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The Scottish Government
Riaghaltas na h-Alba

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Duncan McNeil
Convener
Health and Sport Committee
Scottish Parliament
EH99 1SP

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Dear Duncan

Thank you for the Health and Sport Committee's Stage 1 report on the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill. Ahead of the Stage 1 debate on Tuesday 1 December, I enclose details in Annex A of the Scottish Government's initial response to the recommendations made in the report.

I look forward to continuing to work effectively with the Committee and the wider Parliament in progessing this important Bill.

I hope this information is helpful.

Kind regards

Maureen Watt

MAUREEN WATT

Annex A

Part 1 — TOBACCO, NICOTINE VAPOUR PRODUCTS AND SMOKING

The Committee agrees with the Scottish Government and witnesses that, given the evidence base on the long-term harm of using NVPs is still developing, it is prudent to take a proportionate and balanced approach to the availability for sale of NVPs.

We note the committee's support for this approach.

From the evidence we received, NVPs do have a role to play as a useful smoking cessation tool alongside trained support. We recommend that the Scottish Government considers whether the NHS should provide national guidance on the currently known risks and benefits of using NVPs to stop smoking. This would assist those wanting to quit smoking to make an informed choice about using NVPs to quit smoking (alongside accessing any support provided by smoking cessation classes).

The Scottish Government welcomes this recommendation. We have been working with NHS Health Scotland and NHS Smoking Cessation Leads to ensure a more consistent approach to the advice and support provided by NHS stop smoking services to individuals who want to stop smoking using an NVP. There is consensus on a proposal to adopt a consistent supportive approach to NVP use within NHS stop smoking services. An action plan has been agreed which includes reviewing smokefree policies to ensure consistency of messaging on NVPs, the development of national guidance, resources and training for cessation staff and standardising collection of data on NVP use.

NHS Health Scotland is revising their position statement to reflect current and emerging evidence. The position statement is primarily aimed at NHS Boards and provides advice on NVP use as part of a tobacco cessation attempt. Likewise, we understand that the Scottish Directors of Public Health are revising their position statement to reflect current evidence.

In light of the need for a robust evidence base to demonstrate the impact on health of using NVPs, and the extent of their contribution to smoking cessation, we seek further information from the Scottish Government on how it is supporting research in this area.

The Chief Scientist Office (CSO) is the part of the Scottish Government which funds research to improve the health of the people in Scotland and the services provided by the NHS. Funding is focused on research that has the potential to benefit patients or improve NHS services and follows the strategy Investing in Research: Improving Health. Scotland's universities have a strong track record in health sciences (and in tobacco control research) and are well placed to develop expertise in the field of NVPs and health. We will monitor clinical and other studies, supported by major funding bodies (such as Cancer Research UK,

the Medical Research Council and the National Institute for Health Research, and the National Institute for Health and Clinical Excellence), in the UK and internationally, which investigate the health effects of using NVPs and their contribution to smoking cessation. We will ensure that we are aware of important, high quality studies and maintain dialogue with experts in the field. For example, we are aware that a number of clinical trials internationally are investigating a wide range of questions and await their results.

The Scottish Government is a member of the UK E-cigarette Research Forum and has well established links with academics and research funders who are involved in research into NVPs. We will encourage academic partners, including institutions represented on the Research and Evaluation Working Subgroup of the Ministerial Working Group on Tobacco Control, to engage in the area of NVP research.

Other research and evidence

We will continue to monitor levels of use of NVPs at a population level through regular national surveys, the Scottish Health Survey and the Scottish Adolescent and Lifestyle and Substance Use Survey, and are looking at how questions could be expanded to increase the usefulness of the data collected. We would consider commissioning more detailed surveys when there is a clear need for such data (e.g. in 2014 we commissioned a detailed survey with secondary pupils on e-cigarettes – http://www.gov.scot/Publications/2015/09/4481). We will also note trends in survey data from other parts of the UK and beyond. We will continue to work with ISD and NHS Health Scotland to identify and implement data collection mechanisms, including routine data, which will improve intelligence on NVP use. For example, we have introduced fields in the Smokeline database to gather information about the use of NVPs by those using that service. We will monitor other forms of social evidence and where there is a clear gap in knowledge and understanding we will consider whether we need to undertake or commission research and analysis.

It is concerning to hear that the complexity and cost of registering an NVP as a medicinal product are such that it is unlikely that any NVPs will be registered. As such a potential prize in further encouraging smokers to quit could be lost. We believe that, if the NVP industry is serious about the effectiveness of NVPs to aid smoking cessation, then it is important that the industry works together to pursue licencing of NVPs as medical products. We also invite the Scottish Government to consider working with the UK Government to assess whether the current Medicines and Healthcare Products Regulatory Agency process presents any unreasonable barriers to licensing complex products such as NVPs as medicinal products.

As the Committee recognise, this is a matter for the UK Government and the Medicines and Regulatory Healthcare products Agency (MHRA). However, the MHRA have provided the following information:

'Where electronic cigarettes make medicinal claims concerning smoking cessation and harm reduction we continue to require regulation under medicines legislation as the correct route to marketing. This ensures that these products meet the appropriate standards of safety, quality and efficacy and as a result could be recommended under various NHS stop smoking schemes.

The authorisation procedure makes use of existing flexibilities to apply a risk-proportionate approach to licensing whilst ensuring that the balance of risks and benefits associated with these products is demonstrated. Public assessment reports are made available for all authorised medicinal products including e-cigarettes.

The MHRA continues to provide advice prospectively to applicants to aid understanding of the requirements for a medicines marketing authorisation.

We have recently licensed the e-Voke as a medicine, which means it is a product of acceptable quality and can be an effective aid to smoking cessation The e-Voke is the second product meeting the definition of an e-cigarette to receive a marketing authorisation, but is the first product that electronically produces a vapour containing nicotine for inhalation, and thus would be considered a true e-cigarette, and we hope to see more e-cigarettes and next generation nicotine delivery products submit medicines licensing application in the future.

We want to ensure that licensed nicotine containing products, including e-cigarettes, which make medicinal claims are available and meet appropriate standards of safety, quality and efficacy to help reduce the harms from smoking and will continue to encourage companies to voluntarily submit medicines licence applications for e-cigarettes and other nicotine containing products as medicines. We have recently carried out some work with e-cigarette manufacturers to re-engage industry in the process of medicinal licensing for e-cigarette products'**.**

We are content that the provisions in the Bill restricting the sale of NVPs to those over 18 are sensible, particularly given the detrimental impact of nicotine on adolescent health. This approach also provides consistency with existing alcohol restrictions. We also welcome that the Bill will not criminalise those under-18s who attempt to purchase NVPs given that evidence suggests that NVPs are less harmful than cigarettes.

We note the Committee's support for these provisions.

We agree with the provisions relating to an age verification policy and a defence of due diligence. They build on existing practice in relation to selling tobacco.

We note the Committee's support for these provisions.

We are content with the provisions on proxy purchasing and the approach to retail staff aged under 18 selling NVPs. These mirror those already in place for selling other

age restricted products such as alcohol and should not therefore place an additional burden on retailers and local government. We note, however, that some concerns were raised about the power in the Bill for Ministers to amend the age set for the age verification policy. We therefore seek further information from the Scottish Government on how it envisages it would use this power and in what circumstances.

We note the Committee's support for these proposals. Age 25 has been chosen for this proposal to bring it into line with similar measures already in place for alcohol and with voluntary measures already applied by retailers. There is no immediate intention to exercise the power. However, circumstances may change in future. The power allows the minimum age of 25, which an age verification policy must be based on, to be changed by regulations up or down. This provides flexibility to allow the Scottish Ministers to change the age without recourse to primary legislation. It is conceivable that circumstances might change, for example, where the number of illegal sales reduce thereby allowing the age to be reduced. There are equivalent powers in alcohol licensing legislation which allow the age of 25 to be reduced or increased. If it is considered appropriate to change the minimum age in future, this power would allow legislation on alcohol, tobacco and NVP age verification policies to be changed simultaneously, to ensure consistency and avoid retailers operating different policies.

We are content with the provision to ban NVP sales from vending machines given the difficulties in ensuring a robust age verification scheme for sales from these machines.

We note the Committee's support for this provision.

Given more evidence on the potential harm of using NVPs is required and the proposals that NVPs are to be an age restricted product, we consider it prudent that retailers should have to register their intentions to sell them. Such registration will also provide important information for local and central government on this developing market which can be used to inform future policy and research.

We note the Committee's support for this requirement.

We have some sympathy with the view that NVPs should not be treated the same as tobacco by registering on the same register given that the evidence indicates that NVPs are not as harmful as tobacco products and may help with smoking cessation. However, we also recognise the benefits of retaining the existing STRR in terms of reducing bureaucracy and costs to retailers by building on existing practice.

We note the Committee's support for retaining the existing Scottish Tobacco Retailers Register (STRR).

Whilst we are content with the Bill's proposal to rename the register as being for Tobacco or NVPs we recommend that, in the longer term, the Scottish Government considers whether, given the range of age restricted products, the time is right to

create one age restricted register. This could neutralise the negative association between tobacco and NVPs but also potentially future-proof the register.

The Scottish Government understand the concerns raised by industry and retailers that the requirement to register may appear to conflate tobacco and NVP products. As the Committee highlight in its report, the approach taken in the Bill recognises that the creation of another register and regulatory approach would place an additional burden on retailers of tobacco products, the majority of whom also sell NVPs.

A key aim of the requirement to register is to assist local authorities to enforce the NVP measures in the Bill, including providing advice and support to retailers. The measures in the Bill will be enforced by Local Authority Trading Standards Officers and the approach to enforcement largely mirrors the arrangements in place for tobacco products. Since the other measures in the Bill such as age restriction, proxy purchase, a ban on vending machine sales and powers to restrict domestic advertising of NVPs are similar to measures already implemented for tobacco, providing the same approach to registration is a workable, consistent and straightforward solution. The approach to the regulation of other age restricted products and the associated enforcement do not mirror those in place for tobacco products and NVPs. For example, the regulation of alcohol is enforced by a licensing scheme which places many more requirements on retailers and applies to a much wider sector, such as licensed trade. The creation of a single register would require duplication of efforts by retailers and other sectors as well as those responsible for holding the existing public register, alternatively it could require extensive amendments to the existing statutory regimes. We do not believe that these options are currently proportionate.

However, we recognise that, on the basis of available evidence, NVPs are considerably safer than tobacco that is why we have not sought to regulate them in exactly the same way as tobacco products. In addition to the name of the register changing, we will commit to considering the outward facing aspect of the register and explore opportunities to provide a clear separation between the two products on the website where the register is held.

We seek the Scottish Government‘s views on whether the Bill should be amended to include a ban on premises as suggested by SCOTS (and others) who explain that similar powers exist for Licensing Boards in respect of underage alcohol sales.

Banning orders can ban a person (legal or individual) from selling tobacco from specific premises from where there have been infringements of the tobacco legislation (and if the Bill is passed, NVP legislation). A banning order only prohibits the carrying on of a tobacco business by that person from those premises. It does not prohibit another person from carrying on a tobacco business from those premises. Powers do exist in alcohol legislation to obtain licence for a premises as well as a personal licence, and for that licence to be revoked. However; the alcohol licensing scheme differs vastly from the requirement for retailers to register when they intend to sell tobacco or NVPs. A banning order is a sanction issued by the court; it is issued based on a person having committed three or more criminal offences under tobacco (and NVP) legislation and contravening an order is itself a criminal offence. Applying a banning order to the premises rather than the person, would mean that

no other person (legal or individual) could register to carry on a tobacco business from that premise regardless of whether they had committed an offence or not. We do not consider this proportionate to the aims of the legislation; it is right that the sanction, which is based on the criminal law, and the consequences which flow from that, are borne by the person who has committed the criminal offences.

We understand that there are concerns that a banning order can be circumvented by someone connected to the business, for example a friend or family member of the person that the banning order applies to, registering to carry on the business. However, in order for their registration to be effective they must actually "carry on the business". Where there is reason to believe that the person who has been banned is still effectively running the business, the local authority can apply to the sheriff to for an ancillary order to ban either the newly registered person from carrying on a tobacco business at the specified premises or issue an order to prevent the banned person from being connected to the business at the premises. A local authority can apply for an ancillary order at the same time as a tobacco banning order or later. Carrying on a tobacco business unregistered or breaching an ancillary order is a serious offence carrying a fine of up to £20,000, imprisonment of up to 6 months, or both.

It should be noted that the majority of retailers act responsibly and seek to comply with the law. Only handful of Tobacco Banning Orders have been issued since the introduction of the legislation in 2011. Ultimately, there may be legitimate circumstances where a responsible person who has not committed an offence takes over the carrying on of a tobacco business at a specified premise. There are safeguards already in place to deal with circumstances where a person may seek to circumvent a banning order.

We support the precautionary approach adopted by the Scottish Government in relation to advertising of NVPs given the need to balance encouraging smokers to switch to NVPs as an aid to smoking cessation whilst also not attracting new —never smoked NVP users. We are therefore content that the Bill's proposals in relation to the advertising of NVPs are appropriate given that the evidence on the long-term health impact of NVP use is still developing. We recommend that the Scottish Government works with the ASA to ensure harmonisation of advertising restrictions wherever possible.

We note the Committee's support for this approach. We also note the Committee's recommendation but would highlight that such opportunities are likely to be limited, given the intention to use the powers in the main to ban certain forms of domestic advertising outright, whereas the codes enforced by the Advertising Standards Agency place restrictions which limit how they are advertised. However, the Scottish Government does not intend to use the powers to ban point of sale advertising and so there would be no reason that harmonisation cannot continue in that respect.

However, we request a response from the Scottish Government to the concerns of some witnesses that restricting advertising of NVPs in Scotland to point of sale only will offer a competitive advantage to those already established NVP retailers.

The Scottish Government believe that this is a legitimate concern. Restrictions on advertising might act as a barrier to entry to new entrants as they will be restricted in their ability to communicate product information via the types of advertising affected (advertisement by way of billboards, leafleting, brand sharing, free distribution, free distribution, nominal pricing, and domestic advertising events). This may be particularly disadvantageous to small start-ups with limited budgets for advertising and marketing. It is difficult to predict the impact but at its most extreme it might result in the failure of some, especially, small companies. The cross national nature of the industry, however, should be considered. Although the BCAP/CAP advertising rules and the Tobacco Products Directive restrictions will apply across the UK, these proposals are restricted to Scotland. The Scottish Government is not aware of proposals to restrict domestic advertising in other countries of the UK. This may mitigate the impact on individual companies who trade across all countries of the UK. This risk was set out in the competition assessment which formed part of the Business and Regulatory Impact Assessment of the Bill.

We are concerned at the responses we received that highlighted the potential of NVPs to be made more attractive to young people through flavourings or point of sale advertising and therefore recommend that the Scottish Government monitors these potential risks.

The Scottish Government welcomes this recommendation; it is our intention to keep under review the forms of domestic advertising and marketing that are not banned using the powers in the Bill.

We agree with the proposal to make smoking outside hospital doors and around buildings an offence given the high foot fall in these areas and the concerns regarding drifting second hand smoke. However, by distinguishing between a legally enforceable no-smoking area and those areas of nosmoking set by NHS policy, the unintended consequence could be that compliance with the NHS designated no-smoking areas deteriorates as smokers will be now more aware that there are no penalties for smoking in those areas.

We do have concerns about the feasibility of the proposed approach of setting the same set distance from hospital buildings for all hospital grounds given the experiences of NHS Ayrshire and Arran and Livingston High Court. We question whether identifying the same set distance is achievable given the diversity of purposes of hospitals (such as outpatient, inpatient, secure etc) and the differing sizes and layout of hospital grounds.

We therefore recommend that the Scottish Government reviews its proposal to set out, in regulations, the same set distance from hospital buildings for all hospital grounds within which no-smoking will be legally enforceable. We recommend that the Scottish Government consider whether each NHS board should be able to propose its own legally enforceable perimeter in the regulations. This will enable each health board to reflect the differing topography and grounds of hospitals within each board area. It will also enable the outcome of any discussions between each health board

and relevant local authorities about enforcement to be reflected in each NHS health board's agreed perimeter (see also the next section).

We welcome the Committee's support for the proposal to set an enforceable perimeter within the grounds of NHS Hospitals and we understand the desire to provide a flexible approach to meet the needs of individual hospital grounds. This approach was considered by the Scottish Government when developing the policy. However, we believe it is important that a consistent approach is achieved across all NHS hospital sites in Scotland. One reason for doing so is to provide equity of approach which will avoid situations that would see individuals, particularly patients who may be recovering from serious illness, being required to move a short distance from buildings on one site, and at another site they are required to move much further from the building to avoid committing an offence. The change in law must be communicated clearly to ensure that the public understand when they will be committing an offence. This would become complex where different distances are set at each hospital site and could lead to individuals inadvertently committing an offence as a result of confusion. It would also require Local Authorities take a different approach to enforcement across different hospital sites.

NHS Boards made clear, almost unanimously, in their written evidence to the Committee and to the Scottish Government consultation, that they would like legislation to cover the entirety of hospital grounds. It is reasonable to consider that further consultation offering perimeters of different distances could result in a similar response. The Scottish Government do not believe that this approach is proportionate when attaching a criminal offence. Setting a perimeter around buildings focusses on the areas where there is the highest level of traffic of people on foot leaving and entering the hospital and where there is a risk of smoke entering hospital buildings as a result of people smoking close to the building, in particular at entrances. It is also easier to enforce a prohibition backed by the criminal law near buildings given that some hospital grounds are vast in size.

We understand the concern that people may simply move out with the perimeter, however; this would remain a possibility where different perimeters are set. The Scottish Government will continue to support NHS smoke-free polices which apply to all grounds. This approach allows NHS Boards to make decisions about how they choose to implement and enforce local smoke-free policies. This includes raising public awareness, providing alternatives to tobacco and asking those who visit NHS sites to respect the policy. People who do not comply, including those with impeded mobility and serious illness, do not face a criminal penalty. In considering the introduction of criminal penalties in respect of those who do not comply, the impact of such action needs to be balanced with the commitment to treat all users of hospitals, particularly those who are most vulnerable, with dignity and respect.

The Scottish Government will consult with Health Boards in the development of regulations in respect of the distance of the perimeter to be applied across all NHS hospital sites and how that perimeter should be applied.

With health and social care becoming more integrated, we would welcome clarification from the Scottish Government of whether it proposes to legislate for enforceable no-smoking areas outside other health facilities such as Community Treatment Centres and primary care premises or even more widely to all public buildings.

It is not the intention of the Scottish Government to make it a criminal offence to smoke outside of NHS buildings that are not situated on NHS hospital sites or more widely to other public buildings. However, the Scottish Government will continue to take action to further denormalise smoking in Scotland and these might be steps that are considered in future, particularly where there is evidence and public support for such measures.

We recognise that most patients, visitors and staff will abide by the legally enforceable no-smoking area and each NHS board's policy in relation to smoking in NHS grounds. As such this Bill is intended to address those people who currently persistently smoke in no-smoking areas in hospital grounds despite being asked to stop. We are reassured by the Minister's evidence that local authority officers are not expected to enforce every infringement within the no-smoking area designated under this Bill. Rather the local authority's role is to provide an enforcement mechanism for those who persistently smoke within the legally enforceable no-smoking areas in hospital grounds. Given this we are content with the proposals for local authority enforcement of such areas. We recognise that local authorities already undertake a similar role in relation to other smoke-free legislation.

We note the Committee's support for the enforcement provisions.

We also welcome the provision of a defence within the Bill whereby the person committing the offence would also be allowed the defence that they did not know - and could not reasonably be expected to know - that they were smoking in the no-smoking area. We acknowledge the Scottish Government's intention to advertise the change in the law prior to any legally enforceable no-smoking areas coming into force.

We note the Committee's support for these provisions.

The Finance Committee reported that the Scottish Government provides £2.5 million for enforcement of smoke-free legislation by local authority environmental health officers and as such enforcing no-smoking areas in hospital grounds will need some reprioritisation of duties and resources. We therefore welcome the Government's commitment to consider any breakdown of costs provided by COSLA should there be a short term increase in enforcement costs.

We note the Finance Committee's recommendation. The Scottish Government will consider any breakdown of costs provided by COSLA.

Given the offence will apply to health boards rather than individuals we are content with the Bill's proposed offence of knowingly permitting others to smoke. We

welcome the Minister's reassurance that it is for each health board to decide its staff policy but that discussions between patients and medical staff will enable a compassionate approach to be taken with patients who consider they need to smoke.

We note the Committee's support for these provisions.

We agree with the Bill's proposals to provide for exemptions to the legally enforceable no-smoking area. However we recognise that despite any exemption, it could still be the case that smoking is banned as a result of the health board's policy (albeit it won't be legally enforceable).

Whilst we recognise the intention that any exemptions should apply uniformly across all relevant hospitals we question how such exemptions might be practically applied given the different types of hospital buildings that could be sited within hospital grounds (could an exemption for the grounds of an adult hospice be clearly identified where the same grounds are shared with or are in close proximity to other hospital types?).

Under our recommendation at paragraph 119, NHS boards would be able to take cognisance of how any exemptions might be applied based on their own site layouts before each NHS board recommends its own legally enforceable perimeter for inclusion within the regulations.

We thank the Committee for their recommendation. The provisions in the Bill which provide powers for exemptions could be used to 'allow' exemptions tailored to accommodate the needs of different NHS hospital site layouts e.g. regulations could describe and exempt buildings or land relevant to some sites but not others. This can achieve flexibility in how exemptions are applied across NHS hospital sites in practice. The Scottish Government will consider this in consultation with Health Boards in the development of the regulations.

Part 2 — DUTY OF CANDOUR

We agree with witnesses that being open and honest with people about their care is a key part of building trust especially when things go unexpectedly wrong. We recognise that for many health and care professionals a duty of candour already exists and in that regard including it within this Bill will to some extent build on the good practice already demonstrated by many hardworking and dedicated professionals.

We note the Committee's support for the benefits of being open and honest with people about their care.

However we also recognise that not all health and care professionals are currently subject to a duty of candour and that the different professional requirements can lead to inconsistencies in the way in which such a duty is applied in health and social care organisations.

We note that the Committee recognises the different range of professional requirements in respect of openness and honesty and the inconsistencies that this can give rise to.

We therefore are content with the inclusion of a duty of candour within this Bill. We also welcome the Bill's proposal that the duty of candour applies to organisations. This is important if health and social care organisations are to learn from incidents of unintentional harm and improve their care so that such harm does not arise in future.

We welcome the support of the Committee, as well as the acknowledgement of the important link to learning and improvement.

Whilst the Bill sets out the range of provisions that the duty of candour procedure should include (such as the role of the responsible person, the actions they should take and when as well as how information should be made available) much of the detail of the duty of candour procedure will be set out in regulations later on. As such these regulations will play a significant part in ensuring that the duty of candour procedure is able to be implemented effectively across a wide range of health and care settings.

We welcome and agree with the Committee's recognition of the importance of effective implementation.

Given this we agree with the Delegated Powers and Law Reform Committee that the Bill should be amended at Stage 2 to provide for these regulations to be subject to affirmative procedure.

The regulations will set out matters of detail which may need to be amended from time to time. We will engage with stakeholders in the implementation of the Bill and that engagement may result in refinements to the duty of candour procedure, as set out in the regulations. Such changes would be to the operational detail of the duty of candour and would not detract from the central policy of the duty of candour as set out in the Bill. Therefore, we remain of the view that the regulations would be more suited to scrutiny by the negative procedure.

We note that the guidance on the duty of candour procedure will build on existing candour procedures and processes. This should allay some of the concerns of witnesses that the duty may create an additional administrative burden.

We welcome the Committee's recognition that the guidance will seek to build the duty of candour procedure into existing processes wherever possible.

In relation to witness comments that the duty of candour in the Bill might lead to a 'box ticking exercise' or risk avoidance behaviour in clinical practice we recommend that a wide range of health and care staff should be involved in drawing up the

regulations. This should encourage greater staff ownership of the duty of candour procedure.

In developing the policy for the regulations and associated guidance we will ensure that we involve a wide range of health and care staff in order to encourage greater ownership of the procedure.

We seek the Scottish Government's views on whether the duty of candour procedure will enable patients and their families to challenge the details about an incident where they consider these to be incorrect. We also request clarification of the extent that patients and their families would be involved in identifying the causes of incidents as well as in identifying any future service improvements.

The procedure will give more details as to the ways in which the contact with organisational representatives provides the opportunities for communication and further involvement in the review of the incident. It will be for organisations to determine the ways in which incidents (and subsequent service improvements) will be identified, and this may include identification by patients, carers and relatives.

We support the definition in the Bill of who a responsible person is as it encapsulates the wide range of health and social care providers. However given the complexity with which health and social care is delivered we would seek clarification from the Scottish Government as to the extent to which the duty of candour would apply to:

- **local authorities when they commission, contract or fund health or care services to be provided externally;**
- **specialist educational schools (as suggested by ENABLE Scotland);**
- **providers of healthcare and assistive technology (who may be part of a multidisciplinary team).**

- in this example, a local authority would not be the responsible person but the external body they have commissioned would be, where they are providing a care or social work service. It would be possible for clarity to be established in the commissioning arrangements.
- specialist educational schools: the duty of candour does not apply to education settings, only to care services, health services, and social work services.
- providers of healthcare and assistive technology: the duty of candour will not apply to companies who make or sell equipment or devices that may form part of the wider healthcare or social care being provided by other organisations.

We also seek the Scottish Government‘s response to the concerns of the Care Inspectorate that some providers of care services may choose to establish their business in a way that means they would be exempt from the duty of candour.

We will give further consideration to this matter.

In order for the duty of candour procedure to be effectively implemented it is important staff have the skills and confidence to deliver it. We therefore welcome the provision of additional funding for training and support of organisations which will be subject to the duty of candour.

We welcome recognition of the importance of effective training and support for organisations.

We seek further information from the Scottish Government on the extent to which it will provide additional information and funding to support patients and families through the duty of candour process.

In many cases, this support will be provided through existing support mechanisms and services and will, therefore, not result in direct costs as a result of this procedure. There are likely to be some incidents where direct costs of providing tailored support will require specific sessional provision to clinical and care support staff. The nature and extent of costs will depend upon the existing staff support services and range of specialist psychological care provision already in place. The additional funding we will provide is projected as £456,000 in 2016-17; £460,560 in 2017-18; and £465,965 from 2018-19 onwards. A further breakdown of these costs are provided in table 9 on page 36 of the Financial Memorandum.

Funding of £182,000 has been allocated to the development of resources in support of national implementation. This will include the development of information for patients and families about the duty of candour procedure.

We welcome the Scottish Government's evidence that the apology proposals in the Bill will not replace the role of individual professionals in apologising for any harm caused or potentially caused.

We welcome the Committee's support on this.

We support the provision which makes clear that steps taken under the duty of candour procedure do not amount to an admission of negligence. We note that, to some extent, this reflects guidance and legislation already in place (such as in the Compensation Act 2006).

We welcome the Committee's support on this.

Given this, we recommend that the Scottish Government works with health and care regulators, such as the General Medical Council, to ensure the duty of candour procedure clearly sets out how it relates to other processes already in place.

The guidance will include details of how it should interface with existing processes. The General Medical Council is represented on our Guidance Development Group.

We welcome the clarification provided by the Scottish Government that the need for apologies offered as part of the duty of candour procedure should be exempt from the

Apologies (Scotland) Bill. We will therefore monitor Stage 2 of the Apologies (Scotland) Bill to confirm that this is the case.

We welcome the Committee's support on this.

We seek clarification from the Scottish Government of whether any procedure for apologising, and the duty of candour more generally will recognise the range of patients' communication skills and needs (as recommended by ENABLE Scotland in written evidence).

The regulations will emphasise the importance of recognising different communications skills and needs. Our Guidance Development Group will consider this in detail.

We also seek a response from the Scottish Government to COSLA's concerns, in written evidence, that employer's liability insurance and personal indemnity insurance could be affected by apologising.

We will engage further with COSLA to understand more about the implications of an apology on insurance.

We note that the PM is clear that the harm or potential harm must be unrelated to the course of the condition for which the person is receiving care. It also focuses on unintended harm either caused or potentially caused.

We note the Committee's remarks.

Whilst we are content that the harms listed as triggering the duty of candour are comprehensive, we note witnesses concerns about the potential for relatively minor incidents to trigger the duty of candour. We therefore invite the Scottish Government to consider amending the Bill to reflect the magnitude of the harm or potential harm (such as 'significant' harm) which would trigger the duty of candour.

We note the Committee's view but we do not agree that the list of outcomes in 21(4)(c) could arise from "minor incidents".

We acknowledge the evidence of some witnesses that the harms listed in the Bill differ from those used by other inspection regimes such as the Care Inspectorate. As such there is the potential for confusion or misinterpretation amongst staff.

The potential for confusion or misinterpretation will be addressed through the information that will be developed for organisations by the Care Inspectorate and Healthcare Improvement Scotland.

We therefore recommend that the Scottish Government also considers including within its duty of candour procedure clear guidance on how the triggers for the duty of candour differ from other regulatory regimes but also case studies setting out the

thresholds for activation of the duty of candour procedure (as suggested by Healthcare Improvement Scotland).

We note the Committee's recommendation and we will include these elements in our guidance.

We welcome the provision of an IRHP in the Bill. This will provide not only an independent perspective in those cases where organisations are not clear whether the duty of candour is engaged but also an important check and balance that the procedure is being initiated as intended.

We welcome the Committee's support on this.

Under the Bill in order for the duty of candour procedure to be invoked an unintended or unexpected incident must arise (or could have arisen) 'and' an IRHP must consider that the incident triggered (or could have triggered) the harm and is unrelated to the person's illness or underlying condition.
Given this and witness concerns about the practical challenges of involving an IHRP in small or specialised organisations, we request clarification from the Scottish Government of the extent to which the duty of candour procedure can be invoked prior to receiving the views of the IRHP particularly in those cases where the cause of the harm is clear.

Although the IRHP is independent of the clinical and care staff involved with the event, they will still, in many cases, be within the organisation. The duty of candour procedure is invoked by the responsible person (or their delegate) on the basis of an IRHP having determined that the outcomes linked with the unintended or unexpected incident, unrelated to the person's illness or underlying condition, have occurred. Implementation support guidance will emphasise the importance for smaller organisations of having an agreed arrangement to seek the views of a registered health professional.

We note that under the Bill the duty of candour procedure must set out the training to be provided to the responsible person. In view of the importance of the IRHP in triggering the duty of candour procedure we recommend that the Bill be amended to include a specific requirement to provide training and support on the IRHP role.

We note the Committee's recommendation and we will ensure that it is clear that the organisational duty involves the provision of training and support to all who are involved with the duty of candour procedure. We do not believe that it is necessary to amend the Bill to include a specific requirement for training in respect of the IRHP role.

We would also welcome clarification from the Scottish Government of as to whether the duty of candour procedure will include:

- **a dispute resolution procedure should the IRHP and the organisation disagree about whether the duty of candour procedure is engaged; and**

- **guidance on the order of priority of notification of an IRHP as compared with other regulatory requirements once an unintended incident has occurred.**

- a dispute resolution procedure: people can use the existing NHSScotland complaints procedure for this.
- guidance on the order of priority of notification: we will engage with stakeholders through our Guidance Development Group to fully understand this issue.

We support the provisions of the Bill on reporting compliance with the duty of candour. This will demonstrate how organisations have learned from the unintentional incidents that may have occurred and will also support wider learning across health and care providers. We agree that such reports should only contain anonymised information about the incident or accident.

We welcome the Committee's support.

We have some sympathy with witnesses who called for such annual reports to be aligned with or consolidated within other annual reporting functions in order to reduce the administrative burden on organisations. Given the Scottish Government's intention that the duty of candour procedure will build on existing candour processes, we seek clarification of whether it will consider building on organisations existing annual reporting mechanisms.

The way in which organisations implement their annual reporting obligations as part of the duty of candour procedure will be for them to determine — this may include alignment of internal process with other annual reporting cycles or integration within a wider annual report. The organisation should be able to make it clear how their reporting on the duty of candour procedure will be implemented and where people can locate and access this information.

We are content with the Bill's provisions that Scottish Ministers and others can report on compliance by responsible persons. We agree with the Care Inspectorate and others that this represents a proportionate approach to securing compliance as opposed to the creation of an offence in relation to non-compliance.

We note the Committee's support.

We note that Healthcare Improvement Scotland (HIS) proposes that the Bill be amended to clarify that it is the monitoring body for those independent healthcare services it regulates —and where the legislative powers for regulation have been commenced. We seek the Scottish Government views on this proposed amendment.

We note the Committee's remarks but we do not believe that the provisions need any further clarification. The intention is to commence Part 2 of the Bill so that it will apply to those independent health care services in relation to which HIS has a regulation function.

Finally we invite the Scottish Government to consider whether there would be merit in working with the UK Government and Welsh Assembly to develop UK-wide statistics on the effectiveness of patient safety programmes and responses to adverse incidents to better inform policy making.

We would welcome any chance to share and learn from other colleagues elsewhere in the UK, across the range of work programmes that support patient safety.

Part 3 — ILL-TREATMENT AND WILFUL NEGLECT

We acknowledge that the vast majority of health and social care professionals provide high quality care and that the new offences of wilful neglect and ill-treatment may therefore be engaged in only a small number of instances.

We note and agree with the Committee's acknowledgement of the high quality care provided by the vast majority of health and social care professionals.

We note that these offences already exist for some patients and that as such the new offence proposed in the Bill will extend it to all health and social care service users thereby recognising a wider range of circumstances when people may be vulnerable to ill-treatment or neglect.

We note the Committee's remarks.

Given this, we are content with the Bill's proposal to create a new offence of wilful neglect or ill-treatment.

We welcome the Committee's support in creating the new offences.

Given the number of regulatory bodies and existing legislation which may also be engaged by an incident of alleged wilful neglect or ill-treatment we recommend that the Scottish Government provides guidance as to how these new offences will sit alongside existing process and procedures.

We will work with other organisations to determine what publicity or guidance may be helpful, however it would be inappropriate for the Scottish Government to produce any guidance on the offences, as matters relating to the prosecution of the offences are solely for the Crown Office and Procurator Fiscal Service.

We are content that the Bill does not define wilful neglect and ill-treatment given these terms are already established in Scottish law.

We welcome the Committee's recognition that further definition of these existing terms is not necessary.

We note the clarification of the Minister given above and that the triggers for engaging the duty of candour (unintended or unexpected) and the offence of wilful neglect and ill-treatment (deliberate and with a high level of intention) are separate and distinct.

We note the Committee's remarks.

We are also reassured that given both the duty of candour and the offence of wilful neglect or ill-treatment currently existing in some form for some patients, the concerns of witnesses that parts 2 and 3 will work against each other will not materialise.

We note the Committee's remarks.

Nevertheless, we seek further information from the Scottish Government on what training, support and education it will provide health and social care workers and providers on the new offences.

We agree that it will be important to publicise the new offences so that health and social care workers understand the new offences. These new offences are intended to capture ill-treatment and wilful neglect which clearly falls below the expected standard of care and will never apply to those health and social care workers who set out with nothing but the intention to do their best in delivering care and treatment.

We will consider how best to publicise the new offences and support health and social care workers and providers in understanding what the new offences mean for them.

We agree that the new offences in part three should extend to individual care workers. However we also recognise the comments of witnesses that the way health and social care is delivered is becoming increasingly complex and much more multidisciplinary. As such we seek the Scottish Government's views on whether the definition of care worker includes:

- **care workers employed by an individual or family member under self-directed support;**
- **personal assistants employed by a carer on behalf of a cared for person who lacks capacity.**

The definition of "care worker" in the Bill relates to the employment status of that worker and includes an individual in paid employment with a contract in place. It is immaterial, for the purposes of the Bill, whether the care worker is a family member or whether the money comes from Self-directed Support (SDS) funds. On the information given, both of these examples could fit the definition of "care worker" for the purposes of the offences.

We welcome the extension of the offence of wilful neglect or ill-treatment to organisations as assisting organisations to learn from their failings. It will also challenge organisations to ensure that their procedures and resourcing are robust

and support high quality health and social care given they could be held accountable for any serious failings.

We welcome the Committee's recognition of the responsibility of organisations to ensure that the way their business is arranged or managed does not in any way contribute to the ill-treatment or wilful neglect of anyone receiving care or treatment from their employees.

We recommend that, in order to ensure that the implementation of the new offence is effective, the Scottish Government provides guidance to health and social care organisations on the new offence and in particular on their role and responsibilities.

We recognise that there have been calls for the Scottish Government to produce guidance on the new offences or to provide more detail on what is meant by the terms "ill-treatment" or "wilful neglect", however we are satisfied that these terms already exist in legislation without any guidance. It would not be appropriate for the Scottish Government to provide guidance to the Crown Office and Procurator Fiscal Service on the prosecution of an offence.

We support the use of remedial orders for organisations found guilty of the proposed offence as this will facilitate service improvement. We request further information on how the Scottish Government envisages that publicity orders might work, and in what circumstances.

Publicity orders will allow the court to require companies to publicise their conviction so that customers, shareholders and the general public would be made aware of the offence. We envisage this as an effective punishment in place of, or in addition to a fine. Additionally, publicity orders may be used as alternative to a large fine, perhaps where an organisation is publically funded, non-profit making, or has charitable status.

We have some sympathy with those who questioned whether the burden of proof is too high for organisations to be found guilty of wilful neglect given it requires a 'gross' breach of their duties of care. We therefore recommend that the Scottish Government reviews the matter.

We will give further consideration to this matter.

Finally we seek clarification of some concerns raised in written evidence as to whether:

- **the care provider offence will extend to agencies who provide care workers (raised in the written submission of the Coalition of Care and Support Providers and the Workforce Development Network);**
- **Speech and Language Therapists and Allied Health Professionals whose services are geared to supporting independent living for people with disability (but who are not 'ill') should be included within the Bill.**

The care provider offence will extend to agencies where care workers are providing adult health care or adult social care as part of the adult health care or adult social care provided or arranged for by the care provider.

In respect of Speech and Language Therapists and Allied Health Professionals, the circumstances in which they would be in scope of the offence relates to whether they were providing adult healthcare or adult social care, regardless of whether or not the person receiving care was ill.

Given the Committee has not taken evidence on either of these proposed amendments, should the Bill proceed to Stage 2 then we anticipate taking evidence on these proposed amendments prior to Stage 2 commencing.

We therefore seek a commitment from the Scottish Government to provide the Committee with the draft amendments as well as their purpose and effect, as soon as possible (and no later than early December 2015) to enable the Committee to take oral evidence in a timely manner.

The Scottish Government will endeavour to meet this deadline for any amendments it brings forward relating to these topics.