STATUTORY INSTRUMENTS

2024 No. 302

MENTAL HEALTH, ENGLAND NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) (Amendment) Regulations 2024

Made - - - - 5th March 2024
Laid before Parliament 6th March 2024
Coming into force - - 1st April 2024

The Secretary of State makes these Regulations in exercise of the powers conferred by section 6E(1), (1A), (1B) and (2) and section 272(7) and (8) of the National Health Service Act 2006(1).

Citation, commencement, extent and application

- 1. These Regulations—
 - (a) may be cited as the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) (Amendment) Regulations 2024;
 - (b) come into force on 1st April 2024;
 - (c) extend to England and Wales;
 - (d) apply in relation to England only.

Amendment of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012

2.—(1) The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012(**2**) are amended as follows.

^{(1) 2006} c. 41. Section 6E was inserted by section 20(1) of the Health and Social Care Act 2012 (c. 7); and amended by section 78(1) and (2) of the Health and Care Act 2022 (c. 31), and by paragraph 1(1) and (2) of Schedule 1 and paragraphs 86 and 89(1), (2) and (3) of Schedule 4 to that Act. Subsections (1A) and (1B) of section 6E were inserted by section 78(2) (b) of the Health and Care Act 2022.

⁽²⁾ S.I. 2012/2996 ("the Standing Rules"); relevant amending instruments are S.I. 2013/2891, 2014/1611, 2018/283, 2022/532, 2022/634, 2023/288, 2023/1071 and 2023/1105. Under section 1 of the Health and Care Act 2022, the NHS Commissioning Board was renamed NHS England. On 1st July 2022, in accordance with Chapter A3 of Part 2 of the National Health Service

- (2) In regulation 1 (citation and commencement), in paragraph (2)(d)—
 - (a) in paragraph (v), after "regulations 38 to 41," insert "and";
 - (b) in paragraph (vi), omit "and";
 - (c) omit paragraph (vii).
- (3) In regulation 20 (interpretation)(3)—
 - (a) in the definition of "flat rate payment", for "£219.71" substitute "£235.88";
 - (b) in the definition of "high band payment", for "£302.25" substitute "£324.50".
- (4) In regulation 38 (interpretation)(4), for the definition of "interface services", substitute—
 ""interface services" means services—
 - (a) consisting of clinical triage, assessment or treatment, other than services provided under a primary care contract,
 - (b) to be accessed by a person who requires an elective referral, but provided before the provision of the treatment required as a result of that referral, and
 - (c) arranged by-
 - (i) a relevant body, or
 - (ii) an NHS trust or NHS foundation trust in the exercise of commissioning functions that have been delegated by virtue of arrangements made under section 65Z5(1) of the 2006 Act.".
- (5) In regulation 39 (duty to ensure persons are offered a choice of health service provider)(5)—
 - (a) in each of paragraphs (2)(a)(i) and (2)(b)(i), for "relevant body", substitute "commissioning body";
 - (b) for paragraph (8), substitute—
 - "(8) In paragraph (2)—

"commissioning body" means—

- (a) a relevant body, or
- (b) an NHS trust or NHS foundation trust when exercising commissioning functions of a relevant body that have been delegated by virtue of arrangements made under section 65Z5(1) of the 2006 Act;

"qualifying contract" means an NHS Standard Contract which—

- (a) is signed and in effect before the date on which the referral is made,
- (b) is a commissioning contract for the service required as a result of the referral,
- (c) requires that service to be provided from the location specified in that contract or sets out the criteria to determine how that service will be accessible to patients, and
- (d) is not a contract put in place solely to provide that service to a specified individual.";

Act 2006 (as inserted by section 19 of the Health and Care Act 2022) and S.I. 2022/632, NHS England established integrated care boards to take on the commissioning functions of clinical commissioning groups. As a consequence of those changes, paragraph 1(1) of the Schedule to S.I. 2022/634 substitutes references to "clinical commissioning group" with "integrated care board" in the Standing Rules. In addition, regulation 56(2) of S.I. 2023/1071 omits the definition of "the Board" and replaces it with "NHS England" in the Standing Rules and paragraph 1 of the Schedule to S.I. 2023/1071 substitutes references to "the NHS Commissioning Board" with "NHS England" in the Standing Rules. There are other amending instruments but none is relevant.

- (3) Relevant amendments to regulation 20 were made by S.I. 2014/1611 and 2023/288.
- (4) Regulation 38 was amended by S.I. 2023/1105.
- (5) Relevant amendments to regulation 39 were made by S.I. 2023/1105.

- (c) after paragraph (8), insert—
 - "(9) For the purposes of the definition of "qualifying contract" in paragraph (8), "commissioning contract" means a contract, other than a primary care contract, entered into by—
 - (a) a relevant body when exercising its commissioning functions, or
 - (b) an NHS trust or NHS foundation trust in the exercise of the commissioning functions of a relevant body that have been delegated by virtue of arrangements made under section 65Z5(1) of the 2006 Act.".
- (6) In regulation 40 (services to which the duties as to choice do not apply)(6), for paragraph (1) (a), substitute "services subject to the duty in regulation 52(1) (duty to make arrangements to diagnose or rule out cancer); or".
- (7) In regulation 42D (modification of existing NHS Standard Contract)(7), in paragraph (1)(c), for "(2) and (3)" substitute "(2), (3) and (5)".
 - (8) In regulation 44 (interpretation)(8), in paragraph (1)—
 - (a) in the definition of "eligible referrer", after sub-paragraph (b), insert "(ba) a person acting on behalf of an NHS cancer screening service,";
 - (b) after the definition of "interface services" insert ""NHS cancer screening service" means any cancer screening programme which the Secretary of State has arranged for NHS England or an integrated care board to commission under section 7A of the National Health Service Act 2006(9);";
 - (c) in the definition of "start date", for sub-paragraph (b), substitute "(b) in regulations 52 and 53, an eligible referrer";
 - (d) omit the definition of "treatment for suspected cancer".
- (9) For regulations 52 (duty to make arrangements to provide an appointment with a specialist for those patients urgently referred for treatment for suspected cancer) and 53 (duty to offer alternative provider for treatment for suspected cancer) substitute—

"Duty to make arrangements to diagnose or rule out cancer

- **52.**—(1) A relevant body must make arrangements to ensure that at the end of each data collection period, for persons falling within paragraph (2), the waiting time period to diagnose or rule out cancer did not exceed 28 days in at least 75% of cases where the waiting time period ended in that data collection period.
 - (2) A person falls within this paragraph if—
 - (a) the relevant body has responsibility for that person; and
 - (b) they are a person in respect of whom an urgent referral has been made on or after 1st April 2024 by an eligible referrer—
 - (i) for suspected cancer, or
 - (ii) for breast symptoms (where cancer is not suspected).
- (3) The waiting time period referred to in paragraph (1) begins on the start date and ends on the date when—

⁽⁶⁾ Regulation 40 was amended by S.I. 2013/2891.

⁽⁷⁾ Regulation 42D was inserted by S.I. 2023/1105.

⁽⁸⁾ Regulation 44 was amended by S.I. 2022/634.

⁽⁹⁾ Section 7A was inserted by section 22 of the Health and Social Care Act 2012 (c. 7), and amended by section 42 of the Health and Care Act 2022 and paragraphs 162 and 163 of Schedule 4 to the Levelling-up and Regeneration Act 2023 (c. 55).

- (a) an outcome (either a diagnosis or ruling out of cancer) is communicated to the person or, if earlier, a notification containing an outcome is sent to the person,
- (b) a clinical decision is made that the person requires further interval scanning or testing before a diagnosis of cancer can be made or cancer can be ruled out, or
- (c) a clinical decision is made that the person requires treatment before a diagnosis of cancer can be made or cancer can be ruled out.
- (4) Where—
 - (a) the person concerned did not attend the first appointment made by a health service provider in response to the urgent referral, and
 - (b) that person had not requested in advance of the first appointment that the date for that appointment be rearranged,

the period of time specified in paragraph (5) is excluded from the calculation of the waiting time period specified in paragraph (3).

- (5) The period of time to be excluded for the purposes of paragraph (4)—
 - (a) begins with the start date, and
 - (b) ends on the date on which the health service provider receives notification that the person who has been urgently referred is available again for an appointment with that provider.
- (6) In the exercise of its functions under paragraph (1), a relevant body must have regard to the National Institute for Health and Care Excellence Guideline "Suspected cancer: recognition and referral" published on 23rd June 2015 and updated on 2nd October 2023(10).
- (7) For the purposes of this regulation and regulation 53, cancer is to be regarded as having been ruled out either when a diagnosis of cancer has been excluded or when all reasonable steps to exclude cancer have been completed.

Duty to offer alternative provider to diagnose or rule out cancer

- 53.—(1) Paragraph (2) applies where—
 - (a) there is a person in respect of whom an urgent referral has been made on or after 1st April 2024 by an eligible referrer—
 - (i) for suspected cancer, or
 - (ii) for breast symptoms (where cancer is not suspected);
 - (b) the referral is to a health service provider ("the provider") for—
 - (i) an appointment with a specialist, or
 - (ii) a review of appropriate diagnostic imaging, with a view to a specialist diagnosing or ruling out cancer;
 - (c) the referred person, or a person lawfully acting on their behalf, asks the provider or the relevant body which has responsibility for the person referred to arrange an alternative appointment or review;
 - (d) the provider or the relevant body which has responsibility for the person referred is satisfied that:
 - (i) the person referred will not receive a diagnosis or ruling out of cancer within 28 days beginning with the start date, and

⁽¹⁰⁾ The guidance document is available online at https://www.nice.org.uk/guidance/ng12 or a hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

- (ii) an appointment with a suitable alternative provider may expedite a diagnosis or ruling out of cancer;
- (e) no clinical decision has been made that the person requires further interval scanning or testing;
- (f) no clinical decision has been made that the person requires treatment before a diagnosis of cancer can be made or cancer can be ruled out.
- (2) Subject to paragraph (5), where this paragraph applies, the relevant body which has responsibility for the person referred must, in accordance with paragraphs (3) and (4), take all reasonable steps to ensure that the person is offered an appointment with a specialist or a review of appropriate diagnostic imaging by a specialist with a suitable alternative provider.
- (3) The appointment or review for the purposes of paragraph (2) must seek to enable the diagnosis or ruling out of cancer earlier than the person would have received were they to continue to wait for an appointment or review (as applicable) from the provider.
- (4) If there is more than one suitable alternative health service provider, the person referred must be offered a choice of an appointment with a specialist or a review (as appropriate) as between those providers.
 - (5) Paragraph (2) does not apply if the person—
 - (a) was made aware of the consequences of not attending the first appointment made by the provider in response to the referral, and
 - (b) did not attend the first appointment.
- (6) In the exercise of its functions under paragraph (2), a relevant body must have regard to the NHS England Guidance "National Cancer Waiting Times Monitoring Dataset Guidance" published on 17th August 2023(11)."."
- (10) In regulation 54 (advice and assistance)(12), in paragraph (1)(a)(ii), for "who meet the conditions set out in regulation 47(2) and (3) or 53(1)(a) to (c)" substitute "in the circumstances set out in regulation 47(2) and (3), or in regulation 53(1)(a) to (b)".
 - (11) Omit Part 10 (standing rules: funding of therapies for Multiple Sclerosis).

Saving provision: duties to make arrangements to provide an appointment with a specialist and to offer alternative provider for treatment for suspected cancer

3. Regulations 52 and 53 of the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012, as those provisions were in force immediately before 1st April 2024, continue to apply in respect of any person urgently referred for suspected cancer before 1st April provided that person has not commenced treatment for suspected cancer.

⁽¹¹⁾ The guidance is available at https://www.england.nhs.uk/publication/national-cancer-waiting-times-monitoring-dataset-guidance/ or a hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU.

⁽¹²⁾ Regulation 54 was amended by S.I. 2022/634.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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

5th March 2024

Andrew Stephenson
Minister of State,
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (S.I. 2012/2996) ("the Standing Rules"). They are made under the National Health Service Act 2006 (c. 41) ("the 2006 Act"), as amended by the Health and Care Act 2022 (c. 31) ("the 2022 Act") and they amend the requirements, or 'standing rules', imposed on NHS England and integrated care boards. On 1st July 2022, the NHS Commissioning Board was renamed NHS England and integrated care boards became the successors of clinical commissioning groups, in accordance with the 2022 Act.

Regulation 2 amends the Standing Rules as follows:

Paragraphs 2 and 11 relate to and provide for the revocation of Part 10. The National Institute for Health and Care Excellence ("NICE") approved the treatment to which Part 10 refers such that the funding scheme is obsolete.

Paragraph 3 amends regulation 20 to increase the rates for NHS funded nursing care payable by NHS England or an integrated care board.

Paragraph 4 substitutes the definition of "interface services" in regulation 38, to reflect the fact that these types of service may be managed by a range of healthcare professionals, and may be commissioned by an NHS trust or NHS foundation trust pursuant to arrangements under section 65Z5(1) of the 2006 Act.

Paragraph 5 amends regulation 39 which provides for patients to be offered a choice of health service provider, to ensure that such patient choice extends to providers commissioned by NHS trusts or NHS foundation trusts when exercising functions delegated to them by NHS England or an integrated care board.

Paragraph 7 corrects a typographical omission in regulation 42D.

Paragraph 9 substitutes regulations 52 and 53 of the Standing Rules to create a new duty on relevant bodies to make arrangements to ensure that, at the end of each data collection period, the waiting time period to diagnose or rule out cancer did not exceed 28 days in at least 75% of cases where the waiting time period ended in that data collection period (and, in certain circumstances, to offer a patient an alternative healthcare provider). The guidance referred to in new regulations 52(6) and 53(6) is available at https://www.nice.org.uk/guidance/ng12 and https://www.england.nhs.uk/publication/national-cancer-waiting-times-monitoring-dataset-guidance/ or a hard copy can be obtained by writing to the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU. Paragraphs 6, 8 and 10 make related provision.

Regulation 3 contains a saving provision in relation to the previous duties to make arrangements to provide an appointment with a specialist, and offer an alternative provider, for those people urgently referred for treatment for suspected cancer before 1st April 2024.

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