*Draft Regulations laid before Parliament under section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021, for approval by resolution of each House of Parliament.*

DRAFT STATUTORY INSTRUMENTS

# 2022 No. 000

# MEDICAL DEVICES, ENGLAND
# MEDICINES, ENGLAND

## The Commissioner for Patient Safety (Appointment and Operation) (England) Regulations 2022

| | |
|---|---|
| *Made - - - -* | *** |
| *Coming into force - -* | *** |

The Secretary of State makes the following Regulations in exercise of powers conferred by paragraphs 6(1) and (2) of Schedule 1 to the Medicines and Medical Devices Act 2021(**1**) ("the Act").

The Secretary of State makes these Regulations having carried out a public consultation in accordance with section 45(1) of the Act.

In accordance with section 47(3) and (6)(a) of the Act, a draft of the instrument was laid before Parliament and approved by a resolution of each House of Parliament.

### Citation, commencement, extent and application

**1.**—(1) These Regulations may be cited as the Commissioner for Patient Safety (Appointment and Operation) (England) Regulations 2022.

(2) These Regulations come into force on the day after the day on which they are made.

(3) These Regulations extend to England and Wales.

(4) These Regulations apply to England only.

### Interpretation

**2.** In these Regulations—

"financial year" means—

(a) the period beginning with the date the first Commissioner takes office and ending with 31st March following that date; and

(**1**) 2021 c. 3, to which there are amendments not relevant to these Regulations. See section 1(1) for the definition of "Commissioner".

(b) each successive period of twelve months ending with the 31st March.

**Appointment and tenure of office**

**3.**—(1) The Commissioner is to be appointed for a term of three years.

(2) A person who has held office as the Commissioner is eligible for re-appointment for a second term.

(3) A person who has held office as the Commissioner for two terms is ineligible for reappointment at any time.

(4) The Commissioner may at any time resign by notice in writing to the Secretary of State.

(5) The Secretary of State may remove the Commissioner from office, by notice in writing, if the Secretary of State is satisfied that the Commissioner has—

(a) become unfit or unable properly to discharge the functions of the Commissioner; or

(b) behaved in a way that is not compatible with continuing in office.

**Remuneration**

**4.** The Secretary of State must pay remuneration to the Commissioner.

**Funding**

**5.** The Secretary of State may make payments to the Commissioner of such amounts, at such times and on such conditions (if any) as the Secretary of State considers appropriate.

**Staff and facilities**

**6.** The Secretary of State may provide staff, facilities or other assistance to the Commissioner.

**Business plans**

**7.**—(1) The Commissioner must publish a business plan which sets out, in relation to the discharge of the Commissioner's functions—

(a) the Commissioner's proposed main activities for the period covered by the plan (including the matters the Commissioner intends to consider or investigate), and

(b) the Commissioner's proposed strategic priorities for that period.

(2) A business plan must cover a period of at least 12 months beginning with the date of publication.

(3) The Commissioner must publish a new business plan before the end of the period covered by the preceding business plan.

(4) The first business plan must be published as soon as possible after the first Commissioner takes office.

**Accounts**

**8.** The Commissioner must—

(a) keep accounting records;

(b) prepare a statement of accounts for each financial year; and

(c) send a copy of each such statement of accounts to the Secretary of State as soon as possible after the end of the financial year to which the statement relates.

### Annual report

**9.**—(1) As soon as possible after the end of each financial year the Commissioner must make a report on—

(a) the way in which the Commissioner's functions have been discharged; and

(b) what the Commissioner has found in the course of exercising those functions during the year.

(2) The Commissioner may in particular under paragraph (1)(a) include—

(a) a summary of the Commissioner's activities and an analysis of the effectiveness of those activities in relation to the Commissioner's core duties(**2**);

(b) an account of what the Commissioner has done in the discharge of the Commissioner's functions;

(c) an account of the steps taken by the Commissioner to consult patients or otherwise involve them in the discharge of the Commissioner's functions, and

(d) a summary of how the Commissioner has taken into account the results of any such consultation and anything else resulting from involving patients in the discharge of the Commissioner's functions.

(3) When the Commissioner makes a report, the Commissioner must—

(a) send a copy to the Secretary of State;

(b) lay a copy before each House of Parliament; and

(c) publish the report as soon as possible after the end of the financial year.

### Advisory panel

**10.**—(1) The Commissioner must appoint an advisory panel to provide the Commissioner with advice and assistance relating to the discharge of the Commissioner's functions and encourage good practice in involvement with patients.

(2) The advisory panel must consist of persons who (taken together) represent a broad range of interests which are relevant to the Commissioner's functions.

### Conferring functions on others

**11.** The Commissioner may authorise any member of the Commissioner's staff to exercise any of the functions of the Commissioner.

Signed by authority of the Secretary of State for Health and Social Care

*Name*
Parliamentary Under Secretary of State
Department of Health and Social Care

Date

(**2**) In relation to the core duties mentioned in paragraph 2(a) see section 1(2) of the Medicines and Medical Devices Act 2021 (c. 3).

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make provision about the appointment and operation of the Commissioner for Patient Safety (the "Commissioner") established under the Medicines and Medical Devices Act 2021 (c. 3).

Regulation 2 defines financial year, initially, by reference to the date the first Commissioner starts in the role, with subsequent financial years being for a period of 12 months, ending with 31st March each year.

Regulation 3 provides that the Commissioner will serve for a term of three years and that a Commissioner will be eligible for one further term only. It also provides for the resignation of a Commissioner, or removal by the Secretary of State of the Commissioner if that person has become unfit or unable to properly discharge their functions, or if they have behaved in a way that is not compatible with them continuing in office.

Regulations 4 to 6 provide for the Commissioner to receive remuneration, the funding of the role and for the provision of staff and facilities.

Regulation 7 provides for the preparation of a business plan setting out, in relation to the discharge of the Commissioner's functions, what the Commissioner's proposed main activities for the period covered by the plan will be, including any areas or matters the Commissioner intends to consider, and what the Commissioner's proposed strategic priorities for that period will be.

Regulation 8 requires the Commissioner to keep accounting records and prepare a statement of accounts for each financial year.

Regulation 9 requires the Commissioner to publish an annual report detailing the way in which the Commissioner has discharged their functions and what they have found in the course of exercising these functions during the year.

Regulation 10 requires the Commissioner to appoint an advisory panel to provide advice and assistance relating to the discharge of the Commissioner's functions and encourage good practice in involvement with patients.

Regulation 11 enables the Commissioner to authorise members of staff to carry out any of the Commissioner's functions.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.