STATUTORY INSTRUMENTS

2020 No. 1175

PUBLIC HEALTH

The Health Protection (Notification) (Amendment) (Coronavirus) Regulations 2020

Made - - - -	*at 1.00 p.m. on 26th October 2020*
Laid before Parliament	*at 3.00 p.m. on 26th October 2020*
Coming into force - -	*23rd November 2020*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 45C(1), (2) and (3)(a), 45F(2)(a) and (b), 45P(2) and 60A of the Public Health (Control of Disease Act 1984(**1**).

In accordance with section 45Q(3) of that Act, the Secretary of State is of the opinion that these Regulations do not contain any provision made by virtue of section 45C(3)(c) of the Act which imposes or enables the imposition of a special restriction or requirement or any other restriction or requirement which has or would have a significant effect on a person's rights.

Citation, commencement and application

1.—(1) These Regulations may be cited as the Health Protection (Notification) (Amendment) (Coronavirus) Regulations 2020 and come into force on 23rd November 2020.

(2) These Regulations apply in relation to England only.

Amendment of Health Protection (Notification) Regulations 2010

2. The Health Protection (Notification) Regulations 2010(**2**) are amended in accordance with regulations 3 to 5.

Amendment of regulation 4 (duty to notify causative agents found in human samples)

3. In regulation 4—

(a) for the heading substitute—

(**1**) 1984 c.22. Part 2A was inserted by section 129 of the Health and Social Care Act 2008 (c.14) ("the 2008 Act") and section 60A was inserted by Schedule 11, paragraph 16 of the 2008 Act.

(**2**) S.I. 2010/659, amended by S.I. 2013/235 and S.I. 2020/237; there are other amending instruments, but none is relevant.

"Duty on the operators of diagnostic laboratories to notify Public Health England of causative agents found in human samples and of SARS-Cov-2 or influenza virus tests processed";

(b) in paragraph (1)—

(i) after "where the diagnostic laboratory" insert "—";

(ii) "identifies a causative agent in a human sample" becomes sub-paragraph (a);

(iii) after sub-paragraph (a) insert—

"; or

(b) processes a test for the detection of SARS-CoV-2 and the test result is indeterminate.";

(c) after paragraph (1) insert—

"(1A) The operator of a diagnostic laboratory must also notify Public Health England in accordance with this regulation where the diagnostic laboratory—

(a) processes a test for the detection of SARS-CoV-2 and the test result is negative or void; or

(b) processes a test for the detection of influenza virus and the test result is indeterminate, negative or void.";

(d) in paragraph (2)—

(i) for sub-paragraph (b) substitute—

"(b) where a causative agent is identified, the details of that agent;

(ba) where the test is for the detection of SARS-CoV-2 or influenza virus, the result of the test;";

(ii) at the end of sub-paragraph (j) omit "and";

(iii) in sub-paragraph (k), for "which identified the causative agent." substitute—

"; and

(l) where the result of a test for the detection of SARS-CoV-2 is positive, a telephone number and an email address—

(i) where P is a child or a person with a disability who is unable for that reason to provide the information set out in sub-paragraphs (e) to (j), for an appropriate parent, guardian or carer of that person ;

(ii) otherwise, for P.";

(e) in paragraph (3) for "The notification" substitute "A notification under paragraph (1)(a) where the causative agent identified is not SARS-CoV-2";

(f) after paragraph (3) insert—

"(3A) A notification under paragraph (1A) must be provided in writing within 7 days beginning with the day on which the diagnostic laboratory becomes aware of the test result.

(3B) A notification under paragraph (1)(a) where the causative agent identified is SARS-CoV-2, must be provided in writing within 24 hours of the causative agent being identified.

(3C) A notification under paragraph (1)(b) must be provided in writing within 24 hours of the diagnostic laboratory becoming aware of the test result.";

(g) in paragraph (4)—

(i) for "paragraph (3)" substitute "paragraphs (3) and (3A)";

(ii) for "the case" substitute "a particular case to which one of those paragraphs applies";

(h) in paragraph (7), for "paragraph (1)" substitute "paragraph (1)(a)";

(i) after paragraph (7) insert—

"(7A) For the purposes of paragraphs (1)(b) and (1A), a diagnostic laboratory processes a test where—

(a) the diagnostic laboratory processes the test; or

(b) the test is processed by another laboratory under an arrangement made with that diagnostic laboratory.";

(j) in paragraph (8)—

(i) after "applies" insert "—";

(ii) "the day on which the causative agent" to the end becomes sub-paragraph (a);

(iii) after sub-paragraph (a) insert—

"(b) the time at which the causative agent is identified for the purposes of paragraph (3B), is the time at which the diagnostic laboratory became aware of the identification by the other laboratory.";

(k) after paragraph (8) insert—

"(8A) Where paragraph (7A)(b) applies—

(a) the day on which the diagnostic laboratory becomes aware of the test result for the purposes of paragraph (3A), is the day on which the diagnostic laboratory became aware of the result of the test processed by that other laboratory;

(b) the time at which the diagnostic laboratory becomes aware of the test result for the purposes of paragraph (3C), is the time at which the diagnostic laboratory became aware of the result of the test processed by that other laboratory.";

(l) in paragraph (11)—

(i) before the definition of "causative agent" insert—

""carer" has the meaning given in section 10 of the Care Act 2014(**3**);";

(ii) after the definition of "causative agent" insert—

""child" has the meaning given in regulation 2(7);";

(iii) at the end of the definition of "director of a diagnostic laboratory" omit "and";

(iv) after the definition of "director of a diagnostic laboratory" insert—

""disability" has the same meaning as in the Equality Act 2010(**4**) (see section 6 of, and Schedule 1 to, that Act);

"guardian" has the meaning given in section 107 of the Children and Young Persons Act 1933(**5**);"

(v) at the end of the definition of "operator of a diagnostic laboratory" insert—

""parent" has the meaning give in regulation 2(7).".

(**3**) 2014 c. 23.
(**4**) 2010 c. 15.
(**5**) 1933 c. 12, amended by paragraph 7(a) of Schedule 13 to the Children Act 1989 (c. 41), section 64 of, and Schedule 5 to, the Children and Young Persons Act 1963 (c. 37) and paragraph 1 of Schedule 7 to the Licensing Act 2003 (c. 17); there are other amending instruments, but none is relevant.

Insertion of new regulation 4A

4. After regulation 4 insert—

"**Duty on test providers to notify results of tests for the detection of SARS-CoV-2 or Influenza virus to Public Health England**

4A.—(1) This regulation applies where a test provider carries out on a person ("P") a valid point of care test for the detection of SARS-CoV-2 or influenza virus.

(2) For the purposes of this regulation—

(a) a point of care test is a diagnostic test which is not carried out in a diagnostic laboratory; and

(b) a point of care test is valid if it is carried out in accordance with the instructions provided by the manufacturer of the testing equipment.

(3) The test provider must notify Public Health England of the result of the test, in accordance with paragraphs (4) to (6).

(4) A notification must be provided in writing—

(a) within 24 hours of the time when the test result is received by the test provider, in the case of the result of a test for the detection of SARS-CoV-2 being positive or indeterminate;

(b) within 7 days beginning with the day on which the test result is received by the test provider, in the case of—

(i) the result of a test for the detection of SARS-CoV-2 being negative or void; or

(ii) the result of a test for the detection of influenza virus.

(5) A notification must include the following information, insofar as it is known to the test provider—

(a) in relation to P, their—

(i) first name;

(ii) surname;

(iii) sex;

(iv) date of birth;

(v) NHS number (if known);

(vi) ethnicity;

(vii) current address (including postcode);

(viii) telephone number, where the test is for the detection of SARS-CoV-2 and the result is positive or indeterminate,

(ix) email address, where the test is for the detection of SARS-CoV-2 and the result is positive or indeterminate;

(b) in relation to the test, the—

(i) name of the test provider;

(ii) nature of establishment;

(iii) specimen identification number (if applicable);

(iv) specimen type;

(v) specimen date;

(vi) test method;

(vii) result of test;

(viii) date on which the test was carried out;

(ix) name of the testing equipment manufacturer.

(7) Where P is a child, or a person with a disability who is unable for that reason to provide the information set out in paragraph (5)(a) to the test provider, the test provider must provide Public Health England with, insofar as it is known to the test provider—

(a) the information set out in paragraph (6)(a)(i) to (vii) in relation to P, having obtained it from an appropriate parent, guardian or carer of P ("X"); and

(b) where the test is for the detection of SARS-CoV-2 and the result is positive or indeterminate, X's telephone number and email address.

(8) It is an offence for a test provider to fail without reasonable excuse to comply with this regulation.

(9) A test provider that commits an offence under this regulation is liable on summary conviction to a fine.

(10) In this regulation—

"carer", "child", "disability", "guardian", and "parent" have the meanings given in regulation 4;

"test provider" means a company, partnership, charity, corporation, unincorporated association, or other organisation or body, whether public or private, or sole trader, carrying out point of care tests for the detection of SARS-CoV-2 or influenza virus.".

Amendment of regulation 7 (electronic communications)

5. In paragraph (1)(a) of regulation 7 for "and 4(1)" substitute ", 4(1) and 4A(3)".

Review

6. The Secretary of State must review the effectiveness of the provisions made by these Regulations before the expiry of the period of 12 months beginning with the day after the day on which they come into force.

Matt Hancock
Secretary of State
Department of Health and Social Care

At 1.00 p.m. on 26th October 2020

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health Protection (Notification) Regulations 2010 ("the Principal Regulations") and require diagnostic laboratories that process tests, and persons who carry out point of care tests, for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or influenza virus to notify Public Health England of the results of those tests.

Regulation 3 amends regulation 4 of the Principal Regulations to require diagnostic laboratories to notify Public Health England of the results of the SARS-CoV-2 or influenza virus detection tests which they process.

Regulation 4 inserts a new regulation 4A into the Principal Regulations. This regulation sets out the information that must be provided to Public Health England by those who carry out point of care tests for the detection of SARS-CoV-2 or influenza virus. Point of care tests are diagnostic tests which are carried out otherwise than in a diagnostic laboratory. It provides that someone who fails without reasonable excuse to comply with this regulation commits an offence for which, on summary conviction, that person would be liable for a fine.

Regulation 5 amends regulation 7 of the Principal Regulations to ensure that the notification made under regulation 4A may be made electronically where there is consent.

The net costs imposed on business, the voluntary sector and the public sector by these Regulations have been assessed as being less than £5m in any year and therefore a full impact assessment has not been prepared.