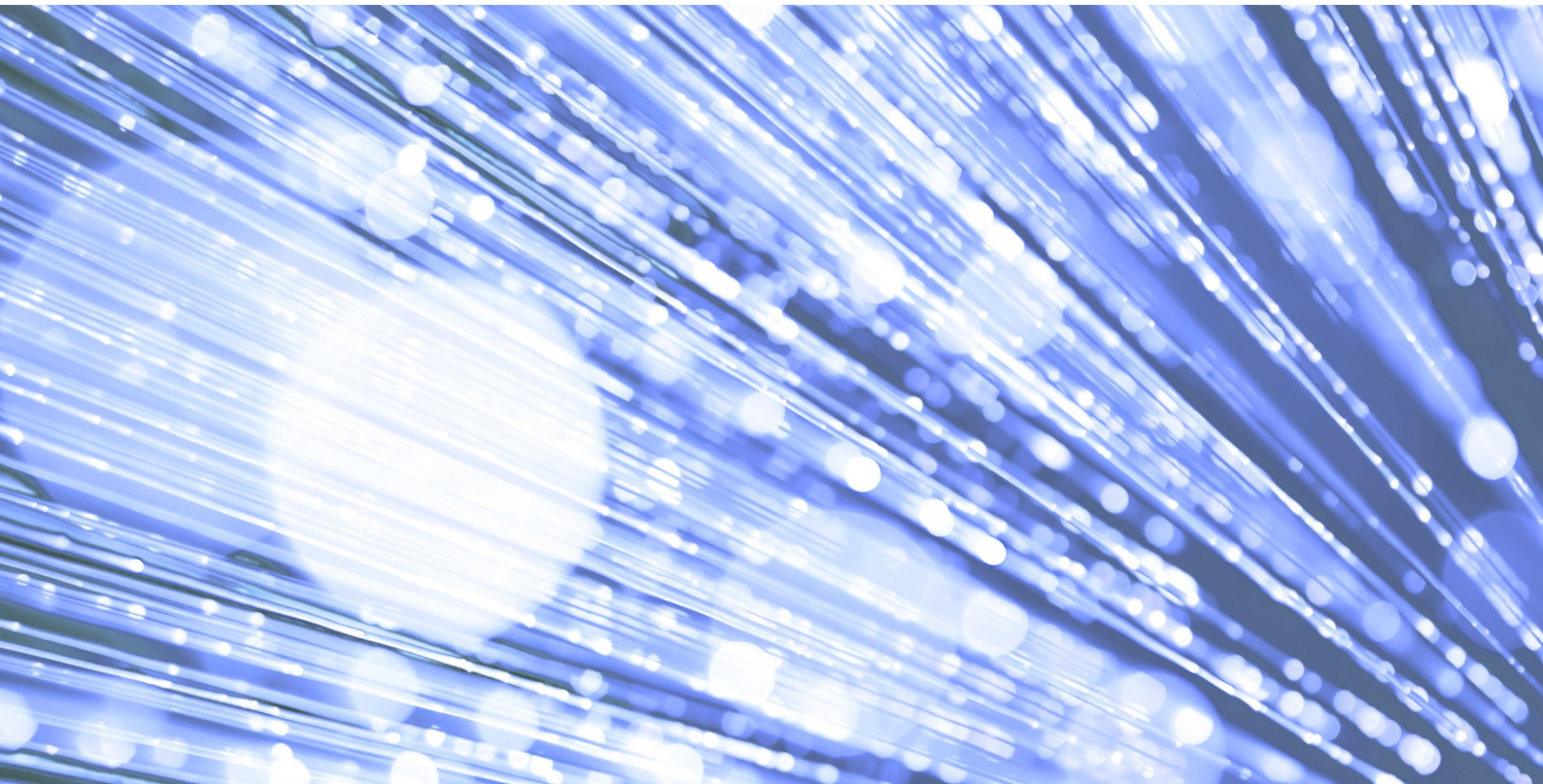


# DCB3058 Compliance with National Data Opt-outs Implementation Guidance

Published 18 March 2019



**Information and technology**  
**for better health and care**

# Data Coordination Board

This information standard (DCB3058) has been approved for publication by the Department of Health and Social Care under [section 250 of the Health and Social Care Act 2012](#).

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Coordination Board (DCB), a sub-group of the Digital Delivery Board.

This information standard comprises the following documents:

- Requirements Specification
- Implementation Guidance.

An Information Standards Notice (DCB3058 Amd 91/2018) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the [NHS Digital website](#). Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

Date of publication: 18 March 2019

## Glossary of Terms

Term / Abbreviation	What it stands for
CPI	Confidential Patient Information
CSG	Clinical Safety Group
DCB	Data Coordination Board
DPIA	Data Protection Impact Assessment
DSP	Data Security and Protection
EIA	Equality Impact Assessment
GDPR	General Data Protection Regulation
GP	General Practitioner
ISN	Information Standard Notice
IT	Information Technology
MESH	Message Exchange for Social Care and Health
NHAIS	National Health Application and Infrastructure Services
NHS	National Health Service
SIGN	Strategic Information Governance Networks
SLA	Service Level Agreement

### Document Control:

The controlled copy of this document is maintained in the NHS Digital corporate network. Any copies of this document held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

# Contents

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<b>1 Introduction</b>	<b>5</b>
1.1 Purpose of document	5
1.2 Scope of document	6
1.3 Out of Scope of Implementation Guidance	6
1.4 What does it mean to be compliant with national data opt-outs	6
<b>2 Background</b>	<b>7</b>
2.1 Clinical safety	7
2.2 Information Standards Notice Process	7
2.3 Related Standards	8
2.4 Related Documents	8
<b>3 Implementation Checklist</b>	<b>11</b>
<b>4 Implementation Timeline</b>	<b>13</b>
<b>5 Resources / Costs</b>	<b>13</b>
<b>6 Planning for Compliancy and Transparency</b>	<b>14</b>
<b>7 Service to check for national data opt-outs</b>	<b>14</b>
<b>8 Training</b>	<b>15</b>
<b>9 Helpdesk</b>	<b>16</b>

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# 1 Introduction

## 1.1 Purpose of document

This guidance supports Health and Adult Social Care organisations to implement the 'DCB3058 Compliance with National Data Opt-outs' information standard which requires **all** in scope organisations, as defined in the 'DCB3058 Compliance with National Data Opt-outs Requirements Specification' document to comply with this standard.

This document enables all Health and Adult Social Care organisations to comply with the national data opt-out by:

- **providing guidance** for key implementation activities for Health and Adult Social Care organisations
- **signposting additional detailed guidance** to support implementation activities
- **signposting further sources of information** relating to the implementation of the national data opt-out

**Organisations MUST comply with the DCB3058 Compliance with National Data Opt-outs information standard. This implementation guidance MUST be followed, and organisations MUST remain compliant on a continuing basis.**

Health and Adult Social Care organisations and professionals MUST use this document when preparing their organisation to be compliant with the national data opt-out standard.

To note:

- 'organisations' refers to Health and Adult Social Care organisations.
- 'service to check for national data opt-outs' refers to the technical solution developed by NHS Digital to check for patients that have a national data opt-out. This service provides the necessary information to organisations to enable them to uphold national data opt-outs for their disclosures of confidential patient information. For further information please refer to the associated technical guidance documentation.
- within this document are assigned terms, namely:

**MUST/SHALL** means that the definition is an absolute requirement that organisations are required to adhere to be compliant with the national data opt-out.

**SHOULD/RECOMMENDED** and **MAY/OPTIONAL** means organisations do not have to adhere to be compliant with the national data opt-out, but the full implications must be understood and carefully weighed before choosing a different course.

## 1.2 Scope of document

This document provides guidance for Health and Adult Social Care organisations to support implementation and compliance with the 'DCB3058 Compliance with National Data Opt-outs' standard. This document **MUST** be read in conjunction with the documents listed in section 2.4. This section details the full list of documentation that are associated with the 'DCB3058 Compliance with National Data Opt-outs' information standard.

This standard does not directly place any requirement on system suppliers to accommodate the national data opt-out functionality within their systems. It is the responsibility of Health and Adult Social Care organisations to self-assess and ensure that they have a system or systems in place to deliver the requirements specified for this standard. IT suppliers need to be aware of these requirements so that they can respond to the organisations and the service providers that they support. The contractual agreement between data providers and IT system suppliers will determine whether IT system suppliers must abide by the standard and at what cost. For information regarding GP IT systems see section 3 (step 6).

## 1.3 Out of Scope of Implementation Guidance

The following areas are out of scope of this document:

- Detailed background and justification for the development of the information standard. National data opt-out background and legal basis information is detailed in the 'DCB3058 Compliance with National Data Opt-outs Requirements Specification' document and the related supporting documentation it lists.
- Detailed technical guidance relating to the service to check for national data opt-outs. This information is available from supporting documentation listed in the 'DCB3058 Compliance with National Data Opt-outs Requirements Specification' document.

## 1.4 What does it mean to be compliant with national data opt-outs

Any health and care organisation which processes and/or disseminates data that originates within the health and adult social care system in England is required to consider if the national data opt-outs should be applied to disclosures of confidential patient information (CPI) for purposes beyond individual care. Such organisations must map and assess whether any of their data disclosures require the national data opt-out to be applied and where necessary have appropriate processes and procedures for implementing the national data opt-out in line with the published National Data Opt-out Operational Policy Guidance and the information standard for upholding. A technical solution to enable organisations to apply national data opt-outs is available to support compliance.

In some cases an organisation may not currently have **any** data disclosures which actually require the application of national data opt-out, for example,

- because the data being disclosed is anonymised in line with the ICO Code of Practice on Anonymisation, or
- consent has been obtained from the individual for their data to be used for the specific purpose, or
- the organisation only uses CPI for individual care.

In such cases these organisations must still be compliant with the national data opt-out standard even though they do not need to apply national data opt-outs. These organisations would need to have processes and procedures in place to ensure that they remain compliant should any changes occur that may require them to apply national data opt-outs to existing or future data disclosures.

## 2 Background

Please refer to 'DCB3058 Compliance with National Data Opt-outs Requirements Specification' and 'Compliance Implementation Guide' documentation for information on the background and the legal basis underpinning the national data opt-out, see section 2.4.

### 2.1 Clinical safety

NHS Digital Clinical Safety Group have provided the following statement:

"The primary purpose of the proposed standard: DCB3058 Compliance with National Data Opt-Outs is for secondary uses<sup>1</sup> only and will therefore have no direct impact on Clinical Safety and as such is not in scope of [DCB0129](#). Consequently, a Clinical Safety Case Report is not required to support Compliance with National Data Opt-Outs. However, changes made to DCB3058 Compliance with National Data Opt-Outs may require modification to the health IT system from which the collection/extraction is made. The safety implications of any such modifications must be considered by the manufacturer and all other parties involved under DCB0129 and the health organisation under [DCB0160](#)."

### 2.2 Information Standards Notice Process

This standard, including any amendments can be found on the NHS Digital information standard [webpage](#).

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<sup>1</sup> purposes other than direct or 'primary' clinical care

## 2.3 Related Standards

The 'DCB3058 Compliance with National Data Opt-outs' standard is related to the following standards:

Reference	Title	Purpose
<a href="#">ISB 0149</a>	NHS Number	The NHS number is required for organisations to use the service to check for national data opt-outs
<a href="#">ISB 1523</a>	Anonymisation Standard for Publishing Health and Social Care Data	Disclosure of information that is anonymised in line with the 'Information Commissioner's Office Code of Practice of Anonymisation' is out of scope of the national data opt-out
<a href="#">DCB0086</a>	Data Security and Protection Toolkit	Organisations are required to use the DSP toolkit to demonstrate national data opt-out compliance

## 2.4 Related Documents

A comprehensive set of documents has been developed by NHS Digital's National Data Opt-out Programme (NDOP) for the Compliance with National Data Opt-outs information standard. These documents are available via weblinks in the associated documentation or the [National Data Opt-out](#) webpages. A summary of these documents is set out in the table below:

Title	Purpose	Reference
<b>DCB Information Standard Documentation</b>		
<i>Information Standards Notice</i>	Notification of publication of a new or amended standard.	Published on <a href="#">Information Standard webpage</a>
<i>Requirements Specification</i>	Outlines the scope of the Information Standard and how it MUST be implemented. Gives an overview of the requirements for organisations and system suppliers, and associated conformance	Published on <a href="#">Information Standard webpage</a>

	<p>criteria (the tests that can be measured to assess whether the standard is being used correctly). Includes key implementation and completion dates.</p>	
<p><i>Implementation Guidance (THIS DOCUMENT)</i></p>	<p>A document containing guidance to support organisations and system suppliers with the implementation of the 'DCB3058 Compliance with National Data Opt-outs' standard, including organisational guidance and information governance.</p>	<p>Published on <a href="#">Information Standard webpage</a></p>
<p><b>Technical Documentation</b></p>		
<p><i>User Guidance (MESH Guidance for using the Check for National Data Opt-outs Service)</i></p>	<p>Guidance for organisations and system suppliers about the service to check for national data opt-outs. This document includes an overview of this service, processes and advice about using this service for disclosures.</p>	<p>Published on <a href="#">Check for National Data Opt-outs Service</a> webpage</p>
<p><i>National Data Opt-out Operational Policy</i></p>	<p>The national data opt-out policy rules that organisations are required to use</p>	<p>Published on <a href="#">compliance with the national data opt-out</a> webpage</p>

	to enable them to comply with national data opt-out policy.	
<i>Compliance Implementation Guide</i>	A step by step guide to assist organisations with compliance with the national data opt-out.	Published on <a href="#">compliance with the national data opt-out</a> webpage
<i>Data Security and Protection (DSP) Toolkit</i>	Online self-assessment tool that all organisations operating via the NHS Standard Contract MUST complete.	Published on the <a href="#">DSP</a> webpage
<b>Health and Care Staff / Organisational Resources</b>		
<i>Factsheets</i>	A series of factsheets about data uses and the national data opt-out for Health and Adult Social Care staff.	Published on <a href="#">guidance for all health and care staff</a> webpage
<i>National Data Opt-out Checklists</i>	Checklists to support organisations with an action list.	Published on <a href="#">guidance for all health and care staff</a> webpage
<i>Data Protection Impact Assessment (DPIA) template</i>	The DPIA is a process to systematically analyse, identify and minimise the data protection risks associated with a new project or service. The DPIA template is for external organisations to use.	Published on <a href="#">guidance for all health and care staff</a> webpage

<i>Guidance and Resource for:</i> -Nursing, Midwifery and care Staff -Estates Staff in Detained and Secure settings -Helpline Staff -Voluntary Sector Staff	Resources to support staff in various areas across Health and Adult Social Care settings.	Published on <a href="#">guidance for all health and care staff</a> webpage
<i>Webinars about the National Data Opt-out</i>	Webinars with subject matter experts to provide national data opt-out information.	Published on <a href="#">guidance for all health and care staff</a> webpage
<b>Patient Resources</b>		
<i>Various resources</i>	A suite of patient-facing information and materials to promote patient understanding of the national data opt-out.	Published on <a href="#">supporting patients – information and resources</a> webpage

### 3 Implementation Checklist

The following steps are to assist organisations to understand the implementation process and to support them to comply with the National Data Opt-out policy. Importantly, please refer to the 'Compliance Implementation Guide' documentation for supporting information.

#### Step 1: Read the Information Standard Notice (ISN)

This is the official notification of the Information Standard, published by the Data Coordination Board (DCB). It provides an outline of the approved standard and timeframe for compliance.

#### Step 2: Read National Data Opt-out Information Standard associated documentation

The documents listed below provide detailed information about the national data opt-out policy and setting up/using the service to check for opt-outs. The following documentation enables organisations to be compliant with national data opt-out policy. These should be read along with other documentation as set out in section 2.4.

- National Data Opt-out Operational Policy Guidance
- User Guidance (MESH Guidance for using the Check for National Data Opt-outs Service)

- Compliancy Implementation Guide

### **Step 3: Identify and discuss with stakeholders**

It is essential to engage with those who are responsible for an organisation's compliance with the National Data Opt-out standard. This **MUST** include, but is not limited to, the information governance lead, Caldicott Guardian, data protection officer, chief information officer, chief clinical information officer, senior information risk owner and others responsible for data protection and compliance. The group **MAY** include information analysts and data processing staff. This includes anyone who is responsible for the processing or handling of patient data and who therefore **MAY** be required to apply the national data opt-out policy.

### **Step 4: Plan implementation**

To ensure organisations plan the implementation for this 'DCB3058 Compliance with National Data Opt-outs' standard the compliance steps detailed in the 'Compliancy Implementation Guide' document **MUST** be followed.

### **Step 5: Check current state of readiness for compliance**

IT Systems:

- Dataflow mapping to identify and provide a comprehensive understanding of all data disclosures
- Check what changes are required to support using the service to check for national data opt-outs

Processes / Documentation:

- Identify any required changes to processes or documents
- Identify additional training needs, see Section 8

### **Step 6: Work with current IT Systems Supplier(s)**

Organisations that have identified the need for the service to check for national data opt-outs solution to support compliance with the National Data Opt-out standard **SHOULD** work with the relevant system supplier(s). Changes to the IT system may be required to incorporate the ability to use the service to check for national data opt-outs. In most cases these changes will be part of the Service Level Agreement (SLA).

Importantly, organisations **MUST** agree with their IT suppliers the dates to align with the implementation timeline, see section 4, to support the service to check for national data opt-outs functionality within their IT systems (see *note* below).

DCB Information Standard and Technical documentation, as listed in section 2.4, detail the changes required for IT systems.

*To note:* to support this information standard principal GP IT systems are configured to support the service to check for national data opt-outs. Organisations that use GP IT systems are not required to request a system change, however, organisations

MUST understand this functionality and the processes to support national data opt-out compliance. For further information regarding change processes for associated GP IT systems please refer to the GP IT Futures [website](#).

### **Step 7: Application of the service to check for national data opt-outs**

Where data disclosures have been assessed to require the application of the national data opt-outs, organisations MUST use the service to check for national data opt-outs. This service enables organisations to submit and receive NHS numbers to apply the removal of national data opt-outs from datasets prior to disclosure. For further information please refer to the supporting DCB Information Standard and Technical documentation and see section 7.

### **Step 8: Transparency (see section 6)**

Organisations operating within the framework of the NHS Standard Contract MUST complete the DSP Toolkit, publish an annual toolkit submission, update and publish a Privacy and Fair Processing Notice.

All other organisations that do not operate via the NHS Standard contract MUST publish a statement of compliance that must be available to the public. This may be as part of an organisation's Privacy and Fair Processing Notice.

### **Step 9: Informing Patients and signposting to National Data Opt-out information**

Patients MUST be informed and made aware of the national data opt-out and signposted to information including what it involves and how they can set a national data opt-out preference. Organisations MAY use the patient materials developed by NHS Digital available [here](#).

## **4 Implementation Timeline**

The planned timeline for organisations to be compliant with the national data opt-out can be found on the [compliance with the national data opt-out webpage](#).

Health and Adult Social Care organisations are expected to adhere to these timeframes to be compliant with this standard and to apply patient national data opt-outs in any disclosures as required using the service to check for national data opt-outs. Compliance with this standard is an ongoing process which organisations are required to evidence on a continuing basis.

## **5 Resources / Costs**

Health and Adult Social Care organisations are obliged to comply with this standard and are responsible for making provision of resources to effect appropriate application of this standard.

## 6 Planning for Compliancy and Transparency

The National Data Opt-out document, '**Compliancy Implementation Guide**' provides a comprehensive guide setting out what organisations are required to do to be compliant with national data opt-outs.

Organisations and/or system suppliers will need to use the **supporting user and technical guidance and documentation**, as detailed in section 2.4, to ensure that they are able to use systems correctly. This document sets out how to use the service to check for national data opt-outs, and how an organisation can comply with the application of national data opt-outs.

Organisations must be transparent with patients as to how and when their preference has been applied. Organisations **MUST** make provision to inform patients of their compliance with the national data opt-out policy in line with the agreed timelines for implementation.

This may include details of how and when the national data opt-out is applied to specific disclosures of confidential patient information processed within their organisation through a data release register. As a minimum, an organisation must publish a compliance statement (e.g. in a privacy notice or on their website) as set out in the Data Security and Protection Toolkit.

## 7 Service to check for national data opt-outs

NHS Digital provides a service that enables organisations to apply national data opt-outs to disclosures of Confidential Patient Information for uses beyond individual care and treatment. This service complies with the GDPR data principles and requires only the NHS number for utilising the service. The service enables organisations to securely submit lists of NHS numbers for those in the cohort for potential disclosure. This list is checked against the Spine central list of NHS numbers of those patients that have recorded a national data opt-out, and removes the NHS numbers of those with a national data opt-out. The cleaned list is returned securely to the submitting organisation which enables national data opt-outs to be applied to disclosures of CPI in accordance with national data opt-out policy.

Organisations **MUST** ensure they can access and use the service if this is appropriate.

Comprehensive information on how to set up and use this service and supporting technical information is set out in the technical documentation: *User Guidance (MESH Guidance for using the Check for National Data Opt-outs Service)*, see section 2.4. Organisations are required to operate this service in line with national data opt-out policy.

For support with technical issues using the 'service to check for national data opt-outs', please see section 9.

## 8 Training

Health and Adult Social Care and system supplier organisations are required to train their staff to enable effective implementation of this standard. Organisations will need to develop a local implementation strategy that supports compliance with the national data opt-out. The strategy SHOULD ensure the identification of skills gaps which might impact on the implementation and continuing organisational compliance. Staff affected will include (but not limited to) clinicians, administrative personnel, informatics personnel and IT services. Organisations are required to evidence this in their training records and staff guidance materials.

Training that MUST be considered includes:

### **Technical / specialist skills:**

- Information Governance, including the ongoing application of the National Data Opt-out Operational Policy Guidance
- Using new/adapted technologies and processes such as the service to check for national data opt-outs

### **General skills:**

- Interpersonal and communication skills to explain the national data opt-out to staff and patients, signpost to further information and to respond to any related queries or issues
- Collaboration between staff to identify and resolve errors to support continuing compliance with this information standard

### **Clinicians and Administration Personnel:**

A local implementation strategy MAY require additional skills and training for staff in, a) the application of the national data opt-out operational policy and b) using the national data opt-out functionality within an IT system as required to apply national data opt-outs for any disclosures of Confidential Patient Information.

### **Informatics and IT Support Services:**

From an IT or Information Management Service perspective, skills MAY be required in:

- Configuring local systems to support functionality of the service to check for national data opt-outs as required
- Creating a submission file, i.e. a list of NHS numbers, from a spectrum of local IT systems for use with the service to check for national data opt-outs
- Creating interfaces between electronic systems to support the service to check for national data opt-outs

### **Information Governance:**

All Health and Adult Social Care organisations involved in the disclosure of confidential patient information that is subject to the application of National Data Opt-out Operational Policy MUST ensure that staff involved in data handling in any respect are fully conversant with the organisation's information governance responsibilities.

For further information regarding the information governance responsibilities of organisations with respect to the national data opt-out, please see 'National Data Opt-out Operational Policy Guidance' document.

## **9 Helpdesk**

### **For technical issues using the 'service to check for national data opt-outs':**

The **National Helpdesk Exeter** provides a First Line IT Support / Incident Logging Service to Systems and Services end users (formerly NHAIS), plus other NHS professionals e.g. GPs and GP Practice staff.

The National Service Desk can be contacted on [exeter.helpdesk@nhs.net](mailto:exeter.helpdesk@nhs.net) or 0300 303 5035.

### **For general enquires:**

NHS Digital can provide help and assistance to organisations, for any queries relating to the national data opt-out or this standard. Please email:

[enquiries@nhsdigital.nhs.uk](mailto:enquiries@nhsdigital.nhs.uk)

('national data opt-out' must be included within the subject title)