

EXPLANATORY MEMORANDUM TO

THE BLOOD AND SAFETY AND QUALITY REGULATIONS AND THE CARE AND SUPPORT (BUSINESS FAILURE) REGULATIONS (CONSEQUENTIAL AMENDMENTS) ORDER 2018

2018 No. 231

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.

2. Purpose of the instrument

- 2.1 This order makes changes to the Blood Safety and Quality Regulations 2005 and the Care and Support (Business Failure) Regulations 2015 which arise as a result of the introduction of the Regulation and Inspection of Social Care (Wales) Act 2016.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Other matters of interest to the House of Commons

- 3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

- 4.1 The Blood Safety and Quality Regulations 2005 (SI 2005/50) implement European Directives setting standards of quality and safety for the collection and testing of human blood and blood components, and their processing, storage and distribution when intended for transfusion. The Regulations also cover the collection and testing of blood and blood components for autologous use.
- 4.2 Following the introduction of the Regulation and Inspection of Social Care (Wales) Act 2016, amendments are required to the definitions of “care home” and “registered person” in regulation 1(3) of the Blood Safety and Quality Regulations 2005
- 4.3 For the purposes of the Blood Safety and Quality Regulations 2005, a care home is a facility at which activities regulated by requirements set out in the Regulations may take place (e.g. a blood transfusion). A registered person is a person responsible for the management of a facility, or in the case of an independent hospital, the person responsible for the management of a hospital blood bank. Under the regulations, the registered person is subject to certain requirements as part of these roles, e.g. providing information to the Secretary of State (regulation 10).
- 4.4 Sections 48 to 52 of the Care Act 2014 impose duties (“temporary duties”) on local authorities in England and Wales and on Health and Social Care trusts in Northern Ireland to ensure that the care and support needs of adults and support needs of carers

continue to be met in circumstances where care providers become unable to carry on because of business failure.

- 4.5 The Care and Support (Business Failure) Regulations 2015 (SI 2015/301) interpret and define “business failure” for the purposes of enforcing temporary duties.
- 4.6 Following the introduction of the Regulation and Inspection of Social Care (Wales) Act 2016, it is necessary to amend the definition of ‘provider’ and the provision defining ‘business failure’ in the Care and Support (Business Failure) Regulations 2015

5. Extent and Territorial Application

- 5.1 This instrument extends to the United Kingdom.
- 5.2 This instrument applies to the United Kingdom.

6. European Convention on Human Rights

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

7. Policy background

What is being done and why

- 7.1 Following the introduction of the Regulation and Inspection of Social Care (Wales) Act 2016, amendments are required to the definitions of “care home” and “registered person” in regulation 1(3) of the Blood Safety and Quality Regulations 2005, which implement European Directives setting standards of quality and safety for the collection and testing of human blood and blood components, and their processing, storage and distribution when intended for transfusion. The Regulations also cover the collection and testing of blood and blood components for autologous use.
- 7.2 This order will ensure that definitions in the Blood Safety and Quality Regulations 2005 reflect new legislation in Wales relevant to those definitions.
- 7.3 Following the introduction of the Regulation and Inspection of Social Care (Wales) Act 2016 amendments are required to the definition of ‘provider’ in the Care and Support (Business Failure) Regulations 2015. An amendment is also required to regulation 2(1)(b) which sets out when a provider’s business is to be treated as a business failure. These amendments ensure that the concept of a “regulated service” which appears in the Regulation and Inspection of Social Care (Wales) Act 2016 is brought into secondary legislation.
- 7.4 This order will ensure that those receiving adult social care in Wales have the same level of protection as adults in England and Northern Ireland in the event of business failure.

Consolidation

- 7.5 There are no plans for the regulations to be consolidated at this time.

8. Consultation outcome

- 8.1 As this order makes no changes to the primary legislation, a consultation was not conducted.

9. Guidance

9.1 The Department of Health and Social Care does not propose to issue any guidance in relation to this order.

10. Impact

10.1 There is no impact on business, charities or voluntary bodies.

10.2 There is no impact on the public sector.

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses but there will be no material effect.

12. Monitoring & review

12.1 The Department of Health and Social Care does not currently plan to undertake a review of the measures introduced in this order, as this order makes no substantive changes to the existing primary legislation.

13. Contact

13.1 Ed Moses at the Department of Health and Social Care email: Ed.Moses@dg.gsi.gov.uk can answer any queries regarding the instrument.