



Department
of Health

Sarah Wilkinson
Chief Executive
NHS Digital
Trevelyan Square
Leeds
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12 September 2017

Dear Sarah,

Thank you for NHS Digital's work supporting the development of the Government response to, and delivery of the recommendations in, the National Data Guardian's (NDG) Review of Data Security, Consent and Opt-Outs.

The review sets out recommendations for new data security standards and a national opt-out for data sharing which makes it clear to individuals when health and care data about them will be used; and, in what circumstances they can opt out. The Government response accepts all of the NDG review's recommendations and describes how we intend to deliver those recommendations.

NHS Digital has a critical role to play in continuing to support this programme, developing the implementation plan for the national opt-out and in preparing the national IT infrastructure that will allow the opt-out to be delivered in practice.

I am writing on behalf of the Secretary of State to provide a Direction to NHS Digital, formerly known as the Health and Social Care Information Centre and hereafter referred to as NHS Digital, to establish and operate a system for the collection and analysis of information, and to exercise such systems delivery functions, in respect of the new national opt-out model and the activities specified and described in this letter.

In accordance with section 254(2)(a) of the Act, the Secretary of State considers that the information is necessary or expedient to have in relation to his functions in connection with the provision of health services or of adult social care in England.

This Direction is given to NHS Digital in exercise of the powers of the Secretary of State for Health under section 254(1) and (6) and section 274(2) of the Health and Social Care Act 2012 ("the Act") and 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 (the Regulations).

In accordance with the activities specified and described in this letter, and under section 254 of the Act and regulation 32 of the Regulations, NHS Digital is directed to:

- (1) Collect the 'patient opt-out data', namely the record of those individuals who have registered an opt-out and store these against an individual's NHS number, as well as relevant technical (or meta) data related to the setting of that opt-out e.g. time and date etc. for audit purposes.
- (2) Establish a national repository for central storage of the patient opt-out data.
- (3) Establish a new national opt-out system to enable health and care organisations to access the patient opt-out data from the national repository, for the purposes of applying patient opt-outs to the patient data that they disseminate in accordance with the opt-out policy.
- (4) In establishing the new system to write to all patients with a current type 2 objection to inform them of the transition to the new national opt-out and that their type 2 objection will be withdrawn. This should make clear any actions needed in line with the policy agreed by the Department of Health.

Analysis on the impact of national opt outs

As part of the system to be established and operated pursuant to paragraphs (1) to (3) above, NHS Digital is directed to:

- (1) Undertake analysis of the patient opt-out data, in order to inform health and care organisations to aid their understanding of how the application of patient opt-outs may impact on the patient data being disseminated, for the purposes of their own analysis, research findings and performance measurement. This may include linking the patient opt-out data to other patient data held by NHS Digital. Any such analysis must be undertaken in such a way as to ensure that individuals are not identified and no confidential patient information is disseminated by NHS Digital.
- (2) Apply NHS Digital Disclosure Control Procedures¹ before data resulting from analysis of patient opt-out data are shared or published.

Handling Type 2 objections with the new National Opt-Out system

Further to the Directions from the Secretary of State for Health dated 8th October 2015² and the Directions dated 15th April 2016³, and as part of the transition from type 2 objections pursuant to paragraph (4) above, NHS Digital is directed to:

¹ http://content.digital.nhs.uk/media/23395/Disclosure-Control-Procedure/pdf/Disclosure_Control_Procedure.pdf

²

[https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/468439/patientobjectionsdirections.pdf] NHS Digital was directed, under Section 254 of the Health and Social Care Act 2012, by the Secretary of State for Health in October 2015 to collect Type 2 objection information from GP practices

- (1) Use the list of NHS Numbers of all Type 2 objectors held within its Patient Objections Management System (POMS) data asset.
- (2) Use the Personal Demographic System (PDS) which holds NHS Numbers, names and address details of all patients, to process the NHS Numbers held in POMS in order to obtain a match of NHS Numbers in the Personal Demographic System (PDS).
- (3) Use the matched data, i.e. demographic data from PDS and Type 2 objectors NHS Numbers, to write to patients to inform them of the new opt-out. For the purposes of writing to individuals here, no confidential patient information will be accessed and no patient data will be processed for any other purpose.
- (4) Further directions will be issued to NHS Digital setting out the agreed transition arrangements and date to commence upholding national opt-outs. NHS Digital will continue to operate the current process to collect and uphold Type 2 objections, as per the Direction issued on 15 April 2016 until further directed to stop doing so.

Notification of changes

NHS Digital is further directed to use the patient opt out data to contact patients with a registered opt-out if there are significant changes to the opt-out policy or if it is withdrawn.

In accordance with section 260 of the Act, NHS Digital will publish the information collected or analysed by complying with this Direction in a form which does not identify any individual or enable any individual to be identified, and may disseminate (other than by way of publication) the information to any persons it considers appropriate.

In exercising the functions under this Direction, NHS Digital must have regard to such priorities, policies, advice or guidance of the Secretary of State as the Secretary of State may notify in writing to NHS Digital.

This Direction supplements the following Directions:

- On the 8th October 2015, NHS Digital was directed by the Secretary of State for Health to collect Type 2 objection information from GP practices.
- On the 15th April 2016, NHS Digital was directed by the Secretary of State for Health to uphold Type 2 objections.

In accordance with regulation 32(2)(a) of the Regulations, the Secretary of State may make payments to NHS Digital for things done in the exercise of the function described in this direction.

In accordance with section 254(5) of the Act, NHS Digital has been consulted before this direction has been given.

Yours sincerely,

A handwritten signature in dark ink, appearing to read 'L. Jackson', written in a cursive style.

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