

POLICY NOTE

THE DUTY OF CANDOUR PROCEDURE (SCOTLAND) REGULATIONS 2018

SSI 2018/57

1. The above instrument was made in exercise of the powers conferred under section 22 (1) and (2) of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (“the 2016 Act”). The instrument is subject to negative procedure.

Policy Objective

2. The policy objective is to introduce a duty of candour in health, care and social work service settings. This applies when individuals have been harmed physically or psychologically during their care or treatment and there has been an unexpected or unintended incident that appears to have resulted, or could result, in an outcome mentioned in section 22 (4) of the 2016 Act. The outcome must relate directly to the incident rather than to the natural course of the person’s illness or underlying condition. The duty of candour procedure is to be followed by responsible persons, as defined in section 25(1) of the 2016 Act. The definition includes Health Boards, the Common Services Agency, independent health care services, local authorities and other providers of care and social work services.

3. Under the duty of candour procedure, responsible persons must undertake the following actions: to notify relevant persons of unexpected or unintended incidents resulting in harm; to provide them with an apology and to review and report on the circumstances which the responsible person considers led to the incident. The term ‘relevant person’ is defined in section 22(3) of the 2016 Act as meaning the person who has received the relevant service or, in certain circumstances, a person acting on behalf of that person. The procedure also places a duty on responsible persons to provide training, supervision and support to anyone carrying out the procedure on behalf of the responsible person.

Background

4. The Scottish Government recognise that when adverse events occur during the provision of treatment or care, openness and transparency is fundamental in promoting a culture of learning and continuous improvement in health and social care settings. The introduction of the duty of candour procedure provisions in the 2016 Act reflect the Scottish Government’s commitment to place people at the heart of health and social care services in Scotland. When harm occurs the focus must be on personal contact with those affected; support and a process of review and action that is meaningful and informed by the principles of learning and continuous improvement.

5. The duty of candour procedure is intended to improve professional practice, patient and service user safety and public confidence. There is an organisational emphasis on staff support and training to ensure effective implementation of the organisational duty. Staff must feel that they have the necessary skills and confidence if they are to be meaningfully involved in the delivery of the duty of candour procedure.

6. The reporting requirements will provide a way for organisations to outline the approaches that they adopt in responding to reports of unintended or unexpected incidents that have resulted in harm. Public reporting will also help to inform people's understanding of the health and social care environment and encourage organisations to involve people in the provision of their treatment and care.

Consultation

7. Key stakeholders were consulted on the proposals to implement the powers in the Act during the development of the Duty of Candour Procedure (Scotland) Regulations 2018.

Equalities Impact Assessment

8. An Equalities Impact Assessment (EQIA) was undertaken at the beginning of the Bill stage of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016.

9. The EQIA confirmed that there are no significant issues that we consider would impact negatively upon the various groups. The EQIA is available [here](#).

Business and Regulatory Impact Assessment

10. A comprehensive Business and Regulatory Impact Assessment (BRIA) was undertaken during the Bill stage of the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016. The BRIA is available [here](#).

11. The Scottish Government does not anticipate that there will be any significant additional costs associated with the requirement for NHS Boards and local authorities to produce reports on the implementation of the duty of candour procedure. As they are already required to produce reports for a range of monitoring, review and accreditation processes and will be expected to integrate duty of candour reporting within those processes.

12. Other organisations that are covered by the Duty of Candour Procedure are regulated by Healthcare Improvement Scotland or the Care Inspectorate and are already required to collate and report information in respect of incidents and complaints as part of the requirements of their registration.

13. NHS Boards; local authorities; and independent providers will be able to incorporate the requirements for the Duty of Candour Procedure within their existing processes to support staff training.

14. Smaller organisations may have additional costs in relation to the requirement for training to be provided to those staff required to carry out the Duty of Candour Procedure. However, the development of national training and implementation resources for these organisations will remove the requirement for organisations to deliver bespoke training.

Healthcare Quality &
Improvement Directorate
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