EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (NOTIFICATION) (AMENDMENT) REGULATIONS 2025

2025 No. 291

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.

2. Declaration

2.1 Ashley Dalton MP, Parliamentary Under-Secretary for State for Public Health and Prevention 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 of Health and Social Care, confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Shayda Moyassari at the Department of Health and Social Care or email: shayda.moyassari@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 Health Protection (Notification) Regulations 2010 (HPNR) are the primary legislative mechanism for infectious disease surveillance in England. They place a statutory duty on registered medical professionals to report suspected or known cases of notifiable infectious diseases, as well as on laboratories that test human samples to report positive test results of notifiable causative agents (organisms and chemicals that directly or indirectly cause disease). Data reported under the Health Protection (Notification) Regulations 2010 informs the UK Health Security Agency (UKHSA) national and local surveillance systems and dictates the appropriate public health intervention.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument applies to the territorial extent of England and Wales only.

4.3 The territorial application of this instrument applies to England only.

5. Policy Context

What is being done and why?

5.1 The overarching objective of this work is to enhance infectious disease surveillance by strengthening the Health Protection (Notification) Regulations 2010 (HPNR) as the primary legislative mechanism for infectious disease reporting. Having access to better data on infectious diseases informs and improves public health action taken in response and can provide the evidence base for such action, for example, increasing vaccination availability and encouraging vaccine uptake (where vaccines are available).

5.2 Whilst recent changes to schedule 1 (of notifiable disease) and schedule 2 (causative agents) have been made in response to outbreaks such as COVID-19 and Mpox to improve our understanding of circulating levels of these diseases, this is a more comprehensive update that reflects updated scientific and clinical advice.

5.3 To inform these changes, the Department of Health and Social Care (DHSC) ran a public consultation between July and November 2023 to seek stakeholder views on the proposals to update the regulations. The amendments being made to the regulations have been informed by the responses to that consultation. The amendments reflect current surveillance needs to inform public health action at a local and national level and are informed by clinical advice from UKHSA.

5.4 The following proposals have been made:

5.4.1 The addition of eight notifiable diseases to be added to schedule 1 of the regulations: Middle Eastern respiratory syndrome (MERS), Influenza of zoonotic origin, Chickenpox (varicella), Congenital syphilis, Neonatal herpes, Acute flaccid paralysis (AFP) or Acute flaccid myelitis (AFM), Dissemination gonococcal infection (DGI) and Creutzfeldt-Jakob disease (CJD).

5.4.2 The addition of ten causative agents to be added to schedule 2 of the regulations: Middle East respiratory syndrome coronavirus (MERS-CoV), Non-human influenza A subtypes, Norovirus, Echinococcus spp, Tick-borne encephalitis virus (TBEV), Toxoplasma (congenital toxoplasmosis), Trichinella spp, Yersinia spp, Respiratory syncytial virus (RSV) and Candidozyma auris.

5.4.3 The regulatory changes will also expand the reporting requirements for diagnostic laboratories in England testing human samples to report negative and void results for RSV, in addition to positive results already required under the HPNR. Adding RSV will provide complete surveillance to monitor the impact of the ongoing vaccination programme.

What was the previous policy, how is this different?

5.5 With the exception of emergency additions to add COVID-19 to the HPNR in 2020 and Mpox in 2022, which were made in response to the outbreaks of COVID-19 and Mpox clade II respectively, a full review of the notifiable diseases and causative agents listed under the HPNR has not taken place since 2010. Following engagement with clinical and scientific experts in UKHSA to develop the proposals, the Department of Health and Social Care ran a public consultation between July and November 2023 to seek stakeholder views on the proposed additions to the regulations. The subsequent amendments to the regulations that are now being made have been informed by the responses to the consultation and further clinical and scientific advice. The amendments reflect current surveillance needs to inform effective public health action at a local and national level.

6. Legislative and Legal Context

How has the law changed?

6.1 The HPNR will place a statutory duty on registered medical professionals to report an additional eight notifiable diseases listed under schedule 1 and on laboratories to report ten additional causative agents listed under schedule 2 to UKHSA. Furthermore, diagnostic laboratories in England testing human samples will be required to report negative and void tests for RSV, in addition to positive tests already required under the HPNR.

Why was this approach taken to change the law?

6.2 Making the reporting of these additional diseases and causative agents mandatory helps ensures that the UKHSA's surveillance is more robust and comprehensive. Having more robust and comprehensive surveillance data helps inform and ensure that effective public health action can be taken at a local, national, and international level. The final amendments reflect the analysis of the responses to the public consultation and clinical advice from UKHSA.

7. Consultation

Summary of consultation outcome and methodology

7.1 The Department of Health and Social Care ran a four-month consultation between 12 July – 15 November 2023, seeking stakeholder views on the proposals to update the HPNR1 .

7.2 The consultation received 151 responses to the online consultation survey. Of these, 33 individuals responded on behalf of an organisation, 74 individuals said they were responding as an individual sharing their professional views, and 44 individuals said they were responding as an individual sharing their personal views and experience (such as a patient, carer or member of the public). Examples of key stakeholders who responded included the Association of Directors of Public Health, NHS Trusts, local authorities, Royal College of Pathologists, and the Terrence Higgins Trust.

7.3 During the consultation process, a webinar took place to engage over 200 key stakeholders on the consultation.

7.4 Overall, most respondents (87%) agreed that the HPNR should be updated at this time. Responses largely cited improved surveillance and public health protection as reasons for this. The Government's response to the public consultation sets out where the responses to the consultation have been reflected in the final set of amendments being made2.

8. Applicable Guidance

8.1 This SI does not require guidance.

[1] Health Protection (Notification) Regulations 2010: proposed amendments - GOV.UK https://www.gov.uk/government/consultations/health-protection-notification-regulations-2010-proposed-amendments/health-protection-notification-regulations-2010-proposed-amendments

[2] Government response to the Health Protection (Notification) Regulations 2010: proposed amendments - GOV.UK https://www.gov.uk/government/consultations/health-protection-notification-regulations-2010-proposed-amendments/outcome/government-response-to-the-health-protection-notification-regulations-2010-proposed-amendments

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

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

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on business, charities or voluntary bodies. Diagnostic private laboratories range in size and, whilst some may be small businesses, there is not expected to be a disproportionate impact for small businesses as the IT system updates that may be required to support implementation are one-time expenses required to update current systems. These costs would fall far below The Equivalent Annual Net Direct Cost to Business threshold of £5 million (EANDCB) that businesses must consider. The Impact Assessment did not look at this in further detail as it would have been disproportionate to do so.

9.3 The legislation does not impact small or micro businesses.

9.4 There is no, or no significant impact on individuals, the public sector, environment, and competition. It is not expected that there will be a disproportionate impact of this policy by protected characteristics because the amendments impact registered medical practitioners, laboratories and UKHSA public health teams, as opposed to English nationals.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 UKHSA public health teams will monitor the effectiveness of these amendments through engagement with key stakeholders. Evaluation of these amendments will continue as part of future reviews of the HPNR, which will seek to assess whether the notifiable diseases and causative agents included within the regulations remain up to date and fit for purpose; this will include monitoring and reviewing notification numbers under schedule 1 and 2.

10.2 This instrument does not include a statutory review clause and is in line with the requirements of the Small Business, Enterprise and Employment Act 2015.

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 Public Health (Control of Disease) Act 1984 (c. 22).

12. European Convention on Human Rights

12.1 As this instrument is subject to negative resolution 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”).