WELSH STATUTORY INSTRUMENTS

2010 No. 1546 (W.144)

PUBLIC HEALTH, WALES

The Health Protection (Notification) (Wales) Regulations 2010

Made - - - - 8 June 2010
Laid before the National
Assembly for Wales - - 10 June 2010

Coming into force
for the purpose of all
regulations except
regulation 4 26 July 2010
for the purpose of
regulation 4 1 October 2010

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 13, 45C(1), (2) and (3)(a), 45F(2)(a) and (b), 45P(2) and 60A of the Public Health (Control of Disease) Act 1984 MI.

In accordance with section 45Q(3) of the Public Health (Control of Disease) Act 1984, the Welsh Ministers declare that they are of the opinion that these Regulations do not contain any provision made by virtue of section 45C(3)(c) of that 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.

Marginal Citations

M1 1984 c. 22. Functions of the Secretary of State under section 13, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c. 32). See section 45T(6) of that Act for the definition of "the appropriate Minister". Sections 45C, 45F, 45P and 45T were inserted into that Act by section 129 of the Health and Social Care Act 2008 (c. 14) ("the 2008 Act") and section 60A was inserted into the Act by section 130 and Schedule 11, paragraph 16 of the 2008 Act.

Title, commencement and application

- 1.—(1) The title of these Regulations is the Health Protection (Notification) (Wales) Regulations 2010 and they come into force—
 - (a) for the purposes of all regulations except regulation 4 on 26 July 2010; and

- (b) for the purposes of regulation 4 on 1 October 2010.
- (2) These Regulations apply in relation to Wales.

Duty to notify suspected disease, infection or contamination in patients

- **2.**—(1) A registered medical practitioner (R) must notify the proper officer M2 of the relevant local authority where R has reasonable grounds for suspecting that a patient (P) whom R is attending—
 - (a) has a notifiable disease;
 - (b) has an infection ^{M3} which, in the view of R, presents or could present significant harm to human health; or
 - (c) is contaminated M4 in a manner which, in the view of R, presents or could present significant harm to human health.
 - (2) The notification must include the following information insofar as it is known to R—
 - (a) P's name, date of birth and sex;
 - (b) P's home address including postcode;
 - (c) P's current residence (if not home address);
 - (d) P's telephone number;
 - (e) P's NHS number;
 - (f) P's occupation;
 - (g) the name, address and postcode of P's place of work or education (if R considers it relevant);
 - (h) P's relevant overseas travel history;
 - (i) P's ethnicity;
 - (j) contact details for a parent of P (where P is a child);
 - (k) the disease or infection which P has or is suspected of having or the nature of P's contamination or suspected contamination;
 - (1) the date of onset of P's symptoms;
 - (m) the date of R's diagnosis; and
 - (n) R's name, address and telephone number.
- (3) The notification must be provided in writing within 3 days beginning with the day on which R forms a suspicion under paragraph (1).
- (4) Without prejudice to paragraph (3), if R considers that the case is urgent, notification must be provided orally as soon as reasonably practicable.
 - (5) In determining whether the case is urgent, R must have regard to—
 - (a) the nature of the suspected disease, infection or contamination;
 - (b) the ease of spread of that disease, infection or contamination;
 - (c) the ways in which the spread of the disease, infection or contamination can be prevented or controlled; and
 - (d) P's circumstances (including age, sex and occupation).
- (6) This regulation does not apply where R reasonably believes that the proper officer of the relevant local authority has already been notified with regard to P and the suspected disease, infection or contamination by another registered medical practitioner in accordance with this regulation.
 - (7) In this regulation—

"child" ("plentyn") means a person under the age of 18 years;

"notifiable disease" ("clefyd hysbysadwy") means a disease or syndrome listed in Schedule 1;

"parent" ("*rhiant*") has the meaning given to it by section 576 of the Education Act 1996 ^{M5}; and "relevant local authority" ("*awdurdod lleol perthnasol*") means the local authority within whose area R attended P on the occasion of forming a suspicion under paragraph (1).

Marginal Citations

- **M2** See section 74 of the Public Health (Control of Disease) Act 1984 (c. 22) ("the 1984 Act") for the definition of "proper officer".
- M3 See section 45A of the 1984 Act for the interpretation of "infection".
- M4 See section 45A of the 1984 Act for the interpretation of "contamination" and related expressions.
- M5 1996 c. 56.

Duty to notify suspected disease, infection or contamination in dead persons

- **3.**—(1) A registered medical practitioner (R) must notify the proper officer of the relevant local authority where R has reasonable grounds for suspecting that a person (P) whom R is attending has died whilst—
 - (a) infected with a notifiable disease;
 - (b) infected with a disease which, in the view of R, presents or could present, or presented or could have presented (whilst P was alive), significant harm to human health; or
 - (c) contaminated in a manner which, in the view of R, presents or could present, or presented or could have presented (when P was alive), significant harm to human health.
 - (2) The notification must include the following information insofar as it is known to R—
 - (a) P's name, date of birth and sex;
 - (b) P's date of death;
 - (c) P's home address including postcode;
 - (d) P's place of residence at time of death (if different from home address);
 - (e) P's NHS number;
 - (f) P's occupation at time of death (if R considers it relevant);
 - (g) the name, address and postcode of P's place of work or education at time of death (if R considers it relevant);
 - (h) P's relevant overseas travel history;
 - (i) P's ethnicity;
 - (j) the disease or infection which P had or is suspected of having had or the nature of P's contamination or suspected contamination;
 - (k) the date of onset of P's symptoms;
 - (1) the date of R's diagnosis; and
 - (m) R's name, address and telephone number.
- (3) The notification must be provided in writing within 3 days beginning with the day on which R forms a suspicion under paragraph (1).
- (4) Without prejudice to paragraph (3), if R considers that the case is urgent, notification must be provided orally as soon as reasonably practicable.

- (5) In determining whether the case is urgent, R must have regard to—
 - (a) the nature of the suspected disease, infection or contamination;
 - (b) the ease of spread of that disease, infection or contamination;
 - (c) the ways in which the spread of the disease, infection or contamination can be prevented or controlled; and
 - (d) P's circumstances (including age, sex and occupation).
- (6) This regulation does not apply where R reasonably believes that the proper officer of the relevant local authority has already been notified with regard to P and the suspected disease, infection or contamination by another registered medical practitioner in accordance with this regulation or regulation 2(1).
 - (7) In this regulation—

"notifiable disease" ("clefyd hysbysadwy") has the same meaning it has in regulation 2; and "relevant local authority" ("awdurdod lleol perthnasol") means the local authority within whose area R attended P on the occasion of forming a suspicion under paragraph (1).

Duty to notify causative agents found in human samples

- **4.**—(1) The operator of a diagnostic laboratory must notify the proper officer of the relevant local authority in accordance with this regulation where the diagnostic laboratory identifies a causative agent in a human sample.
- (2) The notification must include the following information insofar as it is known to the operator of the diagnostic laboratory—
 - (a) name and address of the diagnostic laboratory;
 - (b) details of the causative agent identified;
 - (c) date of the sample;
 - (d) nature of the sample;
 - (e) name of person (P) from whom the sample was taken;
 - (f) P's date of birth and sex;
 - (g) P's current home address including postcode;
 - (h) P's current residence (if not home address);
 - (i) P's ethnicity;
 - (j) P's NHS number; and
 - (k) the name, address and organisation of the person who solicited the test which identified the causative agent.
- (3) The notification must be provided in writing within 7 days beginning with the day on which the causative agent is identified.
- (4) Without prejudice to paragraph (3), if the operator of the diagnostic laboratory considers that the case is urgent, the notification must be provided orally as soon as reasonably practicable.
- (5) In determining whether the case is urgent, the operator of the diagnostic laboratory must have regard to—
 - (a) the nature of the causative agent;
 - (b) the nature of the disease which the causative agent causes;
 - (c) the ease of spread of the causative agent;
 - (d) the ways in which the spread of the causative agent can be prevented or controlled; and

- (e) where known, P's circumstances (including age, sex and occupation).
- (6) This regulation does not apply where the operator of the diagnostic laboratory reasonably believes that the proper officer of the relevant local authority has already been notified in accordance with this regulation by the operator of another diagnostic laboratory in relation to the same causative agent being found in a sample from the same person.
- [F1(6A) This regulation does not apply where the operator of a diagnostic laboratory has made a notification to Public Health Wales in accordance with regulation 4A, 4B, 4C or 4D.]
 - (7) For the purposes of paragraph (1), a diagnostic laboratory identifies a causative agent where—
 - (a) the diagnostic laboratory identifies the causative agent; or
 - (b) the causative agent is identified by another laboratory under an arrangement made with that diagnostic laboratory.
- (8) Where paragraph (7)(b) applies, the day on which the causative agent is identified for the purposes of paragraph (3), is the day on which the diagnostic laboratory became aware of the identification by the other laboratory.
- (9) It is an offence for the operator of a diagnostic laboratory to fail without reasonable excuse to comply with this regulation.
- (10) Any person who commits an offence under this regulation is liable on summary conviction to a fine not exceeding level 5 on the standard scale.
 - (11) In this regulation—
 - "causative agent" ("cyfrwng achosol") means—
 - (a) a causative agent listed in Schedule 2, or
 - (b) evidence of an infection caused by such an agent;
 - "diagnostic laboratory" ("labordy diagnostig") means an institution (or facility within an institution) which is equipped with apparatus and reagents for the performance of diagnostic tests for human infections;
 - "director of a diagnostic laboratory" ("cyfarwyddwr labordy diagnostig") means—
 - (a) the clinical microbiologist, consultant pathologist or other registered medical practitioner or other person in charge of a diagnostic laboratory; or
 - (b) any other person working in the diagnostic laboratory to whom the function of making a notification under this regulation has been delegated by the person mentioned in subparagraph (a);
 - "operator of a diagnostic laboratory" ("gweithredwr labordy diagnostig") means the corporate body that operates the diagnostic laboratory or, if there is no such body, the director of the diagnostic laboratory; and
 - [F2"Public Health Wales" ("Iechyd Cyhoeddus Cymru") means Public Health Wales National Health Service Trust;]
 - "relevant local authority" ("awdurdod lleol perthnasol") means the local authority within whose area the organisation of the person who solicited the test which identified the causative agent is situated.
 - F1 Reg. 4(6A) inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 10(a)

F2 Words in reg. 4(11) inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 10(b)

[F3Duty on the operators of diagnostic laboratories to notify Public Health Wales of SARS-CoV-2 or influenza virus tests processed

- **4A.**—(1) The operator of a diagnostic laboratory must notify Public Health Wales in accordance with this regulation where the diagnostic laboratory processes a test for the detection of SARS-CoV-2 [^{F4}, other than a test in relation to which regulation 4AB applies,] and the test result is positive or indeterminate.
- (2) Where paragraph (1) of regulation 4B applies to the operator of a diagnostic laboratory, the notification required by paragraph (1) must be in accordance with this regulation and regulation 4B.
- (3) The operator of a diagnostic laboratory must also notify Public Health Wales in accordance with this regulation where the diagnostic laboratory—
 - (a) processes a test for the detection of SARS-CoV-2 [F5, other than a test in relation to which regulation 4AB applies,] and the test result is negative or void; or
 - (b) processes a test for the detection of influenza virus and the test result is positive, indeterminate, negative or void.
- (4) The notification must include the following information insofar as it is known to the operator of the diagnostic laboratory—
 - (a) the name and address of the diagnostic laboratory;
 - (b) the date and time the sample was received by the diagnostic laboratory;
 - (c) where a causative agent is identified, the details of that agent;
 - (d) the date of the sample;
 - (e) the nature of the sample;
 - (f) the results of any antimicrobial susceptibility test and any resistance mechanism identified in respect of the sample;
 - (g) name of person ("P") from whom the sample was taken;
 - (h) P's date of birth and sex;
 - (i) P's current home address including postcode;
 - (j) P's current residence (if not home address);
 - (k) P's ethnicity;
 - (1) P's NHS number;
 - (m) the name, address and organisation of the person who solicited the test;
 - (n) where the test is for the detection of SARS-CoV-2 or influenza virus, the result of the test; and
 - (o) where the result of a test for the detection of SARS-CoV-2 is positive or indeterminate, 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.

- (5) Subject to paragraph (7), a notification under paragraph (3) must be provided in writing within 7 days beginning with the day on which the diagnostic laboratory becomes aware of the test result.
- (6) Subject to paragraph (7), a notification under paragraph (1) must be provided in writing within 24 hours of the diagnostic laboratory becoming aware of the test result.
 - (7) A notification which—
 - (a) is under paragraph (1) or (3); and
 - (b) relates to a day 2 or a day 8 test within the meaning of regulation 6AB of, the International Travel Regulations,

must be provided within 48 hours of the time the diagnostic laboratory received the test sample.

- (8) Without prejudice to paragraph (5), if the operator of the diagnostic laboratory considers that a particular case to which that paragraph applies is urgent, the notification must be provided orally as soon as reasonably practicable.
 - (9) For the purpose of this regulation, 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.
 - (10) Where paragraph (9)(b) applies—
 - (a) the day on which the diagnostic laboratory becomes aware of the test result for the purposes of paragraph (3) 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 (1) is the time at which the diagnostic laboratory became aware of the result of the test processed by that other laboratory.
- (11) It is an offence for the operator of a diagnostic laboratory to fail without reasonable excuse to comply with this regulation.
- (12) Any person who commits an offence under this regulation is liable on summary conviction to a fine.
 - (13) In this regulation—

"carer" ("gofalwr") has the meaning given in section 3 of the Social Services and Well-being (Wales) Act 2014;

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

"diagnostic laboratory" ("labordy diagnostig") has the meaning given in regulation 4(11);

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

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

"International Travel Regulations" ("Rheoliadau Teithio Rhyngwladol") means the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020;

"operator of a diagnostic laboratory" ("gweithredwr labordy diagnostig") has the meaning given in regulation 4(11);

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

"Public Health Wales" ("Iechyd Cyhoeddus Cymru") has the meaning given in regulation 4(11).

- F3 Regs. 4A-4D inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 11
- **F4** Words in reg. 4A(1) inserted (31.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, Restrictions, International Travel, Notification and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1212), regs. 1(2), **14(2)**
- Words in reg. 4A(3)(a) inserted (31.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, Restrictions, International Travel, Notification and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1212), regs. 1(2), 14(3)

[F6Duty to notify Public Health Wales of the results of lateral flow device tests undertaken by eligible travellers

- **4AB.**—(1) This regulation applies where a test provider administers or provides a test for the detection of SARS-CoV-2 in accordance with regulation 6AB(2)(a)(ii)(bb) (lateral flow device tests) of the International Travel Regulations.
- (2) The test provider must notify Public Health Wales of the result of the test in accordance with paragraphs (3) to (5).
 - (3) A notification must be provided in writing—
 - (a) where the test provider administered the test, within 24 hours of determining the result of the test;
 - (b) where the test provider did not administer the test, within 24 hours of receiving the information required to be provided by paragraph 1A(b) of Schedule 1C to the International Travel Regulations.
- (4) A notification must include the following information, insofar as it is known to the test provider—
 - (a) in relation to the person who undertook the test ("P"), their—
 - (i) first name;
 - (ii) surname;
 - (iii) sex;
 - (iv) date of birth;
 - (v) NHS number;
 - (vi) ethnicity;
 - (vii) home address (including postcode);
 - (viii) address provided to the test provider as the place where P is able to receive a confirmatory test;
 - (ix) telephone number and email address, where the test result is positive or indeterminate;
 - (b) whether or not P has received a vaccine against SARS-CoV-2;
 - (c) P's passport number or travel document number (as appropriate);
 - (d) the coach number, flight number, or vessel name of the conveyance on which P arrived in Wales;
 - (e) the test reference number given to P in accordance with regulation 6AB(6) of the International Travel Regulations;
 - (f) the country or territory P was travelling from when P arrived in Wales, and any country or territory they transited through as part of that journey;

- (g) the date on which P undertook the test;
- (h) confirmation that the test complies, and was undertaken in accordance with, the requirements applicable under the International Travel Regulations;
- (i) confirmation that the test is a lateral flow device test undertaken by a regulation 2A traveller within the meaning of the International Travel Regulations;
- (j) where the test provider did not administer the test, the date and time that the test provider received the information required to be provided by paragraph 1A(b) of Schedule 1C to the International Travel Regulations;
- (k) the following information about the test—
 - (i) the name of the test provider and a description of its operations;
 - (ii) the specimen number;
 - (iii) the specimen type;
 - (iv) the specimen date;
 - (v) the test method;
 - (vi) the result;
 - (vii) the date on which the test was carried out;
 - (viii) the name of the testing equipment manufacturer.
- (5) 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 (4)(a) to the test provider, the test provider must provide Public Health Wales with, insofar as it is known to the test provider—
 - (a) the information set out in paragraph (4)(a)(i) to (viii) in relation to P, having obtained it from an appropriate parent, guardian or carer of P ("X"); and
 - (b) where the test result is positive or indeterminate, X's telephone number and email address.
- (6) It is an offence for a test provider to fail without reasonable excuse to comply with this regulation.
- (7) A test provider that commits an offence under this regulation is liable on summary conviction to a fine.
- (8) In this regulation, "carer", "child", "disability", "guardian", "International Travel Regulations", "parent" and "Public Health Wales" have the meanings given in regulation 4A.]
 - F3 Regs. 4A-4D inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 11
 - F6 Reg. 4AB inserted (31.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, Restrictions, International Travel, Notification and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1212), regs. 1(2), 14(4)

Duty to notify Public Health Wales of the results of mandatory tests under the International Travel Regulations

- **4B.**—(1) This regulation applies to the operator of a diagnostic laboratory where—
 - (a) the laboratory processes a day 2 test or a day 8 test (within the meaning of regulation 6AB of the International Travel Regulations);
 - (b) the operator is required to send a notification in relation to the test in accordance with regulation 4A of these Regulations; and

- (c) the operator is required to sequence the test sample under paragraph 1ZA or 2ZA of Schedule 1C to the International Travel Regulations.
- (2) The notification required by regulation 4A(1) must, in addition to the information listed in regulation 4A(3), include the following information so far as it is known to the operator of the diagnostic laboratory—
 - (a) name and address of the source laboratory (if different from the diagnostic laboratory);
 - (b) the date of the laboratory report;
 - (c) the following information about the person ("P") from whom the sample was taken—
 - (i) P's age in months and years;
 - (ii) P's address and postcode;
 - (iii) P's occupation;
 - (iv) whether or not P is immunocompromised;
 - (v) whether or not P has received a vaccine against SARS-CoV-2;
 - (d) the following information about the sample—
 - (i) any laboratory comments;
 - (ii) the organism code;
 - (iii) the specimen number, including the laboratory's five-letter unique identifier code;
 - (iv) the specimen type;
 - (v) the specimen date;
 - (vi) the test method applied;
 - (vii) cycle threshold values.
- (3) Where the specimen is to be sent to another laboratory for the purposes of sequencing pursuant to paragraph 1ZA or 2ZA of Schedule 1C to the International Travel Regulations, the operator of the diagnostic laboratory must provide that other laboratory with the specimen number used to fulfil the obligation in paragraph (2)(d)(iii).
- (4) In this regulation, "diagnostic laboratory", "International Travel Regulations", "operator of a diagnostic laboratory" and "Public Health Wales" have the same meaning as in regulation 4A(13).
 - F3 Regs. 4A-4D inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 11

Duty to notify Public Health Wales of the results of genomic sequencing of mandatory test samples under the International Travel Regulations

- **4C.**—(1) The operator of a sequencing laboratory must notify Public Health Wales in accordance with this regulation.
- (2) The notification must include the following information so far as it is known to the operator of the sequencing laboratory—
 - (a) where the sequencing laboratory is not the source laboratory—
 - (i) the name and address of the source laboratory;
 - (ii) the date and time that the specimen was received by the sequencing laboratory;
 - (b) a report of the results of the sequencing;
 - (c) the date of that report;

- (d) a sorted BAM file containing all reads aligning to the SARS-CoV-2 reference genome with unaligned human reads removed;
- (e) any metadata required to reproduce the analysis which produced the results of the sequencing;
- (f) the following information about the specimen—
 - (i) any laboratory comments;
 - (ii) the organism code;
 - (iii) the specimen number;
 - (iv) the specimen type;
 - (v) the specimen date;
 - (vi) the test method applied;
 - (vii) cycle threshold values;
 - (viii) whether the specimen is a variant of concern or a variant under investigation.
- (3) Where the sequencing laboratory is not the source laboratory—
 - (a) the notification must be provided in writing within 96 hours of receiving the specimen; and
 - (b) the sequencing laboratory must—
 - (i) ascertain the specimen number that the source laboratory used to fulfil its obligation in regulation 4B(2)(d)(iii) in respect of the specimen; and
 - (ii) use the same specimen number to fulfil the obligation in paragraph (2)(f)(iii).
- (4) Where the sequencing laboratory is the source laboratory—
 - (a) the notification must be provided in writing within 120 hours of the time SAR-CoV-2 is identified in the specimen; and
 - (b) the sequencing laboratory must use the same specimen number to fulfil the obligation in paragraph (2)(f)(iii) as it used to fulfil the obligation in regulation 4B(2)(d)(iii).
- (5) It is an offence for the operator of a sequencing laboratory to fail without reasonable excuse to comply with this regulation.
- (6) Any person who commits an offence under this regulation is liable on summary conviction to a fine.
 - (7) In this regulation—
 - "director of a sequencing laboratory" ("cyfarwyddwr labordy dilyniannu") means—
 - (a) the clinical microbiologist, consultant pathologist or other registered medical practitioner or other person in charge of the sequencing laboratory; or
 - (b) any other person working in the sequencing laboratory to whom the function of making a notification under this regulation has been delegated by the person mentioned in paragraph (a);
 - "International Travel Regulations" ("Rheoliadau Teithio Rhyngwladol") means the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020;
 - "operator of a sequencing laboratory" ("gweithredwr labordy dilyniannu") means the corporate body that operates the sequencing laboratory or, if there is no such body, the director of the sequencing laboratory;
 - "Public Health Wales" ("Iechyd Cyhoeddus Cymru") has the meaning given in regulation 4(11);

"sequencing laboratory" ("labordy dilyniannu") means a laboratory which sequences a sample pursuant to paragraph 1ZA or 2ZA of Schedule 1C to the International Travel Regulations; "source laboratory" ("labordy tarddiol") means the diagnostic laboratory which provided the notification required by regulation 4A(1) in respect of the specimen.

F3 Regs. 4A-4D inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 11

Duty on test providers to notify results of point of care tests for the detection of SARS-CoV-2 or influenza virus to Public Health Wales

- **4D.**—(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 Wales 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 the 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.
- (6) 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 Wales with, insofar as it is known to the test provider—
 - (a) the information set out in paragraph (5)(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.
- (7) It is an offence for a test provider to fail without reasonable excuse to comply with this regulation.
- (8) A test provider that commits an offence under this regulation is liable on summary conviction to a fine.
- (9) In this regulation, "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.
- (10) In this regulation, "International Travel Regulations" and "Public Health Wales" have the same meaning as in regulation 4A(13).]
 - F3 Regs. 4A-4D inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 11

Duty to provide information to the proper officer [F7 or Public Health Wales]

- **5.**—(1) This regulation applies where a notification has been made by the operator of a diagnostic laboratory to the proper officer under regulation 4 [F9 or Public Health Wales under regulations 4A, [F9 4AB,] 4B, 4C and 4D].
- (2) The proper officer may request that the person (R) who solicited the laboratory test which identified the causative agent to which the notification relates, provide to him or her the information listed at regulation 4(2) insofar as that information was not included in the notification.
- [F10(2A) Public Health Wales may request that R provide to it the information listed at regulation 4A(3), [F114AB(4),] 4B(2) or 4D(5) insofar as that information was not included in the notification.]
- (3) R must provide the information requested under paragraph (2) [F12 or (2A)] insofar as it is known to R.
- (4) The information must be provided in writing within 3 days beginning with the day on which the request is made.
- (5) Without prejudice to paragraph (4), if the proper officer [F13 or Public Health Wales] considers the case to be urgent and informs R of this fact when making the request, the information must be provided orally as soon as reasonably practicable.

- (6) In determining whether the case is urgent, the proper officer [F14 or Public Health Wales] must have regard to—
 - (a) the nature of the causative agent to which the notification relates;
 - (b) the nature of the disease which the causative agent causes;
 - (c) the ease of spread of the causative agent;
 - (d) the ways in which the spread of the causative agent can be prevented or controlled; and
 - (e) where known, the circumstances of the person from whom the sample was taken (including age, sex and occupation).
- [F15(7) In this regulation, "causative agent" ("cyfrwng achosol") and "Public Health Wales" ("Iechyd Cyhoeddus Cymru") have the same meaning as in regulation 4(11).]
 - F7 Words in reg. 5 heading inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 12(a)
 - Words in reg. 5(1) inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 12(b)
 - **F9** Word in reg. 5(1) inserted (31.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, Restrictions, International Travel, Notification and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1212), regs. 1(2), **15(2)**
 - F10 Reg. 5(2A) inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 12(c)
 - F11 Word in reg. 5(2A) inserted (31.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, Restrictions, International Travel, Notification and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1212), regs. 1(2), 15(3)
 - F12 Words in reg. 5(3) inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 12(d)
 - F13 Words in reg. 5(5) inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 12(e)
 - F14 Words in reg. 5(6) inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 12(e)
 - F15 Reg. 5(7) substituted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 12(f)

Duty on the proper officer to disclose notifications to others

- **6.**—(1) This regulation applies where the proper officer has received a notification under regulation 2, 3 or 4.
 - (2) The proper officer must disclose the fact of the notification and its contents to-
 - (a) the Public Health Wales National Health Service Trust M6;
 - (b) the proper officer of the local authority in whose area P usually resides (if different); and
 - (c) the proper officer of the port health authority or local authority in whose district or area a ship, hovercraft, aircraft or international train is or was situated from which P

has disembarked (if known to the disclosing proper officer and if that officer considers disclosure appropriate).

- (3) The disclosure must be made in writing within 3 days beginning with the day that the proper officer receives the notification.
- (4) Without prejudice to paragraph (3), if the disclosing proper officer considers that the case is urgent, disclosure must be made orally as soon as reasonably practicable.
 - (5) In determining whether a case is urgent, the disclosing proper officer must have regard to—
 - (a) the nature of the disease, infection or contamination or the suspected disease, infection or contamination notified;
 - (b) the ease of spread of the disease, infection or contamination;
 - (c) the ways in which the spread of the disease, infection or contamination can be prevented or controlled; and
 - (d) where known, P's circumstances (including age, sex and occupation).

Marginal Citations

M6 Public Health Wales National Health Service Trust was established by S.I. 2009/2058 (W.177).

Electronic communications

- 7.—(1) This regulation applies to—
 - (a) notifications provided under regulations 2(1), 3(1) [F16, 4(1), 4A(1), [F174AB,] 4B(1), 4C(1) and 4D(3)];
 - (b) information provided under regulation 5(3);
 - (c) disclosures made under regulation 6(2);
 - (d) lists provided under regulation 3 (requirement to provide details of children attending school) of the Health Protection (Local Authority Powers) (Wales) Regulations 2010 M7; and
 - (e) reports provided under regulations 10(1) (duty to report Part 2A applications) and 11(1) (duty to report variations or revocations of Part 2A orders) of the Health Protection (Part 2A Orders) (Wales) Regulations 2010 M8.
- (2) Notifications, information, disclosures, lists and reports, which are required to be in writing, may be communicated electronically if—
 - (a) the recipient has consented in writing to receiving the notification, information, disclosure, list or report (as the case may be) by an electronic communication; and
 - (b) the communication is sent to the number or address specified by the recipient when giving that consent.
 - F16 Words in reg. 7(1)(a) substituted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), 13
 - F17 Word in reg. 7(1)(a) inserted (31.10.2021 at 4.00 a.m.) by The Health Protection (Coronavirus, Restrictions, International Travel, Notification and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1212), regs. 1(2), 16

Marginal Citations M7 S.I.2010/1545 (W.143). M8 S.I. 2010/1544 (W.142).

Revocations

8. The Regulations listed in Schedule 3 are revoked.

Edwina Hart
Minister for Health and Social Services, one of
the Welsh Ministers

SCHEDULE 1

Regulations 2(7)

Notifiable Diseases And Syndromes

[F18] Acquired carbapenemase-producing Gram-negative bacteria]

Anthrax

Botulism

Brucellosis

[F18Chikungunya virus disease]

Cholera

[F19Coronavirus Disease 2019 (COVID-19)]

Diphtheria

Encephalitis (acute)

Enteric fever (typhoid or paratyphoid fever)

Food poisoning

Haemolytic uraemic syndrome (HUS)

Infectious bloody diarrhoea

Infectious hepatitis (acute)

Invasive group A streptococcal disease and scarlet fever

Legionnaires' Disease

Leprosy

Malaria

Measles

Meningitis (acute)

Meningococcal septicaemia

[F20 Monkeypox]

Mumps

Plague

Poliomyelitis (acute)

Rabies

Rubella

SARS

Smallpox

Tetanus

[F18Tick-borne viral encephalitis]

[F18Trichinellosis]

Tuberculosis

Typhus

Viral haemorrhagic fever (VHF)

[F18West Nile virus infection]

Whooping cough

Yellow fever

[F18Zika virus disease]

- **F18** Words in Sch. 1 inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), **14**
- **F19** Words in Sch. 1 inserted (6.3.2020) by The Health Protection (Notification) (Wales) (Amendment) Regulations 2020 (S.I. 2020/232), regs. 1, **2(2)**
- **F20** Word in Sch. 1 inserted (15.6.2022) by The Health Protection (Notification) (Wales) (Amendment) Regulations 2022 (S.I. 2022/657), regs. 1(2), **2(2)**
- **F18** Words in Sch. 1 inserted (21.9.2021) by The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021 (S.I. 2021/1063), regs. 1(3), **14**
- **F19** Words in Sch. 1 inserted (6.3.2020) by The Health Protection (Notification) (Wales) (Amendment) Regulations 2020 (S.I. 2020/232), regs. 1, **2(2)**
- **F20** Word in Sch. 1 inserted (15.6.2022) by The Health Protection (Notification) (Wales) (Amendment) Regulations 2022 (S.I. 2022/657), regs. 1(2), **2(2)**

SCHEDULE 2

Regulations 4(11) and 5(7)

Causative Agents

Bacillus anthracis

Bacillus cereus (only if associated with food poisoning)

Bordetella pertussis

Borrelia spp

Brucella spp

Burkholderia mallei

Burkholderia pseudomallei

Campylobacter spp

Chikungunya virus

Chlamydophila psittaci

Clostridium botulinum

Clostridium perfringens (only if associated with food poisoning)

Clostridium tetani

Corynebacterium diphtheriae

Corynebacterium ulcerans

Coxiella burnetii

Crimean-Congo haemorrhagic fever virus

Cryptosporidium spp

Dengue virus

Ebola virus

Entamoeba histolytica

Francisella tularensis

Giardia lamblia

Guanarito virus

Haemophilus influenzae (invasive)

Hanta virus

Hepatitis A, B, C, delta, and E viruses

Influenza virus

Junin virus

Kyasanur Forest disease virus

Lassa virus

Legionella spp

Leptospira interrogans

Listeria monocytogenes

Machupo virus

Marburg virus

Measles virus

[F21Monkeypox virus]

Mumps virus

Mycobacterium tuberculosis complex

Neisseria meningitidis

Omsk haemorrhagic fever virus

Plasmodium falciparum, vivax, ovale, malariae, knowlesi

Polio virus (wild or vaccine types)

Rabies virus (classical rabies) and rabies-related lyssaviruses

Rickettsia spp

Rift Valley fever virus

Rubella virus

Sabia virus

Salmonella spp

SARS coronavirus

[F22Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)]

Shigella spp

Streptococcus pneumoniae (invasive)

Streptococcus pyogenes (invasive)

Varicella zoster virus

Variola virus

Verocytotoxigenic Escherichia coli (including *E.coli* O157)

Vibrio cholerae West Nile Virus Yellow fever virus Yersinia pestis

- **F21** Words in Sch. 2 inserted (15.6.2022) by The Health Protection (Notification) (Wales) (Amendment) Regulations 2022 (S.I. 2022/657), regs. 1(2), **2(3)**
- **F22** Words in Sch. 2 inserted (6.3.2020) by The Health Protection (Notification) (Wales) (Amendment) Regulations 2020 (S.I. 2020/232), regs. 1, **2(3)**
- **F21** Words in Sch. 2 inserted (15.6.2022) by The Health Protection (Notification) (Wales) (Amendment) Regulations 2022 (S.I. 2022/657), regs. 1(2), **2(3)**
- **F22** Words in Sch. 2 inserted (6.3.2020) by The Health Protection (Notification) (Wales) (Amendment) Regulations 2020 (S.I. 2020/232), regs. 1, **2(3)**

SCHEDULE 3

Regulation 8

Revocations

1. The Public Health (Prevention of Tuberculosis) Regulations 1925 M9.

Marginal Citations

M9 S.I. 1925/757.

2. The Public Health (Infectious Diseases) Regulations 1988 M10.

Marginal Citations

M10 S.I. 1988/1546.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations apply in Wales. They place obligations on various persons to disclose information to specified third parties for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination. Regulation 2 obliges registered medical practitioners to notify the proper officer of the relevant local authority if a patient they are attending is believed to have a disease listed in Schedule 1 or is otherwise infected or contaminated in a way that may cause significant harm to others. Regulation

Changes to legislation: There are currently no known outstanding effects for the The Health Protection (Notification) (Wales) Regulations 2010. (See end of Document for details)

3 extends this obligation to cover notification of suspected disease, infection or contamination in a dead body.

Regulation 4 obliges the operators of diagnostic laboratories to notify the proper officer of the relevant local authority if they identify a causative agent listed in Schedule 2, or evidence of such an agent, in a human sample. Regulation 5 enables the proper officer to approach the person who solicited the laboratory test for certain information not provided by the operator of the diagnostic laboratory and obliges that person to provide the information where known.

Regulation 6 obliges the proper officer to disclose notifications under regulations 2, 3 or 4 to other specified bodies with a health protection role.

Regulation 7 enables specified documents to be sent electronically where certain conditions are met.

Regulation 8 revokes 2 sets of regulations.

A regulatory impact assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Welsh Assembly Government, Cathays Park, Cardiff CF10 3NQ.

Changes to legislation:
There are currently no known outstanding effects for the The Health Protection (Notification) (Wales) Regulations 2010.