



House of Lords
House of Commons
Joint Committee on
Statutory Instruments

**Third Report
of Session 2009-10**

Drawing special attention to:

Draft Health and Social Care Act 2008 (Regulated Activities) Regulations 2009

Magistrates' Courts (Drinking Banning Orders) Rules (S.I. 2009/2937)

Audiovisual Media Services Regulations 2009 (S.I. 2009/2979)

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Joint Committee on Statutory Instruments

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Powers

The full constitution and powers of the Committee are set out in House of Commons Standing Order No. 151 and House of Lords Standing Order No. 74, available on the Internet via www.parliament.uk/jcsi.

Remit

The Joint Committee on Statutory Instruments (JCSI) is appointed to consider statutory instruments made in exercise of powers granted by Act of Parliament. Instruments not laid before Parliament are included within the Committee's remit; but local instruments and instruments made by devolved administrations are not considered by JCSI unless they are required to be laid before Parliament.

The role of the JCSI, whose membership is drawn from both Houses of Parliament, is to assess the technical qualities of each instrument that falls within its remit and to decide whether to draw the special attention of each House to any instrument on one or more of the following grounds:

- i. that it imposes, or sets the amount of, a charge on public revenue or that it requires payment for a licence, consent or service to be made to the Exchequer, a government department or a public or local authority, or sets the amount of the payment;
- ii. that its parent legislation says that it cannot be challenged in the courts;
- iii. that it appears to have retrospective effect without the express authority of the parent legislation;
- iv. that there appears to have been unjustifiable delay in publishing it or laying it before Parliament;
- v. that there appears to have been unjustifiable delay in sending a notification under the proviso to section 4(1) of the Statutory Instruments Act 1946, where the instrument has come into force before it has been laid;
- vi. that there appears to be doubt about whether there is power to make it or that it appears to make an unusual or unexpected use of the power to make;
- vii. that its form or meaning needs to be explained;
- viii. that its drafting appears to be defective;
- ix. any other ground which does not go to its merits or the policy behind it.

The Committee usually meets weekly when Parliament is sitting.

Publications

The reports of the Committee are published by The Stationery Office by Order of both Houses. All publications of the Committee are on the Internet at www.parliament.uk/jcsi.

Committee staff

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Instruments reported

At its meeting on 16 December 2009 the Committee scrutinised a number of Instruments in accordance with Standing Orders. It was agreed that the special attention of both Houses should be drawn to three of those considered. The Instruments and the grounds for reporting them are given below. The relevant Departmental memoranda are published as appendices to this report.

1 Draft S.I: Reported for unusual or unexpected use of powers, doubtful *vires* and requiring elucidation

Health and Social Care Act 2008 (Regulated Activities) Regulations 2009 (Draft S.I.)

1.1 The Committee draws the special attention of both Houses to these draft Regulations on the grounds that, if approved and made, they would in several respects make an unusual or unexpected use of the powers conferred by the parent Act, and in two respects give rise to doubt as to whether they were *intra vires*; and that in one respect their purport requires elucidation.

Background

1.2 Chapter 2 of Part 1 of the Health and Social Care Act 2008 creates a system of registration by the Care Quality Commission (“the Commission”) for providers and, in some cases, managers of health and adult social care. Part 2 of these regulations sets out the regulated activities. Section 20 of the 2008 Act enables the Secretary of State by regulations to impose requirements about regulated activities. Parts 3 and 4 of these regulations set out those requirements. Under section 23 of the 2008 Act the Commission must issue guidance about compliance with the requirements. Under section 25 the guidance is to be taken into account for the purposes of certain proceedings, but failure to observe a provision of the guidance does not of itself make a person liable to any civil or criminal proceedings.

1.3 The 2008 Act gives the Commission means by which to enforce the requirements. So, failure to comply with them is a ground for cancellation or suspension of registration (sections 17(1) and 18(2)) with a special procedure for suspension in urgent cases (section 31).

1.4 In addition, section 35 enables regulations under section 20 to provide “that a contravention of or a failure to comply with any specified provision of the regulations is to be an offence”, but the regulations may not provide for the offence to be punishable with a fine exceeding £50,000.

1.5 Regulations under section 20 are normally, under section 162(1), subject to negative procedure only. But section 162(3)(b) applies the draft affirmative procedure when the regulations provide for an offence punishable with a fine of more than level 4 on the standard scale (currently £2,500).

These Regulations

1.6 Part 4 of these regulations sets out requirements (in regulations 9 to 24) with which a registered person must comply. These requirements are drawn in many instances (notably regulations 9, 10, 11, 14, 15, 16, 17, 23 and 24) in general terms more often seen in advisory guidance documents than in regulations. Regulation 27 makes failure to comply with *any* of the requirements an offence punishable by a maximum fine of £50,000. Regulation 27(3) provides for a defence of “due diligence”.

1.7 Examples of failures which under the regulations constitute a criminal offence carrying a maximum penalty of £50,000, are:

- failing, for the purposes of the duty of protecting service users against the risk of inappropriate care, to “regularly seek the views.....ofpersons who are employed for the purposes of carrying on the regulated activity” (regulation 10(1) and (2)(e));
- failing to ensure that those having access to premises are protected against the risks associated with “unsuitable” premises by means of a “suitable” design and layout (regulation 15(1)(a));
- failing, for the purpose of making arrangements to ensure privacy, etc. of service users under regulation 17(1) to “treat service users with consideration”, to “encourage service users to express their views” about their treatment or to “provide appropriate.....encouragement” to service users in promoting their independence (regulation 17(2)(a), (c) and (g));
- failing, in making arrangements connected with the shared or transferred care mentioned in regulation 24(1), to do so by means of “supporting service users.....to obtain appropriate health and social care support”.

1.8 The regulations also provide for guidance issued by the Secretary of State or “an appropriate expert body” to have an effect backed by a criminal sanction and a maximum £50,000 penalty. So, regulations 11(3), 13(2) and 18(b) provide that “the registered person must have regard to any guidance issued by the Secretary of State or an appropriate expert body” about various matters. Arrangements under regulation 16(1)(b) must ensure that equipment is “used correctly in accordance with guidance issued by the manufacturer, the Secretary of State or appropriate expert bodies”.

The issues raised

1.9 This raises four issues:

- 1 Whether the regulations are defective in failing to specify sufficiently the nature of the criminal offences;
- 2 Whether section 35 of the 2008 Act, even if it contemplates the application of criminal offences for all contraventions of all requirements in Part 4, contemplates the application of the highest maximum penalty permitted by the enabling power in all cases, as the enabling power appears to envisage a more selective approach (a view supported by the government’s memorandum to the House of Lords Delegated Powers and Regulatory Reform Committee, at paragraph 65 of Appendix 1 to their 6th Report for 2007-08);

- 3 Whether the Act enables the regulations to frame requirements by reference to unidentified guidance published apart from the regulations and subject to no Parliamentary procedure;
- 4 Whether the Act, in enabling regulations to provide that failure to comply with a “specified provision of the regulations” is to be an offence, also enables the regulations to provide that a failure to have regard to, or to act in accordance with, guidance issued by a third party or by the Secretary of State is to be an offence.

1.10 The Department of Health had, wisely, anticipated at least the first of these issues. In the helpful Annex to the Explanatory Memorandum they point (at paragraph 5) to three previous sets of regulations phrased also in fairly general terms. But, as is acknowledged in paragraph 6 of that Annex, under those regulations proceedings *could not* be brought against a person without prior notice to him specifying how the relevant provision is being contravened and what is required to ensure compliance. Though section 29 of the 2008 Act makes provision for warning notices, failure to issue a notice is not under these regulations a bar to bringing criminal proceedings.

1.11 In response to specific questions raised by the Committee, the Department provided the memorandum printed at Appendix 1.

Offences

1.12 It seems sufficiently clear from the Department’s memorandum (paragraphs 7 and 14) that guidance to be issued by the Commission is central to the understanding of how the regulations are intended to work in practice. The duty on the Commission to issue guidance is already in force, but the Department explains that the Commission “will shortly be publishing draft guidance”. It does not help either House of Parliament in their function of making a judgment on these regulations that the draft regulations have been laid before draft guidance based on them is available.

1.13 Paragraphs 3 to 6 of the memorandum explain that the key issue which will expose a registered person to the possibility of prosecution in any case is a clear failure to protect service users from the risk that is the focus of each registration requirement. But there is a difference between what exposes a person to the risk of committing an offence and what exposes a person to the risk of being prosecuted for it. This is significant because it is the function of the Secretary of State to impose the requirements and create any offences, but under section 90(1)(a) of the 2008 Act it is for the Commission, not the Secretary of State, to prosecute the offences. It is clear, for example, from paragraph 14 of the memorandum that the Secretary of State’s policy is that a person should not be prosecuted for a failure to comply with regulation 14 unless a service user had become inadequately nourished or was clearly at risk of that. But under his regulations a registered person would appear to commit an offence (subject to the “due diligence” defence), even where nobody has been inadequately nourished, if the means by which the registered person secures that outcome does not involve providing “a choice of suitable....food”.

1.14 The Committee has on several occasions reported that the attachment of criminal sanctions to failure to comply with unspecific provisions is contrary to proper legislative practice (see, for example, the Committee’s 8th and 11th Reports for 1996-97). Regulations 9, 10, 11, 14, 15, 16, 17, 23 and 24 appear insufficiently precise to enable a person to decide

what must be done to avoid committing an offence; and in those circumstances a defence of due diligence is of reduced value.

1.15 The Committee accepts it is likely that guidance by the Commission will help to reduce the level of uncertainty created by the regulations. But that guidance can be only about how the requirements are met; it cannot re-define the scope of the requirements imposed by the Secretary of State. The Committee has not seen the proposed draft guidance by the Commission and is not prepared to assume (as the Secretary of State apparently is) that it will render acceptable regulations by the Secretary of State which appear to be formulated in a way inappropriate to criminal offences. Nor does the Commission's duty to act proportionately or its guidance under section 88 (to which paragraph 9(a) and (b) of the Department's memorandum draws attention) have a direct bearing on the scope of the offence created by the Secretary of State.

1.16 In the Committee's view the failure of the Secretary of State to give in regulations 9, 10, 11, 14, 15, 16, 17, 23 and 24 a more adequate indication of exactly what conduct will constitute an offence, or at least to provide a compulsory mechanism whereby that conduct can be established in advance in individual cases, is an unusual and unexpected use of the power conferred by the 2008 Act, and the Committee reports accordingly.

Penalties

1.17 The Committee asked the Department what consideration was given, in setting a maximum penalty of £50,000 in relation to all the provisions of regulations 9 to 24, to maximum penalties fixed by Parliament itself for apparently similar offences, with particular reference to regulations 10(3), 13(2) and 19(3). These examples were chosen because of the contrast with other offences which seemed similar (under sections 65 and 64 of the 2008 Act and section 67 of the Medicines Act 1968) but for which Parliament has provided a much lower maximum penalty (level 4—£2,500; level 4—£2,500; and level 5—£5,000 respectively).

1.18 The Department does not expressly answer the Committee's question in its memorandum, though it explains (paragraph 10) the considerations that were taken into account. It says that consideration was mainly given to the fact that the requirements are concentrated on essential levels of safety and quality. The Committee notes this explanation. It also notes, in connection with regulations 10(1) and 19(3), that paragraph 7.10 of the Department's Explanatory Memorandum laid with the draft describes the offences under sections 64 and 65 of the 2008 Act as being focused on a failure to cooperate and thus warranting a lower fixed penalty than other offences. The Committee is satisfied that the issues raised as to penalties are ones of policy for each House rather than for the Committee.

Sub-delegation: requirements

1.19 Regulations 11(3), 13(2), 16(1)(b) and 18(b) provide that the substance of what must be done, or at least considered, is set out in guidance, not in regulations. The Department confirms that these provisions are intended to refer to existing and to future guidance.

1.20 The Committee asked who were the "appropriate expert bodies" referred to in regulations 11(3), 13(2), 16(1)(b) and 18(b). The explanation is provided in paragraph 12(a) of the Department's memorandum. The Committee notes that the term is not

considered in practice to cover the Care Quality Commission. **The Committee reports regulations 11(3), 13(2), 16(1)(b) and 18(b) as requiring elucidation, provided by the Department in its memorandum.**

1.21 The Committee asked the Department which statutory provision enables a requirement in regulations under section 20 to be framed by reference to guidance to be issued in the future by others. This was because the 2008 Act contains specific provision in sections 21(2) and 23(3) enabling Codes of Practice and guidance (but not regulations) to be framed by reference to such other documents, and provides for the procedural consequences of revisions of those other documents (sections 22(4) and (5) and 24(4) and (5)). The Department acknowledges in paragraph 12(e) of its memorandum that there is no equivalent statutory provision for regulations under section 20.

1.22 The Department also says that the requirements in the regulations do not have the effect of incorporating the guidance referred to, since the requirement imposed is to have regard to the guidance rather than to comply with it. In the case of regulation 16(1)(b) this is plainly not so, as the requirement is that the equipment must be “used correctly in accordance with....guidance”. But it anyway makes no difference whether the requirement is to comply with, or merely to have regard to, the guidance – in either case the extent of what must be done can be ascertained only by looking at guidance which may not exist at the time when these regulations are made.

1.23 Regulations 11(3), 13(2), 16(1)(b) and 18(b) represent precisely the sort of provisions discouraged by paragraph 2.8.1 of the Statutory Instrument Practice. They give to the Secretary of State or other unidentified people the power to set out the matters to which those affected must have regard, or which they must follow, whereas the 2008 Act requires that this be done by regulations subject to a Parliamentary procedure. **The Committee therefore reports regulations 11(3), 13(2), 16(1)(b) and 18(b) as of doubtful vires.**

Sub-delegation: offences

1.24 It follows from the Committee’s view on the third issue that there are doubts whether regulation 27, in its application to regulations 11(3), 13(2), 16(1)(b) and 18(b), is within the power conferred by section 35 to provide for failure to comply with “any specified provisions of the regulations” to be an offence.

1.25 The Committee does not consider that regulation 27 is effective to back unidentified non-statutory guidance with a criminal sanction. Nor, in the case of statutory guidance, is it effective to impose criminal sanctions for which the guidance’s enabling statute does not provide. So far as that enabling statute may provide (as section 25 of the 2008 Act itself does for guidance under section 23) that failure to *comply with* the guidance is to be taken into account in certain circumstances but is *not* an offence, the Committee doubts that section 35 enables the effect of that statute to be modified by providing that failure to *have regard* to the guidance *is* an offence. **The Committee reports regulation 27, so far as it relates to regulations 11(3), 13(2), 16(1)(b) and 18(b), as being of doubtful vires.**

2 S.I. 2009/2937: Reported for not according with proper legislative practice

Magistrates' Courts (Drinking Banning Orders) Rules 2009 (S.I. 2009/2937)

2.1 The Committee draws the special attention of both Houses to these Rules on the ground that they are not in accordance with proper legislative practice.

2.2 In a memorandum printed at Appendix 2, the Ministry of Justice accepts that several provisions of this instrument replicate in effect provisions of the Violent Crime Reduction Act 2006 as they apply in the case of proceedings before magistrates' courts. The Department states that the rules which replicate the primary legislation were included to make the Rules more complete and coherent for a reader to follow. They had been drafted in 2007 but were put on hold, and when they were revived earlier this year the Department failed to note the relevance of the Committee's 27th Report of the 2006-07 Session in which it had reported rule 50 of the Court of Protection Rules 2007 as not being in accordance with proper legislative practice for including in the operative part of the instrument provisions which serve no legislative purpose.

2.3 Accordingly, the Committee reports these Rules, to the extent that they replicate in effect provisions of the Violent Crime Reduction Act 2006, as not being in accordance with proper legislative practice.

3 S.I. 2009/2979: Reported for defective drafting

Audiovisual Media Services Regulations 2009 (S.I. 2009/2979)

3.1 The Committee draws the special attention of both Houses to these Regulations on the ground that they are defectively drafted in one respect.

3.2 Regulation 2 inserts new sections into the Communications Act 2003. New section 368P(2) lists some of them and states that references in them to a provider of an on-demand programme service do not include references to the BBC (in effect its public services – see section 368R). In a memorandum printed at Appendix 3 the Department for Culture, Media and Sport acknowledges that section 368P(2)(b) should not have been included, as it refers to section 368F which makes no reference to a *provider* of an on-demand programme service. The memorandum explains that the intention was to disapply the rules on advertising in section 368F from the BBC, and that this is because under the BBC Agreement advertising is prohibited on the BBC's public services so those rules are superfluous in relation to the BBC. The Department recognises that the section ought to have been so disapplied by subsection (1) of section 368P. The memorandum also helpfully identifies a further error in the list in section 368P(2). The Department proposes to rectify the errors by means of amending regulations in early 2010. **The Committee accordingly reports regulation 2 of these Regulations for defective drafting in so far as the misplaced material queried is included in section 368P inserted into the 2003 Act, acknowledged by the Department.**

Instruments not reported

At its meeting on 16 December 2009 the Committee considered the Instruments set out in the Annex to this Report, none of which were required to be reported.

A memorandum from HM Treasury in connection with the Railway Closures (Minor Modifications) Order 2009 (S.I. 2009/2973) is printed at Appendix 4.

Annex

Instruments to which the Committee does not draw the special attention of both Houses

- *denotes that the written evidence submitted in connection with the instrument is printed with this Report*
- *denotes written evidence has been submitted but not printed*

Draft Instruments requiring affirmative approval

Draft S.I. Communications Act 2003 (Disclosure of Information) Order 2010

Instruments subject to annulment

- **S.I. 2009/2973** Railway Closures (Minor Modifications) Order 2009
- S.I. 2009/3015** Air Navigation Order 2009
- S.I. 2009/3062** Medicines (Exemptions and Miscellaneous Amendments) Order 2009
- S.I. 2009/3063** Medicines for Human Use (Miscellaneous Amendments) (No. 2) Regulations 2009
- S.I. 2009/3071** Medicines (Pharmacies) (Applications for Registration and Fees) Amendment No. 2 Regulations 2009
- S.I. 2009/3081** Provision of Services (Insolvency Practitioners) Regulations 2009
- S.I. 2009/3082** Prison and Young Offender Institution (Amendment) Rules 2009
- S.I. 2009/3093** Local Government Pension Scheme (Management and Investment of Funds) Regulations 2009
- S.I. 2009/3094** Pensions Act 2007 (Supplementary Provisions) (No. 2) Order 2009
- S.I. 2009/3095** Non-Domestic Rating Contributions (England) (Amendment) Regulations 2009
- S.I. 2009/3098** Derelict Land Clearance Area (Drake Gardens, Tavistock) Order 2009
- S.I. 2009/3100** Utilities Contracts (Amendment) Regulations 2009
- S.I. 2009/3101** Private Water Supplies Regulations 2009

S.I. 2009/3102	Common Agricultural Policy Single Payment and Support Schemes Regulations 2009
S.I. 2009/3103	Road Vehicles (Registration and Licensing) (Amendment) (No. 2) Regulations 2009
S.I. 2009/3104	Water Resources Act 1991 (Amendment) (England and Wales) Regulations 2009
S.I. 2009/3112	Care Quality Commission (Registration) Regulations 2009
S.I. 2009/3128	Financial Services and Markets Act 2000 (Market Abuse) Regulations 2009
S.I. 2009/3131	Civil Jurisdiction and Judgments Regulations 2009
S.I. 2009/3135	Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2009
S.I. 2009/3136	Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2009

Instruments not subject to Parliamentary proceedings not laid before Parliament

S.I. 2009/3072	Child Maintenance and Other Payments Act 2008 (Commencement No. 6) Order 2009
S.I. 2009/3085	North Staffordshire Hospital Centre National Health Service Trust (Establishment) Amendment Order 2009
S.I. 2009/3086	Royal Wolverhampton Hospitals National Health Service Trust (Establishment) Amendment Order 2009
S.I. 2009/3087	Local Democracy, Economic Development and Construction Act 2009 (Commencement No. 1) Order 2009
S.I. 2009/3096	Policing and Crime Act 2009 (Commencement No. 1 and Transitional and Saving Provisions) Order 2009
S.I. 2009/3111	Criminal Justice Act 2003 (Commencement No. 8 and Transitional and Saving Provisions) (Amendment No. 2) Order 2009

Appendix 1

Draft S.I: memorandum from the Department of Health

Health and Social Care Act 2008 (Regulated Activities) Regulations 2009 (Draft S.I.)

1. In its letter to the Department of 2nd December 2009 the Joint Committee requested a memorandum on the following points:
 1. *Regulation 27(1) provides that a contravention of, or failure to comply with, any of the provisions of regulations 9 to 24 shall be an offence. In view of the terms in which requirements are expressed in many of those provisions (in particular in regulations 9, 10, 11, 14, 15, 16, 17, 23 and 24), explain, by way of elaboration of what is said in the Annex to the Explanatory Memorandum –*
 - a) *how, as the warning notice procedure under section 29 of the Health and Social Care Act 2008 is not compulsory, an affected person is to know what conduct will expose him to criminal proceedings, without having to take the risk of being subjected to prosecution ex post facto;*
 - b) *what consideration was given, in setting a maximum penalty of £50,000 in relation to all of the provisions in regulations 9 to 24, to the maximum penalties which Parliament itself has fixed for apparently similar offences, with particular reference to regulations 10(3), 13(2) and 19(3).*
 2. *Regulations 11(3), 13(2), 16(1)(b) and 18(b) refer to guidance.*
 - a) *Who are the appropriate expert bodies referred to in those provisions and do they include the Care Quality Commission?*
 - b) *Under what, if any, statutory provision has the guidance been issued?*
 - c) *Why is the guidance not more specifically identified?*
 - d) *Are the references to guidance intended to include references to guidance to be issued after the regulations are made?*
 - e) *If so, which statutory provision enables a requirement imposed under section 20 of the 2003 Act to be framed by reference to such guidance?*
 3. *When is section 23 of the 2008 Act to be brought into force, and when would the guidance under section 23(1) be issued if these regulations were approved and made?*
2. The Department's response to each of the Committee's points is outlined below.

Point 1

3. In relation to paragraph a), the key issue which will expose a registered person to the possibility of prosecution in any particular case is a clear failure to protect service users from the risk which is the focus of each registration requirement. It is only if this risk materialises that further investigation will be required as to how this risk has arisen and whether it arises as a result of a breach of the detailed steps which the registered person is required to take in order to achieve the desired outcome.
4. It may be helpful to illustrate this by reference to specific examples based on the regulations to which the Committee refers.
5. In relation to regulation 9, for example, the trigger for any enforcement action would be that a service user had received or was at clear risk of receiving treatment or care which was inappropriate or unsafe. For example, a person might have fallen out of bed in their care home and been injured or died. The next question would then be whether this unsafe care had come about as a result of a failure on the part of the registered provider to plan for e.g. the provision of guards on the side of the bed where they had been assessed as necessary; or as a result of failure to carry out plans that had been made by failing to install the sides or failing to raise them on a particular occasion.
6. Or, in relation to regulation 14, the trigger for enforcement action would be that a service user had become inadequately nourished or dehydrated or was clearly at risk of that. The next question would then be how this situation had come about. Was it, for example, because the registered person had not provided food which met a person's reasonable cultural requirements – for example for halal meat (in breach of regulation 14(1)(b)); or because they had not provided assistance with eating to a person who was unable to eat by themselves (which would breach 14(1)(c)). It would not be enough to expose a person to a risk of prosecution that a person who was clearly adequately nourished complained that they did not have as much food as they would like.
7. In the Department's view it should be sufficiently clear to the registered person from the guidance to be issued by the Commission under section 23 of the 2008 Act what steps they need to take to comply with the registration requirements. The Commission has already carried out extensive consultation on the guidance about compliance which it will be issuing under section 23. The consultation they carried out earlier this year received over 700 responses, the overall tone of which was extremely positive. The Commission will shortly be publishing on its website (www.cqc.org.uk) a draft of the guidance which it will publish once all the relevant section 20 regulations have been made.
8. As explained in the Explanatory Memorandum, prosecution will only be used for more serious and clear-cut cases. In most cases, it is likely that prosecution will not be the first enforcement action taken by the Commission so that the registered

person will be fully aware of what is required, whether by previous issue of a warning notice or otherwise.

9. There are safeguards against inappropriate prosecution of registered persons in that:

(a) section 4 of the 2008 Act requires the Commission in performing its functions to have regard to the need to ensure that action by the Commission in relation to health and social care services is proportionate to the risks against which it would afford safeguards and is targeted only where it is needed;

(b) section 88 of the 2008 Act requires the Commission to issue guidance in relation to enforcement action. Under subsection (2) of that section the guidance may include guidance about the circumstances in which the Commission is likely to take criminal proceedings for an offence under Part 1 of the Act, relating to registration. The enforcement guidance published by the Commission under section 88 in April 2009 (when registration under the 2008 Act first started) includes the following in relation to prosecution.

“46. We would not start a prosecution unless we were satisfied that it is in the public interest, that there is sufficient, admissible and reliable evidence that an offence has been committed and there is a realistic prospect of conviction. In reaching a decision to prosecute, we will have regard to the principles in the Code for Crown Prosecutors (www.cps.gov.uk/victims_witnesses/code.html). Where another organisation has the power to prosecute, we will liaise with them to ensure effective coordination, to avoid inconsistencies, and to ensure that any proceedings are for the most appropriate offence.”

A failure by the Commission to follow its published guidance would be challengeable by judicial review.

(c) the regulations themselves contain a due diligence defence (regulation 27(3)).

10. In relation to paragraph b), in deciding the appropriate maximum penalty for breach of the requirements in regulations 9 to 24, consideration was mainly given to the fact that these requirements are concentrated on essential levels of safety and quality. Other requirements, breach of which does not attract such a high maximum penalty, are set out in a separate set of regulations subject to the negative resolution procedure – the Care Quality Commission (Registration) Regulations 2009 (S.I. 2009/3112).
11. £50,000 is of course the maximum penalty which would only be imposed by the courts in appropriate circumstances, taking into account any relevant sentencing guidelines issued by the Sentencing Guidelines Council. It is important to

remember that the Commission will be dealing with a range of providers from small care homes to very large businesses and that the courts need to be able to impose a fine which will be taken seriously by larger providers. Other factors relevant to the level of fine will be the offender's history – are there convictions for previous offences for example or have other enforcement actions already been taken without achieving the desired result – and the seriousness of the offence. In the Department's view, there may be exceptional circumstances in which a fine at the higher end of the scale could be appropriate for breach of the regulations specified. Failure to have proper regard to guidance on the handling of medicines for example could have very serious consequences and knowing about complaints is often a key indicator that things may be going badly wrong. All the requirements specified are seen as an integral part of achieving essential safety and quality standards and for that reason it was not thought appropriate to discriminate between them in terms of the maximum possible fine available to the court in appropriate cases.

Point 2

12. In relation to these points:

a) The references to “appropriate expert bodies” in these regulations are intended to refer to bodies which are generally recognised to have expertise on the subject-matter dealt with by the relevant regulation. They would include bodies such as Government Departments, the National Institute for Clinical Excellence, the Medicines and Healthcare Products Regulatory Agency and professional regulators such as the General Medical Council. It is not unreasonable to expect providers of health and social care services to be aware of guidance relevant to the business which they are providing. However, in order to assist providers an Appendix to the Commission's draft section 23 guidance will also set out a list of publications which they would consider relevant.

Whilst the Commission could be regarded as an expert body we do not think that in practice it would be caught by these references because guidance by the Commission is likely to be part of the guidance issued under section 23 of the 2008 Act. Regulation 26 separately requires registered persons to have regard to such guidance.

b) The Commission's list includes a mix of statutory and non-statutory guidance.

c) As explained above, the compliance guidance issued by the Commission under section 23 of the 2008 Act will list the guidance by expert bodies which they consider to be relevant. The regulations do not have the effect of incorporating the content of this guidance into the regulations and failure to comply with the guidance will not itself be an offence under the regulations. Often, guidance by these expert bodies represents the most comprehensive and relevant thinking on a particular issue and it is therefore important to be able to ensure that providers do take it into account. The list in the guidance will be able to be updated easily and in a timely manner. The Commission's intention is to review the section 23 guidance and, in particular, the list in Appendix B in the summer of 2010 and at

regular intervals thereafter. The Commission will contact providers if changes are made and make information available through their website and through stakeholder and advisory groups.

d) It is intended that the references could capture guidance issued after the regulations are made.

e) There is no statutory provision which enables a requirement imposed under section 20 of the 2003 Act to be framed by reference to such guidance, as there is for example in section 23(3) of the Act. But the requirement here does not have the effect of incorporating such guidance since the requirement imposed is to have regard to the guidance in question rather than to comply with it

Point 3:

13. Under article 2 of the Health and Social Care Act 2008 (Commencement No. 13, Transitory and Transitional Provisions and Electronic Communications) Order 2009 (S.I. 2009/3023), 11th December 2009 is the day appointed for the coming into force of section 23 of the 2008 Act.
14. Under section 23(1) of that Act, the issuing of guidance is a matter for the Care Quality Commission rather than the Department or the Secretary of State. In order that those likely to fall within the new registration regime should have plenty of notice as to what is required by the new system, the Commission will shortly be publishing draft guidance on its website. As indicated in paragraph 6 above, this guidance has been the subject of extensive consultation. The final version will be published once the relevant regulations under section 20 of the 2008 Act have been made.

Department of Health
7th December 2009.

Appendix 2

S.I. 2009/2937: memorandum from the Ministry of Justice

<i>Magistrates' Courts (Drinking Banning Orders) Rules 2009 (S.I. 2009/2937)</i>
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1. In its letter dated 2nd December 2009, the Joint Committee on Statutory Instruments (“the Committee”) requested a memorandum on the following points:
 - (1) *To what extent is it agreed that the following provisions of this instrument replicate in effect the following provisions of the Violent Crime Reduction*

Act 2006 as they apply in the case of proceedings before magistrates' courts?

- (a) *Rules 3(1) and (2) replicate section 9(3) to (5);*
- (b) *Rule 3(6) replicates section 9(6)(b);*
- (c) *Rule 3(7) replicates section 9(7)(a);*
- (d) *Rule 3(8) replicates section 9(7)(b);*
- (e) *The words from "shall be made" to "resides and" in rule 4(2) replicate section 5(3) and (4);*
- (f) *Rule 6(1) replicates section 13(6);*
- (g) *Rule 7 replicates section 11(6).*

- (2) *So far as they replicate those provisions, why do they appear in the text of these Rules without any indication that they are merely pointers to existing primary legislation (see the Committee's Report on S.I. 2007/1744 in its 27th Report of the 2006-07 Session).*
- (3) *Why does the instrument not make it clear that it (and rule 6(2) in particular) applies only to proceedings before magistrates' courts?*

2. The Ministry of Justice's response to the Committee's query is set out below.
3. The Ministry agrees that the stated rules replicate the provisions of the Violent Crime Reduction Act 2006.
4. The rules which replicate the primary legislation were included to make the rules more complete and coherent for a reader to follow. These rules were drafted in 2007 but were put on hold until earlier this year when the Ministry proceeded with the making of these rules. Therefore the Ministry did not have the benefit of the JCSI Report on S.I. 2007/1744 in mind at the time the rules were drafted and unfortunately did not read across from that report when the rules were revived. However, the Ministry is grateful to the Committee for drawing attention to the report.
5. Whilst the Ministry accepts that rule 6(2) does not state that it applies only to proceedings in the magistrates' courts, the Ministry believes that the heading and the title of the rules together with the enabling powers stated in the preamble make it clear that the rules only apply to proceedings in the magistrates' courts.
6. The Ministry is not currently aware that the wording of the rules has caused any difficulties in practice, but it will keep this under review and if there is occasion to change the rules the Ministry will seek to take that opportunity to include amendments in relation to the points raised by the Committee.

Appendix 3

S.I. 2009/2979: memorandum from the Department for Culture, Media and Sport

<i>Audiovisual Media Services Regulations 2009 (S.I. 2009/2979)</i>

This memorandum is in response to the Committee's request dated 2 December 2009.

2. The Committee has asked:

“Explain the intended effect of new section 368P(2)(b) of the Communications Act 2003 (inserted by regulation 2) and how that is achieved, given that new section 368F of that Act (also inserted by regulation 2) does not refer to *a provider* of an on-demand programme service.”

3. The Department's response is as follows.

4. The inclusion of new section 368P(2)(b) is a drafting mistake. The intended effect was to disapply the rules on advertising in section 368F from the BBC. This is because under the BBC Agreement advertising is prohibited on the BBC's public services so the rules on advertising are superfluous in relation to the BBC¹. The Department is grateful to the Committee for drawing its attention to the error and apologises for this oversight. The same issue also arises in relation to section 368P(2)(c): sponsorship is prohibited under the BBC Agreement without permission from the Secretary of State so the rules on sponsorship are superfluous in relation to the BBC. Both section 368F (advertising) and section 368G (sponsorship) ought to have been disapplied in relation to the BBC by subsection (1) of section 368P. Instead, they were included in the list in subsection (2).

5. The Department intends to rectify these errors. Subsection(2)(b) and (c) do not have any substantive effect as they stand. The omission from subsection (1) of provision disappling section 368F (advertising) and section 368G (sponsorship) does not have any adverse effect because the purpose of including that provision is simply to avoid duplicating what is in the BBC Agreement.

6. The Department is intending to make further regulations in February 2010 to add additional provisions to Part 4A of the Communications Act 2003 (regulatory regime for on-demand programme services, inserted by these regulations) in order to implement technical standards notified to the Commission. We propose to rectify the errors then.

¹ References to the BBC in this memo and section 368P in effect mean the public services provided by the BBC. The BBC's commercial services, provided by a BBC company, are not included as a consequence of inserted section 368R(6).

Department for Culture, Media and Sport
8 December 2009

Appendix 4

S.I. 2009/2973: memorandum from the Department for Transport

<i>Railway Closures (Minor Modifications) Order 2009 (S.I. 2009/2973)</i>
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By a letter dated 2nd December 2009, the Committee has asked for a memorandum on the following point:

The first sentence of the Explanatory Note (which does not read properly as a sentence) does not appear to fit with article 2 Explain the discrepancy.

The Department apologises for the clumsy English and the incorrect description of the Order set out in the first sentence of the Explanatory Note.

The Department is without delay arranging for the issue of a correction slip. This will explain that the first paragraph of the Explanatory Note should have read as follows:

“This Order provides for a certain type of closure in certain circumstances to be eligible to be treated as a minor modification. This type of closure is the discontinuance of a part of a network that consists of a section of track that runs through or beside a station, but does not serve a platform at that station to allow a train to call there. The circumstances are where the discontinuance will not lead to a reduction in the capacity or capability of the network, and trains that would have used the track will instead use another route which runs through or beside the station.”

The Department regrets the error and, as indicated, is taking immediate steps to remedy it.

Department for Transport
7th December 2009