These notes refer to the Health and Social Care (Quality and Engagement) (Wales) Act 2020 (c.1) which received Royal Assent on 1 June 2020

HEALTH AND SOCIAL CARE (QUALITY AND ENGAGEMENT) (WALES) ACT 2020

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 3: Duty of candour

Section 3 – When the duty of candour applies

11. This section explains when the duty of candour in Part 3 will apply. When the duty applies, an NHS body must take certain steps in accordance with a procedure set out in regulations made under section 4.

12. For the purpose of this Part an NHS body is a local health board, an NHS trust, a special health authority and a primary care provider. A primary care provider is a person who provides general medical services (GP services), general dental services, general ophthalmic services or pharmaceutical services on behalf of a local health board. In accordance with section 11(7), the application of the duty to special health authorities extends to special health authorities established under section 22 of the National Health Service (Wales) Act 2006, but does not include any cross-border special health authority (within the meaning of section 8A(5) of that Act) apart from NHS Blood and Transplant in relation to the exercise of its functions in Wales.

13. The duty of candour procedure will have to be followed where the two conditions in subsections (2) and (3) are met.

14. The first condition is that the service user to whom health care is being or has been provided by the NHS body has suffered an adverse outcome. A service user is treated as having suffered an adverse outcome if the service user experiences, or if the circumstances are such that the service user could experience, any unexpected or unintended harm that is more than minimal. The meaning of "more than minimal harm" will be set out in guidance issued by the Welsh Ministers under section 10 of the Act. The guidance will be developed having regard to existing definitions of harm, such as those used in the National Reporting and Learning System which is the existing system for reporting adverse patient safety incidents in the NHS. For the purpose of the duty of candour, harm includes psychological harm.

15. The duty is triggered not only when harm is known to have occurred but in cases where harm could occur in the future; for example, where an error in the administration of medication may cause an adverse outcome at a future point. The duty may be triggered by an action taken by an NHS body during the provision of health care or by a failure to take action. The harm must be unintended or unexpected which means that the duty does not apply where undesirable outcomes occur as a result of a medical condition.

16. The second condition is that the provision of the health care was or may have been a factor in the service user suffering the outcome. The outcome must therefore relate to the provision of the care by the NHS body rather than being solely attributable to the person's illness or underlying condition. It need not, however, be certain that the health

care caused the harm; it is sufficient that the health care may have been a factor. The application of the duty does not indicate that the NHS body has acted negligently.

Section 4 - Duty of candour procedure

17. This section requires the Welsh Ministers to provide in regulations for a procedure to be followed by an NHS body when the duty of candour applies to the body. The procedure will set out actions to be taken by NHS bodies when the duty applies.

18. Subsections (2) and (3) give detail as to what the regulations must make provision about. The regulations must, for example, require the NHS Body to notify the service user or their representative that the duty of candour has come into effect, to provide information about any further enquiries that will be carried out, and make provision about support and an apology.

Section 5 – Primary care providers: duty to prepare report

19. This section requires a primary care provider to prepare an annual report on whether the duty of candour has come into effect in relation to health care provided by the provider. The section sets out what information the report must contain (but it can include other information).

20. Where a primary care provider has provided health care on behalf of two or more local health boards in a particular financial year, this section will require the provider to prepare a separate report in respect of each local health board.

Section 6 – Supply and summary of report under section 5

21. This section requires a primary care provider, as soon as practicable after the end of a financial year, to send the annual report prepared under section 5 to the local health board to which the report relates.

22. A local health board must prepare a summary of the reports it has received from the primary care providers under subsection (1).

Section 7 – Local Health Board, NHS Trust and Special Health Authority: reporting requirements

23. This section requires local health boards, NHS trusts and special health authorities (including NHS Blood and Transplant in relation to the exercise of its functions in Wales), as soon as practicable after the end of each financial year, to prepare an annual report on the duty of candour. It also makes provision about what that report must contain (but it can include other information).

Section 8 – Publication of section 6 summary and section 7 report

24. This section requires NHS bodies subject to the duty in section 7 to publish the reports prepared under that section.

25. In the case of a local health board, the report must include the summary prepared under section 6 of the reports provided to the local health board by primary care providers providing services on its behalf. The local health board will therefore be responsible for publishing information relevant to the duty of candour in respect of its own services and the services provided by primary care services for its area. This will mean that all of the information about the duty of candour in respect of a local health board area will be published together.

Section 9 – Confidentiality

26. Subsection (1) of this section provides that a report published under section 8 by an NHS body may not name certain individuals. The individuals are: any person to whom

health care is being or has been provided by or on behalf of the body; and any person acting on such a person's behalf. In addition, subsection (2) requires an NHS body, when determining what information to include in a section 8 report, to have regard to the need to avoid including any information which, even though it does not actually give an individual's name, is in the circumstances likely to enable the identification of that individual. Such a circumstance might arise, for example, where the details of a particular patient's care have received media attention. The purpose of this provision is to protect confidentiality.

Section 10 – Guidance given by the Welsh Ministers

27. This section requires NHS bodies, in exercising functions relating to the duty of candour, to have regard to any guidance issued by the Welsh Ministers.

Section 11 – Interpretation of "health care" and other terms

28. This section makes provision about the interpretation of terms used in Part 3 including the meaning of "health care", "illness" and "NHS body".

29. By virtue of subsection (5), where heath care is provided as part of a contract, agreement or arrangement between two NHS bodies, the care is deemed as having been provided by the body providing the care rather than the body which arranged for the care to be provided on its behalf. This means that in relation to such an arrangement, the duty of candour, if engaged, would apply to the provider of the care only. This includes health care provided on behalf of the NHS body by a primary care provider.

30. Under subsection (6), where health care is provided on an NHS body's behalf by a body that is not an NHS body, the duty of candour, if engaged in relation to the health care in question, will apply to the NHS body, not the body which provided the care.