STATUTORY INSTRUMENTS

2013 No. 373

The Controlled Drugs (Supervision of Management and Use) Regulations 2013

PART 2

Accountable officers

Appointment of and support for accountable officers

8.—(1) Each designated body must nominate or appoint, or in a group with one or more other designated bodies must jointly nominate or appoint, a fit, proper and suitably experienced person to be its accountable officer (but paragraph (4) applies in the case of the NHSCB).

(2) Where more than one part of an undertaking is a designated body, an aggregate of parts of that undertaking jointly appointing or nominating an accountable officer is a group of designated bodies for the purposes of this regulation, whether or not the aggregate is, or is part of, a single legal person.

(3) All the designated bodies in a group of designated bodies that are jointly nominating or appointing an accountable officer must be either in England or in Scotland.

(4) The NHSCB must nominate or appoint a fit, proper and suitably experienced person to be its accountable officer in respect of each local intelligence network area, and an accountable officer of the NHSCB may be the accountable officer in respect of one or more than one local intelligence network area.

(5) A person appointed under paragraph (1) or (4) (P) must be a person who satisfies Conditions 1, 2 and 3.

(6) Condition 1 is that P must be—

(a) in the case of the headquarters of regular or reserve forces, or headquarters of regular or reserve forces acting jointly, a senior officer (that is, a brigadier or a person of equivalent or superior rank) of the regular or reserve forces (and sub-paragraphs (b) to (d) do not apply in such cases);

(b) a senior manager of P's designated body;

(c) where designated bodies are jointly acting—

(i) unless paragraph (ii) applies, a senior manager of one of the designated bodies jointly acting, or

(ii) if the designated bodies jointly acting are part of the same undertaking, a senior manager of that undertaking; or

(d) answerable to a senior manager who satisfies sub-paragraph (b) or (c).

(7) Condition 2 is that P must be an officer or employee—

(a) of the designated body that nominates or appoints P; or

(b) if P is nominated or appointed by designated bodies jointly acting—

(i) of one of the designated bodies jointly acting, or

(ii) where those bodies are part of the same undertaking, of that undertaking.

(8) Condition 3 is that P does not, or does only exceptionally, prescribe, supply, administer or dispose of controlled drugs as part of P's duties as an employee or officer—

(a) of P's designated body; or

(b) if P is nominated or appointed by designated bodies jointly acting and those bodies are part of the same undertaking, of that undertaking.

(9) Two or more designated bodies may only jointly nominate or appoint a person to be their accountable officer if they are satisfied that P is capable of properly discharging P's functions under these Regulations in relation to each and all of them.

(10) A designated body of a description given in a sub-paragraph, or a paragraph of a sub-paragraph, of regulation 7 may only jointly nominate or appoint a person to be their accountable officer with another designated body of the same description.

(11) Each designated body that has an accountable officer must provide P with the funds and other resources necessary for enabling P to discharge P's responsibilities as accountable officer (in the case of joint nominations or appointments, this obligation may be discharged through joint arrangements for provision of funds and other resources).

(12) The other resources may include access to and use of information systems, accommodation and staff.

Removal of accountable officers

9. A designated body or a group of designated bodies that has nominated or appointed an accountable officer (P) must remove P from that office if—

(a) P is no longer to be considered a fit and proper person to be an accountable officer; or

(b) P no longer satisfies Condition 1, 2 or 3 in regulation 8(6) to (8).

National lists of accountable officers

10.—(1) Each designated body—

(a) in England must as soon as is practicable notify the CQC in writing of—

(i) any nomination or appointment by it of an accountable officer, or

(ii) the removal from office by it of an accountable officer; or

(b) in Scotland must as soon as is practicable notify HIS in writing of—

(i) any nomination or appointment by it of an accountable officer, or

(ii) the removal from office by it of an accountable officer.

(2) Where the nomination or appointment of an accountable officer, or removal from office of an accountable officer, is by a group of designated bodies, notification under paragraph (1) may be undertaken by the designated body or undertaking of which the accountable officer is or was an employee or officer, on behalf of the group.

(3) The CQC must compile, maintain and publish from time to time, in such manner as it sees fit, a list of accountable officers of designated bodies in England.

(4) HIS must compile, maintain and publish from time to time, in such manner as it sees fit, a list of accountable officers of designated bodies in Scotland.

Duties to secure safe management and use of controlled drugs

11.—(1) An accountable officer (CDAO) of a provider body or a group of provider bodies must—

(a) establish and operate, or ensure that the provider body or each member of the group of provider bodies establishes and operates, appropriate arrangements for securing the safe management and use of controlled drugs by the CDAO's provider body or group of provider bodies; and

(b) review as appropriate, or ensure that the provider body or each member of the group of provider bodies reviews as appropriate, those arrangements.

(2) A CDAO of a commissioning body or a group of commissioning bodies must ensure that any person or undertaking that provides the body or group with relevant services—

(a) establishes and operates appropriate arrangements for securing the safe management and use of controlled drugs; and

(b) reviews as appropriate those arrangements.

(3) The arrangements mentioned in paragraphs (1) and (2) must include—

(a) appropriate arrangements for compliance with the Misuse of Drugs Act 1971(**1**) and subordinate legislation under that Act;

(b) the following systems (which may be part of a single overarching system)—

(i) systems for recording concerns (including complaints) relating to the safe management or use of controlled drugs, and

(ii) incident reporting systems for untoward incidents relating to the safe management or use of controlled drugs; and

(c) up to date standard operating procedures in relation to the management and use of controlled drugs, which cover (amongst other matters) best practice relating to—

(i) the prescribing, supply and administration of controlled drugs, and

(ii) clinical monitoring of patients who have been prescribed controlled drugs.

(4) A CDAO of a provider body or group of provider bodies must ensure that any person who—

(a) as regards that provider body or group of provider bodies is a relevant individual; and

(b) needs information on, or education or training in relation to, the standard operating procedures referred to in paragraph (3)(c),

receives, as appropriate, that information, education or training.

Monitoring and auditing of the management and use of controlled drugs: general duties

12.—(1) An accountable officer (CDAO) of a provider body or a group of provider bodies must—

(a) establish and operate; or

(b) ensure that the provider body or each member of the group of provider bodies establishes and operates,

appropriate arrangements for monitoring and auditing the management and use of controlled drugs by the CDAO's provider body or group of provider bodies.

(2) A CDAO of a commissioning body or a group of commissioning bodies must—

(a) establish and operate appropriate arrangements for monitoring and auditing the management and use of controlled drugs by any person or undertaking that provides the body or group with relevant services; and

(b) ensure that any person or undertaking that provides the body or group with relevant services establishes and operates appropriate arrangements for monitoring and auditing the management and use of controlled drugs.

(**1**) 1971 c. 38.

(3) The arrangements mentioned in paragraphs (1) and (2) must include—

(a) arrangements, as appropriate, for assessing and investigating concerns that are recorded under the systems mentioned in regulation 11(3)(b)(i); and

(b) arrangements, as appropriate, for analysing and responding to incidents reported under the systems mentioned in regulation 11(3)(b)(ii),

having regard to any action that may already have been taken under the standard operating procedures mentioned in regulation 11(3)(c).

Monitoring, assessing, investigating and taking action in relation to relevant individuals

13.—(1) An Accountable Officer (CDAO) of—

(a) a provider body or group of provider bodies must—

(i) establish and operate; or

(ii) ensure that the body or each member of the group of provider bodies establishes and operates,

with regard to any person who, as regards the body or bodies, is a relevant individual (RI) because of relevant activities carried on by it or them;

(b) a commissioning body or group of commissioning bodies must—

(i) establish and operate; or

(ii) ensure that the body or each member of the group of commissioning bodies establishes and operates,

with regard to any person who, as regards the body or bodies, is a RI because of relevant activities provided for it or them,

the arrangements mentioned in paragraph (2).

(2) Those arrangements are appropriate arrangements for—

(a) monitoring and assessing the RI's performance in connection with the management and use of controlled drugs;

(b) determining whether incidents or concerns that relate to the RI's performance in connection with the management and use of controlled drugs require investigation;

(c) investigating such incidents or concerns; and

(d) taking appropriate action with regard to well founded concerns (which may relate to incidents).

(3) Where data in respect of a RI who prescribes controlled drugs, and associated analysis tools, are available to the CDAO's designated body through use of—

(a) in England, ePACT (Electronic Prescribing Analysis and Costs), a system held by the NHSBSA; or

(b) in Scotland, PRISMS (Prescribing Information Systems for Scotland), a system held by the Common Services Agency,

the arrangements under paragraph (2)(a) must include monitoring and assessing the RI's performance using that data and those tools.

(4) A CCG that, for purposes connected with monitoring pharmaceutical remuneration, monitors the management or use of controlled drugs by an individual who is as regards the NHSCB a RI must assist the relevant CDAO of the NHSCB in the carrying out of the CDAO's functions under paragraph (1).

(5) Where it is determined under the arrangements mentioned in paragraph (2)(b) that an incident or a concern requires investigation, the arrangements under paragraph (2)(c) must provide for the CDAO to do one or more of the following—

(a) carry out the investigation themselves;

(b) arrange for the investigation to be carried out by another officer or employee of the designated body, or one of the designated bodies, of which the CDAO is the accountable officer; or

(c) arrange with one or more of the responsible bodies listed in paragraph (6) to carry out the investigation—

(i) on behalf of the CDAO, or

(ii) jointly with either the CDAO or an officer or employee as mentioned in sub-paragraph (b).

(6) The responsible bodies listed in this paragraph are—

(a) a designated body (that is a designated body of which the CDAO is not the accountable officer);

(b) the CQC;

(c) NHS Protect;

(d) HIS;

(e) the Scottish Counter Fraud Services;

(f) the Care Inspectorate;

(g) a police force; and

(h) a regulatory body.

(7) The arrangements under paragraph (2)(d) must include appropriate arrangements for—

(a) determining whether information relating to incidents or concerns that relate to the RI's performance in connection with the management and use of controlled drugs needs to be shared with a responsible body; and

(b) in a case where, following investigation, it appears to the CDAO that there are concerns (which may relate to incidents) that relate to the RI's performance in connection with the management and use of controlled drugs that are well founded, as appropriate—

(i) requesting additional advice, support, mentoring or training for the RI from an appropriate person (for example, a prescribing advisor or a clinical governance lead),

(ii) implementation of a procedure for dealing with serious untoward incidents,

(iii) referral of the concerns to—

(aa) a regulatory body,

(bb) a police force,

(cc) NHS Protect,

(dd) the Scottish Counter Fraud Services, or

(ee) if the CDAO is a CDAO of the NHSCB or a Health Board, an incident panel convened by the CDAO, and

(iv) where the CDAO is a CDAO of the NHSCB or a Health Board, dealing with matters arising out of an incident panel, which may include (but need not be limited to)—

(aa) ongoing monitoring of the individual,

(bb) referral of concerns to a regulatory body,

(cc) referral of concerns to a police force,

(dd) referral of concerns to NHS Protect,

(ee) referral of concerns to the Scottish Counter Fraud Services, and

(ff) implementation of a procedure for dealing with serious untoward incidents.