STATUTORY INSTRUMENTS

2022 No. 125

The Health Protection (Coronavirus, International Travel and Operator Liability) (England) (Amendment) (No. 2) Regulations 2022

Amendment of Schedule 8 (mandatory testing after arrival in England)

- **30.**—(1) Schedule 8 is amended as follows.
- (2) In paragraph 1 (interpretation of Schedule 8), omit sub-paragraph (1)(d)(ii);
- (3) In paragraph 2 (requirement to self-isolate on failure to undertake a mandatory test)—
 - (a) in sub-paragraph (1), for "not a person of the description in regulation 5(1)(a), (c), (d) or (e)" substitute "a person described in regulation 5(1)(b) or (c)";
 - (b) in sub-paragraph (3)—
 - (i) omit ", (c), (d) or (e)";
 - (ii) at the end insert "before the end of the second day after the day on which P arrived in England";
 - (c) in sub-paragraph (4), for the words from "regulation 2 of the Self-Isolation Regulations" to "that P had tested positive," substitute "the relevant self-isolation provisions";
 - (d) omit sub-paragraphs (5) and (6);
 - (e) in sub-paragraph (7), for the words from "(4)(b)" to the end substitute—
 "(4)(b) is—
 - (a) a positive result, P must self-isolate in accordance with paragraph 3(2);
 - (b) an inconclusive result, P must self-isolate in accordance with paragraph 3(6A);
 - (c) a negative result, P may cease to self-isolate in accordance with sub-paragraph (4)";
 - (f) after sub-paragraph (8) insert—
 - "(9) Where P is required to self-isolate in accordance with regulation 9 under this paragraph, regulation 9(11)(a) (departing from England) does not apply to P."
- (4) In paragraph 3 (consequences of test results)—
 - (a) in sub-paragraph (1)—
 - (i) for the words from "Subject to paragraphs 4" to ", where" substitute "Where P is a person described in regulation 5(1)(b) or (c) and";
 - (ii) in paragraph (a)(ii), for "sub-paragraphs (2) and" substitute "sub-paragraph";
 - (b) for sub-paragraph (2) substitute—
 - "(2) Where P is a person described in regulation 5(1)(a) and a mandatory test undertaken by P generates a positive result, P must self-isolate in accordance with the relevant self-isolation provisions until the earlier of—
 - (a) the end of the 10th day after the day P undertook the test;

- (b) any time after the end of the 5th day after the day P undertook the test, where P undertakes, any time after the end of the 4th day after the day P undertook the test, two lateral flow device tests which—
 - (i) are undertaken at least 24 hours apart,
 - (ii) both generate a negative result, and
 - (iii) are provided by a public provider.";
- (c) in sub-paragraph (4), for "Subject to paragraph 4, where" substitute "Where P is a person described in regulation 5(1)(b) or (c) and";
- (d) in sub-paragraph (5), after "Where" insert "P is a person described in regulation 5(1)(b) or (c) and";
- (e) after sub-paragraph (6) insert—
 - "(6A) Where P is a person described in regulation 5(1)(a) and a day 2 test undertaken by P generates an inconclusive result P must self-isolate in accordance with the relevant self-isolation requirements until—
 - (a) where P does not undertake an additional day 2 test, the end of the 10th day after the day P undertook the day 2 test;
 - (b) where P undertakes an additional day 2 test—
 - (i) which generates a negative result, on receipt of the negative result;
 - (ii) which generates a positive result, in accordance with sub-paragraph (2) as if the additional day 2 test was a mandatory test.
 - (6B) In sub-paragraph (6A), an "additional day 2 test" means—
 - (a) a day 2 test;
 - (b) a test—
 - (i) complying with the requirements for a day 2 test specified in paragraphs 6 and 7 (other than the requirement in paragraph 7(1)(f) that the test be administered or provided to P no later than the end of the second 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 (6A)(a).";
- (f) in sub-paragraph (7)(b)(i), for the words from "paragraphs 8 and 9" to "arrived in England)" substitute "paragraph 8";
- (g) after sub-paragraph (7) insert—
 - "(8) Where P is required to self-isolate in accordance with regulation 9 under this paragraph, regulation 9(11)(a) (departing from England) does not apply to P.".
- (5) Omit paragraph 4 (optional tests).
- (6) Omit paragraph 5 (tests otherwise than in accordance with these Regulations).
- (7) In paragraph 6 (day 2 tests: general test requirements)—
 - (a) in sub-paragraph (1), for "regulations 3J(10)(a)(i) and 6(12)(a)" substitute "regulation 6(12)(a)";
 - (b) in sub-paragraph (3), for paragraph (b) substitute—
 - "validated", in relation to a device, means confirmed as having the required sensitivity and specificity using at least 150 positive clinical samples and 250

negative clinical samples against a laboratory-based RT-PCR test that is itself within the performance specification of the target product profile published by the Medicines and Healthcare Products Regulatory Agency for laboratory based SARS-CoV-2 PCR tests, by—

- (i) the Secretary of State;
- (ii) a laboratory which is accredited to ISO standard 15189 or ISO/IEC standard 17025(1) by—
 - (aa) the United Kingdom Accreditation Service(2) ("UKAS"), or
 - (bb) an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation ("ILAC") Mutual Recognition Arrangement(3) or the European co-operation for Accreditation ("EA") Multilateral Agreement(4),

other than a laboratory which processes tests provided by the test provider for the purposes of this Schedule or is owned by the test provider or the device manufacturer(5); or

- (iii) a laboratory which is accredited by UKAS to ISO standard 15189 or ISO/IEC standard 17025(6), other than a laboratory which processes tests provided by the test provider for the purposes of this Schedule or is owned by the test provider or the device manufacturer".
- (8) In paragraph 7 (day 2 tests: private provider requirements)—
 - (a) in sub-paragraph (1)
 - (i) before paragraph (a) insert—
 - "(za) they provide day 2 tests in a single end-to-end testing service (whether or not they arrange with another person ("X") for X to provide one or more elements of the service on their behalf);
 - (zb) a registered medical practitioner has oversight and approval of medical practices undertaken by the test provider, and responsibility for reporting medical issues;
 - (zc) they have an effective system of clinical governance in place which includes appropriate standard operating procedures in relation to the carrying out of day 2 tests;
 - (zd) a registered clinical scientist has oversight of clinical practices undertaken by the test provider, and responsibility for reporting clinical issues;

⁽¹⁾ ISO standards are published in Geneva by the International Organisation for Standardisation, and are available on their website (www.iso.org) or at ISO Central Secretariat, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories was published in November 2017.

⁽²⁾ The United Kingdom Accreditation Service is a company limited by guarantee incorporated in England and Wales under number 3076190.

⁽³⁾ ILAC is an international organisation which coordinates the work of its signatory national accreditation bodies which are themselves involved in the accreditation of conformity assessment bodies, testing laboratories, and medical testing laboratories.

⁽⁴⁾ EA is a regional organisation which coordinates the work of its signatory national accreditation bodies. EA is recognised by and works closely with ILAC.

⁽⁵⁾ A body corporate established under section 232 of the Health and Social Care Act 2012 (c. 7).

⁽⁶⁾ ISO standards are published in Geneva by the International Organisation for Standardisation, and are available on their website (www.iso.org) or at ISO Central Secretariat, International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories was published in November 2017. ISO 15189 Medical Laboratories requirements for quality and competence was published in November 2012.

- (ze) they have systems in place to identify any adverse incidents or quality control issues in relation to day 2 tests and be able to report them as soon as reasonably practicable to the Secretary of State;"
- (ii) omit paragraph (a);
- (iii) in paragraph (g)(ii)—
 - (aa) immediately after paragraph (aa), insert "and";
 - (bb) omit paragraph (cc) (and the "; and" after it);
- (iv) in paragraph (m)—
 - (aa) omit sub-paragraph (i);
 - (bb) in sub-paragraph (ii), after "paragraph" insert "(zb) to (ze) and";
- (b) in sub-paragraph (2), for "has the meaning given in paragraph 3(2)(c) of Schedule 10" substitute "means a service which comprises accepting the booking from the person to be tested, providing the test, collecting and processing the sample to be tested, carrying out genomic sequencing and providing the test result to P".
- (9) Omit paragraphs 7A and 7B (requirements for day 2 LFD tests).
- (10) In paragraph 8 (day 8 tests: general test requirements) omit—
 - (a) in sub-paragraph (1)
 - (i) the "; or" at the end of paragraph (a);
 - (ii) paragraph (b);
 - (b) sub-paragraphs (2) and (3).
- (11) Omit paragraph 9 (day 8 tests: private provider requirements).
- (12) In paragraph 10 (required circumstances for undertaking a day 2 test or a day 8 test)—
 - (a) in sub-paragraph (1), for "regulations 3J(10) and 6(12)(a)" substitute "regulation 6(12) (a)";
 - (b) in sub-paragraph (3)—
 - (i) for the ", and" immediately after paragraph (a), substitute ".".
 - (ii) omit paragraph (b);
 - (c) in sub-paragraph (3B)—
 - (i) for paragraph (b) substitute—
 - "(b) the following information about P—
 - (i) their full name;
 - (ii) their sex;
 - (iii) their date of birth;
 - (iv) their NHS number (if known and applicable);
 - (v) their ethnicity;
 - (vi) the date of their arrival in the United Kingdom;
 - (vii) their coach number, flight number of vessel name (as appropriate);
 - (viii) the date on which they last departed from or transited through a category 2 country or territory;
 - (ix) the country or territory they were travelling from when they arrived in the United Kingdom, and any country or territory they transited through as part of that journey;

- (x) their email address,
- (xi) their telephone number,
- (xii) their passport number, or travel document reference number (as appropriate);
- (xiii) information as to whether or not P has received a vaccine against SARS-CoV-2, and"
- (ii) omit paragraph (c)(i);
- (d) omit sub-paragraph (3C);
- (e) in sub-paragraph (4)—
 - (i) in the words before paragraph (a), omit "and (3C)";
 - (ii) in paragraph (a), for "4(b)(xi) and (xii) of Schedule 10" substitute "(b)(x) and (xi) of that sub-paragraph";
 - (iii) in paragraph (b), for "paragraph 4(b)(xi) and (xii) of Schedule 10" substitute "sub-paragraph (3B)(b)(x) and (xi)".
- (f) in sub-paragraph (6), for "5 letters" substitute "the provider code";
- (g) after sub-paragraph (6) insert—
 - "(7) In sub-paragraph (6) "the provider code" means the 5 letter code issued to the provider by the United Kingdom Health Security Agency for the purposes of identifying tests administered or provided by the provider."
- (13) In paragraph 11—
 - (a) in sub-paragraph (1), omit ", other than a day 2 LFD test,";
 - (b) in sub-paragraph (3) (notification of test results), for the text from "Form A: negative test result" to the end substitute—

"Form A: negative test result

Your coronavirus (COVID-19) test result is negative. It's likely you were not infectious when the test was done.

You should self-isolate again if you get symptoms of coronavirus (COVID-19) – get an NHS coronavirus (COVID-19) test from www.gov.uk/get-coronavirus-test and self-isolate until you get the results.

For advice on when you might need to self-isolate and what to do, go to www.nhs.uk/conditions/coronavirus-covid-19 and read 'Self-isolation and treating symptoms'.

Form B: positive test result

Your coronavirus test result is positive. This means you probably have the virus. You are required to self-isolate.

For more information on self-isolating as an international arrival, go to https://www.gov.uk/guidance/how-to-quarantine-when-you-arrive-in-england

You may be contacted for contact tracing and to check that you are self-isolating.

You must not travel, including to leave the UK, during self-isolation.

Contact 111 if you need medical help. In an emergency dial 999.

Form C: unclear test result

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

Your coronavirus test result is unclear. It is not possible to say if you had the virus when the test was done.

You must take another test or self-isolate for 10 days from the day after your test date.

You may be contacted to check that you are self-isolating.";

- (c) omit sub-paragraph (5)(e)(ii) and (iii).
- (14) Omit paragraph 11A (notification of test results: lateral flow device tests).