Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4

MEDICAL DEVICES

CHAPTER 2

REGULATIONS: INFORMATION SYSTEMS, ADVISORY COMMITTEE

19 Information systems

(1) The Secretary of State may by regulations make provision about the establishment and operation by **[**F1NHS England**]** of one or more information systems for purposes relating to—

(a) the safety and performance, including the clinical effectiveness, of medical devices that are placed on the market;

(b) the safety of individuals who receive or are treated with a medical device, or into whom a medical device is implanted;

(c) the improvement of medical device safety and performance through advances in technology.

(2) The regulations may (among other things) make provision—

(a) specifying descriptions of information in relation to medical devices which may or must be entered or retained in an information system established under subsection (1);

(b) requiring information to be provided to **[**F2NHS England**]** for the purposes of its functions under the regulations;

(c) about the use or disclosure of information contained in an information system established under subsection (1);

(d) requiring **[**F2NHS England**]** to have regard to specified matters in exercising its functions under the regulations.

(3) The provision mentioned in subsection (2)(b) may include provision—

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(a) requiring specified persons or descriptions of persons to whom subsection (4) applies to provide information of a specified description to **[**F3NHS England**]**;

(b) about the manner in which, and the time at which, those persons must provide that information;

(c) enabling **[**F3NHS England**]** to require specified persons or descriptions of persons to whom subsection (4) applies to provide to it in a manner, and at a time, determined by **[**F3NHS England**]**—

(i) information of a specified description;

(ii) information for specified purposes;

(iii) any other information that **[**F3NHS England**]** considers it necessary or expedient to have for the purposes of its functions under the regulations;

(d) about any procedural steps **[**F3NHS England**]** must follow in requiring a person to provide information to it;

(e) requiring specified persons or descriptions of persons to whom subsection (4) applies to record or retain information which they are, or may be, required to provide to **[**F3NHS England**]** under the regulations;

(f) in relation to the enforcement of any requirement imposed by or under the regulations.

(4) This subsection applies to any person who provides services, or exercises any powers or duties, relating to medical devices.

(5) The descriptions of information specified in the provision mentioned in subsections (2)(a), (3)(a) and (3)(c)(i) may include—

(a) unique identifiers associated with medical devices;

(b) information in relation to individuals mentioned in subsection (1)(b);

(c) information about any procedure carried out in relation to a medical device (including information about any person involved in carrying out the procedure).

(6) The provision mentioned in subsection (2)(c) may include provision about—

(a) the analysis by **[**F4NHS England**]** of information contained in an information system (whether alone or in combination with other information) for the purposes mentioned in subsection (1) or for other purposes;

(b) the publication by **[**F4NHS England**]** of information **[**F5that is contained in an information system or has been analysed in combination with such information**]**;

(c) the disclosure (other than by way of publication) of information **[**F6mentioned in paragraph (b)**]** to specified persons or descriptions of persons, or for specified purposes;

(d) the use or further disclosure by any person of information disclosed to them under the regulations.

(7) The provision mentioned in subsection (3)(f) may include provision applying any provision of Chapter 3 of this Part (enforcement), with or without modifications, in relation to a requirement imposed by or under the regulations.

[F7(7A) Regulations under this section may provide that the disclosure of information by virtue of this section does not breach—

(a) an obligation of confidence owed by the person making the disclosure, or

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(b) any other restriction on the disclosure of the information (however imposed), other than a restriction imposed by the data protection legislation.**]**

(8) In this section, "specified" means specified in regulations under subsection (1).

Textual Amendments

F1 Words in s. 19(1) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 21(3)(a)** (with reg. 3)

F2 Words in s. 19(2) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 21(3)(b)** (with reg. 3)

F3 Words in s. 19(3) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 21(3)(b)** (with reg. 3)

F4 Words in s. 19(6) substituted (1.2.2023) by The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023 (S.I. 2023/98), reg. 1(2), **Sch. para. 21(3)(b)** (with reg. 3)

F5 Words in s. 19(6)(b) substituted (1.7.2022) by Health and Care Act 2022 (c. 31), **ss. 101(4)(a)(i)**, 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)

F6 Words in s. 19(6)(c) substituted (1.7.2022) by Health and Care Act 2022 (c. 31), **ss. 101(4)(a)(ii)**, 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)

F7 S. 19(7A) inserted (1.7.2022) by Health and Care Act 2022 (c. 31), **ss. 101(4)(b)**, 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)

Changes to legislation:
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