EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (NOTIFICATION) (AMENDMENT) (CORONAVIRUS) REGULATIONS 2020

2020 No. 1175

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 Currently the Health Protection (Notification) Regulations 2010 S.I. 2010/659 ("the 2010 Regulations") that require reporting of positive Covid-19 results to Public Health England (PHE) do not cover point of care tests ("POCT"). Government foresees a significant increase in the use of POCT testing particularly in the private sector.

2.2 This instrument requires that a test provider, as defined in the regulations, that provides a POCT to an individual for the detection of SARS-CoV-2 (the virus which causes Covid-19) or for the detection of influenza, must notify PHE of the result of that test (whether that result is positive, indeterminate, negative, or void). It is a requirement that, insofar as it is known to the test provider, specified personal information is provided to PHE along with the test result and test information.

2.3 This instrument also requires that where a diagnostic laboratory processes a test for the detection of SARS-CoV-2 or for influenza and that result is indeterminate, negative or void, they must notify PHE of the result of that test. This instrument requires that certain specified information is also provided insofar as it is known to the laboratory. This is an expansion of the existing duty contained in the 2010 Regulations, which requires only the notification of identified (positive) cases.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is made under the negative procedure pursuant to section 45Q(3) of the Public Health (Control of Disease) Act 1984 (c. 22) ("the 1984 Act").

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As this instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

5.1 As this instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The 1984 Act, and regulations made under it, provide a legislative framework for health protection in England and Wales.

6.2 Part 2A of the 1984 Act, as inserted by the Health and Social Care Act 2008, provides a legal basis to protect the public from threats arising from infectious disease or contamination from chemicals or radiation, and includes powers to impose restrictions or requirements on people, and in relation to things and premises, for use in rare circumstances where voluntary cooperation cannot be obtained. The amended 1984 Act sets out a framework for health protection, which requires much of the detailed provisions to be delivered through regulations.

6.3 Specifically, section 45C of the 1984 Act enables the appropriate Minister (defined in section 45T as the Secretary of State for England, or the Welsh Ministers for Wales) to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in England and Wales.

6.4 This instrument is made under section 45C to enable a number of public health measures to be taken for the purpose of reducing the public health risks arising from the disease known as Covid-19 and to manage public health risks arising from influenza.

6.5 This instrument amends the 2010 Regulations, to include a requirement that where POCT for the detection of SARS-CoV-2 or influenza are provided to an individual by a test provider, there is a duty on the test provider to notify PHE of the result and to provide certain specified information, insofar as it is known, as part of that notification. See paragraph 7.4 below for discussion of POCTs.

6.6 In the case of positive and indeterminate test results for SARS-CoV-2, the notification must be made to PHE within 24 hours of the result becoming available. In the case of negative and void POCT results for SARS-Cov-2 and positive, indeterminate, negative and void POCT results for influenza, the notification must be made within 7 days of the result becoming available.

6.7 A test provider is any organisation with a legal personality (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. In practice this captures organisations offering testing services such as third-party providers, employers choosing to develop internal testing programmes etc. These organisations providing testing services would have to report results to PHE on behalf of the individual they are providing the service to. Additionally, where an organisation buys and administers tests themselves (rather than procuring a testing service) they are a test provider and are legally liable to report results to PHE.

6.8 The 2010 Regulations are also being updated to require that where a diagnostic laboratory processes a test for the detection of SARS-CoV-2 or for influenza, they must notify PHE of the result of that test, whether it is positive, indeterminate,

negative or void. It is also a requirement that along with the notification of the test result, specified information must be provided to PHE, insofar as it is known to the laboratory. In the case of positive SARS-CoV-2 test results, it will now be a requirement for laboratories to provide a contact telephone number and email address if this information is available - this is in order to assist with contact tracing in relation to the Covid-19 pandemic.

6.9 This instrument makes provision requiring that positive and indeterminate SARS-CoV-2 results processed in a laboratory must be notified to PHE within 24 hours. Negative and void SARS-CoV-2 results and all influenza results must be notified to PHE within 7 days, unless there is a reason why the laboratory considers that the notification should be made more urgently (which is in line with the existing requirements set out by the 2010 Regulations).

7. Policy background

7.1 The 2010 Regulations created a scheme for notifying actual and suspected cases of infection and contamination in humans to specified bodies with public health responsibilities. This allows prompt action to be taken by those bodies to protect public health where appropriate.

7.2 The list of notifiable diseases was updated on 5th March 2020 to include SARS-CoV-2, following the start of the Covid-19 pandemic.

7.3 Currently Regulation 4 of the 2010 Regulations requires diagnostic laboratories to notify PHE of identified (positive) cases of causative agents (including SARS-CoV-2). Medical practitioners are required to notify local authorities (who will in turn notify PHE), of suspected cases of notifiable diseases (including Covid-19) under Regulation 2.

7.4 The use of POCT has increased since the 2010 Regulations were made for testing of certain infectious diseases, but their use has grown particularly as a result of the Covid-19 pandemic. POCT are diagnostic tests that are not performed in a laboratory or under the supervision of a registered medical practitioner. POCT are performed at or near the person, for example using a lateral flow test. The provider must have relevant competency based trained test operators undertaking or overseeing sample collection, dependent on test sample collection requirements. Under current regulations there is no duty to report any POCT results to PHE, although this does currently happen to a limited extent on a voluntary basis.

7.5 This gap in the 2010 Regulations allows a significant number of test results to go unreported which is detrimental to public health. This is particularly acute in the context of the Covid-19 pandemic but has also had a negative impact on the surveillance of winter respiratory viruses (particularly influenza), which is central to planning for winter pressures and the management of NHS resource. Understanding the distribution of influenza infections in hospitals and communities will also support the management of Covid-19 cases.

7.6 As the use of POCT increases in the private and public sector, the significance of the gap is likely to increase. The gap will: lead to an incomplete picture to inform virus surveillance and future action; undermine efforts to encourage private sector testing; damage our ability to perform epidemiological analysis; and, in the context of the Covid-19 pandemic, will negatively impact on the contact tracing regime.

7.7 To address this problem, this instrument will require that relevant providers (who provide POCT for Covid-19 and / or influenza. For example, this includes organisations offering POCT testing such as, but not limited to, third party test providers, occupational health providers and employers running internal testing programmes not using a third party) report positive, indeterminate, negative and void POCT for the detection of SARS-CoV-2 and influenza test results.

7.8 This instrument will also require that indeterminate, negative and void results for the detection of SARS-CoV-2 and influenza processed in a laboratory must be notified to PHE. It is necessary to collect these additional results in order to assist with virus surveillance and epidemiological analysis which will inform future management of both the Covid-19 pandemic and the management of influenza.

7.9 Requiring this information on patients with negative test results will enable de-duplication (which can only be achieved by being able to identify an individual and their testing history), providing a denominator to allow accurate positivity rates to be determined. Having the full testing history of a patient (i.e. having positive and negative test results of an individual) will also help understand the length of episodes of infection/carriage of the virus and the potential for repeat infection. In addition, knowing the positive and negative results of individual patients will improve understanding of the transmission risks in communities, workplaces and other settings. It will improve understanding of the risk of infection in contacts and will allow linkage to other datasets to determine immunity, understand who is accessing tests and improve the public health actions for Covid-19 and provide insights to improve health access.

7.10 This instrument specifies the data that providers must provide to PHE. The data in relation to the individual that must be provided as part of the notification to PHE in relation to all POCT results (positive, indeterminate, negative, void) for SARS-CoV-2 and influenza mirrors that required under the existing duty on laboratories under the 2010 Regulations with the exception that we are now requiring the collection of two more data items for positive and indeterminate POCTs results for SARS-CoV-2 – a telephone number and email address. These two data items are required to enable contract tracing for positive and indeterminate test results. The purpose for collecting all of this data is set out in paragraphs 7.6 and 7.9 above.

7.11 The duty to notify PHE specifies that the test provider must notify PHE of the required data *insofar as it is known to the test provider*. This exemption has been developed to ensure that is a test provider has a reasonable excuse as to why they are unable to report the data to PHE, such as if an individual does not wish to disclose the information required or they do not have an email address for example, then that test provider is not found to be in breach of their duty.

7.12 This instrument supports the aims of the 1984 Act to protect the public from threats arising from infectious disease or contamination from chemicals or radiation. In line with the 2010 Regulations this instrument provides that it is an offence to fail without reasonable excuse to comply with regulations 4 and 4A. Any person who commits an offence under either of those regulations is liable on summary conviction to a fine.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

10.1 There has been no public consultation in relation to this instrument.

11. Guidance

11.1 The Government has published guidance on reporting results to PHE. This guidance will continue to be updated where necessary.

12. Impact

12.1 There is some impact on business, charities or voluntary bodies.

12.2 Estimates of costs to test providers have been prepared. It is estimated that the cost of establishing the reporting required is under £5m.

12.3 There is no significant impact on the public sector.

12.4 A full Impact Assessment has not been prepared for this instrument because the cost impact has been assessed as lower than the £5m threshold.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation will be kept under regular review.

14.2 A review clause is included in the instrument. A review of the effectiveness of this instrument will take place before the expiry of the period of 12 months starting with the day after the day on which this instrument comes into force.

15. Contact

15.1 Lucie Meggitt at the Department of Health and Social Care lucie.meggitt@dhsc.gov.uk, can be contacted with any queries regarding this instrument.

15.2 Matt Russell, Deputy Director for Private Sector Testing Strategy, at the Department for Health and Social Care can confirm that this explanatory memorandum meets the required standard.

15.3 The Rt Hon Matt Hancock MP, Secretary of State at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.