WELSH STATUTORY INSTRUMENTS

2023 No. 274

The Duty of Candour Procedure (Wales) Regulations 2023

Amendment of the National Health Service (Concerns, Complaints and Redress Arrangements) (Wales) Regulations 2011

14.—(1) The 2011 Regulations are amended as follows.

(2) In regulation 2(1) (interpretation) at the appropriate places insert—

""the 2020 Act" ("*Deddf 2020*") means the Health and Social Care (Quality and Engagement) (Wales) Act 2020;";

""the 2023 Regulations" ("*Rheoliadau 2023*") means the Duty of Candour Procedure (Wales) Regulations 2023;".

(3) For regulation 12(7) (persons who may notify concerns), substitute-

"(7) Where a concern is notified by a member of the staff of the responsible body, the responsible body must, where its initial investigation determines that there has been moderate or severe harm or death—

- (a) unless notification under regulation 4(1) of the 2023 Regulations has already been given, advise the patient to whom the concern relates, or his or her representative, of the notification of the concern, and
- (b) unless paragraph (8) applies, involve the patient, or his or her representative, in the investigation of the concern,

in accordance with Part 5."

- (4) In regulation 12(8) (persons who may notify concerns), omit "informed of or".
- (5) In regulation 22 (procedure before investigation)—
 - (a) in paragraph (1) for "two" substitute "five";
 - (b) at the beginning of paragraph (6), for "The" substitute "Subject to paragraph (7), the";
 - (c) after paragraph (6) insert—

"(7) Where the duty of candour under section 3 of the 2020 Act has come into effect in relation to the subject matter of the concern and notification under regulations 4(1) and 5(1) of the 2023 Regulations has been given, the responsible body is not required to send a copy of the notification of the concern to the patient or his or her representative."