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WELSH STATUTORY INSTRUMENTS

2021 No. 1063 (W. 250)

PUBLIC HEALTH, WALES

The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020 (S.I. 2020/574 (W. 132)) (the "International Travel Regulations") and the Health Protection (Notification) (Wales) Regulations 2010 (S.I. 2010/1546 (W. 144)) ("the Notification Regulations").

Part 2 of these Regulations amend the International Travel Regulations. The International Travel Regulations impose requirements on persons entering Wales after having been abroad.

Currently the International Travel Regulations provide that coronavirus day 2 and day 8 tests must be carried out by public providers, i.e. by the NHS in Wales, England, Scotland and Northern Ireland. Regulations 3 to 7 of these Regulations open up those tests to private sector test providers, provided they comply with specified requirements, including being appropriately accredited, having specified systems in place and making a declaration to confirm compliance. Notification requirements are also placed upon private test providers of day 2 and day 8 tests.

The International Travel Regulations include a requirement for persons arriving in Wales to isolate for a period determined in accordance with those Regulations.

Non-exempt persons are prohibited from entering Wales where they have been in a country or territory listed in Schedule 3A to the International Travel Regulations within the last 10 days of arrival, pursuant

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to regulation 12E of the International Travel Regulations.

Regulation 8 of these Regulations amends Schedule 3A to remove Bangladesh, Egypt, Kenya, Maldives, Oman, Pakistan, Sri Lanka and Turkey from the list of countries or territories to which regulation 12E applies.

Part 3 of these Regulations amend the Notification Regulations which place obligations on various persons for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination. These Regulations 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 Wales National Health Service Trust ("Public Health Wales") of the results of those tests.

Regulation 10 makes miscellaneous amendments to regulation 4 of the Notification Regulations in consequence of regulation 11 of these Regulations.

Regulation 11 inserts a new regulations 4A, 4B, 4C and 4D into the Notification Regulations. Regulation 4A imposes a requirement on diagnostic laboratories to notify Public Health Wales of the results of the SARS-CoV-2 or influenza virus detection tests which they process. Regulation 4B imposes a requirement on diagnostic laboratories to report additional information where they process tests in accordance with the International Travel Regulations. Regulation 4C is inserted to clarify the obligations on laboratories which perform genomic sequencing of positive samples. Regulation 4D sets out the information that must be provided to Public Health Wales 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. Regulations 4A, 4C and 4D provide that someone who fails without reasonable excuse to comply with those regulations commits an offence for which, on summary conviction, that person would be liable for a fine.

Regulation 12 amends regulation 5 of the Notification Regulations to provide that where a notification has been made under regulation 4A, 4B, or 4C Public Health Wales may 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 13 amends regulation 7 of the Notification Regulations to provide that notifications

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made under regulations 4A, 4B, 4C and 4D may be made electronically where there is consent.

Regulation 14 amends Schedule 1 to the Notification Regulations to include acquired carbapenemase-producing Gram-negative bacteria, Chikungunya virus disease, Tick-borne viral encephalitis, Trichinellosis, West Nile virus infection and Zika virus disease to the list of notifiable diseases.

Regulation 15 requires the Welsh Ministers to review the effectiveness of the provisions made in the Notification Regulations 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.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

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WELSH STATUTORY INSTRUMENTS

2021 No. 1063 (W. 250)

PUBLIC HEALTH, WALES

The Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021

Made *19 September 2021*

Laid before Senedd Cymru *20 September 2021*

Coming into force in accordance with regulation 1(2) and (3)

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 45B, 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**) ("the 1984 Act").

In accordance with section 45Q(3) of the 1984 Act, 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 the 1984 Act which imposes or enables the imposition of a special restriction or requirement or any other restriction or

(**1**) 1984 c. 22. Functions exercised under 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 ("the 1984 Act") are exercisable in relation to Wales by the Welsh Ministers by virtue of section 45T(6) of that Act which defines "the appropriate Minister" as being the Welsh Ministers as respects Wales for the purposes of Part 2A of that Act, and section 60A(6) of that Act which defines "the appropriate Minister" as being the Welsh Ministers in relation to Wales for the purposes of section 60A of that Act. Sections 45C, 45F, 45P and 45T were inserted into the 1984 Act by section 129 of the Health and Social Care Act 2008 (c. 14) ("the 2008 Act"), and section 60A was inserted into the 1984 Act by section 130 of, and paragraph 16 of Schedule 11 to, the 2008 Act.

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requirement(**1**) which has or would have a significant effect on a person's rights.

PART 1

General

Title and commencement

1.—(1) The title of these Regulations is the Health Protection (Coronavirus, International Travel and Notification) (Wales) (Miscellaneous Amendments) Regulations 2021.

(2) Regulation 8 comes into force at 4.00 a.m. on 22 September 2021.

(3) All other regulations come into force on 21 September 2021.

PART 2

Amendments to the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020

Amendments to the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020

2. The Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020(**2**) are amended in accordance with regulations 3 to 8.

(**1**) See section 45C(6) of the 1984 Act for the meaning of "special restriction or requirement".

(**2**) S.I. 2020/574 (W. 132), amended by S.I. 2020/595 (W. 136), S.I. 2020/714 (W. 160), S.I. 2020/726 (W. 163), S.I. 2020/804 (W. 177), S.I. 2020/817 (W. 179), S.I. 2020/840 (W. 185), S.I. 2020/868 (W. 190), S.I. 2020/886 (W. 196), S.I. 2020/917 (W. 205), S.I. 2020/942, S.I. 2020/944 (W. 210), S.I. 2020/962 (W. 216), S.I. 2020/981 (W. 220), S.I. 2020/1015 (W. 226), S.I. 2020/1042 (W. 231), S.I. 2020/1080 (W. 243), S.I. 2020/1098 (W. 249), S.I. 2020/1133 (W. 258), S.I. 2020/1165 (W. 263), S.I. 2020/1191 (W. 269), S.I. 2020/1223 (W. 277), S.I. 2020/1232 (W. 278), S.I. 2020/1237 (W. 279), S.I. 2020/1288 (W. 286), S.I. 2020/1329 (W. 295), S.I. 2020/1362 (W. 301), S.I. 2020/1477 (W. 316), S.I. 2020/1521 (W. 325), S.I. 2020/1602 (W. 332), S.I. 2020/1645 (W. 345), S.I. 2021/20 (W. 7), S.I. 2021/24 (W. 8), S.I. 2021/46 (W. 10), S.I. 2021/48 (W. 11), S.I. 2021/50 (W. 12), S.I. 2021/66 (W. 15), S.I. 2021/72 (W. 18), S.I. 2021/95 (W. 26), S.I. 2021/154 (W. 38), S.I. 2021/305 (W. 78), S.I. 2021/361 (W. 110), S.I. 2021/454 (W. 144), S.I. 2021/500 (W. 149), S.I. 2021/568 (W. 156), S.I. 2021/584 (W. 161), S.I. 2021/646 (W. 166), S.I. 2021/669 (W. 170), S.I. 2021/765 (W. 187), S.I. 2021/826 (W. 193), S.I. 2021/863 (W. 202), S.I. 2021/867 (W. 203), S.I. 2021/915 (W. 208), S.I. 2021/926 (W. 211) and S.I. 2021/967 (W. 227).

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Amendments to regulation 2

3. In regulation 2(1) (general interpretation), at the appropriate place insert—

> ""private test provider" ("*darparwr prawf preifat*") means a test provider other than a public provider;";
>
> ""public test provider" ("*darparwr prawf cyhoeddus*") means a person who provides or administers a test exercising powers under the National Health Service (Wales) Act 2006(**1**), the National Health Service Act 2006(**2**), the National Health Service (Scotland) Act 1978(**3**), or the Health and Personal Social Services (Northern Ireland) Order 1972(**4**);";
>
> ""test provider" ("*darparwr prawf*") means a public test provider or a private test provider."

Amendments to regulation 6AB

4.—(1) Regulation 6AB (requirement to book and undertake tests) is amended as follows.

(2) Omit paragraph (2)(c).

(3) In paragraphs (3), (5) and (6), for "public test provider", in each place it occurs, substitute "test provider".

Amendment to regulation 6J

5. In regulation 6J(1) (charge for tests), after "day 8 tests" insert "provided by a public test provider".

Amendments to regulation 17

6.—(1) Regulation 17 (use and disclosure of information) is amended as follows.

(2) In paragraph (2)(a)(iii)—

(a) for "public test provider", in both places it occurs, substitute "test provider";

(b) in sub-paragraph (bb), omit "(within the meaning given by regulation 6AB(2)(c))".

(3) In paragraph (3)(c), for "public test provider" substitute "test provider".

(**1**) 2006 c. 42.
(**2**) 2006 c. 41.
(**3**) 1978 c. 29.
(**4**) S.I. 1972/1265 (N.I. 14).

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Amendments to Schedule 1C

7.—(1) Schedule 1C (mandatory testing after arrival in Wales) is amended as follows.

(2) In paragraph 1—

(a) for the heading substitute "Day 2 tests: general requirements";

(b) the existing provision becomes sub-paragraph (2), and before it there is inserted—

"(1) A day 2 test complies with this paragraph where the test complies with sub-paragraph (2) and—

(a) it is a test provided by a public test provider, or

(b) it is a test provided by a private test provider where the private test provider complies with paragraph 1ZA.";

(c) in sub-paragraph (2), as renumbered by paragraph (2)(b) of this regulation, for "paragraph" substitute "sub-paragraph".

(3) After paragraph 1 insert—

"**Day 2 tests: private test provider requirements**

1ZA.—(1) For the purposes of paragraph 1(1)(b), a private test provider complies with this paragraph where—

(a) 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);

(b) a registered medical practitioner has oversight and approval of medical practices undertaken by the private test provider, and responsibility for reporting medical issues;

(c) 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;

(d) a registered clinical scientist has oversight of clinical practices undertaken by the private test provider, and responsibility for reporting clinical issues;

(e) 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

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reasonable practicable to the Welsh Ministers;

(f) if the private test provider is a laboratory that conducts diagnostic test evaluation for testing in accordance with this Schedule, they have made a declaration to the Secretary of State that they meet the minimum standards for private sector-provided testing at https://support-covid-19-testing.dhsc.gov.uk/InternationalTesting;

(g) they have provided the Secretary of State with a list of all organisations that they work with (whether by sub-contract or otherwise) to carry out the testing service or to carry out genomic sequencing, indicating the nature of the service that each organisation is providing, and kept that list updated as appropriate;

(h) 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;

(i) the laboratory used by the private test provider for the processing of samples meets the relevant requirements for ISO standard 15189 or ISO/IEC standard 17025 in respect of the evaluation of the established molecular detection method and the genome sequencing of samples;

(j) they receive the information required by regulation 6AB(5), 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 Wales;

(k) each day, they notify the Secretary of State in writing of—

(i) the number of tests they sold on that day, and

(ii) in relation to each test sold on that day—

(aa) the date of arrival into the United Kingdom of the person in respect of whom the test was sold;

(bb) whether the person in respect of who the test was sold is a arrival who has not

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within the period of 10 days ending with P's arrival in Wales, been in a non-exempt country or territory, or not;

(cc) whether the person in respect of whom the test was sold is a regulation 2A traveller or not;

(dd) the test reference number given to P in accordance with regulation 6AB(6);

(l) they sequence each sample with a cycle threshold less than 30 (equivalent to 1,000 viral genome copies per millilitre);

(m) 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;

(n) on a request by the Welsh Ministers or the COVID-19 Genomics UK Consortium, they make samples available for the purpose of dual sequencing;

(o) they preserve and transport samples in a manner that enables genome sequencing;

(p) they have in place a process to remove human reads from any data submitted in a notification to Public Health Wales pursuant to the Health Protection (Notification) (Wales) Regulations 2010(**1**);

(q) 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 private test provider ensures that X complies with the following so far as relevant to the carrying out of that element—

(i) paragraphs (b) to (e) and (g) to (p) of this sub-paragraph;

(ii) paragraph 2C(2) to (4).

(2) For the purposes of sub-paragraph (1)(h) and (i), 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 paragraph 2B, as if a

(**1**) S.I. 2010/1546 (W. 144), amended by S.I. 2020/232 (W. 54).

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reference to a test were a reference to a day 2 test.

(3) In this paragraph, "registered clinical scientist" means a person registered as a clinical scientist with the Health and Care Professions Council pursuant to article 5 of the Health Professions Order 2001(**1**)."

(4) In paragraph 2—

(a) for the heading substitute "Day 8 tests: general requirements";

(b) the existing provision becomes sub-paragraph (2), and before it there is inserted—

"(1) A day 8 test complies with this paragraph where the test complies with sub-paragraph (2) and—

(a) it is a test provided by a public test provider, or

(b) it is a test provided by a private test provider where the private test provider complies with paragraph 2ZA."

(5) After paragraph 2 insert—

"**Day 8 tests: private test provider requirements**

2ZA.—(1) For the purposes of paragraph 1(1)(b), a private test provider complies with this paragraph where—

(a) they comply with the requirements of paragraph 1ZA(1)(a) to (e) as if any reference in those provisions to a day 2 test were a reference to a day 8 test;

(b) if the private test provider is a laboratory that conducts diagnostic test evaluation for testing in accordance with this Schedule, they have made a declaration to the Secretary of State that they meet the minimum standards for private sector-provided testing at https://support-covid-19-testing.dhsc.gov.uk/InternationalTesting;

(c) they have provided the Secretary of State with a list of all organisations that they work with (whether by sub-contract or otherwise) to carry out the testing service or to carry out genomic sequencing, indicating the nature of the service that each organisation is

(**1**) S.I. 2002/254. There are amendments not relevant to these Regulations.

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providing, and kept that list updated as appropriate;

(d) 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;

(e) the laboratory used by the private test provider for the processing of samples meets the relevant requirements for ISO standard 15189 or ISO/IEC standard 17025 in respect of the evaluation of the established molecular detection method and the genome sequencing of samples;

(f) they receive the information required by regulation 6AB(5), and they administer or provide the test to P no later than the end of the eighth day after the day on which P arrived in Wales;

(g) each day, they notify the Secretary of State in writing of—

(i) the number of tests they sold on that day, and

(ii) in relation to each test sold on that day—

(aa) the date of arrival into the United Kingdom of the person in respect of whom the test was sold;

(bb) whether the person in respect of whom the test was sold is a regulation 2A traveller or not;

(cc) the test reference number given to P in accordance with regulation 6AB(6);

(h) they sequence each sample with a cycle threshold less than 30 (equivalent to 1,000 viral genome copies per millilitre);

(i) 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;

(j) on a request by the Welsh Ministers or the COVID-19 Genomics UK Consortium, they make samples available for the purpose of dual sequencing;

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(k) they preserve and transport samples in a manner that enables genome sequencing;

(l) they have in place a process to remove human reads from any data submitted in a notification to Public Health Wales pursuant to the Health Protection (Notification) (Wales) Regulations 2010;

(m) 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 private test provider ensures that X complies with the following so far as relevant to the carrying out of that element—

(i) paragraph 1ZA(1)(b) to (e) as applied by sub-paragraph (1)(a);

(ii) sub-paragraph (1)(c) to (l);

(iii) paragraph 2C(2) to (4).

(2) For the purposes of sub-paragraph (1)(d) and (e), 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 paragraph 2B, as if a reference to a test were a reference to a day 8 test."

(6) After paragraph 2A insert—

"**UKAS accreditation**

2B.—(1) Before providing a test, a private test provider must have been accredited by UKAS to the relevant ISO standard.

(2) If the private test provider arranges with another person ("X") for X to carry out any element of the testing service on their behalf, the private test provider must—

(a) ensure that X complies with any provision of this paragraph that is relevant to the carrying out of that element, and

(b) subject to sub-paragraph (3), cease to provide tests under arrangement with X if X fails to comply with any such provision.

(3) Sub-paragraph (2)(b) does not apply to a test that was administered before the date that X failed to comply with this paragraph.

(4) In this paragraph—

"the relevant ISO standard" ("*y safon ISO berthnasol*") means—

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(a) in the case of a test which requires laboratory processing, ISO standard 15189 or ISO/IEC standard 17025, and

(b) in the case of a point of care test, ISO standard 15189 and ISO standard 22870(**1**), and for this purpose "point of care test" means a test processed outside a laboratory environment;

"UKAS" ("*UKAS*") means the United Kingdom Accreditation Service, a company limited by guarantee and incorporated in England and Wales under number 3076190(**2**).

Notification of test results

2C.—(1) This paragraph applies to a private test provider who administers or provides a test to P in the circumstances described in regulation 6AB and paragraphs 1 to 2A of this Schedule.

(2) The private test provider must, within 48 hours of the time when the sample taken for the purposes of the test is received by the diagnostic laboratory—

(a) notify P and, where applicable, any person who arranges the test on P's behalf, by email, letter or text message, the result of P's test, or

(b) make P's test result available to P and, where applicable, any person who arranges the test on P's behalf, 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 private test provider and P's test reference number, and must be conveyed so as to inform P whether the test was negative, positive, or inconclusive."

(7) In paragraph 3, after sub-paragraph (c) insert—

"(d) "single end-to-end testing service" means a service which comprises accepting the booking from the person to be tested, collecting and processing

(**1**) ISO 22870 Point-of-care testing (POCT) requirements for quality and competence was published in November 2016.

(**2**) *See* S.I. 2009/3155, amended by S.I. 2019/696, for the functions of UKAS. S.I. 2009/3155 and S.I. 2019/696 were made under section 2(2) of the European Communities Act 1972 (c. 68) and are accordingly saved by virtue of section 2(2)(a) of the European Union (Withdrawal) Act 2018 (c. 16).

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the sample to be tested, carrying out genomic sequencing and providing the test result to P."

Amendments to Schedule 3A

8. In Schedule 3A (countries and territories subject to additional measures), omit the following entries—

"Bangladesh"

"Egypt"

"Kenya"

"Maldives"

"Oman"

"Pakistan"

"Sri Lanka"

"Turkey".

PART 3

Amendments to the Health Protection (Notification) (Wales) Regulations 2010

Amendment of the Health Protection (Notification) (Wales) Regulations 2010

9. The Health Protection (Notification) (Wales) Regulations 2010(**1**) are amended in accordance with regulations 10 to 14.

Amendments to regulation 4

10. In regulation 4 (duty to notify causative agents found in human samples)—

(a) after paragraph (6) insert—

"(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.";

(b) in paragraph (11), at the appropriate place insert—

""Public Health Wales" ("*Iechyd Cyhoeddus Cymru*") means Public Health Wales National Health Service Trust(**2**);".

(**1**) S.I. 2010/1546 (W. 144), amended by S.I. 2020/232 (W. 54).

(**2**) Public Health Wales National Health Service Trust is established under section 18 of, and paragraphs 5 and 7 of Schedule 3 to, the National Health Service (Wales) Act 2006 (c. 42) and Public Health Wales National Health Service Trust (Establishment) Order 2009 (S.I. 2009/2058 (W. 177)).

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Insertion of new regulations 4A, 4B, 4C and 4D

11. After regulation 4 insert—

"**Duty 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 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 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);

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(k) P's ethnicity;

(l) 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

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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(**1**);

"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(**2**) (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(**3**);

"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);

(**1**) 2014 anaw 4.

(**2**) 2010 c. 15.

(**3**) 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 are relevant.

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

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;

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(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).

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;

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(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,

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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.

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—

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(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

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(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)."

Amendments to regulation 5

12. Regulation 5 (duty to provide information to the proper officer) is amended as follows—

(a) in the heading, after "proper officer" insert "or Public Health Wales";

(b) in paragraph (1), after "regulation 4" insert "or Public Health Wales under regulations 4A, 4B, 4C and 4D";

(c) after paragraph (2) insert—

"(2A) Public Health Wales may request that R provide to it the information listed at regulation 4A(3), 4B(2) or 4D(5) insofar as that information was not included in the notification. ";

(d) in paragraph (3), after "paragraph (2)" insert "or (2A)";

(e) in paragraphs (5) and (6), after "proper officer" insert "or Public Health Wales";

(f) for paragraph (7) substitute—

"(7) In this regulation, "causative agent" ("*cyfrwng achosol*") and "Public Health Wales" ("*Iechyd Cyhoeddus Cymru*") have the same meaning as in regulation 4(11)."

Amendment to regulation 7

13. In paragraph (1)(a) of regulation 7 (electronic communications), for "and 4(1)" substitute ", 4(1), 4A(1), 4B(1), 4C(1) and 4D(3)".

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Amendment to Schedule 1

14. In Schedule 1 (notifiable diseases and syndromes), at the appropriate place insert—

"Acquired carbapenemase-producing Gram-negative bacteria"

"Chikungunya virus disease"

"Tick-borne viral encephalitis"

"Trichinellosis"

"West Nile virus infection"

"Zika virus disease".

Review

15. The Welsh Ministers must review the effectiveness of the provisions made by regulations 10 to 13 before the expiry of the period of 12 months beginning with the day after the day on which they come into force.

Eluned Morgan
Minister for Health and Social Services, one of the Welsh Ministers
19 September 2021