



Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4 U.K.

MEDICAL DEVICES

CHAPTER 2 U.K.

REGULATIONS: INFORMATION SYSTEMS, ADVISORY COMMITTEE

19 Information systems U.K.

- (1) The Secretary of State may by regulations make provision about the establishment and operation by [^{F1}NHS 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 [^{F2}NHS 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 [^{F2}NHS 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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