PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

Fifteenth Delegated Legislation Committee

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

DRAFT HEALTH PROTECTION (CORONAVIRUS, TESTING REQUIREMENTS AND STANDARDS) (ENGLAND) REGULATIONS 2020

Thursday 10 December 2020

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not later than

Monday 14 December 2020

The Committee consisted of the following Members:

Chair: Christina Rees

† Anderson, Stuart *(Wolverhampton South West)* (Con)
† Charalambous, Bambos *(Enfield, Southgate)* (Lab)
† Churchill, Jo *(Parliamentary Under-Secretary of State for Health and Social Care)*
† Double, Steve *(St Austell and Newquay)* (Con)
Efford, Clive *(Eltham)* (Lab)
† Jones, Andrew *(Harrogate and Knaresborough)* (Con)
Jones, Mr Kevan *(North Durham)* (Lab)
† Mangnall, Anthony *(Totnes)* (Con)
† Moore, Damien *(Southport)* (Con)
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
† Richardson, Angela *(Guildford)* (Con)
Spellar, John *(Warley)* (Lab)
Sturdy, Julian *(York Outer)* (Con)
† Throup, Maggie *(Lord Commissioner of Her Majesty's Treasury)*
† Trott, Laura *(Sevenoaks)* (Con)
Twigg, Derek *(Halton)* (Lab)
Whittome, Nadia *(Nottingham East)* (Lab)

Seb Newman, *Committee Clerk*

† attended the Committee

Fifteenth Delegated Legislation Committee

Thursday 10 December 2020

[Christina Rees *in the Chair*]

Draft Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020

11.30 am

The Chair: I remind Members to observe social distancing, and to sit only in places that are marked as available. *Hansard* colleagues would be most grateful if Members could send their speaking notes to hansardnotes@parliament.uk.

The Parliamentary Under-Secretary of State for Health and Social Care (Jo Churchill): I beg to move,

That the Committee has considered the draft Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020.

The Chair: With this it will be convenient to consider the draft Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020.

Jo Churchill: The draft Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2020 will remove covid-19 test services from Care Quality Commission regulatory requirements. Existing exemptions result in certain covid-19 testing providers being within scope of CQC regulation, and other providers being exempt. We want to tidy this up by removing this requirement, while introducing a requirement to apply to the United Kingdom Accreditation Service. This will simplify the complex regulatory system for covid-19 test providers.

The second statutory instrument, the draft Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020, will impose requirements on private test providers to become accredited by UKAS and to reach specified stages in the process towards accreditation within a specific timeframe that starts on 1 January 2021.

Last week, the independent Medicines and Healthcare products Regulatory Agency recommended authorising Pfizer-BioNTech's covid-19 vaccine for use. While we wait for vaccine deployment, testing and contact tracing remain among the most effective ways of controlling the spread of the virus. The more rapidly we can identify people at risk of infection, the more effectively we can reduce the spread of the virus and get life back to normal. During the pandemic, we have built the largest diagnostic network in British history via Test and Trace, but we will defeat the virus only if the public and private sectors work together.

The private sector has a critical role to play in achieving this, and has shown its value time and again throughout the pandemic. It is at the forefront of testing innovation and is keen to support Test and Trace. It is vital that we look to open up our economy, and that NHS Test and Trace suppliers are focused where we need them most, taking pressure off the NHS. However, people must also be assured of the safety and reliability of services. The Government therefore support developing the private testing market, so that we can ensure that everyone has access to simple, effective, high-quality, affordable and reliable tests and test services, whether from a Government or private provider. As the demand for testing continues to grow, the need for public confidence in testing remains as important as ever. We need to support the system so that providers can enter quickly and efficiently, and so that we can meet demand without compromising the quality of testing services or undermining customer confidence.

There is a requirement in England for parties to register with the CQC if they are involved in the removal of bodily cells, tissues or fluid samples, or the analysing or reporting of those samples, for covid-19 testing. That requirement is subject to a number of exemptions. Notably, it depends on the type of covid-19 test sampling and analysis, and on the entity undertaking the sample collection. That has resulted in inconsistencies around requirements, and a degree of confusion. Test providers have voiced concerns about the complexity surrounding entry to the covid-19 testing market, and we have listened.

The first statutory instrument before the Committee will remove the requirement for covid-19 testing providers to register with the CQC by exempting covid-19 testing from being a regulated activity under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. As the CQC is an English regulatory body, this does not apply to any other nation in the UK. The removal of the requirements will prevent confusion over regulations from causing restrictions in total testing capacity, which we are keen to ensure is sufficient. It is vital that we neither restrict testing capacity nor compromise on quality. The change from CQC to UKAS will provide the necessary agile but robust requirements to ensure that testing capacity is not restricted.

I turn to the second statutory instrument. UKAS is the sole accreditation body in the UK, independent of but appointed by Government. Accreditation by UKAS is the recognised gold standard for organisations that offer test services. Recognising the time it can take to gain full UKAS accreditation and the urgent need for high-quality private testing, on 27 November my Department and UKAS launched an adapted three-stage UKAS accreditation process for private test providers, ensuring that new and innovative providers can be accredited faster without compromising on rigorous safety standards.

The instrument requires providers that provide tests commercially to undergo this staged UKAS accreditation process within the specified timeframes. All providers offering test services to the English market will need to gain stage 1 applicant status by 31 December. After 31 December, new entrants to the testing market will be required to achieve UKAS applicant status before offering any test to the English market. The instrument also requires providers to achieve stage 2 UKAS appraisal and stage 3 UKAS accreditation status within a given timeframe.

Employers that provide test services only to their own staff, and organisations that supply tests at no cost, will not be required to gain UKAS accreditation. I would, however, advise that they endeavour to do so, thereby ensuring that their tests are of the highest possible standards.

From 15 December, international arrivals will be able to opt in to testing to release, and all test services used for this purpose will be required to work towards completing, and to have completed within the timeframe, the three-stage process.

Before I set out my final justification for the regulations, let me thank the Joint Committee on Statutory Instruments, which scrutinised them so quickly. I want to explain how tests for the presence of antibodies are covered by the regulations. Current forms of tests for antibodies are not covered by CQC legislation and will not be covered by UKAS legislation. The regulations do not leave any regulatory gap with regard to testing for antibodies, as no legislation existed, but test providers for the presence of antibodies to covid-19 can choose to apply for accreditation if they wish.

The new UKAS accreditation scheme will simplify the process of looking for a commercial test for the presence of covid-19. Consumers will be able to identify providers capable of delivering a quality end-to-end service. From booking to sample collection and reporting results, individuals and businesses will be able to get the assurance they need. We strongly advise that consumers and organisations procure test services only from gold standard providers that have started their journey through the UKAS accreditation, and a list of all those providers will be available on gov.uk.

In conclusion, this legislation will simplify the testing landscape for test providers and regulate the market with consistency. This will help to protect consumers and help test providers. We are enormously supportive of employers who have already chosen to begin testing their staff. They help reduce pressure on the NHS and ensure that Test and Trace can focus on situations where it is needed most. But wherever testing is done, it must be done properly, using the right test for the right purposes. These regulations will help the public to identify the right test services for their purposes. They will also help test providers to enter the market at a time when their services are vital to the country. I therefore commend the regulations to the Committee.

11.40 am

Alex Norris (Nottingham North) (Lab/Co-op): It is pleasure to debate these draft regulations under your chairship, Ms Rees. As we have heard, the two sets of regulations combine to replace the CQC registration requirements for covid-19 test providers with end-to-end accreditation through UKAS. The explanatory memorandum states that the change

"will allow testing providers to qualify for COVID-19 testing and analysis quickly and simply, allowing the market to expand more rapidly….it will also accredit a far wider range of COVID-19 testing-related activities",

and will be cheaper. I have seen from the Government consultation feedback from stakeholders that that has been positively received, and have not heard of any strong reservations, so we do not intend to oppose the change; indeed, we support it. It is a good thing to do. It takes something quite complicated and newly emerging and makes it quite simple and effective.

I have points on which I seek assurance from the Minister. I am conscious that I tend to pepper my speech with these questions; it may be that not all of them can be addressed today, because some of them are granular, so I would appreciate it if those were followed up in writing.

As the Minister said, certain test providers were out of the scope of CQC regulation. If the service provider was taking blood samples via pinpricks or from veins, and the sample did not need lab analysis, it was out of scope; the same would apply if it was taking blood samples or external tissue with a swab, or just analysing or reporting such samples, and was already registered with the CQC for something else. There is quite a gap there, and an uneven playing field; it is possibly quite confusing.

With the market growing, and a growing number of technologies, a universal system is welcome. It also makes sense to broaden the system to cover all parts of these activities, end to end. That can only be of benefit, from a regulatory standpoint. Do the regulations mean that the end-to-end process will cover all entrants, and that all those undertaking those activities will be treated similarly? I wrote my speech before hearing what the Minister said; I think I heard her confirm that, but I want to make sure.

The staged process makes sense, in terms of ensuring quality at the beginning, and making sure that we do not have to wait long periods for providers to enter the market. Providers entering the accreditation process have to meet a range of standards, which include meeting Departments' minimum standards for private testing, having a clinical director and meeting requirements under the Medical Devices Regulations 2002. I understand that the requirements were updated in November, a month after they were initially published. Is this the final list, or does the Minister intend to update them again?

Existing providers will need to achieve stage 1 by the end of the year. After that date, new providers must achieve stage 1 before they can deliver testing. Will the Minister give a sense of how long it will take a new provider to enter a market? Stage 2 will require existing providers to meet UKAS's requirements to ensure that they are progressing towards full accreditation by the end of January, or new providers within four weeks of completing stage 1, if that is later. The 13 key requirements include having carried out a gap analysis in relation to the relevant International Organisation for Standardisation standard; having access to relevant clinical expertise; and having demonstrated meeting technical performance characteristics consistently. Can the Minister confirm that, having talked to providers, she feels that four weeks is adequate time to meet those requirements, particularly for new entrants to the market? What will happen if they do not? Will they get more time? Do they re-enter the system from the beginning? I would be interested to know what happens in the case of failure.

Stage 3 is full accreditation to the relevant ISO standard, whether for lab-based or point-of-care testing. Stage 3 must be met within four months or by 30 June next year, whichever is later. Of course, achieving the standard is really important, and goes a long way to assuring us about fundamental standards of quality and safety, but in such a fast-moving market, if the process takes about six months in total, that is quite a significant window.

Will the Minister share her assessment of the likelihood and the impact of testing providers entering the market at stage 1 or 2, and then failing to achieve stage 3? Are those stage 1 and 2 tests, in her judgment and that of the Department, robust enough to ensure that a risky product will not be out there for months? What safeguards prevent an unscrupulous or low-quality provider from

[Alex Norris]

re-entering the stage 1 process with a slightly different product, with no good-faith intention of ever achieving stage 3?

I have no doubt that those in the CQC will be the people who are most cheered by this. I suspect that, given the significant burdens on their time, they will not miss these responsibilities at all. Of course, every action has an equal and opposite reaction, so the regulations will bring more responsibilities to UKAS. Again, I wonder what assessment has been made of the capacity for UKAS to effectively deliver this scheme—certainly at the beginning, a lot of people could be making applications—and of the resourcing implications of ensuring that UKAS can act effectively, in terms of the business interests, and safely in all our interests.

I am conscious that I have peppered a good dozen questions into my remarks, as I always do. These are important points of clarity, however, because this is such an important area. As the Minister says, we all hope and pray for the vaccine every morning, but in the meantime testing is the significant aspect. It is right, as we wish to do more things, that private businesses—the Minister used the example of businesses—want to do testing, for staffing purposes. However, it is important that we proceed in an effective manner. This is a market that is growing and has little precedent. Even a year ago, we had no idea that we would now need such a market in this country. Risks can come with that. What the Government are doing today to put a shape around that is very sensible; we just need to make sure that it works.

The Chair: Minister, would you like to respond to those peppered points?

11.46 am

Jo Churchill: Thank you, Ms Rees; I will indeed. I will canter through the questions. As the hon. Member for Nottingham North knows, we work effectively together, and if I have missed anything I will come back to him.

The hon. Gentleman was right that all parts of the process, end to end, are treated similarly. I thank him for the measured view he took of what the measures seek to do, which is sort the market out, so the answer to his question is yes. He asked about the list. Yes, this is the final list. He asked about the process. Sign-up on 27 November through to 31 December is stage 1. Stage 2 is that existing providers have to meet the checklist of key requirements for the testing services by 31 January. New providers will need to complete this stage by 31 January or within four weeks of completing stage 1, whichever is later. Providing that the providers pass all assessments and are fully accredited for testing, the instrument will mandate that existing providers should meet stage 3 by 30 June or within four weeks, whichever is later.

We have worked very closely with UKAS to ensure that it has capacity to do this work within the four weeks. We have been assured that the current providers in the market can meet that. UKAS is a recognised mark of gold standard, and that is why we are working closely with it. Since the beginning of the pandemic, we have been working with it to ensure that people can access advice on quality assurance of tests and so on, and become accredited. What is being seen here is a slight lag to make sure that we get this right and introduce the legislation. As I say, my officials have been working with UKAS to ensure that we get the right balance. There are checks and balances in making sure that the adapted three-stage approach allows entry at speed, but also has a check. If a provider has not passed at four weeks, they do not get to move on any further. This preserves the gold standard, and UKAS embraces the innovation, but wants to make sure that its accreditation stays at that standard. Providers that continue to provide and have failed to meet the criteria will be committing an offence that is punishable on summary conviction by an unlimited fine.

If passed, we will review these regulations after six months to ensure that they are suitable and efficient. The hon. Gentleman and I have regular dialogues; if he has any input, I am always happy to listen to it.

That has probably cleared off the majority of the hon. Gentleman's questions. I thank him for his contribution to this important debate. The Government have been clear that the highest priority is saving lives and reducing the spread of the virus while aiming to get life back to normal as soon as possible. The measures and amendments that we have debated today are necessary and proportionate to ensure that everyone can access simple, effective, high-quality testing services that they can count on. Testing is not a silver bullet. It is not the sole solution to the pandemic. However, it is part of the broader solution, and it is helping us to protect jobs and keep businesses open.

Testing is enabling hospital treatment to continue and transport to keep running, and is keeping our children in education. It is vital that we continue to open up the economy, and that NHS supplies are saved for the situations in which they are needed most. To ensure that, we need to enable the provision of new, innovative tests that are as reliable and effective as possible. To that end, the services that wrap around them need accreditation. The regulations will ensure that. They will provide public confidence in testing, and support private providers in entering the market.

As I have said, we need to create an agile regulatory environment for testing providers. We can enable that by removing CQC regulatory requirements for them and replacing them with the gold standard of UKAS accreditation. The measures will simplify the complex regulatory system for test providers, and simplify the process of looking for a commercial test that is reliable, assured by providers, and gives individuals and employers essential assurances about the test that they procure.

In conclusion, this legislation will simplify the regulatory landscape for test providers and regulate the market in a consistent manner. This is beneficial to consumers and test providers alike. I reiterate my thanks to the covid-19 test providers for their pivotal work in the past few months. We review these regulations regularly and assess them in the light of developments. I commend the regulations to the Committee.

Question put and agreed to.

DRAFT HEALTH PROTECTION (CORONAVIRUS, TESTING REQUIREMENTS AND STANDARDS) (ENGLAND) REGULATIONS 2020

Resolved,

That the Committee has considered the draft Health Protection (Coronavirus, Testing Requirements and Standards) (England) Regulations 2020.—*(Jo Churchill.)*

11.53 am

Committee rose.