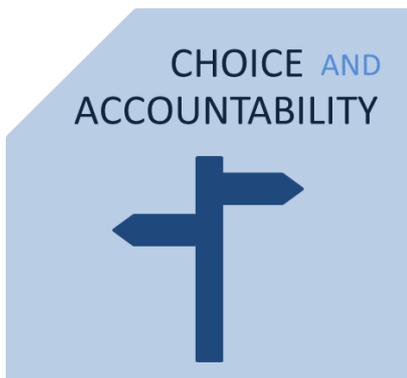
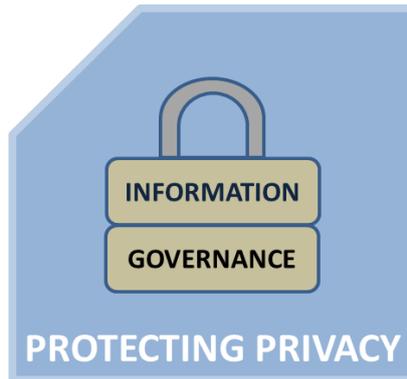


Who Pays? Information Governance Advice for Invoice Validation



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1 Executive Summary

- 1.1 Commissioning organisations must ensure that they have a secure legal basis for every purpose for which they intend to use personal confidential data (PCD). Where there is no statutory basis, they must rely on the use of anonymised data or pseudonymised data.¹
- 1.2 In the absence of a legal basis to use PCD,² patient-level invoice validation was suspended while work progressed to develop new data processing systems for commissioners.
- 1.3 Because of the complexities involved, this work has not progressed as quickly as had been expected.
- 1.4 As it is not feasible to prolong the delay any further, NHS England applied for section 251 support³ to establish a temporary lawful basis for 'necessary' PCD to be used to validate invoices without the need to obtain explicit consent from the individual patient.
- 1.5 This application was approved by the Secretary of State for Health on 22 November 2013 and is valid for 12 months.
- 1.6 The current document explains:
- the conditions associated with those approvals
 - the purposes for which PCD can be used
 - the steps that clinical commissioning groups (CCGs), and commissioning support units (CSUs) that validate invoices on behalf of a CCG, must now take to enable the invoice validation process to proceed lawfully.
- 1.7 It also outlines further work being undertaken to determine the detailed business purposes and data requirements for invoicing. The change process will involve designing, testing and implementing new systems to enable invoices to be validated lawfully, in ways that respect patient confidentiality and that rapidly remove the need for section 251 support.⁴
- 1.8 NHS England is working in partnership with a wide range of organisations, including NHS Shared Business Services (NHS SBS), the Health and Social Care Information Centre (HSCIC) and the Department of Health (DH) to address these outstanding issues.⁵
- 1.9 It is imperative that commissioning, provider and supplier organisations recognise the importance of information governance (IG) controls in relation to invoicing and that they work together to design new systems and to implement changes at a local level.
- 1.10 All organisations need to be mindful of the recommendations of the recent independent review of IG that was chaired by Dame Fiona Caldicott. In particular, the conclusion that health and social care commissioners should be able to meet their objectives without compromising patient confidentiality or the public's trust in the health and social care system.⁶ It is NHS England's intention to ensure that those objectives be met.
- 1.11 CCGs and CSUs must show some flexibility and offer support to providers during this period of change to avoid risks of financial damage.
- 1.12 This document will be refined and reissued as work progresses. Future versions will include additional advice as new systems are developed and more issues are resolved.
- 1.13 In due course, our advice will be issued as

statutory guidance under NHS England's powers.⁷
This advice should be consider a draft of the
guidance which will follow.

SECTION A: CONTEXT

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2 Introduction

2.1 The invoice validation process supports the delivery of patient care across the NHS by:

- ensuring that service providers are paid for the patient's treatment
- enabling services to be planned, commissioned, managed, and subjected to financial control
- enabling commissioners to confirm that they are paying appropriately for the treatment of patients for whom they are responsible
- fulfilling commissioners' duties of fiscal probity and scrutiny
- enabling invoices to be challenged and disputes or discrepancies to be resolved

2.2 The NHS England guidance *Who pays? Determining responsibility for payments to providers*⁸ (Who pays?), helps CCGs to understand their commissioning responsibilities and to determine who pays for a patient's care.

2.3 CCGs and NHS England, which includes CSUs, do not have a legal right to access PCD for the purpose of validating invoices.

2.4 Accordingly, patient-level invoice validation was suspended while work was undertaken to establish new systems to support commissioning needs under the new statutory framework.

2.5 However, the complexities involved mean that work has not progressed as quickly as expected and it is not feasible to prolong the delays any further.

2.6 NHS England therefore applied for section 251 support⁹ to provide a lawful basis for invoice processing while work continues to redesign the data systems.

2.7 On 22 November 2013, the Secretary of State for Health approved applications from NHS England for section 251 support¹⁰ for PCD to be used to validate invoices lawfully, without the need to obtain explicit consent from the individual patient.

2.8 This approval is valid for a period of 12 months and is subject to a number of conditions.

2.9 This document explains:

- the approved data flows
- the purposes for which PCD can be used
- the specific conditions of the approval.

2.10 It also outlines the steps that CCGs, and CSUs who validate invoices on behalf of a CCG, must take to enable the invoice validation processes to be administered lawfully.

2.11 Work will continue over the 12 month term of the approval in order to:

- design and test new processes for validating invoices without using PCD
- implement systems that use anonymised or pseudonymised data
- ensure that any use of PCD is supported by a lawful basis
- move away from depending upon section 251 support for invoice validation

2.12 Commissioning organisations are expected to take the lead in implementing these measures and for coordinating the subsequent work at a local level in preparation for withdrawal of the section 251 support.

2.13 It is important to consider the recommendations of the recent independent

review of IG chaired by Dame Fiona Caldicott (Caldicott 2).¹¹ After a thorough analysis, the review panel found that the majority of commissioning functions could be achieved using anonymous or pseudonymous data.

additional advice as progress is made and issues are resolved.

- 2.14 Where the use of PCD was considered to be necessary, the panel recommended various legal solutions, including support from the HSCIC via its *Data Services for Commissioners Regional Offices* (DSCROs).
- 2.15 The Caldicott 2 Review Panel also made it clear that commissioning organisations are expected to apply the same standards of IG as all other health and social care organisations and that they should demonstrate strong leadership to achieve these goals.¹²
- 2.16 The Government has endorsed all of the review's recommendations, including the conclusion that health and social care commissioners should be able to meet their objectives by compromising neither patient confidentiality nor the public's trust in the health and social care system.¹³
- 2.17 NHS England is working in partnership with a wide range of organisations, including NHS Shared Business Services (NHS SBS), the Health and Social Care Information Centre (HSCIC) and the Department of Health (DH) to address various outstanding issues in relation to the section 251 approvals and the wider objectives of this programme of work.¹⁴ NHS England will lead in this work.
- 2.18 Commissioning, provider, and supplier organisations need to recognise the importance of robust information governance (IG) controls in relation to invoicing; they need to work together to design new systems and to implement change at a local level.
- 2.19 This document will be refined and reissued as this programme of work develops. We will provide

3 Audience

3.1 This guidance should be read by anyone who is involved in the creation, submission, receipt, validation, or payment of invoices for health care services funded by the NHS, including:

- CCGs
- CSUs that provide invoice validation services to CCGs
- NHS SBS, responsible for paying invoices on behalf of a CCG¹⁵
- Suppliers or providers of health and social care services that issue invoices for the payment services funded by the NHS.

3.2 It is also relevant to:

- the HSCIC and its DSCROs
- CCG or CSU *Stage 1 Accredited Safe Havens* (ASHs).

3.3 Caldicott Guardians, Senior Information Risk Owners, and IG managers should also read this advice because it identifies and addresses IG issues within the invoice validation process.¹⁶

3.4 Local IG experts should support their colleagues who are affected by these changes in the interpretation and implementation of this advice.

4 Purpose and Scope

- 4.1 The intention of this document is to provide advice to CCGs and CSUs to support the implementation of the section 251 approvals and the use of 'necessary' PCD for invoice validation purposes.
- 4.2 This advice complements the guidance entitled *Who pays? Determining responsibility for payments to providers* published in September 2013. It explains how PCD can be used lawfully under the provisions of the section 251 approvals.
- 4.3 The term 'necessary' means that it would not be reasonably feasible to achieve the intended purpose without using PCD.¹⁷
- 4.4 Where a CCG is already validating invoices without the need to use PCD, that practice is lawful and should continue. It is therefore out of the scope of this document.
- 4.5 The use of PCD to validate invoices in the following situations is not covered by the section 251 approvals and is not included in this advice:
- any specialist service commissioned by NHS England
 - payment for healthcare services provided to private patients
 - determining which is the responsible commissioner where care is provided over the border with a devolved administration
 - where one provider commissions the services of another provider (i.e., sub-contract arrangements)
 - any invoice validation by local authorities (including public health) or for services jointly commissioned by the NHS and a local authority
- 4.6 NHS England is considering these exceptions and we will issue further advice and guidance in due course.
- 4.7 Commissioners must ensure that they have a secure legal basis to use PCD to validate invoices. Where there is no such statutory basis, the default position is to use anonymised data or pseudonymised data; this principle applies to all invoice validation activity outside the scope of this guidance.
- 4.8 The lawful basis to use PCD for invoice validation for individual, patient-centred services (e.g., individual funding requests, personal health budgets, continuing health care) is usually based on consent.
- 4.9 NHS England is undertaking work to examine the use of consent as a legal basis for invoice validation and other commissioning purposes. This work will advise on the use of patient consent for these purposes.
- 4.10 When that work programme concludes, we will review this reliance on patient consent and provide further guidance.
- 4.11 Other NHS organisations – and independent sector service providers acting as a data processor under contract with a CCG to validate invoices on their behalf – are within neither the scope of this document nor the Section 251 approvals obtained to date.

5 Background

Note: This document contains new terminology. Kindly refer to Appendix A: Glossary before reading this section.

- 5.1 One intention of the section 251 approvals is to enable Stage1 ASHs to identify, design and test practical options for validating invoices using pseudonymised and weakly pseudonymised data (See Appendix A: Glossary).
- 5.2 NHS England will work with a wide range of stakeholders to design and test these new systems, with the aim of ensuring that invoice validation operates on a secure legal platform that respects patient confidentiality and removes the need for section 251 support.
- 5.3 The main purpose of the section 251 approvals, however, is to maintain essential business continuity while these complex cultural and operational changes are undertaken.
- 5.4 There are three section to the approvals:
The first approval adds invoice validation to the existing section 251 approval (CAG 2-03(a) 2013), which allows DSCROs to flow weakly pseudonymised data into a CCG's controlled environment for finance (CEfF) for this purpose (CAG 7-07(a)/2013)
- 5.5 A 'PCD backing-data set' has also been was approved in the second and third approvals. Providers can submit this to the CCG or CSU's CEfF to evidence the payment they are claiming on the invoice. (See Appendix C).²³

The second approval allows this data set to be used for invoice validation within a CCG's CEfF. This approval will enable business continuity while we build capacity and capability into the system (CAG 7-07(b)/2013)

The third approval allows this data set to be used for

invoice validation within a CSU's CEfF for the same purposes. This approval allows CSUs to support CCGs (CAG 7-07(c)/2013)

- 5.6 The CEfF will have limited access to key systems used to support invoice validation. In order to apply for CEfF status, an organisation must be a Stage 1 ASH.

Box 1: Components of an Invoice

- The invoice (i.e., the front 'facing' page) contains details about the service provider, the services provided and the cost of that service
- The 'backing data', which are separate from the invoice, contain evidence to justify the amount claimed
- The invoice number should be included in both the invoice and the backing data. It is a non-identifiable, unique number that is used for reference purposes.
- The NHS number is an identifier and should be regarded as PCD in this context. The NHS number must **not** be used within the invoice (the facing page); however, it should be included in the backing data.
- Likewise, local patient identifiers must not be used within the invoice but they may be included within the backing data

SECTION B: IMPLEMENTATION

6 Implementing Section 251 Support

General Conditions

- 6.1 The section 251 approvals are time-limited and are subject to conditions that CCGs, CSUs and providers must follow in order to validate invoices legally.
- 6.2 The legal requirements, restrictions and exclusions that apply to the Section 251 support are set out in Regulation 7 of the Health Service (Control of Patient Information) Regulations 2002.¹⁸
- 6.3 The specific and standard conditions for approval are listed in the Confidentiality Advisory Group's letter of 22 November 2013.
- 6.4 NHS England and the HSCIC will define the application process, set out the standards expected, and provide detailed information about of these conditions.
- 6.5 Organisations must comply with the law and best practice standards imposed by:
- the Section 251 regulations
 - other laws, such as the Data Protection Act 1998
 - the Secretary of State for Health (as specified in the s251 approval letter)
 - professional bodies such as the General Medical Council
- 6.6 All organisations must respect patient confidentiality in accordance with the NHS Constitution, HSCIC Guidance, and the Statutory Code of Practice once it has been published.¹⁹
- 6.7 The support provided by section 251 must be used only when necessary and only for invoice validation purposes.
- 6.8 'Necessity' is a qualifying condition to justify the lawful use of PCD within (a) Regulation 7; (b) the Data Protection Act 1998; and (c) the Caldicott Principles. See Appendix A.
- 6.9 As part of the standard conditions for approval under the section 251 regulations, the processing of PCD must be consistent with the requirements of the Data Protection Act 1998.
- 6.10 Documented technical and organisational measures must be in place to prevent unauthorised processing of the data.
- 6.11 Section 251 support applies to organisations that have achieved ASH stage 1 accreditation.²⁰
- 6.12 Section 251 support does not amend the conditions imposed upon a Stage 1 ASH under the CAG 2-03(a) 2013 approval. The original application and controls remain the same; the only difference is that invoice validation has been added as an additional purpose.
- 6.13 The approval does **not** allow a Stage 1 ASH to access or process PCD.
- 6.14 The approval does not apply to:
- NHS SBS, because there is no justified purpose for using PCD on the facing page of the invoice (see NHS SBS Good Practice Guide available at <http://www.sbs.njs.uk/home/working-with-suppliers/goodinvoicingpractice>)
 - other NHS SBS activities. (Please note that this advice is not relevant to other *NHS SBS activities, such as where they are contracted to create invoices, debt recovery. This document only concerns invoice validation, which is not a SBS*

function)

- 6.15 The approval does not cover any other NHS organisation or independent sector service provider contracted by a CCG to act as a data processor to validate invoices on its behalf.
- 6.16 These issues are excluded because only further work is necessary before advice can be issued
- 6.17 The approval specifically excludes access to PCD for financial audit purposes. Financial audit concerns the audit and assurance of the effectiveness of procedures to check and verify financial claims and payments, which should not require PCD .

7 Operational Implementation

General conditions

7.1 The section 251 approvals establish a legal basis for the following purposes:

- implementing a PCD data set for the invoice backing data
- enabling access to systems for checking the PCD backing data and confirming the CCG responsible for payment
- testing the feasibility of removing the need for PCD for invoice validation purposes (and providing evidence of the need for access to PCD for invoice validation where this is not possible)
- developing a minimum PCD data set that will lead to the development of an information standard for non-PbR data sent by providers to non-contracting commissioners

Commissioner Tasks

7.2 A CCG or CSU must establish a *controlled environment for finance* (CEfF) before it can receive backing data. See Chapter 8.

7.3 A CCG or CSU may agree with a DSCRO that it will act as the nominated contact point to receive PCD backing data and will validate invoices.

7.4 CCGs should work with providers to (a) explain their requirements for invoicing and backing data; and (b) to implement the changes to ensure that:

- PCD are not included on the invoice facing page
- the invoice is submitted to NHS SBS

- the approved PCD data sets are included on the backing data
- the invoice number is included on the backing data to provide a link between the two sections
- the backing data and a copy of the invoice are submitted to the single secure point of contact provided by the CCG or CSU

7.5 A secure contact point must be established for providers to submit backing data and copy invoices to the CEfF of the CCG or CSU. This contact point must be communicated to providers and to NHS SBS, and it must be registered with NHS England.

7.6 Until a CEfF has been established, the default position is for PCD backing data to be received in the designated DSCRO; in this case, the secure contact point must likewise be communicated to providers and to NHS SBS, and it must be registered with NHS England.

7.7 CCGs, CSUs and providers must agree processes for:

- identifying, reporting and investigating data incidents
- addressing poor data quality issues
- initiating improvement plans.

7.8 Information for CCGs and CSUs on becoming an ASH may be found here:

<http://www.hscic.gov.uk/media/12203/Accredited-Safe-Haven-Accreditation-Process-Stage-1---June-2013/pdf/safe-haven-accred-proc-stage->

[1.pdf](#)

Information for CCGs and CSUs on establishing a CEff, and a list of secure contact points, can be found here:

<http://www.england.nhs.uk/ourwork/tsd/data-info/ig/in-val/>

7.9 CCGs and CSUs should show some flexibility and offer support to providers through this period of change in order to avoid financial damage.

Commissioner Challenges

7.10 The CCG or CSU is responsible for informing the provider if they disagree with the allocation of the CCG responsible for paying the invoice.

7.11 The CCG or CSU must explain to the provider the reason why they do not consider the patient to be their responsibility; for instance:

- the patient is registered with a GP practice that is not a member of the CCG
- the patient has moved to a postcode that is not in the area of residence covered by the CCG's member GP practices
- the treatment is specialised and is the responsibility of NHS England.

7.12 The submission of PCD backing data to the wrong CCG or CSU is a personal data breach.

7.13 CCGs and CSUs must design systems to capture, report, investigate and manage personal data breaches.

Responsibility of the Provider

7.14 The term 'provider' refers to either the supplier or provider of health care commissioned and funded by the NHS.

7.15 The provider is responsible for determining the commissioner of each activity to ensure that the correct commissioner is identified on both the

invoice and on the backing data; for instance, by populating the correct commissioner code field for the type of commissioning data set (CDS).

7.16 The legal framework for the CCG, CSU or DSCRO to receive PCD on the backing data is provided by a combination of:

- section 251 approval (covering CCGs and CSUs)
- forthcoming Directions to the HSCIC from NHS England (covering DSCROs).

7.17 The Section 251 approval includes support for the implementation of a PCD data set on the backing data (See Appendix C). Providers must ensure that any PCD are included only in the backing data section of the invoice.

7.18 The invoice number should be included on both the invoice and backing data. It is used as the non-identifiable unique number for reference purposes.

7.19 The NHS number is an identifier and should be regarded as PCD. It must not be used within the invoice. It is not acceptable to use the NHS number for aligning invoices with the relevant backing data.

Provider Tasks

7.20 The original invoice should be submitted to NHS SBS. It must not include any PCD because the inclusion of such data cannot be justified as being necessary for the purpose of invoice-recording and payment.

7.21 The backing data include necessary PCD under the section 251 approval; therefore this information must not be sent to NHS SBS

7.22 The provider also submits a copy of the invoice, including the backing data, to the CCG identified as the commissioner responsible for payment.

7.23 Provider organisations will be required to submit the backing data to a single secure contact

point, which will be either at the CCG, CSU or DSCRO, as confirmed to the provider by the CCG and registered with NHS England.

7.24 A list of registered secure contact points will be made available here:

<http://www.england.nhs.uk/ourwork/tsd/data-info/ig/in-val/>

7.25 The backing data must **not** be sent to any email address or contact point at the CCG, CSU or DSCRO that has not been registered as the secure address for submitting backing data.

Challenges from Commissioners

7.26 If a CCG or CSU disagrees with the allocation of the CCG responsible for paying the invoice, it should inform the provider and explain why.

7.27 Providers should be aware that the submission of PCD to a CCG that is not responsible for payment is a personal data incident. Systems must be developed to record and deal with such breaches.

7.28 We are developing systems to monitor the source of invoices that are rejected for containing PCD.

7.29 Providers are advised to be diligent in ensuring that their invoicing processes take account of our guidance, and in preventing the accidental disclosure of PCD.

8 Controlled Environment for Finance

8.1 The *controlled environment for finance* (CEfF) is a new concept. It has been established as an interim solution to allow necessary PCD to be received and used for invoice validation purposes within a CCG or CSU.

8.2 The CEfF is distinct from a Stage 1 ASH in that staff within a Stage 1 ASH must have neither access to PCD nor the means to identify an individual patient, whereas CEfF authorised staff will be allowed to access necessary PCD for invoice validation.

8.3 If a CCG or CSU does not intend to hold backing data PCD, then there is no requirement for them to set up a CEfF.

8.4 If CCGs and CSUs decide to operate invoice validation independently of a DSCRO, they must have (a) met the standards to be a Stage 1 ASH and (b) established a CEfF to hold PCD as part of the section 251 conditions.

8.5 CCGs or CSUs that have achieved Stage 1 ASH standards will be eligible to apply for CEfF accreditation. A statement of compliance for CEfF is being developed and further details of the application process will be published shortly.

8.6 Stage 1 ASH and CEfFs must maintain appropriate segregation of their staff and systems.

8.7 Staff within a CEfF should be separated from other staff. PCD should not be passed to other parts of the organisation without a supporting legal basis. Unauthorised staff must not have access to PCD.

8.8 Robust technical and organisational security controls must be in place to separate CEfF staff and processes from other CCG or CSU staff to and ensure the protection of PCD.

8.9 Setting up a CEfF involves:

- separating staff for invoice validation from other staff
- technical and physical isolation of PCD
- creating a secure central point of contact directly into the CEfF for receiving PCD backing data securely
- establishing access controls (i.e., smartcard, role-based access controls, etc.).

9 Conclusion

- 9.1 CCGs and CSUs must ensure that they have a secure legal basis for every specific purpose for which they intend to use PCD.
- 9.2 Section 251 approval allows necessary PCD to be used for invoice validation purposes without the need to obtain explicit patient consent.
- 9.3 CCGs and CSUs need to establish systems in compliance with this advice to ensure that PCD are processed lawfully.
- 9.4 The section 251 applications were designed to allow CCGs and CSUs some flexibility in the way in which they validate invoices locally.
- 9.5 Any backing data from a provider that includes necessary PCD evidence to support an invoice must be submitted to the CEFF via the approved secure contact point.
- 9.6 Alternatively, providers can submit backing data containing necessary PCD to the CCG's nominated DSCRO.
- 9.7 The statutory duration of the section 251 approval is 12 months from 22 November 2013.
- 9.8 During this time, further work must be completed to design and implement new systems and processes to validate invoices using either pseudonymised or weakly pseudonymised data.
- 9.9 A secure legal basis – other than section 251 support – must be established where invoices cannot be validated without PCD.
- 9.10 CCGs and CSUs are expected to work closely with providers to ensure that:
- this is communicated
 - providers understand and implement these new requirements
 - providers are effectively supported while work continues to implement change.
- 9.11 It is important for commissioners to be flexible and to ensure that the risk of financial damage to providers is mitigated.
- 9.12 NHS England will lead this work; however, it is imperative that commissioning, provider and supplier organisations recognise the importance of IG controls in relation to invoicing; and they support us by working together to design new systems and implement change at a local level.
- 9.12 This document provides advice on the implementation of the section 251 approvals, which constitute the first step in a long and complex period of work to resolve a range of issues and to align various systems with the new statutory framework provided by the Health and Social Care Act 2012.
- 9.13 We will publish further advice and guidance in due course, including statutory guidance when as new systems are established.

Appendix A: Glossary

Acronym	Description
ASH	Accredited Safe Haven (referred to as Stage 1 ASH)
CAG	Confidentiality Advisory Group (A HRA committee who provide advice on the approval of section 251 applications to the HRA (for research applications) and the Secretary of State for Health (for non-research applications))
CCG	Clinical Commissioning Group
CDS	Commissioning Data Set
CEFF	Controlled Environment (for Finance)
CSU	Commissioning Support Unit
DH	Department of Health
DSCRO	Data Services for Commissioners Regional Office
DPA	Data Protection Act 1998
HSCA	Health and Social Care Act 2012
HSCIC	Health and Social Care Information Centre
HRA	Health Research Authority
IG	Information Governance
NHS SBS	NHS Shared Business Service
PCD	Personal Confidential Data
SUS	Secondary Use Services

Accredited Safe Haven (ASH)

Established in either a CCG or CSU as a controlled environment where staff can receive *weakly pseudonymised data* under section 251 approval (Reference CAG 2-03(a)/2013) and use the data for commissioning purposes, on the strict condition that staff do not have access to PCD or the means to identify an individual patient. Stage 1 ASH accreditation refers to those organisations that have completed the approval process.

Anonymisation: The process of removing identifiers from a set of data so that there is little or no risk of an individual being identified from those data or by matching them to other data (i.e., identification is not likely to take place)

Backing data: activity information provided with a copy of the invoice to the CCG or CSU to evidence the health care services delivered and amount of payment claimed either under a commissioning contract or under a non-contract agreement. The backing data must follow the framework provided in Appendix B.

Wherever possible, the required data should conform to approved information standards. We recognise, however, that locally specified activity often does not conform to information standards. The data necessary to support such activity should utilise approved information standards as far as is feasible. Additional data items must be specified in the contract schedule between the commissioner and the health service provider. Note that commissioners and providers must conform to the approved meaning of terms and they must seek to collect an additional data item rather than seek to

change the approved meaning of terms.

Caldicott Guardian: A senior person within an organisation who is responsible for (a) ensuring the confidentiality of patient and service-user information and (b) enabling appropriate information sharing.

Clinical Commissioning Group (CCG): CCGs are responsible for commissioning health services to meet all the reasonable health care requirements of their patients, and for meeting the urgent and emergency care requirements of everyone present in their geographic area. Certain services are commissioned directly by NHS England²¹ or by local authorities.²²

Commissioning Data Set (CDS): CDS forms the basis of data on activity carried out by organisations that is reported centrally for monitoring and payment purposes. This Data Sets supports the current version of the Healthcare Resource Group (HRG) used for the calculation of payment and monitoring of services.

Commissioning Support Unit (CSU): CSUs provide a range of managerial and administrative services to CCGs and NHS England's Area Teams. They are currently hosted by NHS England and are therefore legally a part of that organisation.

Consent: The approval or agreement for something to happen after consideration. For consent to be legally valid, the individual must be informed, must have the capacity to make the decision in question, and must give consent voluntarily. Accordingly, individuals should know and understand how their information is to be used and shared (there should be 'no surprises') and they should understand the implications of their decision, particularly where refusing to allow information to be shared is likely to affect the care they receive. This requirement applies to both explicit and implied consent.

Controlled Environment for Finance (CEfF): This is a

new concept established by the section 251 approval. CEfFs are a temporary measure to help CCGs and CSUs to manage the change process. Staff working in a CEfF will be able to see PCD under the terms of s 251 applications. They will therefore be subject to strict conditions to ensure accountability for keeping PCD secure. CEfFs will be aligned with a Stage 1 ASH.

Data controller: Under Part 1, Section 1 of the DPA, a data controller is an individual or an organisation who determines the purposes for which any PCD are or will be processed and the manner of such processing. Data controllers must ensure that any processing of personal data for which they are responsible complies with the DPA.

Data processor: Under Part 1 Section 1 of the DPA, a data processor means any person (other than an employee of the data controller) who processes PCD on behalf of the data controller. Data processors are not directly subject to the Data Protection Act. However, the Information Commissioner recommends that organisations should choose data processors carefully and have in place effective means of monitoring, reviewing, and auditing their processing. A written contract detailing the information governance requirements must be in place to ensure compliance with principle 7 of the DPA.

Data Services for Commissioners Regional Offices (DSCROs)

These are regional outposts of the HSCIC, and operate under the statutory access powers of the HSCIC under the HSCA 2012.

Health and Social Care Act 2012 (HSCA) amended the NHS Act 2006 and established CCGs as independent legal entities with responsibility for commissioning services for their local population and the NHS Commissioning Board ("NHS England") and the Health and Social Care Information Centre.

Health and Social Care Information Centre (HSCIC):

The Health and Social Care Information Centre (HSCIC) was set up as an Executive Non Departmental Public Body (ENDPB) in April 2013 . The functions and duties of the HSCIC are set out in Part 9 of the Health and Social Care Act 2012, in sections 252 to 275, and in Schedule 18

More details can be found here: www.hscic.gov.uk

Identifiable information: See 'PCD'.

Information Governance (IG): How organisations manage the way information and data are handled within the health and social care system in England. It covers the collection, use, access and decommissioning of information as well as the requirements and standards that organisations and their suppliers need to achieve to fulfil the obligations that information be handled legally, securely, efficiently, effectively and in a manner that maintains public trust.

Invoice: A bill for the provision of health care and treatment provided to a patient and submitted by the provider of those services to the CCG responsible for that patient.

Necessity - Many of the conditions for data processing depend on the processing being "necessary" for a particular purpose to which the condition relates. This condition imposes a strict requirement because it will not be met if the organisation can achieve the purpose by some other reasonable means or if the processing is necessary only because the organisation has decided to operate its business in a particular way.

See the Guide to Data Protection published by the Information Commissioners Office 2010 B (9.14)

http://www.ico.org.uk/for_organisations/guidance_index/~media/documents/library/Data_Protection/Practical_application/the_guide_to_data_protection.pdf

Personal Confidential Data (PCD): This term describes personal information about identified or identifiable individuals, which should be kept private or secret. For the purposes of this guide, 'personal' includes the DPA definition of personal data, but it is adapted to include dead as well as living people. 'Confidential' includes both information 'given in confidence' and 'that which is owed a duty of confidence' and is adapted to include 'sensitive' as defined in the Data Protection Act. Used interchangeably with 'confidential' in this document.

Payment by Results (PbR): PbR is the payment system in England under which commissioners pay healthcare providers for each patient seen or treated, taking into account the complexity of the patient's healthcare needs. The two fundamental features of PbR are *currencies* and *tariffs* that are determined nationally. Currencies are the unit of healthcare for which a payment is made, and can take a number of forms covering different time periods from an outpatient attendance or a stay in hospital, to a year of care for a long term condition. Tariffs are the set prices paid for each currency.

Personal data: Under Part 1 Section 1 of the DPA, personal data are Data that relate to a living individual who can be identified from those data, or from those data and other information that is in the possession of, or is likely to come into the possession of, the data controller. It includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

Processing: Under Part 1 Section 1 of the DPA, processing in relation to information or data means obtaining, recording or holding the information or data, or carrying out any operation or set of operations on the information or data, including:

- organisation, adaptation or alteration of the

information or data;

- retrieval, consultation or use of the information or data;
- disclosure of the information or data by transmission, dissemination or otherwise making available; or
- alignment, combination, blocking, erasure or destruction of the information or data.

Pseudonymisation: Data in which individuals are distinguished through the use of a unique identifier, which does not reveal their 'real world' identity, but where the patient's identity can be determined by reversing the process. Data are considered to be anonymised where the recipient of the pseudonymised data set has no means of access to the algorithmic key to re-identify individuals. See also see *weakly pseudonymised data*.

Public interest (test): This test applies when the holder of the information believes that the public good that would be served by sharing the information outweighs both the obligation of confidentiality owed to the individual and the public good of protecting trust in a confidential service.

Section 251 (NHS Act 2006): Section 60 of the Health and Social Care Act 2001 as re-enacted by Section 251 of the NHS Act 2006 allows the Secretary of State for Health to make regulations to set aside the common law duty of confidentiality for defined medical purposes. The Regulations that enable this power are called the *Health Service (Control of Patient Information) Regulations 2002*. Regulation 5 provides the Secretary of State for Health with the power to set aside the common law duty requirement for consent to use personal confidential data for medical purposes other than the provision of direct healthcare and treatment, subject to advice from the Confidentiality Advisory Group. Any reference to section 251 support or approval' actually refers to approval given under the authority of these Regulations.

Sensitive personal data/information: Under Part 1, Section 2 of the DPA, these are data that identify a living individual consisting of information as to his or her: racial or ethnic origin, political opinions, religious beliefs or other beliefs of a similar nature, membership of a trade union, physical or mental health or condition, sexual life, convictions, legal proceedings against the individual, or allegations of offences committed by the individual. See also 'PCD'.

NHS Shared Business Services (NHS SBS): Please visit the NHS SBS website for further information <http://www.sbs.nhs.uk/home/about-nhs-sbs>

Weakly Pseudonymised data: data that include one strong item (e.g., date of birth or NHS number or postcode) that could be matched with other data and lead to the identification of an individual patient. The term is used in conjunction with a CCG or CSU accredited Stage 1 ASH. An ASH is a controlled environment where staff do not have the means to access other information or systems that would enable weakly pseudonymised data to be re-identified when matched to other data or systems. Outside the ASH, weakly pseudonymised data would be considered to be 'personal data' under the terms of the Data Protection Act 1998 (personal data definition section 1). This concept aligns with the definition of *de-identified data for limited access* in the report of the Caldicott 2 Review of information governance.

Appendix B: Backing Data

The following data items, purpose and justification were included in the section 251 applications as the intended backing data set for invoice validation. The data set was created in consultation with colleagues across the NHS and is intended to provide a generic description applicable to data systems (such as SUS) as well as invoice production outside these systems (such as those produced by some small scale providers).

The intention is to test and refine this data set, in order to develop an information standard that will ensure consistency within the invoicing process.

Data Item	Example	Purpose	Justification
Invoice Number	Not PCD	Identifies the relevant invoice and allows associated with backing data	To enable backing data to be matched with the relevant invoice
NHS Number	NHS Number	The unique identifier for the patient	Needed to determine if the individual is the responsibility of the commissioner
Unique Patient Event identifier	Hospital Provider Spell Number/AE or OP Attendance identifier unique within Provider for the patient event	To ensure the same episode of care isn't paid for by the commissioner more than once. For example, a patient may have several attendances of treatment on the same day.	To distinguish between multiple events carried out for a particular patient on the same day.
Unique Patient Identifier	Local Patient Identifier, GP Practice identifier	To ensure any issue or payment is attributed to the same patient	To identify the individual to the healthcare provider. Particularly as NHS Number is not always known by the provider.

Data Item	Example	Purpose	Justification
Geographical Locator (identifying location)	Postcode, LSOA	To resolve issues around services not commissioned via GP or CCG route. Note this is not required in all instances but may be part of a challenge process. Where a Unique Patient Identifier cannot be used or is not relevant.	An NHS Number is not, currently, always present and geographical location is an alternative means of identifying the relevant commissioner. This is required for identifying the usual residence of patients
Provider Details	ODS code of provider submitting invoice related to backing data. IF ODS code not known then Name of provider as displayed on Invoice	To identify who requires reimbursement for the treatment already provided.	Required to match activity, to provider and ensure payment
Point of Delivery	Outpatient, Emergency Admission, Day Case Admission, Maternity, Accident and Emergency	Required in some circumstances to judge that the requested price/payment noted by the provider complies with PBR or local tariff arrangements for that type of patient care event, delivered in this point of deliver setting.	Required to match activity and appropriate tariff.
Relevant date of treatment	Admission Date and Discharge Date of IP Admissions; Arrival Date for AE and Appointment Date for OP.	To identify the relevant commissioner at the point of payment (as outlined in guidance). This may be a period of treatment or the date of attendance and will vary with circumstances.	Date of treatment will help determine the relevant commissioner, especially when the patient moves or circumstances change. It is also used to assess the relevant tariff.

Data Item	Example	Purpose	Justification
Relevant GP Practice's ODS Code (identifying the relevant and unique GP practice)	SUS Derived Practice	To ensure that the appropriate commissioner is identified. This identifies the approximate location of the patient and the fact they are in receipt of medical care.	As CCG are required to pay for those patients they have responsibility for (as outlined in Health and Social Care Act 2012, s. 13). Identifying the relevant practice helps to determine the relevant commissioner.
Description of service (for example, oncology or radiology which may indicate the patient's condition)	Oncology	To identify the treatment and source of the invoice, to facilitate any challenges	Describes service or location to identify point of challenge
Description of treatment (Clinical Code, written description)	Clinical Code	To identify the treatment and attribute the appropriate cost or schedule	Identifies activity
Description of Prescribed Drug	BNF code/name	To identify the prescribed drug or help commissioner confirm that the invoice payment is appropriate. More important where invoice relates to a pre-agreed form of treatment for high cost drugs/ Individual Funding Request (IFR)	To identify tariff or commissioner (for example, those determined by NICE Guidelines) and whether prescription is justified or a non-brand alternative is available.
Per Unit Price	Not PCD	To cross reference the tariff and total price detailed on the related invoice.	To ensure the appropriate tariffs, number of patients or amount of activity is included.

Appendix C: Notes

1. See Appendix A: Glossary.
2. Via the HSCIC's powers established in section 259 of the Health and Social Care Act 2012 to obtain PCD under directions from the Secretary of State for Health or NHS England under Section 254. This work includes building capacity and capability into the system to enable data to flow to the HSCIC regional offices (DSCROs) and out to commissioning organisations' accredited safe havens (Stage 1 ASHs).
3. See Appendix A: Glossary.
4. The plan is to use the HSCIC's powers established in section 259 of the Health and Social Care Act 2012 (as explained in ²).
5. The NHSE IG Taskforce is working in partnership with the HSCIC; Department of Health; CCG and CSU information governance staff, information analysts and finance representatives who have made progress towards developing solutions; NHS Shared Business Services Ltd (NHS SBS); business analysts from the HSCIC; IG experts; and legal advisors in order to identify the business needs and potential legal solutions.
6. Government response to the Caldicott review September 2013
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/251750/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.PDF
7. Sections 13S and 14Z7 of the NHS Act 2006 as established under sections 23 and 26 of the Health and Social Care Act 2012
<http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted>
8. NHS England guidance Who pays? Determining responsibility for payments to providers Gateway Reference 00385
<http://www.england.nhs.uk/wp-content/uploads/2013/08/who-pays-aug13.pdf>
9. See Appendix A: Glossary.
10. Any references to 'section 251 support or approval' refers to approval given under the authority of the Health Service (Control of Patient Information) Regulations 2002.
11. Information: To Share or Not to Share? Independent Information Governance Review
<https://www.gov.uk/government/publications/the-information-governance-review>
12. See the Independent IG Review report (at ¹¹) Chapter 7 – Commissioning.
13. Government response to the Caldicott review September 2013
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/251750/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.PDF
14. The NHSE IG Taskforce is working in partnership with the HSCIC; Department of Health; CCG and CSU information governance staff, information analysts and finance representatives who have made progress towards developing solutions; NHS Shared Business Services Ltd (NHS SBS); business analysts from the HSCIC; IG experts; and legal advisors in order to identify the business needs and potential legal solutions.
15. NHS Shared Business Services (SBS) currently manage invoice payment for NHS commissioners. NHS SBS do not validate

invoices. NHS SBS may provide other services under contract,(for example, creation of an invoice or debt recovery etc.), which is out of the scope of this guidance and of the section 251 support.

16. See Appendix A: Glossary for definitions.
17. The Data Protection Act 1998 Schedule 3 conditions relevant to the first principle for the processing of sensitive personal data – paragraph 8 (1) The processing is *necessary* for a medical purpose etc.
18. The Health Service (Control of Patient Information) Regulations 2002 SI 2002 No 1438 enacts Section 251 of the NHS Act 2006. Regulation 7 sets out Restrictions and exclusions.
19. NHS Constitution
<https://www.gov.uk/government/publications/the-nhs-constitution-for-england> ; HSCIC Guide to Confidentiality
<http://www.hscic.gov.uk/configuideorg>
20. HSCIC Register of Stage One Accredited Safe havens
<http://www.hscic.gov.uk/article/3697/Registrar-of-Stage-One-Accredited-Safe-Havens>
21. <http://www.legislation.gov.uk/ukxi/2012/2996/contents/made>
22. See the Commissioning face sheet for Clinical Commissioning Groups (July 2012)
<http://www.commissioningboard.nhs.uk/files/2012/07/fs-ccg-respon.pdf>
23. Whilst the overarching data set is set out in Appendix B, the detail of the specific data items necessary will need to be set out in a schedule to the contract between the commissioner and the provider and should conform to ISB approved Information Standards and National Collections in so far as this is feasible