The National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016

The Secretary of State for Health, in exercise of the powers conferred by sections 7, 8, 272(7) and (8) of and paragraph 3 of Schedule 6 to, the National Health Service Act 2006(**a**), makes the following Directions:

Citation, interpretation, coming into force and application etc

1.—(1) These Directions—

(a) may be cited as the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016;

(b) come into force on 1st April 2016.

(2) In these Directions—

"the 2006 Act" means the National Health Service Act 2006;

"accidents" includes clinical accidents;

"annual allocation" has the meaning given in paragraph 11(6);

"the Authority" means the National Health Service Trust Development Authority established pursuant to section 28 of the 2006 Act(**b**);

"the Chief Investigator" means the person holding that appointment pursuant to paragraph 3(1);

"commissioner" means a clinical commissioning group(**c**) or the Board(**d**), or a local authority exercising functions pursuant to the 2006 Act in relation to the health service;

"financial year" means a twelve-month period beginning on the 1st of April;

"health service regulator" means the Care Quality Commission(**e**) or Monitor(**f**);

"the Investigation Branch" has the meaning given in paragraph 2(1);

"patient" means users of services provided as part of the health service(**g**) in England;

"professional regulatory bodies" means regulatory bodies within the meaning of section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(**h**);

"provider" means any body or person, other than a clinical commissioning group or the Board, engaged in the provision of goods or services for the purposes of the health service in England;

"safe space principle" has the meaning given in paragraph 6(1).

(3) These Directions are given to the Authority and relate to the following matters provided for in the 2006 Act—

(a) the Secretary of State's function under section 1(1) of continuing the promotion in England of a comprehensive health service designed to secure improvement in the physical and mental health of the people of England, and the prevention, diagnosis and treatment of physical and mental illness(**i**);

(**a**) 2006 c. 41. By virtue of section 271(1) of the National Health Service Act 2006 ("the 2006 Act") the functions of the Secretary of State under those sections as exercised in making these Directions are exercisable only in relation to England. Section 7 was amended by section 21 of the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"). Section 8 was amended by paragraph 5 of Schedule 4 to, and paragraph 3 of Schedule 14 (not yet in force) to, the 2012 Act.

(**b**) The National Trust Development Authority is established by the National Health Service Trust Development Authority (Establishment and Constitution) Order 2012, S.I. 2012/901, amended by S.I. 2013/235 and S.I. 2013/260.

(**c**) The term "clinical commissioning group" is defined in section 275(1) of the 2006 Act to mean a body established under section 14D of that Act.

(**d**) " The Board" is defined in section 275(1) of the 2006 Act to mean the National Health Service Commissioning Board, known generally by its operational title, "NHS England". The Board was established by section 1H(1) of the 2006 Act, which section was inserted in that Act by section 9(1) of the 2012 Act.

(**e**) The Care Quality Commission was established under section 1 of the Health and Social Care Act 2008 (c. 14).

(**f**) Monitor is the body continued under section 61 of the 2012 Act.

(**g**) The "health service" is defined in section 275(1) of the 2006 Act to mean, in relation to England, the health service continued under section 1(1) of the 2006 Act.

(**h**) 2002 c. 17.

(**i**) Section 1(1) was substituted by section 1 of the Health and Social Care Act 2012 (c. 7) ("the 2012 Act").

(b) the Secretary of State's function under section 2 of doing anything which is calculated to facilitate, or is conducive or incidental to, the discharge of any function conferred on the Secretary of State by the 2006 Act;

(c) the Secretary of State's duty under section 1A to exercise his functions in relation to the health service with a view to securing continuous improvement in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness(**a**).

The Healthcare Safety Investigation Branch

2.—(1) The Authority is directed to establish and provide for the operation of a division of the Authority to be known as the Healthcare Safety Investigation Branch ("the Investigation Branch"), in order to assist in discharging the Secretary of State's functions described in paragraph 1(3), and in particular, his duty described under paragraph 1(3)(c).

(2) For the purposes of sub-paragraph (1), "providing for the operation" of the Investigation Branch includes furnishing the Branch with suitable premises, including building facilities services, and, pending the establishment of an investigation team as described in paragraph 3(1)(b), providing the Chief Investigator with administrative support and facilities.

(3) The Authority is directed—

(a) to act as set out in paragraphs 3 to 11;

(b) to impose such requirements on the Chief Investigator in particular and the Investigation Branch generally, as the case may be, as are set out in those paragraphs;

(c) to permit the Chief Investigator and the Investigation Branch to take such actions ancillary to those requirements as the Chief Investigator considers reasonably necessary.

Composition of the Investigation Branch

3.—(1) The Investigation Branch must comprise—

(a) a Chief Investigator, to be appointed by the Authority subject to the approval of the Secretary of State and who may only be dismissed with the approval of the Secretary of State; and

(b) an investigation team, to be appointed by the Authority subject to the approval of the Chief Investigator.

(2) All persons who at any time comprise the Investigation Branch must—

(a) have the skills necessary to carry out investigations, or tasks necessary for the conduct of investigations, described in paragraph 5;

(b) be provided with appropriate training from time to time to enable them to carry out such investigations or tasks, and in particular to enable them to maintain and develop the skills and expertise required for their work.

(3) The Investigation Branch may, at the discretion of the Chief Investigator, consult and pay from the annual allocation the professional fees of specialists on matters requiring expertise in particular fields (such as clinical practice or healthcare technology).

Timing of the establishment of the Investigation Branch

4. The Authority is directed to take such steps as may be reasonably necessary to ensure that the Investigation Branch is established and in a position to commence its activities pursuant to these Directions no later than 1st April 2017.

Investigatory functions

5.—(1)The Authority must ensure that the Investigation Branch exercises the following functions—

(a) the investigation of incidents or accidents which in the view of the Chief Investigator evidence, or are likely to evidence, risks affecting patient safety;

(b) the ascertaining of facts relevant to such risks and analysis of those facts;

(c) the identification of improvements or areas for improvement, if any, which may be made in patient safety in—

(**a**) Section 1A of the 2006 Act was inserted by section 2 of the 2012 Act.

(i) the provision of services as part of the health service, or

(ii) the conduct of other functions carried out for purposes of the health service,

and where appropriate, the making of recommendations in relation to such improvements;

(d) the publication of reports as provided for in paragraph 8;

(e) encouraging the development of skills used to investigate local safety incidents in the health service and to learn from them, including suggesting standards which may be adopted in the conduct of such investigations.

(2) For the purposes of sub-paragraph (1)(a), "risks affecting patient safety" may include, but are not limited to—

(a) risks resulting in repeated, preventable or common occurrences of safety risks or harm to patients;

(b) risks indicating a systemic problem with significant impact in more than one setting; or

(c) those involving new or novel forms of harm or new or novel risks of harm.

(3) It is not the function of the Investigation Branch in conducting investigations and publishing its findings, analysis and any recommendations, to identify civil or criminal liability in any matter, nor to apportion blame or otherwise support fault-based legal or regulatory or other formal action against persons whose actions come under consideration as part of its investigations.

(4) In identifying incidents or accidents for investigation, the Chief Investigator must have regard to—

(a) sub-paragraph (3);

(b) the need to provide findings, analysis and, where appropriate, make recommendations that are relevant for improving current practice and systems in the health service in so far as they relate to or affect patient safety.

(5) The Chief Investigator must be open and transparent about the process that is followed in identifying incidents or accidents for investigation and about the processes that are to be followed in conducting an investigation (further provision in relation to this requirement being made in paragraphs 7 and 8).

Safe Space

6.—(1) In this paragraph, "safe space principle" refers to the principle that, in the view of the Secretary of State—

(a) the Investigation Branch's function of providing findings, analysis and, where appropriate, recommendations pursuant to paragraph 5, is best informed by comprehensive and candid contributions from those whose actions come under consideration in the course of an investigation, bearing in mind the provisions in paragraph 5(3) and (4)(b);

(b) contributions that are comprehensive and candid are more likely to be made where they may be made in the confidence that they will be used not for purposes of apportioning blame or establishing liability but for purposes of identifying improvements or areas for improvement, if any, which may be made in patient safety in the provision of services as part of the health service or the conduct of other functions for purposes of the health service, and making recommendations in relation to such improvements; and

(c) unless there is an overriding public interest or legal compulsion, disclosures for purposes other than making recommendations as described in paragraph (b) of material gathered by the Investigation Branch should accordingly be avoided so as to preserve the confidence in the Investigation Branch's investigatory and reporting process of those whose contributions may be relied on for purposes of current and future investigations.

(2) In conducting any investigation, the Investigation Branch—

(a) must, in respect of the following individuals or bodies as may be concerned in an incident or accident, seek to provide them with similar opportunities to contribute to any investigation into that incident or accident—

(i) patients and, where appropriate, family members or representative;

(ii) providers and individuals, such as staff, within such bodies;

(iii) commissioners and individuals, such as staff, within such bodies;

(iv) health service regulators and individuals, such as staff, within such bodies;

(b) may seek contributions from such other individuals or bodies as the Chief Investigator or the investigation team consider appropriate;

(c) must facilitate and support comprehensive and candid contributions from those whose actions come under consideration in the course of an investigation in respect of how an incident or accident arose;

(d) must seek to encourage sharing of information about incidents and accidents between persons mentioned in paragraph (c) on the one hand, and on the other, the patient whose care is under consideration in the course of an investigation and, where appropriate, that patient's family or representative.

(3) In holding and processing any information and other material the Investigation Branch gathers in the course of an investigation, the Investigation Branch must act in a manner that is consistent with its functions bearing in mind in particular paragraph 5(3) and (4)(b) and the safe space principle.

(4) The Chief Investigator—

(a) must approve all decisions about the disclosure outside of the Investigation Branch of any material gathered by the Investigation Branch;

(b) may, when requested, disclose to the patient, or where appropriate, to the patient's family or representative, material gathered by the Investigation Branch in the course of an investigation in which that patient's care is under consideration, but such disclosure may only be made of such information, in such form (anonymised or otherwise) and to such extent that the Chief Investigator judges, in the individual circumstances of the request, to be consistent with the safe space principle;

(c) must inform the appropriate health service regulator, professional regulatory body or other investigatory body or bodies should the Investigation Branch become aware of evidence of a serious, continuing risk to patient safety, but subject to this sub-paragraph must not volunteer to take further part in the actions that such a body or bodies may subsequently take;

(d) must seek to agree with professional regulatory bodies and other investigatory bodies which have statutory powers to require information, suitable protocols respecting the safe space principle in relation to the exercise of those statutory powers;

(e) must seek to agree with those bodies with which the Authority has a mutual duty to co-operate under section 290 of the Health and Social Care Act 2012 suitable protocols respecting the safe space principle which are to apply as between the Authority and those other bodies in discharging that duty;

(f) must, in considering the application of the provisions of the Freedom of Information Act 2000(**a**) in response to such requests that may be made under that Act, have in mind the safe space principle;

(g) must (so far as permissible within the relevant procedural rules) make representations in respect of the safe space principle to a court or tribunal which is considering whether to require the disclosure of material gathered by the Investigation Branch in the course of conducting its investigations or functions preliminary to such investigations;

(h) must provide information when required by a Court Order or as a matter of statutory requirement, but except as provided for in paragraph (b), in the absence of an overriding public interest, must otherwise seek to avoid voluntary disclosures of material gathered by the Investigation Branch.

(5) In this paragraph—

(a) at sub-paragraphs (2)(a)(i) and (d) and (4)(b), subject to any lawful requirement to the contrary, the Chief Investigator has discretion to decide about the appropriateness of involving members of the family of a patient, or a patient's representative, but so far as reasonable must seek to reflect the wishes of the patient and the patient's representative;

(b) in those sub-paragraphs and this sub-paragraph, "representative" refers to any person who lawfully speaks and makes decisions in connection with the matters in question on behalf of the patient concerned, and whose interest in that capacity has been made known to the Investigation Branch;

(c) in sub-paragraph (4), "investigatory body" includes the Health and Safety Executive, the police and the Crown Prosecution Service.

(6) Notwithstanding the provisions of sub-paragraphs (3) to (5), the Chief Investigator and the Investigation Branch may include in a report or an interim report produced pursuant to paragraph 8(2) or (3) such material that the Chief Investigator considers reasonably necessary to include for the purposes of discharging the functions in paragraphs 5 and 8.

(7) Nothing in this paragraph requires the Chief Investigator or the Investigation Branch to act in breach of the Data Protection Act 1998(**b**).

(**a**) 2000 (c. 36).
(**b**) 1998 (c. 29).

Investigation Principles

7.—(1) The Authority must ensure that, no later than 1st April 2017, the Chief Investigator has developed and published a document setting out the principles consistent with these Directions that are to govern investigations carried out by the Investigation Branch ("the Investigation Principles").

(2) The Investigation Principles must set out, in particular—

(a) the nature of the events, circumstances, or outcomes that will be relevant factors in the Chief Investigator's decision as to the incidents or accidents which will be investigated, bearing in mind the matters mentioned in paragraph 5(4);

(b) the period of time in which the Investigation Branch will generally seek to conclude investigations, and factors that may lead to variation;

(c) the range of procedures and investigation methods which the Investigation Branch may use in conducting an investigation.

(3) The Chief Investigator may review the published Investigation Principles and update if appropriate in light of that review at any time and in any event must do so at least once in each financial year.

Investigation Process & Reports

8.—(1) Before the Investigation Branch begins an investigation, the Chief Investigator must publish the timetable and procedures envisaged for that investigation.

(2) At the end of any investigation the Chief Investigator must publish a report of that investigation which must—

(a) summarise the methodology used to carry out the investigation;

(b) present findings of fact made as a result of the investigation and an analysis of those factual findings so far as consistent with the matters set out in paragraph 5(1)(a) to (c), (3) and (4)(b);

(c) make any recommendations that the Investigation Branch considers appropriate for the purposes of the functions described in paragraph 5;

(d) focus on risks affecting patient safety as referred to in paragraph 5(1)(a) and the making of recommendations, if appropriate, in accordance with paragraph 5(1)(c) that address such risks, rather than focus on the activities of particular individuals;

(e) not include the name of any individual;

(f) be of such length and in such detail as the Chief Investigator considers warranted in light of the nature and severity of the incident or accident the subject of the report.

(3) The Chief Investigator may publish an interim report meeting the requirements of sub-paragraph (2)(a) to (f) which contains interim findings and analysis and, if appropriate, provisional recommendations, on any matter in respect of which the Chief Investigator considers—

(a) there is sufficient certainty of a risk of harm to patients to warrant urgent publication;

(b) that risk is likely to be reduced if knowledge of those interim findings or provisional recommendations is disseminated to the public.

Maintaining the independence of the Investigation Branch

9.—(1) The Authority must ensure that, in establishing and maintaining the Investigation Branch, the Authority takes reasonable steps to protect the independence of the Investigation Branch from the other activities of the Authority.

(2) The Authority must take reasonable steps to prevent other persons from doing anything to undermine the independence of the Investigation Branch.

(3) The Authority must establish a group of independent advisors ("the advisory group") whose role it will be to meet with the Chief Investigator from time to time to discuss with the Chief Investigator the following matters—

(a) the independence of the reports published by the Investigation Branch pursuant to paragraph 8(2) and (3);

(b) the independence of the Investigation Branch in relation to the other activities of the Authority;

(c) the independence of the Investigation Branch in relation to persons other than the Authority.

(4) The Authority may appoint such number of advisors to the advisory group as it and the Chief Investigator may agree, and each appointment shall be made subject to the approval of the Chief Investigator.

(5) The Authority must require the advisory group to report to the Chief Investigator, at such intervals as the Chief Investigator stipulates, with its observations in respect of the matters set out in sub-paragraph (3).

(6) The travelling and other agreed out-of-pocket expenses of members of the advisory group shall be paid from the Investigation Branch's annual allocation.

Annual Reporting obligations and Accountability

10.—(1) The Chief Investigator must report—

(a) to the Authority in relation to budgetary matters including the spending, staffing levels and staffing needs and administrative efficiency of the Investigation Branch;

(b) to the Secretary of State in relation to the performance of functions by the Investigation Branch.

(2) With effect from 1st April 2017, at the beginning of each financial year, the Chief Investigator must prepare and provide to the Secretary of State an annual report of the Investigation Branch's activities for the preceding financial year.

(3) The Authority must ensure that each annual report is published after it has been provided to the Secretary of State and that—

(a) publication includes publication online;

(b) a paper copy is provided free of charge to any person who requests it in writing(**a**).

(4) The Chief Investigator must expect to be called to give evidence to Parliament, in particular to the Health Select Committee and the Public Administration and Constitutional Affairs Committee, about the activities of the Investigation Branch and related matters.

Funding

11.—(1) In relation to the financial year beginning 1st April 2017 and to subsequent financial years, the Chief Investigator must, before the beginning of the financial year, provide to the Authority and publish a budget assessment in relation to that financial year.

(2) The Authority must provide a copy of the budget assessment to the Secretary of State.

(3) The Authority is directed to ensure that in each financial year, it pays to the Investigation Branch the entirety of the annual allocation and any extraordinary payment.

(4) In the event that the Secretary of State makes an extraordinary payment, the Authority and the Investigation Branch must ensure it is spent only on the investigation for which the payment is made.

(5) In the event of any surplus arising, the Authority must seek instructions from the Secretary of State as to its disposal at the end of the financial year, or, in the case of a surplus arising from an extraordinary payment, at the end of the investigation in respect of which the payment was made.

(6) In this paragraph—

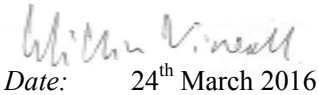
"annual allocation" means the amount of money paid to the Authority by the Secretary of State which is identified by him as money allocated to fund the activities of the Investigation Branch for a given financial year;

"budget assessment" means the Chief Investigator's assessment of the cost of the resources that will be required for the operation of the Investigation Branch over the course of a financial year;

"extraordinary payment" means a payment which is made to the Authority by the Secretary of State to fund a specific investigation by the Investigation Branch, which payment is separately made and in addition to the annual allocation;

"surplus" means any sum of money from the annual allocation which remains unspent by the Investigation Branch at the end of the financial year or, as the case may be, any sum of money from an extraordinary payment which remains unspent by the Investigation Branch at the end of the investigation in respect of which the payment was made.

Signed by authority of the Secretary of State



Name
A member of the Senior Civil Service
Department of Health

Date: 24th March 2016

(**a**) Requests may be made to the NHS Trust Development Authority, NHS Improvement, Southside, 105 Victoria Street, London SW1E 6QT.