

Mid Downs Medical Practice

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National Data-Opt-Out Guidance Policy

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1 Introduction

1.1 Guidance statement

National Data Opt-Out (NDO-O) was introduced along with the Data Protection Act 2018 and GDPR on 25th May 2018. This followed recommendations from the National Data Guardian (NDG) that patients should be able to opt-out of their personal confidential data being used for purposes other than their direct medical care.

The NDG states that, “A patient should be able to state their preference once (online or in person), confident in the knowledge that this will be applied across the health and social care system”.

The percentage of patients who have actively registered¹ a data opt-out is 1,616,720 as at the 1st October 2020, an increase of 38,340 compared to June 2020..

The choice to opt in or out applies only to the healthcare system in England. It does not apply to health and social care services accessed in Scotland, Wales or Northern Ireland.

1.2 Status

This document and any procedures contained within it are contractual and therefore form part of your contract of employment. Employees will be consulted regarding any modifications or change to the document’s status.

1.3 Training and support

The practice will provide support to all within the practice to understand their rights and responsibilities with regards to this information. Additional support will be provided to managers and supervisors to enable them to deal more effectively with matters arising from this guidance.

To assist practices with the National Data Opt-Out policy², NHS Digital provides guidance as does the Royal College of General Practitioners (RCGP) in their [clinical news section](#). The latter has links to a Patient Data Choices [toolkit](#) which provides general practices in England with the materials they need to understand NDO-O.

1.4 Purpose

This guidance provides outline advice on the NDO-O policy with which general practice is required to comply by the revised date of 31st July 2022 – previously this was 31st March 2020. It covers the procedures which need to be in place to enable practices to identify when patient data needs to be removed before it is disclosed to certain third parties.

It should be noted that NDO-O now replaces the previous type 2 opt-out codes which can no longer be used, although any type 2 opt-outs which have previously been submitted to NHS Digital have been automatically converted to national data opt-outs.

¹ <https://digital.nhs.uk/data-and-information/publications/statistical/national-data-opt-out/october-2020>

² digital.nhs.uk/services/national-data-opt-out/operational-policy-guidance-document

Mid Downs Medical Practice is required to ensure that any such data contained in a report or search generated by Emis Web or by any other means has the data removed which belongs to patients who have chosen to opt-out.

2 Scope

2.1 Who it applies to

The NDO-O policy applies to all general practices in England.

Therefore, all staff at Mid Downs Medical Practice are expected to know the requirements of this policy and to provide information to patients to make them aware of their rights and how they can register their choice to either opt in or out.

2.2 Why and how it applies to them

Mid Downs Medical Practice and all staff are to ensure compliance with all requirements of the NDO-O policy. Failure to comply with the policy and any associated [breaches](#) of patient data or confidentiality could lead to prosecution or imposition of [penalties](#) by the Information Commissioners Office (ICO).

2.3 Data Protection Officer's advice

The Data Protection Officer (DPO) at Mid Downs Medical Practice is Paul Anthony. Their advice must always be sought and followed regarding NDO-O matters.

Note: If your practice DPO has not yet been in touch the practice's Information Governance Lead Dr Ragu Rajan it is advisable to contact them as soon as possible to allow greater time for the practice and patients prior to the compliance date of 31st July 2022.

3 Requirements

3.1 Compliance and understanding the National Data Opt-Out

NHS Digital provides information for GP practices³ regarding compliance with and understanding of the National Data Opt-Out⁴. The main points are detailed in this chapter.

3.2 Setting or changing an opt-out choice

A patient has to register their choice to opt out only once, and that registration applies to all healthcare settings and organisations, not just general practice. They can do this by using one of the following:

- a. [Online service](#) – Patients registering need to know their NHS number or their postcode as registered at their GP practice

³ digital.nhs.uk/services/national-data-opt-out/information-for-gp-practices

⁴ digital.nhs.uk/services/national-data-opt-out/understanding-the-national-data-opt-out

- b. Telephone service **0300 303 5678** which is open Monday to Friday between 0900 and 1700
- c. [NHS App](#) – for use by patients aged 13 and over (95% of surgeries are now connected to the NHS App). The app can be downloaded from the [App Store](#) or [Google play](#)
- d. “Print and post”⁵ registration form. Photocopies of proof of applicant’s name (e.g. passport, UK driving licence etc.) and address (e.g. utility bill, payslip etc.) need to be sent with the application. It can take up to 14 days to process the form once it arrives at NHS, PO Box 884, Leeds, LS1 9TZ
- e. Getting a healthcare professional to assist patients in prison or other secure settings to register an opt-out choice. For patients detained in such settings [Guidance](#) is available on NHS Digital and a [Proxy form](#) is available to assist in registration.

3.3 Upholding the opt-out and declaring compliance

As the national data opt-out policy applies to nearly all practices, they need to uphold patient choices to opt out⁶ by removing the records of any patient before using or disclosing information other than for the purpose of that patient’s immediate healthcare.

The national data opt-out compliance and implementation guide⁷ takes users through the steps they need to follow to achieve compliance by the revised date of 31st July 2022.

3.4 Compliance and implementation guide

The National data opt-out: compliance and implementation guide takes users through the steps they need to follow to achieve compliance by the revised date of 31st September 2022. Before doing so, it presents an overview of the process and advises that users should consider:

- How long it will take to be compliant (the advice and guidance of the practice’s DPO will be invaluable in making this assessment)
- Who should be involved in the implementation?

The guide outlines the five steps that need to be taken to achieve compliance.⁸ However, as step 2, implementing a technical solution, will be carried out by clinical system suppliers on behalf of GP practices, they do not need to implement step 3, i.e. set up the technical solution and use the Message Exchange for Social Care and Health (MESH) which accesses the Check for National Opt-Outs Service⁹.

⁵ [Print and Post Opt-in Registration Form](#)

⁶ digital.nhs.uk/services/national-data-opt-out/understanding-the-national-data-opt-out-upholding-the-opt-out-and-declaring-compliance

⁷ digital.nhs.uk/services/national-data-opt-out/compliance-with-the-national-data-opt-out/compliance-implementation-guide

⁸ digital.nhs.uk/services/national-data-opt-out/compliance-with-the-national-data-opt-out/compliance-implementation-guide-assess-data-disclosures-and-update-procedures

⁹ digital.nhs.uk/services/national-data-opt-out/compliance-with-the-national-data-opt-out/check-for-national-data-opt-outs-service

- Step 1 Assess data disclosures and update procedures.
- Step 2 Decide whether to implement a technical solution. Note the four principal GP system suppliers have been commissioned to assist GP practices to comply with the NDO-O by developing and embedding a technical solution in their systems.
- Step 3 Set up the technical solution and use the Message Exchange for Social Care and Health (MESH) which accesses the Check for National Opt-Outs Service. Practices only need to consider doing this if they hold and generate patient data reports using a system/software other than their clinical system.
- Step 4 Implement new processes. This suggests that a Data Protection Impact Assessment (DPIA) should be completed using the format shown at the link which is based on the ICO template.¹⁰ It is strongly advised that completion of the DPIA is left to the practice's DPO.
- Step 5 Plan communications and declare compliance. This step requires practices to consider communications and to declare compliance:
- Internally with all staff
 - Externally with patients including updating the [practice's website and privacy notice](#) using a suggested wording
 - With other organisations with which the practice works who may be affected by the practice becoming compliant with the NDO-O
 - Decide date to declare compliance
 - Declare compliance

3.5 Understanding if the data you use or disclose is in scope

This understanding is covered by a series of nine questions which practices need to ask themselves:

1. Is the use or disclosure [confidential patient information](#)?
2. Is the use or disclosure for [individual care or research and planning](#)?
3. Does the practice have explicit [consent for the use or disclosure](#)? Note that the NDO-O does not apply where explicit consent has been obtained from the patient for a specific purpose and that there are also three other main exemptions:
 - Communicable diseases and risks to public health, such as the COVID-19 pandemic
 - Overriding public interest
 - Information required by law or court order
4. Is the disclosure for the [purpose of monitoring and control of communicable disease](#) or other risks to public health? If it is, NDO-O out does not apply
5. Is the use or disclosure in the [overriding public interest](#)?

¹⁰ [DPIA ICO Template](#)

6. Is the information being disclosed [because of a legal requirement](#)?
7. Is the use or disclosure to an [arms-length body](#)?
8. Is the use or disclosure to [support payment and invoice validation](#)?
9. Is the legal basis for the [use of disclosure Section 251 approval](#)?

3.6 MESSAGE EXCHANGE FOR SOCIAL CARE AND HEALTH (MESH)

In the event that Mid Downs Medical Practice is required to send data that is within scope of data disclosure, an account with MESH will be used. This is the technical solution that will allow the practice to exclude those who have dissented from Health and Social Care Information Centre using personalized confidential data from a dataset. This dataset can then be sent to the research organization in compliance with the NDO-O.

4 Resources to inform patients of their opt-out choices

4.1 General resources

To assist practices, resources are available at the general resources page on NHS Digital's website. A4 posters and patient hand-outs were sent to practices in June 2018 and should already be displayed in patient waiting areas. They can be ordered from this NHS [website](#) and are available to download.

4.2 Accessible resources

These accessible resources include:

- [British Sign Language video](#) of the patient hand-out
- [Audio version](#) of the patient hand-out
- Braille version of the patient hand-out which can be ordered from [NHS England Health Publications](#)
- An easy read booklet of the patient hand-out for patients with learning disabilities as well as a larger print version can be downloaded from the resources for patients [NHS Digital web page](#)

4.3 Tailored resources

These tailored resources, which can also be downloaded from the same link to the NHS Digital web page in the preceding paragraph include guidance for:

- Black and minority (BME) patients
- Carers
- Young people
- Patients with a previous type 2 opt-out

4.4 Other Languages

A patient hand-out in 11 languages is available from the NHS Digital web page.¹¹

5 Section 251

Section 251 of the National Health Service Act 2006 allows the Secretary of State for Health and Social Care to make regulations to authorise or require the processing of confidential patient information (CPI) for prescribed medical purposes and, in so doing, to set aside the common law duty of confidentiality. The only regulations made under this provision are the Health Service (Control of Patient Information) Regulations 2002 (SI 2002/ 1438) (“COPI Regulations”).

The COPI regulations provide 3 legal gateways:

- Regulation 2 permits confidential patient information relating to patients referred for the diagnosis or treatment of cancer to be processed for the medical purposes set out in the regulation.
- Regulation 3 provides specific support for confidential patient information to be processed to diagnose, control or prevent, or recognise trends in, communicable diseases and other risks to public health. This Regulation is exempt from the national data opt – out
- Regulation 5 provides support for confidential patient information to be processed for the medical purposes set out in the Schedule, which includes ‘the audit, monitoring and analysing of the provision made by the health service for patient care and treatment’.

Regulation 2 and 5 approvals from the Secretary of State or Health Research Authority are subject to advice from the Confidential Advisory Group (CAG), which is hosted by the Health Research Authority. Regulation 3 authorisations are managed by Public Health England. Any person wishing to obtain approval under Regulation 2 or 5 must to submit an application to CAG who provide independent expert advice to the relevant decision maker. A standard condition of its advice is that patient objections (i.e. opt-outs) to the use of this information are respected. It has taken a policy position that it will advise that it is not in the public interest to over-ride an opt-out in anything other than the most exceptional circumstances. For the purposes of this policy references made to Section 251 support specifically applied to regulation’s 2 or 5 unless explicitly stated

6 Summary

This guidance enables member practices to understand the NDO-O policy with which general practice is required to comply by 30th September 2020. It covers the requirements and procedures which need to be in place to enable practices to identify when patient data needs to be removed before it is disclosed to certain third parties.

Additionally, it identifies the sources where they can access and download resources to enable them and their patients to understand and follow the guidance required to fulfill their obligations as required by the National Data Guardian.

At the time of publication, all key documents have been referenced in this guidance.

¹¹ digital.nhs.uk/services/national-data-opt-out/supporting-patients-information-and-resources

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