Health (Tobacco, Nicotine etc. and Care)(Scotland) Bill

The Law Society of Scotland

Introduction

The Law Society of Scotland (the Society) aims to lead and support a successful and respected Scottish legal profession. Not only do we act in the interest of solicitor members but we also have a clear responsibility to work in the public interest. That is why we actively engage and seek to assist in the legislative and public policy decision making processes.

To help us do this, we use our various Society committees which are made up of solicitors and non-solicitors and ensure we benefit from knowledge and expertise from both within and outwith the solicitor profession.

The Society’s Health and Medical Law Sub-committee and Criminal Law Committee welcomes the opportunity to consider and respond to the Health and Sport Committee’s call for written evidence on the Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill.

The Health and Medical Law Sub-committee has restricted its response to consideration of Part One and Part Two of the Bill only.

The Society’s Criminal Law Committee, after careful consideration of Part Three: ill-treatment and wilful neglect, does not have any comments to put forward.

Part One : Tobacco, Nicotine Vapour Products and Smoking

- General Comments

We support the aims of Part One the Bill. The harmful effects of tobacco and smoking are undisputed. Statistics speak for themselves in relation to deaths caused by smoking and smoking related disease, including the health of those who breathe in users’ smoke, particularly children.¹ We recognize that the Bill has the potential to address health and wellbeing and reduce the risk of harm caused by smoking and smoking related disease. We agree that the proposals support the key tenets of European health policy² and would enhance the Scottish Government’s Tobacco Control Strategy, ‘Creating a Tobacco-free Generation’³.

We believe that any legislative changes should be firmly tied in with education and prevention of smoking. A combined approach is generally regarded as more effective and provides a more targeted response in

² WHO- Europe. European strategy for child and adolescent health and development. (2005) report Number: EUR/05/5048378
³ http://www.scotland.gov.uk/Publications/2013/03/3766
changing patterns of smoking behaviour and promoting tobacco control \(^4\) and the Tobacco Control Strategy provides a good framework within which to achieve this.

Whilst we recognise that that nicotine vapour products may be a safer alter alternative to conventional cigarettes, more information is still required on the risks and benefits to public health in general and particularly to young people. Minimum age of sale may also help reduce the use of electronic cigarettes as a ‘starter product’ for young people\(^5\).

We previously responded, in December 2014, to the Scottish Government’s consultation on Electronic Cigarettes and Strengthening Tobacco Control in Scotland \(^6\).

**Part Two : Duty of Candour**

- **General Comments**

We consider that that the starting point for any proposals for altering existing approaches should involve a robust review of existing processes together with comparative research as to the beneficial impact of any proposed changes. We refer to our consultation response of January 2015. \(^7\) We remain concerned some of these proposals will be resource intensive and may be cumbersome and impractical to apply.

- **National issues**

We understand that transparency has taken on a particular significance following the Mid Staffordshire NHS Foundation Trust Public Inquiry \(^8\). It is also acknowledged that there can be a lack of faith that legal remedies for injured patients will be successful. Issues of time and expense may also play a part in a patient feeling aggrieved. People may often be reluctant to raise concerns simply because they don’t know how to or because they fear that it will have a negative impact on their relationship with the healthcare professional. \(^9\)

Informing patients about every slight incident, even if there was no harm, may have quite the opposite intended effect and cause patients to lose confidence in hospital and care. A balance has to be struck between providing the patient

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with an apology if something has happened to them, without requiring the doctors to divulge every ‘near miss’. Whilst we support the need for vigilance, we believe that this should also be proportionate.

- **International issues**

Additionally, given the increased emphasis on cross border healthcare and wider international healthcare collaborations, we would support initiatives across the EU that promote good working practice in relation to health care.

We note that that there is a wealth of readily accessible data across the EU via EU reflective of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare and indeed cross border bodies such as bodies such as the European Federation of Nursing Regulators.  

We further note that considerable advances have been made in relation to health care regulation across the EU following the vote by members of the European Parliament on 9 October 2013 to agree new rules governing the movement of healthcare professionals across Europe. As recently as June 2015 the EU published new regulations to improve protection for patients from potentially dangerous healthcare professionals, and from 18 January 2016, regulatory bodies across Europe will be required to operate a warning system to alert each other when a professional is banned from practising in one country, to stop them posing a danger to patients in another EU country.

Any additional legislation should have added value to what is already in existence and that different forms of statutory regime need to work in harmony and enhancing good communication and practice.

- **Referral to existing regulators**

We note concerns expressed in recent press coverage that under the existing regulatory regime, some employers may be deploying referral to existing regulators such as General medical Council. As the Scottish Government will recognise, given the existing protocols for healthcare regulators in Scotland operate to require the regulator to investigate and assess a referral whatever its source or possible motivation, it is considered that this area should be a the subject to further consideration.

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10 For example, Bourgeault I.L.,& Grignon, M.,(2013) ‘Comparison of the Regulation of Health Professional Boundaries across OECD Countries.’ EU Journal of Comparative Economics Vol10 2 199-223  
13 Herald ‘Health Board under fire over reprisal fears’ 27 July 2015 page 5
Specific Comments:

- Section 21

This section describes the trigger for the duty which is “an unintended or unexpected incident” which occurs in the provision of a health service. Health care involves myriad outcomes which are personal to individuals. These can depend on age, general state of health, genes, nutrition and social factors to name a few. The wide scope of the concept of an unintended or unexpected incident in the health care context could potentially lead to the reporting of a large number of “incidents” with staff adopting a cautious approach.

The duty comes into effect when, in the reasonable opinion of a registered health professional, the incident results in a particular outcome. The professional giving the opinion must not have been “involved” in the incident. Does this mean that if a patient has, say, an unexpected adverse reaction to a drug, the whole hierarchy of the medical team treating that patient – junior doctors acting under the supervision of registrars, in turn acting under the supervision of a consultant is barred from giving the opinion and another doctor must be sought to do this? This could lead to practical difficulties.

In specialised areas of medicine or surgery there may not be a suitable “uninvolved” person on site to decide if something amounts to an unintended or unexpected incident. The professional who must give an opinion will have to take time to consider the incident, read case notes and carry out further investigations. There could be a significant amount of time involved.

To trigger the duty of candour, the incident must result in the outcomes listed in subsection (4) or there must be the possibility that it could result in such outcomes. This requires the professional who is giving the opinion to make a decision about causation; a notoriously difficult area in medicine. The Bill refers to the obvious types of harm such as the removal of the wrong limb, but there may be many cases when the connection between the incident and subsequent harm is much more difficult to ascertain. This adds to the resource required in terms of time and money to operate these provisions. Such a decision will only be one person’s opinion but it will trigger the duty of candour. A professional would not make such a decision lightly, since an opinion on causation could conceivably influence a decision to initiate a civil case or disciplinary proceedings against another health professional.

The duty of candour is activated “as soon as reasonably practicable” after becoming aware of the incident. However this could still be some considerable time after the incident. The outcomes of death or shortening of life expectancy or various types of harm could potentially occur years after the incident in question. How in practical terms will such cases come to the attention of the responsible person, -the Health Board- when the staff treating the patient at the time of the incident are unaware of the outcome or have all moved on?
Such protracted cases would impose an even heavier burden on the professional giving the opinion, since it would require them to consider all other treatment or relevant history that had occurred since the incident.

On the question of timing, subsection (4)(c)(v) refers to the patient having suffered pain or psychological harm for a continuous period of 28 days in order for the duty of candour to apply. What is the justification for the 28 day period? Why should the duty not apply if the pain lasts only 10 days? Pain and psychological harm are very variable and subjective. There are bound to be wide differences between patients.

- **Section 23**

This section provides for regulations to set out the duty of candour procedure including “the apology to be provided by the responsible person” to the patient. It is questionable whether the public will feel that an apology compulsorily provided by statute is sincere or meets their needs. Care would need to be taken to ensure that such provision is compatible with other initiatives regarding apologies since most professional healthcare organisations now incorporate some or all of the above elements into their good practice. An apology can be delivered in many ways and is not easily conducive to formula. It relies upon interpretation, emotion and often spontaneity of the parties; both giving and receiving the apology. Such things are difficult to capture and perhaps even more so if this then becomes a requirement. The Compensation Act 2006 gave this a statutory footing in section 2 which provides that ‘an apology, an offer of treatment or other redress shall not, of itself amount to an admission of negligence or breach or statutory duty.’ As a consequence, there is the possibility that the proposals result in duplication of process and remedy. Many NHS boards already have such procedures in place whereby an apology can be made without admission of fault, so would such proposal merely be providing a duplication of processes which already exist?

- **Section 24**

This section provides for reporting and monitoring. It is worth noting that there are other mechanisms in the medical context for reporting adverse incidents, such as routine mortality and morbidity meetings in hospital departments and schemes for reporting adverse drug reactions. It is accepted that these do not necessarily lead to information being provided to patients and relatives, but the annual report envisaged by the Bill will likewise not identify individuals. It is appreciated that one purpose of the report is to identify trends and share information.

It might be more efficient if Health Boards or other “responsible persons” could adapt and utilise the existing mechanisms to monitor and record these incidents.

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