



Department
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The False or Misleading Information Offence: Guidance for Providers

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The False or Misleading Information Offence: Guidance for Providers

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The False or Misleading Information Offence - 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. This guidance sets out the context for the offence and explains how the offence is applied.
3. 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.

“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.
5. 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.
6. 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.
7. This guidance explains the operation of the new offence in more detail.

FOMI – an explanation of the offence

The Offence

The offence is contained at Section 92 of the Care Act 2014.¹

FOMI –A criminal offence

8. FOMI is a criminal offence and the investigating body for that offence will be the police, conducted in line with the “The Director's Guidance On Charging”². The police can pursue all reasonable lines of enquiry to ensure that any evidence or material likely to undermine the prosecution case or assist the defense is provided to the prosecutor and taken into account during any referral for investigative advice or charging.
9. FOMI is a strict liability offence that applies to providers of care services as corporate bodies or partnerships. This means that a prosecutor has to prove that the information was, as a matter of fact, false or misleading, but does not have to prove that there was intent to provide false or misleading information on the part of the corporate body or partnership.
10. The offence has a broad application given that the provision of information which could be construed as false or misleading. However, it will be a matter for the Crown Prosecution Service (CPS) to decide if there is sufficient evidence to pursue a prosecution, in line with the Code of Practice for Crown Prosecutors.³
The wording of the Act is:

- (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.**

False

11. False information is that which can be demonstrably proved to be incorrect. For the purposes of the FOMI offence, there need not be any intent on the part of an organisation to supply or publish false information, only that the information is false or misleading in a material respect.

Misleading

¹ <http://www.legislation.gov.uk/ukpga/2014/23/section/92/enacted>

² http://www.cps.gov.uk/publications/directors_guidance/dpp_guidance_5.html

³ http://www.cps.gov.uk/publications/code_for_crown_prosecutors/

12. 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. The information must mislead the intended audience or recipient in some way, as to cause them to act in a way towards the provider that would otherwise differ had the information been published or provided in a non-misleading way.
13. This can include such acts as publishing relative rather than absolute information (or vice versa) should one form create a more positive impression or choosing to present only one set of data instead of another. Failing to present any information at all on a particular issue, could also create a misleading impression of activity or errors in a particular area.

Which organisations do the FOMI regulations apply to?

14. The offence can only be committed by a “care provider of a specified description” and the explanation of this is also set out in the offence. The wording of the Act is:

(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.

15. The wording in the Care Act 2014 for the FOMI offence means that it can be applied to all publicly run Health and Social Care providers in England, or any person or provider who is delivering services on behalf of or through arrangement with, a publicly funded body. 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.
16. A care provider of a “specified description” means that regulations can specify more precisely than the wording of the act, which care providers the offence applies to. Although the offence as worded in the Care Act 2014, does limit the application of the offence to “publicly funded” health and social care services, this still represents a considerable number of providers.

17. Therefore the regulations limit the care providers to whom FOMI applies to the following—
- an NHS trust established under section 25 of the National Health Service Act 2006(4);
 - an NHS foundation trust; and
 - a person, other than an NHS trust or an NHS Foundation Trust, who provides health services for the purposes of the health service from a hospital. For example: an Independent Sector Treatment Centre.
18. In summary this means all NHS Trust Hospitals and all NHS Foundation Trust Hospitals are within scope of the FOMI offence, as are independent hospitals which are delivering NHS funded services under contract. While these providers are within scope of the offence, the offence does not apply to all the information these providers submit and publish, only the information specified in the regulations.

Which individuals does FOMI apply to and what happens if they are convicted?

19. The FOMI offence can also apply to individuals within a care provider but, only when the care provider has been found to be guilty of the offence. The wording of the Care Act in respect of individuals is:
section 94(1) of the Act

(1) Subsection (2) applies where an offence under section 92(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 93(2) – remedial or publicity orders do not apply).

20. “Director” “manager” and “secretary” refer to senior individuals within an organisation. The use of “secretary” is in the sense of a “company secretary⁵” as set out in the Companies Act 2006⁶. For the purposes of the FOMI offence, a director or manager would have to be equivalent (or near equivalent) in seniority to a company secretary.

Which specified Information does the FOMI offence apply to?

21. Schedule 1 of the regulations⁷ sets out the information which is in scope of the FOMI offence. This is information which the providers in scope of FOMI are

(4) 2006 c. 41

⁵ <http://www.companieshouse.gov.uk/infoAndGuide/faq/secretaries.shtml>

⁶ <http://www.legislation.gov.uk/ukpga/2006/46/contents>

⁷ False or Misleading Information (Specified Care Providers and Specified Information) Regulations 2015

legally required to provide by another piece of legislation. FOMI 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 submitted or published in such a fashion that it could be construed as false or misleading.

22. All NHS Trust Hospitals and NHS Foundation Trust Hospitals are legally required to publish or submit this information⁸. Independent hospitals contracted to provide NHS funded secondary care may be required to submit some of the information above, depending on the nature of the services they are contracted to deliver.

⁸ section 8(1) or (3) of the Health Act 2009

Policy Background

23. The Public Inquiry into Mid-Staffordshire NHS Foundation Trust was established to consider the operation of the commissioning, supervisory and regulatory bodies in relation to their monitoring role at the Trust. The extent of the failings and the fact that they went unknown for so long, raised the very serious question as to why the organisations external to the Trust did not detect them.
24. The Inquiry found that the Trust repeatedly made inaccurate statements about its mortality rates (paragraphs 22.4-22.11 of the report) which led, in part, to a lack of action to investigate issues regarding the quality of care both within the Trust and by other bodies. This also raised difficult issues about the accuracy of public information in the light of poor handling of the raw data. Robert Francis recommended that:

“Any statement made to a regulator or a commissioner in the course of its statutory duties must be completely truthful and not misleading by omission.” – **Report of the Mid Staffordshire Public Inquiry – February 2013**

25. Sir Robert Francis also recommended that it be made a criminal offence for any senior individual to knowingly sign off an NHS Quality Account that contained information they knew to be untrue. The FOMI offence is a lot broader in its application than the recommendation from Francis, chiefly because the NHS publishes or submits a broad range of information and this can affect not just the public’s behaviour towards accessing services, but those of other healthcare bodies.
26. The Care Quality Commission and Monitor do have powers to take action against providers who supply information to them which transpires to be false or misleading in such a way that it is in effect a barrier to inspection. But, these powers do not extend to information providers publish or submit to other agencies, which the regulators may draw upon as part of their monitoring mechanisms. Commissioners are reliant on the information submitted by providers to inform their activity.
27. The Government felt that there was a lack of suitable redress across the health and social care system to cover instances where false or misleading information was published or submitted outside of the regulatory processes. Information published in such a way can put patients at risk of harm or conceal that harm has or is occurring. The FOMI offence makes clear to NHS providers and their leadership, that such behaviour is not acceptable and could be punished in the criminal courts.

Administrative Errors – Policy Intent of FOMI

28. The Department of Health’s intent is that the FOMI offence should apply to errors which present a significant (and potentially immediate) risk of harm to patients and where action through performance management arrangements is an insufficient response to the risk posed to patient safety. In addition, performance management arrangements may not exist or be appropriate for all providers of

services, such as independent providers contracted to deliver NHS services.

29. These sorts of extreme errors might well be unintentional, but could equally be the result of significant negligence on the part of a provider in ensuring that sufficiently robust processes are in place for collecting, submitting or publishing information.
30. All NHS providers should take, on an ongoing basis, to minimise the occurrence of the kind of errors listed above so as to ensure a high level of data cleanliness. Where an NHS provider fails to take any action to minimise these errors, then it could be construed that a sufficient level of negligence has occurred that the FOMI offence might apply.

Clinical Coding – Policy Intent of FOMI

31. Clinical Coding is "the translation of medical terminology as written by the clinician to describe a patient's complaint, problem, diagnosis, treatment or reason for seeking medical attention, into a coded format" which is nationally and internationally recognised.
32. The Mid Staffordshire Public Inquiry covered the matter of coding inaccuracies at the Foundation Trust in considerable detail. For the most part the analysis of evidence focuses on the extent to which the Trust leadership cited errors with coding as the reason for high mortality rates, rather than considering whether there might be any concerns with the quality of care. However, in the context of the FOMI offence, the issue is one of how the application of clinical codes might impact on the data produced by an NHS provider.
33. Clinical Coding errors which lead to false information can occur through administrative errors. Again, these can be the result of having insufficiently robust processes in place, including having systems which allow for a high degree of human error or simply failing to follow best practice guidance.
34. Clinical Coding errors which lead to misleading information can be the result of applying too many or too few clinical codes in respect of patient care. Where such misleading information might mask failings in patient care, it will be a matter for the organisation to justify the rationale for adopting a coding practice, particularly if the coding practice differs from available guidance.
35. NHS providers should also be aware that adopting coding practices which differ from guidance or are otherwise at variance with the practices of other NHS providers can mean that the information they produce may be significantly different to that of other NHS providers. This can make it very difficult to draw any meaningful comparisons of performance between organisations.

Prosecutions under the FOMI offence

Application of the Code of Practice for Crown Prosecutors.⁹

36. The decision to prosecute or to recommend an out-of-court disposal is a serious step that affects suspects, victims, witnesses and the public at large and must be undertaken with the utmost care.
37. It is the duty of prosecutors to make sure that the right person is prosecuted for the right offence and to bring offenders to justice wherever possible. Casework decisions taken fairly, impartially and with integrity help to secure justice for victims, witnesses, defendants and the public. Prosecutors must ensure that the law is properly applied; that relevant evidence is put before the court; and that obligations of disclosure are complied with.
38. Although each case must be considered on its own facts and on its own merits, there are general principles that apply in every case.

The Decision Whether to Prosecute

39. In more serious or complex cases, prosecutors decide whether a person should be charged with a criminal offence and, if so, what that offence should be. They make their decisions in accordance with this Code and the Director of Public Prosecutions' Guidance on Charging. The police apply the same principles in deciding whether to start criminal proceedings against a person in those cases for which they are responsible.
40. Prosecutors must only start or continue a prosecution when the case has passed both stages of the Full Code Test.
41. The Full Code Test has two stages: (i) the evidential stage; followed by (ii) the public interest stage.
42. In most cases, prosecutors should only decide whether to prosecute after the investigation has been completed and after all the available evidence has been reviewed. However there will be cases where it is clear, prior to the collection and consideration of all the likely evidence, that the public interest does not require a prosecution. In these instances, prosecutors may decide that the case should not proceed further.

⁹ http://www.cps.gov.uk/publications/code_for_crown_prosecutors/

The Full Code Test - The Evidential Stage

43. Prosecutors must be satisfied that there is sufficient evidence to provide a realistic prospect of conviction against each suspect on each charge. They must consider what the defence case may be, and how it is likely to affect the prospects of conviction. A case which does not pass the evidential stage must not proceed, no matter how serious or sensitive it may be.
44. When deciding whether there is sufficient evidence to prosecute, prosecutors should ask themselves the following:
- Can the evidence be used in court?
 - the likelihood of that evidence being held as inadmissible by the court; and
 - the importance of that evidence in relation to the evidence as a whole.
 - are there any reasons to question the reliability of the evidence, including its accuracy or integrity.
 - Prosecutors should consider whether there are any reasons to doubt the credibility of the evidence.

The Full Code Test - The Public Interest Stage

45. In every case where there is sufficient evidence to justify a prosecution, prosecutors must go on to consider whether a prosecution is required in the public interest.
46. It has never been the rule that a prosecution will automatically take place once the evidential stage is met. A prosecution will usually take place unless the prosecutor is satisfied that there are public interest factors tending against prosecution which outweigh those tending in favour. In some cases the prosecutor 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.
47. Prosecutors should consider each of the following questions:
- How serious is the offence committed?
 - What is the level of culpability of the suspect?
 - What are the circumstances of and the harm caused to the victim?
 - Was the suspect under the age of 18 at the time of the offence?
 - What is the impact on the community?
 - Is prosecution a proportionate response?
 - Do sources of information require protecting?

What happens if my organisation is convicted of the offence?

48. The Care Act 2014 states that:

Section 93(2) A court before which a care provider is convicted of an offence under section 92 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.**

49. The first penalty for the offence is a fine, the amount of which will be determined by the courts and has no upper limit. Therefore it will be a matter for the court to decide what size the fine should be, taking into account the circumstances surrounding the offence.

50. Alternatively, or in addition to a fine, a convicted care provider can also be required to comply with either or both of either a remedial order or a publicity order issued by the court. The former will set out action that the care provider is required to take to remedy the conduct that has caused the offence to occur in the first place. Whereas the latter requires the care provider to make a public notice about their conviction, what penalties were incurred and what action was required by the remedial order (if such an order has been made). The specifics of how the care provider publicises the information required by the order will be a matter for the court to determine.

51. Where a provider fails to comply with the remedial or publicity orders issued by the court, be it with regard to delivering the action required by the remedial order or failing to publicise in a way that meets the court's requirements, a further unlimited fine can be issued by the court.

What happens if an individual is convicted of FOMI?

52. The FOMI offence can also apply to senior individuals within a care provider but, only when the care provider has been found to be guilty of the offence. The wording of the Care Act in respect of individuals is as follows:

94(1) Subsection (2) applies where an offence under section 92(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.**

53. The FOMI offence as applied to senior individuals is not a strict liability offence as it is for providers. The senior individual would have to be found to have acted (consented or connived) or been derelict in their duties (neglect) in such way to have facilitated the provision of false or misleading information occurring.

(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 a remedial or publicity order under section 93(2) does not apply in these cases).

54. “Director” “manager” and “secretary” refer to senior individuals within an organisation. The use of “secretary” is meant in the sense of a “company secretary¹⁰” as set out in the Companies Act 2006¹¹.

55. In order for an individual to be prosecuted for the FOMI offence, it would have to be demonstrated that either;

a) the individual had knowingly consented to the provision or publication of false or misleading information by the care provider. This would mean that the individual concerned was aware that the information in question could be construed as false or misleading, but was prepared to authorise its publication or submission to whomever it had a legal duty to submit the information. Or:

b) the individual had been sufficiently negligent in their duties to allow false or misleading information to be published. This would mean the individual would have some responsibility in ensuring that the information for publication or submission was not false or misleading and had failed to act in accordance with the responsibility. This could mean failing to ensure that the proper systems were put in place across an organisation for the collection and validation of information or a simple failure to check whether processes had been correctly applied before signing information off.

56. The maximum sentence for a conviction on indictment the court can impose is an unlimited fine or custodial sentence of up to two years imprisonment, or both. Again, it would be a matter for the court to determine which penalty or combination of penalties is most appropriate given the circumstances surrounding the offence.

¹⁰ <http://www.companieshouse.gov.uk/infoAndGuide/faq/secretaries.shtml>

¹¹ <http://www.legislation.gov.uk/ukpga/2006/46/contents>

FOMI – Due Diligence Defence

57. As stated previously, FOMI is a strict liability offence against the care provider and therefore it is not necessary to establish that there was any intent to commit the offence. As stated in paragraph [X] the strict liability aspect of the offence does not apply to senior individuals, where a high standard of proof is required. However, for both the provider and the individual, the Act also incorporates a due diligence defence.

Section 92(2) of the Care Act 2014

(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).

58. This means that in the event of FOMI occurring, a 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 demonstrates that the provider had taken appropriate action.

Case Study – Applying the FOMI Offence

59. An NHS Trust's annual Quality Account is found to contain false or misleading information in respect of its Ambulance Response Rate Times. The information in the report differs to records stored separately in the Trust's records. It appears as though the trust has been underreporting where it has not met the Ambulance Response Rate Times. Consequently the information in the Quality Account shows the Trust performing better than it actually has, which can be considered misleading information.
60. The Trust records show that the information which is used in the Quality Account comes from a different system to the one which shows the lower performance. The system with the lower performance contains all the data entered first hand by the Ambulance teams themselves from their log books. It appears that those two systems are not linked in any way and information must be manually copied from one system to another. During the copying process, different numbers were entered into the Quality Account system.
61. The system which is used for Quality Accounts is considered to be the Trust's official system. The data in that system is validated and "cleaned" before it is submitted or published and subject to checking by senior officials within the Trust. When the information is included in the report and put before the Trust's Board for its approval, a detailed explanation of the figures is given.
62. The Trust has no validation procedures in place for checking the information being transcribed from Ambulance Teams system and it appears that senior individuals in the Trust were not aware the other system existed.

Scenario A – Negligence

63. Investigation of the transposition of the data from the Ambulance teams system to the Trust's official system shows that for two quarters in the past year, all the information was copied across by a temporary member of staff recruited to handle administration. The temporary staff member decided to expedite the data entry process by rounding all times to the nearest minute when entering them onto the new system. By chance, this had the unintended effect of boosting the Trust's response time.
64. While the Trust was clearly negligent in checking the source of the information which was used to feed the Quality Account, this was clearly not done intentionally. The investigation will need to determine whether any patients had been harmed by the information or if harm to patients had been concealed.

Scenario B - Negligence

65. Investigation of the transposition of the data from the Ambulance teams system to the Trust's official system shows that for two quarters in the past year, all the information was copied across by a temporary member of staff recruited to

handle administration. When interviewed, the temporary member of staff states they were instructed by their manager to round all the times down to the nearest minute. The manager didn't explain why and the temporary staff member felt obligated to do what they were told.

66. When interviewed, the manager in question stated that they had wanted to ensure the performance of their area was seen in the best possible light. They had acted on their own initiative to direct the temporary staff member to change the information. Further investigation reveals that no one else in the organisation was aware of the manager's actions. But as the Trust did not check the source of the data which fed the quality account system, the provider is still negligent.

Scenario C –Intent

67. Investigation of the transposition of the data from the Ambulance teams system to the Trust's official system shows that for two quarters in the past year, all the information was copied across by a temporary member of staff recruited to handle administration. When interviewed, the temporary member of staff states they were instructed by their manager to round all the times down to the nearest minute. The manager didn't explain why and the temporary staff member felt obligated to do what they were told.

68. When interviewed, the manager in question stated that they had wanted to ensure the performance of their area was seen in the best possible light. They had acted on their own initiative to direct the temporary staff member change the information. Upon further investigation evidence shows that senior individuals were aware of the discrepancy between the official data feeding the quality account and the ambulance team's data. However, as the Quality Account was near ready for publication, the senior individuals in the Trust decided not to undertake a further validation of the Ambulance Response Time Data. Therefore, despite being aware of concerns about the data, senior individuals put the information forward for publication but did not raise those concerns with the Trust Board or Chief Executive.

FOMI and Individual Negligence

69. Individuals will be prosecuted for a FOMI offence following an assessment by the prosecutor of the evidential and public interest stages of the Code for Crown Prosecutors. The starting point for determining individual negligence will always be with the controlling minds of the organisation i.e. the senior individuals within an organisation. This is because they are ultimately responsible for ensuring the appropriate procedures are in place to ensure that information published or submitted by their organisation is not false or misleading.

70. Consideration also needs to be given to the procedures and processes in place within an organisation for ensuring the controlling minds are properly informed of what is going on. If appropriate procedures are in place and the publication of information considered to be false or misleading still occurs, then there is a question as to whether the controlling minds could reasonably have been expected to be aware of such an occurrence, despite best efforts being made to guard against it.

Case Study – Scenarios A&B

71. In the case study above, in scenarios A and B, senior individuals within the Trust were simply unaware that the ambulance teams system existed and was the source for the data in the Quality Account. The Trust had published false or misleading information as a result of negligence, but it would be for the CPS to determine whether there was sufficient evidence to show senior individuals were negligent in their responsibilities and therefore to pursue prosecution against those individuals. Evidence of such negligence might include a failure on the part of senior individuals to have sufficient validation process in place for the publication of the Quality Account. As the ambulance teams was unknown to most of the trust,

Case Study – Scenario C

72. In scenario C, senior individuals were clearly aware that there was a problem with the data being published in the Quality Account, but chose to publish regardless. The decision to publish the data in the Quality Account despite being aware of the potential problems, would be something senior individuals would have to justify as part of their due diligence defence. It would be for CPS to decide, based on the evidence provided and considering the Guidance for Crown Prosecutors, whether to pursue prosecution against those senior individuals.

73. In scenario C, a conscious decision was made by senior individuals to keep from the Board and Chief Executive the concerns about the Quality Account data. In considering whether to prosecute the individuals, the CPS would have consider whether the public interest could instead be served by management or disciplinary action being taken against the senior individuals in question, instead of prosecution

Case Study – FOMI and The Summary Hospital-level Mortality Indicator (SHMI)

74. This case study shows how a flaw in the design of a data collection can be corrected to create greater clarity in whether the FOMI offence may have been committed.

Summary Hospital-level Mortality Indicator

75. The Summary Hospital-level Mortality Indicator (SHMI) is an indicator which reports on mortality at trust level across the NHS in England using a standard and transparent methodology. It has been produced and published quarterly as an official statistic by HSCIC since October 2011.

76. The original intention was to produce SHMI at individual hospital level. Within HES there is a field that should allow users to identify the site within a Trust where inpatient activity occurred. Although this field has historically had high completion levels (in the region of 95%-99%) this wasn't accurate; a simple check of a trust that was known to have many sites would show all activity coded at one location. Because of this the data cannot accurately assign activity (and in this case, deaths) to anything more granular than Trust level.

77. The problem with the SHMI data detailed above has been identified and the submission of site specific data is now being made simpler and clearer. Reports now include the site code breakdown and submitting Trusts are asked to assure that this correctly records where their activity occurred.

Application of FOMI

78. In this example, the problem with SHMI prior to correction was that it was not possible to check the mortality data for individual hospitals within an NHS trust. Some NHS Trusts consist of four or more hospitals (the largest is Barts Health NHS Trust which has six), which may have varying levels of performance. A hospital with high mortality rates could have its performance masked by included in the overall trust data, providing the other trusts had significantly lower mortality rates. For this example, trusts with multiple sites (i.e. Barts Health NHS Trust which has six sites) where one of the sites with a significantly higher mortality ratio and other sites with a significantly lower mortality ratio, the former is less likely to be detected if the trust submits all activity as attributed to one site only.

79. The provision of such information by any given trust, while potentially misleading about the performance of all hospitals operated by the trust, would not in itself be a consideration for the FOMI offence. As long as the site code data provided by the Trust was accurate for each hospital then it could not be considered that the provision of false or misleading information had occurred.

80. This does not preclude scenarios occurring where a Trust could be found to have committed the offence. For example: A Trust could incorrectly calculate its mortality rate, which would then be false information once submitted, even if the mortality rate was higher than it would've been if reported accurately.
81. Alternatively a Trust could deliberately alter the site code data for one of its hospitals to improve the overall mortality rating for the trust.
82. However, in either of these scenarios, the design of the data collection would make it difficult for anyone to be alerted to the fact that FOMI had occurred. The Trust level data would have to trigger some suspicion that there was a problem; perhaps the mortality rate is suddenly much lower than in previous submissions or a high mortality rate flags categorises the trust as an outlier 'higher than expected'. Even then, a thorough investigation of the source data behind the Trust level data would have to be conducted to determine what the problem was.

Proposals for Expanding FOMI in the Future

83. 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 considering possible additions to the list of specified information in scope of FOMI.
84. 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 changing (be it expanding or decreasing) the scope of FOMI in the future.
85. Our expectation is that possible candidates 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.
86. The HSCIC has recommended that a process for recommending additions to the FOMI list is made through a group supported by HSCIC which ensures all inclusions:
 - Flow through HSCIC
 - Adhere to Information standards
 - Are required under s259 Health and Social Care Act 2012
 - Have passed their full conformance date so every provider should be flowing this data at the appropriate quality
 - Have been assessed for quality via s266 Health and Social Care Act 2012 and any deficits in quality have been notified to the provider
 - Have been assessed for burden as measured by HSCIC using their approved burden methodology
 - Have had any risk to patient care through unforeseen circumstances and perverse incentives assessed and mitigated. Risks would include direct care risks and adverse impacts on protected characteristics

The 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⁽¹²⁾.

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⁽¹³⁾;

“the Information Centre” means the Health and Social Care Information Centre⁽¹⁴⁾.

⁽¹²⁾ 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.

⁽¹³⁾ 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

(14) 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⁽¹⁵⁾ 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,

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

amongst other things, for the monitoring of timed pathways of care for cancer patients and waiting times for cancer services).

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)(16).

EXPLANATORY NOTE

(This note is not part of the Regulations)

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.

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.

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.

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.

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.

(16) 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.