EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (NOTIFICATION) (AMENDMENT) REGULATIONS 2026

2026 No. 535

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.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments and Secondary Legislation Scrutiny Committee.

2. Declaration

2.1 Sharon Hodgson MP, Parliamentary Under-Secretary of State at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Morwenna Carrington, Deputy Director for UK Health Security, at the Department for Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Stephen Atkinson at the Department of Health and Social Care can be contacted by email at the following address with any queries regarding the instrument: stephen.atkinson@dhsc.gov.uk. Alternatively, the department can be contacted by telephone: +44 207 2104926.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument inserts Hantavirus disease (including hantavirus pulmonary or cardiopulmonary syndrome and haemorrhagic fever with renal syndrome) into the list of notifiable diseases by amending Schedule 1 of the Health Protection (Notification) Regulations 2010 ("the 2010 Regulations").

4.2 Whilst "hanta virus" is already included in Schedule 2 (Causative Agents) of the 2010 Regulations and therefore laboratories are required to report positive test results for "hanta virus" to UKHSA, neither "hanta virus" nor the diseases it causes are currently included within the list of diseases set out in Schedule 1 (Notifiable Diseases) that registered medical practitioners must notify to the proper officer of the relevant local authority. Amending Schedule 1 with this update will make Hantavirus disease (including hantavirus pulmonary or cardiopulmonary syndrome and haemorrhagic fever with renal syndrome) a notifiable disease.

4.3 This would mean that doctors would be required to notify their local authority (who in turn would notify the UK Health Security Agency) if they have a patient who they suspect has Hantavirus disease (including hantavirus pulmonary or cardiopulmonary syndrome and haemorrhagic fever with renal syndrome). This will ensure that UKHSA is promptly notified of any potential cases of Hantavirus disease, which will

assist in providing accurate data on the number of cases in England and ensure that information is reported to enable contact tracing, where appropriate.

Where does the legislation extend to, and apply?

4.4 The extent of this instrument is England and Wales.

4.5 The territorial application of this instrument is England only.

5. Policy Context

What is being done and why?

5.1 The 2010 Regulations require registered medical practitioners to notify the proper officer of the relevant local authority if they have reasonable grounds for suspecting that a patient whom they are attending has a notifiable disease, or has an infection which, in the view of the registered medical practitioner, presents or could present significant harm to human health, or is contaminated in a manner which, in the view of the registered medical practitioner, presents or could present significant harm to human health. Prior to this amendment, Hantavirus disease (including hantavirus pulmonary or cardiopulmonary syndrome and haemorrhagic fever with renal syndrome) was not a notifiable disease, and therefore notification relied on a medical practitioner's assessment of the potential for significant harm.

5.2 Whilst domestic cases of Hantavirus disease are rare and of a different strain (Seoul Hantavirus, carried in the UK by both wild brown rats and pet rats; a virus which does not spread between people), in light of the return to the UK of a number of individuals from the ship affected by the Andes strain of the virus (a viral strain that does spread between people), it is considered to be no longer adequate to rely on these provisions.

5.3 This instrument therefore inserts Hantavirus disease (including hantavirus pulmonary or cardiopulmonary syndrome and haemorrhagic fever with renal syndrome) into the list of notifiable diseases in the 2010 Regulations, to ensure that doctors notify local authorities of patients who they have reasonable grounds for suspecting have Hantavirus disease (including hantavirus pulmonary or cardiopulmonary syndrome and haemorrhagic fever with renal syndrome), and provide the relevant information detailed in the 2010 Regulations to allow an appropriate public health response.

6. Legislative and Legal Context

How has the law changed?

6.1 The Public Health (Control of Disease) Act 1984 ("the 1984 Act") and regulations made under it provide a legislative framework for health protection in England and Wales.

6.2 Part 2A of the 1984 Act, as inserted by the Health and Social Care Act 2008, provides a legal basis to protect the public from threats arising from infectious disease. Section 45C of the 1984 Act enables the appropriate Minister (defined in section 45T as the Secretary of State for England, or the Welsh Ministers for Wales) to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in England and Wales. The threat can come from outside England and Wales.

6.3 This instrument is made under section 45C to amend Schedule 1 (Notifiable Diseases) to the 2010 Regulations, to add Hantavirus disease (including hantavirus pulmonary or cardiopulmonary syndrome and haemorrhagic fever with renal syndrome) as a notifiable disease. By adding Hantavirus disease to Schedule 1 of the 2010

Regulations, doctors will be required to notify their local authority (who in turn would notify UKHSA) if they have a patient that they suspect has Hantavirus disease and provide a range of information on the patient that they suspect has the notifiable disease, including name, date of birth, sex, their place of work, home address, the address of anywhere that they are staying that is not their home, overseas travel history and certain information on the timing of diagnosis and symptoms.

6.4 The SI does not impose or enable the imposition of any special restriction or requirement or any other restriction or requirement which has or would have a significant effect on a person's rights.

Why was this approach taken to change the law?

6.5 This is the only possible approach to make the necessary changes.

7. Consultation

7.1 There has been no public consultation in relation to this instrument.

8. Applicable Guidance

8.1 No guidance is published alongside this instrument at this current time.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because there is a low level of impact per business.

Impact on businesses, charities and voluntary bodies

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

9.3 The legislation does impact small or micro businesses. To minimise the impact of the requirements on small or micro businesses (employing up to 50 people), the approach taken is that it would have a minimal additional burden on small businesses because hantavirus infections in people are uncommon. For example, there were only three finished consultant episodes[1] for hantavirus disease in admitted inpatient care in the NHS in England in 2024/25[2] Furthermore, "hanta virus" is already included in Schedule 2 (Causative Agents) of the 2010 Regulations, which requires laboratories to report positive test results of "hanta virus" to UKHSA.

9.4 The basis for the final decision on what action to take to assist small businesses is that no additional support is needed as the impact should be minimal.

9.5 There is no, or no significant, impact on the public sector

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring of this legislation will be kept under regular review.

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[1] Finished Consultant Episodes (FCEs) are not a count of patients. Each episode relates to a period of care for a patient under a single consultant at a single hospital. A patient can have more than one episode of care for the same diagnosis within a reporting period.

[2] hospital admitted patient care activity, 2024/25: Diagnosis https://files.digital.nhs.uk/CC/EA025D/hosp-epis-stat-admi-diag-2024-25-tab.xlsx

10.2 The regulation does not include a statutory review clause.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 The instrument is made under the negative procedure pursuant to section 45Q(3) of the 1984 Act. As required under that section, the instrument includes a declaration that the instrument does not contain any provision made by virtue of section 45C(3)(c) which imposes or enables the imposition of any special restriction or requirement or any other restriction or requirement which has or would have a significant effect on a person's rights.

11.2 The Department regrets that this instrument breaches the rule that statutory instruments subject to the negative procedure should normally be laid, and copies provided to the Committee, 21 days before the instrument comes into force ("the 21-day rule"). In response to the Hantavirus outbreak on the passenger ship MV Hondius, and the return to the UK of a number of its passengers who have been in close contact with infected individuals, urgent action is needed to update the 2010 Regulations for domestic disease surveillance purposes.

12. European Convention on Human Rights

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

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").