STATUTORY INSTRUMENTS

2013 No. 373

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

PART 4

Inspections and supplementary matters

"Relevant premises" for the purposes of section 20 of the Health Act 2006

17.—(1) For the purposes of section 20 of the Health Act 2006 (controlled drugs: power to enter and inspect), the following are prescribed as "relevant premises" in England in so far as entry of them is or may be relevant to the purpose of securing the safe, appropriate and effective management and use of controlled drugs—

(a) in relation to the local lead CDAO of a local intelligence network in England, premises of relevant persons as regards **[**F1NHS England**]** in that area that are not subject to inspection by—

(i) the CQC,

(ii) the General Pharmaceutical Council, or

(iii) an accountable officer of a regular or reserve force;

(b) in relation to the accountable officer of an NHS foundation trust, premises of that NHS foundation trust;

(c) in relation to the accountable officer of an NHS trust, premises of that NHS trust;

(d) in relation to the accountable officer of a regular or reserve force, premises of that regular or reserve force or of members of that regular or reserve force;

(e) in relation to the accountable officer of an English independent Hospital—

(i) premises of that hospital, and

(ii) premises of a person engaged in relevant activities on the hospital's behalf, if those premises are not otherwise subject to inspection by an accountable officer of a designated body by virtue of sub-paragraphs (a) to (d).

(2) For the purposes of section 20 of the Health Act 2006, the following are prescribed as "relevant premises" in Scotland in so far as entry of them is or may be relevant to the purpose of securing the safe, appropriate and effective management and use of controlled drugs—

(a) in relation to the accountable officer of a Health Board—

(i) premises of that Health Board,

(ii) premises of any person or undertaking from which that person or undertaking provides the Health Board with services as part of the health service,

(iii) premises of relevant persons in the area of the Health Board that are not—

(aa) otherwise subject to inspection by HIS, the Care Inspectorate or the General Pharmaceutical Council,

(bb) premises of a regular or reserve force or of members of a regular or reserve force, or

(cc) premises of the Special Health Boards referred to in sub-paragraph (b);

(b) in relation to the accountable officer of—

(i) the Scottish Ambulance Service Board, premises of that Board,

(ii) the National Waiting Times Centre Board, premises of that Board, and

(iii) the State Hospitals Board for Scotland, premises of that Board;

(c) in relation to the accountable officer of a regular or reserve force, premises of that regular or reserve force or of members of that regular or reserve force;

(d) in relation to the accountable officer of a Scottish independent hospital—

(i) premises of that hospital, and

(ii) premises of a person engaged in relevant activities on the hospital's behalf, if those premises are not otherwise subject to inspection by an accountable officer of a designated body by virtue of sub-paragraphs (a) to (c).

(3) Any premises that are prescribed as "relevant premises" under paragraph (1) or (2) in relation to an accountable officer are also so prescribed in relation to constables.

F1 Words in Regulations substituted (6.11.2023) by The Health and Care Act 2022 (Further Consequential Amendments) (No. 2) Regulations 2023 (S.I. 2023/1071), reg. 1(1), **Sch. para. 1**

Supplementary matters relating to inspections

18.—(1) An authorisation given under section 20(5)(a) or (c) of the Health Act 2006 (controlled drugs: power to enter and inspect) must be in writing.

(2) A local lead CDAO or authorised person, when carrying out an inspection of relevant premises, need not give the owner of the relevant premises being inspected notice of the inspection.

(3) Section 20(3) of the Health Act 2006 does not apply as regards the following authorised persons—

(a) a member of staff or person authorised by the CQC entering an English care home;

(b) a member of staff or person authorised by the Care Inspectorate entering a Scottish care home;

(c) a member of staff or person authorised by HIS entering premises of any person who provides relevant services as part of providing health care in Scotland;

(d) an officer of the General Pharmaceutical Council entering a registered pharmacy; or

(e) a member of staff or a person authorised by **[**[F1]NHS England**]** or a Health Board entering premises which are or form part of a private dwelling of a health care professional, if—

(i) the health care professional is providing health care (which includes the services of a pharmacist) at the private dwelling, and

(ii) the private premises are on a statutory register of health care premises or designated as practice premises under arrangements with **[**[F1]NHS England**]** or a Health Board to provide primary medical or dental services.

F1 Words in Regulations substituted (6.11.2023) by The Health and Care Act 2022 (Further Consequential Amendments) (No. 2) Regulations 2023 (S.I. 2023/1071), reg. 1(1), **Sch. para. 1**

Supplementary compliance declarations

19.—(1) The CQC may request a periodic declaration and self assessment from any person registered with it who—

(a) provides health care; or

(b) carries on a care home in England,

which states whether, and if so how, controlled drugs are managed and used at relevant premises of that person.

(2) HIS may request a periodic declaration and self assessment from any person who provides relevant services as part of providing health care in Scotland which states whether, and if so how, controlled drugs are managed and used at relevant premises of that person.

(3) The Care Inspectorate may request a periodic declaration and self assessment from any person carrying on a care home in Scotland which states whether, and if so how, controlled drugs are managed and used at relevant premises of that person.

(4) The General Pharmaceutical Council may request a periodic declaration and self assessment from any person whose premises in England or Scotland are registered with it which states how controlled drugs are managed and used at those premises.

Information management

20.—(1) The records maintained by a designated body in respect of inspections, complaints, untoward incidents and other concerns, and the response to them, may be kept in paper or electronic format, and the accountable officer (CDAO) of that body must ensure that the information in those records is only accessible to—

(a) the CDAO; and

(b) persons who the CDAO is satisfied—

(i) should have access to the information on a need-to-know basis, and

(ii) fully understand the confidential nature of the information and the purposes for which they are being permitted access to it.

(2) Where by virtue of Part 3 a responsible body (RB1) receives information from another responsible body, that information must only be processed by RB1 in so far as is necessary for the purposes of—

(a) the identification of cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs;

(b) the consideration of issues relating to the taking of action in respect of such matters; and

(c) the taking of action in respect of such matters,

and RB1 must ensure that appropriate measures are taken by it to prevent unauthorised processing of the information.

(3) Those measures must include limiting access to the information to persons—

(a) on a need-to-know basis; and

(b) who fully understand the confidential nature of the information and the purposes for which they are being permitted access to it.

[[F2](4) Where a CDAO, a responsible body or someone acting on their behalf is permitted to share information which includes personal data by virtue of a function under these Regulations, it is to be assumed for the purposes of paragraph 5(2) of Schedule 2 to the Data Protection Act 2018 and paragraph 3(2) of Schedule 11 to that Act (exemptions from certain provisions of the data protection legislation: disclosures required by law) that the disclosure is required by this regulation.**]**

(5) Nothing in these Regulations requires, or is to be treated as requiring, any disclosure which—

(a) is prohibited by or under any enactment **[**F3or the**][**F4UK GDPR**]** (taking into account the effect of paragraph (4));

(b) would prejudice or would be likely to prejudice—

(i) any investigation being conducted by any responsible body under any enactment **[**F3or the**][**F4UK GDPR**]**,

(ii) a regular or reserve force's arrangements for service discipline, or

(iii) any civil or criminal proceedings; or

(c) would involve disproportionate cost.

(6) Civil proceedings do not lie against a person in respect of loss, damage or injury of any kind suffered by another person as a result of disclosure of information under these Regulations if it is done in good faith and there are reasonable grounds for doing it.

[F5(7) In this regulation, "personal data" and "the UK GDPR" have the same meaning as in Parts 5 to 7 of the Data Protection Act 2018 (see section 3(2), (10) and (14) of that Act).**]**

F2 Reg. 20(4) substituted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 378(2)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

F3 Words in reg. 20(5) inserted (25.5.2018) by Data Protection Act 2018 (c. 12), s. 212(1), **Sch. 19 para. 378(3)** (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

F4 Words in reg. 20(5) substituted (31.12.2020) by The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (S.I. 2019/419), reg. 1(2), **Sch. 3 para. 96(2)** (with Sch. 3 para. 112); 2020 c. 1, Sch. 5 para. 1(1)

F5 Reg. 20(7) substituted (31.12.2020) by The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (S.I. 2019/419), reg. 1(2), **Sch. 3 para. 96(3)** (with Sch. 3 para. 112); 2020 c. 1, Sch. 5 para. 1(1)

Revocation of the Controlled Drugs (Supervision of Management and Use) Regulations 2006

21. The Controlled Drugs (Supervision of Management and Use) Regulations 2006 are revoked M1.

Marginal Citations

M1 S.I. 2006/3148.

Changes to legislation:
There are currently no known outstanding effects for the The Controlled Drugs (Supervision of Management and Use) Regulations 2013, PART 4.