EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (NOTIFICATION) REGULATIONS 2010

2010 No. 659

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 These Regulations create a scheme for notifying actual and suspected cases of infection and contamination in humans to specified bodies with public health responsibilities. This allows prompt action to be taken by those bodies to protect public health where appropriate.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 Regulations 2 and 3 of these Regulations impose obligations on registered medical practitioners (RMPs), but these Regulations do not contain any sanctions by which these obligations can be enforced. This is because the General Medical Council is in a position to oversee compliance with these obligations. As the professional regulatory body for RMPs, the General Medical Council has a wide range of bespoke enforcement tools at its disposal ranging from warnings to declaring a RMP unfit to practise.

4. Legislative Context

4.1 The Public Health (Control of Disease) Act 1984 ("the 1984 Act"), together with the regulations made under Part 2 of that Act, has been the source of public health legislation for many decades (the 1984 Act is itself a consolidation of legislation dating back to 1936).

4.2 The 1984 Act has recently been substantially updated through amendments made by the Health and Social Care Act 2008 ("the 2008 Act"). The updated legislation is contained predominantly in a new Part 2A of the 1984 Act; the existing Part 2 of the 1984 Act is repealed.

4.3 Part 2A of the 1984 Act provides a health protection framework together with regulation-making powers through which the framework may be supplemented. In relation to England, it is proposed that the regulation-making powers will be exercised in two tranches: the first tranche will make domestic or 'in-country' provision; and the second will make provision in relation to England's international borders, i.e. bespoke provision for ports, airports and international train stations.

4.4 These Regulations form part of the first tranche of regulations, i.e. 'in-country' provision. The other two sets of regulations making up this tranche are the Health Protection (Local Authority Powers) Regulations 2010 and the Health Protection (Part 2A Orders) Regulations 2010. Both these latter two sets of regulations are affirmative

and have been the subject of an earlier joint Memorandum; but it is nonetheless proposed that the three sets of regulations are made and come into force on the same date (with the exception of regulation 4 of these Regulations which is to come into force 6 months later).

4.5 Two commitments relating to the use of the regulation-making powers in Part 2A of the 1984 Act and relevant to these regulations were made in the House of Lords during the passage of the 2008 Act:

- to carry out a 12-week consultation (*21 May 2008: Columns GC591-2*) - this commitment has been met;
- that guidance will be produced (*24 June 2008: Columns 1390-1*) - guidance is currently being developed and will be made available in advance of the provisions coming into force.

5. Territorial Extent and Application

5.1 This instrument extends to England and Wales; but applies to England only.

6. European Convention on Human Rights

As these Regulations are subject to negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 The health protection provisions in the 1984 Act (and regulations made under it) were substantially out of date prior to their amendment by the 2008 Act. They applied only to specific infectious diseases, and took no account of new or emerging diseases or of threats from contamination by chemicals or radiation. The requirements for notification of specific diseases were out of date and inadequate to ensure identification of new or emerging diseases which could endanger human health and did not provide for notification of cases of contamination by chemicals or radiation or of infectious diseases diagnosed by laboratories. The powers of Justices of the Peace (JPs) to make orders were inflexible, being applicable only to medical examination, or removal to or detention in hospital; and many of the local authority powers dated back to Victorian society, and failed to meet the needs of the modern world. In addition, there were insufficient safeguards for people who might be affected by the use of the powers.

7.2 The amendments to the 1984 Act introduced in 2008 comprehensively modernised the legal framework for health protection. The new Part 2A 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. It provides a system where local authorities must in most cases apply to a JP for an order if it is necessary to impose restrictions or requirements on people, or relating to things or premises, thereby better protecting individual rights.

7.3 Part 2A requires regulations to be made relating to some aspects of JP orders, and also provides powers to make regulations concerning duties on registered medical

practitioners and others to notify cases of infection or contamination; various other matters relating to JP orders; and the functions of local authorities relevant to their health protection role. Much of the detail of health protection powers and duties is, therefore, to be set out in regulations.

7.4 These Regulations, which provide updated requirements for notification, allowing identification of threats at an early stage, are one of three sets of regulations that taken together provide a three-way approach to protecting public health in England, complementing the primary legislation. The other two sets of regulations deal with local authority powers and the detail of Part 2A Orders. The updated framework for health protection in England which the 1984 Act and the regulations provide will enable local authorities, JPs, the Health Protection Agency (HPA) and the NHS to make a swift response to infection or contamination presenting significant harm to human health, while providing safeguards for anyone who might be subject to the new powers.

7.5 Statutory notification of infectious diseases has been a crucial health protection measure in England since the late 19th century. Notification enables prompt investigation, risk assessment and response by specified bodies to cases of infectious disease that pose a significant risk to human health.

7.6 The aim of this instrument is to improve and strengthen the notification system by:

- updating the list of infectious diseases that doctors are required to notify in the light of current scientific knowledge;
- making provision for notification by doctors of cases of other infection (e.g. caused by new or emerging diseases) or contamination with chemicals or radiation that may pose a significant risk to human health;
- introducing statutory notifications of specified microorganisms by laboratories testing human samples in recognition of the crucial role that laboratories play in diagnosis.

- ***Consolidation***

7.7 This is not relevant as these are not amending regulations.

8. Consultation outcome

8.1 We consulted formally on a draft version of these Regulations, together with draft versions of the Health Protection (Part 2A Orders) Regulations and the Health Protection (Local Authority Powers) Regulations. The consultation ran for 12 weeks, between July and September 2009. Consultees included local authorities, NHS organisations, public and independent sector microbiology laboratories that test human samples, the Health Protection Agency (HPA), the Chartered Institute of Environmental Health, the Local Government Association (LGA), the Local Authorities Coordinators of Regulatory Services (LACORS), the National AIDS Trust and Liberty. The consultation document is available at: http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_102134

8.2 Sixty-eight responses were received. The majority of respondents broadly supported the regulations. The main issues arising and how we dealt with them are summarised below.

8.3 *Lists of infectious diseases and causative microorganisms* - Most comments on these Regulations suggested changes to the proposed lists of notifiable infectious diseases (Schedule 1) and related causative microorganisms (Schedule 2). We have made some amendments to the lists in the light of the consultation, taking account of advice from the HPA. Notable examples of the suggested changes include:

- Chickenpox – suggested but not included in the list of notifiable diseases because the exceptional cases where public health action is needed will be caught under the provision to require notification of infectious diseases not listed that may pose a significant risk to human health.
- Human influenza virus caused by a new sub-type of virus – several respondents suggested removing it because of the difficulties of defining a 'new' strain, the practicalities of notification with large numbers of cases and the fact that it would be primarily identifiable by laboratories (covered by Schedule 2). We agree with the comments made in consultation and have removed this

8.4 *Sexual health/HIV* - Respondents from the sexual health/HIV sector requested that the provision for notifying infections that are not on the list of notifiable diseases be limited to new and emerging diseases, because they were concerned that otherwise doctors might unnecessarily notify cases of HIV or other sexually transmitted infections (STIs). This could deter individuals at risk from seeking medical advice, testing and treatment. However, some existing diseases may need to be notified in special circumstances, so this is not possible. Conversely, other respondents suggested adding HIV and STIs to the list, but this is not necessary as HIV and genito-urinary medicine (GUM) clinics deal with at-risk contacts of those affected as well as offering advice, treatment and testing.

8.5 *Fines and offences* - There were no objections to the removal of the fine and offence connected with the notification of diseases by doctors ("registered medical practitioners"), although some individuals and a professional body disagreed with the proposal to introduce an offence for laboratories failing to comply with the notification requirements without reasonable excuse. However, none suggested any other workable mechanism to enforce compliance.

8.6 *Nurses and other healthcare professionals* – Some respondents suggested that nurses and other healthcare professionals should also have a duty to notify. However, most notifiable diseases will be diagnosed by a doctor and the majority of patients with a suspected notifiable disease are usually seen by a doctor or would be referred to a doctor promptly. Extending the requirement to notify to healthcare professionals other than doctors could cause confusion about whose responsibility it is to notify and could lead to cases not being notified. Guidance will provide advice for nurses and other healthcare professionals when they suspect a person of having an infectious disease or contamination that could pose a public health risk but are not able to arrange for the patient to see a doctor promptly.

8.7 *Timescales* – After consideration of the responses, we have revised the time limit for notification by laboratories to 7 days for non-urgent cases to make it practicable.

8.8 The consultation response document, which includes a full list of consultees, is available on the Department of Health's website at: www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_111046

9. Guidance

9.1 The Department of Health and the HPA, in collaboration with LGA and LACORS, will make available guidance setting out the detail of the new legislative requirements, including operational guidance to assist those who will be responsible for putting the new legislation into practice.

10. Impact

10.1 These Regulations will impose minor impacts on doctors, NHS and independent laboratories, local authorities and the HPA. Most of the cost is due to changes in notifying infectious disease (costs which will fall predominantly to doctors and laboratories). Primary Care Trusts will benefit from saved administration costs as they will no longer be required to pay doctors a fee for each notification. In the event of an outbreak of infectious disease or contamination presenting a risk of significant harm to human health, the benefits achieved by prompt public health investigation and response to prevent spread of infection or contamination could be substantial and would include, for example, reduced morbidity/mortality and reduced costs to the NHS in assessing and treating affected patients.

10.2 An Impact Assessment, covering these Regulations as well as the Health Protection (Part 2A Orders) Regulations 2010 and the Health Protection (Local Authority Powers) Regulations 2010, is attached to this memorandum. The estimates in the Impact Assessment have not changed as a result of consultation.

11. Regulating small business

11.1 It is possible that there may be a small number of independent diagnostic laboratories which are small businesses and to which this legislation applies.

11.2 It is not considered that the regulations will have a significant impact on these laboratories as they are not likely to identify many notifiable microrganisms and software will be available to extract information automatically from local laboratory databases. The notification requirements apply to the laboratory that first receives the sample. As most independent sector laboratories, according to our information, will usually receive samples from other laboratories, they will not be directly affected by the requirements. We received no comments from independent sector laboratories in the consultation although around 40 such laboratories were e-mailed directly alerting them to the consultation.

12. Monitoring & review

12.1 These Regulations, along with the Health Protection (Local Authority Powers) Regulations 2010 and the Health Protection (Part 2A Orders) Regulations 2010, will be reviewed against their objectives in April 2015, in line with the timing for the review of relevant provisions of the Health and Social Care Act 2008.

13. Contact

Gerry Robb at the Department of Health (tel: 020 7972 4430 or email: gerry.robb@dh.gsi.gov.uk) can answer queries regarding these Regulations.