

## medConfidential briefing in advance of meeting on 30/9/15 with Chris Heaton-Harris MP regarding his Private Members' *Access to Medical Treatments (Innovation) Bill*

Comments apply to the version of the Bill sent by email, dated 9/9/15.

### **Section 2: "The Database"**

medConfidential notes it is rare for databases to be specified in primary legislation. In recent times, such databases have included the child database ContactPoint<sup>1</sup> and the population-scale National Identity Register (ID Cards) database;<sup>2</sup> neither of which survived the transition from a Labour Government. This proposed new database has been described to us as "potentially as toxic as care.data".

While NHS England has done no work at all on how to include "innovative treatments" in the mainstream data flows of the NHS – whether under care.data, or any other programme – the pending 'reset' of care.data may allow such treatments to be included in the mainstream. In such a scenario, how would this database relate to the integrated 'Care Episode Statistics' (Hospital Episode Statistics (HES) + care.data GP extract) database and any more comprehensive Care Episode Histories / Statistics databases?

medConfidential looks forward to a discussion with Chris Heaton-Harris about his intent, and the anticipated benefits of the proposed database. In particular:

- We are interested in the relationship between the proposed database and others – such as care.data / 'Care Episode Statistics', or its replacement.
- We would like to understand why Section 2 uses Regulations, rather than Directions, as was established in statute under the Health and Social Care Act 2012 and is used for information systems such as care.data and more widely? The flawed 2013 Directions to establish care.data, and HSCIC's recent rejection of NHS England's updated 2015 care.data Directions suggests that, in this context, Statutory Instruments should be deployed with extreme caution.
- The opportunity for consent mechanisms to be specified by Statutory Instrument is, however, a welcome enhancement of patients' right to "opt out" that, due to objections by DH, will at present only be manifested in tertiary legislation. On a related point, will existing consent processes for data flows in the NHS be respected? Or will concerned patients, of which there appear to be many, again have to make another consent choice about yet another database?

We are aware of the controversy around this topic, and seek factual information on intent before forming an opinion on the actual proposal and whether it will achieve the stated intent.

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<sup>1</sup> Parliament Library Briefing: <http://researchbriefings.files.parliament.uk/documents/SN05171/SN05171.pdf>

<sup>2</sup> <https://www.gov.uk/government/news/identity-cards-are-to-be-scrapped>

## Clause 2 (5): Marketing to Patients

The name “Saatchi” is iconic in the UK for its association with marketing. Given recent abuses of patient records for marketing purposes<sup>3</sup>, and the ongoing lack of definition in statute of “the promotion of health”<sup>4</sup>, is it the expectation that the patient-level records in this database will be allowed to be used for marketing purposes?

If not, will the Bill ban HSCIC, and all other NHS bodies and care providers from entering into contracts<sup>5</sup> that use patient records for marketing purposes without explicit informed consent?

## Clause 2 (5) (b): Permission for Commercial Reuse?

We note the current draft Bill maintains the loophole for the commercial re-use of the medical records of patients receiving “innovative treatments”. Commercial re-use permits so-called “information intermediaries” (which may also service NHS bodies) to resell data and services to commercial third parties for purposes covered by the over-broad and ambiguous definition, “the promotion of health” – the Government’s “McDonald’s amendment” to the Care Act 2014<sup>6</sup>.

Is this the intent of your Bill?

## Missing Clause: *Reporting to Patients*

Given concerns about how this database will be used in practice, and the overwhelming need for this to be completely transparent, we include medConfidential’s existing briefing on our proposal for “personalised data usage reports” which can provide a patient-readable report on **Health Accesses for Research and Treatment**, and the knowledge gained by such research.

medConfidential

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## About medConfidential

medConfidential is an independent non-partisan organisation campaigning for confidentiality and consent in health and social care, which seeks to ensure that every flow of data into, across and out of the NHS and care system is *consensual, safe and transparent*. Founded in January 2013, medConfidential works with patients and medics, service users and care professionals; draws advice from a network of experts in the fields of health informatics, computer security, law/ethics and privacy; and believes there need be no conflict between good research, good ethics and good medical care.

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<sup>3</sup> See e.g. <https://medconfidential.org/2015/marketing2u-was-your-health-information-sold-to-direct-marketers-by-pharmacy2u/> and <http://www.dailymail.co.uk/news/article-3020480/Your-secrets-sale-NHS-dock-s-revealed-details-patients-bought-prescriptions-online-sold-off.html>

<sup>4</sup> Care Bill ping-pong in House of Lords Hansard, 7 May 2014: Column 1514:

<http://www.publications.parliament.uk/pa/ld201314/ldhansrd/text/140507-0002.htm#14050788000031>

<sup>5</sup> Aggregated, published statistics are not subject to a contract for use. Contracts only apply to flows of patient-level records.

<sup>6</sup> pp5-7, medConfidential briefing for Care Bill ping-pong, 7 May 2014: [https://medconfidential.org/wp-content/uploads/2014/05/medConfidential-briefing-for-Care-Bill-ping-pong\\_07May.pdf](https://medconfidential.org/wp-content/uploads/2014/05/medConfidential-briefing-for-Care-Bill-ping-pong_07May.pdf)