

EXPLANATORY MEMORANDUM TO
THE FALSE OR MISLEADING INFORMATION (SPECIFIED CARE
PROVIDERS AND SPECIFIED INFORMATION) REGULATIONS 2015

2015 No. [XXXX]

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

2. **Purpose of the instrument**

Section 92(1) of the Care Act 2014 (“the Act”) provides that the offence of supplying, publishing or otherwise making available false or misleading information (“the FOMI offence”) will apply to such care providers and such information as is specified in regulations.

Regulation 2 of the Regulations specifies NHS trusts in England, NHS foundation trusts and other persons who provide health services from a hospital pursuant to arrangements made with a public body, as care providers for the purposes of section 92(1) of the Act.

Regulation 3 specifies certain commissioning data sets required by the Health and Social Care Information Centre and certain other information as the information to which section 92(1) of the Act applies.

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

3.1 None

4. **Legislative Context**

Sections 92 to 94 of the Care Act 2014 put in place a new offence on providers who supply, publish or otherwise make available, under a legal obligation, specified types of information that is false or misleading. They also provide for associated criminal sanctions.

The offence is in two parts, covering both providers who are found to be at fault and any director or other senior individual, within a provider that is a body corporate, where that individual is responsible for the provider having committed the offence. The provider must first be found to have committed the offence before any individual can be convicted of the offence.

The primary legislation requires that regulations specify which information and which care providers the FOMI offence applies to. This means that in order for the FOMI offence to take effect, the care providers to whom it applies and the information to which it applies must be specified in regulations. The supply, publication or otherwise making the information

available must also be required under a legal obligation. Unless these requirements are met, the FOMI offence will not apply.

The Schedule to the Regulations sets out the information which is in scope of the FOMI offence. The FOMI offence itself does not place any legal compunction on a provider to submit this information, it simply means that the offence can take effect if any of the information listed below is supplied, published or otherwise made available under a legal obligation in such a fashion that it is false or misleading:

- Information supplied to the Health and Social Care Information Centre for the purposes of commissioning data sets;
 - 010 Accident and Emergency,
 - 020 Out-patient,
 - 030 Elective Admission List - End of Period Census (Standard),
 - 120 Admitted Patient Care – Finished Birth Episode,
 - 130 Admitted Patient Care – Finished General Episode,
 - 140 Admitted Patient Care – Finished Delivery Episode,
 - 150 Admitted Patient Care – Other Birth (including home birth),
 - 160 Admitted Patient Care – Other Delivery (including home delivery),
 - 180 Admitted Patient Care – Unfinished Birth Episode,
 - 190 Admitted Patient Care – Unfinished General Episode,
 - 200 Admitted Patient Care – Unfinished Delivery Episode

- Information supplied for the purposes of the:
 - *Cancer Outcomes Data set*
 - *Hospital and Community Health Services Complaints Collection*
 - *National Cancer Waiting Times Monitoring Data Set*
 - *National Diabetes Audit*
 - *National Maternity Services Data Set*

- NHS Quality Accounts

As stated above, the FOMI offence will only apply to information listed in the regulations when it is required to be supplied, published or otherwise made available under an enactment or other legal obligation. The information can either be collected by a body which has the power to request it or there is an obligation on the providers specified in regulation 2 to publish or submit the information. For example, the information submitted to the Health and Social Care Information Centre for the purposes of commissioning data sets is collected by it under its power in section 259 of the Health and Social Care Act 2012. NHS quality accounts (produced in accordance with the National Health Service (Quality Accounts) Regulations 2010) are required to be published by section 8 of the Health Act 2009.

The information included in the Regulations is that which either informs the mortality data for an NHS provider or where the provision of the information

in a false or misleading way could lead to harm to patients, as alerts might not be issued which trigger an intervention from supervisory or regulatory bodies.

It will be a defence for a care provider charged with the FOMI offence to prove that it took all reasonable steps and exercised all due diligence to prevent the offence from occurring. This means that genuine mistakes would not be caught by the offence where such steps and diligence had been taken.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

The Parliamentary Under-Secretary of State for Health has made the following statement regarding Human Rights:

“In my view, the provisions of the False or Misleading Information (Specified Care Providers and Specified Information) Regulations 2015 are compatible with the Convention rights.”

7. Policy background

The need for a criminal offence in response to the provision of false or misleading information was raised by the Mid Staffordshire NHS Foundation Trust Public Inquiry.

“It should be a criminal offence for a director to sign a declaration of belief that the contents of a quality account are true if it contains a misstatement of fact concerning an item of prescribed information which he/she does not have reason to believe is true at the time of making the declaration.” – Report of the Mid Staffordshire Public Inquiry – February 2013

The Inquiry recommended that there should be a statutory duty on Directors of healthcare organisations to be truthful in any information given to a health care regulator or commissioner, either personally or on behalf of the organisation, where given in compliance with a statutory obligation. Offences under the Fraud Act, the Theft Act and the Perjury Act do not adequately cover the type of misreporting of information that can undermine the ability of regulators and commissioners to oversee care providers.

The Government agreed with the recommendation to make it a criminal offence for a provider or individual to provide false or misleading information in a quality account, but felt that the offence should be applied more widely. In response to the recommendation of the Public Inquiry, the Government made the following commitment:

“There can be no excuse for boards who knowingly supply wrong information about key indicators such as mortality rates, or deliberately withhold information from patients or families about serious harm or death. So where

organisations wilfully generate misleading information or withhold information they are required to provide, we will consider the introduction of additional legal sanctions at a corporate level.” – ‘Patients First and Foremost’ – March 2013, para. 2.34.

The Government went on to state that:

“Mortality data must be interpreted with care, but it must also be accurate so that the public and patients can trust that they are hearing the truth. So there will be tough penalties and possibly criminal sanctions on organisations that are found to be massaging figures or concealing the truth about their performance.” – ‘Patients First and Foremost’ – March 2013 page 39.

The offence forms part of the Government’s overall drive to improve the openness and transparency in the provision of health services, by making clear that a sanction exists for failing to provide or publish accurate or honest information about the performance of services.

8. Consultation outcome

In late April 2014 the Department of Health consulted on the draft regulations containing the list of specified providers and information to be within scope of the FOMI offence. The consultation ran until June 2014 and received a limited number of responses, which we believe was due to the technical nature of the regulations and the limited exposure the consultation received in the media. This is also reflected in the responses received, which were principally from key stakeholder organisations with either a professional or technical interest in the proposals.

The consensus response welcomed the proposed approach of the FOMI offence through regulations, with only one respondent being opposed. While there were concerns raised about the policy the key request from most respondents was that there be guidance on how the offence should operate.

9. Guidance

In light of the consultation responses citing the need for guidance, the Department of Health has worked with Crown Prosecution Service (CPS), the Health and Social Care Information Centre (HSCIC) and other stakeholders to produce guidance for providers on the FOMI offence. This guidance is intended to cover many of the concerns raised in responses to the consultation and also further illustrate the workings of the offence.

The guidance and the response to the consultation can be found online at the following address: <https://www.gov.uk/government/consultations/healthcare-providers-supplying-misleading-information>

10. Impact

10.1 The Department of Health published an impact assessment on the FOMI offence for the passage of the Care Act 2014 through Parliament. This impact assessment can be found online at the following address:

<http://www.parliament.uk/documents/impact-assessments/IA13-14I.pdf>

10.2 The FOMI offence does not require that providers undertake any additional action beyond that which is already required of them in supplying information. This will ensure that there are no additional burdens on those providers who already have robust systems in place to submit accurate information. Providers who do not have robust systems in place may need to change their approach in response to this new offence

11. Regulating small business

11.1 The Regulations will not apply to small businesses.

12. Monitoring & review

12.1 The Department will keep the Regulations under review in order to keep them up-to-date and relevant, to take account of changes in delivery of care and to ensure that the burden on business is justified and proportionate. Regulation 4 of the Regulations commits the Secretary of State to carry out a review of the Regulations by the end of every five year period, and set out the conclusions of the review in a report. The first report must be published before the end of the period of five years beginning when the Regulations first come into force.

13. Contact

Giles Crompton-Howe at the Department of Health, tel: 0113 254 5715 or email: giles.crompton-howe@dh.gsi.gov.uk who will be able to answer any questions about the instrument.