Explanatory Memorandum to the Health Protection (Notification) (Wales) Regulations 2010

This Explanatory Memorandum has been prepared by the Department for Public Health and Health Professions and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Health Protection (Notification) (Wales) Regulations 2010. I am satisfied that the benefits outweigh any costs.

Edwina Hart MBE AM

Minister for Health and Social Services
8 June 2010

1. Description

The Health Protection (Notification) (Wales) Regulations 2010 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.

2. Matters of special interest to the Constitutional Affairs Committee

None

3. Legislative background

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).

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 The updated legislation is mostly contained in a new Part 2A of the 1984 Act, and the existing Part 2 is repealed. A Commencement Order, commencing the changes made to the 1984 Act by the 2008 Act has been made by Welsh Ministers on 8 June and has a coming into force date of 26 July 2010.

Part 2A of the 1984 Act provides a legal basis to protect the public from threats arising from infectious disease or contamination from chemicals or radiation. Overall, the amended 1984 Act sets out a framework for health protection which requires much of the detailed provisions to be delivered through regulations. In relation to Wales, 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 Wales' international borders, i.e. bespoke provision for ports and airports.

These Health Protection (Notification) (Wales) 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) (Wales) Regulations 2010 and the Health Protection (Part 2A Orders) (Wales) Regulations 2010. Both these latter two sets of regulations are subject to the affirmative resolution procedure and were laid before the National Assembly for Wales on 26 April. It is 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 will come into force on 1 October 2010).

Corresponding regulations have been developed and were consulted upon in England. The Health Protection (Local Authority Powers) Regulations 2010, Health Protection (Part 2A Orders) Regulations 2010, and Health Protection

(Notification) Regulations 2010, along with the amendments to the Public Health (Control of Disease) Act 1984, came into force in England on 6 April 2010. The exception to this is the provision in the Health Protection (Notification) Regulations 2010 providing a duty for laboratories to notify, which will come into force in England on 1 October 2010. This is the same date as is proposed for Wales.

Powers
The Health Protection (Notification) (Wales) Regulations 2010 will be made in exercise of the powers conferred by sections 13, 45C(1), (2) and (3)(a), 45F(2)(a) and (b), 45P(2) and 60A of the Public Health (Control of Disease) Act 1984.

These Regulations are subject to the negative procedure as required by section 45Q(1) of the 1984 Act.

4. Purpose & intended effect of the legislation

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, for example by chemicals or radioactive materials. 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 case of contamination by chemicals or radiation or of infectious disease 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.

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.

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.

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 Wales, 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 Wales which the 1984 Act and the regulations provide will enable local authorities, JPs, Public Health Wales 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.

Statutory notification of infectious diseases has been a crucial health protection measure in England and Wales 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.

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.

If these regulations were to be annulled, no updates to the statutory notification system would take place and it would therefore not take account of the full range health protection risks, including other infections or contamination by radiation or chemicals.

Impact

These Regulations will impose a minor impact on doctors, laboratories, local authorities and Public Health Wales. Most of the cost is due to changes in notifying infectious disease (costs which will fall predominantly to doctors and laboratories). Local authorities and Local Health Boards 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.

Guidance

The Welsh Assembly Government, working with the Wales Communicable Disease Legislation Advisory Group, Public Health Wales and other stakeholders 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 in practice.

5. Consultation

The powers in the Public Health (Control of Disease) Act 1984 extend to England and Wales. Welsh Assembly Government officials have therefore been working closely with those in the Department of Health during the development of these regulations as it is considered important to maintain a cohesive approach to public health protection between England and Wales.

In Wales, a Wales Communicable Disease Legislation Advisory Group was established in September 2009 to advise on the content and implementation of the Welsh health protection regulations. This group, comprising of individuals from Public Health Wales, local authorities and other affected stakeholders, has been responsible for advising the Welsh Assembly Government on the development and drafting of the Welsh health protection regulations and the implementation of the new regulations prior to their proposed coming into force.

A formal consultation on the draft versions of these Regulations, together with a draft version of the Health Protection (Local Authority Powers) (Wales) Regulations 2010 and the Health Protection (Part 2A Orders) (Wales) Regulations 2010 was undertaken between 4 November and 13 January 2010. Consultees included local authorities, Public Health Wales, NHS organisations, microbiology laboratories that test human samples, the Chartered Institute of Environmental Health, Food Standards Agency Wales, Professional organisations, the Welsh Local Government Association, the National AIDS Trust and Liberty. The consultation document is available at: http://wales.gov.uk/consultations/healthsocialcare/?lang=en&status=closed

16 responses to the consultation were received. The majority of the respondents broadly supported the regulations as drafted, although some issues were raised which were considered. A detailed analysis of the consultation responses, including how the regulations were amended following the consultation, is available on the Welsh Assembly Government website at:
http://wales.gov.uk/consultations/healthsocialcare/regulations/?lang=en&status=closed

The main issues that arose during the consultation in respect of the Notification Regulations, and how these issues were dealt with, is summarised below:

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 Wales Communicable Disease Legislation Advisory Group and Public Health Wales. 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 – this virus was originally included in Schedule 1, but some 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 from Schedule 1.

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.

Healthcare Associated Infections (HCAIs)

The consultation paper asked if HCAIs should be included in Schedules 1 and 2. Almost all respondents answered that HCAIs should not be included as these infections do not, in the majority of cases, pose a public health threat and HCAIs are captured by existing NHS mandatory surveillance schemes. HCAIs have therefore not been included in Schedules 1 or 2.

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 one organisation disagreed strongly with the proposal to introduce an offence for laboratories failing to comply with the notification requirements without reasonable excuse. This respondent argued that laboratories have reported for many years without a need for statutory requirements. Whilst it is the case currently in Wales that a high notification rate is provided voluntarily by laboratories that test human sample, circumstances may change, and therefore arrangements should be put in place to promote future compliance with the notification requirements.

Nurses and other healthcare professionals

One respondent 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.

Timescales
Following responses received in England and advice from the Wales Communicable Disease Legislation Advisory Group, the time limit for notification by laboratories has been revised from 3 days to 7 days for non-urgent cases to make it practicable.

A full Regulatory Impact Assessment, setting out the costs and benefits of these Regulations as well as the Health Protection (Part 2A Orders) Regulations 2010 and the Health Protection (Local Authority Powers) Regulations 2010, is attached at part 2 of this memorandum.

PART 2 – REGULATORY IMPACT ASSESSMENT

1. Introduction

This Regulatory Impact Assessment aims to appraise the impact of three sets of regulations to protect public health. These regulations take forward the process which began with the Health and Social Care Act 2008 ("the HSC Act") of providing a new, modern framework for the protection of public health from significant harm arising from infectious disease or contamination by chemical or radiological agents.

The HSC Act replaces out-of-date provisions in the 1984 Public Health (Control of Disease) Act 1984 ("the 1984 Act")with new arrangements which:

- take an "all hazards approach" to health protection, rather than focusing only on specified diseases. This enables a quick response to new or unknown diseases or threats (for example SARS or polonium 210);
- take account of developing scientific understanding and provides for a more flexible and proportionate response to outbreaks of infectious disease or incidents of contamination;
- clearly take into account the needs and rights of people who might be affected by them.

Many of the powers in the new Part 2A are contingent powers, to be used in the event of a threat to public health emerging, and a refusal by someone to take voluntary action to address the threat. This combination of circumstances can be expected to arise only rarely, so that the need to use statutory powers to address the threat to public health will occur infrequently. The "Part 2A orders" regulations, and the "Local Authority Powers" regulations, discussed below, are examples of contingent powers (or matters associated with the use of such powers).

Part 2A also allows requirements to be imposed with regard to the recording, notifying and monitoring of public health risks arising from infection or contamination. The "Notification" regulations (see below) address this aspect.

We are introducing three sets of regulations:

i) Health Protection (Notification) (Wales) Regulations 2010

Currently there are provisions in the Public Health (Control of Disease) Act 1984 and the Public Health (Infectious Diseases) Regulations 1988 for statutory notification of specified infectious diseases by registered medical practitioners to the proper officer of the local authority. The new regulations will improve and strengthen these provisions by (a) updating the current list of notifiable diseases (b) introducing provision for notification by registered medical practitioners of other infections or chemical or radiological contamination that present or could present significant harm to human health and (c) introducing statutory notification

of specified infectious micro-organisms by laboratories testing human samples.

ii) Health Protection (Part 2A Orders) (Wales) Regulations 2010

These impose some requirements on local authorities in connection with applications to a Justice of the Peace (JP) for an order under Part 2A to protect the public from infection or contamination. These regulations will provide safeguards for people who might be subject to an order. The regulations cover the evidence to be produced; who must be notified about an application and who can appeal; the person's rights to information and help to access support if needed; and for reports to be sent to the Welsh Ministers.

iii) Health Protection (Local Authority Powers) (Wales) Regulations 2010

These will cover the range and scope of powers local authorities are to have, relating to their health protection role, without needing recourse to a JP. The regulations will replace existing powers in the 1984 Act and will include powers to keep children off school; to disinfect or decontaminate on request; to request action to protect public health; and to prohibit contact with dead bodies which pose a risk.

2. Health Protection (Notification) (Wales) Regulations 2010

2.1 Background

The statutory notification of infectious diseases has been a mainstay of the health protection "armoury" in England and Wales since the late 19th century. Many countries have statutory notification systems in place e.g. France, Germany, the Netherlands, Sweden, USA, Canada, Australia and New Zealand.

The notification system enables prompt investigation and risk assessment of cases of serious disease so that measures can be taken to protect public health. Such measures may include tracing and screening of people who have been in close contact with someone who has a specified infectious disease, ensuring appropriate treatment, immunisation or prophylaxis; or disinfection and decontamination of objects or premises. Currently there are provisions for statutory notification of specified infectious diseases in the Public Health (Control of Disease) Act 1984 and the Public Health (Infectious Diseases) Regulations 1988.

2.2 Reason for updating regulations

The current notification provisions regulations were updated most recently in 1988. In the light of public health developments in the last two decades, they require updating to reflect current threats and opportunities for action to

prevent and control infection and contamination which presents or could present significant harm to human health. For example, the list of notifiable diseases dates back originally to the 1880s, and so does not cover some of the important public health threats today, such as botulism, Legionnaires' disease or diseases caused by exposure to chemicals or radiation. There is also no clear timescale for notification in the current legislation, which may result in missing the window of opportunity for responding effectively to a health threat. Inclusion of all notification requirements in regulations, rather than splitting them between primary legislation and regulations as is the case now, means that they can be amended quickly in future, if necessary, to protect public health.

2.3 Policy objectives

The main aim of the new regulations is to ensure that there is a comprehensive and reliable system for notification of important public health threats from infection or contamination in Wales to enable local authorities, Public Health Wales and the NHS to respond promptly to such threats and control their spread.

The objectives of the proposed changes are:

a. To ensure that registered medical practitioners notify the proper officer of the local authority of suspected or diagnosed cases of notifiable diseases caused by infectious agents, or by other infection or contamination by chemicals or radiation that present or could present significant harm to human health, to enable prompt investigation and response to prevent or control spread of infection or contamination;

b. To ensure timely notification of specified infectious micro-organisms identified by the diagnostic laboratories testing human samples to the proper officer of the local authority so that spread of disease can be prevented or controlled;

c. To ensure all notifications are made in a timely manner that allows preventive or control measures to be taken.

2.4 Options

To achieve the policy objectives, three policy options were considered:
Option 1 - To repeat the current legislative provisions in the new regulations.
Option 2 - To update the list of infectious diseases to be notified by registered medical practitioners.
Option 3 - To proceed as in option 2, and also to introduce:

- statutory notification by registered medical practitioners of other infections or chemical or radiological contamination that present or could present significant harm to human health; and
- statutory notification of specified infectious micro-organisms by diagnostic laboratories testing human samples.

Option 1
For the reasons already explained, the current provisions need updating and therefore option 1 was disregarded.

Option 2
Although this option would update of the list of notifable diseases notified by registered medical practitioners, this option would not include the notification of other infections or chemical or radiological contamination that present or could present harm to human health or require the notification of specified infectious micro-organisms by diagnostic laboratories testing human samples. As the notification of other infections or contamination is the basis of the "all hazards" approach and statutory notification by laboratories will ensure the timely notifications, this option would not fulfil the policy objectives and was not considered appropriate.

Option 3
This option provides a comprehensive and robust notification system that can be updated easily in the future as necessary. Statutory notifcation by registered medical practitioners and laboratories also ensures the timely notification of public health risks, enabling prompt investigation and response to prevent or control of the spread of infection or contamination.

We consulted on option 3. The outcome of the consultation supported this approach.

2.5 Summary of proposed regulations
These regulations make provision for the statutory notification of specified infectious diseases in humans by registered medical practitioners and of specified infectious micro-organisms by laboratories for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in Wales. The regulations also make provision for statutory notification by registered medical practitioners of other infections or chemical or radiological contamination that present or could present significant harm to human health.

These new regulations will replace the current provisions by:

a. Updating the current list of notifiable diseases;
b. Introducing a requirement on registered medical practitioners to notify cases where a patient has died with (but not necessarily because of) a notifiable disease, or other infection or contamination that presents or could present significant harm to human health, unless this has already happened when the patient was alive;
c. Introducing provision for notification by registered medical practitioners of other infections or chemical or radiological contamination that presents or could present significant harm to human health;
d. Introducing statutory notification of specified infectious micro-organisms by diagnostic laboratories testing human samples;

e. Providing timescales for notification by registered medical practitioners and laboratories;
f. Removing provision for nominal payment for notifications by registered medical practitioners, on the basis that the provision of information needed to protect public health is an intrinsic part of the professional duty of a registered medical practitioner, and therefore should be provided without payment.

Overall, the majority of respondents to the consultation agreed with the above proposed changes. However, there were some specific comments and suggestions made during the consultation about the lists of notifiable diseases and organisms and other related issues, which we considered before finalising our response.

2.6 Costs and benefits of the Health Protection (Notification) (Wales) Regulations 2010

Option 1
This no change option would provide no benefit to health protection as the current legislative provisions do not reflect current threats to health protection. This option would also cost local authorities and Local Health Boards in Wales between £6,116 and £18,348 per annum (see 2.6.1 below).

Option 2
This option would have similar costs and benefits to those set out under option 3, however, this option does not include the statutory notification of the full range of health protection risks, including other infections or contamination by radiation or chemicals. Cases of these infections or contamination are very rare (see Annex 1) and therefore the cost savings provided by this option over option 3 is small.

Option 3
The costs and benefits of option 3 are detailed below:

Benefits
Notifications are primarily information to enable prompt investigation and action. They enable local authorities, Public Health Wales, Local Health Boards and other agencies to take necessary actions to prevent further spread of infection or contamination.

In the consultation document we proposed removing two diseases that are currently notifiable by registered medical practitioners from the list - relapsing fever, which is mainly diagnosed by laboratory tests and should be reported by the diagnostic laboratory, and ophthalmia neonatorum, which is usually associated with gonococcal or chlamydial infections and is managed by sexual health rather than health protection services.

Following consultation, we removed leptospirosis from Schedule 1, as the diagnosis on the basis of clinical signs and symptoms is unlikely. We also

removed human influenza caused by a new sub-type of the human influenza virus, as arrangements for notification of cases in the mitigation phase of a pandemic may change according to a range of factors and are, therefore, not suited to a standing statutory requirement.

We proposed adding botulism, brucellosis, invasive group A streptococcal disease, Legionnaires' Disease and SARS to the Schedule 1.

An estimate of the incidence of the infectious diseases that have been added to Schedule 1 and will therefore require notification by registered medical practitioners under the proposed regulations can be found in Annex 1. Most of these infectious diseases occur very rarely. In taking an "all hazards" approach, the draft regulations also require notification by registered medical practitioners of cases of other infections (e.g. new or emerging infections that are not notifiable) or chemical or radiological contamination that present or could present significant harm to human health.

Although the potential incremental benefits of the regulations could be relatively small for much of the time, in the event of a case or outbreak, the impact could be substantial in:

a. reducing morbidity and mortality
b. preventing unnecessary suffering in individuals and families
c. reducing costs to individuals, e.g. due to loss of income or childcare
d. reducing costs to the health service, e.g. inpatient or outpatient care
e. preventing disruption to public services and other businesses due to employee sickness.

As a secondary benefit, data on notifications are also used for surveillance purposes, which provide information that may be relevant, for example, for:

a. reviewing and updating immunisation programmes
b. planning targeted and/or specialist health services, e.g. outreach services or disease-specific clinics designed for high risk groups
c. planning primary care services such as travel health advice.

Without detailed analysis of the incidence (and diagnosis) of the proposed additional notifiable diseases and associated benefits and costs, it is not possible to explicitly quantify these benefits. As we estimate that the additional burdens on registered medical practitioners, laboratories, local health boards, local authorities and Public Health Wales are likely to be small, it would be disproportionate to carry out such detailed analysis.

However, we briefly describe two examples of such benefits, in Italy and in the UK. In Italy there were two outbreaks of hepatitis A reported, which showed clearly that a timely notification, followed by health protection measures (such as immunisation) can help to prevent a considerable number of cases[1]. In the

[1] Bonanni P, et al. Vaccination against hepatitis A during outbreaks starting in schools: what can we learn from experiences in central Italy? Vaccine. 2005 Mar 18;23(17-18):2176-80

UK, an assessment of Legionnaires' disease outbreaks investigations and control measures suggests that such investigations are good value for money[2].

Costs

Costs of updating and extending the current legislative provisions fall on four groups: (i) registered medical practitioners (and local authorities and local health boards); (ii) laboratories; (iii) local authorities; and (iv) Public Health Wales. Costs are considered for each group in this section separately.

2.6.1 Impacts on registered medical practitioners, local authorities and Local Health Boards (LHBs)

Currently, registered medical practitioners (RMPs) are required to notify diseases based on the current list of notifiable diseases. The total number of notifications of infectious diseases (NOIDs) in Wales in 2007 was 6116. In Wales, Local Health Boards are responsible for paying a specified fee to a registered medical practitioner for each notification made. Some local authorities in Wales are also involved in the payment of this fee. Since RMPs currently receive £3.36 per notification, the removal of the nominal payments made to RMPs for notifying diseases is likely, therefore, to reduce such payments by about £20,000 per annum in Wales which is directly equivalent to the savings for the Exchequer. The impact of these provisions on RMPs has already been considered in the context of the Impact Assessment for the Health and Social Care Bill and is not discussed further here. This earlier Impact Assessment can be viewed at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433

There would also be savings to local authorities and LHBs in administration costs associated with processing these payments. We estimate that providing fees for each notification takes approximately 5-15 minutes to process. Assuming an hourly cost of £12 for an administrative worker (see section 2.6.3) we might estimate that Local Authorities and/or Local Health Boards would save £6,116 to £18,348 in Wales nationally per annum.

Some of the additional diseases to be made notifiable are already being reported regularly on a voluntary basis by registered medical practitioners (e.g. Legionnaires' disease, botulism and diseases caused by exposure to chemicals). In addition, most diseases that we propose to add to the list of notifiable diseases, although of significant public health impact, are very rare (e.g. botulism, brucellosis and diseases caused by radiation). We estimate that the total incidence of these diseases is approximately 345 cases per year in Wales (see Annex 1).

We estimate that 50-75% of these diseases are currently being reported by registered medical practitioners on a voluntary basis. The relatively high estimated percentage of voluntary reporting is based on the fact that these

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[2] Lock K, et al. Public health and economic costs of investigating a suspected outbreak of Legionnaires' disease. Epidemiol Infect. 2008 Oct;136(10):1306-14. Epub 2007 Dec 19

conditions are rare but of public health importance, and clinicians regularly seek expert health protection advice. We, therefore, anticipate a minimal increase in the workload for reporting clinicians and, at the receiving end, for local authorities and Public Health Wales (see 2.6.3). We estimate that in total an additional 86 -173 notifications would be made by registered medical practitioners annually in Wales; this assumes that an additional 25-50% notifications of diseases will be made under the new regulations compared to the number of voluntary notifications made now (for details of estimate, see Annex 1).

We assume that each additional notification requires 5-15 minutes of a RMP's time to either complete a written form or to give the required information verbally over the telephone if notification should be made urgently. RMPs include both GPs and hospital doctors (junior doctors and consultants). We therefore take the cost of a RMP's time to be the average of the different costs of GPs and hospital doctors (which is, again, taken to be the average cost of the whole range of hospital doctors)[3]. In addition, we inflate the cost of a RMP's time by 30% (in line with advice from the Better Regulation Executive)[4]. We can, therefore, estimate that an additional £860 to £5536 will fall on RMPs per year for Wales (see following table).

Total additional costs to RMPs

	Lower estimate: 25% increase in notifications	Mid estimate: 35% increase in notifications	Upper estimate: 50% increase in notifications
Number of additional notifications by RMPs	86	121	173
Cost of a RMP's time (per 5/10/15 minutes)	£10.00	£21.00	£32.00
Total additional cost falling on RMPs	£860.00	£2,541.00	£5,536.00

2.6.2 Additional costs to laboratories

All NHS laboratories in Wales currently report voluntarily a wide range of identified micro-organisms for surveillance purposes to Public Health Wales. In the majority of cases, reporting is carried out by electronic extraction of data from laboratory computer systems, and is likely to be complete.

[3] The cost of a minute of an RMP's time is taken from the Unit Costs of Health and Social Care 2008, found at http://www.pssru.ac.uk/uc/uc2008contents.htm See page 109 for the cost of a GP and pages 156-160 for the costs of different hospital doctors time.

[4] BRE advise that employer overheads are set at 30% in addition to staff wages. See paragraph 5.9.2 on page 62 in *Measuring Administrative Costs: UK Standard Cost Model Manual* at www.berr.gov.**uk**/files/file44503.pdf

There are also local arrangements for the laboratories to report identified micro-organisms with significant public health impact to Public Health Wales' local Health Protection Teams urgently, i.e. on the same day. As many of the proposed infectious micro-organisms to be notified under the regulations are already included in the voluntary system or can be added easily, we expect the additional burden on NHS laboratories to be minimal.

The new regulations will also require private laboratories to notify the specified diseases. In Wales, there are 7 Public Health Wales and 5 NHS laboratories reporting approximately 27,000 notifications annually; there are no private laboratories in Wales at present. Whilst we currently do not have any private microbiology laboratories in Wales, the potential for growth in the number of private laboratories necessitates the introduction of statutory reporting and will future proof the legislation.

As we already have complete, or near complete, voluntary reporting from laboratories in Wales, the introduction of statutory notification will have little, if any financial impact on Welsh laboratories. No comments were made during the Welsh consultation that queried the above. However, during the English consultation, some respondents were concerned by the 3 day timescale for non-urgent laboratory notifications proposed in the English and Welsh regulations. Following consideration of the consultation responses, the Department of Health have revised the time limit for non-urgent notification by laboratories to 7 days, from the original proposal of 3 days, to make it practical for laboratories. As some laboratories in Wales test samples from England and visa versa, we consider a common timescale for notification is beneficial. This has been discussed and agreed with the relevant Welsh stakeholders.

2.6.3 Additional costs to local authorities and Public Health Wales from dealing with additional notifications

In 2.6.1, we have estimated that there will be in the region of 86 to 173 additional notifications from RMPs to the proper officer of the local authority. The number of notifications from laboratories is not expected to increase. All local authorities in Wales have appointed an employee of Public Health Wales as their proper officer and notifications are either dealt with by the proper officer or the local authority, depending on the type of notification and local arrangements.

The number of notifications received may increase by 86-173 (between 1.4% to 2.9% increase) as a result of the proposed new notifiable diseases. To estimate the additional burden on local authorities or Public Health Wales from the additional RMP notifications, we might assume that each notification requires 5-15 minutes of administrative time. We take the cost of administrative time here again from the *Administrative Burdens Measurement Exercise.* This estimates that the hourly wage rate of an administrative or clerical worker was £8.28, in 2005 prices. Again, we have updated this estimate to 2008 figures using the Average Earnings Index produced by the Office for National Statistics, and added an additional 30% for employers'

overheads, providing an overall hourly cost estimate of administrative time of £12. The cost estimates are as follows.

Total additional costs to local authorities and Public Health Wales

	Lower estimate	Mid estimate	Upper estimate
Number of additional notifications by RMPs and laboratories	86	121	173
Administration costs to PHW (per notification per 5/10/15 minutes)	£1.00	£2.00	£3.00
Total additional cost to PHW	£86.00	£242.00	£519.00

2.6.4 Additional costs to local authorities

As cases of chemical or radiological contamination will, under the new regulations, require notification, there may be costs to local authorities associated with dealing with these incidents. However, local authorities are already responsible for dealing with such incidents when they arise and therefore we do not expect any additional costs, over and above those which local authorities already incur, as a result of the new regulations.

We consulted on the requirement for the proper officer of the local authority to send copies of individual notifications to the Local Health Board and, as a result of responses we received, we have decided not to introduce such a requirement.

We also removed the requirement for the local authorities to send the new regulations to RMPs in their area, following the consultation, as it is likely to be impracticable. Neither will Public Health Wales be required to send copies of the regulations to laboratories. Non-statutory methods of disseminating the regulations will be used instead.

Therefore, aside from the administrative costs of dealing with the notifications (2.6.3), we estimate that there would be zero additional costs to the local authorities arising from the proposed notification regulations. We estimate that there would be little or no additional cost to the local authorities arising from the proposed notification regulations.

2.6.5 Additional costs to Public Health Wales

As stated in 2.6.3, Public Health Wales receives notifications from RMPs and laboratories as they provide proper officers for local authorities in Wales.

Public Health Wales also already runs a voluntary laboratory surveillance scheme, based mainly on automatic extraction of data from laboratories information management systems for a wide range of organisms. Therefore,

there is little or no additional burden on Public Health Wales from the notification requirements in the regulations.

2.7 Summary of costs for Health Protection (Notification) (Wales) Regulations 2010

Additional costs to:	Lower estimate	Mid estimate	Upper estimate
Registered medical practitioners	£860.00	£2,541.00	£5,536.00
Laboratories	£0	£0	£0
Local authorities/Public Health Wales from dealing with additional notifications	£86.00	£242.00	£519.00
Local Authorities	£0	£0	£0
Public Health Wales	£0	£0	£0
Total Incremental Cost of Option 3	**£946.00**	**£2,783**	**£6,055**
Administrative savings to Local Authorities/Local Health Boards	-£6116.00	-£12,232.00	-£18,348.00
Net cost	-£5,170.00	-£9,449.00	-£12,293.00

The preferred option (option 3) therefore costs between £5,170 and £12,293 less than option 1 (no changes option).

2.8 Risks

There is already a long-standing requirement on registered medical practitioners to report notifiable diseases and a well-established national voluntary surveillance system run by Public Health Wales which has a very high compliance rate. Therefore, the risk of the new notification provisions not being implemented effectively are probably very low. This risk will be mitigated by the provision of information and advice from the Welsh Assembly Government (advised by the Wales Communicable Disease Legislation Advisory Group), local authorities and Public Health Wales about the new requirements and associated training (see section 5 on the costs associated with this training).

The risk of the new notification system not being sensitive to new and emerging infections or contamination by chemicals or radiation has been addressed by including provision for reporting by registered medical practitioners of non-notifiable diseases or disease caused by chemicals or radiation that could present or present a significant risk to human health.

Having the list of notifiable diseases in regulations rather than primary legislation makes it straightforward to update the list in future if necessary.

2.9 Data burdens on the public sector

As mentioned above (section 2.6.1 and 2.6.3) we anticipate a small increase in the workload for reporting clinicians and those receiving this information (local authorities and Public Health Wales).

3. Health Protection (Part 2A Orders) (Wales) Regulations 2010

3.1 Background

An order made under the new Part 2A of the 1984 Act may require a person to be detained, isolated or quarantined, or impose other restrictions on them; or may require a person to do, or not do, certain things, in order to protect public health. A Justice of the Peace (JP) may also make an order about things or premises, for example that they be seized or disinfected, or that premises be closed. In all cases, the JP must be satisfied that clear criteria as to the type and degree of risk, and the necessity for an order, as laid down in the Act, are met. The impact of these provisions was considered in the context of the Impact Assessment for the Health and Social Care Bill and is not repeated here. This Impact Assessment can be viewed at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_080433.

3.2 Reason for intervention

Welsh Minsters are required to make regulations on some aspects of the new arrangements for Part 2A orders and may do so on others (see 3.4 below). It is proposed to use these powers to provide increased safeguards for individuals affected by the new arrangements.

3.3 Policy objectives

The objectives are to:

- set evidential requirements which assist JPs to reach a decision on applications for orders, while being sufficiently flexible to allow applications to be made in an emergency when some details of the circumstances may not be known;
- protect interests of people affected by a JP order, without jeopardising necessary action to protect public health;
- ensure vulnerable people are supported by an obligation on local authorities to provide information or in certain cases to have regard to their welfare;
- to allow monitoring of orders made or applied for by instigating a system of reporting applications for orders.

3.4 Options

Three options for these regulations were considered.
Option 1 - regulate only on things which the Act requires us to regulate about.
Option 2 - use all the Act’s relevant powers to make regulations.
Option 3 - regulate on things which the Act requires us to regulate about, and also on some, but not all, of the matters where we have powers to do so.

Option 3 was proposed and consulted upon for the reasons below.

Option 1
Part 2A **requires** regulations to be made on a limited number of matters, and **allows** regulations to be made on a range of others.

Welsh Ministers **must** make regulations about the evidence to be available to a JP before the JP can be satisfied that the criteria for an order restricting a person, or imposing any requirements on him or her, are met. Part 2A also requires regulations to be made about who must be notified that an application for an order is being made.

Option 1 would therefore mean that regulations would cover only the evidence a JP must have before making an order about a person, and who must be notified of an application for an order. We do not think this would be adequate to meet the policy objectives of these regulations.

Option 2
Part 2A allows (rather than requires) regulations to be made about the following matters relevant to JP orders:
- the evidence to be available for orders about things or premises
- any other persons, in addition to those specified in the Act, who are "affected persons" (that is, who can apply for variation or revocation of an order by virtue of being personally affected)
- the measures to be taken in connection with Part 2A orders. This could cover anything relevant to the taking of measures, including what investigations might be made as part of a medical examination, the manner in which measures are to be taken, who is responsible for execution and enforcement, liability for costs and payments of compensation or expenses.

Regulations may also be made conferring functions on local authorities or other persons in relation to monitoring of public health risks.

A wide range of matters might therefore be covered in the regulations. Option 2 would entail regulations covering all of the topics listed above. While we propose to use the powers to regulate about some of these, we consider that it is not necessary to use all the powers available and that this would incur unjustified expense.

Option 3
This option covers the topics we are required to regulate about together with those which Ministers (during the passage of the Health and Social Care Bill) made a commitment to include in regulations, or which we think are needed to provide a further safeguard for individuals.

We proposed that the regulations should cover:
- the evidence to be available to a JP before making an order about a person;
- that the next of kin of the deceased is an "affected person" if an order involves a dead body or human remains;

- who must be notified of an application for an order - to include the next of kin of the deceased if an order is made involving a body or human remains;
- a local authority duty to provide information to people subject to an order;
- a local authority duty to report applications for orders to the Welsh Ministers;
- a local authority duty of care for anyone whose liberty is restricted by an order so that they cannot care for themselves or any dependents.

We have considered whether the policy objectives could be achieved other than by regulation - for example, through guidance or reliance on good practice. We do not think this would work in respect of any of the duties proposed in these regulations. The possible exception is the duty of care provision, which might be argued to be simply good practice not requiring regulation. On balance, we think it is right to put the matter beyond doubt by statutory requirement. The duties to notify the next of kin, to report orders and to provide information, were agreed by English Ministers during the passage of the Bill to be matters which should be included in the English regulations; we consider these matters should also be included in the Welsh regulations.

The outcome of the consultation supported this approach, with a number of respondents making particular points which are considered below.

3.5 Costs and Benefits

<u>Option1</u>
This option will only require regulation on:

- the evidence that a JP must have before making an order about a person;
- who must be notified that an application for an order is being made, i.e. an "affected person"

The costs and benefits of regulating on these two aspects are provided under option 3 and are estimated at between £0 and £594 (see 3.5.1 and 3.5.3).

<u>Option 2</u>
As explained above, this option would require regulations to use all of the Act's relevant powers to make regulations. Whilst the benefits of this option are that the any requirements are explicit in regulation, it was considered this amount of regulation would incur unjustified expense. For example whilst requiring that certain evidence is presented to a JP before an order about a person can be made is a necessary safeguard, we do not consider the same safeguards need be applied to orders in connection with things or premises.

As explained above, option 2 would entail higher costs for local authorities to deliver the extra requirements. These are difficult to quantify, although they would not be substantial.

The costs and benefits of regulating on those aspects that it is proposed the regulations should cover are provided under option 3 below.

Option 3

This option covers the topics we are required or have made a commitment to regulate about together with those which are considered to be required to provide a further safeguard for individuals. This option is the preferred option.

We believe that there will be no impact on the voluntary sector. The estimated impact on business and the public sector is discussed below.

3.5.1 Evidence that a JP must have before making an order about a person

Benefits

The regulations require evidence to be given by a suitably qualified person on the key aspects of the statutory criteria, for all orders relating to a person. In brief, the evidence must give the reasons for believing that the person is infected or contaminated; summarise the characteristics and effects of the infection or contamination; assess the risk the person poses to others; and assess the options available to deal with the risk, to show why an order is necessary.

The benefits are:

- an increased safeguard for an individual who might be subject to an order, to ensure that an order cannot be made without clearly identifiable grounds;
- JPs will be assisted in reaching their decision, because the grounds for an order will be clearly specified.

Since it is likely that this part of the regulations will formalise what is already best practice, we have assumed that no monetary benefit arises as a result.

Costs

The requirement will impose a minimal extra burden on local authorities in applying for an order. We believe that the requirements formalise what is done now in the course of usual good practice. In addition, we understand from local authorities in Wales that the number of applications for orders is currently low and expected to remain so, between 0 and 2 per annum.

The Impact Assessment for the Health and Social Care Bill assessed the cost of making an application to a JP at £1,500. We assume an additional cost of between 5-15% for each order to comply with the evidential requirements (and for the sake of argument, that all orders will involve a person).

Using a standard cost model this shows additional costs in the range as follows:

	Lower estimate	Mid estimate	Upper estimate
Number of orders (per annum)	**0**	**1**	**2**
Additional cost of making an application to JP	**5%**	**10%**	**15%**
Total costs	**£0**	**£150.00**	**£450.00**

3.5.2 *Affected persons*

Benefits
An “affected person” has the right to apply for variation or revocation of an order. As a result of the consultations in England and Wales, and upon the advice of the Advisory group, we are using the power to regulate about who is to be an affected person to prescribe that, where a person subject to an application for an order has a “decision-maker” (a donee of lasting power of attorney, or enduring power of attorney, under the Mental Capacity Act, or any deputy appointed by the Court of Protection, who is authorised to act for them in that respect), that person is to be an affected person. We are also, as proposed in consultation, prescribing the next of kin of the deceased person in respect of orders involving a dead body or human remains.

The benefits of adding "decision-maker" and "next of kin" to the list of “affected persons” who have the right to apply for variation or revocation of an order are that:

- it is put beyond doubt that any decision-maker for a person has a clear legal right to challenge an order made against a person they are authorised to represent;
- the next of kin will have the opportunity to influence decisions regarding their relative’s final arrangements, which could be of considerable significance to that person.

Costs
We do not think any costs apply to the designation of a decision-maker as an affected person. This situation would arise very rarely, and it is likely that a formal decision-maker would, in practice, be entitled to represent the person in any event - the regulations simply put that beyond doubt.

A next of kin might exercise the right to apply for variation or revocation, therefore impacting on the work of local authorities and JPs. However, an order involving a body or human remains - for example, for burial or cremation - would be a rare occurrence. We might assume less than one a year. It would be inappropriate to assume that the deceased person would have a next of kin, or that the next of kin would always apply for variation or revocation. The impact, therefore, is likely to be somewhat less than one extra application a year nationally, and so can be regarded as having no significant impact or costs.

3.5.3 Persons to be notified of an application for an order

Benefits
For orders relating to people, notification is to be made to the person concerned, or their parent in the case of a child, or any "decision maker" (see above), where decisions about orders are within the scope of the person's authority. Should an application be made for an order involving a dead body or human remains (see above), the next of kin must be notified. For orders relating to things or premises, the owner, or person with custody or control, or occupier, as the case may be, must be notified. The duty will not apply if there are good reasons why the relevant person should not, or cannot, be notified.

The benefit is therefore that those most directly affected by an application for an order will be aware of it and in a position to represent their interests to the JP, or, if an order is made, to apply for variation or revocation if they wish (by virtue of being affected persons under the legislation).

Costs
We do not think that this duty imposes a significant burden on local authorities. In practice, anyone involved in an order in this way would be sure to be notified, unless there were good public health reasons for not doing so. The extra costs would therefore be minimal. No comments were made during the Welsh consultation on who might carry out this work, but we have assumed the costs are attributable to administrative time. We might assume between 2 and 6 hours of administrative time per order. We take the cost of administrative time here, and throughout when looking at the general administrative burden on local authorities under the Part 2A regulations, from the *Administrative Burdens Measurement Exercise*[5]. This estimates that the hourly wage rate of an administrative or clerical worker was £8.28, in 2005 prices. We have updated this estimate to 2008 figures using the Average Earnings Index produced by the Office for National Statistics[6], giving an hourly wage rate for administrative and clerical staff in 2008 of £9.29. In addition, the Better Regulation Executive advises that employers' overheads are included when considering the cost of administrative time[7], providing an overall hourly cost estimate of administrative time of £12. Assuming that there are between 0 and 2 orders per year, the cost range is therefore as follows.

[5] See, in particular, the *Administrative Burdens Measurement Exercise – Technical Summary*, page 20 for details on hourly wage rates of administrative and clerical staff. (Both the full report and technical summary can be found at http://www.berr.gov.uk/whatwedo/businesslaw/better-regulation/simpplan/page35599.html.)
[6] http://www.statistics.gov.uk/StatBase/tsdataset.asp?vlnk=392&More=Y
[7] BRE advice that employer overheads are set at 30% in addition to staff wages. See paragraph 5.9.2 on page 62 in *Measuring Administrative Costs: UK Standard Cost Model Manual* at www.berr.gov.uk/files/file44503.pdf

	Lower estimate	Mid estimate	Upper estimate
Number of orders (per annum)	**0**	**1**	**2**
Cost of administrative time per order (per 2/4/6 hours)	**£24.00**	**£48.00**	**£72.00**
Total costs	**£0**	**£48.00**	**£144**

3.5.4 Duty to report applications for orders to the Welsh Ministers

Benefits
During the passage of the Health and Social Care Bill the UK Minister agreed that all orders in England should be reported centrally. The English regulations require all applications for orders, orders made and any variations or revocation of an order are reported to the Health Protection Agency. The Welsh regulations include equivalent provisions for Welsh orders; all orders, application and variations or revocation of an order will be reported to the Welsh Ministers. Relevant information from these orders will be published by the Welsh Assembly Government annually

The benefits, of all orders being reported centrally, are
- to allow transparency as to the extent of the use of the powers when the new Part 2A comes into force;
- potentially provides a fuller picture of health protection activity than reporting of orders alone.

Costs
We are not aware of any instances of an application which did not result in an order (although the order might have differed in some respects from what was applied for). We do not therefore consider that requiring reporting of applications, rather than of orders actually made, imposes any significant further burden on local authorities. Variations or revocations of an order should not be frequent events and we do not think a requirement to report these will add any significant costs.

This duty will entail the local authority copying the application and the order (with all details of individuals who are the subject of the application removed), together with some relevant administrative details, to the Welsh Ministers. Should an order not be made, the reasons for this are to be given.

We estimate that this would require somewhere in the region of 4-8 hours of administrative time by the local authority, at a cost of £12.00 per hour. Using the standard cost model, this shows costs in the range as follows.

	Lower estimate	Mid estimate	Upper estimate
Number of orders (per annum)	**0**	**1**	**2**
Cost of administrative time per order (per 4/6/8 hours)	**£48.00**	**£72.00**	**£96.00**
Total costs	**£0**	**£72.00**	**£192.00**

3.5.5 Duty to provide information

Benefits
The regulations will require the local authority to give information about how the order works, the reasons for it, the person's right to apply for variation or revocation, and any relevant services available, to anyone who is the subject of an order (one person only per order).

The benefits are:

- the person understands the reasons for the order and what it does and why, and how to apply for variation or revocation if they wish;
- public health protection is improved, because a person who does not understand what an order does will not be a position to comply.

Costs
This duty should not impose a significant burden on the local authority. It requires the authority only to take all reasonable steps to ensure the person understands the reasons for the order and what it does and why, and how to apply for variation and revocation. Nor does it require the authority to provide any particular service; the duty relates to information, not provision. We consider that the requirement formalises good practice, and that no significant extra costs therefore accrue.

3.5.6 Duty of care

Benefits
The need for this duty was supported by respondents to the consultation. The local authority is to be required to have regard to the welfare of any individual who is placed under detention, isolation or quarantine by a JP order, and of any dependents.

The benefit is:

- an extra safeguard for people whose liberty is restricted by an order, to ensure that this does not impact on the person's or dependents' needs for care or essential services.

Costs
The need for action under this duty is likely to arise only rarely. The local authority may charge for any services provided, using their powers in section 93 of the Local Government Act 2003, and will therefore be able to recoup

any costs. We do not consider that additional costs can be identified as arising as a result of this requirement.

3.5.7 Local authority power to charge for measures taken under a JP order

Before the consultation document was issued, it became apparent from discussions with the Department of Health that the legislation does not provide for local authorities to make a charge for the costs of any measures it needs to carry out as a result of a JP order. This could arise, for example, if an order were made for premises to be disinfected or decontaminated, but the owner of the premises was unable or unwilling to carry out the measures required.

A proposal was therefore included in the consultation document that local authorities should be able to make a reasonable charge for reimbursement of costs they might incur if it fell to them to carry out any measures required under a JP order relating to things or premises (not those relating to people). We asked in the consultation paper whether there were any circumstances in which such a charge should not be made, and invited any further comments on the issue. All those who answered this question felt that local authorities should be able to make a charge.

As a result, we have included in the regulations (under powers in local government legislation) a power for local authorities to levy a discretionary charge where it becomes necessary for them to take the required action, because the person to whom the order is directed cannot or will not do so. This will apply only to orders in relation to things or premises, not to people. The amount of the charge must be reasonable, and not exceed the actual costs to the authority. Where the person or business concerned would have difficulty in paying the charge, the authority might choose not to levy a charge, as they have discretion not to do so. In any event, the authority must act reasonably, in accordance with the standard principles applying to public bodies.

Benefits
The circumstances in which this situation might arise will be rare. However, if those rare circumstances do arise, as has happened in the past, this provision will help to ensure there is no disincentive for local authorities to take health protection measures. Public health should therefore be safeguarded.

Costs
We do not think any appreciable costs arise to local authorities or business. The power to levy a charge allows a local authority to recoup costs in the rare circumstances where the expenditure needed might cause problems. To some extent this provision mirrors current powers, which allow a local authority to disinfect articles or premises at an occupier's cost to prevent the spread of disease. The main differences are that this new power to charge applies only in the case of a relevant JP order, and the scope is wider, covering cases of contamination as well as infection. However, the need to

use this provision will arise only rarely, so that the impact on business interests or individuals is unquantifiably small.

3.5.8 Time limit for JP orders about a person

The consultation raised the question of whether the regulations should place a time limit on JP orders, over and above the 28-day limit placed in the Act on orders imposing detention, isolation or quarantine. The regulations therefore impose a 28-day time limit on all orders made in respect of a person. This might apply, for example, if an order were made for a person to stay off work, or requiring their health to be monitored. It could also mean that a one-off event imposed under a JP order - such a medical examination - had to take place within 28 days.

The regulations will not set a time limit for an order about “things” or premises, which will be a matter for the JP.

<u>Benefits</u>
This measure provides an extra safeguard for an individual subject to an order.

<u>Costs</u>
We do not think this measure entails any extra costs. JP orders will be rare in any event. It is also hard to envisage a scenario where a JP would wish to impose a restriction lasting over 28 days but will be prevented from so doing under this regulation. There is a notional possibility that a local authority would need to apply for an extension to an order that would not have been necessary if the order were still running. However, this is likely to happen so infrequently that we do not think that any extra costs can be identified from this requirement.

3.6 Summary of costs arising from the Health Protection (Part 2A Orders) (Wales) Regulations 2010

In summary, we estimate the total extra costs falling to the local authority from these regulations as follows.

		Lower estimate	Mid estimate	Upper estimate
I	Evidence for JP orders	£0	£150.00	£450.00
II	Affected persons	£0	£0	£0
III	Notifications to individuals of order	£0	£48.00	£144.00
IV	Reporting of applications for orders to Welsh Ministers	£0	£72.00	£192.00
V	Duty to provide information	£0	£0	£0
VI	Duty of care	£0	£0	£0
VII	Local authority power to charge	£0	£0	£0
VIII	Time limit for JP orders	£0	£0	£0
	Total cost of these regulations	£0	£270.00	£786.00

3.7 Risks

There are some risks associated with our proposed measures:

- the evidential requirements will delay or hinder applications in an emergency;
- JPs will find the evidential requirements unhelpful and will be deterred from making an order.

Adequate preparation before the regulations come into force should mitigate these risks. In the case of the second, we will work with the Department of Health to liaise with the Ministry of Justice and the Justices' Clerks' Society to try to ensure that clerks advising JPs are apprised of the requirements, along with, of course, the new provisions in Part 2A itself. We are also working with the Wales Communicable Disease Legislation Advisory Group to produce guidance to support implementation. (We have not assigned costs to JPs' clerks from the new requirements, because cases arise only rarely and clerks are unlikely to engage substantially with the changes until presented with a case requiring knowledge.)

We do not foresee any other significant risks.

4. Health Protection (Local Authority Powers) (Wales) Regulations 2010

4.1 Background

Local authorities currently have a range of powers under the Public Health (Control of Disease) Act 1984 to protect public health. Many of these powers are out-of-date. The new Part 2A provides a framework to modernise these powers.

4.2 Reason for intervention

Part 2 of the 1984 Act will be repealed when the new Part 2A is brought into force. Part 2 gives a number of standing powers to local authorities to exercise a public health protection function. The new Part 2A gives powers to JPs so that they may make an order specifying actions to be taken to protect human health, on application by a local authority. However, we think it is necessary for local authorities to retain, in an updated form, some of the powers and duties from Part 2, for use when judicial oversight is not necessary. The Health Protection (Local Authority Powers) (Wales) Regulations 2010 provide these powers and duties.

4.3 Policy objective

We want local authorities to have sufficient powers to enable them to continue to play their front-line role in health protection, while protecting the rights of people who might be affected. To this end, we have retained certain powers from the current Part 2, with some necessary modernisation to these powers in order to meet modern human rights expectations.

4.4 Options

Option 1 - Do nothing, i.e. rely on informal action backed by JP powers.
Option 2 - Use all the Act's relevant powers to make regulations.
Option 3 - Regulate to provide powers and require functions only where a need to do so to protect public health can clearly be seen.

<u>Option 1</u>
We do not believe this is a valid option. Engagement with stakeholders has indicated that there is a need for a local authority to have some powers available to enable formal action to protect public health, without resorting to applying for a JP order. The exercise of powers by a local authority will still be subject to strict criteria regarding their use, equivalent to the requirements that must be satisfied to get a JP order. We therefore consider local authorities should have some powers to protect public health.

<u>Option 2</u>
Part 2A of the Public Health (Control of Disease) Act allows regulations to be made to give local authorities powers in a variety of circumstances. We considered whether all the regulation-making powers should be used and

concluded that at this stage not all are required. For example, we do not currently propose to take an explicit power for a local authority to prohibit or restrict an event or gathering, as we do not think it currently necessary. This can be reviewed as necessary in the future. In the meantime, the local authority could use their request power (see 4.5.4) to deter a gathering, or apply for a JP order as necessary.

Option 3
We propose to regulate to provide powers and require functions only where a need to do so to protect public health can clearly be seen. The regulations therefore retain and/or update the existing legislation to enable local authorities to:

- keep a child away from school;
- require a list of contact details of pupils at a school;
- disinfect or decontaminate;
- request cooperation for health protection purposes;
- restrict contact with dead bodies.

We think the regulations strike the correct balance between action that only a JP order should be able to require, and measures that a local authority can require without reference to a JP.

We proposed, and consulted on, option 3.

4.5 Costs and Benefits

We believe that these regulations will have a negligible impact on business and no impact on the voluntary sector.

Option 1
By pursuing option 1, local authorities would not be able to control public health risks without a JP order. This is not considered reasonable, given that local authorities already have powers and use them to good effect to protect public health. If this option were pursued the number of JP orders and therefore the costs associated with orders is likely to increase (see Part 2A Orders regulations).

Option 2
In addition to the costs and benefits associated with option 3 (below), we do not consider there to be significant health protection benefit from using all the regulation-making powers available to provide powers to local authorities. Whilst we do not consider local authorities would use a power to prohibit or restrict an event or gathering frequently, we do not think there is a need currently to provide regulations on this issue.

Option 3
The costs and benefits associated with this option are below.

4.5.1 Keeping a child away from school

Under current legislation, a local authority can issue a notice to keep a child away from school. Notices made under this power are made very infrequently; voluntary cooperation, where the parent clearly understands the reason for their child being asked to stay away from school, is always the objective. Such voluntary cooperation is more likely to be successful in protecting public health (and the interests of the child in question) than a strict legislative restriction on attendance. Powers to issue a notice are however required for the instances where voluntary cooperation is not forthcoming.

Some small changes to this power have been made in order to modernise it, including:

- the notice of the requirement to stay off school is time-limited to 28 days,
- the headteacher or person in charge must be informed of the notice,
- the parent can request a review of the notice - the local authority must then carry out a review, but only one review has to take place in any one notice period.

At consultation, we asked whether the requirement for a local authority to review a notice would work fairly in practice. The majority of respondents agreed that it would. The Department of Health asked the same question during their consultation exercise. Some of those who did not agree felt that the review would not be undertaken with the appropriate degree of independence. Some respondents also suggested setting out a detailed and independent mechanism for these reviews, but we and the Department of Health do not think this would be proportionate to the numbers likely to be affected. A requirement that the review must be conducted by someone who was not involved in the original decision to issue the notice was considered but we do not believe this would be practicable, because in effect the notice is served by the council as a body. The small size of some environmental health teams and the way in which they work could make it difficult to identify a person who was genuinely independent of the original decision. In practice, liaison with the other health protection professionals in Public Health Wales creates an element of independence in both the original decision to serve the notice and in the review.

Benefits

The chosen policy option of modernisation with the small modifications outlined above ensures that this power protects human health but also safeguards the rights of those that may be affected by its use. There are no cost benefits compared to the current legislative power to keep a child off school.

Costs

Notices to keep a child away from school are currently made very infrequently. Because the numbers involved are so small, we believe the minor modernisations proposed should incur no significant cost burden beyond that currently incurred. They require actions that a local authority

might take as a matter of course under the existing arrangements, even though they are not set down in law. For example, it would be reasonable to expect that a local authority would keep a headteacher appraised of a situation affecting a pupil at their school; it would reasonable for the local authority to regularly review the requirement and the child's health while a notice is in force and on a request by the parent. Current practice is that the health of the child is kept under review over the period of the notice, even though this requirement is not currently set down in legislation.

It is not predicted that this power will create any burden on business.

4.5.2 Local authority power to request a list of names of pupils at a school

Under current legislation, a local authority can require the headteacher of a school to provide the authority with a list of the names and contact details of pupils at the school. This power is to be modernised so it can be used if a child or member of staff is, or is suspected of being, infected or contaminated with an infection or contamination that presents, or could present significant harm to human health.

We believe that the power to request a list of names of pupils at a school if necessary should remain a local authority power, since without this power the authority would then have to apply for a JP order to require these contact details. We do not believe judicial oversight should be required to be able to exercise this power.

At consultation stage, it was proposed that the power would apply only if a child or member of staff at the school was, or was suspected of being, infected or contaminated. Following feedback received during the English and Welsh consultations, we have extended this to include possible exposure to visitors to the school who are, or are suspected of being, infected or contaminated. This slight amendment will have a negligible impact on resources.

During the English consultation, several respondents suggested that this power should be widened to allow local authorities to request the contact details of adults as well as children, for example staff and visitors. However, we and the Department of Health have not revised the regulations in this way on the basis that a local authority may apply for a JP order if the contact details of adults were necessary.

Benefits

The existing power contains a compensation requirement, whereby the local authority is obliged to pay the headteacher 2p per 25 names provided. We have not continued this compensation requirement because we do not consider it has any merit in encouraging compliance. Rather, it just increases costs and the administrative burden of the overall procedure. Dropping the requirement to pay compensation reduces the overall potential burden of the power on local authorities. We therefore assume that the cost to the school of no longer receiving this compensation payment is counteracted by the cost

saving to the local authority (and, possibly, the school itself) of reduced administrative burden, so that the net benefit of the change in policy is assumed to be approximately zero.

Costs
We estimate that the incremental cost of policy changes under this section is zero, compared to the current situation. It is not predicted that this power would create any burden on business.

4.5.3 Local authority power to disinfect/decontaminate

Under current legislation, a local authority may provide a disinfection station to have any article brought there disinfected free of charge. We therefore included in the consultation draft regulations a discretionary power for the local authority to disinfect or decontaminate an article (including a conveyance) or a premises, or have this done (perhaps by using contractors) at the request of the owner of the article or the premises, or the tenant of a premises. In the consultation, we asked whether there was a need for this power to be retained and updated. All respondents who answered this question agreed that there was such a need.

One point picked up during the English consultation was that the regulations should refer to 'articles' rather than 'things' in order to achieve consistency with the parent legislation. We have redrafted the wording accordingly to mirror that in the English regulations.

Benefits
The benefit is that a clear, swift means for a local authority to deal with infection or contamination is in place, so helping to avoid risks to public health.

Costs
The regulations enable the local authority to provide this service only when they consider it necessary, and to pass on their costs for the provision of this service to the service user. Any such services must currently be provided free of charge (although the rarity of their current use makes comparisons invalid). We do not therefore expect any financial impact on the authority because of the modernisation of this power.

There will be a cost impact on individuals or businesses who request this service. This is unquantifiable and will arise only on the occasion where the service is used. It is likely that if the local authority did not provide the service, the individual or business would either need to contract for it privately, or incur greater costs at a later stage to deal with an infection or contamination which takes hold or spreads.

In addition, the local authority can only disinfect/decontaminate premises at the request of the tenant if they are reasonably satisfied that the premises will not be devalued because of disinfection/decontamination.

4.5.4 Local authority power to request cooperation for health protection purposes

Local authorities currently have a number of powers to require people to do certain things to protect public health (for example, to stay off work). We have replaced these provisions with a single, general power for a local authority to request cooperation to prevent, protect against, or control an incidence or spread of infection or contamination presenting significant harm to human health.

In the consultation, we asked whether this power would be helpful. All respondents who answered this question felt that it would. In the consultation, we proposed a discretionary power to pay an incentive payment, compensation or expenses to comply with the request. During the English consultation, several respondents suggested that paying a person money as an incentive not to put people at risk was an unsound principle. The Wales Communicable Disease Legislation Advisory Group has considered this issue and agree incentivising people not to put others at risk is not desirable. We have therefore redrafted the regulation so that the power relates only to compensation payment; this mirrors the English regulation.

In addition, some respondents during the English consultation argued that compensation for compliance should be a mandatory requirement of the local authority rather than a discretionary power. We have considered this issue and agree with the Department of Health that this would impose a non-discretionary financial burden on local authorities, which do not believe would be appropriate. Acting promptly to secure voluntary compliance using this power could prevent the local authority incurring a greater financial burden in the long run if a health protection incident were to develop further.

Currently, local authorities have the power to require a person to discontinue working with food. Some respondents during the consultations in both Wales and England argued strongly for the retention of this power. However, we and the Department of Health believe that the combination of a local authority request power backed up by JP order making powers will be effective in protecting public health in these circumstances. A degree of judicial oversight is necessary to meet human rights concerns, and the threat of formal action is typically enough to ensure compliance.

Benefits

The benefits are:

- the availability of a broad and flexible power to protect public health, which could be backed by an application to a JP for an order if the requested action is not taken, or complied with;
- it helps to future-proof the health protection framework by allowing a local authority to deal with unforeseen threats to public health.

Costs

There might be a very small administrative cost associated with making the requests and following up on them. However, this is no different from the

current powers whereby local authorities have the power to request that someone refrain from working. The administrative costs may also be higher if the JP power were to be relied upon in all circumstances.

Under the existing power, the local authority is obliged to pay compensation to a person that they request stay off work. Under the modernised version of the power, the local authority will have discretion to pay compensation for compliance. There may therefore be a small cost to the local authority of providing the discretionary compensation payment to comply with the request, but this, again, is no different from the current situation when a request is made for someone to stay off work.

The modernisation of this power allows the local authority to make other sorts of requests to protect public health. However, we do not believe it is necessary to quantify any new use of the power since we still believe that it will be used rarely, and the compensation payment is discretionary rather than mandatory. It is not predicted that this power will create any burden on business over what currently exists if someone is requested to stay off work.

4.5.5 Local authority power to restrict contact with dead bodies

We are modernising local authority powers to limit contact with a body that could present significant harm to human health through infection or contamination. This brings forward and modernises the aspects of current powers in this area that it appears desirable to retain, without replicating those provisions that are out of date.

The regulations will empower the local authority to take action, such as having the body moved to a place where contact can be restricted and issue a notice stating that unauthorised contact with the body is prohibited. At the moment, local authorities do have some powers to restrict contact with a body of a person who has died whilst suffering from certain infections, and local authorities do have standing powers to bury or cremate dead bodies where 'no suitable arrangements' have been made. However, the interaction of the powers is slightly updated under these modernised regulations so local authorities can specifically take action to move or restrict access to a body whose condition because of infection or contamination might represent a risk of significant harm to human health.

Benefits
The benefits are:
- any risk to human health from infection or contamination from a body is minimised;
- it provides a flexible way for a local authority to protect public health at minimum cost.

Costs
Making the notice would involve some cost to the local authority in terms of administrative time. There will also be some cost associated with the moving of the body, where necessary. However, we predict that such enforced

movement of the body under these regulations will only be used very rarely. The action required might be as straightforward as moving the body to a lockable room before it is later taken for burial or to a mortuary. More unusual cases may require more costly movement or isolation procedures, but by their nature such cases would be rare. We therefore suggest that this movement power is more for use on a contingent basis, should a health protection professional come across a risk to human health that could be avoided by recourse to it. We, therefore, consider it inappropriate to try to estimate the costs associated with this power. It is not predicted that this power would create any burden on business.

4.6 Summary of costs

These regulations involve, for the most part, the modernisation of existing powers, so we do not believe that any new, significant costs will be incurred because of implementation of these regulations.

4.7 Risks

It is possible that the use of these powers might increase as awareness of the new or revised provisions increases. This brings a notional risk that increased use of legal powers rather than seeking voluntary cooperation could damage relationships between public health officials and those they deal with - members of the general public, headteachers, parents and employers. Should this happen, the likelihood of the power fulfilling the policy objective of protecting against a public health risk would be reduced. We think that public health officials will always prefer to aim for voluntary cooperation as a first step, and that this risk is therefore unlikely to be realised, but we propose that guidance will reinforce the point in order to mitigate this risk.

5. Costs of training and development

We do not believe there are significant extra costs associated with training for the new measures. It is unlikely that recurring costs will arise, although a limited amount of one-off costs will be entailed.

The costs to those receiving training arise from the time required for completion of the appropriate training package at the relevant time. The table below sets out an estimate of the time required for basic training in the new measures for the various groups affected.

The method of delivering the training will be determined by the relevant organisations. For those officers in local authorities and Public Health Wales that will be using the new regulations most frequently, we anticipate that a formal training course will be required. This training may form part of the Lead Officer training programme which provides training for local authority officers with lead responsibility for communicable disease control. Public Health Wales also runs its own training programmes for its health protection teams.

Most people, including laboratory staff and Registered Medical Practitioners, will be in professional positions where they are required, as a matter of usual practice, to undertake “continuing professional development” (CPD) of their skills and competencies. The costs for training in these groups is therefore low.

We assume that solicitors working for local authorities on health protection cases will only be required - or wish - to become accustomed with the changes to the regulations when presented with a case requiring such knowledge. Since they would similarly have had to become accustomed to previous legislation prior to the change in regulations, we assume a zero incremental cost. In addition, we have assumed in this Regulatory Impact Assessment that the number of cases arising under these changes in regulations are small.

We are working with the Wales Communicable Disease Legislation Advisory Group on the development of policy and operational guidance on the new measures to assist the familiarisation process. The costs of producing the guidance will be borne by the Welsh Assembly Government with advice from the Advisory Group.

Person requiring training	Type of training required	Time needed for the training	Additional cost
Scientific & administrative staff in laboratories (2 per laboratory)	New notification requirements	1 hour average per person	Scientific staff: 2 x hourly cost of £26[8] = £52 per laboratory. Admin staff: 2 x hourly cost of £12[9] = £24 per laboratory 12 (number of labs) x £(52+24=76) = £912.00
Registered medical practitioners	New notification requirements Summary of other Part 2A provisions - JP orders and local authority powers	Marginal - information would be conveyed by letter from the Chief Medical Officer Registered medical practitioners may wish to acquaint themselves with the new Part 2A provisions - likely only if presented with a case requiring knowledge	None quantifiable ~ 0, due to the rare nature of cases
Solicitors employed by local authorities	Summary of all new provisions	Only required if presented with a case requiring knowledge	~ 0, due to the rare nature of cases
Public Health Wales, Consultants in Communicable Disease Control (CCDC)	New notification requirements, and other Part 2A provisions - JP orders and local authority powers	8 hours training	7 Consultants in Communicable Disease Control - 7 x 8 x £60[10] =£3,360.00
Environmental Health Officers with lead responsibility for communicable disease	New notification requirements, and other Part 2A provisions - JP orders and local authority powers	8 hours training	22 professionals – 22 x 8 x £26 = £4,576.00
Environmental Health Protection Officers with lead responsibility for chemical and radiological incidents	Summary of all new provisions	2 hours training	22 Environmental Health Protection Officers – 22 x 2 x £26 = £1,144.00

[8] Estimate of the hourly rate of a professional working in science and technology. Administrative burdens exercise page 20 for details on hourly wage rates of internal professional staff. http://www.berr.gov.uk/whatwedo/businesslaw/better-regulation/simpplan/page35599.html

[9] Estimate of the hourly rate of administrative and clerical staff. Administrative burdens exercise. http://www.berr.gov.uk/whatwedo/businesslaw/better-regulation/simpplan/page35599.html.

[10] Estimate of the hourly wage rate for a CCDC plus 30% employer overheads. BRE advise that employer overheads are set at 30% in addition to staff wages. See paragraph 5.9.2 on page 62 in *Measuring Administrative Costs: UK Standard Cost Model Manual* at www.berr.gov.uk/files/file44503.pdf

6. Summary of costs and benefits for the final proposed regulations

	Lower estimate	Mid estimate	Upper estimate
Costs			
Notification Regulations (per annum)	£946.00	£2,783.00	£6,055.00
Part 2A Orders Regulations (per annum)	£0	£270.00	£786.00
Local Authority Powers Regulations (per annum)	None	None	None
TOTAL (per annum)	**£946.00**	**£3,053.00,**	**£6,841.00**
Training (one-off)	£9,992.00	£9,992.00	£9,992.00
Benefits			
Notification Regulations (per annum)	-£6,116.00	-£12,232.00	-£18,348.00

7. Consultation

In Wales, a Wales Communicable Disease Legislation Advisory Group was established in September 2009 to advise on the content and implementation of the Welsh health protection regulations. This group, comprising of experts in health protection from those stakeholders that will be affected by the new regulations, has been responsible for advising the Welsh Assembly Government on the development and drafting of the Welsh health protection regulations and the implementation of the new regulations prior to their proposed coming into force.

The formal consultation on the draft versions of the three sets of regulations ran from 4 November 2010 to 13 January 2011. We invited comments on the draft regulations, and in particular, responses to specific questions set out in the consultation paper. We also sought views on an accompanying set of draft impact assessments.

The following organisations were made aware by email of the consultation:

- Public Health Wales;
- Chief Executives of NHS organisations and the Chief Executives of local authorities. The Directors of Public Protection Wales and subgroups in local authorities were also sent links to the documents;
- Directors of Education in local authorities
- Clinical microbiology laboratories in Wales which test human samples;
- other stakeholder organisations (for example, the Chartered Institute of Environmental Health, the Food Standards Agency Wales, professional organisations, the Welsh Local Government Association, the National AIDS Trust and Liberty).

Sixteen responses to the Welsh consultation were received.

In England, consultation on the same regulations took place shortly before (between July and September 2009) the Welsh consultation. The English consultation yielded sixty-eight responses.

During the English and Welsh consultations the majority of respondents broadly supported the proposed option for each set of regulations, which was to modernise out-of-date provisions using some, but not all, of the regulation-making powers available.

There were however some notable concerns, in particular about the position of people with HIV or other sexually transmitted infections (STIs). Other themes concerned the lists of notifiable diseases and micro-organisms; the impact on local authorities' powers and duties in health protection; and the practical effect on day-to-day health protection measures of increased judicial oversight. These issues, and how we and the Department of Health have dealt with them, are addressed at the relevant points in the Regulatory Impact Assessment and in more detail in the consultation report.

We have endeavoured to meet respondents' concerns where possible. In some instances we think the issue is better covered in guidance than in regulation, which is in the process of being produced to accompany the regulations.

We asked consultees if they thought that the assumptions in the draft Regulatory Impact Assessment appeared reasonable. Most of those who answered this question (7 out of 8) agreed that they were.

This is a Department of Public Health and Health Professions Policy area, however we have worked closely with the Department of Health in England and engaged other Welsh Assembly Government departments during the development of the regulations.

Equality Impact Assessment
An equality impact screening exercise was undertaken on these regulations and issued, alongside the other documents, during the consultation exercise. One respondent commented that the impact assessment did not adequately address the impact on people with a life-long disability such as HIV as opposed to a time-limited infection. Similar comments in relation to people with HIV or another STI were also made during the English consultation. We have considered these points during our assessment and a revised assessment is available on the Welsh Assembly Government website.

8. Competition Assessment

Health Protection (Notification) (Wales) Regulations 2010

The competition filter test	
Question	**Answer yes or no**
Q1: In the market(s) affected by the new regulation, does any firm have more than 10% market share?	No
Q2: In the market(s) affected by the new regulation, does any firm have more than 20% market share?	No
Q3: In the market(s) affected by the new regulation, do the largest three firms together have at least 50% market share?	No
Q4: Would the costs of the regulation affect some firms substantially more than others?	No
Q5: Is the regulation likely to affect the market structure, changing the number or size of businesses/organisation?	No
Q6: Would the regulation lead to higher set-up costs for new or potential suppliers that existing suppliers do not have to meet?	No
Q7: Would the regulation lead to higher ongoing costs for new or potential suppliers that existing suppliers do not have to meet?	No

The competition filter test	
Question	**Answer yes or no**
Q8: Is the sector characterised by rapid technological change?	No
Q9: Would the regulation restrict the ability of suppliers to choose the price, quality, range or location of their products?	No

9. Post implementation review

The three Statutory Instruments 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. We will also ensure that information from the reports to the Welsh Ministers of applications for JP orders (required under the Part 2A Orders Regulations) will be published annually. This will allow the use of applications for orders to be monitored and provide transparency about the reasons for them.

Annexes

Annex 1 - Details on the incidence of diseases that have been added to the notifiable diseases list

Annex 2 - Health Protection Regulations: Details on offences

Details on the incidence of diseases that have been added to the notifiable diseases list

Additional diseases to be notified by registered medical practitioners	Estimated annual incidence	Comments
Any infection which presents or could present significant harm to human health; or contamination in a manner which presents or could present significant harm to human health.	Approximately 180 per year	Based on experience of a large London Health Protection Agency Health Protection Unit, approximately 3% of total notifications and reports are in this category. The reporting is currently happening by the clinicians and others (including emergency services) on a voluntary basis.
Botulism	Very rare	* see source of data
Brucellosis	Very rare	* see source of data
Invasive group A streptococcal disease (including necrotising fasciitis)	Approx 150 per year (including necrotising fasciitis)	This is based on the report of a European enhanced surveillance programme[11].
Legionnaires' disease	Approx 15 per year	* see source of data
SARS	Very rare	In the event of an outbreak numbers would rise. This would not happen on annual basis.
Total	**345**	

* The above estimates are based on epidemiological data available received from Public Health Wales.

Estimated total annual incidence of additional diseases	**345**
Numbers voluntarily reported at present (50-75%)	**173 – 259**
Estimated increase in the number of additional diseases notified (25%-50%)	**86 – 173**
Current annual notifications (approx)	**6000**
Percentage increase	**1.4% to 2.9%**

[11] Lamagni TL, et al. Epidemiology of Severe Streptococcus pyogenes Disease in Europe. J CLIN MICRO, Vol. 46, No. 7, p. 2359–2367.

Health Protection Regulations: Details on offences

1. Broad outline

The power to make regulations to create offences in public health legislation is found within the new Part 2A of the 1984 Act, which was inserted by the HSA Act. The new Part 2A also specifies that those offences may not be punishable with imprisonment, a fine exceeding £20,000 or a further daily fine exceeding 2% of a level 5 standard scale fine (this is a high ceiling for offences because it potentially includes corporate offences/fines).

Following a formal consultation exercise, we are introducing three sets of regulations.

The Health Protection (Local Authority Powers) (Wales) Regulations 2010 roll forward and modernise powers and duties originally given to Local Authorities in relation to their health protection role by the 1984 Act. Amongst other regulations, these regulations ensure that local authorities can:

- keep a child off school if a child's attendance could present a significant risk to human health (because that child has a condition that could be passed to other children);
- obtain a list of contact details of pupils attending a school (where there is a threat to public health and a contact tracing exercise might have to be performed);
- restrict unnecessary contact with a dead body where such contact might represent a risk to human health.

The powers these regulations confer have their origin in the original 1984 Act. They were associated with offences. We are modernising these powers and the associated offences, so when someone breaches the regulations, they commit an offence. Two new fines are also required. We want the fines associated with the offences to be substantial enough to be a credible reason to comply, so the legislation is not a 'paper tiger'.

The Health Protection (Notification) (Wales) Regulations 2010 make provision for the statutory notification of specified infectious diseases in humans by registered medical practitioners and laboratories for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in Wales.

These new regulations will replace the current provisions in the 1984 Act and the Public Health (Infectious Diseases) Regulations 1988, and will:

- update the current list of diseases to be notified by registered medical practitioners, including provision for diseases that may be caused by emerging infectious diseases or chemical or radiological contamination;
- introduce a new requirement for diagnostic laboratories testing human samples to notify specified infectious diseases to the proper officer of the local authority;

- provide timescales for notification by registered medical practitioners and laboratories.

We have dropped the existing offence in the 1984 Act for failure by a registered medical practitioner to report a notifiable disease to the proper officer of the local authority. This is because the current offence provision only appears to have been used extremely rarely and there are other ways in which compliance with this requirement can be encouraged or enforced (e.g. disciplinary procedures by the General Medical Council, the professional regulatory body for registered medical practitioners).

We have created a new offence for failure to report a notifiable infectious disease by a diagnostic laboratory as a deterrent against not reporting and as a sanction when required.

The third set of regulations concerns the requirements to be met before a JP can exercise the power to make certain orders to prevent significant harm to human health from infection or contamination. These regulations do not include offences.

2. What we intend to achieve

The detail of the updated offences, and what they are intended to achieve, is outlined below:

<u>The Health Protection (Local Authority Powers) (Wales) Regulations 2010</u>

- When a parent fails to keep a child off school after being issued a notice to take such action: <u>offence</u>: a fine not exceeding level 2 on the standard scale, and a fine not exceeding 50% of level 1 on the standard scale (see page 52) for every day subsequent that the parent fails to keep the child away. We want the fine to be substantial enough so the parent is compelled to comply with the order; also, we believe that an ongoing fine for non-compliance is necessary; although should this situation of ongoing non-compliance arise, other action would of course be taken to mitigate any ongoing public health risk.
- A headteacher's responsibility to provide contact details of attendees at school to the local authority when asked to do so: <u>offence</u>: a fine for the headteacher not exceeding level 1 on the standard scale. This low fine relies on a headteacher's professional sense of responsibility and their general duty to comply with the law.
- For unauthorised contact with a dead body (where contact with that body has been restricted) and for unauthorised entry into a room where a dead body is held: <u>offences</u>: fines not exceeding level 3 on the standard scale. These fines have to be reasonably high to encourage compliance with the order. Certain individuals might have very strong feelings regarding their contact with a deceased next of kin being restricted, even if such a restriction is in place to protect their health. The regulations also require that any person in charge of premises where a dead body is lying must cooperate with the local authority if it wishes to relocate the body, and that non-cooperation will be an offence, again with a fine not exceeding level 3 on the standard scale. The new offence is necessary, we feel, to give teeth to the requirement. In addition, following the English consultation in which an influential stakeholder organisation argued in

favour of the following approach, it is a requirement for the local authority to serve the notice stating the terms of the restriction on any person having charge or control of the premises where the dead body is located. Failure of the person to put up the notice, or for any person to remove or deface the notice, is also an offence with a fine not exceeding level 3 of the standard scale.

The Health Protection (Notification) (Wales) Regulations 2010

- For failure by a diagnostic laboratory to report a notifiable infectious disease to the proper officer: offence: a fine not exceeding level 5 on the standard scale, which we consider appropriate for the nature of the offence. The offence would apply to the corporate body for the laboratory, or if there is not one, to the director of the laboratory.

The fines associated with the offences to be substantial enough to be a credible reason to comply, but we do not want them to be excessive or unrealistic. Of course, we want to fulfil the policy objective of protecting public health, and while the offence is necessary to ensure that the legislation is enforceable, if an offence is actually committed, it implies someone has been exposed to a public health risk probably unnecessarily. Therefore, we have taken other broad powers to request people to take action to protect public health; and the new Part 2A gives local authorities very flexible powers to go to a Justice of the Peace (JP) to obtain orders to get people to do things to protect public health, should the situation warrant it. The new Part 2A of the 1984 Act also outlines the offence committed should the JP's order be breached.

One of the regulations regarding requirements to be met before a JP can exercise powers to make certain orders concerns the next of kin's right to apply for variation or revocation of a notice requiring the burial or cremation of a body. The next of kin might exercise their right to apply for variation or revocation of an order, and therefore impact on the work of JPs; the next of kin may also apply for legal aid for help in making such a variation or revocations. However, as the Regulatory Impact Assessment explains, we expect a JP order for disposal of a body would be a rare occurrence. It could not be assumed that the deceased person would have a next of kin or that the next of kin would always apply for variation or revocation. Therefore, the impact would be significantly less than one extra application a year nationally and can be regarded as having no significant impact on the work of JPs or legal aid.

3. Changes to what happens now

The table below outlines the changes to what happens now as regards the existing powers and associated offences we are modernising.

Existing related power (under the unamended 1984 Act)	**Estimated frequency of use of power (*not* associated offence), as indicated in the Regulatory Impact**	**Associated offence**	**To be carried over?**

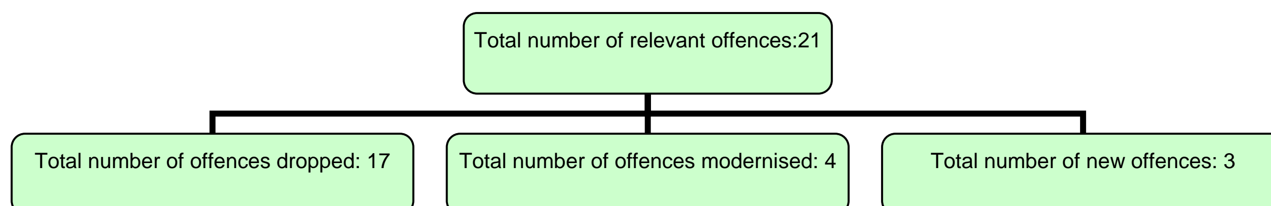
	Assessment		
S21 Exclusion from school of child liable to convey notifiable disease	Infrequently	Punishable by a level 1 fine.	Yes, but at level 2
S22 List of day pupils at school having case of notifiable disease (requiring principal to supply a list)	Infrequently	Punishable by a level 1 fine.	Yes, still at level 1
S43, S44, and S45, concerning restricting contact with a dead body	Infrequently	All three Sections enforced by three separate level 1 fines.	2 (not 3) similar offences at level 3; 2 new offences at level 3
S11 Cases of notifiable disease and food poisoning to be reported	This is a standing duty	Punishable by a level 1 fine	No – this offence will be removed, but there will be a new offence to enforce a new requirement on diagnostic laboratory testing human samples to report notifiable infectious diseases to the Proper Officer. The penalty will be a level 5 fine.

The table above shows that the current powers that these regulations update are not used frequently (except of course for the standing notification requirements), and we see no reason to expect any significant increase in the use of the powers upon 'modernisation'. An offence occurs in relation to the notification requirements about once every twenty years nationally. We are not aware of any offences being committed in relation to the current "contingent" powers.

These powers need to be on the statute book to provide the tools health protection professionals may need to do their job. Their contingent nature means we do not anticipate them being used frequently. In most cases, we anticipate that they would give professionals the authority to take action and encourage cooperation, rather than having to resort to the powers themselves. As such, we think the offences associated with these powers would be used considerably less frequently than the powers themselves. We have not therefore attempted to cost up the legal impact of these regulations as we believe it would be so low so as to be negligible.

We are dropping a large number of offences from public health legislation without any form of modernisation. We are only rolling forward or introducing offences as

outlined in the table above. A ‘balanced account’ of the number of offences to be dropped, modernised and introduced when these regulations come into force is shown below.



There is no next of kin right to apply for variation or revocation of an order concerning burial or cremation of a dead body under the unamended 1984 Act. This is a new (but as explained above, extremely limited in scope and effect) feature of the legislation.

4. What commitments have been given, and to whom

As explained in paragraph 1, the Public Health Act (Control of Disease) Act 1984, was amended by the insertion of a new Part 2A by the Part 3 of the Health and Social Care Act 2008. Provisions for JP orders and the proposed accompanying regulations (the “Part 2A orders” regulations) replace most of the requirements and prohibitions in the existing Part 2 in the 1984 Act. However, there are certain standing responsibilities and requirements that local authorities need to fulfil in regard to health protection without resort to a JP, not covered by the new Part 2A itself, but about which the new Part 2A does confer powers to make regulations. We need to make such regulations so local authorities and healthcare professionals have the requisite tools available to fulfil their function to protect human health from risks of infection or contamination.

A commitment was made in the House of Lords during the passage of the 2008 Act that next of kin would be told if an application for an order was made in relation to burial or cremation of a dead body of a relative.

5. Concluding remarks

As explained in the Regulatory Impact Assessment, we consulted on draft regulations from November 2009 to January 2010; England also consulted upon their draft regulations from July to September 2009. The consultations led to one new offence in relation to restricting contact with and access to a dead body (see above).

We believe these regulations would not have a significant legal impact either in terms of an increase in the frequency of offences; or in terms of legal aid.

Fines: the standard scale
The current levels on the standard scale are:

Level 1	£200
Level 2	£500
Level 3	£1000
Level 4	£2500
Level 5	£5000