

Draft Regulations laid before Senedd Cymru under section 45Q(4) of the Public Health (Control of Disease) Act 1984 (c. 22), for approval by resolution of Senedd Cymru.

DRAFT WELSH STATUTORY
INSTRUMENTS

2021 No. (W.)

PUBLIC HEALTH, WALES

**The Health Protection (Coronavirus
Restrictions) (No. 5) (Wales)
(Amendment) (No. 17) Regulations
2021**

EXPLANATORY NOTE

(This note is not part of the Regulations)

Part 2A of the Public Health (Control of Disease) Act 1984 enables the Welsh Ministers, by regulations, to make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in Wales.

These Regulations are made in response to the serious and imminent threat to public health which is posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Wales.

These Regulations amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 (S.I. 2020/1609 (W. 335)) (“the principal Regulations”). The amendments—

- insert a new regulation 16A into the principal Regulations which—
 - requires the person responsible for certain premises to take reasonable measures to ensure that adults are on the premises only if they have what is commonly referred to as a “COVID pass” (that is – evidence of either vaccination, participation in a relevant vaccine trial, a negative test for coronavirus, or a positive test within the last 6 months which has been followed by the appropriate period of isolation);

- specifies that the premises to which this requirement applies are—
 - nightclubs and other places where music is provided for dancing if they serve alcohol and are open at any time between midnight and 5 a.m. (and the requirement to have a COVID pass applies to such premises at any time, including times outside these hours, if they are open and are providing music for people to dance);
 - premises where an event is being held with over 10,000 people in attendance if they are all seated, or over 500 indoors and 4,000 outdoors if they are not all seated;
- specifies exceptions to the requirement for—
 - premises holding wedding or civil partnership receptions, or wakes;
 - open air events which are free and unticketed, and which have multiple entry points;
 - protests and picketing;
 - open air mass-participation sporting events such as running and cycling races;
- makes it clear that for venues that do not always provide music for dancing the requirement applies only at those times when music for dancing is provided;
- exempts those working or providing a voluntary service at premises from being required to have evidence of vaccination or testing in order to be on the premises;
- includes some interpretative provisions relating to vaccines and testing;
- inserts a new regulation 30A which permits enforcement officers (in this context police officers and police community support officers and any other person designated for the purposes of this regulation) to require evidence from a person who an officer suspects may be in possession of false or misleading evidence of a person's vaccination or testing status;
- creates an offence in new regulation 40A of possessing false or misleading evidence of vaccination or testing status;
- makes consequential amendments to Schedule 8 to the principal Regulations (which provides for enforcement of the “reasonable measures” regime in Part 4 of those Regulations) so as to permit local authority enforcement officers to use the powers in the Schedule in relation to reasonable measures taken under the new regulation 16A.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory impact assessment has not been prepared as to the likely cost and benefit of complying with these Regulations.

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2021 No. (W.)

PUBLIC HEALTH, WALES

**The Health Protection (Coronavirus
Restrictions) (No. 5) (Wales)
(Amendment) (No. 17) Regulations
2021**

Made

*Coming into force at 7.00 a.m. on 11 October
2021*

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

In accordance with section 45Q(4)(2) of that Act, a draft of this instrument has been laid before and approved by a resolution of Senedd Cymru.

These Regulations are made in response to the serious and imminent threat to public health which is posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Wales.

The Welsh Ministers consider that restrictions and requirements imposed by these Regulations are proportionate to what they seek to achieve, which is a public health response to that threat.

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- (1) 1984 c. 22. Sections 45C, 45F and 45P were inserted by section 129 of the Health and Social Care Act 2008 (c. 14). The functions under these sections are conferred on “the appropriate Minister”. Under section 45T(6) of the 1984 Act the appropriate Minister, as respects Wales, is the Welsh Ministers.
- (2) Section 45Q was inserted by section 129 of the Health and Social Care Act 2008.

Title and coming into force

1.—(1) The title of these Regulations is the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 17) Regulations 2021.

(2) These Regulations come into force at 7.00 a.m. on 11 October 2021.

Amendment to the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020

2.—(1) The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020⁽¹⁾ are amended as follows.

(2) After regulation 16 insert—

“Specific measures applicable to premises where music is provided for dancing or at which specified events are held

16A.—(1) Where regulation 16(1) applies to a person responsible for premises described in paragraph (2), the reasonable measures to be taken by the responsible person under Step 3 of that regulation must include measures to ensure that a person aged 18 or over is only permitted to be present on the premises if the person possesses evidence—

- (a) complying with the requirements in paragraph (6), that the person has completed a course of doses of an authorised vaccine,
- (b) that the person has participated in, or is participating in, a clinical trial, within the meaning of regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004⁽²⁾, of a vaccine for vaccination against coronavirus carried out in the United

(1) S.I. 2020/1609 (W. 335) as amended by S.I. 2020/1610 (W. 336), S.I. 2020/1623 (W. 340), S.I. 2020/1645 (W. 345), S.I. 2021/20 (W. 7), S.I. 2021/46 (W. 10), S.I. 2021/57 (W. 13), S.I. 2021/66 (W. 15), S.I. 2021/95 (W. 26), S.I. 2021/103 (W. 28), S.I. 2021/172 (W. 40), S.I. 2021/210 (W. 52), S.I. 2021/307 (W. 79), S.I. 2021/413 (W. 133), S.I. 2021/502 (W. 150), S.I. 2021/542 (W. 154), S.I. 2021/583 (W. 160), S.I. 2021/668 (W. 169), S.I. 2021/686 (W. 172), S.I. 2021/722 (W. 183), S.I. 2021/862 (W. 201), S.I. 2021/925 (W. 210) and S.I. 2021/970 (W. 228).

(2) S.I. 2004/1031 as amended by section 116 of the Care Act 2014 (c. 23) and by S.I. 2004/3224, S.I. 2005/2754, S.I. 2005/2759, S.I. 2006/562, S.I. 2006/1928, S.I. 2006/2984, S.I. 2007/289, S.I. 2007/3101, S.I. 2008/941, S.I. 2010/231, S.I. 2010/551, S.I. 2010/1882, S.I. 2011/2581, S.I. 2012/134, S.I. 2012/504, S.I. 2012/1641, S.I. 2012/1916, S.I. 2013/532, S.I. 2016/190, S.I. 2016/696, S.I. 2019/593, S.I. 2019/744, S.I. 2019/1094 and S.I. 2020/1488.

Kingdom in accordance with the requirements of those Regulations,

- (c) of a negative result from a qualifying test taken by the person no more than 48 hours before the person enters the premises, or
- (d) of a positive result from a polymerase chain reaction test taken by the person no more than 180 days and no less than 10 days before the person enters the premises.

(2) The premises referred to in paragraph (1) are—

- (a) premises that meet all of the following conditions—
 - (i) the premises are authorised for the sale or supply of alcohol,
 - (ii) the premises provide live or recorded music for members of the public or members of the venue to dance, including nightclubs, discotheques and dance halls, and
 - (iii) the premises are open at any time between midnight and 5.00 a.m. (however where this condition is met, the requirement in paragraph (1) applies to the premises at any time they are open, subject to paragraph (3)(a) or (e));
- (b) premises at which an event is taking place and more than 10,000 people are in attendance at any time;
- (c) premises at which an event is taking place to any extent indoors, where—
 - (i) more than 500 people are in attendance at any time, and
 - (ii) not all the persons attending the event are normally seated during the event;
- (d) premises at which an event is taking place outdoors, where—
 - (i) more than 4,000 people are in attendance at any time, and
 - (ii) not all the persons attending the event are normally seated during the event.

(3) But paragraph (1) does not apply to premises—

- (a) of a kind described in paragraph (2)(a) at any time when music is not being provided for members of the public or members of the venue to dance;

- (b) at which an event is held outdoors, where—
 - (i) a person is not required to obtain a ticket or pay a fee in order to gain entry to the event, and
 - (ii) there are two or more points of entry for persons attending the event;
- (c) at which a protest, or picketing carried out in accordance with the Trade Union and Labour Relations (Consolidation) Act 1992(1), is being held;
- (d) at which a mass participation sporting event is being held outdoors, such as a marathon, cycling race or triathlon;
- (e) used for the celebration of—
 - (i) a solemnisation of a marriage, formation of a civil partnership or alternative wedding ceremony, or
 - (ii) the life of a deceased person,
 at any time when they are used for any of those purposes.

(4) In paragraph (1) the reference to a person aged 18 or over does not include a person working or providing voluntary services at the premises.

(5) For the purposes of paragraph (2)(b) to (d), a person working, or providing voluntary services at the event, is not to be treated as being in attendance at the event.

(6) For the purposes of paragraph (1)(a), the evidence that a person has completed a course of doses of an authorised vaccine must—

- (a) show that—
 - (i) the course of doses was administered to the person in the United Kingdom, under the United Kingdom vaccine roll-out overseas, or in a relevant country, and
 - (ii) the day on which the person enters the premises is more than 14 days after the day on which the person completed that course of doses;
- (b) in relation to course of doses of vaccines administered in the United Kingdom, be provided to the person by or on behalf of the Government of the United Kingdom, the Scottish

(1) 1992 c. 52.

Ministers, the Welsh Ministers or a Northern Ireland department (including by means of letter, text message, e-mail, the NHS COVID Pass website⁽¹⁾ or the NHS smartphone app developed and operated by the Secretary of State);

- (c) in relation to a course of doses of vaccines administered by a relevant country, be the EU digital COVID certificate or Centers for Disease Control and Prevention vaccination card.

(7) For the purposes of paragraph (1)(d), where a person has isolated for a period of less than 10 days calculated in accordance with regulation 6(5) or 7(5), the reference to “10 days” is to be treated as a reference to the number of days for which the person was required to isolate.

(8) For the purposes of paragraph (6)(a), where a person has received a dose of an authorised vaccine in the United Kingdom and a dose of a vaccine under the United Kingdom vaccine roll-out overseas, the person is deemed to have received a course of doses of a vaccine under the United Kingdom vaccine roll-out overseas.

(9) For the purposes of this regulation—

- (a) a test is a qualifying test if it is capable of detecting the presence of coronavirus, and is—
 - (i) a polymerase chain reaction test provided or administered under the National Health Service Act 2006⁽²⁾, the National Health Service (Wales) Act 2006⁽³⁾, the National Health Service (Scotland) Act 1978⁽⁴⁾, or the Health and Personal Social Services (Northern Ireland) Order 1972⁽⁵⁾, or
 - (ii) a lateral flow test, the results of which may be submitted through the NHS public reporting system⁽⁶⁾.
- (b) a person has completed a course of doses if the person has received the complete course of doses specified—

(1) Available at <https://covid-status.service.nhsx.nhs.uk>

(2) 2006 c. 41.

(3) 2006 c. 42.

(4) 1978 c. 29.

(5) S.I. 1972/1265 (N.I. 14).

(6) Available at <https://www.gov.uk/report-covid19-result>

- (i) in the summary of product characteristics approved as part of the marketing authorisation for the authorised vaccine, or
- (ii) in the instructions for usage approved as part of the authorisation by the licensing authority on a temporary basis under regulation 174 of the Human Medicines Regulations 2012⁽¹⁾ for the authorised vaccine.

(10) In this regulation—

- (a) “authorised vaccine” means a medicinal product for vaccination against coronavirus authorised—
 - (i) in relation to doses received in the United Kingdom—
 - (aa) for supply in the United Kingdom in accordance with a marketing authorisation, or
 - (bb) by the licensing authority on a temporary basis under regulation 174 of the Human Medicines Regulations 2012;
 - (ii) in relation to doses received in a relevant country, for supply in that country following evaluation by the relevant regulator for the country;
- (b) “the licensing authority” has the meaning given in regulation 6(2) of the Human Medicines Regulations 2012;
- (c) “marketing authorisation” means—
 - (i) in relation to a vaccine authorised for supply in the United Kingdom or in a member State, has the meaning given in regulation 8(1) of the Human Medicines Regulations 2012;
 - (ii) in relation to a vaccine authorised for supply in a relevant country other than a member State, means a marketing authorisation granted by the relevant regulator for the country;
- (d) “relevant country” means a country listed in the first column of the table in paragraph (11);

(1) S.I. 2012/1916.

- (e) “relevant regulator” in relation to a relevant country, means the regulator identified in the corresponding row of the second column of the table in paragraph (11), and a reference to a regulator in that table is a reference to the regulatory authority of that name designated as a Stringent Regulatory Authority by the World Health Organization pursuant to the operation of the COVAX Facility⁽¹⁾;
- (f) “United Kingdom vaccine roll-out overseas” means the administration of vaccine against coronavirus to—
 - (i) Crown servants (within the meaning given in section 12(1)(a) to (e) of the Official Secrets Act 1989⁽²⁾), government contractors (within the meaning given in section 12(2) of the Official Secrets Act 1989) or other personnel posted or based overseas and their dependants under the scheme known as the Foreign, Commonwealth and Development Office staff COVID-19 vaccination programme,
 - (ii) residents of the British overseas territories, the Channel Islands and the Isle of Man, as part of a programme agreed in the overseas territory with the United Kingdom government, or
 - (iii) military or civilian personnel, government contractors and their dependants at a military posting overseas, including the British overseas territories, the Channel Islands and the Isle of Man, under the vaccination scheme provided or approved by the UK Defence Medical Services.

(11) The table referred to in the definitions of “relevant country” and “relevant regulator” follows—

<i>Relevant country</i>	<i>Relevant regulator</i>
a member State	European Medicines Agency
Andorra	European Medicines Agency

(1) A list of the national regulatory authorities designated as Stringent Regulatory Authorities has been published by the World Health Organization and is available online at https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

(2) 1989 c. 6.

Iceland	European Medicines Agency
Liechtenstein	European Medicines Agency
Monaco	European Medicines Agency
Norway	European Medicines Agency
San Marino	European Medicines Agency
Switzerland	Swissmedic
the United States of America	United States Food and Drug Administration
Vatican City State	European Medicines Agency

”

(3) In regulation 18(1), after “16(1)” insert “or 16A(1)”.

(4) In regulation 25(3)(a)(i), after “16(1)” insert “or 16A(1)”.

(5) In regulation 26, after “16(1)” insert “and 16A(1)”.

(6) After regulation 30 insert—

“Powers relating to offence of possessing false or misleading evidence relating to vaccination or coronavirus test results

30A. Where an enforcement officer has reasonable grounds for suspecting that a person is committing an offence under regulation 40A, the officer may require the person to produce any evidence of a kind described in regulation 16A(1) which the officer suspects is in the person’s possession.”

(7) After regulation 40 insert—

“Offence of possessing false or misleading evidence relating to vaccination or coronavirus test results

40A. It is an offence for a person (“P”) to possess evidence of a kind described in regulation 16A(1) which P knows is false or misleading.”

(8) In Schedule 8—

(a) in paragraph 1—

(i) in sub-paragraph (1)(a), after “16” insert “or 16A”;

(ii) in sub-paragraph (2)(b), after “16” insert “or 16A”;

(b) in paragraph 2—

(i) in sub-paragraph (3)(a), after “16” insert “or 16A”;

(ii) in sub-paragraph (4)(b)(ii), after “16” insert “or 16A”;

(iii) in sub-paragraph (4)(c), after “16” insert “or 16A”;

- (c) in paragraph 3(3)(c), after “16” insert “or 16A”;
- (d) in paragraph 4(1)(b), after “16” insert “or 16A”.

Name

First Minister, one of the Welsh Ministers

Date