

**EXPLANATORY MEMORANDUM TO**  
**THE HEALTH PROTECTION (NOTIFICATION) (AMENDMENT) REGULATIONS**  
**2022**

**2022 No. 616**

**1. Introduction**

- 1.1 This explanatory memorandum has been prepared by Department of Health and Social Care (DHSC) and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

**2. Purpose of the instrument**

- 2.1 This instrument makes provision for the purpose of making monkeypox a notifiable disease and monkeypox virus a notifiable causative. This means doctors are required to notify the relevant local authority when they have reasonable grounds for suspecting a patient has monkeypox and that laboratories are required to notify the United Kingdom Health Security Agency (UKHSA) when monkeypox virus has been identified.
- 2.2 This will ensure that UKHSA is promptly notified of any cases of monkeypox, 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.

**3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory Instruments*

- 3.1 The instrument is made under the negative procedure pursuant to section 45Q(3) of the Public Health (Control of Disease) Act 1984 (c. 22). This instrument comes into force the day after it is laid, in breach of the 21-day rule, so that urgent action can be taken to respond to the increased prevalence of monkeypox, including through community transmission, that is being observed in England. We are bringing these provisions forward now to make clear the legal obligations placed on: (a) practitioners to notify their relevant local authority when they have reasonable grounds for suspecting a patient has monkeypox; and (b) laboratories to notify UKHSA if they identify monkeypox virus when they test a sample.

**4. Extent and Territorial Application**

- 4.1 The territorial extent of this instrument is England and Wales only.
- 4.2 The territorial application of this instrument is England only.

**5. European Convention on Human Rights**

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

## **6. Legislative Context**

- 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 (“the 2008 Act”), provides a legal basis to protect the public from threats arising from infectious disease or contamination from chemicals or radiation. It includes powers to impose restrictions on people, and in relation to things and premises, for use in rare circumstances where voluntary cooperation cannot be obtained.
- 6.3 The amended 1984 Act sets out a framework for health protection which requires much of the detailed provisions to be delivered through regulations. Specifically, section 45C of the 1984 Act enables the Secretary of State, who is defined as the appropriate Minister in section 45T as respect to England) to make regulations to prevent, protect against, control and provide a public health response to the incidence or spread of infection or contamination in England. The threat can come from outside England.
- 6.4 This instrument is made under powers including those conferred by section 45C of the 1984 Act, in order to support public health measures put in place for the purpose of reducing the public health risks arising from monkeypox.
- 6.5 This instrument amends the Health Protection (Notification) Regulations 2010, listing monkeypox as a notifiable disease and monkeypox virus as a notifiable causative agent.
- 6.6 Listing monkeypox as a notifiable disease this will require doctors to notify their local authority, and in turn UKHSA, if they have a patient, they suspect of having monkeypox. The effect of the amendments made by these Regulations will also require doctors to provide a range of information on the patient they suspect has monkeypox, including name, date of birth, sex, their place of work, home address, the address of anywhere they are staying that is not their home, overseas travel history and certain information on the timing of diagnosis and symptoms.
- 6.7 Likewise, in listing monkeypox virus as a notifiable causative agent, laboratories will be required to notify UKHSA if they identify monkeypox virus when they test a sample.

## **7. Policy background**

### *What is being done and why?*

- 7.1 The amendments to the 1984 Act made by the 2008 Act comprehensively modernised the legal framework for health protection. Part 2A of the 1984 Act, as inserted by the 2008 Act, takes an “all hazards” approach to health protection, where the criterion for action is based on the potential of an infection or contamination to present significant harm to humans, rather than on specific infectious diseases.
- 7.2 Regulation 2(1)(b) of the Health Protection (Notification) Regulations 2010 requires registered medical practitioners to notify the proper officer of the relevant local authority if a patient whom they are attending 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 medical practitioner, presents or could present significant harm to human health. Prior to

coming into force of the amendments made by these Regulations, monkeypox was not a notifiable disease, and therefore notification relied on a medical practitioner's assessment of the potential for significant harm. While we believe cases have been reliably notified to date, the increased incidence of monkeypox in the United Kingdom compared to past years and, the existence of unlinked incidents with no travel history to monkeypox-endemic countries indicates that monkeypox is being transmitted within the community for the first time. There is also the reporting of multiple cases in other non-endemic countries. Therefore, we consider it is no longer appropriate to rely upon regulation 2(1)(b) to ensure that practitioners notify suspected cases of monkeypox. Instead, this instrument inserts monkeypox into the list of notifiable diseases, putting beyond doubt the obligation being placed upon practitioners to notify patients suspected of having monkeypox and to provide the relevant information detailed in the Regulations to allow an appropriate public health response.

- 7.3 Placing a legal duty on registered medical practitioners to report suspected monkeypox cases, and provide the associated information, will facilitate prompt public health action and, if required, support implementation of timely prevention and control measures. It will also help to ensure an accurate estimate of the burden of disease in England, which will inform control strategies, including the need and planning for post-exposure prophylaxis, vaccines and antivirals.
- 7.4 Similarly, prior to this amendment, monkeypox virus was not a notifiable causative agent, and therefore laboratories were not under an obligation to report positive tests directly to UKHSA. While results were being reported to registered medical practitioners and then notified to local authorities and UKHSA, in light of the increasing prevalence and community transmission of monkeypox, the Department no longer considers it appropriate to rely solely on this method of reporting. Accordingly, this instrument places a duty on diagnostic laboratories to notify UKHSA directly to assess the coordinated public health response to monkeypox.

## **8. European Union Withdrawal and Future Relationship**

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

## **9. Consolidation**

- 9.1 DHSC will keep the need for consolidation of the Health Protection (Notification) Regulations 2010 (S.I. 2010/659), which this instrument amends, under review.

## **10. Consultation outcome**

- 10.1 There has been no consultation in relation to this instrument.

## **11. Guidance**

- 11.1 No guidance is published alongside this instrument at the current time.

## **12. Impact**

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.

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

### **13. Regulating small business**

13.1 This instrument applies to activities that are undertaken by small businesses.

13.2 To minimise the impact of the requirements on small businesses (employing up to 50 people), the approach taken is that it would have a minimal additional burden on small businesses because doctors and laboratories are already voluntarily taking this practice.

13.3 The basis for the final decision on what action to take to assist small businesses as the impact should be minimal.

### **14. Monitoring & review**

14.1 The approach to monitoring of this instrument will be kept under regular review.

14.2 The regulation does not include a statutory review clause.

### **15. Contact**

15.1 Nick Gunning at the Department of Health and Social Care Telephone: 02079725715 or email: [Nicholas.gunning@dhsc.gov.uk](mailto:Nicholas.gunning@dhsc.gov.uk) can be contacted with any queries regarding the instrument.

15.2 Morwenna Carrington, Deputy Director for UK Health Security at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Sajid Javid, Secretary of State, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.