The Secretary of State for Health, in exercise of the powers conferred by sections 16(d), 20, 59(1), 65(1) and (3), 86(2), 87(1) and (2), and 161(3) and (4) of the Health and Social Care Act 2008(1), makes the following Regulations:

In accordance with section 20(8) of the Health and Social Care Act 2008, the Secretary of State has consulted such persons as the Secretary of State considers appropriate.

PART 1

GENERAL

1.—(1) These Regulations may be cited as the Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012.

(2) These Regulations shall come into force on—

(a) 18th June 2012 for all provisions except regulations 3 and 5(b);

(b) on 1st October 2012 for regulation 3;

(c) on 1st April 2013 for regulation 5(b).

(1) 2008 c.14. “Prescribed” and “regulations” are defined in section 97(1).
PART 2

AMENDMENTS TO THE CARE QUALITY COMMISSION (REGISTRATION) REGULATIONS 2009

Amendments to the Care Quality Commission (Registration) Regulations 2009

2. The Care Quality Commission (Registration) Regulations 2009(2) are amended as follows in this Part.

Amendments to regulation 16

3. In regulation 16 (notification of death of service user)—
   (a) for paragraph (1)(b) substitute—
       “(b) which has, or may have, resulted from the carrying on of a regulated activity.”;
   (b) for paragraph (2) substitute—
       “(2) Subject to paragraph (4), where the service provider is a health service body or a provider of primary medical services, the registered person must notify the Commission without delay of the death of a service user where the death—
       (a) either—
           (i) occurred whilst services were being provided in the carrying on of a regulated activity,
           (ii) has, or may have, resulted from the provision of services by a health service body in the course of carrying on a regulated activity, or
           (iii) has, or may have, resulted from the provision of primary medical services in the course of carrying on a regulated activity and those services were provided within the period of two weeks prior to the death of the service user; and
       (b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user’s illness or medical condition would naturally have taken if that service user was receiving appropriate care and treatment.”;
       and
   (c) after paragraph (5) insert—
       “(6) In paragraph (2), “provider of primary medical services” means a person who provides primary medical services pursuant to one of the following sections of the National Health Service Act 2006(3)—
       (a) section 3 (Secretary of State’s duty as to provision of certain services),
       (b) section 83(2)(b) (primary medical services),
       (c) section 84 (general medical services contracts),
       (d) section 92 (arrangements for the provision of primary medical services),
       and provision of primary medical services shall be construed accordingly(4).”.

(2) S.I. 2009/3112, as amended by S.I. 2010/49
(3) 2006 c.41.
(4) Paragraph 3 of Schedule 2 to S.I. 2010/781 which provides that the provision of primary medical services is not a regulated activity ceases to have effect on 1st April 2012 in relation to all activities carried on by providers of out of hours services and on 1st April 2013 for all other purposes: see Regulation 3(8) of S.I. 2010/781 as inserted by Regulation 2(3) of S.I. 2011/2711.
Amendment to regulation 17

4. In regulation 17 (notification of death or unauthorised absence of a service user who is detained or liable to be detained under the Mental Health Act 1983)—

(a) in paragraph (1), after “death” insert “in any location” and after “absence” insert “from a relevant location”;

(b) after paragraph (2) insert—

“(2A) The registered person must notify the Commission without delay of the return to a relevant location after a period of unauthorised absence of a service user whose absence is required to be notified under paragraph (1).”;

(c) in paragraph (3), after sub-paragraph (c) insert—

“(ca) “relevant location” means a location used to provide secure psychiatric services under a contract with an English NHS body(5) or the Secretary of State; and”; and

(d) omit sub-paragraph (d).

Amendment to regulation 18

5. In regulation 18 (notification of other incidents)—

(a) omit paragraph (2)(c) and (d);

(b) after sub-paragraph (2)(g) insert—

“(h) any placement of a service-user under the age of eighteen in a psychiatric unit whose services are intended for persons over that age where that placement has lasted for longer than a continuous period of 48 hours.”;

(c) after paragraph (4) insert—

“(4A) The registered person must notify the Commission of the following events, which occur whilst services are being provided in the carrying on of a regulated activity, or as a consequence of the carrying on of a regulated activity—

(a) any request to a supervisory body made pursuant to Part 4 of Schedule A1 to the 2005 Act(6) by the registered person for a standard authorisation;

(b) any application made to a court in relation to depriving a service user of their liberty pursuant to section 16(2)(a) of the 2005 Act.

(4B) Any notification required to be given in respect of an event in paragraph (4A) shall be given once the outcome of the request or application is known or, if the request or application is withdrawn, at the point of withdrawal and shall include a statement as to—

(a) the date and nature of the request or application;

(b) whether the request or application was preceded by the use of an urgent authorisation, within the meaning of paragraph 9 of Schedule A1 to the 2005 Act;

(c) the outcome of the request or application or reason for its withdrawal; and

(d) the date of the outcome or withdrawal.”.

(5) 2008 c.14. “English NHS body” is defined by section 97(1).

(6) Schedule A1 was inserted into the Mental Capacity Act 2005 (c.9) by paragraph 1 of Schedule 7 to the Mental Health Act 2007 (c.12).
Insertion of new Regulation 22A

6. After regulation 22 (appointment of liquidators) insert—

“Form of notifications to the Commission

22A. Notifications made pursuant to regulations 14 to 18 and 21 and 22 must be made using the forms provided by the Commission for this purpose.”.

Revocation of Regulation 26

7. Regulation 26 (penalty notices) is revoked.

Insertion of new Part 7: Review

8. After Part 6 (compliance, guidance and offences) insert—

“PART 7

REVIEW

Review

27.—(1) Before 1st October 2017, the Secretary of State must—
(a) carry out a review of these Regulations;
(b) set out the conclusions of the review in a report; and
(c) publish the report.
(2) The report must in particular—
(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
(b) assess the extent to which those objectives are achieved; and
(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.”.

Amendment to Schedule 3

9. In Schedule 3 (information to be included in the statement of purpose), for paragraph 3 substitute—

“3. The following information—
(a) in relation to the service provider and any registered manager—
(i) full name,
(ii) business address,
(iii) business telephone number,
(iv) electronic mail address where available; and
(b) in relation to the registered person—
(i) the address to which the Commission may send any document, notice or other communication required to be delivered by these Regulations or the Act, and
(ii) where the registered person consents to service by such means, an electronic mail address to which the Commission may send any document, notice or other communication required to be delivered by these Regulations or the Act.’.

PART 3
AMENDMENT TO THE CARE QUALITY COMMISSION (ADDITIONAL FUNCTIONS) REGULATIONS 2011

Amendments to the Care Quality Commission (Additional Functions) Regulations 2011

10.—(1) The Care Quality Commission (Additional Functions) Regulations 2011(7) are amended as follows.

(2) In regulation 4(2) (review of decisions to record and monitor telephone calls in high security hospitals), after “calls” insert “pursuant to direction 34(5) and (6) of the 2011 Directions(8)”.

PART 4
AMENDMENT TO THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) REGULATIONS 2010 AND REVOCATION OF THE CARE QUALITY COMMISSION (REGISTRATION) AMENDMENT REGULATIONS 2010

Amendment to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

11. In the table in Schedule 4 (fixed penalty offences) to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010(9), before the entry in respect of regulation 27 of these Regulations insert —

| “Regulation 25 of the Care Quality Commission (Registration) Regulations 2009” | Contravention of, or failure to comply with, any of the provisions of regulations 12 and 14 to 20 of the Care Quality Commission (Registration) Regulations 2009 | £1250 in the case of an offence committed by a service provider £625 in the case of an offence committed by a registered manager |

Revocation of the Care Quality Commission (Registration) Amendment Regulations 2010

12. The Care Quality Commission (Registration) Amendment Regulations 2010(11) are revoked.

(7) S.I. 2011/1551.
(9) S.I. 2010/781.
(10) S.I. 2009/3112.
(11) S.I. 2010/49.
Signed by authority of the Secretary of State for Health.

Simon Burns
Minister of State,
Department of Health

22nd March 2012
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Care Quality Commission (Registration) Regulations 2009 (“the Registration Regulations”), the Care Quality Commission (Additional Functions) Regulations 2011 (“the Additional Functions Regulations”) and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (“the Regulated Activities Regulations”).

Part 2 of the Regulations makes amendments to the Registration Regulations.

Regulation 3 makes various amendments to regulation 16 of the Registration Regulations as to the requirements for the notification of death of a service user.

Regulation 4 amends regulation 17 of the Registration Regulations so that a registered person has to notify the Commission of unauthorised absences of patients detained under the Mental Health Act 1983 in English NHS establishments providing secure psychiatric services. It also requires notification once the service user returns to the secure facilities and clarifies that the requirement to notify the death of a service user applies to any location.

Regulation 5 amends regulation 18 of the Registration Regulations so that a registered person must notify the Commission of a request or application for the deprivation of liberty safeguards to apply at the same time as giving notification of the outcome of such a request or application, including whether the request or application has been withdrawn. It also requires a registered person to notify the Commission where a person under the age of 18 has been admitted to an adult psychiatric unit for more than 48 hours.

Regulation 6 inserts a new provision requiring notifications to be made on forms provided by the Commission.

Regulation 7 revokes regulation 26 of the Registration Regulations consequential to the amendment at Part 4 of these Regulations.

The Secretary of State is required by regulation 8 to review the operation and effect of the Registration Regulations and publish a report.

Regulation 9 amends Schedule 3 to the Registration Regulations to insert a new requirement for the statement of purpose to include an address for the service of any communications required by the Registration Regulations, including an electronic email address.

Part 3 of the Regulations makes an amendment to the Additional Functions Regulations to exclude recording of telephone calls in high security hospitals under direction 34(7) of the High Security Psychiatric Services (Arrangements for Safety and Security at Ashworth, Broadmoor and Rampton Hospitals) Directions 2011.

Part 4 of the Regulations amends Schedule 4 to the Health and Social Care (Regulated Activity) Regulations 2010 so as to insert the fixed penalty offence under regulation 25 of the Registration Regulations and revokes the Care Quality Commission (Registration) Amendment Regulations 2010(12) consequentially.

An impact assessment of the effect that this instrument will have on the costs and benefits to the service providers in question is available on the Department of Health’s web site at http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/index.htm and is published with the Explanatory Memorandum alongside the instrument at http://www.legislation.gov.uk.

(12) S.I. 2010/49.
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