EXPLANATORY MEMORANDUM TO

THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES) (AMENDMENT) REGULATIONS 2026

2026 No. [XXXX]

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 His Majesty.

2. Declaration

2.1 Minister Ahmed, Parliamentary Under-Secretary of State for Health Innovation and Safety confirms that this Explanatory Memorandum meets the required standard.

2.2 Suzy Powell, Director of Emergency Preparedness and Health Protection at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Hayley Hible at the Department of Health and Social Care Telephone: 020 7210 2816 or email: EventHealthcare@DHSC.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 The instrument amends the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations").

4.2 The 2014 Regulations contain a list of "regulated activities" which fall within the core regulatory remit of the Care Quality Commission (CQC) [1], the body established to oversee and regulate the provision of certain health and social care services.

4.3 The Treatment of Disease, Disorder or Injury (TDDI) is a CQC-regulated activity in the existing 2014 Regulations, subject to certain exceptions. Two of those exceptions are relevant here. The first is TDDI provided in a sports ground or gymnasium (including associated premises) where it is provided for the sole benefit of persons taking part in, or attending, sporting activities and events as set out in schedule 1. The second is the provision of treatment under temporary arrangements to deliver healthcare to those taking part in, or attending, sporting or cultural events as set out in schedule 1. Both are excluded from that list and, therefore, CQC's main regulatory powers.

4.4 This instrument will, from a specified date (see paragraph 6.4), remove these exceptions with the result that TDDI provided in the above circumstances will become a regulated activity. Once reclassified in this way, it will be an offence for a person or body to provide services for the newly regulated TDDI purposes on or after the specified date, unless they have registered to do so with CQC. Once registered, a

[1] The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 https://www.legislation.gov.uk/uksi/2014/2936/schedule/1

registered person or body must then comply with the wider suite of rules that apply to those who register with CQC.

Where does the legislation extend to, and apply?

4.5 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.6 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England.

5. Policy Context

What is being done and why?

5.1 The Manchester Arena Inquiry (MAI) Volume 2-II report[2] made recommendations to establish a standard for the level of healthcare at events and that the Department of Health and Social Care should give urgent consideration to making the necessary changes in the law to enable the Care Quality Commission to become the regulator in this important area. Therefore, for the latter, we are seeking to remove exceptions that have, to date, applied to providers being required to register with CQC when undertaking TDDI in event healthcare at sporting venues and gymnasiums and under temporary arrangements at sporting and cultural events.

5.2 TDDI is the Treatment of Disease, Disorder or Injury[3]. This term covers a wide range of treatments, such as emergency treatment and ongoing care for long-term conditions, when provided by or under the supervision of a defined list of healthcare professionals or by a team which includes a healthcare professional. The defined list is available on CQC's website[4].

5.3 TDDI does not include first aid when provided unexpectedly or in potentially dangerous situations by healthcare professionals where immediate action is required; delivered by first-aid specific organisations; or delivered by non-healthcare professionals. First aid is, according to CQC's website[5], the initial response to a sudden illness, condition or injury or exacerbation of an existing illness, and restricted to the aim of either alleviating it immediately through simple procedures and/or preventing it from worsening until professional medical help is available. First aid will not be regulated under these amendments.

5.4 Additionally, CQC is aware of significant risk in the provision of independent medical care at temporary sporting and cultural events and is concerned that continuing to have unregulated care in these settings and others (e.g. sporting activities) will have a negative effect. Serious harm has occurred in relation to this currently unregulated care and CQC state it should be regulated in order to improve safety and quality of healthcare provision[6]. Removing the exceptions will enable CQC to regulate TDDI in

[2] Manchester Arena Inquiry Volume 2: Emergency Response https://assets.publishing.service.gov.uk/media/6363d597e90e0705a35f5754/MAI-Vol2-Part_Ii_Accessible.pdf
[3] Treatment of disease, disorder or injury - Care Quality Commission https://www.cqc.org.uk/guidance-regulation/providers/registration/scope-registration/regulated-activities/treatment-disease-disorder-or-injury
[4] Glossary of terms - Care Quality Commission https://www.cqc.org.uk/guidance-regulation/providers/registration/scope-registration/glossary-terms
[5] Treatment of disease, disorder or injury - Care Quality Commission https://www.cqc.org.uk/guidance-regulation/providers/registration/scope-registration/regulated-activities/treatment-disease-disorder-or-injury#:~:text=First%20aid%20is:%20*%20the%20initial%20response,worsening%20until%20professional%20medical%20help%20is%20available.
[6] 20190304 The state of care in independent ambulance services FINAL (cqc.org.uk) https://www.cqc.org.uk/publications/major-report/state-care-independent-ambulance-services

these instances, supporting the government's commitment to improving healthcare for all.

What was the previous policy, how is this different?

5.5 A range of providers administer TDDI at sports grounds and gymnasiums and/or under temporary arrangements at sporting/cultural events; these providers may be registered with CQC for other services they provide which are currently separately listed as regulated activities by the 2014 Regulations or may provide no such services and therefore hold no such registration. However, providers in either category are currently not required to register with CQC for the TDDI they might provide at sporting venues and gymnasiums or under temporary arrangements at sporting and cultural events. This is due to two exceptions in the 2014 regulations that mean the provision of TDDI in a sports ground or gymnasium or under temporary arrangements at sporting and cultural events are not regulated.

5.6 The proposed amendments will remove these exceptions and bring these activities within the regulatory scope of CQC by adding them to the list of regulated activities set out in Schedule 1 to the 2014 Regulations.

5.7 From the date on which the change comes into force, providers carrying out the regulated activity of TDDI within a sporting or cultural event site will be required to register with, and will be subject to regulation by, CQC thereafter.

5.8 There is a cross reference to the exceptions within another exception at Schedule 1 Paragraph 9 (3) which relates to transport services provided within the confines of the site or venue being used for sporting activities/events or cultural events. We are not proposing this exception is removed because it would have wider unintended consequences, such as, for example, transport of a member of the public within the event site in an ambulance would be in scope *even if* that ambulance was there only for first aid purposes.

6. Legislative and Legal Context

How has the law changed?

6.1 The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 detail the powers and duties CQC has, and information about the duties that people providing and managing services have. These regulations contain definitions of the services and activities that people must be registered to provide, including TDDI.

6.2 These changes will remove 4(3)(f) and 4(3)(g) from the list in Schedule 1 of the exceptions to the regulations, enabling CQC to regulate the provision of TDDI in a sports ground or gymnasium and/or under temporary arrangements at sporting and cultural events, meaning those providing TDDI in a sports ground or gymnasium or under temporary arrangements at a sporting or cultural event must register with CQC. The exception regarding transport services provided within the confines of the site or venue will not be removed (Schedule 1, paragraph 9(3)).

6.3 The specific exceptions are 4(3)(f) the provision of treatment in a sports ground or gymnasium (including associated premises) where it is provided for the sole benefit of persons taking part in, or attending, sporting activities and events and (4)(3)(g) the provision of treatment (not being first aid for the purposes of paragraph 9 of Schedule 2) under temporary arrangements to deliver health care to those taking part in, or attending, sporting or cultural events.

6.4 The amendments will be brought into force for the purposes of enabling persons who wish to carry out the newly regulated activities to apply, from 7th September 2026, to be registered with CQC. The amendments will then be brought into force for all other purposes from 6th December 2027, after which point it will be an offence to carry out the activities if not registered. From that latter date the full range of CQC regulatory rules and powers will also apply to those carrying out the new activities as they would to any other person carrying out any regulated activity.

6.5 The aim of these variable commencement arrangements is to allow time for those wishing to register with CQC in respect of the new activities before the legal requirement to do so (and the associated offence for not doing so) starts to apply.

Why was this approach taken to change the law?

6.6 The government have chosen to remove both exceptions (4(3)(f) and 4(3)(g) in their entirety. This approach was taken so that the relevant health care provision, identified by the MAI and CQC, is regulated. This will ensure that healthcare in relation to TDDI can be regulated in sports grounds and gymnasiums as well as under temporary arrangements at sporting and cultural events, regardless of the size of the event, allowing for the improvement of provisions of healthcare for all users. This also gives clarity to event organisers so they are better able to source an appropriate level of care effectively and without confusion around the type of care provision they would receive.

6.7 It is important to ensure providers of medical care and those utilising such services know exactly which services are being regulated. To amend the regulations and exceptions rather than remove them wholesale would create ambiguity and a lack of clarity around who would need to register with CQC for the purpose of regulation and potential legal challenges should enforcement be required.

6.8 Removing the exceptions will enable CQC to regulate providers in these circumstances and take enforcement action where necessary which is only able to be done via legislative change.

7. Consultation

Summary of consultation outcome and methodology

7.1 From 26 April 2024 to 21 June 2024, a public online consultation was established to gather views on DHSC's proposal, with an email address provided for those wishing to make further comment. An Easy Read version was made available from 13 August 2024 to 27 September 2024.

7.2 Consultation respondents were asked whether they agreed or disagreed with the proposal to fully remove the exception relating to treatment in a sports ground or gymnasium (including associated premises), and whether they agreed or disagreed with the proposal to fully remove the exception relating to treatment at temporary cultural and sporting events, with an option to explain their answer. They were also asked whether there would be an effect on sporting activities or local cultural and sporting events as a result of the outlined proposal and a disproportionate effect on small businesses[7]. Most respondents (56%) agreed with the proposal to remove the

[7] Government response to the results of the consultation on changing regulations relating to the CQC - GOV.UK https://www.gov.uk/government/consultations/changes-to-regulations-relating-to-the-care-quality-commission/outcome/government-response-to-the-results-of-the-consultation-on-changing-regulations-relating-to-the-cqc

exception relating to treatment in a sports ground or gymnasium (exception 4(3)(f)), whilst 19% disagreed and 25% chose 'don't know'. Most respondents (55%) agreed with the proposal to remove the exception relating to treatment at cultural and sporting events (exception 4(3)(g)), whilst 20% disagreed and 25% chose 'don't know'.

7.3 Some free-text responses showed misconceptions that the proposal would regulate first aid, which will remain an unregulated activity as clarified in the consultation response. There were other considerations on whether existing structures were sufficient in regulating provision and that the government should consider which body is the most appropriate to regulate the sector. The consultation response addressed these concerns and reaffirmed that the government's priority is to keep the public safe, with CQC best placed to regulate healthcare in this sector. Whilst 31% of respondents agreed that there would be a disproportionate effect on small businesses, a number of free-text responses identified this as a positive change to drive up standards of healthcare.

8. Applicable Guidance

8.1 For the registration process, guidance will be issued by CQC to providers on how they should prepare and the information that is required. This will include a dedicated inbox and a dedicated system whereby providers can make contact with CQC via the National Customer Service Centre who will forward enquiries to the registration team. CQC will issue the guidance around August 2026 following a consultation.

8.2 CQC already have powers available to hold providers to account, reflected within CQC's enforcement policy[8], which includes taking action where poor care is identified, registered providers are not meeting the required standard or providers are delivering regulated care whilst unregistered. CQC may work with a provider without using enforcement powers to rectify this, or may take enforcement action, including the pursuit of criminal sanctions where appropriate. Further information on CQC's enforcement powers and policy can be found on their website.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A De Minimis Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies will be two direct costs. These are a CQC registration fee (on-going cost, estimated on a per-business basis) and the administrative burden (cost of implementation).

9.3 The estimated cost to TDDI providers needing to register with CQC is an annual registration cost of £994 for a provider with a single location and a one-off implementation cost of around £150 per provider through administrative costs, such as staff cost, borne by a provider to register. However, the exact overall cost to the sector is not known as there is uncertainty around the number of providers needing to register as the sector is currently unregulated. CQC has provided modelling for

[8] Enforcement policy - Care Quality Commission https://www.cqc.org.uk/guidance-regulation/providers/enforcement/enforcement-policy

registering applications based 25-1000 requiring registration, with transition dates allowing for the larger figure.

9.4 Using the estimated number of providers of 100-1000, the total cost of registration fees across all newly regulated providers is estimated at between £99,400 to £994,000 per annum (£994 per provider). The cost of administrative burden is estimated at between £14,900 to £742,800 (one-off implementation cost). There may be some additional costs for new business that are created and have to register in the future. The number of new businesses that are created each year are uncertain; however, it is likely that these additional costs would be low.

9.5 The legislation does impact small or micro businesses.

9.6 DHSC has considered whether smaller, solo operator-type providers be allowed to continue without regulation. If allowed to do so, they would be able to provide reduced fees compared to those required to register with CQC. DHSC considers this could encourage event and sporting organisers to choose unregulated providers (potentially unknowing that a provider is not registered with CQC), resulting in an unfair market environment for private providers of TDDI and a lack of appropriately regulated healthcare provision at events.

9.7 For those providers of TDDI who work as solo operators and volunteers, some may choose to cease operating or to reduce their provision to not include TDDI. Others may decide to become part of larger organisations who register with CQC and therefore continue to operate. DHSC has considered only requiring larger organisations to register, however, allowing smaller businesses to continue to provide unregulated healthcare would leave service users vulnerable to inadequate care.

9.8 Regarding reducing fees for smaller businesses. Provider fees payable depend on the type and size of a provider and as such, a smaller business would pay less than those with multiple locations, rendering a change to the fee structure unnecessary. Furthermore, CQC is legally obliged to consult should they wish to amend fees, which they are not proposing to do before the SI comes into force. Changing the fee structure would delay the implementation of the amendments which would mean an extended period of TDDI provision in this context being unregulated. This delay is not acceptable to DHSC nor CQC, where fees are already dependent on the number of sites.

9.9 There is no significant impact on the public sector because the direct cost will be borne by the registered providers, not those using the services of such providers. Some providers may choose to increase their service costs to cover cost of registration, but it is not foreseen that cost increases would be burdensome as the ongoing cost is only an annual registration fee.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, the Parliamentary Under-Secretary of State for Health Innovation and Safety has made the following statement.

"The instrument does not include a statutory review clause because the Statutory Guidance under section 31(7) of the Small Business, Enterprise and Employment Act 2015 states that a statutory review period may be inappropriate when there is not expected to be an annualised net impact on business greater than £10 million. That

would be the case here and in the absence of any other factors that would make it particularly desirable to include a review clause I do not consider it appropriate to include such a clause. The legislation will be reviewed as part of DHSC's wider non-statutory review of the impact of the Event Healthcare Standard."

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 The Parliamentary Under-Secretary of State 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) Regulations 2026 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").