase offence is not directly relevant to the content of the Bill, Paragraph 17(2) of Schedule 2 is required to maintain the status quo in relation to the Welsh Ministers’ powers to prescribe the form of the FPN for the proxy purchase offence. This consequential amendment does not, therefore, constitute additional powers for the Welsh Ministers.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

Regulations on the form of the FPN for the proxy purchase offence, drafted under the provisions of the Health Act 2006, will be laid shortly and will come into force on 1st October 2015.

These regulations, once in force, will continue to apply until such time as the Welsh Ministers use these regulation-making powers.

SCHEDULE 3 – FURTHER PROVISION IN CONNECTION WITH SPECIAL PROCEDURE LICENCES

REGULATIONS RELATING TO	Application for special procedure licence
BILL PART	Schedule 3
SECTION	Paragraph 4(4)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>Paragraphs 1-4 of Schedule 3 provide details of the process that an applicant for a special procedure licence must follow, including the information that they must provide to the local authority to obtain a licence. This information includes the special procedure(s) to which the application relates, and details on the basis that the procedure is to be performed (for example, a peripatetic basis).</p> <p>Paragraph 4(4) enables the Welsh Ministers to make regulations to make further provision about the procedure that the local authority must follow in dealing with an application for a special procedure licence, which could include any additional information that is to be included in an application.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The power enables the Welsh Ministers to prescribe the process that the local authority must follow in dealing with an application for a special procedure licence. For example, the regulations may establish the timeframe within which the local authority must determine the application and how they must inform the applicant of their decision. The regulations could also require that additional information is supplied with an application, such as a photograph of the applicant.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The power is required to ensure that applications for a special procedure licence are dealt with consistently by local authorities. The power also provides the Welsh Ministers with the flexibility to respond to different circumstances or changes in practice. For example, whilst a special procedure licence must bear a photograph of the licence holder, the process by which the photograph is supplied to the local authority may vary depending upon the facilities available within the local authority. Some local authorities may have photography facilities, whereas others may require a passport style photograph to be supplied by the applicant. The regulations will therefore enable provision to be made to take account of this type of variation.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

REGULATIONS RELATING TO	Contents of special procedure licence
BILL PART	Schedule 3
SECTION	Paragraph 5(3)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>Paragraph 5 of Schedule 3 specifies the content of a special procedures licence. The licence must, amongst other things, state the name of the licence holder, name the authority by which the licence is issued and the special procedure that is authorised by the licence.</p> <p>Paragraph 5(3) provides the Welsh Ministers with a regulation-making power to make further provision about the form and contents of special procedure licences.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The power will enable the Welsh Ministers to specify further details in relation to special procedures licences. For example, the form of the licence (i.e. its dimensions and style) may be prescribed so that all special procedures licences issued in Wales have a consistent appearance and are recognisable by the public.</p> <p>The regulations may also specify the content of the licence, for example whether it contains a special procedure licence number, or information about the applicable mandatory licensing conditions that the holder of the licence must adhere to. For example, the licence may specify that the licence holder is only permitted to undertake body piercing of the ear using a “hygienic piercing instrument” or is only permitted to practice acupuncture if they use single-use needles.</p>	
WHY THE REGULATION IS REQUIRED	
<p>The regulations will provide the Welsh Ministers with the ability to adapt the form and contents of the special procedure licence to changing circumstances. In addition, it is expected that the information to be contained on the licence in relation to the mandatory licensing conditions is likely to be dependent upon the conditions developed under Section 52; therefore flexibility is required in these regulations.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

REGULATIONS RELATING TO	Delegation of functions
BILL PART	Schedule 3
SECTION	Paragraph 20(4)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	
<p>Paragraph 20 of Schedule 3 delegates the specified functions of a local authority to its licensing committee. This allows the licensing committee to make the decisions in relation to those functions listed under paragraph 20 (1).</p> <p>Paragraph 20(4) provides the Welsh Ministers with a regulation-making power to make provision about the procedures applicable to licensing committees and their sub-committees for the purpose of the exercise of the delegated functions under this paragraph, including public access and the availability of records. Subject to any regulations made by the Welsh Ministers, paragraph 20(5) enables each licensing committee and its sub-committees to regulate its own procedure.</p>	
WHAT CAN THE REGULATION ACHIEVE?	
<p>The regulation-making power enables the Welsh Ministers to require that the licensing committee or sub-committee considering cases in relation to Part 3 of the Bill (for example, the refusal of an application for a special procedure licence) has specified procedures in place. The regulations may therefore require that the committee has procedures in place to take valid decisions (for example the number of committee members required to take a valid decision), and to ensure the public has access to committee proceedings and its records.</p>	
WHY THE REGULATION IS REQUIRED	
<p>Ensuring the licensing committee has provisions in place to ensure proper exercise its functions will provide transparency in relation to the local authority's exercise of their powers under this Part. The regulations will also ensure that a consistent approach to the consideration of cases in relation to provisions in this Part is adopted by all local authorities in Wales.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	

Schedule 4 – Provision of toilets: consequential amendments

There are no provisions that confer powers on the Welsh Ministers to make subordinate legislation in Schedule 4 to the Bill.

OTHER SECONDARY LEGISLATION

PART 6 – PROVISION OF TOILETS

GUIDANCE RELATING TO	Delegation of functions
BILL PART	Part 6
SECTION	91(8)
METHOD OF BRINGING INTO FORCE	Guidance
DESCRIPTION OF THE GUIDANCE	
<p>Section 91 requires a local authority to prepare and publish a local toilets strategy. To assist local authorities with their duty, the Welsh Ministers may issue guidance to local authorities about the matters which they should take into consideration when preparing, reviewing or publishing a local toilets strategy. A local authority must have regard to any guidance issued.</p>	
WHAT CAN THE GUIDANCE ACHIEVE?	
<p>It is intended that the guidance will comprehensively cover the issues that local authorities may wish to consider when preparing, reviewing or publishing their local toilets strategy. The guidance will provide information on the mechanisms the local authority could employ to assess the need for toilets in their area, as well as suggested parties that are likely to be interested in the provision of local toilets. The guidance will also provide information on the methods by which the local authority could publicise those toilets that are available in their area for use by the public.</p>	
WHY THE GUIDANCE IS REQUIRED	
<p>The power enables the Welsh Ministers to issue guidance in relation to local toilets strategies and provide details upon the issues the local authority should take into consideration when preparing, reviewing or publishing a local toilets strategy.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
N/A	

REGULATIONS RELATING TO	Power to make byelaws in relation to toilets
BILL PART	Part 6
SECTION	94(1)
DESCRIPTION OF THE BYELAWS?	
<p>Section 93(1) enables a local authority (including a community council) to provide toilets in its area for use by the public. Section 94(1) provides these authorities with the power to make byelaws in relation to the conduct of persons using or entering any toilets provided by them.</p>	
WHAT CAN THE BYELAWS ACHIEVE?	
<p>The byelaws powers are exercisable by local authorities and may be introduced by them if they see fit to do so. The byelaws enable the local authority to make provision about the conduct of persons using or entering any toilets provided by them, and enable the local authority to take action (by way of issuing a fixed penalty notice) for contravention of the byelaws. An example of the conduct that may be specified in the byelaws is that no person is permitted to write on or deface the toilet; a person also must not affix any picture or written material to it.</p>	
WHY THE BYELAW-MAKING IS REQUIRED	
<p>Section 93(1) restates the existing byelaw-making power provided to local authorities (including community councils) in Wales by Section 87 of the Public Health Act 1936. The process to make these byelaws is to be provided by the Local Government Byelaws (Wales) Act 2012.</p>	
Other relevant information (work done to date, policy documents, Ministerial Statements etc.)	
<p>Local Government Byelaws (Wales) Act 2012 - http://www.legislation.gov.uk/anaw/2012/2/contents/enacted</p>	