

PUBLIC HEALTH (WALES) BILL

Statement of Policy Intent for Subordinate Legislation

November 2016

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STATEMENT OF POLICY INTENT FOR SUBORDINATE LEGISLATION

This document provides an indication of the current policy intention for the subordinate legislation that 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:

- Re-state restrictions on smoking in enclosed and substantially enclosed public and work places, and give Welsh Ministers a regulation-making power to extend the restrictions on smoking to additional premises or vehicles;
- Place restrictions on smoking in school grounds, hospital grounds and public playgrounds;
- Provide for the creation of a national register of retailers of tobacco and nicotine products;
- Provide Welsh Ministers with a regulation-making power to add to the offences which contribute to a Restricted Premises Order (RPO) 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 practitioners and businesses carrying out "special procedures" (namely, acupuncture, body piercing, electrolysis and tattooing);
- Introduce a prohibition on the intimate piercing of persons under the age of 16 years;
- Require Welsh Ministers to make regulations to require public bodies to carry out health impact assessments in specified circumstances;
- Change the arrangements for determining applications for entry onto the pharmaceutical list of health boards (LHBs), to a system based on the pharmaceutical needs of local communities;
- Require local authorities to prepare a local toilets strategy to plan how they will meet the needs of their communities for accessing toilet facilities for public use: and
- Enable a 'food authority' under the Food Hygiene Rating (Wales) Act 2013 to retain fixed penalty receipts resulting from offences under that Act, for the purpose of enforcing the food hygiene rating scheme.

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

REGULATIONS RELATING TO	Duties regarding additional smoke- free premises and smoke-free vehicles
BILL PART	Chapter 1 of Part 2
SECTION	4(2)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

Section 4(1) requires managers of smoke-free workplaces and public premises to take reasonable steps to prevent smoking in those premises.

The power, in Section 4(2), enables Welsh Ministers to make regulations to place corresponding duties on a person or description of person in respect of premises in Sections 7, 8 or 9 of the Bill, and any additional smoke-free premises (designated by virtue of Section 10) and smoke-free vehicles (designated by virtue of Section 12) designated by Welsh Ministers.

WHAT CAN THE REGULATIONS ACHIEVE?

This power enables Welsh Ministers to place a duty on managers of school grounds, hospital grounds and public playgrounds, any additional smoke-free premises and those responsible for smoke-free vehicles in Wales to take reasonable steps to prevent smoking in their premises/vehicles. 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.

When placing a restriction on smoking in school grounds, hospital grounds and public playgrounds on the face of the Bill, consideration was given to placing a duty on managers of those places in Wales to take reasonable steps to prevent smoking in the grounds for which they are responsible. It was decided not to place such a duty on the face of the Bill due to the extensive and dispersed nature of such places.

In relation to smoke-free vehicles, the Health Act 2006 and the Smoke-free Premises etc. (Wales) Regulations 2007 (as amended by the Smoke-free Premises etc. (Wales) (Amendment) Regulations 2015) 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. In relation to any additional smoke-free premises designated under Section 10, it is also intended to decide on a case by case basis whether or not to place the duty on the manager of those premises.

WHY THE REGULATIONS ARE REQUIRED

This power is required to create the offence of failing to prevent a person from smoking in any additional smoke-free premises and smoke-free vehicles designated

by regulations, or to extend the offence to school grounds, hospital grounds and public playgrounds if it becomes necessary to support enforcement. This will enable enforcement 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 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 (as amended by the Smoke-free Premises etc. (Wales) (Amendment) Regulations 2015).

REGULATIONS RELATING TO	Conditions to be met if choosing to
	designate an area of school grounds in
	which smoking is permitted.
BILL PART	Chapter 1 of Part 2
SECTION	7(6)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

Section 7(5) allows a person in charge of a school in Wales which provides residential accommodation for pupils, to designate an area of the grounds where smoking would be allowed. This power, in section 7(6), enables Welsh Ministers to make regulations specifying conditions relating to any such designation.

WHAT CAN THE REGULATIONS ACHIEVE?

This power enables Welsh Ministers to specify conditions in which a person in charge of a school may designate a smoking area in the grounds. For example, conditions could include the size or location of the designated area, and the specific times at which it applies.

Regulations made under Section 7(6) can also require the person in charge to keep records about any such designation, and can set out the circumstances in which a designation is to cease to have effect.

This will ensure that whole grounds cannot be deemed to be not smoke-free, and that smoking areas cannot be applied in an ad-hoc way.

It is the current policy intention that there will be no obligation on the person in charge of the school grounds to designate areas where the smoke-free requirements do not apply. The power is included so that the person in charge has the freedom to designate a smoking area if required, for example if (s)he feels that pupils in residential schools over the age of 18 are being put in danger as a result of leaving the school grounds to smoke.

WHY THE REGULATIONS ARE REQUIRED?

This power may be used to add clarity to the smoke-free regime in school grounds that provide residential accommodation for pupils, so that managers may designate smoking areas (if they so wish) in a consistent way.

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

REGULATIONS RELATING TO	Conditions to be met if choosing to designate an area of hospital grounds in which smoking is permitted.
BILL PART	Chapter 1 of Part 2
SECTION	8(5)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

Section 8(4) allows a person in charge of a hospital in Wales to designate an area where smoking would be allowed. This power, in section 8(5), enables Welsh Ministers to make regulations specifying conditions relating to any such designation.

WHAT CAN THE REGULATIONS ACHIEVE?

This power enables Welsh Ministers to specify conditions in which a person in charge of a hospital may designate a smoking area in the grounds. For example, conditions could include the size or location of the designated area, and the specific times at which it applies.

Regulations made under Section 8(5) can also require the person in charge to keep records about any such designation, and can set out the circumstances in which a designation is to cease to have effect.

This will ensure that whole grounds cannot be deemed to be not smoke-free, and that smoking areas cannot be applied in an ad hoc way.

It is the current policy intention that there will be no obligation on the person in charge of the hospital grounds to designate areas where the smoke-free requirements do not apply. The power is included so that the person in charge has the freedom to designate a smoking area if required, for example if (s)he feels that staff or patients are being put in danger as a result of leaving the hospital grounds to smoke.

WHY THE REGULATIONS ARE REQUIRED?

This power may be used to add clarity to the smoke-free regime in hospital grounds so that managers may designate smoking areas (if they so wish) in a consistent way.

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

REGULATIONS RELATING TO	Additional smoke-free premises
BILL PART	Chapter 1 of Part 2
SECTION	10(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

This power permits 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 but must not already be designated as smoke-free by the Bill. Being 'smoke-free' in these provisions means that smoking is not permitted, unless an exemption applies. The regulations allow 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.

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 is to be permitted. The designation would have to be in accordance with any conditions set out in the regulations.

Under this power, the additional smoke-free premises may not be a private dwelling (NB. private dwellings being used as a workplace are covered by Section 5).

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.

WHAT CAN THE REGULATIONS ACHIEVE?

This power will allow 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 in addition to school grounds, hospital grounds and public playgrounds which are introduced by Sections 7, 8 and 9 of the Bill. This could cover a range of settings – previous suggestions for future smoke-free areas have included beaches, open café areas where food is being eaten, college and university grounds, and outside school gates.

The regulation-making power enables 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.

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 Welsh Ministers. Any designation would have to comply with specific requirements in the regulations.

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

Section 11 limits Welsh Ministers' power under Section 10(1) to designate dwellings as additional smoke-free premises. Dwellings may only be designated as smoke-free by Welsh Ministers to the extent that they are not enclosed or substantially enclosed and are workplaces or open to the public, and may only be made smoke-free during the times that a person under the age 18 is present.

WHY THE REGULATIONS ARE REQUIRED

This power is required to continue to ensure that smoking behaviours are not renormalised by permitting smoking 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 Welsh Ministers may designate an additional smoke-free place 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 but Welsh Ministers have not used this power.

REGULATIONS RELATING TO	Smoke-free vehicles
BILL PART	Chapter 1 of Part 2
SECTION	12(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

This power permits Welsh Ministers to make regulations providing for vehicles to be smoke-free. It enables 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. 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 is prohibited in a smoke-free vehicle, unless Welsh Ministers make regulations to provide for exemptions.

WHAT CAN THE REGULATIONS ACHIEVE?

This power will allow 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.

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.

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, or unless the private rental includes a driver, in which case the rental is a workplace and so should be smoke-free.

WHY THE REGULATIONS ARE REQUIRED?

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 (for example buses), vehicles that are workplaces (for example taxis), and private vehicles carrying persons under the age of 18.

The restatement of the Health Act 2006 creates a need to re-establish the smokefree regime for vehicles. This power permits Welsh Ministers to do this.

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

Section 95 of the Children and Families Act 2014 amended Section 5 of the Health Act 2006 to provide enabling powers for Welsh Ministers to make regulations to prohibit smoking in private vehicles carrying persons under the age of 18. This power was used to make the Smoke-free Premises etc. (Wales) (Amendment) Regulations 2015.

Regulations made under the 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	13(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

This power allows Welsh Ministers to make regulations to exempt premises, or specified areas within premises in Wales, from the requirement to be smoke-free.

WHAT CAN THE REGULATIONS ACHIEVE?

This power will enable Welsh Ministers to allow smoking 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.

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. A temporary exemption for prison cells was inserted into these regulations by The Smoke-free Premises etc. (Wales) (Amendment) Regulations 2016.

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 when regulations are made under this power. It is also the intention to retain all other existing exemptions, apart from the exemption for prison cells which is due to expire on 5 April 2017.

It is not currently intended to provide any further exemptions for workplaces and public premises additional to those already provided for by the Smoke-free Premises etc. (Wales) Regulations 2007.

WHY THE REGULATIONS ARE REQUIRED?

This power is required to enable 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. 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. 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 temporary exemption for prison cells, inserted into these regulations by The Smoke-free Premises etc. (Wales) (Amendment) Regulations 2016, will cease on 5 April 2017.

REGULATIONS RELATING TO	Smoke-free signs
BILL PART	Chapter 1 of Part 2
SECTION	14(1)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	

This power permits 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.

WHAT CAN THE REGULATIONS ACHIEVE?

Smoke-free signs communicate the requirement to refrain from smoking in smoke-free premises, places and vehicles. This power will enable Welsh Ministers to make regulations detailing the technical specification of smoke-free signs. This will ensure consistency in the signs displayed.

The intention is to specify requirements for signs in respect of the obligation to refrain from smoking. 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, school grounds, hospital grounds and public playgrounds, or on other non-enclosed or non-substantially enclosed smoke-free premises (referred to as "additional smoke-free premises" in the Bill).

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.

The requirements for the signs to be displayed in non-enclosed or non-substantially enclosed smoke-free premises by virtue of Sections 7, 8 and 9, and by regulations made under Section 10, 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.

In addition, separate signs are required to communicate exemptions from the smokefree regime, for example, managers of school grounds and hospital grounds may designate an outside smoking area. Regulations may include requirements relating to such signs.

Regulations made under this section cannot require smoke-free signs to be

displayed in premises used as dwellings.

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 in 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 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.

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 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	14(3)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

Section 14(1) requires those who occupy or manage smoke-free public premises or workplaces, school grounds, hospital grounds or public playgrounds, to display smoke-free signs. The power in Section 14(3) permits 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 10) and smoke-free vehicles (designated by virtue of Section 12).

WHAT CAN THE REGULATIONS ACHIEVE?

Smoke-free signs will communicate the requirement to refrain from smoking in smoke-free premises in Wales.

This power will enable Welsh Ministers to require managers or occupiers of additional smoke-free premises and smoke-free vehicles to display smoke-free signs.

Should Welsh Ministers make regulations under Section 10 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.

There is no intention to change the requirement under Regulation 6 of the Smoke-free Premises etc. (Wales) Regulations 2007, which 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 also no intention to change the position in relation to the Smoke-free Premises etc. (Wales) (Amendment) Regulations 2015, relating to smoking in cars carrying those under 18, which does not include a requirement to provide signage.

Regulations made under this section cannot require smoke-free signs to be displayed in premises used as dwellings.

WHY THE REGULATIONS ARE REQUIRED?

This power is needed to enable 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 therefore used for regulations made under Section 14(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.

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

Section 6(2) of the Health Act 2006 provides 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 made by virtue of 14(1) will provide requirements, for the first time, for signs to be displayed in places which are not enclosed or substantially enclosed.

REGULATIONS RELATING TO	Enforcement authorities
BILL PART	Chapter 1 of Part 2
SECTION	15(1)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	

This power requires 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.

WHAT CAN THE REGULATIONS ACHIEVE?

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, school grounds, hospital grounds and public playgrounds, as well as any additional smoke-free premises. Section 15(4) permits the designated enforcement authority to make arrangements with another enforcement authority for a case it is dealing with to be taken over by that authority.

WHY THE REGULATIONS ARE REQUIRED?

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.

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

Section 10(1) of the Health Act 2006 provides Welsh Ministers with powers to make regulations to designate the bodies or descriptions of bodies 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.

For smoke-free private vehicles carrying persons under the age of 18, the Smoke-free Premises etc. (Wales) (Amendment) Regulations 2015 designate the Police in addition to county and county borough councils in Wales as the relevant enforcement authority.

REGULATIONS RELATING TO	The meaning of "enclosed",
	"substantially enclosed" and "not
	enclosed or substantially enclosed" in
	relation to smoke-free premises
BILL PART	Chapter 1 of Part 2
SECTION	25(7)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

This power permits Welsh Ministers to make regulations to define what is meant by the terms "enclosed", "substantially enclosed" and "not enclosed or substantially enclosed" in relation to smoke-free places.

WHAT CAN THE REGULATIONS ACHIEVE?

The power enables Welsh Ministers to clarify which areas of workplaces and premises open to the public are required to be smoke-free.

WHY THE REGULATIONS ARE REQUIRED?

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", "substantially enclosed" and "not enclosed or substantially enclosed".

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

Section 2(5) of the Health Act 2006 provides Welsh Ministers with powers to make regulations that specify what "enclosed" and "substantially enclosed" means. 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.

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	27(2)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	

Section 27 of the Bill places a duty on the registration authority to maintain a register of retailers of tobacco and nicotine products.

This power will allow Welsh Ministers to make regulations to specify which organisation will undertake the role of the registration authority. Section 27(8) provides that the regulations can specify Welsh Ministers as the registration authority. This may be required to ensure the register remains operational.

WHAT CAN THE REGULATIONS ACHIEVE?

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.

WHY THE REGULATIONS ARE REQUIRED

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.

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 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 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.

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

N/A

REGULATIONS RELATING TO	The application form for the register of
	retailers of tobacco and nicotine
	products, information contained within
	the form and accompanying fee.
BILL PART	Chapter 2 of Part 2
SECTION	28(3)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	

Section 28 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.

This power will enable Welsh Ministers to provide details about 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.

Before making any regulations under section 28(3), Welsh Ministers must consider whether there are persons who are likely to be affected by the regulations, and carry out a consultation with any representative persons whom they consider it appropriate to consult.

WHAT CAN THE REGULATIONS ACHIEVE?

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.

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 and nicotine products by persons under 18.

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.

WHY THE REGULATIONS ARE REQUIRED

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.

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	31(6)	
METHOD OF BRINGING INTO FORCE	Negative	
DESCRIPTION OF THE REGULATIONS		

Section 31 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;

- 1. upon receiving notice from a registered person to revise the register, in respect of matters detailed in Section 30(1); or
- 2. to correct any inaccuracies in the register of which it becomes aware, other than by notification by a registered person.

Section 31 outlines the process the registration authority must follow when revising the register.

The power in Section 31(6) will enable Welsh Ministers to make regulations to allow the registration authority to charge a fee in connection with making revisions to the register.

WHAT CAN THE REGULATIONS ACHIEVE?

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.

WHY THE REGULATIONS ARE REQUIRED

When the register initially becomes operational, it is intended that any revisions made to it will not incur a fee. However, it may be necessary to review this position and consider charging 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.

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

N/A

REGULATIONS RELATING TO	To allow Welsh Ministers to exclude
	certain premises from the requirement to
	register.
BILL PART	Chapter 2 of Part 2
SECTION	33
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGILL ATIONS	

Section 33 of the Bill provides that regulations can be made which would exempt certain premises from the requirement to be listed on the register of retailers of tobacco and nicotine products.

The regulations will set out the types of premises that would be exempt.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations will specify the premises where the exemption would apply, resulting in the retailers not being required to register.

WHY THE REGULATIONS ARE REQUIRED

Some retailers are not in a position to sell tobacco or nicotine products to anyone under the age of 18. The power will enable Welsh Ministers to exempt such premises, for example tobacco wholesalers who do not sell tobacco products to the general public, or members clubs where membership is restricted to over 18s and sale of tobacco or nicotine products is restricted to full members only.

Premises could also be excluded from the registration requirement if they only sell nicotine products not covered by the regulations made using the power in section 47(2).

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

The Children and Young Persons Act 1933, as amended by The Children and Young Persons (Sale of Tobacco etc.) Order 2007 (S.I. 2007/767), makes it illegal to sell tobacco to those aged under 18.

Section 91 of the Children and Families Act 2014 (purchase of tobacco etc. on behalf of persons under 18) prevents the proxy purchase of tobacco for those under 18.

The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 prevent the sale of nicotine inhaling products to, or proxy purchase for, those under 18.

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	34	
METHOD OF BRINGING INTO FORCE	Negative	
DESCRIPTION OF THE REGULATIONS		

This power provides regulation-making powers to enable 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).

WHAT CAN THE REGULATIONS ACHIEVE?

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.

WHY THE REGULATIONS ARE REQUIRED

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).

Other relevant information (work done to date, policy documents,	Ministeria
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	47(2)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

Section 47 of the Bill contains definitions of terms used within Chapter 2 of Part 2. This power will enable Welsh Ministers to specify in regulations what is included within the definition of "nicotine product" specifically in relation to the register of retailers of tobacco and nicotine products.

WHAT CAN THE REGULATIONS ACHIEVE?

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.

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.

WHY THE REGULATIONS ARE REQUIRED

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).

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.

Use of the power will provide appropriate clarity which would otherwise not be provided.

Other relevant informati	on (work done to date	, policy documents,	, Ministeria
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	48
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

Local authorities in Wales have been able to 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;

- 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.

As a result of the Children and Families Act 2014, offences relating to the sale of nicotine products are also included with the Restricted Premises Order system.

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.

Section 48 of the Bill amends Section 12D of the Children and Young Persons Act 1933 to allow Welsh Ministers to make regulations to amend the definition of tobacco or nicotine offences. This will enable 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.

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.

In addition, the Bill provides that before making regulations under Section 48, Welsh Ministers must consider where there are persons who appear to be representative of the interests of those likely to be affected by the regulations, and to consult with them accordingly.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations will allow Welsh Ministers to add further tobacco and nicotine offences to those which can currently trigger a local authority requesting a Restricted Premises Order. 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.

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.

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 display ban.

WHY THE REGULATIONS ARE 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. This is more appropriate for subordinate legislation as this will provide the required flexibility to be able to respond to any new offences which may be created in this area in the future.

Other relevant in	nformation (worl	k 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	57(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

This power enables 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 subsection (2), 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 54 and comprises acupuncture, body piercing, electrolysis and tattooing. A profession falls within subsection (2) if it is one that is regulated by a body mentioned in paragraphs (a) to (ga) of Section 25(3) of the National Health Service Reform and Health Care Professions Act 2002 – namely:

- (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 REGULATIONS ACHIEVE?

The power enables Welsh Ministers to require that members of a specified profession require a 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.

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 professional practice of its members.

WHY THE REGULATIONS ARE REQUIRED

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

their scope of professional 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	57(3), 57(4)	
METHOD OF BRINGING INTO FORCE	Affirmative	
DESCRIPTION OF THE REGULATIONS		

This power enables 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 54 and comprises acupuncture, body piercing, electrolysis and tattooing.

Welsh Ministers will only be able to exempt an individual who is:

- (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
- (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:

- a register maintained by the Health and Care Professions Council that is specified in or under regulations; 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 and that is
 specified in or under regulations.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations will enable 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.

The regulations enable Welsh Ministers to specify the registers that are classed as qualifying registers in relation to the exemption from the requirement to be licensed.

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 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 REGULATIONS ARE REQUIRED

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 professional 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	59(1), 59(4), 59(5)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

These powers require 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 specified in the regulations must require the applicant to demonstrate knowledge of infection control, first aid and the duties imposed by the legislation in relation to the special procedures they wish to perform.

Licensing criteria may also relate to (among other things):

- (a) an individual's eligibility for a licence (including by reference to, among other things, standards of competence);
- (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.

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 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 91(4).

Before the regulations are made, Section 61 requires 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 REGULATIONS ACHIEVE?

The regulations will provide 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 circumstances in 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.

Licensing criteria will require the applicant to demonstrate an appropriate knowledge of infection control and first aid, and an understanding of the requirements of the legislation in relation to the procedures to be performed. For example, a requirement will be that the individual is able to demonstrate that they have specific knowledge or have undertaken training in relation to infection control and first aid 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 REGULATIONS ARE 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 by all local authorities. 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 to reflect changing practices or additional special procedures.

Other relevant in	nformation (work done to	date, policy	documents,	Ministeria
Statements etc.))				

N/A

REGULATIONS	Mandatory licensing conditions
BILL PART	Part 3
SECTION	60(1), 60(5)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

Section 60 requires Welsh Ministers to make regulations that set out the mandatory licensing conditions that are to apply 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 specified in the regulations must include conditions imposing requirements in connection with:

- (a) the verification of the age of an individual on whom a special procedure is to be performed;
- (b) infection control, standards of hygiene, and first aid;
- (c) consultation to be carried out before and after a special procedure is performed; and
- (d) record keeping.

The conditions specified in the regulations must also include a condition prohibiting the performance of a special procedure in circumstances where the individual on whom the procedure would otherwise be performed is, or appears to be, intoxicated, whether by virtue of drink, drugs or any other means.

The mandatory licensing conditions may also make further provision relating to (among other things):

- (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 (including, among other things, facilities and equipment available there, and cleaning and maintenance);
- (b) the way in which a special procedure is to be performed (including by reference to, among other things, equipment used in, or in connection with, its performance, and protective clothing);
- (c) information to be provided by a licence holder (whether by display or otherwise), and to a licence holder, before and after a special procedure is performed:
- (d) displaying a licence;
- (e) information to be provided to a local authority in the case of the conviction of a licence holder for a relevant offence;
- (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.

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.

Before the regulations are made, Section 61 requires 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.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations will provide Welsh Ministers with the ability to develop tailored and specific licensing conditions that relate to an individual special procedure. The regulations will require a licence holder to verify the age of a customer when required and to comply with infection control, hygiene and first aid requirements. The provision of information by the licence holder to clients both before and after a special procedure is carried out and the records to be maintained will also be specified in the regulations.

Details about how the licence holder must 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 require the licence holder to provide information to the local authority when they have been convicted of a relevant offence specified in section 63(3).

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.

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 REGULATIONS ARE 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.)

REGULATIONS RELATING TO	Discretion to grant application for specia	
	procedure licence	
BILL PART	Part 3	
SECTION	63(5)	
METHOD OF BRINGING INTO FORCE	Affirmative	
DESCRIPTION OF THE REGULATIONS		

Section 63 of the Bill provides discretion to a local authority to grant or refuse an application for special procedure licence if the applicant has been convicted of a relevant offence and that offence is not spent for the purposes of the Rehabilitation of Offenders Act 1974.

Relevant offences are listed in section 63(3) as offences under:

- (a) Part 3 of the Bill Special Procedures;
- (b) Part 4 of the Bill Intimate Piercing;
- (c) Section 1 of the Tattooing of Minors Act 1969 (c.24);
- (d) Section 33 of the Health and Safety at Work etc. Act 1974 (c.37); or
- (e) Part 8 of the Local Government (Miscellaneous Provisions) Act 1982 (c.30).

Section 63(5) enables Welsh Ministers to make regulations to amend the list of relevant offences in Section 63(3) by adding, varying or removing a description of an offence.

WHAT CAN THE REGULATIONS ACHIEVE?

Section 63 provides that if a local authority is satisfied that all of the applicable licensing criteria are met in respect of the performance of the special procedure, but the applicant has been convicted of a relevant offence, the authority may if it thinks fit to do so having regard to the nature of the offence and the special procedure to which the application relates, issue a special procedure licence.

If a local authority considers the nature of the relevant offence and decides not to issue a special procedure licence, the authority must give notice to the applicant that it is refused.

Section 63 provides additional clarity for the applicant, and the local authority, as to how a relevant offence should be considered in the context of an application for a special procedure licence.

Section 63(5) allows Welsh Ministers to amend by regulations the list of relevant offences which apply to applications for special procedure licences.

WHY THE REGULATIONS ARE REQUIRED

The regulations enable Welsh Ministers to amend the list of relevant offences which a local authority may have regard to when considering whether or not to exercise its discretion to issue a special procedure licence. The regulations provide flexibility to

add, vary or remove offences to reflect changes to how existing special procedures are performed or when new procedures are added to the list of special procedures by regulations made under section 90(1).
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	66(8)	
METHOD OF BRINGING INTO FORCE	Affirmative	
DESCRIPTION OF THE REGULATIONS		

Section 66 establishes that a person carrying on a business, in the course of which a special procedure is performed, must comply with two 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 67. 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 67(3)(c)).

This power provides Welsh Ministers with the ability to make regulations to exempt certain premises or vehicles from the approval requirements.

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.

WHAT CAN THE REGULATION ACHIEVE?

This power will enable Welsh Ministers to exempt specific premises or vehicles from either or both of the approval requirements in Section 66, 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.

WHY THE REGULATIONS ARE REQUIRED

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.

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.)	

REGULATIONS RELATING TO	Approval of premises and vehicles in respect of performance of special
	procedure
BILL PART	Part 3
SECTION	67(3), 67(7), 67(8), 67(9)
METHOD OF BRINGING INTO FORCE	67(3)(a) or (c)- Affirmative
	67(3)(b) or (d), 67(7), 67(8), 67(9) -
	Negative

DESCRIPTION OF THE REGULATIONS

Section 67 requires Welsh Ministers to make regulations in relation to the approval of premises and vehicles.

Regulations made under Section 67(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. The mandatory conditions may also include conditions relating to the inspection of the premises and vehicles approved, and the display of an approval certificate.

Regulations made under Section 67(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.

In addition, regulations made under Section 67 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.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulation-making power in Section 67(3) will allow Welsh Ministers to make specific provision in relation to the performance of special procedures from premises and vehicles. As the regulations will enable 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 have 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.

WHY THE REGULATIONS ARE 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 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 requirements in relation to approved premises and vehicles are transparent and obtainable. Approval conditions relating to the display of approval certificates will also allow members of the public to ascertain whether or not a premises/vehicle is approved for special procedures.

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.)

REGULATIONS RELATING TO	Approval Certificates
BILL PART	Part 3
SECTION	68(4)
METHOD OF BRINGING INTO FORCE	Negative

DESCRIPTION OF THE REGULATIONS

Section 68 makes provision about the form and content of approval certificates, such as the inclusion of the date the approval was provided and the special procedure in respect of which the premises or vehicle is approved.

Section 68(4) provides Welsh Ministers with a regulation-making power to make further provision about the form and content of approval certificates. Approval certificates are designed to allow members of the public to ascertain whether or not a premises or vehicle is approved for special procedure(s).

WHAT CAN THE REGULATIONS ACHIEVE?

Regulations made under Section 68(4) enable Welsh Ministers to make further provision about the form and content of approval certificates.

WHY THE REGULATIONS ARE REQUIRED

The regulations enable Welsh Ministers to ensure approval certificates are designed in such a way as to allow members of the public to readily ascertain whether or not a premises or vehicle is approved for special procedure(s). The regulations will ensure that each local authority in Wales has the same requirements in relation to the content of approval certificates.

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

REGULATIONS RELATING TO	Voluntary termination of approval
BILL PART	Part 3
SECTION	69(5)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	

Section 69 establishes that where a person who has an approved premises or vehicle under section 67, in respect of a special procedure, and they wish that approval to cease to have effect, they may voluntarily give notice to the local authority to that effect. The authority must take reasonable steps for bringing the notice to the attention of any persons the authority thinks likely to be affected by the notice.

Section 69(5) provides that regulations may make further provision about notice under this section, including (among other things) about information to be included.

WHAT CAN THE REGULATIONS ACHIEVE?

This section makes provision for a person who had previously applied for a premises or vehicle approval to give notice to the local authority that they wish for that approval to cease to have effect, and provides details about the information that must be provided in that notice. The local authority to which the notice is given must take reasonable steps to bring the notice to the attention of persons it thinks likely to be affected (for example, licence holders listed as operating from the premises or vehicle).

Regulations made under section 69(5) will enable Welsh Ministers to make further provision about the notice given by special procedure practitioners, including (among other things) the information that must be included in that notice.

WHY THE REGULATIONS ARE REQUIRED

The regulations enable Welsh Ministers to require persons who have previously applied for a premises or vehicle approval to provide certain details should they give voluntary notice for their approval to cease. The regulations will ensure that each local authority in Wales has the same requirements in relation to the content of voluntary termination notices. The regulations will ensure sufficient information is provided to a local authority to enable it to promptly bring the notice to the attention of potentially affected persons (i.e. other practitioners working at the premises).

Other relevant in	formation (worl	k done to date	, policy docun	nents, Ministeria
Statements etc.)				

REGULATIONS RELATING TO	Fees
BILL PART	Part 3
SECTION	73(4), 73(5)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	

Section 73 provides a local authority with the ability to charge a fee to the holder of a special procedure licence or a premises or vehicle approval. This fee may be applied either periodically or otherwise for as long as the licence/approval has effect.

Section 73 also gives the local authority the power to determine the amount of a fee charged, having regard to the costs incurred or expected to be incurred by the authority in connection with Part 3.

Regulations made under 73(4) may make provision about the way in which a local authority is to determine the amount of the fee. Regulations made under 73(5) may also make provision for the way the fee is paid; repayment of a fee (or proportion of it) in cases of overpayment; and recovery of a fee due to an authority and unpaid.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations may make provision about the way in which a local authority is to determine the amount of the fee charged, having regard to the costs incurred or expected to be incurred by the authority in connection with Part 3, as well as the way the fee is paid, repaid or recovered if unpaid. This will ensure that the licence fee structure reflects the range of special procedures covered by the legislation.

WHY THE REGULATIONS ARE REQUIRED

The regulations will enable local authorities to adopt a consistent approach when determining the fee that must be paid by a licence holder. The regulations will also provide consistency on the way payment should be made; repayment to the applicant in cases of overpayment; and recovery of unpaid fees.

Other relevant in	nformation (work done to	date, polic	y documents,	Ministerial
Statements etc.)					

REGULATIONS RELATING TO	Adding or removing special procedures
	to /from the list covered by the licensing
	system
BILL PART	Part 3
SECTION	90(1)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

This power enables Welsh Ministers to amend the list of special procedures in Section 54 by adding or removing a type or description of a procedure to or from the list, or by varying a reference to a type or description of a procedure.

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.

In order for a procedure to be added to the list, 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 91(5) and includes harm to an individual's physical or mental health.

WHAT CAN THE REGULATIONS ACHIEVE?

This power will enable 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 54.

WHY THE REGULATIONS ARE REQUIRED

It is likely 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 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 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 in	nformation (work	done to date,	policy documents,	, Ministeria
Statements etc.)				

REGULATIONS RELATING TO	Interpretation of "body piercing"
BILL PART	Part 3
SECTION	91(1), 91(3)
METHOD OF BRINGING INTO FORCE	Affirmative
DESCRIPTION OF THE REGULATIONS	

This Section provides Welsh Ministers with a power to amend the definition of "body piercing" by describing objects that may be implanted in an individual's body.

WHAT CAN THE REGULATIONS ACHIEVE?

The power will enable 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.

WHY THE REGULATIONS ARE REQUIRED

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 Welsh Ministers to react to changing trends and ensure the definition remains up to date.

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.

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

PART 4 - INTIMATE PIERCING

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

PART 5 - HEALTH IMPACT ASSESSMENTS

REGULATIONS RELATING TO	Carrying out of health impact assessments by public bodies
BILL PART	Part 5
SECTION	105
METHOD OF BRINGING INTO FORCE	Affirmative

DESCRIPTION OF THE REGULATIONS

Section 105 provides a regulation-making power to allow Welsh Ministers to make provisions that will specify the circumstances in which public bodies must carry out health impact assessments, and the way in which they are to be carried out. The regulations may also cover other matters, such as the assistance to be given to public bodies in carrying out health impact assessments by Public Health Wales NHS Trust.

WHAT CAN THE REGULATIONS ACHIEVE

A health impact assessment is an assessment of the likely effect, both in the short and long term, of a proposed action or decision on people's physical and mental health. It is intended that the regulations will strengthen the position of health impact assessment in Wales by making their use mandatory in specified circumstances and their application more consistent, in order to ensure that any potential impacts on the health and well-being of communities and individuals have been adequately considered as part of decision making processes.

The regulations are also intended to complement and support the implementation of other Welsh Government legislation, most notably the Well-being of Future Generations (Wales) Act 2015.

To ensure that excessive demands are not being placed on public bodies and their clients, the regulations may make provision for exceptions where there are impact assessments in place which meet the criteria outlined in the Welsh Government guidance which would accompany the legislation. For example, if Environmental Impact Assessment criteria were revised to be consistent with those for health impact assessment, anyone undertaking the former would not have to undertake a separate one on health.

Before making regulations under Section 105, Welsh Ministers must consider whether there are persons who appear to be representative of interests of those likely to be affected by the regulations, and carry out a consultation with those people.

WHY THE REGULATIONS ARE REQUIRED

The intention is for the regulations to take a proportionate approach which ensures that health impact assessments are used when it is appropriate to do so, but without requiring one to be undertaken on all decision making processes.

The provisions therefore provide that Welsh Ministers must make regulations setting out the requirements for the carrying out of health impact assessments by public bodies. The aim is that the assessments should be limited to policies, plans and programmes which have outcomes of national or major significance, or which have a significant effect at the local level on public health. The detailed requirements for these assessments will be developed through a process of consultation and the final regulations setting out the circumstances and the way in which a public body must carry them out will need to be formally approved by the National Assembly for Wales before taking effect.

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

REGULATIONS RELATING TO	Publication of health impact assessments
BILL PART	Part 5
SECTION	106(4)
METHOD OF BRINGING INTO FORCE	Negative

DESCRIPTION OF THE REGULATIONS

Section 106(4) provides a regulation-making power which will enable Welsh Ministers to make provision about how health impact assessments are to be published, including (among other things) the time at which they are to be published.

WHAT CAN THE REGULATIONS ACHIEVE

The regulations will provide the technical detail of how and when health impact assessments carried out under this legislation will be published. Guiding principles for health impact assessments include that the process must be open, transparent and participatory. The intention is to ensure that the provisions are in line with this international best practice.

WHY THE REGULATIONS ARE REQUIRED

The power is required to provide technical detail to the legislative scheme. The negative procedure is used because the regulations will be of a technical nature and the detail may need to be amended from time to time.

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

REGULATIONS RELATING TO	Public bodies covered by the provisions on health impact assessments
BILL PART	Part 5
SECTION	107(2)
METHOD OF BRINGING INTO FORCE	Affirmative

DESCRIPTION OF THE REGULATIONS

Section 107(2) will provide a regulation-making power to add, remove or amend the list of public bodies which must carry out health impact assessments under Section 105.

WHAT CAN THE REGULATIONS ACHIEVE

This power will enable Welsh Ministers to amend the list of public bodies required to carry out health impact assessments. The intention is to ensure that the benefits of health impact assessments, such as the provision of the best available evidence on health for decision making, are available as appropriate to all public bodies.

WHY ARE THE REGULATIONS REQUIRED

To ensure alignment with the Well-being of Future Generations (Wales) Act 2015, the current intention is that all of the public bodies covered by that Act (including Welsh Ministers) will also be covered by the requirements to carry out health impact assessments. However, in the future it is possible that new public bodies could be created, existing public bodies could have their name or functions altered, or amendments to the list of public bodies covered by the Well-being of Future Generations (Wales) Act 2015 could be made. The regulations will therefore provide Welsh Ministers with the flexibility to update the list of public bodies required to carry out health impact assessments without recourse to further primary legislation.

It is recognised for example that adding one or more public bodies to the list of those to undertake health impact assessments in certain circumstances could potentially be regarded as placing an onerous burden on them. To provide additional safeguards that such impacts are fully considered, any changes to the list will need to be formally approved by the National Assembly for Wales.

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

The public bodies covered by the Well-being of Future Generations (Wales) Act 2015 are listed in Part 2 - Section 6 of that Act.

PART 6 - PHARMACEUTICAL SERVICES

REGULATIONS RELATING TO	The preparation and publication of an
	assessment of needs for pharmaceutical
	services in its area by a health board
BILL PART	Part 6
SECTION	108(1),(2)
METHOD OF BRINGING INTO FORCE	(1) Negative (2) Affirmative
DESCRIPTION OF THE REGULATIONS	

Section 108(1) inserts Section 82A in to the National Health Service (Wales) Act 2006. Section 82A will place a duty on health boards to prepare and publish an assessment of needs for pharmaceutical services in its area.

Section 82A also provides a regulation-making power. Welsh Ministers must by way of regulations, specify a date by which a health board is to prepare and publish its first assessment; make provision about the circumstances in which a health board should review and if appropriate revise its assessment; and make provision about the way in which an assessment is to be published.

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.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations will ensure that every health board has made, maintains and publishes an assessment of the needs for pharmaceutical services in its area.

WHY THE REGULATIONS ARE REQUIRED

The regulations are needed to maximise the public health role of community pharmacies so it is necessary for a health board to fully understand the need for pharmaceutical services within its area when making arrangements for their provision.

The regulations will also provide consistency in relation to the pharmaceutical needs assessment and ensure that each health board in Wales provides the same level of information, and abides by the same procedural requirements.

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.

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 health board
BILL PART	Part 6
SECTION	109(3), (4), (5), (6), (7), (9), (11)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATIONS	

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.

Section 109(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 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. Section 109(3) also inserts a new Section 2C in Section 83 of the NHS (Wales) Act which gives the Welsh Ministers the power to prescribe, in regulations, the procedure for local health boards to use when determining whether or not to grant an application and the matters to be taken into account for the purposes of determining whether or not to grant an application.

Section 109(7) gives Welsh Ministers powers to make regulations which specify the circumstances in which a health board may invite persons to make an application for inclusion in a pharmaceutical list.

Section 109(7) also enables Welsh Ministers to make regulations that specify circumstances in which a health board may, or must, remove a person from its pharmaceutical list for breaches of a term or condition of arrangements made with the health board for the provision of pharmaceutical services. In accordance with Section 109(8), the regulations will place conditions on such a removal, in particular that before removing a person from the pharmaceutical list a health board must issue that person with a notice detailing the breach and the action required to remedy it, and may only remove that person if he/she has then failed to comply with that notice.

Section 109(11) amends section 84 of the NHS (Wales) Act 2006. It provides that if regulations made under Section 83 of the NHS (Wales) Act 2006 contain provisions about the removal of a person from a pharmaceutical list, the regulations must make provision about the giving of notice of a health board's intention to remove and the right to make representations.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations are needed to 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 health board has identified a need for those services, and where necessary, by allowing health boards to issue invites to provide services in areas with unmet need.

The regulations will also ensure that where, by breaching their terms of service, persons providing pharmaceutical services fail to do so effectively, that the 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

Welsh Ministers must make regulations that require each health board 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 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.)

PART 7 - PROVISION OF TOILETS

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

PART 8 – MISCELLANEOUS AND GENERAL

REGULATIONS RELATING TO	Consequential and transitional provisions
BILL PART	8
SECTION	122(1)
METHOD OF BRINGING INTO FORCE	Negative or affirmative
DESCRIPTION OF THE REGULATIONS	•

Section 122(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.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations will permit Welsh Ministers to make amendments to provisions as outlined above in order to give full effect to the provisions of the Bill.

WHY THE REGULATIONS ARE REQUIRED

These regulations are required to allow Welsh Ministers to make supplementary, incidental, consequential, transitional, transitory 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.

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.

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

REGULATIONS RELATING TO	Commencement provisions
BILL PART	8
SECTION	123(2)
METHOD OF BRINGING INTO FORCE	No procedure applicable to
	commencement order

DESCRIPTION OF THE POWER

Section 123(2) provides that Welsh Ministers may appoint by order that provisions not listed in Section 123(1) shall to come into force on a specified date.

Section 123(1) provides that the following Sections will come into force on the day Royal Assent is received:

- Section 1:
- Sections 117 to 122;
- Section 123; and
- Section 124.

The enforcement date for the remaining Sections will be determined by Welsh Ministers by statutory instrument.

WHAT CAN THE POWER ACHIEVE?

The power will enable 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.

WHY THE POWER IS REQUIRED

This power is required to allow Welsh Ministers to set commencement dates by order, as noted above. Such orders will be confined to commencement and are technical in nature.

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

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 REGULATIONS		

Schedule 1 makes provision about the fixed penalty notices that may be issued for offences under Chapter 1 of Part 2 (smoking) 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 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.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulations will state the form of a fixed penalty notice issued in relation to Part 2, Chapter 1 (smoking) 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.

WHY THE REGULATIONS ARE REQUIRED

This power is required in order to ensure that the information included on the fixed penalty notice remains accurate. This will enable Welsh Ministers to include additional information to be included on the fixed penalty notice if required.

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, Welsh Ministers will require regulation-making powers relating to the penalty form.

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 4 of that Schedule gives powers to 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.

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 REGULATIONS	

Schedule 1 covers fixed penalty notices. Paragraph 6 of Schedule 1 provides Welsh Ministers with the power to make regulations to prescribe the amount set for a fixed penalty notice issued for the offences below.

Part 2, Chapter 1 (smoking)

- Smoking 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 in any smoke-free private vehicles.

Part 2, Chapter 2 (retailers of tobacco and nicotine products)

- 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 30 (duty to notify certain changes).

WHAT CAN THE REGULATIONS ACHIEVE?

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 in the consideration of appropriate levels for all offences.

WHY THE REGULATIONS ARE REQUIRED

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.

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.

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 REGULATIONS	

Schedule 1 of the Public Health Bill covers fixed penalty notices. Paragraph 9 of Schedule 1 provides Welsh Ministers with the power to make regulations to state the discounted penalty for a fixed penalty notice issued for the offences below.

Part 2, Chapter 1 (smoking)

- Smoking 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 in any smoke-free private vehicles.

Part 2, Chapter 2 (retailers of tobacco and nicotine products)

- 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 30 (duty to notify certain changes).

A discounted amount is payable if the penalty is paid within 15 days, beginning with the day the fixed penalty notice is issued.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulation-making power will allow Welsh Ministers to set a discounted amount for fixed penalty notice levels across the relevant offences in Part 2, Chapters 1 and 2 to ensure consistency in the consideration of appropriate amounts for all offences.

WHY THE REGULATIONS ARE REQUIRED

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.

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.

SCHEDULE 2 – SMOKING AND NICOTINE INHALING DEVICES: CONSEQUENTIAL AMENDMENTS

REGULATIONS RELATING TO	Fixed penalty notices
BILL PART	Schedule 2
SECTION	Paragraph 17
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE POWER/REGULATION	

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).

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.

The consequential amendment at Paragraph 17(2) of Schedule 2 amends Schedule 1 to the Health Act 2006 so as to retain Welsh Ministers' powers to specify in regulations the form of the FPN in relation to the proxy purchase offence.

WHAT CAN THE REGULATION POWER ACHIEVE?

The regulation-making power enables Welsh Ministers to prescribe in regulations the form of the FPN in relation to the proxy purchase offence.

WHY THE REGULATION IS REQUIRED

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 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.

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 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 Welsh Ministers.

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, came into force on 1 October 2015.

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 REGULATIONS	

Paragraphs 1-4 of Schedule 3 provide details of the process that an applicant for a special procedures 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).

Paragraph 4(4)(a) enables Welsh Ministers to make regulations to make provision about the way in which a local authority is to determine the amount of the fee that is to accompany an application made to it.

Paragraph 4(4)(b) enables Welsh Ministers to make further provision about the applications for special procedure licences including, among other things, about the way in which an application is to be made, the information to be provided and the way in which an application is to be dealt with by a local authority.

WHAT CAN THE REGULATIONS ACHIEVE?

The regulation making power enables Welsh Ministers to provide detail of how a local authority is to determine the fee that must be paid by an applicant when applying for a premises or vehicle approval.

Welsh Ministers may also 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.

WHY THE REGULATIONS ARE REQUIRED

The power is required to ensure that fees are set in a consistent manner by local authorities and applications for special procedure licences are dealt with following a common process. The power also provides 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.

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

N/A

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 REGULATIONS	•

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.

Paragraph 5(3) provides Welsh Ministers with a regulation-making power to make further provision about the form and contents of special procedure licences, including (among other things) about the inclusion of information about the applicable mandatory licensing conditions.

WHAT CAN THE REGULATIONS ACHIEVE?

The power will enable 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.

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.

WHY THE REGULATIONS ARE REQUIRED

The regulations will provide 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 60, and therefore flexibility is required in these regulations.

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

REGULATIONS RELATING TO	Delegation of functions
BILL PART	Schedule 3
SECTION	Paragraph 21(4)
METHOD OF BRINGING INTO FORCE	Negative
DESCRIPTION OF THE REGULATION	

Paragraph 21 of Schedule 3 delegates 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 21(1).

Paragraph 21(4) provides Welsh Ministers with a regulation-making power to make provision about the procedures applicable to licensing committees and their subcommittees 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 Welsh Ministers, paragraph 21(5) enables each licensing committee and its sub-committees to regulate its own procedure.

WHAT CAN THE REGULATION ACHIEVE?

The regulation-making power enables 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.

WHY THE REGULATION IS REQUIRED

Ensuring the licensing committee has provisions in place to ensure proper exercise of 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.

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.

GUIDANCE AND BYELAWS

GUIDANCE RELATING TO	Local toilet strategies preparation and review
BILL PART	Part 7
SECTION	110(7)
METHOD OF BRINGING INTO FORCE	Guidance
DESCRIPTION OF THE GUIDANCE	

Section 110 requires a local authority to prepare and publish a local toilets strategy. To assist local authorities with their duty, Welsh Ministers must issue guidance to local authorities about the matters which they should take into consideration when preparing, reviewing, consulting on or publishing a local toilets strategy. A local authority must have regard to any guidance issued.

Guidance issued by the Welsh Ministers under Section 110(7) must make provision about the assessment of the need -

- (a) for toilets to be available for use by users of highways and active travel routes;
- (b) for toilets to be available for use by users of other sites and facilities that, are facilities of particular significance for transport;
- (c) for toilets to be available for use in the vicinity of sites and in connection with events that are of particular significance or of cultural, sporting, historic, popular or national interest; and
- (d) for toilets located in premises that are publicly funded to be available for use by the public.

Guidance issued by Welsh Ministers must also make provision about promoting public awareness of toilets available for use by the public.

WHAT CAN THE GUIDANCE ACHIEVE?

It is intended that the guidance will comprehensively cover the issues that local authorities must consider when preparing, reviewing, consulting on 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.

WHY THE GUIDANCE IS REQUIRED

The power enables 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, consulting on or publishing a local toilets strategy.

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

GUIDANCE RELATING TO	Local toilet strategies: interim progress statements
BILL PART	Part 7
SECTION	111(5)
METHOD OF BRINGING INTO FORCE	Guidance
DESCRIPTION OF THE GUIDANCE	

Section 111 requires a local authority that has published a local toilets strategy under section 110 to prepare and publish an interim progress statement. To assist local authorities with their duty, Welsh Ministers must issue guidance to local authorities about the matters which they should take into consideration when preparing an interim progress statement.

WHAT CAN THE GUIDANCE ACHIEVE?

It is intended that the guidance will comprehensively cover the issues that local authorities should consider when preparing an interim progress statement. This will include the steps that the authority has taken in accordance with its local toilets strategy during the statement period.

WHY THE GUIDANCE IS REQUIRED

The power enables Welsh Ministers to issue guidance to local authorities about the matters which they should take into consideration when preparing an interim progress statement. The requirements relating to the interim progress statements strengthen the local accountability mechanisms relating to the toilets strategies by strengthening the information to be provided to local populations.

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

REGULATIONS RELATING TO	Power to make byelaws in relation to
	toilets
BILL PART	Part 7
SECTION	114(1)

DESCRIPTION OF THE BYELAWS?

Section 113(1) enables a local authority (including a community council) to provide toilets in its area for use by the public. Section 114(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.

WHAT CAN THE BYELAWS ACHIEVE?

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.

WHY THE BYELAWS ARE REQUIRED

Section 114(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.

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

Local Government Byelaws (Wales) Act 2012 - http://www.legislation.gov.uk/anaw/2012/2/contents/enacted