



Department
of Health

Draft Health Service Safety Investigations Bill



Draft Health Service Safety Investigations Bill

Presented to Parliament
by the Secretary of State for Health
by Command of Her Majesty

September 2017



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Any enquiries regarding this publication should be sent to us at

Patient Safety Team
Room 235
Richmond House
79 Whitehall
London SW1A 2NS
patientsafetyteam@dh.gsi.gov.uk

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Foreword

The NHS has a unique place at the heart of our society and is, by some distance, the institution that makes us most proud to be British.

The NHS treats more than one million people every 36 hours. Its 1.4 million staff are dedicated to providing an outstanding service for patients, families and carers every day. It is their work, alongside the value that this Government and the British public put on the ideas and principles that have underpinned the NHS as an institution since its inception in 1948, which has made it one of the best and most effective health systems in the world today.

The care received by the vast majority of NHS patients and their families is truly superb – a credit to NHS staff doing a brilliant job in challenging circumstances. Since Robert Francis QC's report on the terrible failings at Mid-Staffordshire NHS Foundation Trust, much has been done to reset the fundamental standards for care and improve leadership, quality and safety in the NHS. And we have made huge progress: MRSA rates are some of the lowest we have ever had, the four main hospital harms have fallen by 8% over three years; and our new inspection scheme has resulted in a transformed approach towards openness and transparency when things go wrong.

However, medical treatment and care is complex and there is always the potential to do harm, or fall short of the standards of care. We know that there are around 24,000 serious incidents of healthcare harm in the NHS each year, and research suggests that around 150 deaths each week could have been avoidable were it not for problems in care. Incidents such as these can have a devastating impact upon patients, families and NHS staff alike, which is why delivering the safest possible care remains a key Government priority. Our aim is to make the NHS the safest healthcare and highest quality healthcare system in the world.

This draft Bill is an opportunity to bring about a whole-system change to how the NHS investigates and learns from healthcare error. It will promote transparency and openness, reassuring patients, families and NHS staff that every effort will be made to prevent the same mistakes happening again.

Inspired by the airline industry, where a learning culture has led to dramatic improvements in safety, more is already being done to support the NHS to investigate significant harms. Building on the Healthcare Safety Investigation Branch – in operation since April 2017 – this draft Bill will create a statutory

Health Service Safety Investigations Body, independent of the NHS and at arm's length from Government, with new powers that will enable it to discharge its investigation functions fully and effectively. The body will play a pivotal role in safety improvement using established investigative methods. Importantly, it will investigate for the sole purpose of learning, not to attribute blame or individual fault, providing a safe space for staff and patients to be open and candid when things go wrong. The new body will be an exemplar of healthcare safety investigative practice and will help embed a culture of learning across the NHS in England.

This Government believes an independent body whose purpose is to investigate patient safety risks across the NHS with a focus on learning from these incidents, is the right approach for patients, their families, carers, NHS staff and the public.

We lay before Parliament the Draft Health Service Safety Investigations Bill and welcome the scrutiny of fellow Parliamentarians and others with an interest in improving patient safety in the NHS.



A handwritten signature in black ink, reading "Jeremy Hunt". The signature is written in a cursive style with a prominent "J" and "H".

RT. HON. JEREMY HUNT
SECRETARY OF STATE FOR HEALTH



A handwritten signature in black ink, reading "Philip Dunne". The signature is written in a cursive style with a prominent "P" and "D".

PHILIP DUNNE MP
MINISTER OF STATE FOR HEALTH

Draft Health Service Safety Investigations Bill

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Establish the Health Service Safety Investigations Body and to confer the function of carrying out investigations and other functions on that body; to make provision for, and in connection with, the accreditation by that body of NHS foundation trusts and NHS trusts to carry out investigations; to make provision in connection with investigations carried out by that body or accredited NHS foundation trusts or NHS trusts; and for connected purposes.

BE IT ENACTED by the Queen’s most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

PART 1

ESTABLISHMENT OF THE HEALTH SERVICE SAFETY INVESTIGATIONS BODY

1 The Health Service Safety Investigations Body

- (1) A body corporate called the Health Service Safety Investigations Body is established.
- (2) In this Act that body is referred to as “the HSSIB”.
- (3) Schedule 1 contains further provision about the HSSIB.

PART 2

FUNCTIONS OF THE HEALTH SERVICE SAFETY INVESTIGATIONS BODY

*HSSIB's investigation function***2 Function of investigating**

- (1) The HSSIB has the function of investigating qualifying incidents occurring during the provision of NHS services or occurring at premises at which those services are provided.
- (2) The function conferred by subsection (1) is exercisable for the purpose of addressing risks to the safety of patients by facilitating the improvement of systems and practice in the provision of NHS services.
- (3) The function conferred by subsection (1) is not exercisable for the purpose of the HSSIB assessing or determining –
 - (a) blame,
 - (b) civil or criminal liability, or
 - (c) whether action needs to be taken in respect of an individual by any panel, committee or tribunal of a regulatory body.
- (4) Nothing in subsection (3) prevents the HSSIB from –
 - (a) disclosing information, documents, equipment or other items under section 29, or
 - (b) publishing a report under section 31 or 32 or sending a draft of such a report to any person under section 31(7).
- (5) In subsection (3)(c) “regulatory body” means –
 - (a) the General Medical Council,
 - (b) the General Dental Council,
 - (c) the General Optical Council,
 - (d) the General Osteopathic Council,
 - (e) the General Chiropractic Council,
 - (f) the General Pharmaceutical Council,
 - (g) the Nursing and Midwifery Council,
 - (h) the Health and Care Professions Council, or
 - (i) any other regulatory body (within the meaning of Schedule 3 to the Health Act 1999) established by an Order in Council under section 60 of that Act.
- (6) In this Part –
 - (a) references to qualifying incidents are to incidents that have (or may have) implications for the safety of patients and which meet the criteria determined under section 3(1)(a), and
 - (b) references to investigations are to investigations into qualifying incidents carried out under this Part and any related term is to be read accordingly (except in sections 15 and 16).

3 Publication of criteria, principles and processes

- (1) The HSSIB must determine and publish –

- (a) the criteria to be used by it for determining which qualifying incidents it investigates;
 - (b) the principles which are to govern investigations;
 - (c) the processes to be used in carrying out investigations;
 - (d) the processes for determining the involvement of the following in investigations –
 - (i) officers of NHS foundation trusts, NHS trusts, the National Health Service Commissioning Board or clinical commissioning groups;
 - (ii) persons providing NHS services (other than NHS foundation trusts or NHS trusts) and officers of such persons (in the case of bodies corporate);
 - (iii) persons providing services to NHS foundation trusts, NHS trusts or person falling within sub-paragraph (ii) and officers of such persons (in the case of bodies corporate);
 - (iv) persons employed by NHS foundation trusts, NHS trusts, the National Health Service Commissioning Board, clinical commissioning groups or persons falling within sub-paragraph (ii) or (iii);
 - (v) patients and their families.
- (2) The processes determined under subsection (1)(c) must include –
- (a) the procedures and methods to be used in investigations;
 - (b) the time periods within which the HSSIB aims to complete investigations.
- (3) The processes determined under subsection (1)(d)(v) must secure that patients and their families are involved in investigations if, and so far as, reasonable and practicable.
- (4) Different processes under subsection (1)(c) or (d) may be determined for different descriptions of investigation.
- (5) If the HSSIB revises the criteria, principles and processes it must publish them as revised.
- (6) In determining or revising the criteria, principles and processes the HSSIB must consult –
- (a) the Secretary of State, and
 - (b) any other persons the HSSIB considers appropriate.
- (7) The HSSIB must review the criteria, principles and processes –
- (a) at least once during the period of three years beginning with their publication under subsection (1);
 - (b) at least once during each period of five years beginning with the completion of the previous review.
- (8) The HSSIB must publish a document explaining how the processes determined under subsection (1)(d) are to operate in practice (and revise and publish the document as revised if those processes are revised).
- (9) A document published under subsection (8) must be in such terms that it is capable of being easily understood by the persons mentioned in subsection (1)(d)(v) and the HSSIB must ensure that the document is easily accessible to such persons.

- (10) The HSSIB must publish a list of investigations (both those in the process of being carried out and those that have been completed or discontinued) and keep that list up to date.

4 Representations from Secretary of State and others

- (1) Before deciding whether or not to investigate a qualifying incident, the HSSIB must consider any representations made by –
- (a) the Secretary of State, and
 - (b) any other persons the HSSIB considers appropriate.
- (2) The HSSIB must consider any request made to it by the Secretary of State to carry out an investigation into a particular qualifying incident or qualifying incidents falling within a particular description.

Carrying out investigations

5 Entry to premises and inspection

- (1) An investigator may enter and inspect premises if –
- (a) the investigator reasonably believes that the premises are qualifying premises,
 - (b) the investigator considers it necessary to inspect the premises for the purposes of carrying out an investigation, and
 - (c) entry to the premises is authorised (see subsection (4)).
- (2) Premises are qualifying premises for the purposes of this Part if –
- (a) they are owned or controlled by an English NHS body, or
 - (b) they are used for or in connection with –
 - (i) the exercise of the functions of an English NHS body, or
 - (ii) the provision of NHS services,
 but premises that are used wholly or mainly as a private dwelling are not qualifying premises.
- (3) If the investigator considers it necessary or expedient for the purposes of carrying out the investigation and it is authorised, the investigator may –
- (a) inspect and take copies of any documents at the premises;
 - (b) inspect any equipment or item;
 - (c) seize and remove from the premises any documents, equipment or item (unless that would risk the safety of any patient);
 - (d) interview any of the persons falling within subsection (6) in private.
- (4) References in this section to an action under subsection (1) or (3) being “authorised” are to –
- (a) the English NHS body owning, controlling or using the premises, or the person providing the NHS services, giving consent to the taking of the action, or
 - (b) the action being authorised by a warrant under section 6.
- (5) In subsection (3)(a) the reference to inspecting and taking copies of any documents includes requiring any documents which are kept in electronic form to be produced in a form in which they are legible and can be taken away.
- (6) The following persons fall within this subsection –

- (a) members of the council of governors of an NHS foundation trust;
 - (b) officers or members of an NHS foundation trust, an NHS trust, the National Health Service Commissioning Board, a clinical commissioning group or a Special Health Authority (an “English NHS body”);
 - (c) persons providing NHS services (other than NHS foundation trusts or NHS trusts) and their officers (in the case of bodies corporate);
 - (d) persons providing services to –
 - (i) an NHS foundation trust,
 - (ii) an NHS trust, or
 - (iii) persons falling within paragraph (c) and their officers (in the case of bodies corporate);
 - (e) persons employed by an English NHS body or a person falling within paragraph (c) or (d);
 - (f) patients or members of a patient’s family who consent to be interviewed.
- (7) An investigator who proposes to take any action under subsection (1) or (3) must, if required to do so, produce a duly authenticated document showing authorisation from the HSSIB to take the action.
- (8) An investigator who proposes to take any action under subsection (1) or (3) which is authorised by virtue of subsection (4)(b) must, if required to do so, produce the warrant granted under section 6.
- (9) In this Part references to an investigator are to a person authorised by the HSSIB to carry out functions in relation to investigations on the HSSIB’s behalf.

6 Warrant authorising entry to premises and inspection

- (1) Subsection (2) applies if the English NHS body owning, controlling or using qualifying premises, or the person providing NHS services –
- (a) has not consented to the taking of one or more actions by an investigator under section 5(1) or (3), or
 - (b) has purported to consent but has prevented the investigator from taking one or more of those actions.
- (2) The investigator may give a notice to the body or person specifying the actions under section 5(1) or (3) which the investigator requests to take.
- (3) A notice under subsection (2) must also –
- (a) explain the reasons for, and the importance of, taking the actions specified in the notice,
 - (b) specify the date on which the investigator proposes to take those actions, and
 - (c) explain that the Chief Investigator may apply for a warrant under subsection (4) authorising the taking of those actions.
- (4) The Chief Investigator may apply to a justice of the peace for a warrant authorising the taking of one or more actions specified in the application if –
- (a) the actions were specified in a notice under subsection (2), but
 - (b) the body or person to which the notice was given has not complied with the requests made in the notice by the date specified in the notice.
- (5) An application under subsection (4) must –

- (a) specify the reasons for taking the actions specified in the application,
 - (b) state the names of the investigators who would be authorised by the warrant to take those actions, and
 - (c) state that the body or person to which the notice under subsection (2) was given has not complied with the requests made in the notice by the date specified in the notice.
- (6) No more than six persons may be specified as investigators under subsection (5)(b).
- (7) A warrant granted on an application under subsection (4) authorises the taking of the actions specified in the warrant for a period of one month beginning with the date on which the warrant was granted.
- (8) See paragraph 2(1)(a) of Schedule 1 for the meaning of references in this Part to the Chief Investigator.

7 Requiring the provision of information, documents, equipment or other items

- (1) This section applies if, for the purposes of carrying out an investigation, an investigator considers it necessary or expedient to obtain any information, documents, equipment or other items from a person falling within subsection (12) who the investigator has reasonable grounds to believe is able to provide the information, documents, equipment or other items.
- (2) The investigator may give the person a notice –
- (a) requiring the person to provide the investigator with specified information, documents, equipment or other items relating to any qualifying incident being investigated,
 - (b) requiring the person to provide that information or equipment, or those documents or other items, before the end of the period of 28 days beginning with the date on which the notice is given, and
 - (c) stating the grounds for the investigator believing that the person is able to provide that information or equipment or those documents or other items.
- (3) If the notice requires the person to provide specified information by giving an oral explanation, the notice must make arrangements for the provision of the explanation.
- (4) If the notice requires the person to provide anything which is kept in electronic form, the notice may require it to be provided in a form in which it is legible.
- (5) The notice must give an explanation of –
- (a) the right to apply for a review under section 8,
 - (b) the procedure for applying for a review,
 - (c) the consequences of failing to comply with the notice, and
 - (d) the right to apply for an appeal under section 12 if a penalty notice is given to the person under section 9.
- (6) A duly authenticated document showing authorisation from the HSSIB for the investigator to exercise the powers conferred by this section must be attached to the notice.
- (7) A person may not be required under a notice to provide –

- (a) anything the provision of which would risk the safety of any patient,
 - (b) anything the provision of which the person would be entitled to refuse to produce in any proceedings in any court on the grounds that it is the subject of legal professional privilege, or
 - (c) anything the provision of which might incriminate the person.
- (8) The provision of information under a notice does not breach –
- (a) any obligation of confidence owed by the person providing it, or
 - (b) any other restriction on the provision of information (however imposed).
- (9) But nothing in subsection (8) authorises a provision of information which contravenes the Data Protection Act 1998.
- (10) An investigator may withdraw a notice by giving notice of withdrawal to the person to whom the notice was given.
- (11) Nothing in this section prevents an investigator from requesting a person not falling within subsection (12) to provide any information, documents, equipment or other items which the investigator considers it necessary or expedient to obtain for the purposes of carrying out an investigation.
- (12) The following persons fall within this subsection –
- (a) an NHS foundation trust, an NHS trust or any other person providing NHS services;
 - (b) any person providing services to a person falling within paragraph (a);
 - (c) the National Health Service Commissioning Board;
 - (d) a clinical commissioning group;
 - (e) a Special Health Authority;
 - (f) the Care Quality Commission;
 - (g) Monitor;
 - (h) the Health Research Authority;
 - (i) the Human Tissue Authority;
 - (j) the Human Fertilisation and Embryology Authority;
 - (k) the National Institute for Health and Care Excellence;
 - (l) Health Education England;
 - (m) the Health and Social Care Information Centre;
 - (n) the Health and Safety Executive.
- (13) References to specified information, documents, equipment or other items, in relation to a notice under subsection (2), are to information, documents, equipment or other items –
- (a) specified in the notice, or
 - (b) falling within a category which is specified in the notice.

8 Notices under section 7: right of review

- (1) This section applies if a person has been given a notice under section 7(2).
- (2) The person may apply to the Chief Investigator for a review of the decision to give the notice.
- (3) The application must be made before the end of the period of 28 days beginning with the date on which the notice was given.

- (4) If the person applies for a review, the provision made in the notice by virtue of section 7(2)(b) is to be disregarded.
- (5) The Chief Investigator must review the decision to give the notice before the end of the period of 14 days beginning with the date on which the application under subsection (2) was made.
- (6) On the review, the Chief Investigator may –
 - (a) confirm the notice,
 - (b) vary the notice, or
 - (c) withdraw the notice.
- (7) If the Chief Investigator confirms or varies the notice, the Chief Investigator must give the person a notice specifying –
 - (a) the reasons for the decision to confirm or vary the notice, and
 - (b) the period within which the specified information, documents, equipment or other items must be provided.
- (8) If the notice as confirmed or varied requires the person to provide specified information by giving an oral explanation, the notice must make arrangements for the provision of the explanation.
- (9) Section 7(13) applies in relation to a notice under section 7 which is confirmed or varied under this section.

9 Non-compliance with section 7: penalty notice

- (1) This section applies where –
 - (a) a person falling within subsection (10) fails to comply with a notice under section 7, or
 - (b) in purporting to comply with a notice under section 7 a person falling within subsection (10) –
 - (i) provides any information or document which the person knows or suspects is false in a material respect, or
 - (ii) provides any equipment or item which the person knows or suspects has been tampered with.
- (2) On or after the compliance day, the Chief Investigator may give a notice (a “penalty notice”) to the person requiring the person to pay to the HSSIB a penalty of an amount specified in the notice.
- (3) The amount specified in the penalty notice must not exceed £20,000.
- (4) A penalty notice must –
 - (a) state why the Chief Investigator thinks that the person is liable to pay the penalty,
 - (b) specify a date before which the penalty must be paid,
 - (c) specify how the penalty must be paid,
 - (d) explain the effect of subsections (6) to (8),
 - (e) explain how the Chief Investigator may enforce the payment of the penalty, and
 - (f) explain the right to apply for an appeal under section 12.

- (5) The date specified in the notice by virtue of subsection (4)(b) must fall after the end of the period of 28 days beginning with the date on which the penalty notice is given.
- (6) The Chief Investigator must withdraw a penalty notice by giving the person to whom it was given notice of withdrawal if –
 - (a) the penalty notice was given as a result of the application of subsection (1)(a) (person failing to comply with a notice under section 7), and
 - (b) the person complies with the notice under that section before the date specified in the penalty notice by virtue of subsection (4)(b).
- (7) Where notice of withdrawal is given to a person under subsection (6), the Chief Investigator may require the person to pay a fee of an amount specified in the notice.
- (8) Any amount specified under subsection (7) in a notice of withdrawal must not exceed the administrative cost to the HSSIB of dealing with the penalty notice.
- (9) In subsection (2) “the compliance day” means –
 - (a) in a case where the person given the notice under section 7 does not apply for a review under section 8, the day after the end of the period mentioned in section 7(2)(b);
 - (b) in a case where the person given the notice under section 7 applies for a review under section 8, the day after the end of the period specified in the notice given by virtue of section 8(7)(b).
- (10) The following persons fall within this subsection –
 - (a) an NHS foundation trust, an NHS trust or any other person providing NHS services;
 - (b) any person providing services to a person falling within paragraph (a);
 - (c) the National Health Service Commissioning Board;
 - (d) a clinical commissioning group.

10 Penalty notice: power to amend maximum amount

- (1) The Secretary of State may by regulations made by statutory instrument amend section 9(3) so as to specify a different amount for the amount for the time being specified (“the specified amount”).
- (2) A statutory instrument containing regulations under subsection (1) may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.
- (3) Subsection (2) does not apply to a statutory instrument containing regulations under subsection (1) which amend the specified amount for the purpose only of reflecting changes in the value of money.
- (4) A statutory instrument falling within subsection (3) is subject to annulment in pursuance of a resolution of either House of Parliament.

11 Enforcement of payment under penalty notice

- (1) This section applies where an amount is payable by a person to the HSSIB under a penalty notice under section 9.

- (2) Any amount which is not paid by the payment date is recoverable by the HSSIB summarily as a civil debt.
- (3) No action may be taken by the HSSIB to recover any amount before –
 - (a) the end of the period specified in section 12(3), or
 - (b) any appeal made under section 12 has been determined, abandoned or withdrawn.
- (4) In subsection (2) the reference to the payment date is to –
 - (a) in a case where the person does not apply for an appeal under section 12, the date specified in the penalty notice by virtue of section 9(4)(b), or
 - (b) in a case where the penalty notice given to the person is confirmed or varied by the Chief Investigator on appeal, the date specified in the notice under section 12(6).
- (5) This section does not apply where an amount is payable by a person to the HSSIB under a penalty notice which is confirmed or varied by the First-tier Tribunal under section 12.

12 Penalty notice: right of appeal

- (1) A person may appeal to the First-tier Tribunal against a decision of the Chief Investigator to give a penalty notice under section 9 to the person.
- (2) An appeal under subsection (1) must be made only on one or both of the following grounds –
 - (a) that the person is not liable to the imposition of a penalty under section 9;
 - (b) that the amount of the penalty is too high.
- (3) An appeal under subsection (1) must be brought before the end of the period of 28 days beginning with the date on which the penalty notice was given.
- (4) On an appeal the Tribunal may –
 - (a) confirm, vary or withdraw the penalty notice, or
 - (b) remit the decision as to whether to confirm, vary or withdraw the penalty notice to the Chief Investigator.
- (5) Subsection (6) applies where –
 - (a) a decision is remitted to the Chief Investigator under subsection (4)(b), and
 - (b) the Chief Investigator confirms or varies the penalty notice.
- (6) The Chief Investigator must give the person to whom the penalty notice was given a notice specifying the date before which the amount specified in the penalty notice must be paid.

13 Non-compliance with section 7: report to Secretary of State

- (1) This section applies where –
 - (a) a person falling within subsection (4) fails to comply with a notice under section 7, or
 - (b) in purporting to comply with a notice under section 7 a person falling within subsection (4) –

- (i) provides any information or document which the person knows or suspects is false in a material respect, or
 - (ii) provides any equipment or item which the person knows or suspects has been tampered with.
- (2) As soon as reasonably practicable after the beginning of the compliance day, the Chief Investigator must report the person’s non-compliance with the notice to the Secretary of State.
- (3) In subsection (2) “the compliance day” has the meaning given by section 9(9).
- (4) The following persons fall within this subsection –
 - (a) a Special Health Authority;
 - (b) the Care Quality Commission;
 - (c) Monitor;
 - (d) the Health Research Authority;
 - (e) the Human Tissue Authority;
 - (f) the Human Fertilisation and Embryology Authority;
 - (g) the National Institute for Health and Care Excellence;
 - (h) Health Education England;
 - (i) the Health and Social Care Information Centre;
 - (j) the Health and Safety Executive.

14 Function of giving advice on effect of sections 5 to 13

- (1) The HSSIB must publish guidance explaining the effect of sections 5 to 13.
- (2) If the HSSIB revises the guidance the HSSIB must publish it as revised.

15 Co-operation regarding logistical issues

- (1) This section applies where –
 - (a) the HSSIB is carrying out an investigation into a qualifying incident under this Part, and
 - (b) a listed person is also carrying out an investigation into the same or a related incident.
- (2) The HSSIB must co-operate with the listed person regarding any logistical issues relating to an investigation being carried out by the listed person.
- (3) The listed person must co-operate with the HSSIB regarding any logistical issues relating to an investigation being carried out by the HSSIB.
- (4) The following are listed persons –
 - (a) an NHS foundation trust, an NHS trust or any other person providing NHS services;
 - (b) the National Health Service Commissioning Board;
 - (c) a clinical commissioning group;
 - (d) a Special Health Authority;
 - (e) the Care Quality Commission;
 - (f) Monitor;
 - (g) the Health Research Authority;
 - (h) the Human Tissue Authority;

- (i) the Human Fertilisation and Embryology Authority;
 - (j) Health Education England;
 - (k) the Health Service Commissioner for England;
 - (l) the Parliamentary Commissioner for Administration;
 - (m) any regulatory body as defined by section 2(5);
 - (n) the Health and Safety Executive.
- (5) In this section a “logistical issue” means an issue that relates to the practical arrangements for co-ordinating the investigations that are being carried out by the HSSIB and the listed person into the same incident or a related incident (for example, the sequencing of those investigations).
- (6) The HSSIB must publish guidance to be taken into account by the HSSIB and a listed person about when an incident is to be regarded as related to another incident for the purposes of this section.
- (7) If the HSSIB revises the guidance the HSSIB must publish it as revised.

HSSIB's function of giving assistance

16 Function of giving assistance

- (1) For the purposes of this section giving assistance includes –
- (a) disseminating information about best practice in carrying out investigations;
 - (b) developing standards to be adopted in carrying out investigations;
 - (c) giving advice, guidance or training.
- (2) The HSSIB must give assistance to persons falling within subsection (3) in carrying out investigations into incidents occurring during the provision of NHS services or occurring at premises at which those services are provided if the HSSIB has been requested to provide the assistance by –
- (a) the person to whom it is to be given,
 - (b) the Secretary of State,
 - (c) Monitor, or
 - (d) a Special Health Authority whose functions include the oversight of the performance and governance of NHS trusts.
- (3) The following persons fall within this subsection –
- (a) an NHS foundation trust;
 - (b) an NHS trust;
 - (c) the National Health Service Commissioning Board;
 - (d) a clinical commissioning group.
- (4) Subsection (2) does not apply if –
- (a) the assistance requested is giving advice, guidance or training, and
 - (b) the HSSIB determines that it is impracticable for it to give the assistance.
- (5) The HSSIB may give assistance to any persons not falling within subsection (3) in relation to any matter connected with carrying out investigations if the HSSIB has been requested to provide the assistance by the person to whom it is to be given.

- (6) But the HSSIB may give assistance under subsection (5) only to the extent that the assistance does not to any significant extent interfere with the exercise by the HSSIB of any function conferred on it by this Act.
- (7) The activities which the HSSIB may carry out in, or in connection with, giving assistance under subsection (5) are not restricted to activities carried out in the United Kingdom.
- (8) The HSSIB may impose charges for or in connection with giving assistance under subsection (5).
- (9) Charges under subsection (8) may be calculated on the basis that the HSSIB considers to be the appropriate commercial basis.

HSSIB's functions: supplementary

17 Functions: supplementary

- (1) The HSSIB may do anything which is calculated to facilitate, or is conducive or incidental to, the discharge of any functions conferred on it by this Act.
- (2) The power under subsection (1) includes power for the HSSIB to do the following –
 - (a) enter into agreements;
 - (b) acquire and dispose of property;
 - (c) supply materials, facilities and services to any person;
 - (d) develop and exploit ideas and exploit intellectual property.
- (3) The HSSIB must exercise the functions conferred on it by this Act effectively, efficiently and economically.

18 Failure to exercise functions

- (1) This section applies if the Secretary of State considers that –
 - (a) the HSSIB is failing or has failed to exercise any of its functions, and
 - (b) the failure is significant.
- (2) The Secretary of State may direct the HSSIB to exercise such of its functions, in such manner and within such period, as the direction specifies.
- (3) If the HSSIB fails to comply with a direction under this section, the Secretary of State may –
 - (a) exercise the functions specified in the direction, or
 - (b) make arrangements for some other person to exercise them on the Secretary of State's behalf.
- (4) The reference in subsection (1)(a) to exercising a function includes a reference to exercising it properly.

PART 3

INVESTIGATIONS BY ACCREDITED FOUNDATION OR NHS TRUSTS

*Interpretation***19 External and internal investigations**

- (1) For the purposes of this Part an external investigation is an investigation carried out by a trust which a relevant person has requested to be carried out into a qualifying incident occurring –
 - (a) during the provision of NHS services by, or on behalf of, another trust (“a providing trust”), or
 - (b) at premises at which those services are provided.
- (2) In subsection (1), “relevant person” means –
 - (a) a providing trust,
 - (b) Monitor, or
 - (c) a Special Health Authority whose functions include the oversight of the performance and governance of NHS trusts.
- (3) For the purposes of this Part an internal investigation is an investigation which a trust has decided to carry out, and which the HSSIB has approved, into a qualifying incident occurring –
 - (a) during the provision of NHS services by or on behalf of that trust, or
 - (b) at premises at which NHS services are provided by or on behalf of that trust.
- (4) The HSSIB must determine and publish –
 - (a) the criteria to be used for determining the type of incidents that may be the subject of an external or internal investigation, and
 - (b) the processes to be used for approving investigations under subsection (3).
- (5) If the HSSIB revises the criteria or processes the HSSIB must publish them as revised.
- (6) In this Part references to qualifying incidents are to incidents that have (or may have) implications for the safety of patients and which meet the criteria determined under subsection (4)(a).
- (7) In this Part a “trust” means an NHS foundation trust or an NHS trust.
- (8) In this Part references to a trust’s investigators are to persons authorised by the trust to carry out functions in relation to investigations on the trust’s behalf.

*Accreditation***20 Accreditation to carry out external investigations**

- (1) A trust may apply to the HSSIB to be accredited to carry out external investigations.
- (2) The HSSIB may accredit a trust that has applied under subsection (1) to carry out external investigations.

- (3) The HSSIB must determine and publish the criteria to be used in determining whether to accredit a trust under subsection (2).
- (4) The criteria must include criteria for securing –
 - (a) that a trust and its investigators understand the principles that are to govern investigations;
 - (b) that a trust has satisfactory processes –
 - (i) to ensure the independence of the investigators carrying out investigations, and
 - (ii) to deal with any actual or potential conflicts of interest;
 - (c) that a trust and its investigators are capable of –
 - (i) applying the prohibition on disclosure of any information, documents, equipment or other items (see section 28), and
 - (ii) handling confidential information securely;
 - (d) that a trust and its investigators –
 - (i) are capable of carrying out investigations without adversely affecting the exercise by the trust of its functions under the National Health Service Act 2006, and
 - (ii) have the capacity to deal with investigations and any matter connected to investigations;
 - (e) that satisfactory processes are used in carrying out investigations;
 - (f) that procedures are in place to involve the following in investigations –
 - (i) individuals involved in the provision of NHS services to be investigated, and
 - (ii) patients and their families;
 - (g) that a satisfactory system is used for receiving, handling and recording complaints relating to investigations.
- (5) In subsection (4)(e) the reference to satisfactory processes being used in carrying out investigations includes providing reports that meet the requirement in section 31(4).
- (6) The HSSIB may make an accreditation under subsection (2) subject to such conditions as it considers appropriate.

21 Accreditation to carry out internal investigations

- (1) This section applies where a trust is accredited under section 20(2) to carry out external investigations.
- (2) The trust may apply to the HSSIB to be accredited to carry out internal investigations.
- (3) The HSSIB may accredit a trust that has applied under subsection (2) to carry out internal investigations.
- (4) The HSSIB must determine and publish the criteria to be used in determining whether to accredit a trust under subsection (3).
- (5) The criteria must include criteria for securing –
 - (a) that a trust meets the criteria for accreditation to carry out external investigations under section 20;

- (b) that a trust has carried out a sufficient number of external investigations and that those investigations were carried out to a sufficiently high standard;
 - (c) that the trust is capable of carrying out an internal investigation to a sufficiently high standard.
- (6) The HSSIB may make an accreditation under subsection (3) subject to such conditions as it considers appropriate.

22 Accreditation: supplementary

- (1) The HSSIB must notify the Secretary of State of each application for accreditation that it receives under section 20(1) or 21(2).
- (2) The HSSIB must determine and publish the procedure for a trust to be accredited under section 20(2) and 21(3).
- (3) The HSSIB may revise the criteria determined under section 20(3) and 21(4).
- (4) Before determining or revising the criteria determined under section 20(3) or 21(4), the HSSIB must carry out a public consultation.
- (5) The HSSIB must publish guidance as to the carrying out of external and internal investigations.
- (6) If the HSSIB revises any procedure, criteria or guidance, the HSSIB must publish it as revised.
- (7) The HSSIB must publish and keep up to date—
 - (a) a list of trusts which are accredited under section 20(2) or 21(3), and
 - (b) a list of external and internal investigations (both those in the process of being carried out and those that have been completed or discontinued).

Functions relating to investigations

23 Functions relating to investigations

- (1) A trust may do anything that is necessary for the carrying out of an external investigation or internal investigation (as the case may be).
- (2) The power under subsection (1) may not be exercised so as to require entry to any premises, any person to be interviewed or the provision by any person of any information, document, equipment or other item.
- (3) A trust must notify the HSSIB if it intends to carry out an external investigation.
- (4) Where a trust is accredited under section 20(2) or 21(3), the trust must publish the principles and procedures it intends to use in carrying out external and internal investigations.
- (5) If a trust revises the principles and procedures, it must publish them as revised.
- (6) In carrying out an investigation, a trust must take into account any guidance published under section 22(5) relating to external investigations or internal investigations (as the case may be).

- (7) A trust may, if requested to do so by another trust, provide that trust with advice regarding the carrying out of external investigations or internal investigations.

24 Co-operation regarding logistical issues

- (1) This section applies where –
- (a) a trust is carrying out an external investigation or an internal investigation into a qualifying incident, and
 - (b) a person falling within subsection (4) or (5) is also carrying out an investigation into the same or a related incident.
- (2) Subject to section 28, the trust and its investigators must co-operate with the person falling within subsection (4) or (5) regarding any logistical issues relating to the investigation being carried out by that person.
- (3) A person falling within subsection (4) must co-operate with the trust and its investigators regarding any logistical issues relating to the investigation being carried out by the trust.
- (4) The following persons fall within this subsection –
- (a) a trust or any other person providing NHS services;
 - (b) a clinical commissioning group.
- (5) The following persons fall within this subsection –
- (a) the National Health Service Commissioning Board;
 - (b) a Special Health Authority;
 - (c) the Care Quality Commission;
 - (d) Monitor;
 - (e) the Health Research Authority;
 - (f) the Human Tissue Authority;
 - (g) the Human Fertilisation and Embryology Authority;
 - (h) Health Education England;
 - (i) the Health Service Commissioner for England;
 - (j) the Parliamentary Commissioner for Administration;
 - (k) any regulatory body as defined by section 2(5);
 - (l) the Health and Safety Executive.
- (6) In this section a “logistical issue” means an issue that relates to the practical arrangements for coordinating the investigations that are being carried out by the trust and the person falling within subsection (4) or (5) into the same or a related incident (for example, the sequencing of those investigations).
- (7) The HSSIB must publish guidance to be taken into account by a trust and a person falling within subsection (4) or (5) about when an incident is to be regarded as related to another incident for the purposes of this section.
- (8) If the HSSIB revises the guidance the HSSIB must publish it as revised.

25 Co-operation regarding general issues

- (1) A person falling within section 24(4) must co-operate with a trust and its investigators regarding any general issues relating to an external investigation or internal investigation being carried out by that trust.

- (2) In this section a “general issue” means an issue relating to the carrying out of an investigation that does not affect the substance of an investigation (for example, the provision of access to premises, information or staff by a person falling within section 24(4)).

Review and revocation

26 Review and revocation of accreditation

- (1) The HSSIB must review the accreditation of a trust under section 20(2) or 21(3) for the purpose of determining whether it continues to meet the accreditation requirements.
- (2) The accreditation requirements are –
 - (a) the criteria determined under section 20(3) and any conditions under section 20(6) to which the accreditation is subject, or
 - (b) the criteria determined under section 21(4) and any conditions under section 21(6) to which the accreditation is subject.
- (3) A review must be carried out –
 - (a) at least once during the period of three years beginning with the date on which the accreditation was given;
 - (b) at least once during each period of three years beginning with the completion of the previous review.
- (4) The HSSIB must notify the trust as to whether or not the review is being carried out in response to concerns that the trust no longer meets the accreditation requirements.
- (5) Subsection (6) applies if, on a review under subsection (1), the HSSIB determines that a trust no longer meets the accreditation requirements.
- (6) The HSSIB may by notice –
 - (a) require the trust –
 - (i) to take such actions as are specified in the notice to secure that the trust meets the accreditation requirements, and
 - (ii) to take those actions before the end of the period specified in the notice, or
 - (b) revoke the accreditation of the trust.
- (7) Before revoking the accreditation of a trust under subsection (6)(b), the HSSIB must notify the Secretary of State that it intends to do so.
- (8) If a trust is accredited under section 21(3) and the HSSIB revokes the accreditation of a trust under section 20(2), the HSSIB must also revoke the accreditation of the trust under section 21(3).
- (9) If the accreditation of a trust under section 21(3) is revoked under subsection (6)(b), the HSSIB must review for the purposes of this section the accreditation of the trust under section 20(2) for the purpose of determining whether the trust continues to meet –
 - (a) the criteria determined under section 20(3), and
 - (b) any conditions under section 20(6) to which the accreditation is subject.

- (10) The HSSIB must determine and publish the criteria to be used in determining whether to carry out a review in response to concerns that a trust no longer meets the accreditation requirements.
- (11) If the HSSIB revises the criteria it must publish them as revised.

Evaluation

27 Evaluation of accreditation

- (1) Within four years of the coming into force of this Part, the HSSIB must carry out an evaluation of the effectiveness of the process of accrediting trusts under sections 20(2) and 21(3).
- (2) The HSSIB must –
 - (a) publish a report on the outcome of the evaluation, and
 - (b) send a copy of the report to the Secretary of State.

PART 4

INVESTIGATIONS UNDER PART 2 OR 3: DISCLOSURE AND REPORTS

CHAPTER 1

PROHIBITION ON DISCLOSURE

28 Prohibition on HSSIB or trust disclosing things held by it in connection with investigations

- (1) This section applies where –
 - (a) the HSSIB is carrying out, or has carried out, an investigation under Part 2, or
 - (b) a trust accredited under section 20(2) or 21(3) (referred to in this Chapter as an “accredited trust”) is carrying out, or has carried out, an investigation under Part 3.
- (2) The HSSIB or the accredited trust must not disclose to any person any information, document, equipment or other item which is held by it in connection with the investigation.
- (3) Subsection (2) does not apply to any information, document, equipment or other item which is in the public domain.
- (4) Subsection (2) is subject to sections 29, 30 and 31(5).
- (5) Nothing in this Chapter –
 - (a) prevents the HSSIB from disclosing any information, document, equipment or other item to any of its investigators or other employees;
 - (b) prevents an accredited trust from disclosing any information, document, equipment or other item to any of the investigators or other employees in the team carrying out the investigation.
- (6) In this Chapter –

- (a) references to disclosing information, documents, equipment or other items include permitting access to such information, documents, equipment or other items,
- (b) references to the HSSIB or an accredited trust include any of its investigators or other employees, and
- (c) references to any information, documents, equipment or other items held by the HSSIB or an accredited trust include information about any such information, documents, equipment or items.

29 Exceptions from prohibition on disclosure: evidence of offence etc

- (1) In this section and section 30 –
 - (a) references to information, documents, equipment or items, in relation to the HSSIB, are to information, documents, equipment or items which the HSSIB is prohibited from disclosing under section 28, and
 - (b) references to information, documents, equipment or items, in relation to an accredited trust, are to information, documents, equipment or items which the trust is prohibited from disclosing under that section.
- (2) Subsection (3) applies if it appears to the HSSIB or an accredited trust that any information, document, equipment or item may provide evidence of the commission of an offence.
- (3) The HSSIB or the accredited trust may disclose the information, document, equipment or item to the police.
- (4) Subsection (5) applies if it appears to the HSSIB or an accredited trust that any information, document, equipment or item may provide evidence of a continuing risk to the safety of any patient which the HSSIB or the accredited trust considers to be serious.
- (5) The HSSIB or the accredited trust may disclose the information, document, equipment or item to such of the following persons as the HSSIB or the trust thinks appropriate for the purposes of dealing with the risk in question –
 - (a) the NHS foundation trust, the NHS trust or other person providing the NHS services to which the investigation relates;
 - (b) the National Health Service Commissioning Board or clinical commissioning group commissioning the NHS services to which the investigation relates;
 - (c) a Special Health Authority whose functions include the oversight of the performance and governance of NHS trusts;
 - (d) the Care Quality Commission;
 - (e) Monitor;
 - (f) the Health and Safety Executive;
 - (g) the Secretary of State.
- (6) Subsection (7) applies if it appears to the HSSIB or an accredited trust that any information, document, equipment or item may provide evidence of misconduct by any individual providing NHS services, or managing the provision of those services, which the HSSIB or the trust considers to be serious.
- (7) The HSSIB or the accredited trust may disclose the information, document, equipment or item to such of the regulatory bodies, as defined by section 2(5),

as the HSSIB or the trust thinks appropriate for the purposes of dealing with the misconduct in question.

- (8) Subsection (9) applies if it appears to the HSSIB or an accredited trust that any information, document, equipment or item may provide evidence of one or more of the following –
 - (a) the commission of an offence;
 - (b) a continuing risk to the safety of any patient which the HSSIB or the trust considers to be serious;
 - (c) misconduct by any individual providing NHS services, or managing the provision of those services, which the HSSIB or the trust considers to be serious.
- (9) The HSSIB or the accredited trust may disclose the information, document, equipment or item to such of the following persons as the HSSIB or the trust thinks appropriate for the purposes of safeguarding any patient –
 - (a) an NHS foundation trust, an NHS trust or other person providing NHS services;
 - (b) the National Health Service Commissioning Board;
 - (c) a clinical commissioning group.
- (10) An accredited trust must, if requested to do so by the HSSIB, disclose to the HSSIB any information, document, equipment or item held by it in connection with any investigation that the trust is carrying out or has carried out under Part 3.
- (11) The HSSIB must publish guidance as to –
 - (a) the types of circumstances in which the powers conferred by this section may be exercisable,
 - (b) the types of information, documents, equipment or items in respect of which those powers may be exercisable, and
 - (c) the processes which may be used for disclosing information, documents, equipment or items in exercise of those powers.
- (12) If the HSSIB revises the guidance the HSSIB must publish it as revised.

30 Exceptions from prohibition on disclosure: application to High Court

- (1) A person who is a party to proceedings in the High Court, or otherwise entitled to appear in them, may apply to the Court for an order that any information, document, equipment or item be disclosed to the person for the purposes specified in the application.
- (2) Any person who does not fall within subsection (1) may apply to the High Court for an order that any information, document, equipment or item be disclosed to the person for the purposes specified in the application.
- (3) The HSSIB or an accredited trust may make representations to the High Court about any application under subsection (1) or (2) in relation to any information, document, equipment or item.
- (4) The Court may make an order on an application under subsection (1) or (2) only if it determines that the interests of justice served by disclosing the information, document, equipment or item in question outweigh any adverse impact –

- (a) on future investigations under Part 2 or 3 by deterring persons from participating in them, or
 - (b) on the ability of the Secretary of State to secure the improvement of the safety of NHS services.
- (5) The purposes specified in an application under subsection (1) or (2) may include admitting the information, document, equipment or item in the proceedings in the High Court (in the case of an application under subsection (1)) or in any other proceedings (in the case of an application under subsection (2)).

CHAPTER 2

REPORTS

31 Reports following investigation etc

- (1) This section applies where –
 - (a) the HSSIB has completed an investigation under Part 2, or
 - (b) a trust accredited under section 20(2) or 21(3) (an “accredited trust”) has completed an investigation under Part 3.
- (2) The HSSIB or the accredited trust must publish a report on the outcome of the investigation.
- (3) The report must –
 - (a) contain a statement of findings of fact made as a result of the investigation and an analysis of those findings, and
 - (b) make such recommendations as to the action to be taken by any person as the HSSIB or the accredited trust considers appropriate.
- (4) The report must focus on ascertaining the risks to the safety of any patient involved in the incident investigated and any recommendations under subsection (3)(b) must focus on addressing those risks (rather than the activities of individuals involved in the incident).
- (5) The report may include any information or document, or information about any information, document, equipment or other item, to which the prohibition on disclosure under section 28(2) applies only if the HSSIB or the accredited trust determines that its inclusion would not have any adverse impact –
 - (a) on future investigations under Part 2 or 3 by deterring persons from participating in them, or
 - (b) on the ability of the Secretary of State to secure the improvement of the safety of NHS services.
- (6) If a report includes recommendations under subsection (3), the report must –
 - (a) identify the person or persons who are to take the action specified in the report, and
 - (b) specify the deadline for those persons to publish a report under section 34.
- (7) Before it publishes a report the HSSIB or the accredited trust must send a draft of the report to every person who participated in the investigation.

- (8) The HSSIB or the accredited trust must notify every person to whom a draft report is sent that the person has an opportunity to comment on the draft report before the deadline specified in the notice.
- (9) If a person's comments on a draft report are not to be taken into account in the report published under subsection (1) the HSSIB or the accredited trust must give the person an explanation of its reasons.
- (10) Where a report under section 32 contained recommendations under section 32(3)(b), the references in subsection (3)(b) above to recommendations are to any further recommendations.

32 Reports during investigation etc

- (1) This section applies where –
 - (a) the HSSIB is carrying out an investigation under Part 2, or
 - (b) a trust accredited under section 20(2) or 21(3) (an “accredited trust”) is carrying out an investigation under Part 3.
- (2) The HSSIB or the accredited trust may publish a report on any matter relating to the investigation (an “interim report”).
- (3) An interim report may –
 - (a) contain a statement of findings of fact made as a result of the investigation to date and an analysis of those findings, and
 - (b) make such recommendations as to the action to be taken by any person as the HSSIB or the accredited trust considers appropriate.
- (4) Subsections (4) to (9) of section 31 apply in relation to an interim report as they apply in relation to a report under that section.

33 Admissibility of reports under section 31 or 32

- (1) Subject to subsection (3), the following are not admissible in any proceedings falling within subsection (2) –
 - (a) a report under section 31 or 32, or
 - (b) a draft of such a report sent to any person under section 31(7).
- (2) The proceedings are –
 - (a) proceedings to determine civil or criminal liability;
 - (b) proceedings before any employment tribunal;
 - (c) proceedings before any panel, committee or tribunal of a regulatory body as defined by section 2(5) (including proceedings for the purposes of investigating an allegation);
 - (d) proceedings to determine an appeal against a decision made in proceedings falling within paragraphs (a) to (c).
- (3) The High Court may order that a report under section 31 or 32 is admissible in the proceedings on an application by a person who is a party to the proceedings or otherwise entitled to appear in them.
- (4) The HSSIB or the trust which published the report (as the case may require) may make representations to the High Court about any application under subsection (3).

- (5) The Court may make an order under subsection (3) only if it determines that the interests of justice served by admitting the report outweigh any adverse impact –
- (a) on future investigations under Part 2 or 3 by deterring persons from participating in them, or
 - (b) on the ability of the Secretary of State to secure the improvement of the safety of NHS services.

34 Reports on action to be taken

- (1) This section applies where –
- (a) a report under section 31 includes any recommendations under section 31(3)(b), or
 - (b) a report under section 32 includes any recommendations under section 32(3)(b).
- (2) Before the deadline specified under section 31(6)(b) the addressees of the report must –
- (a) publish a report on the actions they are to take in pursuance of section 31(3)(b) or 32(3)(b), and
 - (b) advise any specified person where the report can be found or send a copy of it to that person.
- (3) In this section –
- (a) references to the addressees of the report are to the persons identified in it under section 31(6)(a), and
 - (b) references to any specified person are to any person specified in a notice given to the addressees by the HSSIB or the trust.

PART 5

SUPPLEMENTARY AND FINAL PROVISIONS

CHAPTER 1

SUPPLEMENTARY PROVISIONS

35 Interpretation

- (1) This section applies for the purposes of this Act.
- (2) “Clinical commissioning group” means a clinical commissioning group established under section 14D of the 2006 Act.
- (3) “Monitor” means the body continued in existence by section 61 of the Health and Social Care Act 2012.
- (4) “NHS foundation trust” has the meaning given by section 30 of the 2006 Act.
- (5) “NHS services” means services provided in England for the purposes of the health service continued under section 1(1) of the 2006 Act.
- (6) “NHS trust” means a National Health Service trust established under section 25 of the 2006 Act.
- (7) “Notice” means notice in writing.

- (8) “Patients” means individuals for whom NHS services are provided.
- (9) “Premises” includes a vehicle.
- (10) “Special Health Authority” means a Special Health Authority established under section 28 of the 2006 Act.
- (11) References to documents include personal and medical records.
- (12) In this section “the 2006 Act” means the National Health Service Act 2006.

36 Consequential amendments

- (1) Schedule 2 contains amendments consequential on this Act.
- (2) The Secretary of State may by regulations made by statutory instrument make provision in consequence of this Act.
- (3) Regulations under subsection (2) may –
 - (a) include transitional, transitory or saving provision;
 - (b) repeal, revoke or otherwise amend any provision of an Act or subordinate legislation (including legislation passed or made in the same Session as this Act).
- (4) A statutory instrument containing (whether alone or with other provision) regulations under subsection (2) that repeal or otherwise amend any provision of an Act is not to be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.
- (5) A statutory instrument containing regulations under subsection (2) that do not repeal or otherwise amend any provision of an Act is subject to annulment in pursuance of a resolution of either House of Parliament.
- (6) “Subordinate legislation” has the same meaning as in the Interpretation Act 1978.

37 Abolition of NHS trusts in England: consequential amendments

- (1) On the coming into force of section 179 of the Health and Social Care Act 2012 (abolition of NHS trusts in England), this Act is amended as follows.
- (2) In section 3(1)(d) –
 - (a) in sub-paragraphs (i), (iii) and (iv) omit “, NHS trusts”, and
 - (b) in sub-paragraph (ii) omit “or NHS trust”.
- (3) In section 5(6) –
 - (a) in paragraphs (b) and (d) omit “, an NHS trust”, and
 - (b) in paragraph (c) omit “or NHS trusts”.
- (4) In the following provisions omit “, an NHS trust” –
 - (a) section 7(12)(a),
 - (b) section 9(10)(a), and
 - (c) section 15(4)(a).
- (5) In section 16(3) omit paragraph (b).
- (6) In the heading to Part 3 omit “or NHS trusts”.

- (7) In section 19—
 - (a) in subsection (2)—
 - (i) at the end of paragraph (a) insert “or”, and
 - (ii) omit paragraph (c) (and the “or” preceding it), and
 - (b) in subsection (7), omit “or an NHS trust”.
- (8) In section 24(4)(a) omit “, an NHS trust”.
- (9) In section 29—
 - (a) in subsection (5)—
 - (i) in paragraph (a) omit “, the NHS trust”, and
 - (ii) omit paragraph (c), and
 - (b) in subsection (9)(a) omit “, an NHS trust”.
- (10) In section 35, omit subsection (6).
- (11) In section 38(3), omit “or NHS trusts”.

38 Territorial limit of exercise of functions

- (1) The functions conferred on the HSSIB by this Act are exercisable only in relation to England.
- (2) Subsection (1) does not apply to—
 - (a) the functions under section 16(5) and (8),
 - (b) the function under section 30(3),
 - (c) the function under section 33(4), or
 - (d) the functions under section 17(1) to the extent that they relate to any function under section 16(5) or (8), 30(3) or 33(4).
- (3) The functions conferred on NHS foundation trusts or NHS trusts by this Act are exercisable only in relation to England.
- (4) Subsection (3) does not apply to—
 - (a) the function under section 30(3) or 33(4), or
 - (b) the functions under section 23(1) to the extent that they relate to any function under section 30(3) or 33(4).

CHAPTER 2

FINAL PROVISIONS

39 Extent

- (1) Subject to subsection (2), this Act extends to England and Wales only.
- (2) Any amendment or repeal made by this Act has the same extent as the provision to which it relates.

40 Commencement

- (1) Section 37 and this Chapter come into force on the day on which this Act is passed.

- (2) The remaining provisions of this Act come into force on such day as the Secretary of State may by regulations appoint.
- (3) Regulations under this section may –
 - (a) appoint different days for different purposes, and
 - (b) make transitional, transitory or saving provision.
- (4) Regulations under this section are to be made by statutory instrument.

41 Short title

This Act may be cited as the Health Service Safety Investigations Act 2017.

SCHEDULES

SCHEDULE 1

Section 1

THE HEALTH SERVICE SAFETY INVESTIGATIONS BODY

PART 1

CONSTITUTION

Status

- 1 (1) The HSSIB is not to be regarded –
 - (a) as the servant or agent of the Crown, or
 - (b) as enjoying any status, immunity or privilege of the Crown.
- (2) The HSSIB's property is not to be regarded –
 - (a) as the property of the Crown, or
 - (b) as property held on behalf of the Crown.

Membership

- 2 (1) The HSSIB is to consist of –
 - (a) a Chief Investigator appointed in accordance with paragraph 3,
 - (b) other members appointed in accordance with paragraph 4,
 - (c) a chair appointed by the Secretary of State, and
 - (d) at least four other members so appointed.
- (2) The Chief Investigator is to be the chief executive of the HSSIB.
- (3) The number of executive members must be less than the number of non-executive members.
- (4) In this Schedule –
 - (a) references to executive members of the HSSIB are references to the members mentioned in sub-paragraph (1)(a) and (b), and
 - (b) references to non-executive members of the HSSIB are references to the members mentioned in sub-paragraph (1)(c) and (d).

The Chief Investigator: role, appointment and status

- 3 (1) The Chief Investigator is responsible to the Secretary of State for the conduct of the HSSIB (including the carrying out of investigations by the HSSIB).
- (2) The Chief Investigator is appointed by the non-executive members with the consent of the Secretary of State.
- (3) The Chief Investigator is to be an employee of the HSSIB.

Other executive members: appointment and status

- 4 (1) The other executive members of the HSSIB are appointed by the non-executive members.
- (2) The non-executive members may not appoint more than five other executive members without the consent of the Secretary of State.
- (3) The other executive members are to be employees of the HSSIB.

Non-executive members: tenure

- 5 (1) A person holds and vacates office as a non-executive member of the HSSIB in accordance with that person's terms of appointment (subject to the following provisions of this paragraph).
- (2) A person may at any time resign from office as a non-executive member by giving notice to the Secretary of State.
- (3) The Secretary of State may at any time remove a person from office as a non-executive member on any of the following grounds –
 - (a) incapacity,
 - (b) misbehaviour, or
 - (c) failure to carry out his or her duties as a non-executive member.
- (4) The Secretary of State may suspend a person from office as a non-executive member if it appears to the Secretary of State that there are or may be grounds to remove the person from office under sub-paragraph (3).
- (5) A person may not be appointed as a non-executive member for a period of more than three years.
- (6) A person who ceases to be a non-executive member is eligible for reappointment for a period of up to two years.

Non-executive members: suspension from office

- 6 (1) This paragraph applies where a person is suspended under paragraph 5(4).
- (2) The Secretary of State must give notice of the decision to suspend to the person; and the suspension takes effect on receipt by the person of the notice.
- (3) The notice may be –
 - (a) delivered in person (in which case the person is taken to receive it when it is delivered), or
 - (b) sent by first class post to the person's last known address (in which case the person is taken to receive it on the third day after the day on which it is posted).
- (4) The initial period of suspension must not exceed six months.
- (5) The Secretary of State may at any time review the suspension.
- (6) The Secretary of State –
 - (a) must review the suspension if requested in writing by the person to do so, but
 - (b) need not review the suspension before the end of the period of three months beginning with the start of the initial period of suspension.

- (7) Following a review during a period of suspension, the Secretary of State may –
- (a) confirm the suspension,
 - (b) revoke the suspension, or
 - (c) suspend the person for another period of not more than six months from the expiry of the current period.
- (8) The Secretary of State must revoke the suspension if the Secretary of State –
- (a) decides that there are no grounds to remove the person from office under paragraph 5(3), or
 - (b) decides that there are grounds to do so but does not remove the person from office under that provision.
- 7 (1) Where a person is suspended from office as the chair under paragraph 5(4), the Secretary of State may appoint a non-executive member as interim chair to exercise the chair's functions.
- (2) Appointment as interim chair is for a term not exceeding the shorter of –
- (a) the period ending with either –
 - (i) the appointment of a new chair, or
 - (ii) the revocation or expiry of the existing chair's suspension, and
 - (b) the remainder of the interim chair's term as a non-executive member.
- (3) A person who ceases to be the interim chair is eligible for reappointment.

Non-executive members: payment

- 8 (1) The HSSIB must pay to the non-executive members such remuneration as the Secretary of State may determine.
- (2) The HSSIB must pay or make provision for the payment of such pensions, allowances or gratuities as the Secretary of State may determine to or in respect of any person who is or has been a non-executive member.
- (3) If a person ceases to be a non-executive member and the Secretary of State decides that there are exceptional circumstances which mean that the person should be compensated, the HSSIB must pay compensation to the person of such amount as the Secretary of State may determine.

Staff

- 9 (1) The HSSIB may appoint such persons to be employees of the HSSIB as it considers appropriate.
- (2) Employees of the HSSIB are to be paid such remuneration as the HSSIB may determine.
- (3) Employees of the HSSIB are to be appointed on such other terms and conditions as the HSSIB may determine.
- (4) The HSSIB may pay or make provision for the payment of such pensions, allowances or gratuities as it may determine to or in respect of any person who is or has been an employee of the HSSIB.

- (5) Before making a determination as to remuneration, pensions, allowances or gratuities for the purposes of sub-paragraph (2) or (4), the HSSIB must obtain the approval of the Secretary of State to its policy on that matter.

Procedure

- 10 (1) The HSSIB may regulate its own procedure.
- (2) The validity of any act of the HSSIB is not affected by any vacancy among the members or by any defect in the appointment of any member.

Committees

- 11 (1) The HSSIB may appoint such committees and sub-committees as it considers appropriate.
- (2) A committee or sub-committee may consist of or include persons who are not members or employees of the HSSIB.
- (3) The HSSIB may pay such remuneration and allowances as it may determine to any person who –
- (a) is a member of a committee or a sub-committee, but
 - (b) is not an employee of the HSSIB,
- whether or not that person is a non-executive member of the HSSIB.
- (4) Before making a determination as to remuneration or allowances for the purposes of sub-paragraph (3), the HSSIB must consult the Secretary of State.

Exercise of functions

- 12 The HSSIB may arrange for the exercise of any of its functions on its behalf by –
- (a) any non-executive member,
 - (b) any employee (including any executive member), or
 - (c) a committee or sub-committee.

Assistance in exercise of functions

- 13 (1) The HSSIB may arrange for persons to assist it in the exercise of its functions in relation to –
- (a) a particular case, or
 - (b) cases of a particular description.
- (2) Such arrangements may include provision with respect to the payment of remuneration and allowances to, or amounts in respect of, such persons.

Funding

- 14 (1) The Secretary of State may make payments to the HSSIB out of money provided by Parliament of such amounts as the Secretary of State considers appropriate.
- (2) Payments made under sub-paragraph (1) may be made at such times and on such conditions (if any) as the Secretary of State considers appropriate.

Borrowing

- 15 The HSSIB may, with the consent of the Secretary of State, borrow money temporarily by way of overdraft.

Use of income from charges

- 16 Where the HSSIB receives income from imposing charges under section 16(8), it must ensure that the income is used for exercising its functions.

Payments into the Consolidated Fund

- 17 Amounts paid to the HSSIB under a penalty notice under section 9 must be paid into the Consolidated Fund.

Losses and liabilities etc

- 18 (1) Section 265 of the Public Health Act 1875 (which relates to the protection of members and officers of certain authorities from personal liability) has effect as if a reference to the HSSIB were included in the authorities referred to in that section.
- (2) In its application to the HSSIB as a result of sub-paragraph (1), section 265 of that Act has effect as if any reference in that section to that Act were a reference to this Act.
- (3) In section 71(2) of the National Health Service Act 2006 (schemes for meeting losses and liabilities etc of certain health service bodies: bodies eligible to participate), after paragraph (fa) insert –
- “(fb) the Health Service Safety Investigations Body,”.

Accounts

- 19 (1) The HSSIB must keep proper accounts and proper records in relation to the accounts.
- (2) The Secretary of State may give directions to the HSSIB as to –
- (a) the content and form of its accounts, and
- (b) the methods and principles to be applied in the preparation of its accounts.
- 20 (1) The HSSIB must prepare annual accounts in respect of each financial year.
- (2) The HSSIB must send copies of the annual accounts to the Secretary of State and the Comptroller and Auditor General within such period after the end of the financial year to which the accounts relate as the Secretary of State may direct.
- (3) The Comptroller and Auditor General must –
- (a) examine, certify and report on the annual accounts, and
- (b) lay copies of them and the report before Parliament.
- (4) In this paragraph and paragraph 21, “financial year” means a period of 12 months ending with 31 March.

Reports and other information

- 21 (1) As soon as practicable after the end of each financial year, the HSSIB must prepare an annual report on how it has exercised its functions during the financial year to which the report relates.
- (2) The report must, among other things, set out the measures that the HSSIB has taken to promote economy, efficiency and effectiveness in the use of resources for the exercise of its functions.
- (3) The report may include a list of –
- (a) any amounts payable to the HSSIB under a penalty notice under section 9, and
 - (b) the persons by whom those amounts are payable.
- (4) The HSSIB must send a copy of the report to the Secretary of State.
- (5) The Secretary of State must lay a copy of the report before Parliament.
- (6) The HSSIB must publish the report once it has been laid before Parliament.
- (7) Subject to sub-paragraph (8), the Secretary of State may require the HSSIB to provide to the Secretary of State such other reports and information relating to the exercise of its functions as the Secretary of State may request.
- (8) The Secretary of State may not require the HSSIB to provide any reports or information that relate to an investigation that the HSSIB is carrying out or has carried out.

Seal and signature

- 22 (1) The application of the HSSIB’s seal must be authenticated by the signature of any member of the HSSIB or any other person who has been authorised (generally or specially) for that purpose.
- (2) A document purporting to be duly executed under the HSSIB’s seal or to be signed on its behalf must be received in evidence and, unless the contrary is proved, taken to be so executed or signed.

PART 2

TRANSFER SCHEMES

Transfer schemes

- 23 (1) The Secretary of State may make one or more property transfer schemes or staff transfer schemes in connection with the establishment of the HSSIB by this Act.
- (2) A “property transfer scheme” is a scheme for the transfer to the HSSIB of any property, rights or liabilities of the National Health Service Trust Development Authority relating to the discharge of the Authority’s functions pursuant to the Directions.
But this does not include any rights or liabilities under or in connection with a contract of employment.
- (3) A “staff transfer scheme” is a scheme for the transfer to the HSSIB of any rights or liabilities –

- (a) under or in connection with a contract of employment entered into by the National Health Service Trust Development Authority, and
- (b) which relate to the discharge of the Authority’s functions pursuant to the Directions.

Supplementary

- 24 (1) The things that may be transferred under a property transfer scheme or a staff transfer scheme include –
- (a) property, rights and liabilities that could not otherwise be transferred;
 - (b) property acquired, and rights and liabilities arising, after the making of the scheme;
 - (c) criminal liabilities.
- (2) A property transfer scheme or a staff transfer scheme may make supplementary, incidental, transitional or consequential provision and may, for example –
- (a) create rights, or impose liabilities, in relation to property or rights transferred;
 - (b) make provision about the continuing effect of things done by, or on behalf of, the National Health Service Trust Development Authority or the Healthcare Safety Investigation Branch in respect of anything transferred;
 - (c) make provision about the continuation of things (including legal proceedings) in the process of being done by, or on behalf of, or in relation to, the National Health Service Trust Development Authority or the Healthcare Safety Investigation Branch in respect of anything transferred;
 - (d) make provision for references to the National Health Service Trust Development Authority or the Healthcare Safety Investigation Branch in an instrument or other document in respect of anything transferred to be treated as references to the HSSIB.
- (3) A property transfer scheme may make provision for the shared ownership or use of property.
- (4) A staff transfer scheme may make provision which is the same as or similar to the TUPE regulations.
- (5) A property transfer scheme or a staff transfer scheme may provide for the scheme to be modified by agreement.

Interpretation

- 25 (1) For the purposes of this Part –
- (a) an individual who holds employment in the civil service is to be treated as employed by virtue of a contract of employment, and
 - (b) the terms of the individual’s employment in the civil service are to be regarded as constituting the terms of the contract of employment.
- (2) In this Part –
- (a) “civil service” means civil service of the State;

- (b) “Directions” means the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 made under section 7 of the National Health Service Act 2006;
- (c) “Healthcare Safety Investigation Branch” means the division of the National Health Service Trust Development Authority established pursuant to paragraph 2(1) of the Directions;
- (d) “National Health Service Trust Development Authority” means the Special Health Authority established under the National Health Service Trust Development Authority (Establishment and Constitution) Order 2012 (S.I. 2012/901);
- (e) “TUPE regulations” means the Transfer of Undertakings (Protection of Employment) Regulations 2006 (S.I. 2006/246);
- (f) references to the transfer of property include references to the grant of a lease.

SCHEDULE 2

Section 36

CONSEQUENTIAL AMENDMENTS

Public Records Act 1958 (c. 51)

- 1 In Part 2 of the table in paragraph 3 of Schedule 1 to the Public Records Act 1958 (definition of public records) insert at the appropriate place –
“Health Service Safety Investigations Body (except for any record that is prohibited from being disclosed by section 28 of the Health Service Safety Investigations Act 2017).”

Public Bodies (Admission to Meetings) Act 1960 (c. 67)

- 2 After paragraph 1(o) of the Schedule to the Public Bodies (Admission to Meetings) Act 1960 (public authorities to which that Act applies) insert –
“(p) the Health Service Safety Investigations Body.”

Parliamentary Commissioner Act 1967 (c. 13)

- 3 In Schedule 2 to the Parliamentary Commissioner Act 1967 (departments etc subject to investigation) insert at the appropriate place –
“The Health Service Safety Investigations Body.”

House of Commons Disqualification Act 1975 (c. 24)

- 4 In Part 3 of Schedule 1 to the House of Commons Disqualification Act 1975 (other disqualifying offices) insert at the appropriate place –
“Chair, Chief Executive or other member of the Health Service Safety Investigations Body.”

Copyright, Designs and Patents Act 1988 (c. 48)

- 5 In section 48(6) of the Copyrights, Designs and Patents Act 1988 (material communicated to the Crown in the course of public business) after “the Care Quality Commission,” insert “the Health Service Safety Investigations Body,”.

Employment Rights Act 1996 (c. 18)

- 6 (1) The Employment Rights Act 1996 is amended as follows.
- (2) In section 49B(7) (regulations prohibiting discrimination because of protected disclosure) after paragraph (g) insert –
“(ga) the Health Service Safety Investigations Body;”.
- (3) In section 50(8) (right to time off for public duties) after paragraph (ad) insert –
“(ae) the Health Service Safety Investigations Body;”.
- (4) In section 218(10) (change of employer) after paragraph (cd) insert –
“(ce) the Health Service Safety Investigations Body.”

Freedom of Information Act 2000 (c. 36)

- 7 In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (public authorities to which that Act applies) insert at the appropriate place –
“The Health Service Safety Investigations Body.”

National Health Service Act 2006 (c. 41)

- 8 (1) The National Health Service Act 2006 is amended as follows.
- (2) In section 9(4) (NHS contracts) after paragraph (kc) insert –
“(kd) the Health Service Safety Investigations Body;”.
- (3) In section 247C(2) (Secretary of State’s duty to keep health service functions under review) after paragraph (ea) insert –
“(eb) the Health Service Safety Investigations Body;”.
- (4) In section 253(1A) (emergency powers) after paragraph (c) insert –
“(ca) the Health Service Safety Investigations Body;”.

Health Act 2009 (c. 21)

- 9 In section 2(2) of the Health Act 2009 (duty to have regard to NHS Constitution) after paragraph (h) insert –
“(i) the Health Service Safety Investigations Body.”

Equality Act 2010 (c. 15)

- 10 In Part 1 of Schedule 19 to the Equality Act 2010 (public authorities to which the public sector equality duty applies), under the heading “Health, social care and social security”, after the entry relating to the Health and Social Care Information Centre insert –
“The Health Service Safety Investigations Body.”

HEALTH SERVICE SAFETY INVESTIGATIONS BILL

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Health Service Safety Investigations Bill as published in Draft on 14 September 2017 (Bill Cm 9497).

- These Explanatory Notes have been prepared by the Department of Health in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Bill. They are not, and are not intended to be, a comprehensive description of the Bill.

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Overview of the Bill

- 1 The Bill makes provision in relation to three main subject matters:
 - First, the establishment of the Health Service Safety Investigations Body (“HSSIB”) as an independent statutory body, with powers to conduct investigations into incidents or accidents within the NHS which appear to evidence risks affecting patient safety.
 - Second, the Bill creates a ‘safe space’ within which participants can provide information for the purposes of an investigation by imposing a prohibition on the disclosure of information held by the HSSIB in connection with an investigation. Information will only be able to be disclosed in certain limited circumstances or by order of the High Court.
 - Third, the Bill makes provision for the accreditation of NHS trusts and foundation trusts to carry out investigations into patient safety with the benefit of ‘safe space’.

Policy background

- 2 The policy to establish an independent healthcare safety investigations body was set out in *Learning not Blaming*, the Government response to three reports: *Freedom to Speak Up consultation*, the Public Administration Select Committee report *Investigating Clinical Incidents in the NHS*, and the *Morecambe Bay Investigation Report* (March 2015).
- 3 Establishing the HSSIB as a new independent body corporate with the overarching purpose to conduct investigations into the most serious risks that affect the safety of patients aligns with the Department’s drive to improve patient safety and delivers the Government’s 2017 manifesto commitment to “legislate for an independent healthcare safety investigations body in the NHS”.
- 4 Policy development proposals to establish a healthcare safety investigation branch were informed by broad stakeholder engagement and recommendations from the Public Administration and Constitutional Affairs Committee (PACAC). This led to the establishment of the Healthcare Safety Investigation Branch (“the Investigation Branch”) in 2016 under Directions given to the NHS Trust Development Authority (TDA) (this is a special health authority subject to Secretary of State Direction which operates alongside Monitor under the umbrella body NHS Improvement). The Investigation Branch commenced operation on 1 April 2017. Whilst welcoming the establishment of the Investigation Branch, PACAC, as well as health experts and patient and family advocates have argued that for the Investigation Branch to be truly effective it needs to be completely independent of the NHS and to have powers analogous to those of the Air Accident Investigation Branch (AAIB).
- 5 The policy to establish the ‘safe space’ provision within the bill is comparable to similar legal provisions for bodies that investigate air and marine accidents. The success of these investigation branches in using ‘safe space’ principles to improve safety, by promoting learning and not attributing blame, is a founding principle behind establishing ‘safe space’ for health service investigations within the provisions of this Bill. The Department consulted on principles of ‘safe space’ in *Providing a safe space in healthcare safety investigations* between October and December 2016. Feedback from this consultation informed the drafting of the ‘safe space’ provisions of the Bill.

- 6 The overarching aim for the system of accreditation set out in the Bill, which would enable approved NHS trusts and foundation trusts to conduct 'safe space' investigations, is to improve local safety investigations and spread a just culture of learning within the NHS.

Legal background

- 7 The relevant legal background is explained in the policy background section of these Notes.

Territorial extent and application

- 8 Clause 39 sets out the territorial extent of the Bill, which describes the jurisdictions in which the Bill forms part of the law. The extent of a Bill can be different from its application. Application is about where a Bill produces a practical effect. Clause 38 makes provision for the territorial limit of the exercise of functions conferred on HSSIB and accredited trusts.
- 9 The Bill extends to England and Wales only.
- 10 In addition to its core investigatory functions, the HSSIB has the function of disseminating information about best practice in carrying out investigations, developing standards to be adopted in carrying out investigations and giving advice, guidance or training to English NHS bodies under clause 16. Where requested to do so, the HSSIB may also give such advice or assistance to NHS and non-NHS bodies in Wales, Scotland and Northern Ireland, as well as to bodies outside the UK, and may charge for those services. The exercise of this function does not affect extent
- 11 The HSSIB's functions, apart from the function of providing advice and assistance to bodies outside England and the function of making representations at a High Court district registry in Wales (in relation to an application for the disclosure of documents or the admissibility of the HSSIB's reports under clause 30(3) or 33(4) respectively), are only exercisable in relation to England (clause 38). Apart from the function of making representations at a High Court district registry in Wales (in relation to an application for the disclosure of documents or the admissibility of the HSSIB's reports under clause 30(3) or 33(4) respectively), the functions conferred on accredited NHS foundation trusts and NHS trusts are exercisable only in relation to England.
- 12 See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom. The table also summarises the position regarding legislative consent motions and matters relevant to Standing Orders Nos. 83J to 83X of the Standing Orders of the House of Commons relating to Public Business.

Commentary on provisions of Bill

Part 1: Establishment of Health Service Safety Investigations Body

Clause 1: The Health Service Safety Investigations Body

- 13 Clause 1 establishes the Health Service Safety Investigations Body (the HSSIB) as a body corporate. It also gives effect to Schedule 1.

Schedule 1: The Healthcare Safety Investigation Body

Part 1: Constitution

- 14 The Schedule provides for the HSSIB's governance arrangements. It includes details of the membership of the HSSIB and the process for appointments, including the appointment of the chief executive, and sets out the HSSIB's financial and reporting obligations.
- 15 The HSSIB's status is confirmed as a non-Crown organisation, in line with the status of other non-Departmental Public Bodies. The HSSIB is not to be regarded as a servant or agent of the Crown and will not enjoy any status, immunity or privilege of the Crown. The HSSIB's property will not be regarded as property of, or property held on behalf of, the Crown.
- 16 The Schedule sets out the requirements for the membership of the Board of the HSSIB. It provides that the Board must consist of the chair, the chief executive and other members of the HSSIB. The chief executive is also known as the Chief Investigator. The chair and at least four other non-executive members must be appointed by the Secretary of State. The chief executive is appointed by the non-executive members, with the consent of the Secretary of State. The number of non-executive members must exceed the number of executive members and no more than five executive members could be appointed without the consent of the Secretary of State. This is intended to ensure that the HSSIB's board remains at an appropriate size and composition and to ensure that appointment of any additional members is justified.
- 17 The schedule makes provision for the terms and conditions of appointment and tenure of office for the HSSIB's non-executive members. The maximum term of office for non-executive members is five years (the initial appointment can be for three years plus possible reappointment for a further two). The Secretary of State may suspend or remove a non-executive member from office, on the grounds of incapacity, misbehaviour, or failure to carry out duties properly.
- 18 The Secretary of State must provide the individual with notice of the suspension, and there is a process for review of the suspension. There is also provision for the Secretary of State to appoint an interim chair when a chair is suspended. The suspension must be for an initial period of not more than six months. It may be reviewed by the Secretary of State at any time and must be reviewed if the person suspended requests this.
- 19 It is required that the HSSIB must pay to non-executive members such remuneration and allowances as the Secretary of State may decide. The HSSIB can make arrangements for pensions, allowances and gratuities to be paid to non-executive members or former non-executive members. These arrangements would be for the HSSIB to determine with the approval of the Secretary of State.
- 20 The HSSIB is provided with powers to employ staff on such pay, terms and conditions as it may determine, following Secretary of State approval of its policy on the remuneration, pensions etc. of employees.

These Explanatory Notes relate to the Health Service Safety Investigations Bill as published in Draft on 14 September 2017 (Bill Cm 9497)

- 21 The HSSIB has the power to regulate its own procedure and any vacancy amongst the members does not affect the validity of its actions.
- 22 The HSSIB may appoint committees and sub-committees, and pay remuneration and allowances to committee members if they are not members or employees of the HSSIB.
- 23 The HSSIB can delegate authority to carry out its functions to other persons.
- 24 The HSSIB can obtain assistance from experts and others in exercising its functions.
- 25 The Secretary of State is allowed to fund the HSSIB's activities to the extent that the Secretary of State considers appropriate. The HSSIB holds the power to temporarily borrow money by overdraft with the consent of the Secretary of State. Any income that the HSSIB generates in connection with the exercise of its functions must be re-invested in carrying out those functions. Any income from penalties should be paid into the Consolidated Fund.
- 26 The HSSIB is included in the list of authorities covered by section 265 of the Public Health Act 1875. The effect of this is to protect members and officers of the HSSIB from personal liability in certain circumstances. Sub-paragraph (3) includes the HSSIB in the list of bodies eligible to enter into schemes for meeting losses and liabilities as set out in section 71 of the National Health Service Act 2006.
- 27 As a non-Departmental Public Body, the HSSIB is required to keep proper accounts and prepare a set of accounts in each financial year. The HSSIB is required to prepare these accounts in the form, and with the content, and using methods and principles determined by the Secretary of State. The HSSIB must send its annual accounts to the Comptroller and Auditor General who is responsible for examining, certifying and reporting on the accounts and for laying copies of the audited accounts (and his report on them) before Parliament.
- 28 The HSSIB must publish an annual report on how it has exercised its functions. The annual report must be laid before Parliament and a copy sent to the Secretary of State. The HSSIB is also required to provide further reports and information about its own functions to the Secretary of State as required. The HSSIB is also required to provide the Secretary of State with further reports and information to the requests, in so far as they relate to the exercise of their functions in the round, but not the details of specific investigations.
- 29 Examples of the information that might be requested are:
 - Information about salaries for auditing
 - Performance data for parliamentary scrutiny
 - Costing data for budget setting
 - Employee data for equalities monitoring
- 30 The HSSIB may also include, in its annual report, details of any penalties issued, to whom they were issued and the amounts of the penalties.
- 31 The HSSIB's seal must be signed by any member of HSSIB for it to be authenticated.
- 32 The HSSIB will only be conducting investigations in England.

Part 2: Transfer schemes

- 33 This part contains provision about schemes for the transfer of staff, property, rights and liabilities from the NHS Trust Development Authority to the HSSIB.
- 34 This makes provision for a property transfer scheme or staff transfer scheme in connection

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with the establishment of the HSSIB.

- 35 This will allow for the transfer to the HSSIB of any property, rights or liabilities of the NHS Trust Development Authority connected with the discharge of the HSSIB's functions under the Directions which established the Investigation Branch as part of NHS Improvement in April 2016.
- 36 In particular, this provision provides that a staff transfer scheme may require that employees of the NHS Trust Development Authority who are employed for the purposes of carrying out functions of the Investigation Branch are transferred to the HSSIB, under terms which are the same as, or similar to, those made by the Transfer of Undertakings (Protection of Employment) Regulations 2006, which provides certain protections of employment rights for transferred staff.
- 37 The staff transfer scheme does not make provision for rights and liabilities relating to an individual's contract of employment.

Part 2: Functions of the Health Service Safety Investigations Body

HSSIB's investigation function

Clause 2: Function of investigating

- 38 Clause 2 gives the HSSIB the function of investigating incidents that have (or may have) implications for the safety of patients and which meet the criteria the HSSIB will determine for which incidents it investigates (under clause 3). These are 'qualifying incidents'.
- 39 The aim is that the HSSIB will gather general lessons from investigating specific incidents, and share these with the NHS. The scope of the HSSIB's investigations will extend to all incidents occurring during the provision of NHS care or on premises where NHS care is provided. For instance, this means that the HSSIB could investigate an incident that occurred during the provision of NHS services in a private hospital or privately owned care home. HSSIB could also investigate an incident such as an assault that occurred not during the provision of NHS care but on premises providing NHS care. The purpose is to address risks to the safety of patients by facilitating improvement of systems and practice in the provision of NHS services. The HSSIB's investigative function is not for the purposes of assessing or determining blame, civil or criminal liability, or action to be taken by a professional regulator in respect of an individual. However, this does not stop the HSSIB from making any assessments in deciding whether it may be appropriate, and what may be appropriate, to disclose under the exceptions to the prohibition on disclosure, set out at clause 29, or from making any assessments in drafting or publishing a final report of an investigation under clauses 31 and 32.
- 40 This Clause also defines a number of professional regulatory bodies relating to healthcare in England that are referred to in other Bill clauses.

Clause 3: Publication of criteria, principles and processes

- 41 The HSSIB must develop, and then publish criteria for identifying the incidents it will investigate, and the principles and processes that will govern those investigations, including how interested parties (e.g. patients, families, and staff, including those of NHS England, CCGs and those providing services to the NHS) will be involved in those investigations. The processes must include the time periods within which the HSSIB aims to complete investigations and involve patients and families in investigations if, and so far as, reasonable

and practicable. The Department expects that HSSIB will make all necessary efforts to involve patients and families in investigations. However, where individuals cannot be reached, despite efforts made by HSSIB, or where they refuse to participate, this should not prevent HSSIB from proceeding with its investigation.

- 42 In developing these criteria, principles and processes the HSSIB must consult the Secretary of State and any other persons the HSSIB considers appropriate.
- 43 The HSSIB must review the criteria, principles and processes at least once in the first three years after publication and at least once every five years after the first review, and if revising following review consider any views of the Secretary of State or other persons the HSSIB considers appropriate. The aim of these provisions is to encourage the HSSIB to change and improve its methods as it becomes more experienced in conducting safety investigations within the health service.
- 44 The HSSIB must also publish a document setting out how the involvement of those persons listed in clause 1(d) (i.e. patients and families) will work in practice; and the document must be easily accessible and worded so that patients and their families can understand it. The HSSIB must also publish and maintain a list of ongoing, discontinued and completed HSSIB investigations.

Clause 4: Representations from Secretary of State and others

- 45 Clause 4 requires the HSSIB to consider any representations made by the Secretary of State or other persons before deciding whether to investigate a qualifying incident. The HSSIB must consider any request made to it by the Secretary of State to carry out a particular investigation.

Carrying out investigations

Clause 5: Entry to premises and inspection

- 46 In carrying out its function of investigating incidents, the HSSIB will engage with those providing the NHS care under investigation and managing the organisations where the investigation is taking place. It is expected that in most cases, the staff and organisation will co-operate with the HSSIB investigators, consent to the investigators' entry to premises and provide relevant documents. However, where consent is not given, clause 5 gives the HSSIB powers to enter and inspect premises.
- 47 This clause enables HSSIB investigators to enter and inspect 'qualifying' premises for the purposes of an investigation. These are similar powers to investigatory bodies in other safety-critical industries, such as the Air Accident Investigations Branch (AAIB). Premises are 'qualifying' if they are owned or controlled by an English NHS body or used for or in connection with the exercise of the functions of an English NHS body or the provision of NHS services. The clause provides that premises used wholly or mainly as a private dwelling are not qualifying premises. An 'English NHS body' means an NHS Trust, an NHS Foundation Trust, a clinical commissioning group, the NHS Commissioning Board (also known as NHS England), and any Special Health Authority.
- 48 If authorised, an HSSIB investigator may enter and inspect premises; inspect and take copies of documents (electronic documents must be produced in a form that can be easily read and transported); inspect any physical piece of equipment or object and remove any documents, equipment or items (unless doing so would put a patient's safety at risk), if the HSSIB considers it necessary or expedient for the purpose of furthering the investigation.
- 49 An HSSIB investigator will be 'authorised' to enter or inspect premises if:

- the English NHS body owning, controlling or using the premises, or the person providing the NHS services, has given its consent; or
 - a warrant has been obtained in accordance with clause 6.
- 50 This clause also gives the investigator the power to interview in private a range of individuals employed by, or representative of, an ‘English NHS body’, or a separate body providing services to an ‘English NHS body’. An investigator may also interview a patient or a member of the patient’s family if they consent to be interviewed. Investigators proposing to enter premises or inspect, seize or remove any documents, equipment or items must, if asked, present a duly authenticated document showing authorisation from the HSSIB to take that action. If the investigator is acting under a warrant, obtained in accordance with clause 6, then that must similarly be produced.

Clause 6: Warrant authorising entry to premises and inspection

- 51 Clause 6 allows an HSSIB investigator to issue a formal notice if the English NHS body that owns, controls, uses or proposes to use the premises in question or the person providing NHS services at those premises has not consented to the investigator entering or inspecting the premises or inspecting and taking equipment, items or copies of documents as provided for under clause 5(2) and (3). The notice must specify what actions the investigator wants to take (for example, enter the premises), explain the reasons for taking the actions, specify when the investigator would like to take the actions and explain that the Chief Investigator has the power to apply for a warrant that would authorise the investigator taking the action.
- 52 The clause outlines the process the Chief Investigator would have to follow to obtain a warrant if a body has not complied with requests set out in a notice by the date specified in the notice. The Chief Investigator may apply to a justice of the peace for a warrant. The application must specify the reasons for taking the actions specified in the application; the names of the investigators (up to a maximum of six) who would be authorised by the warrant to take those actions; and state that the body or organisation to which the notice under clause 6(2) was given has not complied with the requests in the notice by the date specified in the notice.
- 53 A warrant granted would be valid for a period of one month from the date it was given. This means that up to six investigators would be authorised to take the action specified in the warrant, such as enter specific premises, without needing permission from the English NHS body owning, controlling, using or proposing to use NHS services at the premises in question. The Department expects that less than six inspectors would normally be required, but the Bill makes provision for up to six investigators to provide for investigations where a larger number of investigators may be necessary.

Clause 7: Requiring the provision of information, documents, equipment or other items

- 54 Clause 7 makes provision for an investigator to obtain information, documents, equipment or other items if the investigator considers obtaining it necessary or expedient for carrying out an investigation. An investigator may ask anyone to provide information, documents, equipment or items.
- 55 In relation to the persons listed in clause 7(12), an investigator may serve a notice on that person requiring them to provide specified information, documents, equipment or other items. The persons listed are providers and commissioners of NHS services, Special Health Authorities, and other health bodies such as CQC and Monitor.

- 56 The notice must set out what information, documents, equipment or other items the investigator requires, the timeframe for providing this information (within 28 days after being notified), and explain why the investigator thinks the person would be able to provide the information, documents, equipment or items.
- 57 The notice must also explain that there is a right of review of the request, set out how to apply for a review, the penalties associated with not complying with the notice, and the process of appealing against those penalties.
- 58 Should the information being sought by the investigator need to be given by way of an oral explanation, then the notice must set out practical arrangements for this.
- 59 A notice may not require a person to provide anything if doing so puts a patient's safety at risk, or if the information is protected by legal professional privilege, or if it might incriminate the person. Provision of information required by a notice would not breach any obligation of confidence owed by the person providing it or any other restriction on the provision of information, for example imposed by an employment contract. However, the clause does not authorise provision of information in contravention of the Data Protection Act (DPA). This means that although provision of information to the HSSIB is permitted, all parties must continue to respect principles set out in the DPA, such as those concerning handling data securely.
- 60 An investigator may withdraw a notice by notifying the body in writing.

Clause 8: Notices under section 7: right of review

- 61 Clause 8 allows a person who has been given a written notice requiring provision of information, documents, equipment or items by an HSSIB investigator to request a review of the decision to give the notice by the Chief Investigator. The application for a review must be made within 28 days of the date on which the notice was given. If the person applies for a review then they are exempt from the original requirement within the request notice to provide the information requested within 28 days, as set out in Clause 7(2).
- 62 The Chief Investigator must review the decision of the investigator to give the notice within 14 days. The Chief investigator may confirm the original notice, make changes to it or withdraw the original notice altogether.
- 63 If the Chief Investigator confirms or changes the original notice, and therefore the body is still required to provide information, then the Chief Investigator must give the person a written notice explaining the reasons for the Chief Investigator's decision and the timeframe within which the specified information, documents, equipment or items would then have to be provided.

Clause 9: Non-compliance with section 7: penalty notice

- 64 Clause 9 makes provision for the Chief Investigator to issue financial penalties to specified health bodies and providers of NHS services that do not comply with a notice requiring the provision of information, documents, equipment or other items under section 7. Such a penalty notice may also be given to the specified body or person who, in purporting that they are complying with a notice, provides information or documents they know or suspect to be false in a material respect. Similarly penalties arise where the person or body, in purporting they are complying with a notice, provides equipment or other items that they know or suspect have been tampered with.
- 65 The specified bodies are NHS trusts, foundation trusts and other providers of NHS services, persons and bodies that provide services to such trusts and other providers, and NHS England and Clinical Commissioning Groups. The HSSIB will have discretion as to whether a

monetary penalty should be applied and how much it should be, up to a maximum of £20,000. As the bodies concerned are all involved in the commissioning or provision of publicly funded NHS services, it is anticipated that the Chief Investigator would seek to proceed by consent wherever possible, and would only rarely take the step of imposing a penalty. Nevertheless, the Bill will make this power available in the event of any non-compliance.

- 66 The penalty notice cannot be given before the time for complying with the section 7 notice has passed (including where the time is extended in the event that a review leads to the notice being varied or confirmed). The penalty notice must give the recipient at least 28 days in which to pay the penalty. It must explain the rationale, be clear on when and in what way the fine must be paid, explain how payment may be enforced, state that the recipient has the right to appeal (see clause 12) and explain the circumstances and the arrangements by which a penalty notice may be withdrawn. If the section 7 notice (to provide information, documents, equipment or other items) is complied with within the time stipulated for payment, the penalty notice must be withdrawn by withdrawal notice. In that case, an administrative fee may be payable, and the withdrawal notice must specify the amount of the administrative fee. The payment date specified on the penalty notice must be at least 28 days after the notice is issued.

Clause 10: Penalty notice: power to amend maximum amount

- 67 Clause 10 gives power to the Secretary of State to change the maximum amount of the monetary penalty that may be imposed by penalty notice under section 9. The power is exercisable by the making of regulations: where the maximum amount is to rise only so as to reflect changes in the rate of inflation, the regulations require the negative resolution procedure. Where the increase proposed is for the purpose of reflecting other factors, the regulations would be subject to approval by the House of Commons and the House of Lords (affirmative resolution) before becoming law.

Clause 11: Enforcement of payment under penalty notice

- 68 Clause 11 provides for the penalty to be recoverable summarily as a civil debt. The debt is regarded as due if it has not been paid by the date specified on the penalty notice as originally issued, or on the revised date as confirmed or varied by the Chief Investigator as a result of an appeal.
- 69 The HSSIB cannot take action to recover the penalty amount before the time for making an appeal against the penalty has passed (28 days – see clause 12(3)) or, where an appeal is brought, before the determination, abandonment or withdrawal of that appeal.
- 70 In the situation where the First-tier Tribunal confirms or varies a penalty notice, these provisions about recovery of the penalty amount as a civil debt do not apply.

Clause 12: Penalty notice: right of appeal

- 71 Clause 12 sets out the right to appeal the decision of the Chief Investigator to give a penalty notice under clause 9. Appeal is to the First-tier Tribunal. The First-tier Tribunal is a multi-jurisdictional tribunal established by section 3 of the Tribunals, Courts and Enforcement Act 2007. It deals with a range of administrative and regulatory matters.
- 72 There are two grounds for appeal: that the body is not liable to the imposition of the payment of a penalty; or that the amount of payment sought by the HSSIB is too high.
- 73 Appeals must be brought within 28 days of when the financial penalty notice is given. The Tribunal may confirm, vary or withdraw the penalty notice, or pass the matter back to the Chief Investigator. If the decision is referred back to the Chief Investigator, and the Chief Investigator confirms or varies the penalty (so that a financial penalty of some kind remains)

written notice must be given setting out the date by when the penalty would then have to be paid.

Clause 13: Non-compliance with section 7: report to Secretary of State

- 74 Clause 13 imposes a duty on the Chief Investigator of the HSSIB to notify the Secretary of State where specified bodies have failed to comply with a notice requiring the provision of information, documents, equipment or other items under clause 7. Non-compliance with clause 7 includes where a person, in purporting that they are complying with a notice, provides any information or documents which the person knows or suspects is false in a material respect, or provides equipment or items which the person knows or suspects has been tampered with. The specified bodies are national bodies with responsibility for health care in England.

Clause 14: Function of giving advice on effect of sections 5 to 13

- 75 Clause 14 requires the HSSIB to publish guidance explaining the effect of clauses 5 to 13, and publish any revisions of the guidance. The clauses in question are those giving the HSSIB powers in relation to the inspection of premises, the issuing of notices requiring production of information, documents, equipment or other items (subject to review) and the powers to enforce such notices, which include powers to impose a penalty of up to £20,000 for non-compliance (which is subject to a right of appeal). These clauses also include the duty to make reports to the Secretary of State about non-compliance with information requests, as well as the procedures to appeal against these decisions.

Clause 15: Co-operation regarding logistical issues

- 76 Clause 15 requires mutual co-operation between the HSSIB and a range of specified health-related investigatory bodies where they are investigating the same or related incidents. The arrangement is reciprocal, and applies to practical arrangements for the co-ordination of such investigations. The specified organisations each have functions that may involve them in investigations or enquiries of their own. The HSSIB must publish guidance clarifying how incidents should be regarded as related for this purpose and must publish any revisions to the guidance.

HSSIB's function of giving assistance

Clause 16: Function of giving assistance

- 77 In addition to its core investigatory functions, the HSSIB has the function of disseminating information about best practice, developing standards to be adopted in carrying out investigations and providing advice, guidance or training. Where requested to do so, the HSSIB must give assistance to the following NHS bodies in England relating to the carrying out of investigations into incidents occurring during the provision of NHS services: NHS trusts, NHS foundation trusts, and the National Health Service Commissioning Board (which uses the operational title NHS England) and clinical commissioning groups. The Secretary of State, Monitor, a Special Health Authority responsible for the oversight of the performance and governance of NHS trusts (currently the NHS Trust Development Authority, which operates under the umbrella of NHS Improvement) or the body itself may request the assistance. If the assistance sought is the provision of advice, guidance or training, the HSSIB would not be bound to provide this assistance if it decided it was impracticable for it to do so.
- 78 The HSSIB may also give assistance to other bodies, including NHS bodies in Wales, Scotland and Northern Ireland and non-NHS bodies in the UK and elsewhere. The HSSIB may only give assistance to such bodies where requested to do so by the bodies themselves. HSSIB may only provide assistance in these circumstances where the assistance does not significantly

interfere with the HSSIB's exercise of its functions.

- 79 Except in the case of the listed NHS bodies in England, the HSSIB may charge a fee for sharing its expertise on a commercial basis.

Clause 17: Functions: Supplementary

- 80 Clause 17 enables the HSSIB to carry out the corporate activities that are likely to be necessary in order for it to carry out its statutory work and function as an organisation. This includes powers to enter into agreements, buy or sell property, supply goods and services and develop, own and exploit intellectual property.
- 81 The clause places the HSSIB under the same duty of efficiency as other public bodies in the health service.

Clause 18: Failure to exercise functions

- 82 Clause 18 provides for intervention by the Secretary of State, should the HSSIB fail significantly to carry out its functions or fail to carry them out properly. In that event, the clause confers on the Secretary of State a power to direct the HSSIB as to the exercise of its functions, setting a time frame if appropriate. In the event that the HSSIB were not to comply with such directions, the Secretary of State may exercise the functions in question herself/himself, or arrange for another party to do so.

Part 3: Investigations by accredited foundation or NHS trusts

- 83 Part 3 makes provision for the HSSIB to set out criteria and processes whereby NHS trusts and NHS foundation trusts may apply to be accredited by the HSSIB to carry out investigations to which the prohibition on disclosure of information would apply

Interpretation

Clause 19: External and internal investigations

- 84 Clause 19 defines the two types of investigation that a trust may undertake if it is accredited – internal and external investigations.
- 85 An external investigation is an investigation undertaken by an accredited NHS trust or foundation trust into a qualifying incident at a separate NHS trust or NHS foundation trust. Such an incident could have occurred during the provision of NHS services that a trust provides or has commissioned from another health provider, or could have occurred at premises where those services are provided. The NHS trust or foundation trust at which the incident occurred, Monitor or a Special Health Authority responsible for the oversight of the performance and governance of NHS trusts (currently the NHS Trust Development Authority, which operates under the umbrella of NHS Improvement), may request an accredited trust to carry out an external investigation.
- 86 An internal investigation is an investigation undertaken by an accredited NHS trust or foundation trust into a qualifying incident occurring during the provision of NHS services provided or commissioned by that same NHS trust or foundation trust, or occurring on premises where those services are provided.
- 87 The HSSIB must determine and publish criteria, for both external and internal investigations, that define which incidents would qualify to be investigated by accredited trusts. The HSSIB must also publish the processes for deciding whether to approve internal investigations. If the

HSSIB revises the criteria or processes, it must publish the revised version.

- 88 ‘Qualifying incidents’ are defined for the purposes of Part 3 of the Bill as incidents that have (or may have) implications for the safety of patients and meet criteria determined by the HSSIB. An ‘investigator’ in Part 3 of the Bill refers to persons authorised by the NHS trust or foundation trust that is accredited by the HSSIB to carry out functions relating to investigations on that trust’s behalf.

Accreditation

Clause 20: Accreditation to carry out external investigations

- 89 Clause 20 sets out the arrangements by which a trust may be accredited by the HSSIB to undertake external investigations.

- 90 The clause makes provision for trusts to apply to the HSSIB to be accredited for external investigations and for the HSSIB to accredit these trusts. The HSSIB must determine and publish criteria that it will use in deciding whether to accredit a trust to do external investigations. The clause sets out key issues that the criteria must address:

- Trusts must show they understand the principles of investigations as set out in clause 3 of this Bill;
- Trusts must have processes that ensure independence of investigators and address actual or potential conflicts of interest;
- Trusts must be capable of applying the provisions set out in clause 28 which protect information from disclosure except in specified circumstances, and deal securely with confidential information;
- Trusts must show the capacity to carry out investigations and that this will not compromise its other functions as a health provider;
- Trusts must show they have the right processes in place to undertake these investigations effectively and can produce reports that focus on safety issues and learning, rather than on individuals’ actions and blame;
- Trusts must show they have procedures in place to involve, in investigations, relevant healthcare staff, patients and patients’ families; and
- Trusts must show they can handle complaints relating to these investigations effectively.

- 91 The HSSIB can apply conditions to a Trust when it is accredited in respect of external investigations.

Clause 21: Accreditation to carry out internal investigations

- 92 Clause 21 sets out the arrangements by which a Trust may be accredited by the HSSIB to undertake internal investigations, as defined by clause 20.

- 93 The clause establishes that a Trust may only be accredited to do internal investigations if it is already accredited to do external investigations. The clause makes provision for Trusts to apply to the HSSIB to be accredited for internal investigations and for the HSSIB to accredit these Trusts.

- 94 The HSSIB must determine and publish criteria that it will use in deciding whether to accredit a Trust to do internal investigations.
- 95 The clause sets out key issues that the criteria must address, including that:
- Trusts must meet all the criteria for external investigations set out in clause 20
 - Trusts must have carried out a sufficient number of external investigations effectively; and
 - Trusts must show they can also carry out internal investigations effectively.
- 96 The HSSIB can apply conditions to a Trust when it is accredited in respect of internal investigations.

Clause 22: Accreditation: Supplementary

- 97 Clause 22 specifies other HSSIB duties relating to accreditation. The clause states that the HSSIB must notify the Secretary of State of each application for accreditation, both external and internal. It sets out that the HSSIB must publish details of the procedure for trusts to be accredited, guidance on how to carry out external and internal investigations, a list of Trusts accredited for external and internal investigations, and a list of those investigations.
- 98 The clause also makes provision for the HSSIB to revise the criteria it sets out for external and internal investigations. Before finalising or revising these criteria, the HSSIB must undertake a public consultation. Revised criteria must also be published.

Functions relating to investigations

Clause 23: Functions relating to investigations

- 99 Clause 23 sets out the duties of an accredited trust and the actions it may take in carrying out external or internal investigations.
- 100 The clause allows an accredited trust to do the things it needs to do in order to carry out external or internal investigations. However, this power does not allow an accredited trust to enter and inspect premises without permission, or to require any person to be interviewed or to provide information or other material. Instead, a duty of co-operation with accredited trusts is placed upon those organisations which are investigated (clauses 24 and 25).
- 101 An accredited trust must notify the HSSIB before beginning an external investigation (whereas an internal investigation has to be approved by the HSSIB). A trust must publish its investigation principles and procedures for external or internal investigations. A trust must have regard to guidance on carrying out external or internal investigations, published by the HSSIB, as set out in clause 22 (6). A trust is able to give advice to another trust (if that trust requests this) on how to carry out an external or internal investigation.

Clause 24: Co-operation regarding logistical issues

- 102 Clause 24 recognises that, in parallel to a trust carrying out an external or internal investigation, other health bodies may also be investigating the same or related incident, raising logistical issues.
- 103 The clause sets out the duty for trusts accredited by the HSSIB to co-operate with other trusts and clinical commissioning groups and with investigatory agencies and bodies regarding the practical arrangements for carrying out an internal or external investigation.
- 104 Other providers of NHS services and clinical commissioning groups must co-operate in the

same way with accredited trusts. The listed national bodies do not have a corresponding formal duty to co-operate with accredited trusts and their investigators, though this should not preclude co-operation with accredited trusts, where this is reasonable and practicable.

105 The HSSIB must publish guidance clarifying how incidents should be regarded as related for the purpose of logistical co-operation in this clause.

Clause 25: Co-operation regarding general issues

106 Clause 25 sets out a duty for certain bodies, listed at clause 24(4), providing or commissioning NHS services, to co-operate with a trust accredited by the HSSIB and its investigators regarding any general issues that relate to an investigation. These issues would include but are not limited to, providing access to premises, providing access to information and providing for staff to be interviewed.

Review and revocation

Clause 26: Review and revocation of accreditation

107 Clause 26 sets out the arrangements for the HSSIB to review and revoke the accreditation of a trust to undertake external or internal investigations.

108 The clause imposes a duty on the HSSIB to review all accredited trusts against the relevant accreditation criteria for external or internal investigations, and against any conditions attached to a trust's accreditation.

109 The HSSIB can review an accredited trust at any time, but must undertake a review of each accredited trust at least once within the first three years after each trust has been accredited and then at least once within three years of the last review. If the HSSIB is carrying out the review because of concerns that a trust is failing to meet the accreditation criteria, or any conditions placed on its accreditation, the HSSIB must inform the Trust of this reason.

110 On reviewing a trust, if the HSSIB decides the trust is not meeting the accreditation criteria and/or accreditation conditions for that trust, the HSSIB can instruct the trust to take actions to meet these accreditation requirements, by a certain date, or the HSSIB can revoke the trust's accredited status. Before revoking a trust's accreditation, the HSSIB must inform the Secretary of State of this decision.

111 If a trust's accreditation to undertake external investigations is revoked, its accreditation to undertake internal investigations is also automatically revoked. If a trust's accreditation to undertake internal investigations is revoked, its accreditation to undertake external investigations must be reviewed to establish whether the trust is still meeting the accreditation requirements.

112 The HSSIB must also publish, and may revise, the criteria it will use to decide whether a review of a trust's accreditation should be triggered in response to concerns that the trust is not meeting its accreditation requirements.

Evaluation of accreditation

Clause 27: Evaluation of accreditation

113 Clause 27 sets out provisions placing a duty on the HSSIB to assess the effectiveness of the process of accrediting trusts to undertake external and internal investigations after no longer than four years from the commencement of the provisions set out in this Part of the Bill.

114 The HSSIB must then publish a report of its findings and send a copy to the Secretary of State.

Part 4: Investigations under Part 2 or 3: Disclosure and reports

Chapter 1: Prohibition on disclosure

Clause 28: Prohibition on HSSIB or trust disclosing things held by it in connection with investigations

- 115 Clause 28 prohibits the disclosure of any information, document, equipment or other item held by the HSSIB or an accredited trust in connection with an investigation, unless one of the exceptions set out in clause 29 applies or the High Court makes an order for disclosure under clause 30.
- 116 Disclosure of information, documents, equipment or other items includes permitting access to such information, documents, equipment or other items [clause 28(6)(a)].
- 117 The prohibition does not apply to any information, document, equipment or item which is in the public domain.
- 118 The prohibition on disclosure does not prevent the HSSIB's employees and investigators from sharing protected information, documents, equipment or items with each other [clause 28(5)(a)]. Similarly, an accredited trust may share protected information, documents, equipment or items with the investigators or other employees in the team carrying out the investigation [clause 28(5)(b)].

Clause 29: Exceptions from prohibition on disclosure: evidence of offence etc

- 119 The HSSIB or an accredited trust may disclose information, documents, equipment or other items held by it in connection with an investigation in the circumstances set out in this clause.
- 120 Where it appears to the HSSIB or an accredited trust that any information, document, equipment or item may provide evidence of the commission of an offence, the HSSIB or an accredited trust may disclose the information, document, equipment or item to the police [clause 29(2)].
- 121 Where it appears to the HSSIB or an accredited trust that any information, document, equipment or item may provide evidence of a continuing and serious risk to the safety of any patient, it may disclose the information, document, equipment or item to the persons listed in clause 29(4). The reference to a Special Health Authority whose functions include the oversight of the performance and governance of NHS trusts in clause 4(c) would include the NHS Trust Development Authority (which operates alongside Monitor under the umbrella of NHS Improvement). The Secretary of State is listed at 29(4)(g) in order to include the Medicines and Healthcare products Regulatory Agency which is responsible for addressing safety issues relating to medicines and medical devices, but falls directly under the responsibility of the Secretary of State as an executive agency of the Department of Health.
- 122 Where it appears to the HSSIB or an accredited trust that any information, document, equipment or item may provide evidence of serious misconduct by any individual providing NHS services, or managing the provision of NHS services, the HSSIB or the accredited trust may disclose the information, document, equipment or item to one of the professional regulatory bodies listed in clause 2(5) [clause 29(6)].
- 123 Where it appears to the HSSIB or an accredited trust that any information, document, equipment or item may provide evidence of the commission of an offence, evidence of a serious and continuing risk to the safety of patients or evidence of serious misconduct, the

HSSIB or the accredited trust may disclose the information, document, equipment or item to an NHS trust, foundation trust or other person providing NHS services, or to NHS England or a CCG as appropriate for the purposes of safeguarding any patient [clause 29(8)].

124 An accredited trust must disclose to the HSSIB any protected information, document, equipment or item that it holds for the purposes of an investigation where requested to do so by the HSSIB [clause 29(9)].

125 An accredited trust must disclose material to the HSSIB if requested. In addition the HSSIB must publish guidance which sets out more detail on what kinds of material it may disclose, using what processes, and in which circumstances.

Clause 30: Exceptions from prohibition on disclosure: application to High Court

126 Clause 30 makes provision for any person to apply to the High Court for an order that information, documents, equipment or items that are held by the HSSIB or an accredited trust in connection with an investigation be disclosed to the person making the application. The Court can order the disclosure for the purposes specified in the application, which may include admitting the information, document, equipment or item in legal proceedings.

127 The Court may only allow the information, document, equipment or item to be disclosed if it determines that the interests of justice served by disclosing the information, document, equipment or item in question outweigh any adverse impact on:

- future investigations by the HSSIB or an accredited trust by deterring persons from participating in them, or
- on the ability of the Secretary of State to secure the improvement of the safety of NHS services.

Chapter 2: Reports

128 This chapter makes provision for the HSSIB's reports of its investigations.

Clause 31: Reports following investigation etc

129 Clause 31 is applicable to investigations being carried out by both the HSSIB and trusts that are accredited by HSSIB. This clause obliges the HSSIB and accredited trusts to report the outcome of investigations and specifies that the report must:

- set out the findings of fact, and any analysis, conclusions and recommendations arising from those findings;
- focus on the wider lessons for patient safety across the system, and not the actions of individuals;
- identify what actions are to be taken, by whom, and by when; and
- the HSSIB or the accredited trust must not include any material in the report that is protected from disclosure under clause 28, unless it considers this would not discourage participation in future investigations or hamper the ability of the Secretary of State to improve the safety of NHS services.

130 Before publishing such a report the HSSIB or the accredited trust must:

- circulate a draft report to all organisations and individuals who participated in the investigation and ask them to comment by a set deadline; and

- where applicable, explain why these comments have not been taken into account in the final report.

Clause 32: Reports during investigation etc

131 Clause 32 outlines how the HSSIB can make interim reports during an investigation. These should contain findings of fact and recommendations for action. The aim is to address urgent risks to patient safety quickly, or issues that are known early in an investigation, so that swift action can be taken and lessons learned across the NHS.

132 Such interim reports are subject to the same conditions as final reports, as set out in section 31(4) to (9).

Clause 33: Admissibility of reports under section

133 Unless the High Court makes an order to the contrary, final and interim reports published by the HSSIB and accredited trusts following an investigation (including drafts of those reports) are not admissible in certain types of proceedings, including:

- proceedings to determine civil or criminal liability;
- proceedings before an employment tribunal;
- proceedings before any panel, committee or tribunal of a regulatory body as defined in clause 2(5);
- proceedings to determine an appeal against a decision made in any of the above types of proceedings.

134 The High Court may order that a report by the HSSIB or an accredited trust is admissible in proceedings in response to an application to the court by a person who is a party to proceedings or otherwise entitled to appear in them. The HSSIB or the accredited trust in question would be able to make representations to the court to explain its reasons for not wanting the report to be considered as evidence in the proceedings.

135 The Court may only make an order that a report of HSSIB or an accredited trust is admissible if it determines that the interests of justice served by admitting the report outweigh any adverse impact on future investigations by the HSSIB or an accredited trust by deterring persons from participating in them or the ability of the Secretary of State to secure the improvement of the safety of the NHS.

Clause 34: Reports on action to be taken

136 Clause 34 sets out what should happen when a report from the HSSIB makes recommendations for future action. The addressees of the report must respond by the HSSIB's deadline by publishing a report setting out how they will be implementing its recommendations, sending a copy of the response to relevant bodies or informing them about where a copy of the response can be found.

Part 5: Supplementary and final provisions

Chapter 1: Supplementary Provisions

Clause 35: Interpretation

137 Clause 35 provides definitions that apply throughout the Bill. A number of the definitions rely on terms used in the National Health Service Act 2006.

Clause 36: Consequential amendments

138 This clause confers a power on the Secretary of State to make such provision as she/he considers appropriate in consequence of the Act. Such provision must take the form of regulations may include transitional, transitory or saving provision and may repeal revoke or amend any provision in primary or secondary legislation. Regulations that repeal, revoke or amend the provision of an Act must be approved by affirmative resolution of both Houses of Parliament before they can be made law. Other regulations made under the powers in this section are subject to the negative procedure, so are made by laying them before Parliament. Subsection (1) gives effect to relevant consequential amendments set out in Schedule 2 to the Bill.

Schedule 2: Consequential amendments

139 This Schedule makes consequential amendments to the following Acts to include references to the HSSIB where appropriate:

- Public Records Act 1958
- Public Bodies (Admission to Meetings) Act 1960
- Parliamentary Commissioner Act 1967
- House of Commons Disqualification Act 1975
- Copyright, Designs and Patents Act 1988
- Employment Rights Act 1996
- Freedom of Information Act 2000
- National Health Service Act 2006
- Health Act 2009
- Equality Act 2010.

Clause 37: Abolition of NHS trusts in England: consequential amendments

140 Clause 37 sets out consequential amendments to this Bill relating specifically to the abolition of NHS trusts as a result of section 179 of the Health and Social Care Act 2012 coming into force. Section 306(4) of the 2012 Act provides that section 179 is to come into force on such date as the Secretary of State may by order appoint. There is at present no order appointing a date for the coming into force of section 179.

Clause 38: Territorial limit of exercise of functions

141 Clause 38 provides that the HSSIB's functions, apart from the function of providing advice and assistance to bodies outside England in accordance with clause 16(5) and the function of making representations at a High Court district registry in Wales in relation to an application for the disclosure of documents under clause 30(3) or the admissibility of the HSSIB's reports under clause 33(4), are only exercisable in relation to England.

142 Accredited trusts may exercise the function of making representations at a High Court district registry in Wales in relation to an application for the disclosure of documents under clause 30(3) or the admissibility of the accredited trust's report under clause 33(4). The functions conferred on accredited NHS trusts or foundation trusts are otherwise only exercisable in England.

Chapter 2: Final provisions

Clause 39: Extent

143 Clause 39 sets out the territorial extent of the Bill, that is the jurisdictions within which the Bill forms part of the law.

144 The Bill extends to England and Wales only.

Clause 40: Commencement

145 This clause provides that certain provisions of the Bill come into force on the day that this Act is passed. These are the Final Provisions (Chapter 2 of Part 5 dealing with extent, commencement and the Act's title) and section 37 (which depends on the coming into force of section 179 of the Health and Social Care Act 2012). The remaining provisions of the Act are to come into force on the day or days specified by the Secretary of State in regulations. The power to make commencement regulations includes a power to make transitional, transitory or saving provision.

Clause 41: Short title

146 This clause states the Bill's short title

Commencement

147 The provisions of the Bill will come into force as provided for by clause 40 of the Bill. The Final Provisions (Chapter 2 of Part 5) and section 37 (which depends on the coming into force of section 179 of the Health and Social Care Act 2012) come into force on Royal Assent. The remaining provisions in the Bill are to be brought into force by regulations to be made by the Secretary of State.

Financial implications of the Bill

148 A full impact assessment has been carried out to assess the impact of setting up the HSSIB as an independent body corporate.

149 The Bill will result in two types of effect (costs and savings):

- First-order effects that relate directly to the independent investigations undertaken by the HSSIB
- Second order effects. It will be for other parts of the system, to respond to the recommendations and guidance, and implement them amongst NHS providers. Since these impacts depend on the decisions of others, they are categorised as second order effects.

150 Three first-order costs have been identified: to the HSSIB, the NHS and public involved, and the Courts.

151 The Healthcare Safety Investigation Branch, the “Investigation Branch”, established as a branch of the NHS Trust Development Authority, a special health authority forming part of NHS Improvement, has an agreed annual budget of £3.8million. The Bill will establish a new body ‘the HSSIB’ to take over the functions of the Investigation Branch. This will require a small executive function with a cost of around £200,000 plus £100,000 for shared services. This will increase the total annual budget from £3.8million to £4.1million.

152 NHS providers will need to participate in the HSSIB investigations as appropriate. It is estimated that the combined direct costs of different NHS providers participating in 30 HSSIB investigations for NHS providers could be between £26,880 and £32,160. The estimated costs to the public of participating in HSSIB investigations could amount to £3,300 per annum.

153 The costs to the courts from challenges arising from the HSSIB to obtain information or from individuals requesting access to evidence from the HSSIB ‘safe space’ investigation is estimated to be £104,550 in total over a period of 10 years.

154 The primary second-order cost to the setup of the HSSIB would be the cost of implementing HSSIB recommendations. NHS Improvement (the umbrella body comprising the NHS Trust Development Authority, as mentioned above, and Monitor) will have a key role in ensuring many of the HSSIB recommendations are implemented and will need to reach a view on the affordability and sustainability of those measures. NHS Improvement will be expected to challenge NHS trusts and foundation trusts where their proposals for meeting the HSSIB’s recommendations are costly, inefficient, or ineffective.

Parliamentary approval for financial costs or for charges imposed

155 A money resolution is required to cover the proposed government funding of the HSSIB.

156 The Bill does not impose charges and a ways and means resolution is not required.

Compatibility with the European Convention on Human Rights

157 The Secretary of State proposes to make a statement under section 19(1)(a) of the Human Rights Act 1998 that, in his view, the provisions of the Bill are compatible with the European Convention on Human Rights on introduction of the Bill [in the Commons].

Annex A - Territorial extent and application in the United Kingdom

The Bill extends to England and Wales only.

The HSSIB’s functions are exercisable only in England, except:

- i. Its ability under clause 16(5) to give assistance (on request) about carrying out investigations and to charge for those services under clause 16(8).
- ii. The HSSIB may make representations to the High Court in Wales if an application for disclosure of information it holds is made to that Court [clause 30(3)].
- iii. The HSSIB may also make representations to the High Court in Wales about the admissibility of their report in any proceedings [clause 33(4)].

The functions conferred on accredited NHS trusts and foundation trusts are only exercisable in relation to England, although accredited trusts may make representations to the High Court in Wales in relation to an application for disclosure of information under clause 30(3) or the admissibility of reports under clause 33(4).

See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom.¹

Provision	Extends to E & W and applies to England ?	Extends to E & W and applies to Wales?	Extends and applies to Scotland?	Extends and applies to Northern Ireland?	Would corresponding provision be within the competence of the National Assembly for Wales?	Would corresponding provision be within the competence of the Scottish Parliament?	Would corresponding provision be within the competence of the Northern Ireland Assembly?	Legislative Consent Motion needed?
1 Establishment of the Health Service Safety Investigations Body Clause 1	Yes	No	No	No	Yes	Yes	Yes	No
2 Functions of the Health Service Safety Investigations Body								

¹ References in this Annex to a provision being within the legislative competence of the Scottish Parliament, the National Assembly for Wales or the Northern Ireland Assembly are to the provision being within the legislative competence of the relevant devolved legislature for the purposes of Standing Order No. 83J of the Standing Orders of the House of Commons relating to Public Business.

Provision	Extends to E & W and applies to England ?	Extends to E & W and applies to Wales?	Extends and applies to Scotland?	Extends and applies to Northern Ireland?	Would corresponding provision be within the competence of the National Assembly for Wales?	Would corresponding provision be within the competence of the Scottish Parliament?	Would corresponding provision be within the competence of the Northern Ireland Assembly?	Legislative Consent Motion needed?
Clause 2 - 15	Yes	No	No	No	Yes	Yes	Yes	No
Clause 16	Yes	Yes	No	No	Yes	Yes	Yes	No
Clause 17 - 18	Yes	No	No	No	Yes	Yes	Yes	No
3 Investigations by accredited foundation or NHS trusts								
Clause 19 - 27	Yes	No	No	No	Yes	Yes	Yes	No
4 Investigations under Part 2 or 3: Disclosure and reports								
Clause 28 - 29	Yes	No	No	No	Yes	Yes	Yes	No
Clause 30	Yes	Yes	No	No	Yes	Yes	Yes	No
Clause 31 - 32	Yes	No	No	No	Yes	Yes	Yes	No
Clause 33	Yes	Yes	No	No	Yes	Yes	Yes	No
Clause 34	Yes	No	No	No	Yes	Yes	Yes	No
5 Supplementary and final provisions								
Clause 35 - 41	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 1 - 2	Yes	No	No	No	Yes	Yes	Yes	No

Minor or consequential effects²

The following provision that applies to England have effects outside England, all of which are, in the view of the Government of the United Kingdom, minor or consequential:

Clause 2: Function of investigating

There may be cross-border implications where individuals not residing or working in England receive care from an English NHS provider, and that care is then the subject of an investigation.

² References in this Annex to an effect of a provision being minor or consequential are to its being minor or consequential for the purposes of Standing Order No. 83J of the Standing Orders of the House of Commons relating to Public Business.

Subject matter and legislative competence of devolved legislatures

In the context of this Bill, health policy and funding is within the legislative competence of the Scottish Parliament, the National Assembly for Wales and the Northern Ireland Assembly. In the view of the Department, this Bill would not provide for any legislation that the respective Devolved Legislature could not legislate for, and no legislative consent motion is required in relation to any provision of the Bill.

HEALTH SERVICE SAFETY INVESTIGATIONS BILL

EXPLANATORY NOTES

These Explanatory Notes relate to the Health Service Safety Investigations Bill as published in Draft on 14 September 2017 (Bill Cm 9497).

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