



Department
of Health

False or Misleading Information

Response to the consultation on the application of
the offence through regulations

February 2015

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False or Misleading Information

The Department of Health

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Introduction

1. The Care Act 2014 has put in place a new criminal offence applicable to care providers who supply, publish or otherwise make available certain types of information that is false or misleading, where that information is required to comply with a statutory or other legal obligation. The offence also applies to the 'controlling minds' of the organisation, where they have consented or connived in an offence committed by a care provider.
2. The need for a criminal offence in response to the provision of false or misleading information was raised by the Public Inquiry into Mid Staffordshire NHS Foundation trust.
3. ***“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
4. The Government accepted 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. 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.
5. The offence is in two parts. The first is a strict liability offence where a provider is found to have published or provided false or misleading information. The second is where a director or other senior individual are found to have been culpable in the offence. This means that the provider must first be found to have committed the offence before any individual can be prosecuted.
6. The scope of the offence is wide, applying to any information that is required under an enactment or legal obligation and any providers of publicly funded secondary care. However, the scope can be limited via secondary legislation to apply to certain types of information provided by certain types of provider. In late April 2014 the Department of Health consulted on the draft regulations containing the list of specified information to be within scope of the FOMI offence.
7. The draft regulations we consulted focused the scope for the FOMI offence to applying only to NHS Trusts, NHS Foundation Trusts and independent providers of secondary care services delivering NHS funded care. The scope was further focused to only applying to the datasets specified in the regulations.

Consultation On The Regulations

8. In late April 2014 the Department of Health consulted on the draft regulations containing the list of specified 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.

What We Heard

9. 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 comment from most respondents was that there should be guidance on how the offence should operate.
10. In light of these comments, 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.

Key Themes in the Consultation Responses

11. The guidance is intended to provide a full response to many of the concerns raised by respondents to the consultation. However, a summary of the key themes raised by responses to the consultation is provided here and as a summary of what is covered by the guidance.
 - *What is the intent of the policy?*
 - *Is it to improve the quality of information or protect the recipients of information from taking action they otherwise wouldn't e.g. failing to investigate a poor performing provider because the published information does not trigger any "alerts" in monitoring systems?*
12. The offence forms part of the Government's overall drive to improve 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.
13. As was observed in the responses of the HSCIC and Standardisation Committee for Care Information (SCCI). The FOMI offence should act as a driver to both improve the integrity of data requests made to NHS providers and also the data received. This should, in turn, improve the overall quality of data. As illustrated in the guidance, flaws in the development of data requests can present problems for challenging the data provided. Errors in data, intentional or otherwise, are much harder to detect when the

information request itself is unclear.

- *What is meant by 'misleading' information?*
14. Misleading information is not necessarily false (although it can be), but instead can be factually accurate information that is presented in such a way that the meaning of the information is distorted. This is covered in more detail in the guidance.
- *FOMI being used to address failings which would/should be handled through performance management.*
15. As a criminal offence, the decision to prosecute will be a matter for the Crown Prosecution Service (CPS), considering the available evidence and whether the public interest would be served in bringing a prosecution. In some cases the CPS may be satisfied that the public interest can be properly served by offering the offender the opportunity to have the matter dealt with by an out-of-court disposal rather than bringing a prosecution. Such a disposal might be that appropriate action be taken by the relevant supervisory or performance management bodies.
16. Where the offence is brought before the courts, the penalty on conviction is an unlimited fine for a care provider. In addition, a convicted care provider can also be required to comply with one or both of either a remedial order or a publicity order issued by the court.
17. More detail on this issue can be found in the guidance.
- *Concern about trying to differentiate between poor quality data and something that would fall within scope of FOMI.*
 - *Lack of consistency in how data is presented across the NHS and while differences in presentation can be misleading, they are not strictly wrong.*
 - *Information that is believed to be true at the time that subsequently changes and become inaccurate. The time lag between submissions and return of data can be long enough to reduce the usefulness of the information received*
 - *Clinical coding of data which is done in a way that, while not strictly incorrect, can present a skewed view of service performance*
18. The expectation is that NHS providers will endeavour to submit or publish the most accurate information possible. It is understood that ambiguity in information can arise because of the way in which data is requested or the time lag between submission and publication. Determining whether the FOMI offence may have been committed will be a matter for those investigating the offence and then for the CPS to decide whether there is sufficient evidence to pursue a prosecution and that it would be in the public interest to do so.
19. FOMI is a strict liability offence and therefore it is not necessary to establish that there was any intent to commit the offence. However, while the provision of false or misleading information may have occurred, the Act also incorporates a due diligence defence.
20. This means that in the event of FOMI occurring without intent, an NHS or other

healthcare provider would have the opportunity to demonstrate what action it took to mitigate against the publication of false or misleading information occurring. It would be a matter for the Court to decide whether the due diligence defence put forward, demonstrate that the provider had taken appropriate action.

- *Why not cover primary care or commissioning?*
- *By choosing to focus on secondary care there is a risk that the provision of false or misleading in other parts of the care system is seen as less important and allowed to continue.*

21. The scope of the FOMI offence is set in the Care Act 2014. The Act limits the scope of the offence to all Health and Social Care providers of publicly funded services in England. The key element is that the services provided must be funded by the public purse. This would typically be through contracts independent providers have with the NHS or with Local Authorities to deliver services.

22. As the primary legislation excludes primary care and commissioning, data collections for those areas cannot be covered by these regulations. At this time,

23. The FOMI offence was developed in response to the Mid Staffordshire Public Inquiry. The recommendation was for an offence focused specifically on Quality Accounts, which are only published by NHS Trusts and NHS Foundation Trusts. However, the scope of the offence in the Care Act 2014 was made very broad by design, so as to be flexible in its application in the future.

Comments on the scope of the regulations

24. The majority of responses were not opposed to the list of information to be within scope of the FOMI offence, with two exceptions being suggested for removal.

- *The Maternity Data Set – is this not yet fully operational and sufficiently robust as to provide an adequate test for FOMI. It is recommended for inclusion at a later date.*

25. Following discussion with the HSCIC, the Maternity Data Set is planned to become fully operational in May 2015. The FOMI regulations are planned to commence in April 2015 and we feel that this represents a sufficiently small timeframe of risk, in terms of the data set being sufficiently rigorous as to support clarity as to whether the offence had been committed or not, to leave the data in the regulations.

- *The Cancer Outcomes Data set – presently this information is not required in such a way that meets the statutory or other legal obligation component for inclusion in the regulations.*

26. Our view is that the legal changes to bring the Cancer Outcomes Data Set into the scope of FOMI are resolvable. We therefore propose to keep the Cancer Outcomes Data Set in the regulations, with a later date for commencement of April 2017, and work to make the necessary changes within that timeframe.

27. Another concern raised was that by focusing the regulations on a relatively narrow list, there is a risk that falsifications are tolerated in areas out of scope of FOMI. This is most definitely not the case. The expectation is that the NHS will endeavour to deliver as accurate information as possible in responding to requests or publishing material about the performance of services. In addition, the amount of data that the NHS is required to submit or publish that is suitable for inclusion in the scope of FOMI is limited. Including data collections that are insufficiently robust can mean that making a determination as to whether FOMI has occurred problematic.

Expanding FOMI over time.

28. The HSCIC, the lead organisation in England for the collection, analysis and publication of health and social care data, is supportive of there being a future process for adding to the list of specified information in scope of FOMI.

29. The Department of Health will work the HSCIC and other relevant stakeholders, such as Ministry of Justice, Crown Prosecution Service and the Standardisation Committee for Care Information to develop a process for reviewing (be it expanding or decreasing) the scope of FOMI in the future.

30. Our expectation is that all possible areas for inclusion (or removal) from the scope of the FOMI regulations, will be subject to advice from the HSCIC and SCCI as to whether they are appropriate for inclusion (or removal) and the basis for this. All proposals will be subject to the approval of the Secretary of State for Health, before any regulations containing a revised list of specified information are laid before Parliament for scrutiny.

Next Steps

31. The regulations (found at Annex B) will be laid before Parliament, alongside this response and the guidance, the earliest possible opportunity and subject to debates in both the House of Commons and the House of Lords.
32. It will be the decision of Parliament as to whether these regulations require amendment before coming into force. If no changes are required to the regulations, then we intend to bring them into force in early 2015.

Annex A - The Bill clauses

False or misleading information

91 Offence

- (1) A care provider of a specified description commits an offence if—
- (a) it supplies, publishes or otherwise makes available information of a specified description,
 - (b) the supply, publication or making available by other means of information of that description is required under an enactment or other legal obligation, and
 - (c) the information is false or misleading in a material respect.
- (2) But it is a defence for a care provider to prove that it took all reasonable steps and exercised all due diligence to prevent the provision of false or misleading information as mentioned in subsection (1).
- (3) “Care provider” means—
- (a) a public body which provides health services or adult social care in England,
 - (b) a person who provides health services or adult social care in England pursuant to arrangements made with a public body exercising functions in connection with the provision of such services or care, or
 - (c) a person who provides health services or adult social care in England all or part of the cost of which is paid for by means of a direct payment under section 12A of the National Health Service Act 2006 or under Part 1 of this Act.
- (4) “Health services” means services which must or may be provided as part of the health service.
- (5) “Adult social care”—
- (a) includes all forms of personal care and other practical assistance for individuals who, by reason of age, illness, disability, pregnancy, childbirth, dependence on alcohol or drugs, or any other similar circumstances, are in need of such care or other assistance, but
 - (b) does not include anything provided by an establishment or agency for which Her Majesty’s Chief Inspector of Education, Children’s Services and Skills is the registration authority under section 5 of the Care Standards Act 2000.
- (6) “Specified” means specified in regulations.
- (7) If a care provider commits an offence under either of the provisions mentioned in subsection (8) in respect of the provision of information, the provision of that information by that provider does not also constitute an offence under subsection (1).
- (8) The provisions referred to in subsection (7) are—
- (a) section 44 of the Competition Act 1998 (provision of false or misleading information) as applied by section 72 of the Health and Social Care Act 2012 (functions of the OFT under Part 1 of the Competition Act 1998 to be concurrent functions of Monitor), and
 - (b) section 117 of the Enterprise Act 2002 (provision of false or misleading information) as applied by section 73 of the Health and Social Care Act 2012 (functions of the OFT under Part 4 of the Enterprise Act 2002 to be concurrent functions of Monitor).
- (9) If a care provider commits an offence under subsection (1) in respect of the provision of information, the provision of that information by that provider does not also constitute an offence under section 64 of the Health and Social Care Act 2008 (failure to comply with request to provide information).

92 Penalties

- (1) A person who is guilty of an offence under section 90 is liable—
- (a) on summary conviction, to a fine;
 - (b) on conviction on indictment, to imprisonment for not more than two years or a fine (or both).
- (2) A court before which a care provider is convicted of an offence under section 90 may (whether instead of or as well as imposing a fine under subsection (1)) make either or both of the following orders—
- (a) a remedial order,
 - (b) a publicity order.
- (3) A “remedial order” is an order requiring the care provider to take specified steps to remedy one or more of the following—
- (a) the conduct specified in section 90(1),
 - (b) any matter that appears to the court to have resulted from the conduct,
 - (c) any deficiency, as regards the management of information, in the care provider’s policies, systems or practices of which the conduct appears to the court to be an indication.
- (4) A “publicity order” is an order requiring the care provider to publicise in a specified manner—
- (a) the fact that it has been convicted of an offence under section 90,
 - (b) specified particulars of the offence,
 - (c) the amount of any fine imposed, and
 - (d) the terms of any remedial order made.
- (5) A remedial order may be made only on an application by the prosecution specifying the terms of the proposed order; and any such order must be on such terms (whether those proposed or others) as the court considers appropriate having regard to any representations made, and any evidence adduced, in relation to that matter by the prosecution or on behalf of the care provider.
- (6) A remedial order must specify a period within which the steps referred to in subsection (3) are to be taken.
- (7) A publicity order must specify a period within which the requirements referred to in subsection (4) are to be complied with.
- (8) A care provider that fails to comply with a remedial order or a publicity order commits an offence and is liable on conviction on indictment to a fine.

93 Offences by bodies

- (1) Subsection (2) applies where an offence under section 90(1) is committed by a body corporate and it is proved that the offence is committed by, or with the consent or connivance of, or is attributable to neglect on the part of—
- (a) a director, manager or secretary of the body, or
 - (b) a person purporting to act in such a capacity.
- (2) The director, manager, secretary or person purporting to act as such (as well as the body) is guilty of the offence and liable to be proceeded against and punished accordingly (but section 91(2) does not apply).

(3) The reference in subsection (2) to a director, manager or secretary of a body corporate includes a reference—

- (a) to any other similar officer of the body, and
- (b) where the body is a local authority, to a member of the authority.

(4) Proceedings for an offence under section 90(1) alleged to have been committed by an unincorporated association are to be brought in the name of the association (and not in that of any of the members); and rules of court relating to the service of documents have effect as if the unincorporated association were a body corporate.

(5) In proceedings for an offence under section 90(1) brought against an unincorporated association, section 33 of the Criminal Justice Act 1925 and Schedule 3 to the Magistrates' Courts Act 1980 apply as they apply in relation to a body corporate.

(6) A fine imposed on an unincorporated association on its conviction for an offence under section 90(1) is to be paid out of the funds of the association.

(7) Subsection (8) applies if an offence under section 90(1) is proved—

- (a) to have been committed by, or with the consent or connivance of, an officer of the association or a member of its governing body, or
- (b) to be attributable to neglect on the part of such an officer or member.

(8) The officer or member (as well as the association) is guilty of the offence and liable to be proceeded against accordingly (but section 91(2) does not apply).

Annex B – Draft Regulations

Draft Regulations laid before Parliament under section 125(4)(m) of the Care Act 2014, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2015 No.

NATIONAL HEALTH SERVICE, ENGLAND

PUBLIC HEALTH, ENGLAND

False or Misleading Information (Specified Care Providers and Specified Information) Regulations 2015

Made - - - - *2015*

Coming into force in accordance with regulation 1(1)

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 92(1) of the Care Act 2014⁽¹⁾.

A draft of these Regulations was laid before Parliament in accordance with section 125(4)(m) of the Care Act 2014, and was approved by a resolution of each House of Parliament.

Citation, commencement and interpretation

—(1) These Regulations may be cited as the False or Misleading Information (Specified Care Providers and Specified Information) Regulations 2015 and come into force—

except as provided by sub-paragraph (b), at the end of the period of 21 days beginning with the day on which these Regulations are made, and

in the case of paragraph 1 of Part 2 of the Schedule and regulation 3 insofar as it applies to that paragraph, on 1st April 2017.

In these Regulations—

“the Act” means the Care Act 2014;

“commissioning data set” or “CDS” means a collection of patient-level data on a particular activity;

“health service hospital” has the same meaning as in section 275(1) of the National Health Service Act 2006⁽²⁾;

“the Information Centre” means the Health and Social Care Information Centre⁽³⁾.

⁽¹⁾ 2014 c. 23. Section 92(6) of the Care Act 2014 provides that “specified” means specified in Regulations. Section 125(1) of that Act provides that the power to make regulations is exercisable by the Secretary of State.

⁽²⁾ 2006 c. 41. The definition of “health service hospital” was amended by the Health and Social Care Act 2012 (c. 7), section 55(1) and paragraph 138(1) and (2)(b) of Schedule 4.

Specified care providers

The care providers specified for the purposes of section 92(1) of the Act (offence of supplying etc false or misleading information) are—

- an NHS trust established under section 25 of the National Health Service Act 2006,
- an NHS foundation trust, and
- a person who, pursuant to arrangements made with a public body, provides health services in England from a hospital (as defined in section 275(1) of the National Health Service Act 2006) that is not a health service hospital.

Specified information

The information specified for the purposes of section 92(1) of the Act is the information—

- referred to in the third column of the table in Part 1 of the Schedule, to the extent that it is supplied to the Information Centre, or to another person on the Centre’s behalf, for collation for the purposes of the corresponding commissioning data sets listed by type and description in that table;
- listed in Part 2 of the Schedule.

Review

- (2) Before the end of each review period, the Secretary of State must—
 - carry out a review of these Regulations,
 - set out the conclusions of the review in a report, and
 - publish the report.

The report must in particular—

- set out the objectives intended to be achieved by regulations 2 and 3,
- assess the extent to which those objectives are achieved, and
- assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved in a way that imposes less regulation.

In this regulation, “review period” means—

- the period of five years beginning from the end of the period referred to in regulation 1(1)(a), and
- subject to paragraph (4), each successive period of five years.

If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

Signed by authority of the Secretary of State for Health

Date

Name
Under Secretary of State
Department of Health

⁽³⁾ The Health and Social Care Information Centre is a body corporate established by section 252 of the Health and Social Care Act 2012 (c. 7).

SCHEDULE

Regulation 3

PART 1

Commissioning data sets

<i>CDS Type</i>	<i>CDS Description</i>	<i>Data</i>
CDS 010	Accident and Emergency	Data of all monthly accident and emergency attendances (individual visits to an accident and emergency department to receive treatment from the accident and emergency service)
CDS 020	Out-patient	Data of all monthly out-patient attendances (individual visits) (including ward attenders and nurse and midwife attendances) and monthly numbers of cancelled or missed out-patient appointments
CDS 030	Elective Admission List – End of Period Census (Standard)	Monthly data of patients remaining on elective admission lists on a particular date, including details of all booked, planned and waiting list admissions
CDS 120	Admitted Patient Care - Finished Birth Episode	Monthly data of all birth episodes that have finished (deliveries resulting in a registrable birth (all live births and still births after 24 weeks gestation) in a health service hospital or in another organisation where the delivery was funded by the NHS)
CDS 130	Admitted Patient Care - Finished General Episode	Monthly data of all finished general episodes of admitted patient care (day case and inpatient) under the care of a consultant, midwife or nurse
CDS 140	Admitted Patient Care - Finished Delivery Episode	Monthly data of all finished delivery episodes (deliveries which have resulted in a registrable birth in a health service hospital or in another organisation where the delivery was funded by the NHS)
CDS 150	Admitted Patient Care - Other Birth Event	Monthly data of all finished other birth events (NHS funded home births and all other birth events which are not NHS funded)

CDS 160	Admitted Patient Care - Other Delivery Event	Monthly data of all finished other delivery episodes (NHS funded home deliveries and all other delivery events which are not NHS funded)
CDS 180	Admitted Patient Care – Unfinished Birth Episode	Data relating to birth episodes that were unfinished as at midnight on 31st March of each year
CDS 190	Admitted Patient Care – Unfinished General Episode	Data, for NHS and private patient care (day case and inpatient), for all general episodes that were unfinished as at midnight on 31st March of each year and of all unfinished short-stay informal psychiatric patients who are resident in hospital or on leave of absence (home leave) on 31st March of each year and who have been in hospital for less than 12 months
CDS 200	Admitted Patient Care – Unfinished Delivery Episode	Data of delivery episodes, in a health service hospital or in another organisation where the delivery episode was funded by the NHS, that were unfinished as at midnight on 31st March of each year

PART 2

Other specified information

Cancer Outcomes and Services Data Set

1. Data relating to all patients (both adult and paediatric) diagnosed with cancer or receiving cancer treatment in, or funded by, the National Health Service in England provided to Public Health England⁽⁴⁾ for collation for the purposes of the Cancer Outcomes and Services Data Set (a data set used to build indicators of activity, performance and outcomes of cancer care in England), other than the information referred to in paragraph 3.

Hospital and Community Health Services Complaints Collection

Information supplied to the Information Centre, or to another person on the Centre's behalf, for collation for the purposes of the Hospital and Community Health Services Complaints Collection (data which is used for the purpose of monitoring written hospital and community complaints (by service area, profession and type) received by the National Health Service each year).

National Cancer Waiting Times Monitoring Data Set

Information supplied to the Information Centre, or to another person on the Centre's behalf, for collation for the purposes of the National Cancer Waiting Times Monitoring Data Set (a patient-level data set used, amongst other things, for the monitoring of timed pathways of care for cancer patients and waiting times for cancer services).

⁽⁴⁾ Public Health England is an executive agency of the Department of Health.

National Diabetes Audit

Information supplied to the Information Centre, or to another person on the Centre's behalf, for collation for the purposes of the National Diabetes Audit (an annual clinical audit of patient-level data used for the monitoring of complications from diabetes and care provided to people with diabetes).

National Maternity Services Data Set

Information supplied to the Information Centre, or to another person on the Centre's behalf, for collation for the purposes of the National Maternity Services Data Set (a patient-level data set that captures key information at each stage of the maternity service care pathway).

Quality Accounts

The information contained in documents published under section 8 of the Health Act 2009 (duty of providers to publish information)⁽⁵⁾.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. Section 92 of the Care Act 2014 ("the Act") creates an offence of supplying, publishing or otherwise making available information which is false or misleading in a material respect. The offence will apply: to such care providers and such information as is specified in regulations; and, where the information is supplied, published or made available under an enactment or other legal obligation.

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

3. Regulation 3 specifies information provided to the Health and Social Care Information Centre for the purposes of certain commissioning data sets, listed in Part 1 of the Schedule, and certain other information, listed in Part 2 of the Schedule, as the information to which section 92(1) of the Act applies.

4. Regulation 4 requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years beginning with the day on which provisions of these Regulations first come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

5. A full Impact Assessment has not been produced for this instrument as no, or no significant, impact on the private sector or civil society organisations is foreseen. A full impact assessment has been produced in relation to the relevant provisions of the Act and a copy is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS or at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/275546/FOMI_IA.pdf.

⁽⁵⁾ 2009 c. 21. The National Health Service (Quality Accounts) Regulations 2010 (S.I. 2010/279, as amended by S.I. 2011/269 and 2012/3081) set out the prescribed information, general content and form of quality accounts to be published under section 8 of the Health Act 2009.