
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision regarding the candour procedure to be followed by NHS bodies under Part 3 of the Health and Social Care (Quality and Engagement) (Wales) Act 2020.

Regulation 2 defines the terms used within these Regulations.

Regulation 3 makes provision in respect of whom the NHS body is required to notify and communicate with under the candour procedure. These Regulations refer to this person as the “relevant person” and refer to the NHS body that owes the duty of candour to the relevant person as the “responsible body”.

Regulation 4(1) requires the responsible body, on first becoming aware of a notifiable adverse outcome, to notify the relevant person by telephone, audio-visual communication (such as a video call), or a face-to-face meeting. Regulation 4(3) makes provision in respect of the information to be included in such notification.

Regulation 5 requires the responsible body to provide written notification to the relevant person within five working days after the in-person notification provided under regulation 4(1). Regulation 5(2) makes provision regarding what the written notification must include.

Regulation 6 requires a responsible body to notify the relevant person of the results of any further enquiries carried out by the body in respect of the circumstances in which the duty of candour came into effect.

Regulation 7 makes further provision in respect of communication between the responsible body and the relevant person required by virtue of these Regulations.

Regulation 8 requires the responsible body to provide training and information about services which can provide assistance and support to staff.

Regulation 9 provides that the responsible body must keep a written record (which includes an electronic record) for each notifiable adverse outcome in respect of which the candour procedure is followed.

Regulation 10 requires the responsible body to designate a person to be responsible for maintaining strategic oversight of its operation of the candour procedure.

Regulation 11 requires the responsible body to designate a responsible officer to take overall responsibility for the effective day to day operation of the candour procedure and to ensure that the responsible body complies with the requirements of these Regulations.

Regulation 12 sets out limitations on the provision of information.

Regulation 13 provides that an apology or other step taken in accordance with the candour procedure is not an admission of negligence or breach of a statutory duty.

Regulation 14 makes amendments to the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011 in consequence of these Regulations.

The Welsh Ministers’ Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from Welsh Government, Cathays Park, Cardiff, CF10 3NQ and is published on www.gov.wales.