

DATA PROTECTION ACT 1998

UNDERTAKING

Data Controller: Health and Social Care Information Centre

1 Trevelyan Square
Boar Lane
Leeds
LS1 6AE

I, Mr Kingsley Manning, Chair of Health and Social Care Information Centre (HSCIC), hereby acknowledge the details set out below and undertake to comply with the terms of the following Undertaking:

1. HSCIC is the data controller as defined in section 1(1) of the Data Protection Act 1998 (the 'Act'), in respect of the processing of personal data carried out by HSCIC and is referred to in this Undertaking as the 'data controller'. Section 4(4) of the Act provides that, subject to section 27(1) of the Act, it is the duty of a data controller to comply with the data protection principles in relation to all personal data in respect of which it is a data controller.
2. The Information Commissioner (the 'Commissioner') was made aware of an ongoing concern with the way in which HSCIC shares patient data for purposes other than direct care. The Commissioner has received a complaint about this matter and further information about this concern has been supplied through correspondence and discussions between HSCIC and the Information Commissioner's Office.
3. In January 2014 a leaflet was sent to all households in England offering patients the chance to opt out of their personal confidential information being shared by HSCIC for purposes other than direct care, known as the 'Type 2 objection'. Patients were instructed to inform their GP if they decided to apply the Type 2 objection to their own personal confidential data.
4. HSCIC has a duty to share some patient information with third parties for the purposes of direct care. For example, HSCIC may share information to aid nationally approved screening programmes, such as NHS breast screening, and so the Type 2 objection will not be applied in these cases.

5. For legal and technological reasons HSCIC was not able to collect, record or implement the Type 2 objections registered by patients with their GPs. This has resulted in Type 2 objections not being implemented for approximately 700,000 patients.
6. By not being able to collect, record and apply the Type 2 objections it appears that the HSCIC has shared patients' data with other organisations against their wishes for purposes beyond their direct care, for example for research or other secondary purposes. Whilst the Commissioner understands that the HSCIC can point to legitimate reasons for the sharing, the offer of a patient opt out was made but not implemented.
7. On 15 April 2016, the Secretary of State for Health issued a Direction to HSCIC. This resolved the legal issues that prevented HSCIC from previously implementing Type 2 objections. The Direction sets out how Type 2 objections should be applied. The full text of the Direction can be found in Annex A. On this basis, a legal solution is in place, and Type 2 objections will be implemented in accordance with the Direction and as set out in this undertaking.
8. The Commissioner has accepted that there are specific circumstances in which a Type 2 objection will not apply, for example where there are technical barriers to the objection being applied, or where there is an overriding public interest in full data sets being shared by HSCIC. The Direction sets out where the Type 2 objection will not apply. Annex B lists the expected extent of the IT services referred to in the Direction paragraph 1(g)(ii).
9. The Commissioner is concerned about the way in which HSCIC has communicated with the general public about this matter. Although a statement has been placed on the HSCIC website explaining that patient opt outs have not yet been implemented, HSCIC has not otherwise taken steps to inform affected patients of this issue.
10. The Commissioner is aware that the issue of the sharing of patient data on a national basis is currently under the review of Dame Fiona Caldicott, the National Data Guardian. Dame Fiona's review is expected to clarify the policy framework regarding patient data and opt out policy across the Health and Care System. The approach to the application of Type 2 objections as reflected in the Direction is informed by this

review.

11. The Commissioner has considered the data controller's compliance with the provisions of the Act in the light of this matter. The relevant provision of the Act is the First Data Protection Principle. This Principle is set out in Schedule 1 Part I to the Act and provides that

Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless—

- (a) at least one of the conditions in Schedule 2 is met, and*
- (b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.*

The Commissioner has also considered the fact that some of the data disclosed in this incident consisted of information as to the physical or mental health or condition of the data subjects. Personal data containing such information is defined as 'sensitive personal data' under section 2(e) of the Act.

12. The Commissioner considers that a breach of the Act has taken place as data subjects' personal data has been processed unfairly, outside of their reasonable expectations. Having been given the opportunity to opt out of their data being shared by HSCIC for purposes other than direct care, they would expect this opt out to be applied.
13. Following consideration of the remedial action that has been taken by the data controller, it is agreed that in consideration of the Commissioner not exercising his powers to serve an Enforcement Notice under section 40 of the Act, the data controller undertakes as follows:

The data controller shall, as from the date of this Undertaking and for so long as similar standards are required by the Act or other successor legislation, ensure that personal data are processed in accordance with the First Data Protection Principle in Part I of Schedule 1 to the Act, and in particular that:

- (1) HSCIC should establish and operate a system to process and uphold Type 2 objections, in accordance with the Direction from the Secretary of State. This process should be completed within six months of the date of this undertaking.**

- (2) HSCIC should ensure measures are put in place so that any patients affected by this incident can be made aware that it is possible that their personal data has been shared with third parties against their wishes. This process should be completed within six months.**
- (3) HSCIC should ensure measures are put in place so that any patients who have previously registered a Type 2 objection, or patients who register a Type 2 objection in future, are provided with clear fair processing information that enables them to understand how the Type 2 objection will be applied and how their data will be used.**
- (4) HSCIC should contact recipients of data sets it provided in the period January 2014 – April 2016 (where Type 2 objections can be processed and upheld in accordance with the Direction) and make them aware that the datasets may include records relating to patients who have chosen to opt out. HSCIC should do this within three months.**
- (5) HSCIC should contact recipients of data sets it provided in the period January 2014 – April 2016 (which included patient data where Type 2 objections can be processed and upheld in accordance with the Direction) and where the agreement allowed the recipient to onwardly disseminate the data, to make them aware that this data should no longer be disseminated further. HSCIC should do this within three months.**
- (6) HSCIC should contact recipients of data sets it provided in the period January 2014 – April 2016 (which included patient data where Type 2 objections can be processed and upheld in accordance with the Direction) to inform them that, where possible, the data sets should be destroyed or deleted and replaced with a new data set, which reflects patient opt outs, provided by HSCIC in its place. Whether it is possible to destroy or delete the data will depend on whether or not it has already been processed and used, such as in a research study or as part of business intelligence information made available to a Trust. HSCIC will collect and retain a certificate of destruction where it is possible**

for data to be destroyed or deleted.

- (7) HSCIC should revisit the matter of objections following the completion of the National Data Guardian review and consider whether its systems and processes can be modified to allow the Type 2 objection to be applied in circumstances where this is not currently possible.**

Signed:

Kingsley Manning
Chair
Health and Social Care Information Centre

Dated:

Signed:

Stephen Eckersley
Head of Enforcement
For and on behalf of the Information Commissioner

Dated:

Annex A

Direction to the Health and Social Care Information Centre to process Type 2 objections

Andy Williams
Chief Executive
Health and Social Care Information Centre
1 Trevelyan Square
Boar Lane
Leeds LS1 6AE

14 April 2016

Dear Andy

Direction to the Health and Social Care Information Centre to process Type 2 objections

Further to the Health and Social Care Information Centre (Patient Objections) Directions 2015,¹ I am writing to set out the steps that the Health and Social Care Information Centre (HSCIC) is to take upon collecting information about patients who have registered Type 2 objections.

Please accept this letter as a direction given under section 254(1) and (6) of the Health and Social Care Act 2012 ("the 2012 Act"), regulation 32 of the National Institute for Health and Social Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 and sections 274(2) and 304(9)-(12) of the 2012 Act.

1. With effect from 29 April 2016, HSCIC is directed to establish and operate a system to process and uphold Type 2 objections, where reasonably practicable and in accordance with the following principles.
 - a. Type 2 objections are the requests expressed by patients and lodged with their GP Practice that indicate that personal confidential information that relates to them should not be disseminated or published by HSCIC for purposes beyond their direct care.
 - b. A Type 2 objection applies only to a patient's personal confidential information. This has the same meaning as "confidential patient information" defined in section 251 (11) of the National Health Service Act 2006.

¹ For the avoidance of doubt, the Health and Social Care Information Centre (Patient Objections) Directions 2015 continue to have effect.

Accordingly, a Type 2 objection will not apply to information that is not “confidential”, including:

- i. aggregated information;
 - ii. information that is otherwise anonymised in accordance with the Information Commissioner’s Office Code of Practice on Anonymisation;² or
 - iii. patient registration information disclosed to the Office for National Statistics under section 43 of the Statistics and Registration Service Act 2007.
- c. A Type 2 objection will not apply to the disclosure of a patient’s personal confidential information for the purpose of facilitating the patient’s direct care. This includes all disclosure of a patient’s personal confidential information for the purpose of allowing his or her participation in National Screening Programmes endorsed by the UK National Screening Committee.
- d. Additionally, a Type 2 objection will not apply to the disclosure of a patient’s personal confidential information where:
- i. The disclosure is required by law;
 - ii. The patient has explicitly consented to that disclosure (whether before or after registering their Type 2 objection);
 - iii. The disclosure is authorised in accordance with section 261(4) of the 2012 Act where the HSCIC is disseminating personal confidential information to the person from whom the HSCIC collected the personal confidential information;
 - iv. The disclosure is authorised under regulation 3 (Communicable disease and other risks to public health) of the Health Service (Control of Patient Information) Regulations 2002 (SI 2002/1438) (“the 2002 Regulations”);
 - v. The disclosure is to the Office for National Statistics for the purpose of producing official statistics;

² Information Commissioner’s Office *Anonymisation: Managing Data Risk Code of Practice* (November 2012), available: <https://ico.org.uk/media/1061/anonymisation-code.pdf>

- vi. Where there is an overriding public interest in the disclosure.

- e. A Type 2 objection will apply to the disclosure of a patient's personal confidential information approved under regulation 2 (Medical purposes related to the diagnosis or treatment of neoplasia) or regulation 5 (Approval for processing information) of the 2002 Regulations, in cases where the approval is subject to the Confidentiality Advisory Group standard condition that the wishes of patients who have withheld or withdrawn their consent are respected, except in respect of disclosures to the Office for National Statistics specified in (d)(v) above and disclosures under the approvals specified in (f) below.

- f. A Type 2 objection will not apply to the disclosure of a patient's personal confidential information under the following approvals:
 - i. National Cancer Registration Service (PIAG 03(a)/2001);

 - ii. National Congenital Anomalies and Rare Diseases Registration Service (CAG 10-02(d)/2015);

 - iii. Assuring Transformation: Enhanced Quality Assurance Process Data flow (Disclosure by HSCIC to NHS England) (CAG 8-02 (c)/2014).

- g. It will not be considered reasonably practicable for HSCIC to process and uphold Type 2 objections where HSCIC cannot do so for technical reasons, for example in the following cases:
 - i. Systems in which the application of Type 2 objections would require significant and system-wide IT development changes which are neither practical nor cost-effective to implement (e.g. given the pending replacement of the system and/or where there is an overriding need for the system to continue operating.) The only system presently believed to meet these criteria is the Cancer Waiting Times system.

 - ii. Systems which are primarily used to support direct care but where the data are also accessed for purposes to which Type 2 objections would otherwise apply, and where it would not be reasonably practicable to segregate those purposes and apply Type 2 objections (e.g. payment notification generated as part of Electronic Prescription Service).

- iii. Where an NHS Number cannot be identified for a record (either because the field is blank or an invalid NHS Number has been recorded).
- iv. Data Services for Commissioners Regional Offices (DSCROs), which currently use local IT systems but are in the process of migrating onto the central HSCIC IT system. In this case HSCIC is directed to apply Type 2 objections in accordance with the principles in this letter by 14 October 2016.
- v. Disclosure to Public Health England for the National Drug Treatment Monitoring Service, which involves disclosures authorised by patient consent and disclosures authorised by Regulation 5 approval (ECC 5-05(e)/2012). It is not currently possible to segregate the two classes of information. In this case HSCIC is directed to apply Type 2 objections in accordance with the principles in this letter by 14 October 2016.

In such cases, HSCIC must:

- a. Make every reasonable and practicable effort to overcome the technical barriers as soon as possible; and
 - b. Uphold objections in accordance with the above principles as soon as reasonably practicable.
2. With effect from 29 April 2016, HSCIC is further directed to analyse how Type 2 objections may affect the data it releases in order to support recipient organisations to understand how the application of Type 2 objections may affect their own analysis, research findings and performance measurement.

JEREMY HUNT

Annex B

A list of the IT services referred to in direction clause 1(g)(ii) in Annex A

Alert Viewer

Bowel Cancer Screening System – query tool

Counter Fraud reports - Address Occupancy Report

Counter Fraud reports - Multiple Registrations History Report

Demographics Batch Service

Electronic Prescription Service

Open Exeter - Caldicott Guardian Report

Overseas Visitor Status

Service User Death Report (Secondary Care)