

Agenda – Health and Social Care Committee

Meeting Venue:

Committee Room 3 – Senedd

Meeting date: 17 September 2015

Meeting time: 09.15

For further information contact:

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Committee Clerk

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1 Introductions, apologies and substitutions

(09.15)

2 Public Health (Wales) Bill: evidence session 6

(09.15 – 10.15)

(Pages 1 – 56)

Dr Rodney Berman, British Medical Association (Wales)

Dr Stephen Monaghan, British Medical Association (Wales)

Dr Jane Fenton-May, Royal College of General Practitioners Wales

Break (10.15 – 10.30)

3 Public Health (Wales) Bill: video of evidence gathered regarding Part 3 (Special Procedures)

(10.30 – 10.40)

4 Public Health (Wales) Bill: evidence session 7

(10.40 – 11.15)

(Pages 57 – 67)

Paul Burgess, British Association of Cosmetic Nurses

Andrew Rankin, British Association of Cosmetic Nurses

Ashton Collins, Save Face

Brett Collins, Save Face

Break (11.15 – 11.25)



5 Public Health (Wales) Bill: evidence session 8

(11.25 – 12.00)

Dr Fortune Ncube, Consultant Epidemiologist and Consultant in Public Health
Medicine

6 Public Health (Wales) Bill: evidence session 9

(12.00 – 12.30)

(Pages 68 – 70)

Nick Pahl, British Acupuncture Council

Lunch (12.30 – 13.15)

7 Public Health (Wales) Bill: evidence session 10

(13.15 – 14.00)

(Pages 71 – 75)

Sarah Calcott, British Body Piercing Association
Lee Clements, British Tattoo Artist Federation

8 Papers to note

(14.00 – 14.05)

Minutes of the meetings on 9 and 15 July 2015

(Pages 76 – 81)

**Public Health (Wales) Bill: additional information from the Minister for Health and
Social Services**

(Pages 82 – 92)

Public Health (Wales) Bill: consultation responses

**Regulation and Inspection of Social Care (Wales) Bill: the Minister for Health and
Social Services response to the Committee's Stage 1 report**

(Pages 93 – 109)

**Safe Nurse Staffing Levels (Wales) Bill: correspondence from the Minister for
Health and Social Services**

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General and financial scrutiny of the Minister for Health and Social Services and the Deputy Minister for Health: additional information from the Minister for Health and Social Services

(Pages 111 – 116)

National Professional Lead for Primary Care in Wales: correspondence from the Minister for Health and Social Services

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The Care and Support (Eligibility) (Wales) Regulations 2015: correspondence from the Older Peoples Commissioner

(Pages 118 – 119)

P-04-603 Helping Babies Born at 22 Weeks to Survive: correspondence from the Chief Medical Officer

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Medium term plans for health boards and NHS trusts: correspondence from the Minister for Health and Social Services

(Pages 121 – 122)

Review of the Financial Ring Fencing Arrangements for Mental Health Services in Wales: correspondence from the Minister for Health and Social Services

(Page 123)

[Review of the financial ring fencing arrangements for arrangements for mental health services in Wales – Report to the Minister for Health and Social Services](#)

(PDF, 1.5MB)

9 Motion under Standing Orders 17.42(vi) and (ix) to resolve to exclude the public from the remainder of this meeting and for item 1 of the meeting on 23 September 2015

(14.05)

10 Public Health (Wales) Bill: consideration of evidence

(14.05 – 14.20)

(Pages 124 – 129)

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[Public Health \(Wales\) Bill](#) / [Bil Iechyd y Cyhoedd \(Cymru\)](#)

Evidence from BMA Cymru Wales – PHB 76 / Tystiolaeth gan BMA Cymru
Wales – PHB 76

PUBLIC HEALTH (WALES) BILL – GENERAL PRINCIPLES

Consultation by the National Assembly for Wales' Health and Social Care Committee

Response from BMA Cymru Wales

4 September 2015

INTRODUCTION

BMA Cymru Wales is pleased to provide a response to the consultation by the National Assembly for Wales' Health and Social Care Committee on the general principles of the Public Health (Wales) Bill.

The British Medical Association (BMA) is an independent professional association and trade union representing doctors and medical students from all branches of medicine all over the UK and supporting them to deliver the highest standards of patient care. We have a membership of over 153,000, which continues to grow every year. BMA Cymru Wales represents some 7,000 members in Wales from every branch of the medical profession.

RESPONSE

When the Welsh Government published the Public Health White Paper in 2014, BMA Cymru Wales expressed extreme concern that the proposals contained within it represented a significant step backwards from the more innovative high-level proposals that had been contained within the preceding Public Health Green Paper published in 2012.

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We have therefore been further disappointed that the now-published Public Health (Wales) Bill currently contains a narrower set of proposals than even the White Paper.

Whilst we are nonetheless broadly supportive of many of the proposals that have been brought forward within the Bill as published, we do feel that it represents a missed opportunity to provide more ground-breaking legislation that could have made Wales an international exemplar in the field of public health.

Health Impact Assessment (HIA)

We are particularly disappointed by the absence of proposals within the Bill to place Health Impact Assessment (HIA) on a statutory footing.

As far back as 1999 the then Welsh Assembly Government committed to taking forward HIA, and set out its approach in a document entitled *'Developing Health Impact Assessments in Wales'*.

In the present Assembly term, the idea of introducing HIA in Wales on a statutory basis was also consulted upon by the Welsh Government in the Public Health Green Paper published in 2012. The subsequently published summary of responses to that Green Paper stated that *"there was a high level of support for the concept of using Health Impact Assessment as a method for ensuring health issues are considered as part of policy making."* It also stated that a clear majority of those who responded indicated that Welsh Ministers, Welsh Government departments and local authorities should be required to use HIA.

We also note that the Minister for Health and Social Services, Mark Drakeford, expressed support last year for undertaking HIA in relation to local authority planning and licensing applications. During a plenary debate on an update statement on the Public Health White Paper on 7 October 2014, he said: *"I would be very keen—I always have been—to be able to make the public health impact one of the considerations that local authorities are able to take into account in making planning and licensing determinations."*

The Chief Medical Officer for Wales, Dr Ruth Hussey, has also expressed her support for HIA, telling the Health and Social Care Committee on 8 October 2014: *"...we should be using health impact assessments at the beginning of a process to ask how we can get the most health benefit from whatever proposals, policies or services we are developing, and to ask whether we can get added value."*

Given this recent consideration and expression of support, we were extremely surprised and disappointed to see that the idea of legislating to require HIA in specific circumstances was dropped in the Public Health White Paper and has not been reinstated in the Bill as published.

[Appendix 1](#) to this submission outlines in more detail our case for placing HIA on a statutory footing in Wales through incorporation of such a proposal within the Bill. We suggest a requirement for the use of HIA be placed on the face of the Bill, with regulations subsequently being brought forward to specify in exactly which circumstances a mandatory HIA would be required. In the first instance we would suggest that these regulations could require that HIA is made mandatory in relation to Strategic and Local Development Plans, certain larger scale planning applications, the development of new transport infrastructure, Welsh Government legislation, certain statutory plans such as Local Well-being Plans, new NHS developments (e.g. new hospitals) and health service reconfiguration proposals.

Minimum unit pricing for alcohol

In our responses to both the Public Health Green Paper and the Public Health White Paper, we expressed strong support for the proposal to introduce minimum unit pricing for alcohol in Wales. We are disappointed that, owing to the on-going legal challenge to a similar proposal in Scotland, it has not been possible to include this proposal in the current Bill. However, we recognise that the Welsh Government has recently published a draft Bill for consultation aimed at taking the initiative forward in future should the legal challenge in Scotland be appropriately resolved.

We are pleased that the Welsh Government therefore still intends, if possible, to introduce minimum unit pricing for alcohol at a later date, and we look forward to responding positively to the consultation on the Draft Public Health (Minimum Price for Alcohol) Bill in due course.

Obesity and nutritional standards

The Public Health White Paper sought views on introducing nutritional standards in certain public sector settings, as well as asking what other steps could be taken on these issues.

We are especially disappointed that those proposals have now been dropped and that there are no specific proposals within the Bill directed at tackling obesity. We believe this further weakens the impact that this Bill will have.

In our view, the proposals for introducing nutritional standards in both pre-school settings and care homes should be reinstated, as well as being extended to cover hospitals in Wales by way of an update to the implementation of the All Wales Nutrition and Catering Standards for Food and Fluid Provision for Hospital Inpatients (2012).

Our members witness first-hand the effects of obesity on the health of their patients. We would therefore also like to see further measures brought forward aimed at assisting people in Wales to make healthier nutritional choices. While doctors have a key role in providing advice on dietary choices and physical activity patterns, we feel this needs to be supported by a comprehensive range of public health interventions to tackle the obesity epidemic. In our view, individual programmes alone are likely to have little effect and legislative measures are also required to help people make healthy choices as part of a comprehensive strategic approach.

We do, however, recognise that some of the legislative changes we would wish to see may be outside the competence of the Welsh Assembly. We have, for instance, repeatedly called for the introduction of a standardised, consistent approach to food labelling, calling for all pre-packaged products to have front of pack labelling based on a 'traffic light' colour coding system combined with information on guideline daily amounts (now known as reference intake). We have been disappointed that neither the EU nor the UK Government has backed mandatory 'traffic light' labels for food packaging.

We remain concerned that unhealthy food is positively marketed to a young audience and feel there should be a complete ban on the advertising and marketing of unhealthy foodstuffs. This should include product placement and inappropriate sponsorship programmes targeted at school children.

It should also be noted that a significant proportion of the UK population is consuming saturated fat, salt and added sugar at levels above recommended guidelines; and too little fruit, vegetables, oily fish, and fibre. More therefore needs to be done to promote healthy eating. One option that could be considered would be to subsidise the cost of fruit and vegetables.

Maternal obesity is associated with increased maternal and fetal risks in pregnancy, as well as increased intervention rates and an increased risk of major chronic disease for their offspring in adulthood. With rates of obesity in pregnancy rising across the UK, steps need to be taken to ensure that young people understand the importance of health and wellbeing before pregnancy – giving attention to their diet and optimal body weight before planning a pregnancy. This could include offering nutrition education and counselling, which have been shown to improve knowledge and behaviour. We also support the need to provide education and support aimed at promoting and prolonging the duration of breastfeeding.

We recognise that physical activity levels in Wales and the rest of the UK are very low and have been declining for the past 30 years, whilst sedentary activity is increasing. Promoting physical activity is therefore an important aspect to reducing levels of obesity in the UK. Initiatives such as the application of the Active Travel (Wales) Act 2013 can play a contributory role, alongside the promotion of other activities that involve physical exercise.

Other initiatives which could be taken forward would be to require all NHS premises to clearly display the healthcare risks involved with junk food and drinks, especially in catering areas and on vending machines; and for NHS premises to ban the sale of junk food and unhealthy drinks or offer subsidised healthier options.

Tobacco and nicotine products

BMA Cymru Wales is largely supportive of the proposals laid out in Part 2 of the Bill and would consider that on balance the available evidence favours their enactment. In particular, we support:

- creating a national register of retailers of tobacco and nicotine products;
- adding to the offences which contribute to a Restricted Premises Order (RPO);
- prohibiting the handing over of tobacco or nicotine products to people under the age of 18; and
- restricting the use of nicotine inhaling devices such as electronic cigarettes in enclosed and substantially enclosed public and work places, bringing the use of these devices in line with existing provisions on smoking.

E-cigarettes

While e-cigarettes have the potential to reduce tobacco-related harm, by helping smokers of conventional cigarettes to cut down and quit, we believe that a strong regulatory framework is required for their sale and use in order to:

- prohibit their use in workplaces and public places to limit second hand exposure to the vapour exhaled by the user, and to ensure their use does not undermine smoking prevention and cessation by reinforcing the normalcy of cigarette use;
- restrict their marketing, sale and promotion so that it is only targeted at smokers as a way of cutting down and quitting, and does not appeal to non-smokers, in particular children and young people; and
- ensure they are safe, quality assured and effective at helping smokers cut down or quit.

Emerging evidence suggests that e-cigarettes are predominantly used together with conventional cigarettes by current smokers, for the purposes of cutting down or quitting smoking or to circumvent smoke free legislation.¹ It is evident that the risks of using e-cigarettes with tobacco cigarettes (dual use) are likely to be much less beneficial than quitting smoking completely, or switching exclusively to e-cigarette use.

Current evidence suggests that e-cigarettes are primarily effective in helping smokers reduce the intensity of smoking (by cutting down), rather than the duration of smoking (by quitting). We support a regulatory framework that helps to ensure they are effective cessation aids.

Data from the 2011 International Tobacco Control Four Country Survey (Australia, Canada, UK, US) confirms that individuals report using e-cigarettes because they believe they are less harmful than cigarettes (79.8%), to reduce smoking (75.8%), and to help quit smoking (85.1%).^{2,3}

E-cigarettes are no doubt less harmful than smoking tobacco and, while we welcome the recent research published by Public Health England,⁴ we believe that there needs to be much more research into the safety of their long-term use.

¹ Grana R, Benowitz N & Glantz SA (2014) E-cigarettes: A scientific review. *Circulation* **129**: 1972 - 87

² Adkinson SE, O'Connor RJ, Bansal-Travers M et al (2013) Electronic nicotine delivery systems: international tobacco control four country survey. *American Journal of Preventative Medicine* **3**:201

³ http://www.ash.org.uk/files/documents/ASH_891.pdf

⁴ Public Health England. E-cigarettes: an evidence update (2015) Available at: <https://www.gov.uk/government/publications/e-cigarettes-an-evidence-update>

While BMA Cymru Wales supports the use of licensed nicotine replacement therapies (NRT) as a smoking cessation aid, it should be recognised that the consumption of nicotine is not risk-free. Nicotine is a highly addictive substance and users can become physically dependent.⁵ We are also concerned by the lack of regulation to ensure the efficacy, quality and safety of e-cigarettes including the variable concentration of nicotine in these devices.

Nicotine withdrawal is associated with craving, anxiety and stress.⁶ Research suggests that nicotine may be an important mechanism by which tobacco promotes tumour development, progression and resistance to cancer treatment; this is a particular issue for dual-use of e-cigarettes and conventional cigarettes.⁷ The physiological effects of nicotine include increased blood pressure, increased heart rate, transient tachycardia and vasoconstriction.^{8,9,10}

Symptoms of nicotine toxic overdose include tremors, nausea, vomiting, convulsions, neuromuscular blockade, diarrhoea and gastrointestinal irritation.

Chronic exposure to nicotine is associated with an increased risk of stroke, hypertension, reproductive disorders, peptic ulcer disease and high total cholesterol.¹¹

⁵ Markou A (2008) Neurobiology of nicotine dependence. *Philosophical Transactions of the Royal Society* **363** (1507): 3159-68

⁶ Benowitz NL (2010) Nicotine addiction. *New England Journal of Medicine* **362**(24): 2295-303

⁷ Warren GW & Singh AK (2013) Nicotine and lung cancer. *Journal of Carcinogenesis* **12**:1

⁸ Benowitz NL (2010) Nicotine addiction. *New England Journal of Medicine* **362**(24): 2295-303

⁹ Institute of Medicine (2001) *Clearing the smoke: assessing the science base for tobacco harm reduction*. Washington: National Academy Press.

¹⁰ Bhatnagar A, Whitsel LP, Ribisil KM et al (2014) Electronic cigarettes: a policy statement from the American Heart Association. *Circulation* (Epub ahead of print 24.08.14).

¹¹ Institute of Medicine (2001) *Clearing the smoke: assessing the science base for tobacco harm reduction*. Washington: National Academy Press.

In addition to nicotine, e-cigarettes have been found to contain a range of other substances with negative health implications.^{12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29} Studies have also indicated that bystanders can be exposed to vapour emitted from e-cigarette use,^{30,31,32,33} and the World Health Organisation (WHO) has warned of the potential adverse health effects of exposure to toxicants and particles contained within e-cigarette vapour.³⁴

Despite the evidence of risk associated with using e-cigarettes, it is nonetheless worth emphasising that substituting tobacco with e-cigarettes is likely to substantially reduce exposure to tobacco-specific toxins and the potential health risks associated with exclusive e-cigarette use are therefore likely to be very much lower than the risks of smoking tobacco cigarettes.

On balance, however, whilst we believe that more research is required around the extent to which hand to mouth use of e-cigarettes either breaks or reinforces smoking behaviours – and the actual effectiveness of e-cigarettes in helping smokers to quit – from our overall view of the evidence that is currently available, we would agree that their use should be banned in enclosed public and work places as is currently the case for smoking tobacco.

In our view, it is vital that the use of e-cigarettes does not undermine the success of conventional tobacco control measures by reinforcing the normalcy of smoking behaviour in a way that other products containing nicotine do not. This specifically relates to the way these devices commonly resemble tobacco

¹² Etter JF (2010) Electronic Cigarettes: A survey of users. *BMC Public Health* **10**: 231.

¹³ Grana R, Benowitz N & Glantz SA (2014) E-cigarettes: A scientific review. *Circulation* **129**: 1972 - 87

¹⁴ Vardavas CI, Filippidis FT & Agaku IT (2014) Determinants and prevalence of e-cigarette use throughout the European Union: a secondary analysis of 26,566 youth and adults from 27 countries. *Tobacco Control* **10**: 1136.

¹⁵ Cahn Z & Siegel M (2011) Electronic cigarettes harm reduction strategy for tobacco control: a step forward or a repeat of past mistakes? *Journal of Public Health Policy* **32**: 16 – 31.

¹⁶ Cheng (2014) Chemical evaluation of cigarettes. *Tobacco Control* **23**: ii1 1-7

¹⁷ US Food and Drug administration (2009) Evaluation of e-cigarette. St Louis, MO: US Food and Drug Administration.

¹⁸ US Food and Drug administration (2009) Evaluation of e-cigarette. St Louis, MO: US Food and Drug Administration.

¹⁹ Vickerman KA, Carpenter KM, Altman T et al (2013) Use of electronic cigarettes among state tobacco cessation quitline callers. *Nicotine and Tobacco Research* **10**: 1787 - 91

²⁰ Cahn Z & Siegel M (2011) Electronic cigarettes harm reduction strategy for tobacco control: a step forward or a repeat of past mistakes? *Journal of Public Health Policy* **32**: 16 – 31.

²¹ US Food and Drug administration (2009) Evaluation of e-cigarette. St Louis, MO: US Food and Drug Administration.

²² Etter JF (2010) Electronic cigarettes: a survey of users. *BMC Public Health* **10**: 231.

²³ Grana R, Benowitz N & Glantz SA (2014) E-cigarettes: A scientific review. *Circulation* **129**: 1972 - 87

²⁴ Cahn Z & Siegel M (2011) Electronic cigarettes harm reduction strategy for tobacco control: a step forward or a repeat of past mistakes? *Journal of Public Health Policy* **32**: 16 – 31.

²⁵ Goniewicz ML, Knysak J, Gawron M et al (2013) Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tobacco Control* **23**(2): 113-9

²⁶ Williams M, Villarreal A, Boshilow K et al (2013) Metal and Silicate particles including nanoparticles are present in electronic cigarette cartomizer fluid an aerosol. *PLOS one* **8**(3): e57987.

²⁷ Grana R, Benowitz N & Glantz SA (2014) E-cigarettes: A scientific review. *Circulation* **129**: 1972 - 87

²⁸ Farsalinos K, Romagna G, Alliffranchini et al (2013) Comparison of the cytotoxic potential of cigarette smoke and electronic cigarette vapour extract on cultured myocardial cells. *International Journal of Environmental Research and Public Health* **10**(10): 5146-62.

²⁹ Vardavas CL, Anagnostopoulos N, Kougias M et al (2012) Short term pulmonary effects of using an electronic cigarette: Impact on respiratory flow resistance, impedance, and exhaled nitric oxide. *Chest* (**141**)6.

³⁰ Grana R, Benowitz N & Glantz SA (2013) Background paper on e-cigarettes (electronic nicotine delivery systems) San Francisco: University of California.

³¹ Schripp T, Makewitz D, Uhde E et al (2012) Does e-cigarette consumption cause passive vaping? *Indoor Air* **23**(1) 25-31

³² Pellegrino RM, Tinghino B, Mangiaracina G et al (2012) Electronic cigarettes: and evaluation of exposure to chemicals and fine particulate matter (PM) *Annali di Igiene: Medicina Preventiva e di Comunita* **24**:279 - 88

³³ McAuley TR, Hopke PK, Zhao J et al (2012) Comparison of the effects of e-cigarette vapour and cigarette smoke on indoor air quality. *Inhalation Toxicology* **24**: 850-7

³⁴ World Health Organisation (2014) Electronic nicotine delivery systems. Geneva: World Health Organisation.

cigarettes, in terms of appearance, nomenclature and the way they are used, as well as features such as flavouring and styling that are potentially highly attractive to children, and may include cigarette brand reinforcement. And because e-cigarettes commonly resemble tobacco cigarettes, and may not be immediately distinguishable from them, we also believe that restricting their use in current smoke-free areas will aid the managers of such premises in their ability to enforce the current smoking ban.

It is our concern that the e-cigarette marketing methods used across a range of advertising media and locations are likely to appeal to children, young people and non-smokers. These include point-of-sale displays; advertising via television, radio, in-print media and online; on billboards near schools; at university freshers' fairs; and the marketing of flavoured e-cigarettes.³⁵

BMA Cymru Wales is also concerned that e-cigarette marketing may have an adverse impact, reinforcing conventional cigarette smoking habits, as well as indirectly promoting tobacco smoking, increasing the likelihood of young people starting to smoke.^{36,37,38}

The e-cigarette market increased by 340% in 2013, and is estimated to be worth £193 million.³⁹ There are now more than 450 brands of e-cigarette, and 7,700 unique flavours.⁴⁰

E-cigarette promotion ranges from being advertised as 'a healthier alternative to smoking traditional tobacco products', to evocative advertising with phrases such as 'love your lungs', 'vape with style', 'smoking is so last season' and 'add flavour to your lifestyle'. The advertising and promotion also frequently makes positive associations with recreational activities, sports and youth culture, and can incorporate celebrity endorsements.^{41 42 43 44} The UK Advertising Standards Authority (ASA) has previously ruled that certain e-cigarette advertisements were considered misleading and made unsubstantiated claims relating to health.⁴⁵

In terms of accessibility, e-cigarettes can be bought from a variety of high street outlets, ranging from newsagents, superstores, and pharmacies to pubs and specialist shops. E-cigarettes and liquid nicotine can also be purchased online, even in wholesale quantities.⁴⁶

The legal status of e-cigarettes varies around the world. In some countries (eg Denmark, Canada, Israel, Singapore, Australia and Uruguay) the sale, import, or marketing of e-cigarettes is either banned, regulated in various ways, or the subject of health advisories by government health organisations. In others (eg New Zealand), e-cigarettes are regulated as medicines and can only be purchased in pharmacies.

³⁵ English PM (2013) Re: EU policy on e-cigarettes is a "dog's dinner" says UK regulator (rapid response) *BMJ* **347**: f6871.

³⁶ Andrade M, Hastings G & Angus K (2013) Promotion of electronic cigarettes: tobacco marketing reinvented? *BMJ* **347**: f7473

³⁷ National Institute for Health and Care Excellence (2013) Tobacco: harm reduction approaches to smoking. Manchester National Institute for Health and Care Excellence.

³⁸ Cancer Research UK (2013) The marketing of electronic cigarettes in the UK. London: Cancer Research UK.

³⁹ Public Health England (2014) E-cigarette uptake and marketing. London: Public Health England.

⁴⁰ Zhu S-H, Sun JY, Bonnevie N et al (2014) Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. *Tobacco Control* **23**: iii3-9

⁴¹ Andrade M, Hastings G & Angus K (2013) Promotion of electronic cigarettes: tobacco marketing reinvented? *BMJ* **347**: f7473

⁴² Grana R, Benowitz N & Glantz SA (2013) Background paper on e-cigarettes (electronic nicotine delivery systems) San Francisco: University of California.

⁴³ Cancer Research UK (2013) The marketing of electronic cigarettes in the UK. London: Cancer Research UK.

⁴⁴ US Senate report (14.4.14) Gateway to addiction? A survey of popular electronic cigarette manufacturers and targeted marketing to youth.

⁴⁵ www.asa.org.uk/Rulings/Adjudications/2013/5/Nicocigs-Ltd/SHP_ADJ_219974.aspx (Last accessed October 2014)

⁴⁶ Kamerow D (2014) The poisonous "juice" in e-cigarettes. *BMJ* **348**: g2504

In the UK, e-cigarettes are subject to regulation under the General Product Safety Regulations 2005, the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009, and by trading standards.⁴⁷ Worryingly, there is no requirement for manufacturers of e-cigarettes to list the nicotine content of their products, to include childproof safety features, or to take measures to protect against accidental overdose.⁴⁸

Laboratory analysis of e-cigarettes indicates that labelling of nicotine levels in e-cigarette liquid may be inconsistent and misleading.⁴⁹ The Trading Standards Institute and others have stated that safety concerns have come to light around some brands of e-cigarettes, including electrical safety, the need for proper labelling, and the provision of child resistant packaging.^{50 51}

BMA Cymru Wales would advocate the introduction of stringent guidelines in terms of appropriate labelling and childproof safety features.

Extending restrictions to non-enclosed spaces

We recognise that a clear case can be made that banning smoking in certain circumstances in open spaces will have a positive health benefit in the same way as it does within enclosed spaces. We note that whilst voluntary smoking bans have been effective in some areas when applied to open spaces, in others they remain largely ignored and extremely hard to enforce locally.

We therefore support the proposals in the Bill that create the provision to extend statutory restrictions on smoking and e-cigarettes to certain non-enclosed spaces which could include such locations as hospital grounds and children's playgrounds.

Careful consideration may, however, need to be given to how this is applied in order to take account of the impact on individuals using e-cigarettes if they are forced to share a defined combined 'smoking area' with users of tobacco cigarettes.

We note the approach that has been advocated in the Bill of enabling additional locations that could come under the scope of these restrictions to be subsequently specified in regulations, and welcome the stipulation that the addition of new locations can only be supported when Welsh Ministers are satisfied that doing so is likely to contribute towards the promotion of the health of the people of Wales.

National register and Restricted Premises Orders (RPOs)

BMA Cymru Wales welcomes the provisions within the Bill to establish a tobacco retailers' register. We believe it is a proportionate and reasoned measure which need not be overly bureaucratic or burdensome on retailers.

We believe that its establishment would be a pragmatic step that will help to prevent underage sales and sales of illegal tobacco. It will also assist in ensuring compliance with the point of sale display and advertising regulation.

The additional information that will be gathered as a consequence of the introduction of the register and the strengthened RPO regime, will assist local authority trading standards officers in identifying where tobacco is, or is not, permitted to be sold and thereby help in enforcing tobacco and nicotine offences.

⁴⁷ Trading Standards Institute (2010) Response of the Trading Standards Institute to MHRA consultation on the regulation of nicotine containing products. Basildon, Essex: Trading Standards Institute.

⁴⁸ Benowitz NL (2010) Nicotine addiction. *New England Journal of Medicine* **362**(24): 2295-303

⁴⁹ US Food and Drug Administration (2009) Evaluation of e-cigarette. St Louis, MO: US Food and Drug Administration.

⁵⁰ Trading Standards Institute (2010) Response of the Trading Standards Institute to MHRA consultation on the regulation of nicotine containing products. Basildon, Essex: Trading Standards Institute.

⁵¹ North East Lincolnshire Council press release (05.01.12) Use e-cigarettes with care, warn trading standards officers.

Creating a new offence for knowingly handing over tobacco and nicotine products to a person under the age of 18 is also something that we support.

Additional suggestions

To ensure successful and expedient implementation of the Public Health (Wales) Bill we would urge the Welsh Government to ensure an appropriate commensurate budget to ensure that the general public is made fully aware of the implications of the Bill coming in to force.

In addition to the Bill, BMA Cymru Wales would advocate regulating e-cigarettes as a licensed medicinal product to best reflect their use for harm reduction, bringing them in line with other existing NRT products, and ensure effectiveness, quality and safety. This form of regulation would also provide the necessary controls on their marketing and promotion.

Special procedures

The proposals in the bill to create a compulsory, national licensing system for practitioners of specified procedures in Wales – such as acupuncture, body piercing, electrolysis and tattooing – seem reasonable in our view.

We also support the proposal to give Ministers the power to amend the list of special procedures to which this licensing system will apply through regulations.

As we previously indicated in our response to the Public Health White Paper, we would suggest that consideration could also be given to including the following additional procedures under the proposed licensing system:

- laser hair removal;
- chemical peels;
- dermal fillers;
- scarification/branding; and
- sub-dermal implantation (or 3D implant).

Intimate piercing

We are supportive of the plan to prohibit the intimate piercing of anyone under the age of 16 in Wales. The proposals in this section of the Bill would therefore seem reasonable.

Pharmaceutical Services

The Bill includes provision to require each local health board to publish an assessment of the need for pharmaceutical services in its area with the aim of ensuring that decisions about the location and extent of pharmaceutical services are based on the pharmaceutical needs of local communities.

Whilst such a proposal seems superficially reasonable, we are concerned about the experience in England where the interpretation of a similar requirement for pharmaceutical need assessments has led to the withdrawal of dispensing rights for some GP practices, with potentially catastrophic impact on some rural communities if this were to be repeated in Wales. The experience in England is that there seems to be no mechanism whereby the pharmaceutical needs assessment considers the wider primary healthcare needs of a locality – particularly a rural one. As such, we would be concerned that the resultant provision of additional pharmaceutical services under section 81 of the National Health Service (Wales) Act 2006 would be unlikely to compensate for the closure of a local GP practice.

The *Cost of Service Inquiry*⁵² conducted in 2010 by the Department of Health in England demonstrated the cross-subsidy of services provided under the General Medical Services (GMS) contract by dispensing

⁵² <http://www.pwc.co.uk/government-public-sector/publications/cost-of-service-inquiry-for-community-pharmacy.jhtml>

in rural dispensing practices. Many of these dispensing practices rely on the additional profit from dispensing to remain viable when catering for often small and dispersed registered patient lists.

The additional pharmaceutical services mentioned in the Explanatory Notes which accompany the Bill – flu immunisation, smoking cessation and emergency contraception (and indeed many others) – are ones that are provided under GMS services already. However, there have been instances in England where, because such services have not been provided under a pharmaceutical contract, there has been a determination that there were unmet pharmaceutical needs and thus applications to provide additional pharmaceutical services were agreed. This led to the closure of dispensing services even in areas that have been defined as controlled localities (i.e. areas that have been designated as being ‘rural in character’ such that, in certain circumstances, doctors can provide pharmaceutical services to certain of their eligible patients.) This, in turn, can have a huge negative impact on the provision of GMS services in such localities. With current GP recruitment problems this could be devastating for rural areas and lead to directly to GP practice closures.

Ideally, we would therefore suggest that controlled localities be excluded from the proposed provisions of the Bill. Failing that, as an absolute minimum, GMS services similar to extended pharmaceutical services should be required to be considered in any pharmaceutical needs assessment, and all pharmaceutical needs assessments should include a risk assessment to existing GMS provision of any new approvals to provide pharmaceutical services.

In the light of these quite serious concerns, the view of BMA Cymru Wales is that we believe the provisions in this section of the Bill might improve the planning and delivery of pharmaceutical services, but only as narrowly defined and in isolation.

We further believe that the proposals will encourage existing pharmacies to adapt and expand services according to local need – an aim we can most certainly support.

However, it must be recognised that the proposals relating to pharmaceutical services in the Bill have the potential to seriously undermine public health in Wales if (as they have in England) they negatively impact on the provision of GMS GP services in rural areas and lead to the closure of existing GP practices.

Provision of toilets

We welcome the proposed provisions in this section of the Bill. These proposals seem both sensible and reasonable, and we are therefore happy to provide our support.

APPENDIX 1 – The case for Health Impact Assessment (HIA)

Introduction

Pre-assessing new policies, plans or programmes in order to avoid any unforeseen negative impacts on the environment or equalities is already well-established within decision-making by public bodies in Wales. However, there is clearly also a strong case to be made that we should be equally seeking to avoid or minimise any negative impacts on the health and well-being of the Welsh population, as well as promoting positive impacts. Indeed, this would appear to be both a logical and desirable development of an already well-established approach.

It also makes sense in light of the accepted recognition that health is, to a large extent, determined by factors outside of healthcare provision. Known as the wider determinants of health, these include social and community factors; access to services; and economic and environmental factors.

It can hopefully be taken as a given that public bodies in Wales would wish to avoid negative impacts on health that could arise from decisions they might be taking, or from the application of new policies they might be adopting. But if we are considering potential deleterious consequences that are neither

intended nor envisaged, it cannot simply be assumed that these will be obvious in the first instance and hence mitigated against automatically.

If such outcomes are therefore to be systematically avoided, it would seem logical that some form of pre-decision assessment needs to be undertaken before decisions are made, plans approved or new policies adopted. This would maximise the likelihood that something that might not otherwise be obvious can be brought to the fore and properly considered in a timely manner.

HIA is a well-established tool that can fulfil this role. The World Health Organisation (WHO) defines HIA as *'a means of assessing the health impacts of policies, plans and projects in diverse economic sectors using quantitative, qualitative and participatory techniques. HIA helps decision-makers make choices about alternatives and improvements to prevent disease/injury and to actively promote health.'*⁵³ A definition known as the Gothenburg Consensus describes HIA as a combination of procedures methods and tools by which a policy, programme or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population.⁵⁴

As practiced in Wales, HIA assesses the implications for health and wellbeing through the broad lens of the wider determinants of health. It is a process which considers to what extent the health and wellbeing of a population may be affected, whether positively or negatively, by a proposed action – be it a policy, programme, plan or project. As such it can provide an opportunity to identify ways in which health benefits can be maximised as well as how health risks can be minimised. It can not only identify health impacts and health inequalities affecting the general population, but also those affecting vulnerable groups (e.g. children, young people, the elderly etc.). It can be used to identify opportunities for health improvement, as well as to fill identified gaps in service provision or delivery.

For as long as its application in decision-making by Welsh public bodies remains optional, however, its effectiveness in avoiding un-envisaged negative impacts on health – or in identifying ways in which health benefits might be maximised – will in our view be substantially reduced. It might only be through the undertaking of an HIA that an unforeseen negative impact on health might be identified.

Relationship with existing policy and legislation

The use of HIA can also be seen as a logical progression of the current policy direction in Wales, complementing the aims of many recent developments in legislation.

For instance, the Active Travel (Wales) Act 2013 requires Welsh Government and Welsh local authorities to undertake continuous improvement through the development of transport infrastructure that can facilitate travel by active means – thereby helping people to undertake healthier travel options. However, whilst this will lead to a certain amount of new transport infrastructure being developed to further the aims of this Act, it is possible that other new transport infrastructure may also be developed alongside which is not assessed for its impact on health and which might therefore have an un-considered negative impact, or might not be developed in a manner which maximises the opportunities for promoting health benefits. In our view it therefore makes sense for all new transport infrastructure to be assessed for its impact on health so that health concerns can be brought to the fore whether or not the infrastructure in question is being specifically developed to further the aims of the Active Travel (Wales) Act 2013. That way Wales can adopt a more holistic approach to furthering this policy aim.

Another example of where HIA could provide added benefit can be highlighted in relation to planning considerations, where we would also argue that it might not be seen as sufficient to only require HIAs to be undertaken at the level of the over-arching Local Development Plan (LDP). Generalised land use allocations within an LDP will not necessarily reveal the impact on health that individual development

⁵³ <http://www.who.int/hia/en/>

⁵⁴ European Centre for Health Policy. Health impact assessment: main concepts and suggested approach. Gothenburg consensus paper. Brussels: WHO European Centre for Health Policy. 1999. Available at: <http://www.euro.who.int/document/PAE/Gothenburgpaper.pdf>

proposals, which are subsequently brought forward during the lifetime of the plan, might have. It may only become apparent once the specific details of individual planning applications are known what impacts they could have on a broad-range of public policy considerations, including health. It might therefore be considered that certain categories of planning applications – e.g. housing developments above a certain size – could be subject to HIA.

Application

HIAs need not be overly burdensome. This is often used as an argument against their use being made a requirement, but the first stage in the process should be a screening exercise which can determine whether an HIA would both be valuable and feasible within a particular decision-making context.

In our view, it would be too simplistic to just dismiss this as a tick box exercise. A methodology could be developed which would ensure those policies, plans and programmes which should be subject to an HIA could then go on to be subject to a suitably more rigorous assessment – but for those for which this would not be necessary, this can also be straightforwardly identified.

Additionally, HIA need not be undertaken as a stand-alone process but could also be undertaken as part of a wider, but integrated, impact assessment. An example of this is the approach which was employed in Tasmania⁵⁵ as a result of legislation introduced there in 1996. That legislation required all proposed developments requiring an environmental impact assessment (EIA) to also be subject to an HIA, with these being carried out as part of one integrated assessment.

Indeed it should be recognised that broad HIA can provide added benefits even in circumstances where EIA is already required. Even though there may be a requirement within EIA to consider human health, this may be done in a manner which could be much narrower in scope than would be required in an HIA. At present, for instance, EIA undertaken in accordance with current EU regulation only looks at negative risks and implications for health, and only those which may be caused by environmental determinants.

Undertaking HIA alongside other assessments, as part of a wider integrated assessment, could be seen as a worthwhile adjunct to the recently passed Well-being of Future Generations (Wales) Act 2015 which seeks to promote a healthier Wales as one of its seven identified well-being goals. Whilst this Act requires public bodies in Wales to set objectives that will further each of these well-being goals, it does not however establish a specific requirement for Welsh public bodies to consider the impact on health of other decisions they may make, or of new policies they may adopt, when these are outside of those which are specifically being brought forward to further the aims of the Act. A mandatory application of HIA by Welsh public bodies could therefore ensure that the impact on health and wellbeing is considered more widely across the board, thereby more effectively delivering the intention of a health-in-all-policies approach.

HIA is an open and transparent process which promotes the active inclusion and participation of key stakeholders and communities affected. It can therefore ensure greater involvement of these groups in decisions that affect them. As such, it can bring reassurance in relation to certain decisions that potential impacts on health and well-being are properly understood.

Existing requirements for HIA use in Wales

It should be recognised that there are already circumstances in which HIA is referenced in existing guidance in Wales. Examples include the *Vibrant and Viable Places: New Regeneration Framework (2013)*⁵⁶ which includes the need for a HIA to be included in all Stage 2 bids for Welsh Government funding; the *Welsh Transport Appraisal Guidance (WeITAG), 2008*⁵⁷; the *Collections, Infrastructure and*

⁵⁵Ewan C, Young A, Bryant E, Calvert E, Calvert D. *National framework for environmental and health impact assessment*. Canberra: National Health and Medical Research Council, Australian Government Publishing Service, 1994. Available at: <https://www.nhmrc.gov.au/guidelines-publications/eh10>

⁵⁶<http://gov.wales/topics/housing-and-regeneration/regeneration/vibrant-and-viable-places/?lang=en>

⁵⁷<http://gov.wales/topics/transport/planning-strategies/weltag/?lang=en>

*Markets Sector Plan*⁵⁸ which covers the management of waste; and the *Minerals Technical Advice Note (MTAN) 2: Coal*⁵⁹, which provides planning advice in relation to facilities for coal extraction including open-cast mining. These include circumstances in which HIA has already been made a mandatory requirement in Wales.

Making HIA a statutory requirement

Given that there are already circumstances in which Welsh Government has specified that HIA should be undertaken, it could therefore be a logical progression to include a statutory requirement for HIA in certain defined circumstances. Indeed, such a provision could substantially strengthen the scope and impact of the Public Health (Wales) Bill, as well as being seen as an evolution of the existing approach.

The principle for HIA to be a requirement in specific situations could be incorporated on the face of the Public Health (Wales) Bill, with the intention that regulations would subsequently be produced which could then specify in exactly which particular situations a mandatory HIA would be required. That way the requirement for mandatory HIA could initially be applied in a number of discrete areas where it is most apparent that this would be of benefit, with scope for this to be easily broadened to further areas in the future. This would be a similar approach, for instance, to the manner in which the provisions of the Welsh Language (Wales) Measure 2011 are being applied.

In the first instance, we would suggest that regulations could require that HIA is made mandatory in relation to Strategic and Local Development Plans, certain larger scale planning application, the development of new transport infrastructure, Welsh Government legislation, certain statutory plans such as Local Well-being Plans, new NHS developments (e.g. new hospitals) and health service reconfiguration proposals.

Summary

We feel that a mandatory requirement for HIA in certain defined circumstances would be entirely in line with the wider Welsh Government policy direction and recent legislative developments.

It would ensure greater consideration within decision-making of ways in which negative impacts on health can be mitigated against and positive health benefits maximised, thereby ensuring unforeseen impacts are avoided at the same time as providing greater reassurance for communities in the way such decisions are reached.

Legislating for mandatory HIA could provide a significant contribution to improving the future health and well-being of the Welsh population, at the same time as helping Wales to become a World leader in the application of public health policy.

⁵⁸http://gov.wales/topics/environmentcountryside/epq/waste_recycling/publication/cimsectorplan/?lang=en

⁵⁹<http://gov.wales/topics/planning/policy/mineralstans/2877461/?lang=en>

Tobacco and Nicotine Products

The Bill includes proposals to ban the use of nicotine inhaling devices, such as e-cigarettes, in enclosed spaces like restaurants, pubs and at work. Shops will also have to join a register for retailers of tobacco and nicotine products, and it will become an offence to “hand over” tobacco and e-cigarettes to anyone under the age of 18.

Question 1

Do you agree that the use of e-cigarettes should be banned in enclosed public and work places in Wales, as is currently the case for smoking tobacco?

Yes, we do. As the Bill states this should include all nicotine inhaling devices. It will be easier for organisations to manage a total ban on smoking tobacco and use of nicotine inhaling devices including e cigarettes. The actual vapour being exhaled by those “vaping” can be very annoying to others and it is also a poor example to children, who may follow the example and either vapour or smoke. There will also be some residual nicotine in the vapour which may have harmful effects on others. It has been known for many years that nicotine is addictive and it also has adverse medical effects so should not be encouraged in any manner.

Question 2

Do you believe the provisions in the Bill will achieve a balance between the potential benefits to smokers wishing to quit with any potential dis-benefits related to the use of e-cigarettes?

Yes. Those wishing to quit smoking need to gradually reduce their use of the e-cigarettes over time and restrictions on use will help enhance this behaviour. We are not aware of any dis-benefits.

Question 3

Do you have any views on whether the use of e-cigarettes re-normalises smoking behaviours in smoke-free areas, and whether, given their appearance in replicating cigarettes, inadvertently promote smoking?

|Yes, we feel that the use of e-cigarettes normalises the behaviour in smoke free zones and potentially encourages others to take up the habit. Some patients only used e-cigarettes in public areas, where they are accepted due to social pressures to conform. They were actually upset to learn that e-cigarettes contained nicotine as they thought they are was only steam or water. Some of the also shared the -cigarettes and were unaware of potential risk of spreading infections such as viral hepatitis. The same is also true of hocker or bubble pipes which should be made to include these into the Bill.

Question 4

Do you have any views on whether e-cigarettes are particularly appealing to young people and could lead to a greater uptake of their use among this age group, and which may ultimately lead to smoking tobacco products?

Yes we do have concerns about risks to young people as there is an increasing social trend to their use in these age groups partly due to social pressures.

Question 5

Do you agree with the proposal to establish a national register of retailers of tobacco and nicotine products?

Yes

This may need to be modified to include pharmacies if the law is changed to allow short term use of e cigarettes to be used for smoking cessation therapy.

Question 6

What are your views on creating a new offence for knowingly handing over tobacco and nicotine products to a person under 18, which is the legal age of sale in Wales?

We support this.

This may need to be modified if the law is changed to enable the use of e-cigarettes to be used short term for smoking cessation on prescription as some of the patients may be under 18 years of age.

Special Procedures

The Bill includes a proposal to create a compulsory licensing system for people who carry out special procedures in Wales. These special procedures are tattooing, body piercing, acupuncture and electrolysis. The places where these special procedures are carried out will also need to be approved.

Question 7

What are your views on creating a compulsory, national licensing system for practitioners of specified special procedures in Wales, and that the premises or vehicle from which the practitioners operate must be approved?

We support this. People are very often unaware of the risks related to these procedures due to infection, allergy or potential carcinogens in some inks used for tattoos. They are also unaware of the potential for life long scarring resulting occasionally in disfiguring or disabling deformity from procedures which have complications. They are also unaware that it is difficult to remove evidence of piercing or tattooing, when they no longer want the associated affect.

Question 8

Do you agree with the types of special procedures defined in the Bill?

Yes

Question 9

What are your views on the provision which gives Welsh Ministers the power to amend the list of special procedures through secondary legislation?

We support this

Question 10

Do you have any views on whether enforcing the licensing system would result in any particular difficulties for local authorities?

No

Intimate piercings

The Bill includes a proposal to ban intimate body piercings for anyone under the age of 16 in Wales.

Question 11

Do you believe an age restriction is required for intimate body piercing? What are your views on prohibiting the intimate piercing of anyone under the age of 16 in Wales?

Yes

Question 12

Do you agree with the list of intimate body parts defined in the Bill? Whether any other types of piercings (for example naval piercing, tongue piercing) should be prohibited on young people under the age of 16.

We believe naval, lip, nose and tongue piecing should be added to the list. These have high risk of infection and complication and the implications of these need to be understood fully by the person having the procedure, hence the support to restrict this to over 16 year olds.

Community pharmacies

The Bill will require local health boards in Wales to review the need for pharmaceutical services in its area, and that any decisions relating to community pharmacies are based on the needs of local communities.

Question 13

Do you believe the proposals in the Bill will achieve the aim of improving the planning and delivery of pharmaceutical services in Wales?

Yes

Question 14

What are your views on whether the proposals will encourage existing pharmacies to adapt and expand their services in response to local needs?

We believe that if need is shown in an area potentially pharmacies will respond but there may be restrictions due to suitable premises or staff availability.

Public toilets

The Bill includes a proposal that will require local authorities to prepare a local strategy to plan how they will meet the needs of their communities for accessing public toilet facilities. However, the Bill does not require local authorities to actually provide toilet facilities.

Question 15

What are your views on the proposal that each local authority in Wales will be under a duty to prepare and publish a local toilets strategy for its area?

We support this. Some people restrict their activity due to lack of available accessible public toilets in the area. The published data should include data on the current toilets including opening times and accessibility especially for disabled toilets.

Question 16

Do you believe that preparing a local toilet strategy will ultimately lead to improved provision of public toilets?

We hope that this will be the case but the strategy will need to be open to public comment

Question 17

Do you believe the provision in the Bill to ensure appropriate engagement with communities is sufficient to guarantee the views of local people are taken into account in the development of local toilet strategies?

Yes

Question 18

What are your views on considering toilet facilities within settings in receipt of public funding when developing local strategies?

These should be included but some may need to have restrictions to those using the settings for their prime purpose.

Other comments

Question 19

Do you believe that the issues included in this Bill reflect the priorities for improving public health in Wales?

Yes

Question 20

Are there any other areas of public health which you believe require legislation to help improve the health of people in Wales?

Minimum alcohol pricing which is already being considered

Question 21

Are there any other comments you would like to make on any aspect of the Bill?

No



British Association of Cosmetic Nurses

National Assembly for Wales / Cynulliad Cenedlaethol Cymru
[Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol](#)

[Public Health \(Wales\) Bill / Bil Iechyd y Cyhoedd \(Cymru\)](#)

Evidence from the British Association of Cosmetic Nurses – PHB 33 / Tystiolaeth gan Gymdeithas Nyrsys Cosmetig Prydain – PHB 33

Consultation – Public Health (Wales Bill) – Submission by the British Association of Cosmetic Nurses (BACN).

Introduction

1. The BACN is delighted to have been invited to comment on the above Bill as it passes through the Committee stages of the National Assembly for Wales. The format of our response will follow the guidelines that were sent with the invitation to provide evidence. We have also sent confirmation of our willingness to attend a meeting of the Committee on 17th September 2015 if required.

The BACN – An Introduction

2. The BACN was formed in 2009 by a small group of registered Nursing and Midwifery Council nurses who wanted to provide a forum for networking and mentoring in what was and still is the rapidly growing sector of non-surgical aesthetic treatments.
3. The BACN is now the largest Professional Association in the field of non-surgical aesthetic treatments and has over 600 members – a number of which practise in Wales. A detailed breakdown of our constitution, governance and activities can be found on our website at:

www.bacn.org.uk

Regulation in the UK – Non- Surgical/Aesthetic Treatments

4. It is worth reiterating that there is no regulation at all in England, Wales, Scotland or Northern Ireland for non-surgical aesthetic treatments. There is regulation by governing councils and statutory legislation for prescription medication. The problem is interpretation of regulation, the difficulty of enforcing it and the maintenance of best practice standards under the legislation (and of course, fillers are not prescription drugs therefore not regulated).

England

5. There is a lot of activity going on in England with regard to potential models of regulation following the publication of the Keogh Report on 'Non-Surgical Cosmetic Interventions' on 11th September 2014.
6. This report was commissioned by the Secretary of State for Health and looked in particular at the need for regulation in the non-surgical sector. The findings outlined a principle of self-regulation for England and initiated a consultative process amongst stakeholders led by Health Education England (HEE). The BACN was a member of the Expert Reference Group established by the HEE to review the findings of the Keogh Report.
7. The findings of the Expert Reference Group were published in December 2014 and final comments were provided to the Secretary of State for Health by 31st March 2015. The HEE is currently considering the responses prior to making recommendations to the Minister of Health.
8. The Keogh Report identified the absence of any regulation for dermal fillers. The Department of Health have expressed the desire to address this through the introduction of statutory legislation which focuses on dermal fillers and possibly other non-prescription treatments. This would have the effect of bringing these treatments under the jurisdiction of statutory regulated healthcare professionals which, we believe, is to be welcomed.

Scotland

9. The Scottish Executive is about to announce a licensing system for aesthetic businesses. The BACN has contributed to the development process and been invited to sit on the Health Inspection Service (HIS) which will inspect premises. They are now looking at establishing standards and have looked towards the BACN Competency Framework as a guide in this area. At the moment there are no plans to establish an overarching body to oversee standards or to look

at the assessment of competence. This function will be performed by the Chief Medical Officer for Scotland and as yet there are no proposals for review.

BACN Competency Framework

10. The BACN Competency Framework is the only set of standards published for the non-surgical aesthetic sector which is also accredited by the RCN. As part of the HEE process the Competency Framework was adapted to also include hair restoration and various laser treatments. We recommend the standards in the Competency Framework to the National Assembly for Wales as the basis for setting a national set of standards in this area either through primary or secondary legislation and to include non-surgical cosmetic interventions.

Joint Council Model

11. The BACN in its final submission to the HEE also recommended the establishment of an over- arching body, a 'Joint Council' that would own and update standards and take a strategic view on regulation in the sector. It also suggested that there is an Accreditation Body established under the wing of the Joint Council to review training programmes that are outside the usual remit of academic institutions and OFQUAL.
12. Detailed discussions are now taking place on the format, remit and financing of a Joint Council between the HEE and some of the key Professional Associations that oversee activity in the non-surgical sector. However, without legislation this process is subject to the industry and professional bodies agreeing an acceptable way of working which is proving very difficult.
13. One option that has been suggested is the establishment of a 'Voluntary Register' in England. It is the view of the BACN that this is fraught with difficulties in terms of who is required to register, who keeps the register and who polices it. It is also open to misinterpretation by the public if it is not clear what the register has been established to do. An approval to be on a register that is just based on premises inspection, availability of policies and procedures for the activity or hygiene gives no guarantees in relation to the competence of the persons providing treatments.

The Welsh Proposals – Comments

14. The BACN in this section respond to the key areas outlined in the 'Guidance Notes' for responders and the questions that are asked to be covered. The

single most important point to make here is that the proposals published in the Bill refer to licensing 'Special Procedures' and 'Cosmetic Procedures' but no reference is made to 'aesthetic procedures' (see para 107 in Guidance Notes). The BACN would support licensing however do not believe that a 'Public Health Bill' is the most appropriate route or vehicle to achieve the desired aims for the reasons set out below.

15. The risks associated with aesthetic procedures include serious facial scarring and blindness, which require rapid and expert identification and intervention. The importance of and need to identify competence is reflected by the serious complications that can occur in aesthetic procedures. In its current form we would question the extent to which the Bill refers to such competence and the ability of it to be measured and verified by the arrangements suggested.
16. Experience tells us that the public are frequently not judicious in determining the true meaning of any licence, kite mark or title. Any such annotation is usually perceived, without question, as competence in the broadest sense. Any move to license practitioners to all but the fullest measure is likely to cause confusion at best and misplaced trust at worst.
17. By virtue of the prescription status of certain popular treatments, unregulated practitioners cannot work in isolation, but are subject to the overview of regulated healthcare prescribers. Any move to license those who are unregulated would have to entertain the complexities of this impinging upon those who are regulated from another source. e.g. NMC or GMC.
18. The draft proposals do appear to discuss providing exemptions to 'members of specific professions' (see para 120 in Guidance Notes) who are overseen by 'Governing Councils'. Our position on this is with regard to nurses in particular where we would agree that such exemptions are appropriate. The alternative would seem to be a layering of regulation upon regulation. We would question the benefits as set against the complexities of such a measure.
19. The emphasis of the Bill appears to be on 'Special Procedures' being carried out in 'an unhygienic fashion' (Para 108 of the Guidance Notes) and the need for practitioners to 'employ safe working practices' (Para 108 of the Guidance Notes). Para 115 of the Guidance Notes refers to the lack of a 'Competency Test' for practitioners and also to there being no requirement 'for consent forms, pre and post-procedure consultation, aftercare advice or record keeping' which are all critical points. However we refer to Para 14 in this submission which states that the suggested framework for licensing is inadequate to support the assessment of professional competence.
20. The principle of licensing individuals as well as premises (Para 117 of the Guidance Notes) is thoroughly endorsed by the BACN from its experience of the non-surgical sector in the UK. This is necessary to avoid large chains of

- clinics or bodies providing ‘Special Procedures’ registering on bloc under the licensing system and then having a number of individuals carrying out ‘Special Procedures’ without a licence and redress for the patient.
21. Recognition in the Bill of the need to update various ‘Special Procedures’ via secondary legislation is also welcomed by the BACN from its experience of the rapidly changing ‘non-surgical aesthetic sector’ in the UK.
 22. The BACN notes that it is local authorities in Wales who are being charged with the responsibility for licensing and enforcing the conditions of the licence (Para 122 of the Guidance Notes) and questions if they have the specialist expertise and resources to do this in respect of aesthetic treatments. If the area of ‘non-surgical aesthetic treatments’ did come under some kind of licensing procedure how would local authorities ensure that they have the relevant expertise to assess competence.
 23. The power of local authorities to issue ‘Stop Notices’ to practitioners (Para 123 of the Guidance Notes) who have contravened the licensing rules is good in theory but may be very difficult to implement in practice. It also places the Licensing Authority in a position where ‘loss of business income’ could be part of a major counter claim.
 24. It is suggested that the legislation will ‘institute a system of mandatory licensing for those practitioners who provide special procedures in Wales, to which national standards will be attached and enforced by local authorities’ (Para 125 of the Guidance Notes) however this is dependent on agreement being reached on national standards. It is our experience in the field of non-surgical aesthetic treatments that this is a major issue. As referred to earlier the BACN has developed its own ‘Framework of Standards and Competencies’ to meet this gap and this is now being incorporated into a broader framework by the HEE in England. It has taken over 18 months to agree this framework with numerous stakeholders participating.
 25. Reference in Para 127 of the Guidelines to ‘Public confidence and client understanding will be further enhanced by the requirement for practitioners to provide pre- and post - procedure consultations’ is definitely recognised by the BACN with regard to non-surgical aesthetic procedures but only if the regulations and enforcement procedures deliver an effective process for monitoring.
 26. The Bill talks about possible exemptions to the arrangements for persons carrying out ‘Special Procedures’. In England this matter has been discussed in great depth with a number of ‘Professional Bodies/Governing Councils’ making the case that existing arrangements are adequate to cover any negligence by a practitioner or to deal with a complaint from a member of the public.

BACN – Concluding Statement

27. The BACN maintains that there is a need to regulate ‘non-surgical cosmetic interventions’ in Wales but does not believe it fits well within a ‘Public Health Bill’ that has not been designed for this purpose and concentrates on premises and hygiene regulation only. The extensive work done by the HEE in England provides an excellent backdrop to the issue of regulation in Wales. However the BACN is concerned about the length of time it has taken and the fact that there is still no clear set of proposals or structures agreed.
28. We consider that there are two options involved with regard to providing a regulatory framework for non-surgical cosmetic interventions in Wales:

Option 1

Adopting the framework currently being developed in England where considerable work has been undertaken to define the area and the standards/competency involved. However this is subject to agreements being reached and final proposals published.

Option 2

Reviewing what emerges from the process in England and then deciding if a more regulated framework via statute is necessary in Wales. This would enable Wales to make its own decision on regulation but could mean considerable delays which would not be in the interest of the general public or regulated medical professionals.

The BACN is happy to work with the Welsh Assembly whichever approach it decides to take with regard to the issue of regulating ‘non-surgical cosmetic interventions’ separately from this current Bill.

Sharon Bennett – Chair – on behalf of the BACN Board

Andrew Rankin – Vice Chair – on behalf of the BACN Board

Paul Burgess – CEO – BACN

29th August 2015.

Public Health (Wales) Bill / Bil Iechyd y Cyhoedd (Cymru)

Evidence from Save Face – PHB 46 / Tystiolaeth gan Save Face – PHB 46

What are your views on creating a compulsory, national licensing system for practitioners of specified special procedures in Wales, and that the premises or vehicle from which the practitioners operate must be approved?

‘The principal purpose of regulation of any (healthcare) profession is to protect the public from unqualified or inadequately trained practitioners. The effective regulation of a therapy thus allows the public to understand where to look in order to get safe treatment from well-trained practitioners in an environment where their rights are protected. It also underpins the (healthcare) professions’ confidence in a therapy’s practitioners and is therefore fundamental in the development of all (healthcare) professions.’

We would question how the identified risks have undergone an appropriate assessment, and analysis of achievable, quantifiable and desirable outcomes which justifies the measures (and investment of public funds and resources) proposed.

In February 2011, the Government published the Command Paper ‘Enabling Excellence – Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers’. This document sets out the current Government’s policy on regulation, including its approach to extending regulation to new groups. In particular, it sets out the Government’s policy that, in the future, statutory regulation will only be considered in ‘exceptional circumstances’ where there is a ‘compelling case’ and where voluntary registers, such as those maintained by professional bodies and other organisations, are not considered sufficient to manage the risk involved. The paper also outlines a system of what is called ‘assured voluntary registration’. The Health and Social Care Act 2012 has implemented a number of the policies described in the Command Paper. The Professional Standards Authority for Health and Social Care now has powers to accredit voluntary registers of people working in a variety of health and social care occupations. The idea behind this is to provide assurance to the public that these registers are well run and that they require their registrants to meet high standards.

Has The Assembly considered supporting established Professional Associations to explore and develop more robust voluntary self regulatory frameworks (self-funded)? Well organised and appropriately focused professional bodies are better placed to establish;

- Standards of training and accreditation
- Codes of Conduct
- Standards of Practice
- Public and professional education
- Credible influence on both practitioner and consumer behaviour
- Appropriate expertise
- Flexibility to respond to public and professional concerns
- Hold, manage and publish registers of members
- Hold members accountable to Standards
- Manage complaints and report/refer to appropriate statutory regulators (e.g. Public/Environmental Health/MHRA)

The British Institute & Association of Electrolysis should be consulted and may prove to be the best vehicle to protect the public- sign posting consumers to properly trained professionals?

Alliance of Professional Tattooists
The Association of Professional Tattoo Artists
Association of Professional Piercers
Tattoo and Piercing Industry Union

The above (Tattoo) bodies should be brought together to collaborate, sharing experience and expertise to inform developing their own model for self regulation.

The British Acupuncture Council is a recognised body registered with The Professional Standards Authority. This model is one, other Associations should aspire to.

Do you agree with the types of special procedures defined in the Bill?

We trust that the list has been devised based on evidence of harm caused, high risk behaviour and poor practice related to these procedures. We would question how the measures proposed will impact on public health more effectively than encouraging and supporting more robust self regulation.

Acupuncture already has a model for registration and regulation, The British Acupuncture Council. We would question the need for this procedure to be included in the legislation, but perhaps the authorities should signpost the public to regulated practitioners (Registered members of The BAC).

What are your views on the provision which gives Welsh Ministers the power to amend the list of special procedures through secondary legislation?

We are very pleased the Assembly has had the foresight to ensure provision for flexibility to respond and adapt in a timely fashion. Statutory regulation should only be imposed if Voluntary self or co-regulation fails to deliver improved standards of safety and practice. With the exception of Acupuncture, this model of self- regulation has not yet been explored. The problem always lies with a lack of recognised standards of practice, training and accreditation and inclusion on a register which is accessible to the public and holds practitioners accountable. In the interests of gathering information and data, we would ask of the assembly whether the licensing process could include a questionnaire on other potentially high risk procedures performed and by whom and facilitate some form of reporting for members of the public who wish to raise concerns or complaints, as a means of gathering data for risk assessment to inform decisions on whether ,and for what procedures the list should be extended. Also, if in the course of inspection, the officer observes anything which he or she sees as a risk to public health, they record and report to appropriate authority/regulator.

The Bill includes a list of specific professions that are exempt from needing a licence to practice special procedures. Do you have any views on the list?

We appreciate the exempted professionals are accountable to their own statutory regulators, but the procedures included do not fall within their recognised scope of practice, and we feel it would be appropriate, in the interests of clarity for the public, that ALL those providing these procedures should be subject to the same mandatory licensing and inspection. It is our experience that regulated healthcare professionals are capable of unsafe practice in inappropriate environments. Their regulators do not inspect premises, would not be in a position to manage complaints and the process for appraisal and revalidation would not include any of these procedures.

Do you have any views on whether enforcing the licensing system would result in any particular difficulties for local authorities?

Effective enforcement requires more than the process of licensing; application, verification, inspection and publication on a register. It must be supported with education, motivation and deterrent.

Education

The public must be familiar with the regulation and actively seek licensed providers.

- This can best be achieved by providing license holders with materials to promote their licensed status- badge, poster, logo for website and social media. The website and social media 'badge' should have an embedded link to the register- so that consumers can verify their license, and provide feedback on the service. The logo could say, 'click to verify'. Display should be compulsory.
- Articles about the licensing and regulation should be published in all trade and specialist magazines. It may be possible to require trade/specialist publications to include a statement about licensing wherever services are advertised. Not unlike the 'Drink Aware Campaign'.
- The register itself should also provide a platform for public education and should include advice and information to support the consumer to make safe choices and be aware of risks.
- The licensing process itself affords the opportunity to educate the practitioners, establish standards and provide guidelines. Save Face has provided model templates and guidelines on patient information, consent, complaints management, adverse event reporting, confidentiality/data protection, record keeping, infection control etc. which have been welcomed by our registrants and provide a clear bench mark for our inspectors to measure against.

Motivation

In a competitive market, providers will recognise the 'marketing value' of the logo/license. If the process is supportive, providers will see added value to obtaining a license.

Deterrent

- With the necessity of online presence, it is not difficult, with routine searches (Google, Facebook and Twitter) to identify providers and check they are licensed. This pro active activity, if neglected, allows unscrupulous providers to practice with impunity. They need to know they cannot fly, 'under the radar'.
- Fixed penalties, escalating for persistent offenders must be applied without exception. The penalty should be sufficient to act as a deterrent and should not be preceded with a warning.
- Advertising of unlicensed services (print media) should be prohibited, with fixed penalties applied.
- Reporting process must be accessible and responsive. To identify issues, to monitor and audit success/failure, to inform continuous improvement and to promote public confidence in the regulation.

Clearly, Education and motivation could be provided through self regulatory models, the deterrent aspects would be weak, without legislation to enable enforcement, but perhaps the Assembly could consider a model for co-regulation- when standards are breached, there is enforcement by local authorities?

Problems:

Lack of appropriate knowledge/expertise exploited by practices

Enforcement officers applying standards not applicable to specialism.

Reluctance of public to report/ or lack of understanding- who to report to and for what?

Lack of public/consumer engagement

Lack of engagement with trainers and professional bodies

Lack of targeted resources to prevent harm, rather than act retrospectively to punish when harm is caused.

Poor data collection for audit

Lack of consistency across regions.

Safe practices will be more inclined to register, whilst high risk services go 'underground'. It is our experience that the public who use unsafe services are less likely to raise concerns or make complaints, for a variety of reasons.



- There is none who will take responsibility
- They don't know who to complain to
- They are embarrassed
- They have been intimidated/ threatened

THIS needs to be addressed as a matter of priority. Current licensing models tend to cling to the four corners of the legislation (has the practitioner/premises breached the terms of the licensing?) This fails the consumer.

Do you believe the proposals relating to special procedures contained in the Bill will contribute to improving public health in Wales?

We believe the proposals have the potential to contribute to public health in Wales. Lessons might be learned from similar regulations applied in London Boroughs and Nottingham. This must not be perceived, either by the licensees or the public as 'just another income generator'. The officers must be well trained, well informed, understand the wider regulatory framework and be clear on their public protection responsibilities which may at times, go beyond the four corners of this Act, and require referral to or collaboration with other statutory or executive bodies. Complaints must be recorded, resolved and audited. 360 degree feedback must be encouraged and published to inform continuous improvement.

It is our opinion that **effective** regulation would be more expensive and complicated than anticipated. It is currently estimated that the cost of fully implementing this licensing bill would cost in excess of £6m of public funding and is the second most expensive item on the health bill. This would place an additional burden on already challenged public services at a time when there must be higher priorities. Local Authorities are not best placed to implement the measures proposed and

do not have sufficient resources to do so. However, when practice breaches standards and legislation already in place (Health and Safety Legislation) they should have clear responsibilities and publicly accessible processes to act and prosecute; this is already assumed and expected.

Save Face propose it is not in the public's interest to allocate such a significant amount of public funding to such services. These are elective procedures and there are other forms of introducing more stringent standards across the board that would be cost neutral to the tax-payer but would be income generate for the local authorities who would still have ownership of applying legislation where standards have been breached to apply enforcement action. Save Face propose that it would it would be more appropriate cost effective and efficient to contract the ownership and management to a third party scheme. To Contract the development of standards, assessment model and audit to a third party organization who would submit a competitive tender for the contract. This would facilitate business growth and job creation in Wales whilst mitigating risk and cost to each authority. The appointed origination would have the existing infrastructure and training framework to implement the model at a far greater pace and would have access to the areas of specialism required to create a fit for purpose set of standards to assess both the suitability of the practitioner and the environment in which the treatments are performed. It would also have the necessary experience and infrastructure to develop and raise consumer awareness of the register, a vital element of successful licensing which other public facing registers have failed to do.

This model has proven significantly more effective in other cases of accreditation that are managed on an outsourced basis on behalf of the government in other areas requiring the application of a stringent set of standards. For example there are several of government appointed health and safety accreditation schemes including; Safecontractor, Altius, Constructionline and in utilities; Gas Safe which is managed by Capita PLC on behalf of the UK government.



Case History (Not Wales)

I reported to Public Health England.

I was referred to the local Authority

I was contacted and spoke to a nurse who understood and acknowledged my concerns

The Inspectors established the salon was not licensed to provide IPL hair removal or permanent makeup and did an unannounced inspection, but did not find the provision of dermal fillers as within their scope, so declined to take any action or any investigation of my complaint!

The full name of the nurse is not published, the salon will not provide it to me, therefore I cannot complain to The NMC (Nursing and Midwifery Council-) in any case, they would require more 'evidence'. There is no regulator who can take any action without further evidence, and no regulator who will use their authority (and resources) to investigate, based on my complaint....Presumably we will have to wait for a member of the

public to contract Hep B or Hep C and be able to trace it to a shared syringe of dermal filler or botulinum toxin, before any action is taken, This is unacceptable,

We are happy to provide further and better particulars, upon request ,on any of the comments we have made.

Save Face

Agenda Item 6

National Assembly for Wales / Cynulliad Cenedlaethol Cymru

[Health and Social Care Committee](#) / [Y Pwyllgor Iechyd a Gofal Cymdeithasol](#)

[Public Health \(Wales\) Bill](#) / [Bil Iechyd y Cyhoedd \(Cymru\)](#)

Evidence from British Acupuncture Council – PHB 15 / Tystiolaeth gan Y
Cyngor Aciwbigo Prydeinig – PHB 15

British Acupuncture Council

Response to Consultation on Public Health (Wales) Bill

What are your views on creating a compulsory, national licensing system for practitioners of specified special procedures in Wales, and that the premises or vehicle from which the practitioners operate must be approved?

The British Acupuncture Council (BACc) believes that the introduction of a new compulsory national licensing scheme for special procedures will remove many of the anomalies which have arisen in the enforcement of Local Government Miscellaneous Provisions Act (1982) as amended by the Local Government Act 2003. The existence of non-mandatory model byelaws has not always led to consistent adoption of similar models by local authorities, and the BACc's experience is that local enforcement across the UK as a whole has been variable, with many authorities blurring the distinction between legal requirements and best practice advice in enforcement. A standardised system across Wales will both eradicate idiosyncratic interpretations of the law and create a single reference point for discussion and consultation on any variations which might be required in line with developments in health and safety requirements.

It follows that the BACc supports any provision to approve the premises or vehicles in which or from which special procedures are performed. The provision of clear guidance as outlined in the consultation document would set down a standard which would enable practitioners to ensure their premises were satisfactory, and as above, make very clear what upgrades and updates may be required in future.

In summary, the BACc supports these proposals, with the caveat that the advantages of a centralised system could be undermined unless suitable consultation procedures are in place for future development of the licensing conditions. The BACc was heavily involved in the drafting of the model byelaws by the Department of Health in 2005/6 and was able to bring important practitioner concerns to the fore when the national guidelines were created. The special procedures covered by this proposal range from the minimally invasive to the necessarily near-surgical, and it is important to enshrine a level of proportionality into guidelines affecting a range of techniques to avoid an unnecessary and unfair levelling up of requirements. This has to involve input from the professions, and the BACc hopes that this will be taken into account if these proposals become law.

Do you agree with the types of special procedures defined in the Bill?

The types of procedure outlined in the Bill are consistent with those in primary legislation elsewhere in the UK, except Greater London where 'special treatments' has a wider definition under the London Local Authorities Act 1991. The BAcC would not wish to see any changes to this list at this stage.

However, the emergence of variations on the standard theme has been considerable over the last forty years, and there are a number of techniques used in Traditional East Asian medicine, for example, which are proscribed by regulatory bodies like the BAcC but may actually be used by practitioners who choose not to register with a voluntary association. The example of 'wet cupping', a procedure widely used in China, demonstrates how there may well be variations to any of the named disciplines in the Bill which could be advertised and used without reference to the provisions of the Bill for want of inclusion within the definitions. The BAcC would welcome further discussion during the implementation of the Bill about the scopes of practice of the various techniques and what a local authority could reasonably claim to hold jurisdiction over.

What are your views on the provision which gives Welsh Ministers the power to amend the list of special procedures through secondary legislation?

The BAcC believes that such a provision is essential to avoid unnecessary expense or unnecessary delay in extending the range of procedures covered by the legislation. As noted above, however, the BAcC would welcome explicit rules for consultation if secondary powers are invoked in this way.

The Bill includes a list of specific professions that are exempt from needing a licence to practice special procedures. Do you have any views on the list?

The BAcC is pleased to see that registration under the Professional Standards Authority's AVR scheme has been accepted as a basis for exemption. Its experience of submitting itself to this new scheme has been that the requirements for accreditation have been onerous and robustly enforced, and have demonstrated this is not a 'soft option.'

The only cautionary note which the BAcC would like to sound is in relation to the exemption granted to registrants of professions regulated by statute. Its experience is that while most doctors and physiotherapists who undertake acupuncture belong to the relevant special interest bodies within their professions (the British Medical Acupuncture Society and Acupuncture Association of Chartered Physiotherapists), many other registered professionals like osteopaths and chiropractors go 'off the radar' in the absence of equivalent special interest bodies within their professions. This has meant that neither safety nor training standards of such practitioners are vetted, and the BAcC does not believe that this is entirely adequate. Set against the argument that the threat of loss of title ensures compliance with appropriate rules is the counter argument that you can't know what you don't know, and that it is not satisfactory to find out that something has gone wrong after it has gone wrong.

The BAcC would favour some form of explicit statement that there were powers within the Bill to inspect the premises of exempted practitioners where concerns has been raised about their standards of practice, and would be happy to see this enforced in relation to its own members. The logic applied in Greater London is that the exemption is granted on the assumption of maintaining exemplary standards, and therefore failure to maintain standards

should set aside the veil of exemption. Given that there are several published and readily accessible standards for safe acupuncture practice and recognised training, the BAcC believes that a local authority should have powers within the Bill to inspect and enforce precisely as it does with other licensees.

Do you have any views on whether enforcing the licensing system would result in any particular difficulties for local authorities?

The BAcC is generally satisfied that the system as outlined in the Bill can be enforced effectively by local authorities, and believes that the clarity of the national statements and guidelines will eradicate those problems which it has met elsewhere. These have primarily been the generation of idiosyncratic rules by local Environmental Health Officers based on their personal beliefs, and the turnover of staff which has meant that incoming officers have not been properly inducted into the system, and have applied it somewhat arbitrarily. The new licensing arrangements should ensure that the reference material is available and consistently applied across the principality.

Do you believe the proposals relating to special procedures contained in the Bill will contribute to improving public health in Wales?

There is no doubt that a clear statement of standards and enforcement will be of benefit to public health in Wales, not least because an increasingly well-informed public used to electronic access to information will be able to find out easily what the relevant standards are and have confidence that anyone licensed within the new system has met and continues to meet them. This will also benefit the practitioners themselves, whose profile will be enhanced by demonstrating that the public can have trust that they are safe and competent.

The BAcC is grateful for having been invited to participate in the consultation, and would welcome any future invitations to be involved in the drawing up of detailed guidelines for acupuncture and acupuncture practitioners.

4th August 2015

Agenda Item 7

National Assembly for Wales / Cynulliad Cenedlaethol Cymru

[Health and Social Care Committee / Y Pwyllgor Iechyd a Gofal Cymdeithasol](#)

[Public Health \(Wales\) Bill / Bil Iechyd y Cyhoedd \(Cymru\)](#)

Evidence from British Body Piercing Association – PHB 08 / Tystiolaeth gan Cymdeithas Prydain ar gyfer Tyllu'r Corff – PHB 08

Public Health (Wales) Bill: Consultation questions

Special Procedures

The Bill includes a proposal to create a compulsory licensing system for people who carry out special procedures in Wales. These special procedures are tattooing, body piercing, acupuncture and electrolysis. The places where these special procedures are carried out will also need to be approved.

Question 7

What are your views on creating a compulsory, national licensing system for practitioners of specified special procedures in Wales, and that the premises or vehicle from which the practitioners operate must be approved?

The British Body Piercing Association has set in place codes of practice and ethics which all members have adopted and use these in their work place. (please find attached) We have the most up to date training and follow the guide lines set by local boroughs. Body piercers need to be more regulated within their premises and have a recognised body in which they can rely on for support and further training.

Question 8

Do you agree with the types of special procedures defined in the Bill?

Yes, all of these areas of work are those of great skill and performed incorrectly can result in emergency medical treatment. Which in turn has consequences? The ability of the body piercer is defined not only by the teachings of the body piercer but confidence and ongoing support.

Question 9

What are your views on the provision which gives Welsh Ministers the power to amend the list of special procedures through secondary legislation?

By being able to amend current special procedures and aim to put in place newer protocol fits with keeping in with what consumers want. They want to know the best place to have a body piercing, and to know that the studio is certified.

Body piercing is something that has been used for years and does hold a rite of passage to not be regulated, but a huge percentage of body piercers do not withhold a basic understanding of body piercing. By bringing a standard of body piercing there would be far lesser impact on consumers not achieving the desired outcome and encounter problems.

Question 10

Do you have any views on whether enforcing the licensing system would result in any particular difficulties for local authorities?

By enforcing new licensing systems it brings the industry to a professional standing, Currently there are two candidates that have been working within the body piercing industry outside of EHO, TPIU and The Association of Professional Piercers, (APP) neither of these organisation warrant the merit of the body piercer you can simply fill in a form and make a payment, The memberships are not built to aid the body piercer.

By bringing new regulations that are within a workable ability for piercing professionals I believe this will only impact in a positive light. Local authorities should be able to rely on potential training and associations to give help and guidance, but also be able to liaise with local business to keep them up to date with new requirements.

By having more understand of the job that a body piercer does I believe will help to encourage people to want to push forward and become the industry recognised people they are.

Intimate piercings

The Bill includes a proposal to ban intimate body piercings for anyone under the age of 16 in Wales.

Question 11

Do you believe an age restriction is required for intimate body piercing? What are your views on prohibiting the intimate piercing of anyone under the age of 16 in Wales?

The use of age restrictions is something that needs to come in to affect more, especially with in intimate areas of the body. The BBPA do use an age restriction within the codes of practices and ethics, Which is highly regarded with in the studios of our members. Prohibiting intimate piercings for under the age of 16 will give moral standing. Being able to allow a parent or guardian to stand guardian of the person I feel will be adequately sufficient for above the waist piercings. Female's nipples should be considered for piercing over 18 only. However anything below the waist I believe should only be in performed by someone who has adequate knowledge of the anatomy of the genitals and has had further training with in this specific area and should not be performed on anyone under the age of 18.

Actively working with the in industry allows me to be in constant communication with piercers and pierce'es on average the majority of under 16's are already aware that they will need a parent or guardian to be present when having their piercing performed.

Question 12

Do you agree with the list of intimate body parts defined in the Bill? Whether any other types of piercings (for example naval piercing, tongue piercing) should be prohibited on young people under the age of 16.

Yes, in my opinion the list is correct. I believe that the environment that the intimate piecing is taking place should be performed in a stricter platform. An utilised area which can be designated to the use of genital piercings only.

Their also needs to be more information and advise based around these piercing for the general public.

The basis of body piercing is training and consultation, the tool book creates a

really good basis to go forward with however it does not promote the ability's of the body piercer.

Weather a body piercer is piercing an ear, an belly button or a nipple the client knows they will have to be contact made in that particular area.

Other comments

Question 19

Do you believe that the issues included in this Bill reflect the priorities for improving public health in Wales?

Yes. There is a huge potential to be able to create a better environment for every one today.

Agenda Item 8.1

Health and Social Care Committee

Meeting Venue: **Committee Room 3 – Senedd**

Meeting date: **Thursday, 9 July 2015**

Meeting time: **09.17 – 11.52**

This meeting can be viewed on [Senedd TV](#) at:

<http://senedd.tv/en/3026>

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Wales



Concise Minutes:

Assembly Members:

David Rees AM (Chair)
Alun Davies AM
John Griffiths AM
Altaf Hussain AM
Elin Jones AM
Lynne Neagle AM
Gwyn R Price AM
Lindsay Whittle AM
Kirsty Williams AM

Witnesses:

Dr Julie Bishop, Public Health Wales
Dr Quentin Sandifer, Public Health Wales
Dr Gillian Richardson, Aneurin Bevan Health Board
Dr Sara Hayes, Abertawe Bro Morgannwg University Health Board

Committee Staff:

Llinos Madeley (Clerk)
Helen Finlayson (Second Clerk)
Catherine Hunt (Second Clerk)
Sian Giddins (Deputy Clerk)
Rhys Morgan (Deputy Clerk)

Transcript

View the [meeting transcript](#).

1 Regulation and Inspection of Social Care (Wales) Bill: discussion on order of consideration for Stage 2 proceedings

1.1 The Committee agreed, in principle, the order of consideration for Stage 2 proceedings of the Regulation and Inspection of Social Care (Wales) Bill.

2 Introductions, apologies and substitutions

2.1 Apologies were received from Darren Millar.

3 Public Health (Wales) Bill: evidence session 2

3.1 Apologies were received from Professor Mark Bellis.

3.2 The witnesses responded to questions from Members.

3.3 The witnesses agreed to provide the Committee with a note on:

- the collaboration work being undertaken by Public Health Wales, Sport Wales and the Welsh Government to encourage physical activity in improving the health of local people;
- their views on whether financial incentives should be offered to assist local authorities in providing public toilets;
- their views on implementing a minimum age restriction for all body piercings;
- any additional tobacco control measures which should be considered for inclusion in the Bill; and
- any evidence which demonstrates the effect of residual and third hand vapours from e-cigarettes.

4 Public Health (Wales) Bill: evidence session 3

4.1 The witnesses responded to questions from Members.

5 Papers to note

5.1 Minutes of the meetings on 17 and 25 June 2015

5.1a The Committee noted the minutes of the meetings on 17 and 25 June 2015.

6 Motion under Standing Orders 17.42(vi) and (ix) to resolve to exclude the public from the remainder of the meeting

6.1 The motion was agreed.

7 Public Health (Wales) Bill: consideration of evidence

7.1 The Committee considered the evidence received.

8 The Committee's forward work programme

8.1 The Committee agreed its outline forward work programme from September to October 2015, and agreed to return to this item at a later date.

8.2 In light of the Minister for Health and Social Services indication that he intended to move a financial resolution for the Safe Nurse Staffing Levels (Wales) Bill early in the autumn term, the Committee agreed to write to the Business Committee to request an extension to the deadline for the completion of Stage 2 proceedings.

8.3 The Committee discussed its forward work programme from November 2015 to March 2016, and agreed to return to this item at a later date.

Health and Social Care Committee

Meeting Venue: **Committee Room 3 – Senedd**

Meeting date: **Wednesday, 15 July 2015**

Meeting time: **09.18 – 11.55**

This meeting can be viewed on [Senedd TV](http://senedd.tv/en/3013) at:
<http://senedd.tv/en/3013>

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Concise Minutes:

Assembly Members:

David Rees AM (Chair)
Alun Davies AM
John Griffiths AM
Altaf Hussain AM
Elin Jones AM
Darren Millar AM
Lynne Neagle AM
Gwyn R Price AM
Lindsay Whittle AM
Kirsty Williams AM

Witnesses:

Julie Barratt, Chartered Institute for Environmental Health
Robert Hartshorn, Directors of Public Protection Wales
Paul Mee, Directors of Public Protection Wales
Naomi Alleyne, Welsh Local Government Association
Simon Wilkinson, Welsh Local Government Association

Committee Staff:

Llinos Madeley (Clerk)
Christopher Warner (Clerk)
Helen Finlayson (Second Clerk)
Catherine Hunt (Second Clerk)

Sian Giddins (Deputy Clerk)
Rhys Morgan (Deputy Clerk)
Gareth Howells (Legal Adviser)
Amy Clifton (Researcher)
Elfyn Henderson (Researcher)
Victoria Paris (Researcher)
Philippa Watkins (Researcher)

Transcript

View the [meeting transcript](#).

1 Introductions, apologies and substitutions

1.1 No apologies were received.

2 Public Health (Wales) Bill: evidence session 4

2.1 The witness responded to questions from Members.

2.2 The witness agreed to provide the Committee with:

- a note on an incident identified by Public Health England relating to acupuncture; and
- details of a study on the transition of children who used sweet cigarettes into smoking.

3 Public Health (Wales) Bill: evidence session 5

3.1 The witnesses responded to questions from Members.

4 Papers to note

4.1 Minutes of the meetings on 1 July 2015

4.1a The Committee noted the minutes of the meeting on 1 July 2015.

4.2 Inquiry into alcohol and substance misuse: additional information from the Deputy Minister for Health

4.2a The Committee noted the additional information.

4.3 Regulation and Inspection of Social Care (Wales) Bill: correspondence from the Older People's Commissioner for Wales

4.3a The Committee noted the correspondence.

5 Motion under Standing Orders 17.42(vi) and (ix) to resolve to exclude the public from the remainder of this meeting

5.1 The motion was agreed.

6 Public Health (Wales) Bill: consideration of evidence

6.1 The Committee considered the evidence received.

7 Inquiry into alcohol and substance misuse: consideration of draft report

7.1 The Committee considered and agreed the draft report subject to minor amendments.

8 Fourth Assembly Committee Legacy: consideration of approach

8.1 The Committee considered and agreed its approach to its Fourth Assembly legacy work.

Agenda Item 8.2

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



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: LF/MD/0688/15

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

4 September 2015

Dear David,

Public Health (Wales) Bill

I would like to thank you and the Committee for the opportunity to discuss the Public Health (Wales) Bill on 1 July 2015.

I am pleased to provide the Committee with further information on the following issues, which were raised during the session:

- a) the Welsh Government's view of the legislative competence of the National Assembly for Wales to impose restrictions on the sale of high sugar products and alcohol, and to ban the sale of conventional cigarettes in Wales;
- b) details of medical assistance sought as a consequence of undergoing any of the special procedures covered in the Bill, including the cost of providing treatment;
- c) details of the evidence I referred to that most users of e-cigarettes also use conventional tobacco cigarettes;
- d) information on the success rate of using e-cigarettes as a smoking cessation method in comparison to other options; and
- e) further information on the human rights issues associated with the Bill in relation to smoking and the use of e-cigarettes in private dwellings which are also workplaces, and on the powers of entry provisions included in the Bill.

This information is presented below.

Legislative competence of the National Assembly for Wales to impose restrictions on the sale of high sugar products and alcohol, and to ban the sale of conventional cigarettes in Wales

The Welsh Government continues to keep under review the potential public health benefits to be derived from the imposition of restrictions on the sale of high sugar products or on how alcohol is displayed by retailers. It is not Welsh Government policy to introduce a ban on the sale of conventional cigarettes in Wales. As such, detailed policy proposals have not been developed or consulted upon, nor have legislative provisions been drafted. The Committee will appreciate that any assessment of competence pursuant to section 108 of the Government of Wales Act 2006 is concerned with actual provisions of Assembly Acts, not general policies, and that in the absence of draft provisions, it is not possible to express a concluded view on competence. Nevertheless, in order to assist the Committee, set out below is a list of factors that would likely be considered during any competence analysis of draft provisions.

Section 108 of the Government of Wales Act 2006 sets out the extent of the Assembly's competence. Section 108(4) provides that a provision is within competence if it relates to one or more subjects listed under the headings in Part 1 of Schedule 7 to the Act, and does not fall within any of the exceptions in that Part. Consideration would therefore need to be given to whether the provisions would relate to Schedule 7 subjects, having regard to the purpose and effect of the provisions. The Schedule 7 subjects which may be relevant to both topics include the 'promotion of health', 'prevention, treatment and alleviation of disease, illness, injury, disability and mental disorder', and 'protection and well-being of children'. 'Food and food products' may also be relevant to restrictions on high sugar products and alcohol.

However, consideration would also need to be given to whether the provisions would fall within Schedule 7 exceptions. In relation to imposing restrictions on the sale of high sugar products and alcohol, a number of exceptions may be relevant, including the 'consumer protection' exception under heading 4 and the 'licensing' exception under heading 12. In relation to banning tobacco, consideration would need to be given to whether the provisions would fall within the 'products standards and safety' exception or the 'intellectual property' exceptions under heading 4.

Section 108(6)(c) of the Government of Wales Act 2006 further provides that, even where a provision falls within section 108(4), it will be outside the Assembly's competence if it is incompatible with Convention rights or with EU law. It is highly likely that any provisions which seek to reduce the consumption of high sugar products and alcohol would constitute an interference with possessions, falling within the scope of Article 1 of the First Protocol, and potentially an interference with the right to freedom of expression provided for by Article 10 of the Convention. Without further detail relating to the specific proposals, it is difficult to assess whether they would be within competence. In relation to banning the sale of tobacco, careful consideration would need to be given to whether any provisions would contravene the principle of the free movement of goods, specifically the prohibition

of quantitative restrictions and measures having equivalent effect to such restrictions at Article 34 of the Treaty on the Functioning of the European Union.

Notwithstanding issues of competence, any amendments tabled to the Public Health (Wales) Bill would need to comply with Standing Order 26.61.

Details of medical assistance sought as a consequence of undergoing any of the special procedures covered in the Bill, including the cost of providing treatment

Available evidence suggests that most of the complications associated with special procedures are skin infections, although there are a range of complications of varying severity which can arise. Current NHS data collection systems do not provide information on the number of people requiring medical assistance from such complications, and so the Welsh Government is not in a position to provide the requested data.

Each of the four procedures covered by the Bill involve the piercing of the skin, and as such pose a potential risk to health if they are carried out in an unhygienic fashion. I am therefore satisfied that the proportionate regulation of these procedures is appropriate, in order effectively to protect the public from potential harm.

To illustrate the type of harms that can result and their impact on the NHS, a study in England found that complications were reported with 27.5% of body piercings, with problems serious enough to seek further help in 12.9% of cases. Among 16-24 year olds, 5.1% of piercings resulted in help being sought from a pharmacist, 3% from a GP, and 0.6% from an A&E department, with 0.9% requiring a hospital admission. While we have not identified similar data for the other special procedures, evidence from the USA, for example, suggests a complication rate with tattoos of 2-3%. Further information is provided in the Bill's Explanatory Memorandum at paragraphs 541-556.

As the Committee is aware, we have also become aware of recent specific instances of harm being caused in Wales from poor practice. Nine individuals were hospitalised and required surgery in relation to pseudomonas infection following piercings conducted at one establishment in Newport. As Dr Gill Richardson explained in her evidence to the Committee on 9 July 2015, this incident will have cost Aneurin Bevan University Health Board, Public Health Wales and the local authority around £0.25 million.

Evidence that most users of e-cigarettes also use conventional tobacco cigarettes

The majority of e-cigarette users are "dual users" who continue to smoke conventional tobacco products. Varying suggestions have been made about the likely proportion of dual users, ranging from three fifths of all adult users in 2015 according to an ASH UK survey,¹ to approximately 85% of all users according to the Smoking Toolkit Study². Further details of these studies are given below:

¹ ASH factsheet 33: Use of electronic cigarettes in Great Britain. May 2015

<http://www.ash.org.uk/information/facts-and-stats/fact-sheets>

² Smoking Toolkit Study. Trends in electronic cigarette use in England.

<http://www.smokinginengland.info/latest-statistics/> (accessed 27th August 2015. Please note this slide is updated quarterly)

ASH factsheet 33: Use of electronic cigarettes in Great Britain. April 2014 and 20 October 2014, accessed at <http://www.ash.org.uk/information/facts-and-stats/fact-sheets> in February 2015. This factsheet has been updated to feature 2015 data since use in the RIA. Findings included:-

- An estimated 2.1 million adults in Great Britain currently use electronic cigarettes; and
- About one third of users are ex-smokers and two-thirds are current smokers.

The total sample size was 12,269 and fieldwork was undertaken between 5 and 14 March 2014. All surveys were carried out online. This is the source which was used in the Regulatory Impact Assessment (RIA) for the Public Health (Wales) Bill, proportioned to Wales.

ASH factsheet 33: Use of electronic cigarettes (vapourisers) among adults in Great Britain. May 2015 – available at <http://www.ash.org.uk/information/facts-and-stats/fact-sheets>.

Findings included:

- An estimated 2.6 million adults in Great Britain currently use electronic cigarettes; and
- Nearly two out of five users are ex-smokers and three out of five are current smokers.

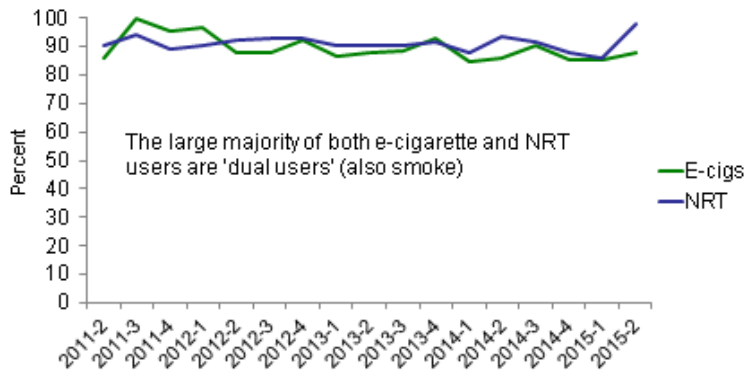
The total sample size for this study was 12,055 and fieldwork was undertaken between 26 February and 12 March 2015. All surveys were carried out online.

Smoking Toolkit Study. Trends in electronic cigarette use in England. Updated 23 April 2015 – available at <http://www.smokinginengland.info/latest-statistics/>

This study involved monthly household surveys, with each month involving a new representative sample of approximately 1,800 respondents, of whom approximately 450 are smokers.

The findings are illustrated in the graph below.

Proportion of e-cigarette and NRT users who are smokers



N=2355 e-cigarette users and N=2302 NRT users of adults who smoke or stopped in past year

www.smokinginengland.info/files/STS#stcs

13

The 2015 ASH data were not available at the time of preparing the Bill's RIA. The 2014 ASH data were therefore applied in the RIA, in order to enable us to make our best current assessment of costs and benefits, as they provide an estimate of the current number of adult e-cigarette users in Great Britain as well as the proportion of e-cigarette users who still currently smoke (the so called 'dual users'). The RIA will be reviewed during Stage 2 of the Bill process and consideration will be given to revising the costs and benefits on the basis of new evidence and data available at the time of the review.

Applying the 2014 ASH data, it is estimated that there are around 100,800 e-cigarette users in Wales and that two thirds of e-cigarette users use them alongside tobacco products. Such "dual users" are still exposing themselves to the health harms from tobacco smoking³, which may have negative implications for individuals and public health. Continuing to smoke any conventional cigarettes confers essentially the full cardiovascular risk, and cancer risk may only be modestly affected, because smoking duration is more important than intensity.⁴ NICE indicates there may be some harm reduction benefits from reduced tobacco consumption if cessation is not an option⁵.

Based on these same sources, Public Health England stated in its 2015 report that around two-thirds of e-cigarette users also smoke. Given this figure, it suggests that data are needed on the natural trajectory of 'dual use', ie whether dual use is more likely to lead to smoking cessation later or to sustain smoking.⁶

³ <http://www.nhs.uk/chq/Pages/2344.aspx?CategoryID=53>

⁴ Background Paper on E-cigarettes (Electronic Nicotine Delivery Systems). Rachel Grana, PhD MPH; Neal Benowitz, MD; Stanton A. Glantz, PhD. Center for Tobacco Control Research and Education University of California, San Francisco WHO Collaborating Center on Tobacco Control. Prepared for World Health Organization Tobacco Free Initiative December 2013.

⁵ <https://www.nice.org.uk/guidance/ph45>

⁶ E-cigarettes: an evidence update: A report commissioned by Public Health England. Public Health England. August 2015

The use of e-cigarettes as a smoking cessation method in comparison to other options

While many smokers quit without recourse to smoking cessation services and products, it is recognised that nicotine products can play an important role in helping smokers to quit altogether, or to reduce their consumption of tobacco products. Nicotine products include traditional forms of licensed nicotine replacement therapy (NRT), such as nicotine patches, gums and lozenges. There is evidence to suggest that long-term use of NRT concurrent with smoking is not associated with an increased incidence of harm, including cardiovascular events or cancer, with the latest analysis of outcome at 12.5 years from study outset⁷.

At present, the health effects of long-term e-cigarette use have not been established⁸. The most robust evidence comes from a Cochrane Review⁹ of 13 completed studies on smoking cessation, published in December 2014. This reported there is some evidence from two trials that nicotine-containing e-cigarettes help smokers to stop smoking long-term, or reduce the amount smoked, compared with non-nicotine e-cigarettes. However the Cochrane reviewers concluded that the quality of the evidence overall is low because it is based on a small number of studies. The one study¹⁰ that compared e-cigarettes to nicotine patches found no significant difference in six-month abstinence rates. However, the authors noted that there was insufficient statistical power in the study, therefore a clinically important difference cannot be ruled out.

The Bill's Explanatory Memorandum provides details of some relevant studies, and we are continuing to monitor the literature. We are aware of more recent studies and analyses, for example a study which shows daily use of e-cigarettes while smoking appears to be linked to an increase in attempts to stop smoking and reducing the amount smoked, but not with cessation. However, the same study found that non-daily use of e-cigarettes while smoking does not appear to increase attempts to stop smoking, nor reduce the amount smoked¹¹. Another recent paper, which looked at 11 published studies, suggested that smokers who use e-cigarettes are about 30% less likely to quit smoking than smokers who do not use e-cigarettes¹².

A great deal has been learnt across the UK in providing effective smoking cessation support since the introduction of specialist services in 2000. A study of data from English

⁷ <https://www.nice.org.uk/guidance/PH45/chapter/9-The-evidence>

⁸ Pisinger Charlotta, Døssing Martin, A systematic review of health effects of electronic cigarettes, *Preventive Medicine* (2014), doi:10.1016/j.ypmed.2014.10.009

⁹ Electronic cigarettes for smoking cessation and reduction (Review). 2014. The Cochrane Collaboration. Published by John Wiley & Sons, Ltd. Available at: <http://www.cochrane.org/features/new-cochrane-evidence-shows-electronic-cigarettes-facilitate-smoking-cessation>

¹⁰ Bullen C, Howe C, Laugesen M, McRobbie H, Parag V, Williman J, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet* 2013;382(9905):1629–37.

¹¹ Is the use of electronic cigarettes while smoking associated with smoking cessation attempts, cessation and reduced cigarette consumption? A survey with a 1-year follow-up. Leonie S. Brose, Sara C. Hitchman, Jamie Brown, Robert West and Ann McNeill. *Addiction* Volume 110, Issue 7, pages 1160–1168, July 2015

¹² <https://tobacco.ucsf.edu/meta-analysis-all-available-population-studies-continues-show-smokers-who-use-e-cigs-less-likely-quit-smoking> March 2015

specialist stop smoking services¹³ looked at 126,890 treatment episodes in 24 stop smoking services in 2009/10 to assess the association between intervention characteristics and success rates. There was substantial variation in success rates across intervention characteristics after adjusting for smoker characteristics:

- NRT used on its own was associated with higher success rates than no treatment at all;
- NRT combined with Varenicline (a prescription medicine used to treat nicotine addiction) was more successful than NRT used on its own;
- Group support was linked to higher success rates than one-to-one support;
- Primary care settings (such as in GP surgeries and hospitals) were less successful than specialist clinics.

It is often stated that smokers are up to four times more likely to successfully quit with support from cessation services. Evidence to support this statement comes from studies which found that:

- When comparing like-for-like types of smokers, the success rate of those who quit with no support is typically three to four per cent¹⁴;
- One large study in England found that breath-test validated quit rates at 12 months were 15 per cent for smoking cessation services and 20 per cent for specialist services¹⁵.

In Wales, smokers are supported to quit by a range of services including the Stop Smoking Wales service and an increasing provision of smoking cessation services in community pharmacies. Dr Julie Bishop, director of health improvement for Public Health Wales recently commented that Stop Smoking Wales had “already started work to ensure that smokers who choose to use e-cigarettes to help them quit also have access to specialist behavioural support”¹⁶.

Human rights issues in relation to smoking and the use of e-cigarettes in private dwellings which are also workplaces

The current law on smoking in private dwellings which are also work-places

The current smoke-free policy is implemented by the Health Act 2006 and the Smoke-free Premises etc. (Wales) Regulations 2007 (“2007 Regulations”). Regulation 3 of the 2007 Regulations contains a number of exceptions to the smoke-free requirements of the Health Act 2006 in relation to dwellings which are also used as workplaces. The policy rationale underpinning these exceptions was that a person’s private dwelling should never be

¹³ Brose, West, McDermott, Fidler, & McEwan (2011). What makes for an effective stop-smoking service

¹⁴ Hughes JR, Keely J, Naud S (2004). Shape of the relapse curve and long-term abstinence among untreated smokers. *Addiction*. 2004;99:29-38

¹⁵ Ferguson J, Bauld L, Chesterman J, Judge K. (2005) The English smoking treatment services: one-year outcomes. *Addiction*. 100 Suppl 2:59-69.

¹⁶ Page 4, The I newspaper 19 August 2015

required to be smoke-free solely by virtue of the fact that a person attends the dwelling to provide specific services (“the excepted services”).

These “excepted services” are:

- (i) to provide personal or health care for a person living in the dwelling;
- (ii) to assist the domestic work of the household in the dwelling;
- (iii) to maintain the structure or fabric of the dwelling; and
- (iv) to install, inspect, maintain or remove any service provided to the dwelling for the benefit of a person living in it.

The 2007 Regulations achieved this general policy objective through a combination of two provisions:

- (i) Regulation 3(1)(b), which provides that part of a private dwelling can only ever be smoke-free if used *solely* for work purposes (or is shared with another private dwelling – Regulation 3(1)(a)); and
- (ii) Regulation 3(3), which provides that even if there are parts of a private dwelling that are used solely for the purposes of work, those parts are not required to be smoke-free if the work consists solely of the excepted services.

The majority of the parts of dwellings that are used to provide excepted services will only be used *partly* for those purposes. Regulation 3(1)(b) provides that those parts are not required to be smoke-free. Regulation 3(3) ensures that any parts of the dwelling that are used *solely* for the purposes of the excepted services are not inadvertently caught by the requirement to be smoke-free (for example a room that is used only as a place where physiotherapists attend to provide physiotherapy to the householder, or a room in a house that is only used by domestic attendants to keep cleaning equipment etc.).

The rationale for the policy of never requiring a part of a private dwelling to be smoke-free only because excepted services are provided there is linked to the requirement for smoke-free premises to be smoke-free all of the time (i.e. 24 hours a day)¹⁷, and not just when being used as a place of work. The nature of the excepted services is such that, ordinarily, they are provided only intermittently (for example, weekly, monthly or annually). As such, it is considered that it would be disproportionate to criminalise the occupant should he or she happen to be smoking when passing through the relevant part of the house, despite the fact that that part of the dwelling may not be used for work purposes for, for example, six months.

A distinction may be drawn in this respect between the excepted services, where the dwelling’s occupant has not chosen to run a business from the home and is merely receiving particular types of service intermittently, and where the occupant has opted to run a business from the home, and is using a part of the home solely for that purpose. In the latter, a conscious decision has been made to make part of the home a workplace, and generally, that workplace would be used more regularly than the excepted services would be provided. As such, it is considered proportionate to require parts of dwellings that are used solely as workplaces (i.e. places from which business are carried on) to be smoke-free all of the time.

E-cigarettes and private dwellings

¹⁷ Section 2(2) provides that smoke-free premises are required to be smoke-free all of the time.

The current position outlined above will be considered further in the context of the Public Health (Wales) Bill, particularly in light of the fact that the Bill will require any parts of dwellings that are used partly or solely as workplaces to be smoke-free, but only when being used as a workplace. In the absence of any relevant exemptions in regulations made under section 10 of the Bill, section 6 will require parts of private dwellings that are workplaces to be smoke-free when used as a place of work. In this context, being 'smoke-free' means that smoking and the use of nicotine inhaling devices ("NIDs") will be prohibited.

In developing our policy in relation to NIDs in dwellings that are used as workplaces, three options were considered:

- (i) to allow the use of NIDs at all times;
- (ii) to prohibit the use of NIDs (and smoking) at all times; and,
- (iii) to prohibit smoking and the use of NIDs when the relevant part of the dwelling is being used as a workplace (i.e. the approach taken in the Bill).

In determining the approach to be taken in the Bill, full consideration was given to Article 8 of the European Convention on Human Rights. I am content that the Bill strikes the right balance between occupiers' rights to use NIDs in their own homes, and the health benefits that arise as a result of restricting their use.

The evidential basis for prohibiting the use of NIDs in parts of dwellings that are workplaces is the same as for restricting the use of NIDs more generally. It is considered that the use of NIDs normalises smoking behaviour. NIDs such as e-cigarettes mimic the sensation and appearance of smoking a cigarette¹⁸ and provide some of the additional behavioural cues that are known to be important in tobacco dependence, including the 'hand to mouth' action. In this context, it is considered that there are significant public health benefits from prohibiting the use of NIDs in dwellings that are workplaces, particularly where children may be present. Examples of such workplace scenarios include:

- child minding services offered from a person's private dwelling;
- hairdressing services offered from a private dwelling (i.e. where people, including children, attend the dwelling to have their hair cut);
- music or language lessons or other private tuition offered from a private dwelling (i.e. where people, particularly children, attend the private dwelling for the lesson / tuition);
- physiotherapy services provided in a private dwelling (i.e. where people, including children, attend the private dwelling for physiotherapy treatment); and
- cupcake decorating party services for children provided from the kitchen of a private dwelling (i.e. the child and their friends attend the private dwelling for a birthday party).

It is also considered that prohibiting the use of NIDs in parts of dwellings that are workplaces will preserve the improved air environment that has resulted from the Health

¹⁸ Public Health England. Electronic Cigarettes: A report commissioned by Public Health England. Professor John Britton and Dr Ilze Bogdanovica. UK Centre for Tobacco and Alcohol Studies Division of Epidemiology and Public Health, University of Nottingham. 2014

Act 2006. NIDs contain various chemicals that are vaporised and emitted into the air, and studies have suggested that e-cigarette aerosol can contain some of the toxicants present in tobacco smoke, albeit at levels which are much lower.^{19 20} Again, my view is the approach taken in the Bill has particular health benefits in relation to workplaces generally, especially those that are likely to be attended by children and young people.

In developing the policy, consideration was also given to the fact that, in practice, the effect of the restriction will be very minimal. The prohibition will only apply during working hours and, even then, the occupant will be free to use a NID in an adjoining room. To cite the example given in Annex A to your letter, the partial restriction on the right to use a NID would not prevent Mr A from leaving the living room to go to, for example, the kitchen, to use his NID.

I would also note that the powers provided at section 10 of the Bill will allow the Welsh Ministers to make regulations to exempt premises, or specified areas within premises, from the requirement to be smoke-free. Any such exemptions may be in respect of both smoking and the use of NIDs, smoking only, or the use of NIDs only. Consideration will be given to whether these powers should be exercised to provide an exemption, in relation to NIDs, for private dwellings that are particular types of workplaces and where children are never present.

Powers of entry

The powers of entry in the Bill relate to local authorities and other enforcement authorities. It is not envisaged that any non-public authorities will be designated as enforcement authorities. Public authorities and the Courts are subject to the European Convention on Human Rights pursuant to section 6 of the Human Rights Act 1998.

The provisions in the Bill relating to powers of entry provide safeguards that the powers may only be exercised following consideration and approval of a warrant by a Justice of the Peace. In view of this, I am content that the powers of entry to private dwellings with a warrant are proportionate, and the safeguards presented by consideration and approval of the warrant by a Justice of the Peace are sufficient to ensure there is no unjustified interference with a person's protected human rights.

A Justice of the Peace should not sign a warrant authorising an Authorised Officer to act in a way which would constitute an unjustified interference with a person's protected human rights. Should the Justice of the Peace consider it necessary to do so in the individual circumstance, he/she can also attach conditions to a warrant, such as timings or other restrictions.

In relation to giving notice of entry, in many circumstances, this would defeat the purpose of entering the premises. If notice of entry were to be served, a person could simply hide

¹⁹ Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. Hajek et al. 2014. *Addiction*, 109, 1801-1810 doi:10.1111/add.12659

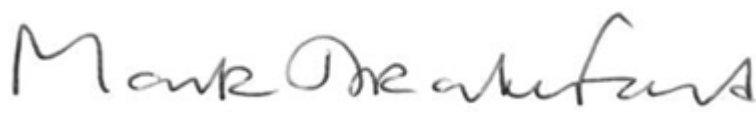
²⁰ Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. Farsalinos and Polosa. *Therapeutic Advances in Drug Safety*. Apr 2014; 5(2): 67-86. doi: 10.1177/2042098614524430 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4110871/>

or dispose of any evidence or documents that were in the dwelling before the Authorised Officer attended on the specified date.

I am aware that the UK Government Department of Health published a report in December 2014 following a review of the health and care powers of entry, to ensure they achieve the right balance between the need to respect the rights of individuals and the need to enforce the law to protect public health. Fifty four powers of entry in primary and secondary legislation were identified in the context of health and care. The review found that the majority of these are vital and proportionate. Accordingly, forty one powers of entry were retained. Where powers of entry were retained, the Department of Health worked with the Home Office to ensure the appropriate safeguards were in place, which included a 'long-stop' option for bodies to seek a warrant. The Welsh Government has not carried out a separate review of powers of entry.

I hope that the information provided in this letter answers the questions raised by Committee members, and I look forward to answering any further questions from members in due course.

Best wishes

A handwritten signature in black ink, reading "Mark Drakeford", enclosed in a thin black rectangular border.

Mark Drakeford AC / AM

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol

Minister for Health and Social Services

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



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: LF/MD/0774/15

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

8 September 2015

Dear David,

Regulation and Inspection of Social Care (Wales) Bill

You will recall, during the General Principles debate on the Bill on 14 July, I confirmed that I would provide a detailed response to your Committee's Stage 1 report and its 46 recommendations. Whilst there is no strict requirement to provide a response to every single one of the recommendations, I felt it was important to answer them under the same headings that your report provided to help you understand the consideration that I have given them. My detailed response is included with this letter.

I am copying this letter to Jocelyn Davies AM, chair of the Finance Committee, as I am aware that she provided her Committee's response to you for inclusion in your report.

Best wishes,

Mark.

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

Recommendations from the Health and Social Care Committee Stage 1 Report into the Regulation and Inspection of Social Care (Wales) Bill.

I would like to thank the Committee for their support for the Regulation and Inspection of Social Care (Wales) Bill and for the detailed scrutiny of its provisions that has been undertaken. I am pleased that the Committee has recognised that this Bill takes positive steps to provide much needed accountability, transparency and stability to the social care sector in Wales. I am reassured to see that the Committee has acknowledged and welcomed a number of our proposals including those for a responsible individual and market stability reporting.

I welcome the vast majority of recommendations made by the Committee and provide further detail on each recommendation below.

General Principles and the Need for Legislation

I am grateful for the Committee's support for the general principles of the Bill

In terms of **recommendation 2**, the Committee will understand that the First Minister has indicated he will provide a response to the Flynn Review later this month. That response will cover the key policy responses to Dr Flynn's review, and I will therefore be able to provide further detail after that point. In terms of this Bill, the Committee will be aware of Dr Flynn's comments within the Executive Summary of her report, where she acknowledged the ongoing dialogue as the Bill had been developed. She noted how that dialogue had

'considered how emergent findings might be reflected: by ensuring that those who own and gain from the provision of services, that is, Board members, are held accountable; by allowing regulators to take action against a corporate body rather than a single service; and by ensuring that information about services providing care and support is accessible to individuals receiving care and to their families'

These three priority findings are, I believe, strongly reflected within this Bill. For example, the new requirements around Responsible Individuals are a significant new approach to accountability of providers in our sector. The move to a service model will allow action by the regulator at a series of levels. The new requirements about published annual reports will transform the information available to the public about care services in Wales.

In addition, Dr Flynn set what she described as an 'ambitious' list of ideas in terms of the new regulatory regime. These will be important contributors to the process of implementation and the regulations that will flow from the Bill. I will ensure that the technical groups we will establish to take forward regulations will consider how these ideas could be taken forward.

However, after reading Dr Flynn's report and considering her ideas I have decided to seek to amend the Bill in one very important way. I will be proposing an amendment on the face of the Bill that establishes in primary legislation the criteria by which we will establish whether someone is fit to register to deliver services in our sector.

I have provided additional information in response to **recommendation 3** as appendices to this letter.

I have sought further advice in response to the concerns raised by both the Committee and stakeholders in respect of amending the Bill to require all those exercising functions under the Bill to have due regard to the United Nations Conventions on the Rights of the Child, the Rights of the Disabled People and the United Nations Principles for Older Persons (**recommendation 4**). Based on this advice I am satisfied that such an amendment is not required and I am **rejecting** this recommendation. The protection of protect vulnerable individuals' rights. This is best achieved I believe through the creation of a framework of regulation which ensures that regulators have appropriate functions at their disposal to promote and maintain high standards in the provision of social care services and, where necessary, intervene to safeguard vulnerable individuals from harm. In my view the Bill creates this framework. The Bill adopts an approach which is designed to ensure that the interests of vulnerable individuals are protected; this will occur through the imposition of detailed duties on providers of social care services, and the conferral of tailored powers upon regulators established for the purposes of safeguarding the interests of the vulnerable. The relevance of the Conventions and Principles lies in informing policy development by the Welsh Government and I am confident that that system of regulation created by the Bill has been informed by those Conventions and Principles. I would re-iterate what I said to the Committee when I gave evidence, that if the Committee is of the view that there are gaps or weaknesses in the regulatory systems established by the Bill that could be resolved by bringing forward amendments to the Bill I would be happy to consider those further.

Moving on to **recommendation 5**, I am happy to **accept** this in part and thank the Committee and stakeholders for drawing this issue to my attention. I have again sought further advice in respect of the United Nations Convention on the Rights of Disabled People and I am of the view that the obligation to provide detail in the annual report on the public sector equality duty will necessarily cover the principles contained in the Convention on the Rights of Disabled People. However, I will bring forward an amendment ensuring that duties under the United Nations Principles for Older People are reported on by the Care and Social Services Inspectorate Wales (CSSIW) in its annual report.

Engagement with the Public

I was very pleased to see the duties to engage the public within the Bill recognised by both the Committee and stakeholders. I am satisfied that the Bill as it stands sets out very clearly the Welsh Government's expectation that CSSIW and Social Care Wales (SCW) must work closely with citizens in carrying out their work. However, in acknowledgement of the views expressed by both the Committee and stakeholders I am happy to provide more detail on those expectations in response to **recommendation 6 below**. I believe very strongly that the precise ways in which the public should be involved in the work of both CSSIW and SCW should not be dictated by Government but should be developed in conjunction with the sector, stakeholders and the public.

Whilst I remain unconvinced about the need to specify the requirement for CSSIW to engage lay inspectors, I am certainly of the view that the public should play an active role in the inspection process. I will bring forward an amendment to ensure that this expectation is met. As such I am **accepting recommendation 7** and **partially accepting recommendation 9** in that the amendment will be a general requirement rather than a specific one.

CSSIW has taken significant steps forward over the past few years in improving its engagement and involvement of users, carers and citizens. I would expect this development to continue. The National Advisory Board and its developing regional presence can continue to provide a voice for citizens and to retain oversight of and challenge to the work of CSSIW. Beyond this I will expect CSSIW to develop strong community links in order to ensure that those closest to care can inform and shape its work. I expect CSSIW to take on board the important wider perspectives that those involved in the sector, and those who are not, can bring. In respect of SCW, I am firmly of the view that public involvement and engagement should extend beyond the presence of its lay-led board and the lay-led requirements this Bill establishes for workforce regulation. With its role leading improvement in our sector, Social Care Wales must stand as an exemplar as to how engagement with and involvement of citizens can make a positive difference to the outcomes for people in Wales.

I am happy to **accept recommendation 8** and agree that the Bill could be strengthened in respect of carers in certain sections and will bring forward amendments accordingly.

Accountability and Transparency

I **accept recommendation 10** in principle; I have made clear my intention to work with the sector in the development of these regulations and also my intention to consult on these regulations prior to introduction. However to add clarity I will bring forward an amendment providing more detail as to the content of the annual return on the face of the Bill. I will also bring forward an amendment specifying that the first set of regulations drafted in relation to annual returns must follow the affirmative procedure.

In **recommendation 11** the committee has asked for an outline of how the provisions relating to Responsible Individuals (RIs) apply to UK-wide or multinational organisations which provide social care services within Wales. The requirements for a RI are a central part of this Bill, they cement the link between the front line and the Boardroom. As such whilst some flexibility in the system is essential the fundamental premise of this provision must be retained i.e. those gaining from the social care sector in Wales must hold primary responsibility and accountability for the quality and safety of the care being provided. In applying these principles it is clear that the RI provisions contained within section 19 of the Bill must apply to large organisations in exactly the same way as to smaller organisations.

The prevention of unsuitable individuals providing social care services in Wales is a fundamental aspect of this Bill. I have decided, following the Flynn Review, that this is an aspect of the Bill that represents a clear opportunity to strengthen our regulatory regime by being absolutely clear about who can and who cannot register to deliver services. I therefore **accept recommendation 12 in principle** as more clarity could be added on the face of the Bill regarding the fit and proper person test that must be satisfied before registration is granted to deliver social care services in Wales. I will bring forward an amendment accordingly.

In my previous letter to the Committee I set out my intention to use the regulation making powers in sections 26 and 27 of the Bill, and the powers to issue guidance set out in section 28 of the Bill, to require providers and/or Responsible Individuals to have appropriate whistle-blowing policies and procedures in place. On this basis I am **rejecting recommendation 13** as I am reluctant to bring forward an amendment of this nature. There

are a range of other very important requirements upon which regulations and guidance could be drafted using the powers contained in sections 26, 27 and 28 of the Bill, and there is no intention to list any of these on the face of the Bill. An indicative list could have the effect of being interpreted as an exhaustive list, thus potentially limiting the extent of areas in which regulations and guidance could be brought forward. The powers in sections 26 and 27 are wide and are intended to be so. That is why the affirmative procedure has been ascribed to these powers so that the Assembly will have the opportunity to scrutinise the necessity and appropriateness of each of the requirements.

I note the Committee's **recommendation 14** and **accept** this on the basis that I will keep sections 19, 21 and 24 of the Social Services and Well-being (Wales) Act under review.

Regulated Services

Recommendation 15 refers to the placing of advocacy services as a regulated service on the face of the Bill. We discussed this issue in Committee and I have given this recommendation further thought. However, my views have not changed from those expressed previously. Although children's advocacy services are well-established my intention is not to take a piecemeal approach but to bring all advocacy services within the regulatory regime at the same time, once full and proper discussions have taken place with the entire sector. However, whilst I am **rejecting** this amendment I am happy to re-iterate my commitment that advocacy will be first in line to become a new regulated service in the first relevant tranche of regulations made under section 2(h) of the Bill.

The Committee has asked for further detail in **recommendation 16** outlining how I will monitor and assess whether the requirement to register should be extended to preventative services and innovative service delivery models emerging under the Social Services and Well-being Act 2014. I **accept** this and can advise the Committee that the relevant duties at section 15 of the 2014 Act will be commenced in April 2016. Once those provisions are commenced it will take time for such services and models to emerge. During that period I will be receiving updates and intelligence from both CSSIW and local authorities themselves. As is currently the case I will be continuing to meet CSSIW on a regular basis and to receive advice on a range of regulatory issues. There will be a continued expectation that CSSIW will advise me of any changes in the sector requiring my attention including new services requiring regulation.

Recommendation 17 concerns outlining the arrangements and support that will be put in place for social care providers during the transition to the service-based model of registration. I am happy to **accept** this recommendation. I have asked CSSIW to undertake an exercise looking into transition planning to include training requirements, dissemination of information and communication of key messages. I envisage that this planning may include the establishment of tools to assist providers during transition such as a support helpline.

The Committee raised concerns regarding how the Bill will deliver a culture of regulation and inspection in which the support and improvement strands of CSSIW's work do not compromise the delivery of robust and effective regulatory activity and enforcement and asked for further detail regarding this in **recommendation 18**, which I **accept**. I do not consider that there is a conflict of the nature described and sections 4 and 67 of the Bill specifically refer to the roles of both CSSIW and SCW being to promote and maintain high

standards. In fact the Bill will, for the first time, make adherence to quality standards a regulatory requirement and provide CSSIW with a range of strengthened enforcement powers and offences with stronger penalties. It is these factors that will ensure robust and effective regulatory activity and enforcement and the involvement of service users and lay people will provide the additional layer of scrutiny which I described in Committee.

Definition of Care

The Committee and stakeholders have expressed concerns that the definition of care in section 3 of the Bill does not take into account the definition of well-being in the 2014 Act. This is reflected in **recommendation 19** which I am **accepting** in principle. Having considered this issue further I am still of the view that the regulatory requirements imposed by section 26 of the Bill, which specifically refer to the well-being outcomes, ensure that well-being is taken into account in the Bill, and the direct correlation to the definition of well-being between both the Bill and the 2014 Act is achieved by section 187. As such I do not intend to bring forward an amendment to the Bill itself but I will be amending the Explanatory Notes for the Bill to make this clearer. I will be bringing forward an amendment to the Explanatory Notes to include examples of what we intend “care” and “support” to relate to, and these will I be along the lines of those included in the Public Services Reform (Scotland) Act 2010 which establishes a similar regime.

With reference to **recommendations 20 and 21** I have reflected further and am happy to say I **accept** both recommendations and will bring forward appropriate amendments.

Inspections

Recommendation 22, which I **accept**, refers to the Committee receiving more information on the outcomes-based inspections which will be undertaken by CSSIW and raises concerns regarding resource and capacity implications following the introduction of a new system. Representatives from CSSIW who gave evidence to Committee were clear that work on outcomes-based inspections had already commenced and so this will not be a completely new system for them or service providers. There will clearly be implications once the new system is fully operational and I anticipate that this will be examined in far more detail in the work on transition which I have asked CSSIW to undertake. Once that information is to hand I would be happy to make a statement.

Recommendations 23, 24 and 25 I **accept** and will bring forward relevant amendments. In respect of 23 and 25, I will ensure that the requirement for appropriate training for inspectors is included in the relevant code that must be prepared pursuant to section 32 and section 161A. I also **accept recommendation 26** and agree that it is essential for regulations to make clear rights and processes for re-inspections.

Power to Charge Fees

I note both the comments from Committee and stakeholders however I feel it is clear under section 185 of the Bill as drafted that the regulations to be made under section 38 relating to the charging of fees, will be subject to the affirmative procedure. I am therefore not minded to bring forward an amendment to section 38 to add that a statement of consultation will be required as the provision of information on the consultation undertaken is included in the Explanatory Memorandum that will be laid alongside the regulations as part of the current established legislative process, as such I **reject recommendation 27**.

Local Authority Social Services

I acknowledge the comments of both the Committee and stakeholders regarding the commissioning of social care services by local authorities and agree wholeheartedly that effective commissioning practices lie at the heart of the delivery of excellent social services. I agree that there is scope to clarify the role of CSSIW in this area on the face of the Bill so **accept recommendation 28** and I will bring forward an amendment to achieve this at stage 2. I am unable to extend this amendment to include local health boards (LHBs) as CSSIW's powers under this Bill do not extend to LHBs. However I do expect an increasingly integrated approach to be taken to commissioning and will look towards producing appropriate guidance.

Market Stability and Financial Sustainability

I have reflected on both the views of the Committee and stakeholders in respect of **recommendations 29, 30, 31 and 33** and am happy to **accept** all four recommendations. I will bring forward an amendment to section 62 of the Bill to make clear that an analysis of commissioning should be included in market stability reports. I cannot imagine a situation where consultation would not take place prior to the introduction of regulations, however as it is felt that this requires clarification, I will bring forward amendments to sections 55, 58 and 62 of the Bill to make clear that consultation will take place prior to the introduction of regulations under these sections. In addition, I will bring forward a further amendment to section 55 to ensure that local authorities must consult with a LHB with which it carried out a population needs assessment pursuant to section 14 of the 2014 Act.

Recommendations 32 and 35 refer to ensuring appropriate resourcing and support for both local authorities and CSSIW in the preparation of market stability reports and the oversight of the regime itself. I **accept** both recommendations and re-iterate my comments to the Committee; the Regulatory Impact Assessment prepared for the Bill identifies the resource requirements for all market oversight related work. This has been arrived at in consultation with stakeholders. In respect of **recommendation 34**, section 58 contains a regulation making power which provides flexibility should the need arise to change the criteria for those subject to market stability reporting. However it remains the case that the primary responsibility for ensuring the due diligence for contractual arrangements remains with local authorities rather than the Welsh Government.

Social Care Wales

I am happy to **accept recommendation 36**. I am reassured that the Committee found the majority of stakeholders to be broadly in favour of extended functions for Social Care Wales. I believe that combining the regulation and service improvement functions to be a logical and progressive approach which can result in shared learning and added value. This view was also endorsed in a report produced for my consideration by the Strategic Improvement Steering Group which provided advice on the establishment of Social Care Wales.

However, I am mindful of the need to put in place measures aimed at mitigating against any perceived conflict of interest that might arise as a result of combining functions. The Bill itself establishes, importantly, a new statutory role for the regulator of Registrar, ensuring there is clear accountability for the regulatory functions of Social Care Wales. I have also established a Transition to Social Care Wales Advisory Panel to develop a transition plan

for my consideration by March next year. As one of its priorities, I have asked the panel to consider governance options for Social Care Wales and specifically to explore and recommend an approach designed to mitigate against any conflict of interest. The panel, which includes stakeholders from across the sector, is currently considering this very important issue so I don't want to pre-empt any recommendations that the panel might make, however I will ensure that Members are updated on the work of this group as it develops its recommendations.

I also **accept recommendation 37** to provide further detail about why there is a need to rebrand the Care Council for Wales as Social Care Wales. The Transition to Social Care Wales Advisory Panel is also considering issues around communications and branding for Social Care Wales which I will update you on as part of my commitment to keep members informed of progress in that work.

Essentially, the case for rebranding centres around the need to convey the significance of the shift to Social Care Wales and the prominence of the service improvement function in particular. The organisation will have responsibility for demonstrating clear leadership to driving improvement across the sector. I therefore believe a modest level of rebranding to be necessary in order to raise awareness of this significant development and to ensure that Social Care Wales can successfully be positioned at the heart of change

Social Care Workforce

I have listened carefully to the range of expression and views from stakeholders and the Committee on the matter of workforce regulation. It has been a rich discussion about a key area of the Bill, given its direct impact upon public assurance. The Bill builds on the foundation of workforce regulation put in place over the last 15 years and paves the way forward for an approach that continues to strengthen the workforce and provide public assurance for the future.

I have signalled that I am in favour of strengthening public assurance in relation to domiciliary care staff and further to that, adult residential care workers. I commit to registration of the domiciliary workforce within the lifetime of the next Welsh Government. In this way I therefore accept the principle behind **recommendation 38**. However it is not viable to move immediately to registration of this workforce without significant risk to service continuity. I will therefore use the medium term to develop the workforce, and our understanding of it, to allow an effective transition to formal registration in due course. I will work with the providers of such services to ensure that the public has access to information about the workforce, its background, qualifications, training and other important information. Using the registration requirements from the service regulator, the Welsh Government will ensure that citizens will have an unprecedented understanding of the staff that are delivering care in people's homes. This will significantly enhance public assurance. But it will also be an opportunity to make a step change in the capabilities and skills of this workforce. I will use the levers at the Welsh Government's disposal, including funding, to prioritise the development of domiciliary workers. A clear and ambitious programme to support career and skill development will be put in place, as part of our wider commitment to the care workforce across health and social care.

On the matter of foster carers, the white paper opened up the question of potential registration and responses were ambivalent, acknowledging the comprehensive vetting processes already operated by local authorities and fostering agencies. Work is taking place with relevant stakeholders to develop a national approach to fostering services in Wales, as part of our wider strategy for looked after children. The aim is to set a new direction for fostering services, linked to the Social Services and Well-being (Wales) Act and this Bill. In this context, I **accept recommendation 39** to explore the potential benefits of applying registration to foster carers.

The Committee also recommended in **recommendation 40** that I reconsider whether the Bill is flexible enough to respond to the regulatory needs of the future workforce. I **accept** this recommendation and have given this matter further consideration. I have reached the conclusion that the Bill upholds the key principles of rigorous lay-led regulation whilst at the same time enabling flexibility of process through regulations and then rules determined by Social Care Wales.

It is vital that the Bill provides clarity to the sector on the relevance of the various provisions to the different elements of the workforce. The committee recommended that I ensure that the terminology used in the Bill achieves this. I **accept recommendation 41** and have looked again at the language of the Bill. I am of the view that the Bill, in following the well-established approach of the Care Standards Act, is already sufficiently clear in how it applies to the social care workforce, including how it relates to the various professions who make a valuable contribution to it. I think it is understood by those working in the sector and moving away from this approach could cause confusion. In order to provide an additional safeguard against any misinterpretation of the Bill, I have asked my officials to look again at the Explanatory Notes to see if they can be further developed to provide greater clarity. I will also ensure that the implementation of the Bill is supported by awareness raising events and publicity material to ensure that all of those affected have a clear understanding of its implications.

Regulation will also be strengthened by relevant bodies and regulators co-operating with each other to ensure coherent workforce regulation and development across sectors and jurisdictions. I therefore **accept recommendation 42 in principle**. The Bill requires Social Care Wales and CSSIW to co-operate with each other and with those relevant authorities listed in section 175. There is a strong history of positive cooperation between regulators across the UK and we are in dialogue with the UK government to explore if this can be formalised on the face of the Bill.

Part 7 of the Bill brings provides the basis for a distinct addition to workforce regulation which would have wide ranging implications for workers, employers and the public at large. In view of this, I **accept recommendation 43** that these regulations should be taken forward through full consultation with the sector and a regulatory impact assessment. I am happy to place this commitment on the face of the Bill.

Cooperation and Joint Working

On the issues of cooperation and joint working, I welcome the broad support that these provisions received. These are new and, I believe, important parts of the Bill. I note the shared view across stakeholders and the Committee that it is important to provide as much opportunity as possible for cooperation and joint working across public services, and for the

law to enable rather than limit these behaviours. The Bill therefore seeks to set out clearly and constructively the expectation and powers for such cooperation. It provides powerful new duties on regulators to share information when well-being is at risk, a provision I was pleased to see endorsed by many stakeholders including WLGA and ADSS Cymru.

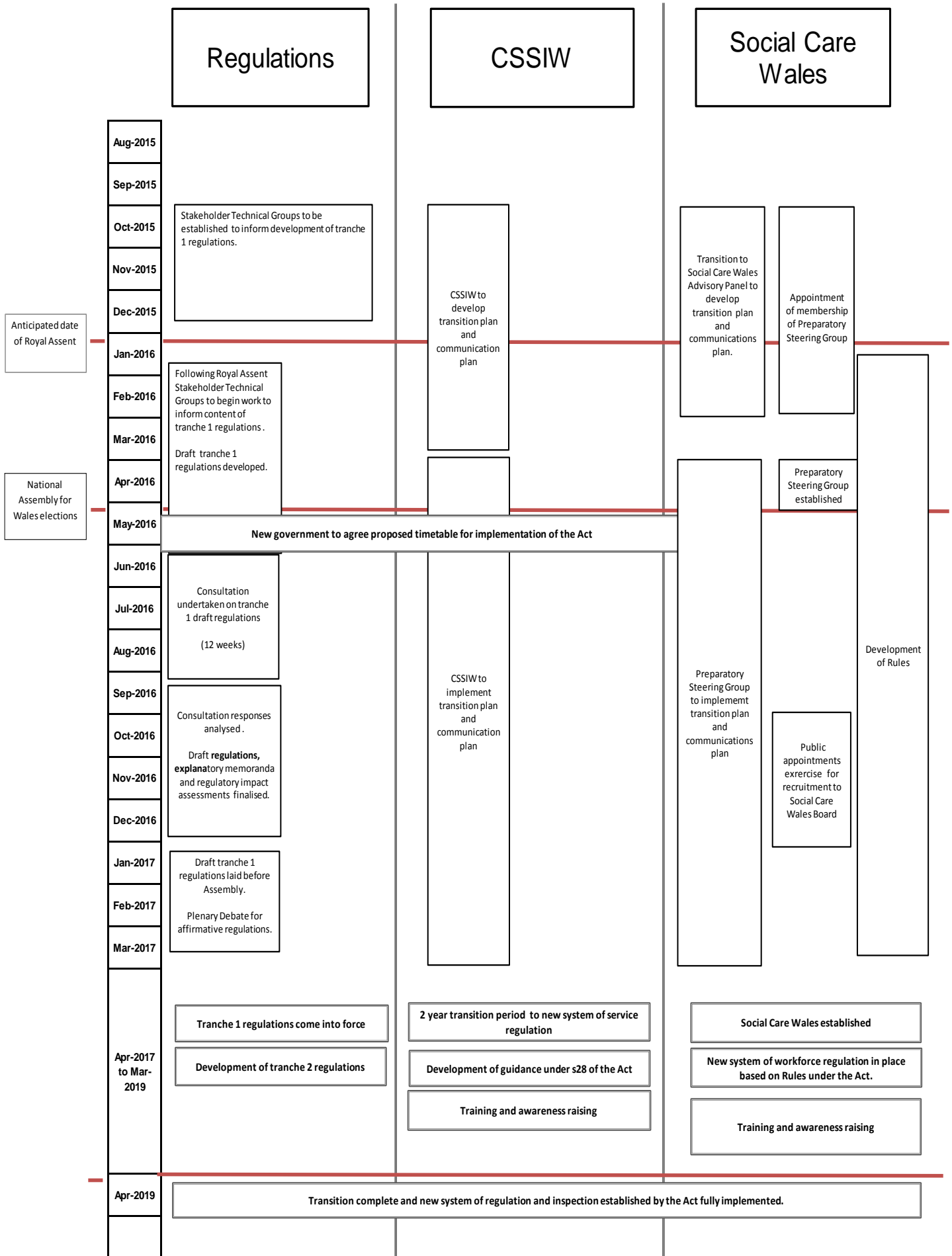
The Committee and stakeholders rightly raised the lack of non-Welsh bodies in the list of authorities in section 175 of the Bill. As I said in Committee, it is my firm intention that this list will include such bodies when it comes into force, but I have been working with officials and the UK Government to establish how that can be achieved most appropriately. In **recommendation 44**, the Committee ask me to set out the non-Welsh bodies I would intend to add to the list. Discussions are ongoing regarding this list of bodies and it would not be appropriate at this time for me to pre-empt the outcome of those discussions by including a list of non-Welsh bodies in this response so I am **unable to accept** this recommendation at this stage.

I also **accept recommendation 45**, although as in this case, it is not always possible to guarantee such consent when it often relies on external factors and the actions of organisations outside the control of the Welsh Government.

The Committee also reported on their considerations regarding the integration of health and social care, and specifically the opportunities for joint working between the relevant regulators - HIW and CSSIW. As both of these bodies reported in their evidence to the Committee, and as I said in scrutiny, there is no legislative barrier to working together given that the functions they both carry out are on behalf of Welsh Ministers. In **recommendation 46** the Committee asks me to set out how the Bill provides a basis for joint working, and whether the Bill is suitably flexible to respond to the outcomes of the green paper on NHS Quality currently out to consultation. Again I am happy to **accept** this recommendation. The Bill sets out clear powers and duties on regulators to share information, work together and to cooperate. It allows for regulators to carry out functions, such as inspections, jointly and it allows regulators to delegate functions in some circumstances. In section 180 it establishes a powerful new duty on such regulators to share information where that is necessary or expedient to protect the well-being of an individual in Wales.

In terms of the future, the Bill sets out functions in relation to Welsh Ministers, and not structures. This means that if and / or when the regulatory landscape is changed following the current consultation, these functions will remain and will apply to the new systems. If some of these regulatory functions were to be required to be passed onto a body other than Welsh Ministers this could be achieved through the legislation that would be required by the other changes.

Appendix A – Timeline for Implementation



Appendix B – Proposed Timings of Legislation Based on Implementation Timeline

Tranche 1 (by April 2017)

Section	Description
2 (1)(h) - Regulated Services	Regulation of additional services: advocacy.
6(1)(d) & (2) – Application for Registration as a service provider	Form and content of application for registration to provide a regulated service.
9(2); 9(3)(a)(ii); 9(3)(b) – Application for variation of registration as a service provider	Form, content and time limit for application to vary registration as a service provider.
19(6) – Responsible Individuals	The specific circumstances in which an individual may be designated as a responsible individual by the Welsh Ministers.
26(1) – Regulations about regulated services	Standards & requirements to be placed upon on service providers.
27(1) - Regulations about responsible individuals	Duties of responsible individuals
29(1) – Service providers who are liquidated.	Requirement for an appointed person to notify the Welsh Ministers of their appointment
30(1) – Service providers who have died	Provision relating to a service provider who has died.
43 – Failure by service provider to comply with requirements in regulations	Offence of failing to comply with provisions of regulations made under section 26.
44 – Failure by responsible individual to comply with requirements in regulations	Offence of failing to comply with regulations made under section 27
51(b) – Penalty Notices	Detail of fixed penalty notice scheme.
78(2)(b) – Meaning of “social care worker”	Provide that persons are to be treated as social care workers.
79 (1)(b) – The register	Register maintained by SCW to include managers, children’s home workers, social work students
90(1)(c) and (d) – Content of register	Information required in an entry in the register.
109(6) – List of persons removed from the register	Form and content of the list; publication; circumstances in which an entry may be removed from the list.
173(1) – Proceedings before panels	Proceedings before (a) registration appeals panels; (b) interim orders panels; and (c) fitness to practise panels.
172(5)(b) – Duty to establish panels etc.	Persons who may not be members of a panel.

Appendix B – Proposed Timings of Legislation Based on Implementation Timeline

Tranche 2 (by April 2018)

Section	Description
8(2) & 8 (3) – Annual returns	Form, content and time limit for annual return by service providers.
32/56(2) - Service Inspections	Code of practice about manner in which inspections are carried out, including the frequency of inspections.
55 – 144A of Act - Annual report by local authorities	Form and content of annual reports by local authorities.
55 – 144B of Act – Local Market Stability Reports	Form, timing and content of local market stability reports
58(1); (4) – Specifying criteria for application of market oversight regime	Criteria for determining whether, and extent to which, s60 applies to a service provider.
60(6); (7) – Assessment of financial sustainability of service provider	Obtaining appropriate information and the making of assessments.
62(1); (3) – National Market Stability Report	Timing, publication and content of the national market stability.
110(5) – Use of title ‘social worker’ etc.	Organisations who may maintain a ‘relevant register’ – <i>subject to changes elsewhere in the UK.</i>
118(4)(d) – Preliminary consideration	Persons who may not carry out preliminary consideration - <i>subject to changes elsewhere in the UK.</i>
124(5)(d) – Duty to investigate	Persons who may not carry out investigations - <i>subject to changes elsewhere in the UK.</i>

Section 28 – Guidance about regulations under sections 26 & 27 to be developed by CSSIW once regulations have been developed.

Remaining regulations will be developed by April 2019 or as and when required.

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



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: LF/MD/0775/15

David Melding AM
Chair of the Constitutional and Legislative Affairs Committee
National Assembly for Wales
Cardiff Bay
Cardiff
CF99 1NA

Dear David,

8 September 2015

Regulation and Inspection of Social Care (Wales) Bill

You will recall, during the General Principles debate on the Bill on 14 July, I confirmed that I would provide a detailed response to your Committee's Stage 1 report and its 14 recommendations. Whilst there is no strict requirement to provide a response to every single one of the recommendations, I feel that it is important to help you understand the consideration that I have given to each of them.

I am copying this letter to David Rees AM, Chair of the Health and Social Care Committee.

Best wishes,

Mark

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

Recommendations from the Constitutional and Legislative Affairs Committee Stage 1 Report into the Regulation and Inspection of Social Care (Wales) Bill.

I thank the Constitutional and Legislative Affairs Committee for their detailed consideration of the Regulation and Inspection of Social Care (Wales) Bill. I have considered each of your recommendations and am responding accordingly.

Recommendations 2, 3 and 4 call for a number of amendments to be made to the Bill, I am happy to confirm that I **accept** all three recommendations and will bring forward amendments in response to all three recommendations at stage two. My response to recommendation 2 will take the form of amending a number of sections to ensure a duty to consult applies, for example to sections 35 and 38.

In respect of recommendation 3 I accept the principle of this recommendation, however I will not be bringing forward an amendment to change the procedure for regulations introduced under section 6(1)(d) of the Bill. I will however bring forward amendments to put more detail directly on the face of the Bill regarding the fitness test to provide services and be nominated as a Responsible Individual. I believe this goes beyond the intention for this recommendation so trust the Committee will be satisfied by this approach.

I will bring forward an amendment to put extra detail regarding the content of the annual return directly on the face of the Bill, this will set out some of the standard information that will be required. I will also propose amendments to the Bill at stage two so that the first set of regulations drafted under this section will be subject to the affirmative procedure.

As previously indicated I have considered **recommendation 5** in further detail, I remain of the view that it would not be helpful to list on the face of the Bill some of the potential circumstances in which Welsh Ministers may designate a Responsible Individual. Such an amendment would not in my view enhance the Bill and could instead have the unintended consequence of the list being interpreted as exhaustive and tie the hands of Welsh Ministers in dealing with unlisted and unexpected circumstances. On this basis I am **rejecting** this recommendation.

I have reviewed sections 26-30 of this Bill in response to **recommendation 6** and noted the views of the Committee but am of the view that there is inherent risk in placing further detail on the face of the Bill. I intend the power to be wide so that the things that providers may be required to do may be many and varied. The Assembly will have the opportunity to review the appropriateness of each of the requirements that may be imposed via the affirmative procedure. There is further detail in the Explanatory Notes which accompany the Bill. I am happy to commit to review that information to see if additional detail can be provided, however I am **rejecting** this amendment.

Recommendations 7, 8, 9 and 10 call for amendments to be made to the Bill to apply the super affirmative procedure to a number of sections of the Bill relating to ratings, offences, penalty notices and financial sustainability. I am happy to accept the principle behind the recommendations, which would require a 12 week consultation on the draft regulations themselves with a statement from the Minister regarding the consultation and detailing what the regulations change. I will give effect to this recommendation by making amendments to the Explanatory Notes detailing that it would be our intention to follow the procedure set out

in section 33 of the Social Services and Well-being (Wales) Act 2014 for substantive regulations.

The committee recommended in **recommendation 11** that the affirmative procedure is applied to section 110(5) relating to protection of title. Protecting titles of social care workers is a significant regulatory intervention and because of this I have already considered that the affirmative procedure should apply to section 110(2) where the titles of other social care workers, in addition to social workers are protected. However, I am not of the view that the affirmative procedure is needed in relation to section 110(5) as this will only need to be used if there are changes to those relevant regulators listed in subsection (4). Such changes will only be made to keep the Bill up to date. The regulation making power will not therefore substantially affect the provisions of the Bill. I am therefore **rejecting** this recommendation.

Recommendation 12 calls for an amendment to the Bill to apply the affirmative procedure to the making of regulations under section 124(5)(d). The Committee's report refers to the fact that this is because section 124 relates to the right to a fair trial under the European Convention on Human Rights and this could therefore potentially be compromised by the composition of a fitness to practise panel. Section 124(5) deals with those persons who are precluded from carrying out an investigation. Provision in relation to the composition of the panel adjudication decisions is set out in section 172. This is to ensure that there is a separation between those carrying out investigations into a person's fitness to practise and those adjudicating on those issues. The regulation making power in section 125(5)(d) enables persons to be added to that list of persons who cannot carry out an investigation. It does not allow the Welsh Ministers to 'take away' from that list. Therefore the separation between investigation and adjudication required by Article 6 of the European Convention on Human Rights will always be maintained irrespective of whether regulations are made or not. As such, this detail is relatively minor in the overall legislative scheme and I am concerned that applying the affirmative procedure in line with **recommendation 12** would tie up National Assembly and Government resources. I am therefore **rejecting** this recommendation.

The power in section 135(2) is included in order to enable the lists of persons to whom Social Care Wales is required to disclose details of undertakings agreed with a registered person to be kept up to date and adjusted if the key organisations or structures within social care change. The disclosure of undertakings is a significant feature of public protection and as such, it is important that the list of persons to whom disclosure must be made is carefully and thoroughly considered. I therefore **accept** the **recommendation 13** that these regulations should be subject to the affirmative procedure.

Recommendation 14 calls for an amendment to apply the negative procedure commencement orders that include transitory, transitional or saving provisions in accordance with section 254(3). I am **rejecting** this recommendation as the making of commencement orders is not normally subject to any procedure, as they bring into force what the National Assembly has already approved, I see no reason to therefore deviate from the current convention in relation to commencement orders.

Agenda Item 8.5

Mark Drakeford AC / AM

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: LF/MD/0600/15

David Rees AM
Chair
Health and Social Care Committee
National Assembly for Wales
Cardiff Bay
Cardiff
CF99 1NA

17 July 2015

Dear David,

Safe Nurse Staffing Levels (Wales) Bill

In my letter to you of 25 June regarding the Safe Nurse Staffing Levels (Wales) Bill, I set out my intention to table the Welsh Government's amendments before the summer recess.

I write to update you about progress. Further work is being undertaken on the amendments and I am continuing to work with the Member in Charge.

The amendments will be tabled before the end of the summer recess.

I will continue to keep you updated on progress.

Mark Drakeford AC / AM

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Ein cyf/Our ref SF/MD/2115/15

David Rees AM
Chair, Health and Social Care Committee

17 July 2015

Dear David,

Thank you for your letter dated 24 June 2015 in which you ask a series of questions in follow up to my appearance at your Committee on 17 June. Responses to each question can be found below.

A breakdown of the additional £6.8 million planned care performance and £6.8 million Health Board winter pressures allocations provided during 2014-15 (details of which were outlined in paragraph 8 of your written paper), by individual health board.

The breakdown of the additional winter pressures allocations by NHS organisation are detailed in the table below:

Local Health Board	WAST Winter pressures	Unscheduled Care Winter pressures	Winter pressures - lost planned care	Total
	£m	£m	£m	£m
Aneurin Bevan HB		0.5	0.4	0.9
AbertaweBM HB		3.4	0.4	3.8
Betsi Cadwaladr HB		0.0	3.0	3.0
Cardiff & Vale HB		0.0	1.1	1.1
Cwm Taf HB		2.9	0.5	3.5
Hywel Dda HB		0.0	0.9	0.9
Powys HB		0.0	0.4	0.4
WAST	8.0			8.0
Total	8.0	6.8	6.8	21.6

Details of the general make up of primary and secondary care budgets, to include information about:

- **the allocations made to primary and secondary care respectively in 2014-15;**

The table below details the revenue resource allocations provided to Local Health Boards in Wales for 2014-15.

2014-15 Revenue Resource Allocations	£m
General Medical Services	469.1
General Dental Services	143.7
Pharmaceutical Services	158.9
Hospital and Community Healthcare Services	4,856.5
	5,628.2

Basis of calculation – derived from the split of final resource limits to Health Boards for 2014-15 as per HSSG Finance records

The Committee should note that the “resource allocations” above will exclude other funding that is provided to LHBs or to external bodies for both primary and secondary related purposes that are controlled through central health budgets not delegated to NHS organisations. These will cover services that are reimbursed either on an actual cost basis, for example, ophthalmic services, projects funded through grants and budgets for education and training budgets of NHS staff.

It should also be noted that the HCHS allocation of £4,856.5 million includes funding for the provision of certain primary care services which are not subject to separate primary care resource allocations. Examples include primary care prescribed drugs and appliances.

- **the proportion of the 2014-15 overspend that was attributable to primary and secondary care respectively; and**

I do not recall this question being asked in committee, and it is not something that can be identified easily for the reasons stated above. In overall terms health boards are responsible for the provision of both primary and secondary care services. Performance is monitored and reported on an aggregate level and not separately across primary and secondary care headings.

Any calculation to split the above on a national level would require a level of apportionment locally and nationally; the splitting of central budgets and matching of information between allocations and the published accounts to try and identify the different the variances. I have not asked officials to make this retrospective calculation as the figures would have to be heavily caveated for the reasons stated above.

- the increases/decreases for primary and secondary care budgets respectively for each of the last five years, particularly as a proportion of the overall departmental budget.

The table below details the revenue resource allocations provided to Local Health Boards in Wales for 2010-11 to 2014-15 and the percentage increase over the five year period.

	2010-11	2011-12	2012-13	2013-14	2014-15	Percentage increase over the 5 years
	£m	£m	£m	£m	£m	%
Primary Care allocations	729	740	754	766	772	5.9%
Hospital and Community Health Services allocations	4,624	4,740	4,768	4,672	4,856	5.0%
Total	5,353	5,480	5,522	5,438	5,628	5.2%

**From 2011-12 the annual allocation for prescribing was transferred into the HCHS allocation, 2010-11 has been re-presented on a consistent basis to provide a comparative. Basis of calculation – derived from the split of final resource limits to Health Boards for each year as per HSSG Finance records*

Clarification of the date on which health boards in Wales were informed that overspends and brokerage funding provided at the end of 2013-14, before the commencement of the National Health Service Finance (Wales) Act 2014, would not need to be repaid.

I am sure that the committee will understand that the NHS outturn performance each year is not finalised until all final accounts, including the NHS summarised accounts, are laid by the Auditor General in the Assembly. This was in July 2014 for the financial year 2013/14. The new requirements of the NHS Finance (Wales) Act 2014 came into effect before the 2013/14 outturn was completed i.e. April 2014.

In my written statements in May and June 2014, covering the new planning arrangements introduced on the 1st April, I made it clear that the new regime signaled a significant change in financial management arrangements. As part of the new arrangements, I was clear that we would not continue to provide additional funding to organisations which did not have robust plans in place and continued to incur deficits year on year, and this has commitment has been met since the introduction of the new regime.

In my written statement in June 2004, I outlined that I would only approve plans that could pass a rigorous process to ensure that we end any concept of a deficit culture. Only two plans, namely those of Cardiff and Vale and Cwm Taf University Health Board's, included the repayment of 2013/14 deficits in their plans, but in both cases the prepayment was planned for year three of their plans (2016/17). During the approval process, both boards were told by officials that the confirmation of the arrangements regarding non repayment of 2013/14 deficits would be confirmed later in year and that they should focus on delivery of their approved plan in the meantime. This had no impact on their 2014/15 plans because the repayments were not planned until year 3 of their respective plans.

In my written statement in June I also stated that I would be working with the Finance Minister over the summer to look at how the required funding outlined by the independent Nuffield Trust Report published in June could be funded. When the 2015/16 budget was announced (including the additional funds for 2014/15) at the end of September, my officials confirmed that the repayment of 2013/14 overspends would not be pursued via presentations made to Chairs and Chief Executives following the budget announcement. The content of the presentations and confirmation of the approach was also shared with auditors as soon as practical during a regular update meeting after the budget announcement.

While the non repayment intent was made clear from early Autumn, it should be noted that 2014/15 was the first year that the legislation and audit approach on the new regime was to be operated. My officials worked closely with the AGW staff on the practical application and interpretation of the legislation during the months leading up to the year end. Officials clearly set out the need to draw a line under the old regime during these discussions.

Following the work outlined above, the final clarification of the 2013/14 non repayment was requested to be put in writing by the auditors and health boards as part of the year end process so that it could be clearly set out in the published accounts. Officials did this on 5th May 2015 in a letter that stated that the 2013/14 deficits and brokerage would not need to be repaid but any deficits incurred under the new financial regime would need to be recovered.

The above has subsequently been covered in the underlying published health board and NHS summarised accounts to correctly reflect the agreed reporting requirements under the new financial regime and in my written statement covering 2014/15 outturn.

An update on work that the Welsh Government is undertaking on financial flows across health board boundaries.

The Welsh Government has been working with NHS Wales on financial flows across health board boundaries for some time but the principles have not been finalised due to the significant planned service changes that needed to be implemented.

The current financial flows mechanism was first reviewed two years ago by Directors of Finance with principles being put forward for consideration. It was agreed that this work needed to be reviewed by Chief Executives and others to reflect the proposed changes resulting from the changing patient flow arrangements that would arise through the South Wales programme and other reconfiguration plans.

This work is now being led by the NHS Collaborative Director Bob Hudson. It has been agreed that this work will be updated to the next meeting of Chief Executives in September where the new principles for income and financial flows can be considered for application starting in 2016/17.

What statistical techniques are used by Welsh Government and health boards to seek to predict winter pressures and is this reflected in general annual allocations made to health boards?

Changes in overall patterns of demand relating to the different seasons are well understood and largely predictable, for example every year there are more A&E attendances in the summer months than in the winter. The Welsh Government, LHBs and Public Health Wales regularly review and analyse trends over time to understand what drives overall demand, patterns of demand and the age of patients using services.

While seasonal pressures are understood, these can never be accurately predicted on a day to day basis too far in advance. Evidence shows that within each season there can be significant variation in daily demand and pressure caused by changes in the weather. This has disproportionate impact in Wales given its age profile, in particular the high proportion of elderly people. The other major factor that leads to changes in demand, particularly in the winter, is the prevalence of infectious disease which has a significant impact of unscheduled care services and is again related to age.

The NHS develop specific plans for winter which include demand predictions and contingencies for the weather with an extra £40 million allocated for winter pressures in 2014/15. The annual allocation to health boards reflects demand and expenditure throughout the year.

Clarification of when the Auditor General's office was made aware that NHS organisations would not be required to repay 2013-14 brokerage and overspends, in light of the statement in the Auditor General's Report NHS Wales: Overview of Financial and Service Performance 2013-14 that "the Department will not only require repayment of any 2013-14 brokerage funding in 2014-15, but also repayment of any 'deficit' by those NHS bodies not meeting their financial targets".

As the Committee will appreciate there are regular meetings between auditors and my officials. As stated earlier, I have been advised that some discussions on intent would have been discussed throughout 2014/15 but this became more formal post the budget announcement in September and through to the year end. I understand that the AGW's report was published on 14th October and the confirmation discussions post the budget announcement may not have been in time to firm up any references made in the AGW's report particularly when the first application of the legislation and its implications were being discussed up to the publication of the 2014/15 accounts.

What data is collected to demonstrate the increase in complexity of patient cases and its impact on the capacity of health services in Wales? The Committee would particularly welcome month-by-month figures of length of stay and hospital bed capacity, if available, for each of the last five years.

The Patient Episode Database for Wales (PEDW) captures various data on hospital admissions that can be used, both individually and collectively, to identify increases in patient complexity. The following are typical examples of data items which are routinely analysed by Welsh Government and NHS providers to demonstrate changes in the presenting caseload.

- Patient Diagnoses – captures primary diagnosis and presenting comorbidities via ICD10 coding;
- Operative Procedure – captures any operative procedure(s) and intervention(s) performed using the OPCS4 coding classification;
- Patient Age – for example to analyse the impact of an ageing population on hospital stays;
- Duration of Hospital Stay – used to identify changes in variation to the distribution of hospital stays linked to age and case mix;
- Mortality Outcomes – for example to monitor the impact on palliative care resources from changes in the number of deaths;
- Healthcare Resource Groups – uses standard groupings of clinically similar treatments with common levels of healthcare resource;
- Admission Dates – used to analyse changes in seasonal variation in association with other factors.

Further data to demonstrate case complexity changes are available from a range of datasets and collections. For example, this includes access data from Accident & Emergency and call data from Ambulance services.

The attached spreadsheet includes tables and charts showing five year trends for average length of stay (ALOS). The elective (main surgical specialties) ALOS chart for Wales shows a reduction of approximately 0.4 days over the five years. This is particularly significant given that daycase rates have increased by 9% over the same period, which in isolation would serve to increase the ALOS. Conversely, emergency ALOS has increased by approximately 0.2 days over the period as reductions in efficiency have been neutralised by the impact of an ageing population. The effect of diverting previously admitted (short stay) patients to assessment units is also a factor in the increasing ALOS outcomes. The emergency ALOS chart also highlights the seasonal variation of hospital stays, in particular the winter and post winter peaks.

Hospital bed capacity is also provided in the attached, although data prior to 2013 is only available quarterly. This shows that between 2010/11 and 2014/15 there was a reduction of 1,088 in the numbers of beds available across Wales, a 9% decrease. The increase in day surgery and emergence of assessment units and other admission avoidance initiatives have contributed significantly to a reduced demand for beds.

Best wishes

Mark Drakeford

Mark Drakeford AC / AM

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

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

Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref MB/MD/1761/15

David Rees AM
Chair
Health and Social Care Committee
National Assembly for Wales

17 July 2015

Dear David,

I am pleased to inform you that after an open competition exercise, Dr Richard Lewis has been appointed as the National Professional Lead for Primary Care in Wales. Dr Lewis' role will be to provide a clinical leadership role to help rebalance the focus towards locally planned and provided healthcare.

Dr Lewis' current role is Welsh Secretary of the British Medical Association (BMA) and is also a practicing General Practitioner (GP) in the South Wales Valleys. As a GP with over 25 years experience and with a 10-year leadership role in the BMA, he has the detailed knowledge, experience, and understanding of the current strengths and challenges of the primary care system in NHS Wales.

I will be announcing this appointment today at the launch of the primary care workforce plan. The workforce plan, which will be subject to a six-week period of engagement, has been developed as a result of an action set out in the overall plan for primary care services in Wales. It puts in place immediate and medium-term actions to build stronger foundations for planning the workforce that we need in the future, for supporting the onward development of clusters and for investing in the wider primary care workforce through education and training. It also includes actions to be taken in support of key sections of the current workforce, in response to recognised pressures that continue to affect parts of Wales as new models of care develop.

This letter is being copied to the opposition spokespeople.

Best wishes,

Mark,

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

David Rees AM
Chair, Health & Social Care Committee
Legislation Office
National Assembly for Wales
Cardiff Bay
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Cambrian Buildings
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31 July 2015

Dear Chair

Social Services & Wellbeing (Wales) Act 2014 – Code of Practice on Advocacy

Given the Committee's recommendations following its scrutiny of the Care and Support (Eligibility) (Wales) Regulations 2015, I thought it would be helpful to outline the main points that I have raised in response to the Welsh Government's consultation on the Code of Practice on Advocacy, as part of my statutory function to keep under review the adequacy and effectiveness of the law affecting the interests of older people in Wales.

1. The Act gives an explicit commitment to enable people to make their own decisions and control their own lives, and to provide help to ensure people's voices are strong, clear, listened to and acted upon. For people who struggle to have their voice heard, **independent advocacy** will be vital. Independent advocacy is a keystone on which the success of this new legislation ultimately rests; it is a **golden thread that must be woven throughout** the Act's entire regulations and codes of practice. I am not yet satisfied that this has been fully realised.
2. **A rights-based approach** must underpin the delivery of public services. Whilst there is much rhetoric about the duty of individuals to coproduce their own solutions to achieving their wellbeing outcomes, this is not met with an equal entitlement to independent advocacy. Genuine coproduction happens when there is parity between all parties so I am concerned that currently the Code of Practice on Advocacy proposes a test which rests on the decision of

the professional and risks compromising coproduction. A paradigm shift is needed to truly transform social services and this will include redressing the current imbalance of power which risks preventing those who need access to independent advocacy from obtaining it. Whilst I am mindful of the financial constraints on local authorities, effective use of independent advocacy is good for individuals, good for safeguarding and good for the public purse.

3. **Culture change** within local authorities will be vital to translating the intent of the Act into practice and there must be good awareness of the right to independent advocacy by those discharging their duties under the Act. Independent advocacy should be seen not only as a key way to make real the aspiration of the Act in relation to voice and control, but also as integral and essential to ensuring the quality and effectiveness of public services. However, the need for culture change within local authorities is currently an omission from the Code of Practice on Advocacy and related areas. Local authority staff must view independent advocacy in a positive light in order for it to be embedded within day-to-day practice. I will therefore be interested to see how this will be addressed.

Whilst I am disappointed that the recommendations that I made in my report '*A Business Case for Advocacy Services in Wales*'¹ has not been taken forward, I remain committed to making sure that older people have access to effective advocacy, including independent advocacy, when needed². The Code of Practice in relation to Measuring Social Services Performance does not appear to propose any indicators that will capture the level of access to independent advocacy services, which I have highlighted as a concern and I will pay close attention to this in the implementation of the Act.

Yours sincerely



Sarah Rochira
Older People's Commissioner for Wales

¹ A Business Case for Advocacy, May 2014, Older People's Commissioner for Wales

² Priority five: Tackling prejudice, inequality and discrimination, Framework for Action 2013-17, Older People's Commissioner for Wales

Agenda Item 8.9



Dr Ruth Hussey OBE
Prif Swyddog Meddygol/Cyfarwyddwr Meddygol, GIG Cymru
Chief Medical Officer/Medical Director NHS Wales

Llywodraeth Cymru
Welsh Government

David Rees AM
Chair, Health and Social Care Committee

11th August 2015

Dear David,

Petition P-04-603 Helping babies born at 22 weeks to survive

Thank you for your letter of the 14 July, requesting further information about the timescales for the work that is being undertaken jointly by the Maternity and Neonatal Networks.

The joint Maternity and Neonatal document on 'Care at the margins of viability' is due to be presented at both the September and October steering committees on maternity and neonatal networks with the final document being presented at the Neonatal Steering Group on the 6 November 2015.

The guidance will be based on current British Association of Perinatal Medicine guidance using evidence from medical literature and professional consensus.

As part of this work, feedback is also being sought from parents and BLISS (charity working to provide the best possible care and support for all premature and sick babies and their families), on both the guidelines and parent information leaflets.

Having met with Ms Emma Jones, the petitioner, on the 18 February 2015, Dr Heather Payne, Senior Medical Officer for maternity and child health will offer a further meeting with Ms Jones in order to gather her comments on the draft document. This feedback will then be presented to the Maternity and Neonatal Networks who are responsible for the issue of the guidance.

Best wishes

DR RUTH HUSSEY OBE
CHIEF MEDICAL OFFICER / MEDICAL DIRECTOR NHS WALES

cc: William Powell AM, Chair of the Petitions Committee



BUDDSODDWR MEWN POBL
INVESTOR IN PEOPLE

Pack Page 120

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Ein cyf/Our ref: SF/MD/1929/15

David Rees AM
Chair,
Health and Social Care Committee
National Assembly for Wales
Cardiff Bay
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12 August 2015

Dear David

I refer to my written statement on 10 June regarding the approval of integrated medium-term plans for health boards and NHS trusts. As you will recall, during the passage of the NHS Finance (Wales) Act 2014 and NHS Wales Planning Framework, I provided assurances that appropriate checks would be put in place to ensure integrated medium-term plans are both robust and deliverable.

I approved five plans in June (Cwm Taf and Aneurin Bevan university health boards; Powys Teaching Health Board; Public Health Wales and Velindre NHS Trust) and I said my officials would continue to work with Abertawe Bro Morgannwg and Cardiff and Vale university health boards to further develop and test the detail of their plans. This work has been completed and both organisations' integrated medium-term plans have been approved in 2015-16.

However, continued approval has been given subject to a number of terms and conditions, of which progress will be closely scrutinised over the coming months. These conditions include:

- Providing evidence of improved performance across tier one targets and ensuring quality standards are maintained and improved across all services;
- Ensuring good financial management of the plan.

Performance against these conditions will be tracked through chief executive and chair bilateral discussions; quality, safety, and delivery meetings; and joint executive team meetings. Where there is an unacceptable level of variance from the agreed plan, an organisation will be subject to increased monitoring and challenge, support and escalation arrangements and it may lose the privileges associated with being a part of the medium-term planning regime.

My decision demonstrates the ongoing and necessary rigour in operating the arrangements set out in the NHS Wales Planning Framework and the NHS Finance (Wales) Act 2014.

A copy of this letter has been sent to Elin Jones AM, Kirsty Williams AM and Darren Millar AM and placed in the National Assembly library.

A handwritten signature in black ink that reads "Mark". The letters are cursive and slightly slanted to the right.

Mark Drakeford AC / AM

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

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



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref SF/MD/1221/15

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Ann Jones AM
Chair of Children, Young People and Education Committee
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17 August 2015

Dear colleague,

I am pleased to enclose a copy of the *Review of the Financial Ring Fencing Arrangements for Mental Health Services in Wales*.

The review concludes that the stated original purpose of the ring fence – to protect expenditure on mental health services – has largely been achieved. It makes a series of proposals for improving the system for the future which I will consider.

I am also copying this letter to opposition spokespeople.

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

Agenda Item 10

By virtue of paragraph(s) vi of Standing Order 17.42

Document is Restricted