STATUTORY INSTRUMENTS

2018 No. 677

The Health Service Products (Provision and Disclosure of Information) Regulations 2018

PART 1

Introductory

Citation and commencement

1.—(1) These Regulations may be cited as the Health Service Products (Provision and Disclosure of Information) Regulations 2018.

(2) Subject to paragraphs (3) and (4), these Regulations come into force on 1st July 2018.

(3) Part 3 comes into force on 1st August 2018.

(4) Regulation 29 comes into force on 1st January 2019.

Interpretation: general

2. These Regulations are to be interpreted in accordance with Schedule 1.

Application

3. Nothing in these Regulations—

(a) requires a person who provides primary medical services under Part 4 of the 2006 Wales Act, or any person who provides services under Part 7 of that Act, to record, keep or provide information relating to any Welsh health service products [M1] which are supplied by the person in providing the services in question;

(b) requires a person who provides primary medical services under section 2C(1) of the 1978 Act, or any person who provides pharmaceutical care services under section 2CA(1) of that Act, to record, keep or provide any information relating to any Scottish health service products [M2] which are supplied by the person in providing the services in question;

(c) requires a person who provides primary medical services or pharmaceutical services under Part 2 or 6 of the 1972 Order to record, keep or provide information about Northern Ireland health service products [M3] which are supplied by the person in providing the services in question.

Marginal Citations

M1 See the definition of "Welsh health service products" in section 264A(15) of the National Health Service Act 2006.

M2 See the definition of "Scottish health service products" in section 264A(13) of the National Health Service Act 2006.

M3 See the definition of "Northern Ireland health service products" in section 264A(12) of the National Health Service Act 2006.

Exception: products not known to be health service products

4. Nothing in these Regulations requires a UK producer [M4] to record and keep, or provide, information about a product if the producer could not reasonably have known, at the time the producer purchased or supplied the product, that it was, or was to be, a UK health service product [M5].

Marginal Citations

M4 See the definition of "UK producer" in section 264A(1) of the National Health Service Act 2006.

M5 See the definition of "UK health service products" in section 264A(14) of the National Health Service Act 2006.

Information required to be provided via an [F1NHS England] online gateway

5.—(1) This regulation applies where a question arises as to whether any information required to be provided by, or under, these Regulations electronically via an **[**F1NHS England**]** online gateway has been so provided.

(2) For the purposes of these Regulations, it is to be presumed—

(a) that the relevant information has been successfully provided electronically via the relevant online gateway only if **[**F1NHS England**]** has successfully recorded the information;

(b) that the relevant information was provided at the time it was recorded by **[**F1NHS England**]**;

(c) that the person providing the information is the person identified as such by the information recorded by **[**F1NHS England**]**;

(d) that a return made on behalf of a body corporate is made with the authority of that body.

(3) The presumptions in paragraph (2) are rebuttable.

Textual Amendments

F1 Words in reg. 5 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. 58(2)** (with reg. 3)

Changes to legislation:
There are currently no known outstanding effects for the The Health Service Products (Provision and Disclosure of Information) Regulations 2018, PART 1.