



Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 2

HUMAN MEDICINES

[^{F1}CHAPTER 1A

REGULATIONS: INFORMATION SYSTEMS

Textual Amendments

- F1** Pt. 2 Ch. 1A inserted (1.7.2022) by Health and Care Act 2022 (c. 31), ss. 101(3), 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)

7A Information systems

- (1) The appropriate authority may by regulations make provision about the establishment and operation by [^{F2}NHS England] of one or more information systems for purposes relating to—
- the safety of human medicines, including the safety of clinical decisions relating to human medicines;
 - the quality and efficacy of human medicines.
- (2) The regulations may (among other things) make provision—
- about the information in relation to human medicines which may or must be entered or retained in an information system established under subsection (1);
 - requiring information to be provided to [^{F3}NHS England] for the purposes of its functions under the regulations;
 - about the use or disclosure of information contained in an information system established under subsection (1);

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- (d) requiring [F³NHS England] to have regard to specified matters in exercising its functions under the regulations.
- (3) The provision mentioned in subsection (2)(a) and (b) may relate to—
- (a) information for specified purposes,
 - (b) information that [F³NHS England] considers it necessary or expedient to have for the purposes of its functions under the regulations,
 - (c) information (including information relating to individuals) which is of a specified description, or
 - (d) information (including information relating to individuals) which is of a description set out in a direction in writing given by the appropriate authority.
- (4) The provision mentioned in subsection (2)(b) may include provision—
- (a) requiring, or enabling [F³NHS England] to require, specified persons or descriptions of persons to whom subsection (5) applies to provide information to [F³NHS England];
 - (b) about the manner in which, and the time at which, those persons must provide information, or for those matters to be determined by [F³NHS England];
 - (c) about any procedural steps [F³NHS England] must follow in requiring a person to provide information to it;
 - (d) requiring specified persons or descriptions of persons to whom subsection (5) applies to record or retain information which they are, or may be, required to provide to [F³NHS England] under the regulations;
 - (e) in relation to the enforcement of any requirement imposed by or under the regulations.
- (5) This subsection applies to any person who provides services, or exercises any powers or duties, relating to—
- (a) human medicines,
 - (b) health, or
 - (c) education.
- (6) The provision mentioned in subsection (2)(c) may include provision about—
- (a) the analysis by [F⁴NHS England] of information that is 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 that 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 mentioned 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) Regulations conferring on the appropriate authority a power to give a direction by virtue of subsection (3)(d) must —
- (a) provide that the power includes power to vary or revoke the directions by a subsequent direction, and
 - (b) in the case of a power exercisable in relation to Wales or Scotland, require the Secretary of State—

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- (i) where a proposed direction relates to Wales, to consult the Welsh Ministers before giving it, and
 - (ii) where a proposed direction relates to Scotland, to consult the Scottish Ministers before giving it.
- (8) Where regulations under subsection (1) include provision by virtue of subsection (4) (a) which requires, or enables [^{F5}NHS England] to require, the provision of individual health information held for the purposes of the health service established under section 1 of the National Health Service (Scotland) Act 1978, the regulations must provide for the information to be collected by the Scottish Ministers, or a person designated by them, on behalf of [^{F5}NHS England], subject to specified exceptions.
- (9) Regulations by virtue of subsection (8) may—
 - (a) confer powers or duties (including discretions) on the Scottish Ministers, a designated person or [^{F5}NHS England];
 - (b) provide for powers or duties conferred on the Scottish Ministers to be treated for the purposes of section 2 of the National Health Service (Scotland) Act 1978 as functions relating to the health service (within the meaning of that Act).
- (10) Where regulations under subsection (1) include provision by virtue of subsection (4) (a) which requires, or enables [^{F5}NHS England] to require, the provision of individual health information held for the purposes of the health service in Wales, the regulations must provide for the information to be collected by the Welsh Ministers, or a person designated by them, on behalf of [^{F5}NHS England], subject to specified exceptions.
- (11) Regulations by virtue of subsection (10) may confer powers or duties (including discretions) on the Welsh Ministers, a designated person or [^{F5}NHS England].
- (12) Regulations under subsection (1) 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
 - (b) any other restriction on the disclosure of the information (however imposed), other than a restriction imposed by the data protection legislation.
- (13) In this section—
 - “data protection legislation” has the meaning given by section 3(9) of the Data Protection Act 2018;
 - “health service”, in relation to Wales, has the meaning given by section 206(1) of the National Health Service (Wales) Act 2006;
 - “human medicine” has the same meaning as in Part 2 (see section 9);
 - “individual health information” means information (however recorded) which relates to—
 - (a) the physical or mental health or condition of an individual,
 - (b) the diagnosis of an individual’s condition, or
 - (c) an individual’s care or treatment,or is (to any extent) derived directly or indirectly from information relating to any of those matters;
 - “specified” means specified in regulations under subsection (1).

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Textual Amendments

- F2** Words in s. 7A(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(2)(a)** (with reg. 3)
- F3** Words in s. 7A(2)-(4) 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(2)(b)** (with reg. 3)
- F4** Words in s. 7A(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(2)(b)** (with reg. 3)
- F5** Words in s. 7A(8)-(11) 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(2)(b)** (with reg. 3)

7B Offence of disclosing information

- (1) A person to whom information is disclosed under regulations under section [7A\(1\)](#) commits an offence if the person uses or discloses that information in contravention of the regulations.
- (2) A person guilty of an offence under this section is liable—
 - (a) on summary conviction in England and Wales, to imprisonment for a term not exceeding 51 weeks, to a fine or to both;
 - (b) on summary conviction in Scotland or Northern Ireland, to imprisonment for a term not exceeding 6 months, to a fine not exceeding level 5 on the standard scale or to both.
- (3) In relation to an offence committed before the coming into force of section 281(5) of the Criminal Justice Act 2003, the reference in subsection [\(2\)\(a\)](#) to 51 weeks is to be read as a reference to 6 months.]

Changes to legislation:

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