#### STATUTORY INSTRUMENTS

## 2021 No. 150

# The Health Protection (Coronavirus, International Travel) (England) (Amendment) (No. 7) Regulations 2021

#### Insertion of Schedule 2C

19. After Schedule 2B insert—

#### "SCHEDULE 2C

Regulation 3B(9)

Mandatory testing after arrival in England

#### **Interpretation of Schedule 2C**

- 1.—(1) In this Schedule—
  - (a) "default self-isolation period" means—
    - (i) in the case of a non-Schedule B1A arrival, the period specified in paragraph (7)(a) of regulation 4 (requirement to self-isolate);
    - (ii) in the case of a Schedule B1A arrival, the period specified in paragraph 10(a) of Schedule B1A;
  - (b) "mandatory test" means a day 2 test or a day 8 test within the meaning of regulation 3B(11);
  - (c) "non-Schedule B1A arrival" means a person to whom paragraph (1)(a) or (b) of regulation 4 applies;
  - (d) "P" means, subject to paragraph 13, a person required to undertake a mandatory test under regulation 3B (requirement to book and undertake tests);
  - (e) "private provider" means a test provider other than a public provider;
  - (f) "public provider" means a test provider who provides or administers a test under the National Health Service Act 2006, the National Health Services (Wales) Act 2006, the National Health Service (Scotland) Act 1978, or the Health and Personal Social Services (Northern Ireland) Order 1972;
  - (g) "relevant self-isolation provisions" means—
    - (i) in relation to a Schedule B1A arrival, regulation 4 and Schedule B1A;
    - (ii) in relation to a non-Schedule B1A arrival, regulation 4;
  - (h) "Schedule B1A arrival" means a person to whom Schedule B1A (additional measures) applies;
  - (i) "the Self-Isolation Regulations" means the Health Protection (Coronavirus, Restrictions) (Self-Isolation) (England) Regulations 2020 M1.
- (2) Where this Schedule requires P to continue to self-isolate in accordance with the relevant self-isolation provisions—

- (a) regulation 6 (offences and penalties) applies in relation to that requirement as it applies in relation to the relevant self-isolation provisions;
- (b) such a requirement to self-isolate does not apply in respect of a person exempt from regulation 4.

## Requirement to self-isolate on failure to undertake a mandatory test

- 2.—(1) This paragraph applies where—
  - (a) either—
    - (i) P fails to undertake a day 2 test, or
    - (ii) P's day 2 test generates a negative or inconclusive result, and
  - (b) P fails to undertake a day 8 test.
- (2) Subject to sub-paragraph (3), P must continue to self-isolate in accordance with the relevant self-isolation provisions until the end of the 14th day after the day on which they arrived in England.
  - (3) Where P undertakes a test to which paragraph 3(7)(b) applies and which generates—
    - (a) a positive result, paragraph 3(1) applies as if the test were a mandatory test;
    - (b) a negative result, paragraph 3(4) applies as if—
      - (i) P had taken both a day 2 test and a day 8 test, and
      - (ii) both tests had generated a negative result.

## Consequences of test results

- **3.**—(1) Subject to paragraphs 4 (optional tests) and 5 (tests other than in accordance with these Regulations), where a mandatory test undertaken by P in accordance with regulation 3B generates a positive result—
  - (a) the following do not apply in relation to P—
    - (i) regulation 4(9)(a) or, as the case may be, paragraph 13(1)(a) of Schedule B1A (leaving self-isolation to travel in order to leave England);
    - (ii) subject to sub-paragraph (2), regulation 2 (requirements on person notified of positive test) of the Self-Isolation Regulations, and
  - (b) P and, subject to sub-paragraph (3), any person who is self-isolating with P must continue to self-isolate in accordance with the relevant self-isolation provisions until the end of the 10th day after the day P undertook the test.
- (2) Regulation 2 of the Self-Isolation Regulations continues to apply to a person within regulation 3B(1)(b).
- (3) Where a person ("B") is self-isolating with P pursuant to the relevant self-isolation provisions, the requirement to self-isolate under sub-paragraph (1)(b) does not apply to B where—
  - (a) the test referred to in sub-paragraph (1) is P's day 8 test, and
  - (b) B undertook a day 2 test that generated a positive result.
- (4) Subject to paragraph 4, where P's day 2 test and day 8 test both generate a negative result, P must continue to self-isolate in accordance with the relevant self-isolation provisions until the later of—
  - (a) the end of the default self-isolation period;
  - (b) the day on which P receives the result of their day 8 test.

- (5) Where a mandatory test undertaken by P generates an inconclusive result P must continue to self-isolate in accordance with the relevant self-isolation provisions—
  - (a) until the end of the 10th day after the day P undertook the test,
  - (b) where P undertakes a test to which sub-paragraph (7) applies and the test generates a negative result, until the later of—
    - (i) the end of the default self-isolation period;
    - (ii) the day on which P receives the negative result, or
  - (c) where P undertakes a test to which sub-paragraph (7) applies and the test generates a positive result, until the end of the 10th day after the day P undertook the test.
- (6) Where sub-paragraph (5)(c) applies, P is not required to undertake a day 8 test in accordance with regulation 3B.
  - (7) This sub-paragraph applies to—
    - (a) a day 8 test;
    - (b) a test—
      - (i) complying with the requirements for a day 8 test specified in paragraphs 8 and 9 (other than the requirement in paragraph 9(1)(e) that the test be administered or provided to P no earlier than the end of the seventh day after the day on which P arrived in England),
      - (ii) undertaken in the circumstances specified in paragraph 10 (other than the circumstances in paragraph 10(2) about when a test must be undertaken), and
      - (iii) undertaken during the period specified in sub-paragraph (5)(a).

#### **Optional tests**

- **4.**—(1) This paragraph applies where P—
  - (a) is a non-Schedule B1A arrival, and
  - (b) undertakes a day 2 test which generates a negative or inconclusive result.
- (2) P may undertake a test in accordance with Schedule 2A (optional testing after arrival in England), and, where the test generates a negative result, regulation 4(13A) applies in relation to P for the purpose of determining when P ceases to be required to self-isolate.
  - (3) P must in any event undertake the day 8 test booked in accordance with regulation 3B.
- (4) Where P ceases to be required to self-isolate under these Regulations in accordance with regulation 4(13A), paragraph 3(1), (4) and (5) do not apply in relation to P's day 8 test.

#### Tests other than in accordance with these Regulations

- **5.**—(1) This paragraph applies where—
  - (a) P is a non-Schedule B1A arrival,
  - (b) P undertakes a day 2 test which generates a negative result,
  - (c) while P is self-isolating under these Regulations, P subsequently undertakes a test other than in accordance with these Regulations, and
  - (d) P is notified that such test generates a positive result.
- (2) P ceases to be required to self-isolate in accordance with these Regulations, and regulation 2 of the Self-Isolation Regulations applies in relation to P.

#### Day 2 tests: general test requirements

- **6.**—(1) For the purposes of regulation 3B(11)(a), a day 2 test complies with this paragraph where—
  - (a) it is a test provided by a public provider, or
  - (b) it is a test provided by a private provider—
    - (i) on or after 1st March 2021,
    - (ii) where the test complies with sub-paragraph (2), and
    - (iii) where the private provider complies with paragraph 7.
  - (2) A test complies with this sub-paragraph where—
    - (a) it is a semi-quantitative test for the detection of coronavirus which—
      - (i) targets a minimum of two distinguishable SARS-CoV-2 genes other than the S gene and performance reference controls,
      - (ii) includes routine in silico assurance against every variant of concern, and
      - (iii) produces a test solution that provides extracted nucleic acid that is suitable for whole genome sequencing using a specified method,
    - (b) it is, in relation to a Schedule B1A arrival, a test that can be self-administered,
    - (c) the manufacturer of any device used for the purposes of the test states that the device—
      - (i) uses an established molecular detection method,
      - (ii) has a specificity and a sensitivity greater than 99% (with a 95% two-sided confidence interval entirely above 97%),
      - (iii) has a limit of detection of less than or equal to 1000 SARS-CoV-2 copies per millilitre, and
      - (iv) is suitable for identifying every variant of concern, and
    - (c) any device used for the purposes of the test—
      - (i) can be put into service in accordance with Part 4 of the Medical Devices Regulations 2002, other than solely by virtue of regulation 39(2) of those Regulations, and
      - (ii) has been validated no more than 18 months before the test is administered or provided to P.
  - (3) For the purposes of sub-paragraph (2)—
    - (a) "specified method" means a targeted sequence method specific to SARS-CoV-2 or an equivalent—
      - (i) amplicon method, or
      - (ii) sequence bait capture method;
    - (b) "validated", in relation to a device, has the meaning given by paragraph 2(2)(d) of Schedule 2A;
    - (c) "variant of concern" means a variant of SARS-CoV-2 identified in a designation made by the Secretary of State for the purposes of this paragraph and published in a manner as appears to the Secretary of State to be appropriate.

#### Day 2 tests: private provider requirements

- 7.—(1) For the purposes of paragraph 6(1)(b)(iii), a private provider complies with this paragraph where—
  - (a) they comply with the requirements of paragraph 3(1)(a) and (e) to (h) of Schedule 2A as if any reference in those provisions to an appropriate test were a reference to a day 2 test,
  - (b) they have made a declaration to the Department of Health and Social Care that they meet the minimum standards for private sector-provided testing at https://support-covid-19-testing.dhsc.gov.uk/InternationalTesting,
  - (c) the person responsible for the taking of samples meets the relevant requirements for accreditation to ISO standard 15189 or ISO/IEC standard 17025 in respect of the taking of samples,
  - (d) the laboratory used by the test provider for the processing of samples meets the relevant requirements for accreditation to—
    - (i) in respect of the evaluation of the established molecular detection method, ISO standard 15189 or ISO/IEC standard 17025;
    - (ii) in respect of the genome sequencing of samples, ISO standard 15189,
  - (e) they receive the information required by paragraph 10(3) or (4) (as appropriate), and they administer or provide the test to P no later than the end of the second day after the day on which P arrived in England,
  - (f) they sequence each sample with a cycle threshold less than 30 (equivalent to ~1,000 viral genome copies per millilitre),
  - (g) in respect of the sequencing of samples, they must secure a reference genome coverage breadth of at least 50% and at least 30 times coverage,
  - (h) on a request by the Secretary of State or the COVID-19 Genomics UK Consortium, they make samples available for the purpose of dual sequencing,
  - (i) they preserve and transport samples in a manner that enables genome sequencing,
  - (j) they have in place a process to remove human reads from any data submitted in a notification to Public Health England pursuant to the Health Protection (Notification) Regulations 2010 M2, and
  - (h) if they arrange with another person ("X") for X to carry out any element of the single end-to-end testing service on their behalf, the test provider ensures that X complies with the following so far as relevant to the carrying out of that element—
    - (i) paragraph 3(1)(e) to (h) of Schedule 2A as applied by sub-paragraph (1)(a);
    - (ii) sub-paragraph (1)(c) to (i);
    - (iii) paragraph 11(2), (3) and (4).
- (2) For the purposes of sub-paragraph (1)(h), "single end-to-end testing service" has the meaning given in paragraph 3(2)(c) of Schedule 2A.
- (3) For the purposes of sub-paragraph (1)(c) and (d), a person or laboratory (as the case may be) meets the relevant requirements for accreditation to a standard where the person who is the operator of the laboratory complies with the requirements of regulation 6 of the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 M3 as if—
  - (a) a reference to an applicable test were a reference to a day 2 test;
  - (b) a reference to a test provider were a reference to a private provider.

#### Day 8 tests: general test requirements

- **8.**—(1) For the purposes of regulation 3B(11)(b), a day 8 test complies with this paragraph where—
  - (a) it is a test provided by a public provider, or
  - (b) it is a test provided by a private provider—
    - (i) on or after 1st March 2021,
    - (ii) where the test complies with sub-paragraph (2), and
    - (iii) where the private provider complies with paragraph 9.
  - (2) A test complies with this sub-paragraph where—
    - (a) it is a semi-quantitative test for the detection of coronavirus which targets a minimum of two distinguishable SARS-CoV-2 genes other than the S gene and performance reference controls,
    - (b) it is, in relation to a Schedule B1A arrival—
      - (i) a test which requires laboratory processing, and
      - (ii) a test which can be self-administered,
    - (c) the manufacturer of any device used for the purposes of the test states that the device—
      - (i) uses an extracted molecular method,
      - (ii) has a specificity and a sensitivity greater than 95% (with a 95% two-sided confidence interval entirely above 90%), and
      - (iii) has a limit of detection of less than or equal to 1000 SARS-CoV-2 copies per millilitre, and
    - (d) any device used for the purposes of the test—
      - (i) can be put into service in accordance with Part 4 of the Medical Devices Regulations 2002, other than solely by virtue of regulation 39(2) of those Regulations, and
      - (ii) has been validated no more than 18 months before the test is administered or provided to P.
- (3) For the purposes of sub-paragraph (2) "validated", in relation to a device, has the meaning given by paragraph 2(2)(d) of Schedule 2A.

#### Day 8 tests: private provider requirements

- **9.**—(1) For the purposes of paragraph 8(1)(b)(iii), a private provider complies with this paragraph where—
  - (a) they comply with the requirements of paragraph 3(1)(a) and (e) to (h) of Schedule 2A as if any reference in those provisions to an appropriate test were a reference to a day 8 test,
  - (b) they have made a declaration to the Department of Health and Social Care that they meet the minimum standards for private sector-provided testing at https://support-covid-19-testing.dhsc.gov.uk/InternationalTesting,
  - (c) in relation to a test which requires laboratory processing—
    - (i) the person responsible for the taking of samples meets the relevant requirements for accreditation to ISO standard 15189 or ISO/IEC standard 17025 in respect of the taking of samples, and

- (ii) the laboratory used by the test provider for the processing of samples meets the relevant requirements for accreditation to ISO standard 15189 or ISO/IEC standard 17025 in respect of the processing of samples,
- (d) in relation to a point of care test, they meet the relevant requirements for accreditation to ISO Standard 15189 and ISO standard 22870,
- (e) they receive the information required by paragraph 10(3) or (4) (as appropriate), and they administer or provide the test to P no earlier than the end of the seventh day after the day on which P arrived in England,
- (f) if they arrange with another person ("X") for X to carry out any element of the single end-to-end testing service on their behalf, the test provider ensures that X complies with the following so far as relevant to the carrying out of that element—
  - (i) paragraph 3(1)(e) to (h) of Schedule 2A as applied by sub-paragraph (1)(a);
  - (ii) sub-paragraph (1)(b) to (e);
  - (iii) paragraph 11(2), (3) and (4).
- (2) For the purposes of sub-paragraph (1)(f), "single end-to-end testing service" has the meaning given in paragraph 3(2)(c) of Schedule 2A.
- (3) For the purposes of sub-paragraph (1)(c) and (d), a person or laboratory (as the case may be) meets the relevant requirements for accreditation to a standard where the person who is the operator of the laboratory complies with the requirements of regulation 6 of the Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020 as if—
  - (a) a reference to an applicable test were a reference to a day 8 test;
  - (b) a reference to a test provider were a reference to a private provider.

#### Required circumstances for undertaking a day 2 test or a day 8 test

- 10.—(1) The circumstances mentioned in regulation 3B(11)(a) and (b) are as follows.
- (2) In relation to—
  - (a) a day 2 test, P undertakes the test no later than the end of the second day after the day on which P arrived in England;
  - (b) a day 8 test, P undertakes the test no earlier than the end of the seventh day after the day on which P arrived in England.
- (3) Subject to sub-paragraph (4), at the time the test is booked P notifies the test provider that P is to undertake the test under these Regulations, and provides the test provider with—
  - (a) the information set out in paragraph 4(b)(i) to (v) and (vii) to (xiii) of Schedule 2A, and
  - (b) their home address, and—
    - (i) where P is a person to whom regulation 4(1)(a) or (b) applies, the address or addresses at which they intend to self-isolate, or are self-isolating, in accordance with regulation 4 (if different from their home address), or
    - (ii) where P is a person to whom regulation 4(1)(d) applies, the address of the accommodation designated for the purposes of Schedule B1A.
- (4) Where P is a child, or a person with a disability who is unable for that reason to provide the notification and information set out or referred to in sub-paragraph (3) to the test provider—

- (a) the notification and information set out or referred to in sub-paragraph (3), other than the information set out in paragraph 4(b)(xi) and (xii) of Schedule 2A, is provided to the test provider on P's behalf by another person ("Y"), and
- (b) either the information set out in paragraph 4(b)(xi) and (xii) of Schedule 2A is provided by Y to the test provider or, where appropriate, Y provides their own telephone number and email address to the test provider.
- (5) At the time the test is booked the test provider gives P a test reference number and, where appropriate, also provides that test reference number to Y.

#### Notification of test results

- 11.—(1) This paragraph applies to a private provider who administers or provides a test to P in the circumstances described in paragraph 10.
  - (2) The private provider must, within 24 hours of the result becoming available—
    - (a) notify P or, where paragraph 10(4) applies, Y by email, letter, or text message, of the result of P's test, or
    - (b) make P's test result available to P, or where paragraph 10(4) applies, to Y via a secure web portal,

in accordance with sub-paragraph (3).

(3) The notification of P's test result must include P's name, date of birth, passport number, or travel document reference number (as appropriate), the name and contact details of the test provider and P's test reference number, and must be conveyed using one of the following forms of words, as appropriate—

Your comonavirus test result is negative. You did not have the virus when the test was done.

If you took the test on day 2 of your self-isolation you must continue to self-isolation until you have completed the 10 day self-isolation period and received a negative test result for a test taken on day 8 if yes out to the test on day 8, you may stay self-isolating in the self-isolation period and received a negative test result for a test taken on day 8 if yes out the test of the test of the yes of the y

## (4) Where—

- (a) regulation 4 or 4A of the Health Protection (Notification) Regulations 2010 applies in relation to the test provider, or
- (b) if the test provider arranges with another person ("X") for X to carry out any element of the single end-to-end testing service on their behalf, either of those regulations applies to X in the carrying out of that element,

the regulation applies as if it required the information described in sub-paragraph (5) to be included in the notification to Public Health England.

- (5) The information mentioned in sub-paragraph (4) is—
  - (a) the date on which P last departed from or transited through a non-exempt country or territory,
  - (b) P's coach number, flight number or vessel name (as appropriate),
  - (c) the country or territory P was travelling from when P arrived in England, and any country or territory they transited through as part of that journey,
  - (d) the date on which P undertook the appropriate test.

## Charge for day 2 tests and day 8 tests

- **12.**—(1) The Secretary of State or a person designated by the Secretary of State may impose a charge in respect of mandatory tests provided by a public provider.
  - (2) The Secretary of State—
    - (a) must publish details of the charges in such manner as the Secretary of State considers appropriate; and
    - (b) may recover any sum owed by a person pursuant to such a charge as a debt.

## Application of regulation 3B - exclusion of certain diplomatic etc. personnel

- **13.**—(1) Regulation 3B does not apply where P is—
  - (a) a person described in paragraph 1(1)(a) to (h) or (k) M4 of Schedule 2 or a member of the family forming part of their household;
  - (b) a person described in paragraph 1(1)(i) or (j) of Schedule 2 where the conditions in sub-paragraph (2) are met;
  - (c) a member of the family forming part of the household of a person to whom paragraph (b) applies, where—
    - (i) the conditions in sub-paragraph (2) are met in relation to the person to whom paragraph (b) applies,
    - (ii) the Foreign, Commonwealth and Development Office has been notified of P's arrival, and
    - (iii) the Foreign, Commonwealth and Development Office has confirmed that P is not required to comply with regulation 3B.
- (2) The conditions specified in this sub-paragraph are that, prior to P's departure to the United Kingdom—
  - (a) the relevant head of the mission, consular post, or office representing a foreign territory in the United Kingdom, or a Governor of a British overseas territory (as the case may be), or a person acting on their authority, confirms in writing to the Foreign, Commonwealth and Development Office that P is required to undertake work in the United Kingdom which is essential to the foreign territory represented by the mission or consular post, the foreign territory represented by the office or the British overseas territory, and
  - (b) the Foreign, Commonwealth and Development Office has then confirmed in writing to the person giving the confirmation referred to in paragraph (a) that—
    - (i) it has received that confirmation, and

- (ii) P is travelling to the United Kingdom to conduct official business with the United Kingdom and is not required to comply with this Schedule.
- (3) Where a word or expression is defined for the purposes of Schedule 2 and is used in this paragraph, the same definition applies for the purposes of this paragraph.".

## **Commencement Information**

II Reg. 19 in force at 15.2.2021 at 4.00 a.m., see reg. 1(1)

#### **Marginal Citations**

M1 S.I. 2020/1045, amended by S.I. 2020/1375, 2020/1518 and 2021/97.

**M2** S.I. 2010/659, amended by S.I. 2013/235, 2018/378, 2020/237, 2020/674 and 2020/1175.

**M3** S.I. 2020/1549.

M4 Paragraph 1 was amended by S.I. 2020/942.

## **Changes to legislation:**

There are currently no known outstanding effects for the The Health Protection (Coronavirus, International Travel) (England) (Amendment) (No. 7) Regulations 2021, Section 19.