EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) (AMENDMENT) (CORONAVIRUS) (NO. 2) REGULATIONS 2020

2020 No. 1550

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ("DHSC") 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 The purpose of this instrument is to remove Care Quality Commission ("CQC") registration requirements for COVID-19 test providers, who may have been in the scope of CQC registration under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations").

2.2 This is achieved by exempting any activity carried on for the purpose of testing for the presence of COVID-19 in an individual, or for the presence of antibodies to COVID-19, from being a regulated activity for the purposes of the Health and Social Care Act 2008 ("the Act"). In addition, any activity carried on for the purposes of processing, analysing or reporting the results of a test for the presence of COVID-19, or for the presence of antibodies to COVID-19, is exempted from being a regulated activity.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is laid under the draft affirmative procedure pursuant to section 162 of the Health and Social Care Act 2008.

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 This entire instrument applies to England only.

3.3 In the view of DHSC, for the purposes of House of Commons Standing Order No. 83P of the Standing Orders of the House of Commons relating to Public Business, the subject-matter of this instrument would not be within the devolved legislative competence of any of the Northern Ireland Assembly as a transferred matter, the Scottish Parliament or the National Assembly for Wales if equivalent provision in relation to the relevant territory were included in an Act of the relevant devolved legislature.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is set out in Section 3 under "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)".

5. European Convention on Human Rights

5.1 The Secretary of State for Health and Social Care, the Rt Hon Matt Hancock MP at the Department of Health and Social Care has made the following statement regarding Human Rights:

"In my view the provisions of the Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 The Act established the CQC and gave it the function of maintaining a registration system for providers of health and adult social are who carry out regulated activities, which is a term defined in section 8 of the Act. Providers of regulated activities are required to meet the requirements imposed by the provisions of the Act and regulations made under it.

6.2 The 2014 Regulations are made under section 20 of the Act and prescribe the kinds of activities that are regulated activities for the purposes of Part 1 of the Act, and the requirements that apply in relation to the way in which those activities are carried on. Providers of regulated activities are required to register with the CQC. Section 10 of the Act provides that it is an offence to carry on a regulated activity without being registered with the CQC.

6.3 The removal of saliva or mucus samples and the examination of these samples is a 'regulated activity' within paragraph 7 of Schedule 1 of the 2014 Regulations. Therefore, COVID-19 test providers involved in the taking or examination of such samples are currently required to be registered with the CQC.

6.4 Schedule 2 to the 2014 Regulations sets out a list of activities which are exempt from being regulated activities for the purposes of the Act. This instrument amends Schedule 2, by inserting a new paragraph 12 into Schedule 2. New paragraph 12 of Schedule 2 exempts any activity carried on for the purpose of testing for the presence of COVID-19 in an individual, or for the presence of antibodies to COVID-19, from being a regulated activity for the purposes of the Act. In addition, this instrument exempts any activity carried on for the purposes of processing, analysing or reporting the results of a test for the presence of COVID-19, or for the presence of antibodies to COVID-19, from being a regulated activity.

7. Policy background

What is being done and why?

7.1 The CQC monitors, inspects and regulate services to make sure they meet fundamental standards of quality and safety. This includes hospitals, GPs and doctors, care homes and other services (e.g. dentists, ambulances and mental health services).

7.2 COVID-19 test providers involved in the removal of bodily cells, tissues or fluid samples, or the analysing and reporting of such samples, are currently required to be registered with and regulated by, the CQC, in accordance with paragraph 7 of Schedule 1 of the 2014 Regulations.

7.3 However, due to the terminology used in Schedule 1 of the 2014 Regulations, certain COVID-19 test providers would be within the scope of CQC regulation, whilst other providers would be exempt, depending on the type of COVID-19 test sampling and

analysis undertaken. Specifically, if a provider is taking a blood sample by means of a pin prick or from a vein and that sample does not need to go to a laboratory for analysis, that provider will not need to register with the CQC in relation to that activity. Further, if a provider is already registered with the CQC to carry on any other regulated activity, they will not need to additionally register for diagnostic and screening procedures, if their services solely involve taking blood samples, taking tissue samples by means of a swab specimen from any external part of the body or from the mouth, ear, nose or throat, or analysing and reporting the results of those samples.

7.4 These complexities in the 2014 Regulations means that it can be difficult for new entrants into the COVID-19 testing market to navigate their way through the regulations, resulting in delays and costs being incurred. Registration with the CQC for these activities could take up to 10 weeks if there were very large numbers of new providers requiring registration concurrently, during which time the entities would not be able to provide these services.

7.5 This instrument seeks to remedy those complexities, by removing the CQC regulatory requirements relating to COVID-19 test sampling and test examination, including antibody testing. It also ensures that as novel, non-clinical testing technologies and methods develop in response to better understanding of COVID-19 do not need to be individually exempted from CQC regulation.

7.6 Assurance of these activities will be replaced on the same day with an end-to-end COVID-19 testing accreditation scheme for test providers, by the United Kingdom Accreditation Service (UKAS). UKAS is the government appointed national accreditation body that assesses and accredits organisations, including medical laboratories and point of care testing services. This accreditation process will provide a comprehensive, single point of regulation for COVID-19 testing and analysis.

7.7 It will allow testing providers to qualify for COVID-19 testing and analysis quickly and simply, allowing the market to expand more rapidly. In addition to the assurance it will provide for these previously CQC-regulated activities, it will also accredit a far wider range of COVID-19 testing-related activities that cover sampling, point of care testing, lab-based testing, analysis and reporting of results. It is also expected that the cost of the UKAS accreditation process shall be lower than for CQC registration, allowing for greater ease for providers to enter the market whilst still assuring a quality service.

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/ trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 No consolidation is being undertaken.

10. Consultation outcome

10.1 A range of test manufacturers, test providers, industry representative groups and employers running COVID-19 employee testing programmes have been consulted regarding removing CQC registration requirements for COVID-19 testing providers,

and replacing it with the comprehensive UKAS accreditation scheme. Overall, the feedback from stakeholders was largely in favour of this approach.

10.2 Stakeholders recognised the value of not having to duplicate cost and effort in any parallel registration with the CQC. In order to mitigate some stakeholder concerns about any accreditation scheme being able to respond to provider innovation, UKAS have agreed to allow for new providers to apply for COVID-19 testing accreditation, whilst in parallel to apply for a flexible scope that allows providers to make changes to their accredited procedures within an agreed remit. UKAS have stated that early notice of proposed change by providers to UKAS can reduce assessment timelines to a matter of days.

11. Guidance

11.1 The Government will update its guidance on the assurance of COVID-19 testing in the private sector and this will be available on https://www.gov.uk/coronavirus. In addition, the CQC has detailed guidance, which is available at https://www.cqc.org.uk/guidance-providers. Further information on the UKAS accreditation process is available on https://www.ukas.com/the-route-to-accreditation/how-to-apply/.

12. Impact

12.1 The impact on business, charities or voluntary bodies, which is in relation to removal of the requirement to register with the CQC for COVID-19 test sampling and test examination, is expected to be either zero or a net benefit to businesses.

12.2 CQC registration for COVID-19 test sampling and test examination will be replaced in separate legislation by the requirement for UKAS registration followed by a Stage Two Appraisal status and the full UKAS accreditation. The required fees for UKAS registration and Stage Two Appraisal status are lower than for the CQC and we expect the costs required to attain UKAS registration will be similar.

12.3 There is no, or no significant, impact on the public sector.

12.4 An Impact Assessment has not been prepared for this instrument because it has not been assessed to exceed the +/- £5m threshold that would require a detailed impact assessment. This initial assessment includes expected costs related to the replacement requirement for UKAS registration for COVID-19 test sampling and test examination.

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. However, as this legislation will reduce the regulatory burden on all businesses, it should be seen as a positive step by small businesses and will reduce barriers to entry into the market for COVID-19 testing.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is based on the CQC's ongoing requirement to monitor the providers present on their register. If, as a result of this instrument, the CQC receives enquiries on the UKAS accreditation scheme, then the CQC's contact centre will engage DHSC to ensure that appropriate action is taken.

14.2 This instrument does not include a statutory review clause; however, the 2014 Regulations do include such a clause.

15. Contact

15.1 Chris Hughes at the Department of Health and Social Care chris.hughes@dhsc.gov.uk, can be contacted with any queries regarding the instrument.

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