Submissions from medConfidential and the British Medical Association and a response from the Department of Health and Social Care

medConfidential submission on the The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023

This Instrument abolishes the public body that is the independent statutory safe haven for data in the NHS, coming into effect at midnight of the day it is made. Given the series of questions we ask below, we start with what should be a relatively simple one: **will the formal, signed, SI be published on legislation.gov.uk (etc.) before it has come into effect, abolishing what has long been the sole statutory safe haven for patient records in the NHS?** This unanswered question epitomises the problems with this SI and the process which led to it.

The Health and Social Care Information Centre (HSCIC, also known as NHS Digital) aims to be an extremely transparent organisation – it may have failed at times, but the body acts as a creature of statute and takes its responsibilities as seriously as it has been allowed to by the constraints placed upon it. NHS England is a very different beast.

HSCIC / NHS Digital is not an insignificant public body – it runs the systems that, were you to cross the river and be wheeled into Guy's Hospital, allow the NHS to figure out who you are and what records you have. The Information Centre is the 'digital memory' of the NHS, being taken over without substantive recognition of everything it actually does. None of those foundational systems are mentioned in the paperwork Members have received – the focus is entirely on "secondary uses" of data which are generally planning and research.

At the despatch box in passing the clause enabling this Regulation, Ministers promised this SI "would not in any way weaken the safeguards we have in place for the safe and appropriate use of patient data"[1] and that "NHS Digital's current obligations in terms of its data functions, and particularly the safeguards that apply to patient data, will become obligations on NHS England".[2]

The status quo for data currently held by the statutory safe haven, i.e. the Information Centre, is that an analyst at NHS England wishing to do an analysis[3] must write down what that analysis is, and then NHS Digital has an independent panel which makes a recommendation on the project – all decisions being minuted, and all approved decisions appearing in a public register. Certain types of decisions may go to a different statutory panel, the Confidentiality Advisory Group at HRA, and NHS Digital must have regard to CAG's advice.

"Taking advice" from a Group with some independent members is not the same as the current independent challenge or oversight with real consequences, and allowing a single body to 'mark its own homework' on its own uses of data indisputably weakens existing safeguards. If NHS England expects their creation of new words to match the current actions, they must say so explicitly to avoid the backsliding they are creating the scope for.

[1] https://hansard.parliament.uk//commons/2022-03-30/debates/159B83EA-68DF-4A72-AFB7-189970DE9114/HealthAndCareBill#contribution-040BFC1D-BDFF-44D0-A388-3EA4954D6E3F
[2] ibid.
[3] Say, an assessment of the viability of Chorley A&E, or Lewisham hospital…

In limiting safeguards only to "relevant" data functions, the SI as drafted ensures that the obligations that applied to all of the former statutory safe haven's uses of data will *not* apply to all of NHS England's uses of data. Public trust requires public bodies' consistent good governance of *all* the patient data it handles and uses, not just particular subsets.

All the Instrument does is to substitute "NHS England" for "HSCIC" in statute, but the changes as a result go far beyond. As a consequence of those changes, an analyst at NHS England may wish to do that same analysis, and there may be a review, but there may not be a paper trail – and according to all the documents shared by DHSC and NHS England, there may be nothing else made publicly available about it. Certain types of decisions may still go to the different statutory panel, but NHS England need only have regard to their advice in a narrow manner. Data made available to third parties is at the whim of the political discretion of NHS England[4] – and following the culture of the Johnson premiership who initiated these changes,[5] all internal decisions will be assumed to be valid, with no safeguards needed.

The House of Lords recognised the complexity of this take-over when it voted to exclude[6] this single public body from the scope of regulations during the passage of the Health and Care Bill in 2022, and the sole reason given in the House of Commons for rejecting the Lords amendment was "Because the Amendment would limit the power to transfer functions under the Bill".[7] Relevant citations and quotes from the SLSC's 20th Report of the 2021–22 Session[8] will be well known to members of the Committee.

Promises were made at the despatch box in debate; are they being kept? It is clear that they *could* be met through this Instrument, as the changes in clause 17 of the SI – amending s262 of HSCA 2012 – shows. Those changes are not in themselves problematic, but they do amend the 2012 Act beyond the simple renaming of public bodies.

One document which some members of the Committee will have seen[9] refers to the ability of NHS England to effectively issue directions to itself on how it will use and comply with data requirements.[10] medConfidential has understood for some time that NHS England believes that NHS England will have the powers to direct NHS England – the red line under "Chief Delivery Officer" on the diagram provided to some members and on the following page shows that to be the case, but it is unclear from where that power originates in this Instrument.

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[4] Technically, NHS Digital could have done the same – but NHSD is not tasked with burying bad news about the NHS; NHS England is.

[5] The abolition of NHS Digital was a decision of the Johnson administration – with commensurate attention to detail – accelerated under the Truss administration, and has continued. There was an opportunity to do this in primary legislation in the 2022 Act, but the Government chose instead to use this statutory instrument approach. Former Secretary of State for Health, Therese Coffey, ordered the timescale of the merger be rushed through literally as the Truss Government collapsed: https://www.hsj.co.uk/policy-and-regulation/exclusive-nhs-england-and-nhs-digital-merger-to-be-brought-forward-orders-coffey/7033505.article

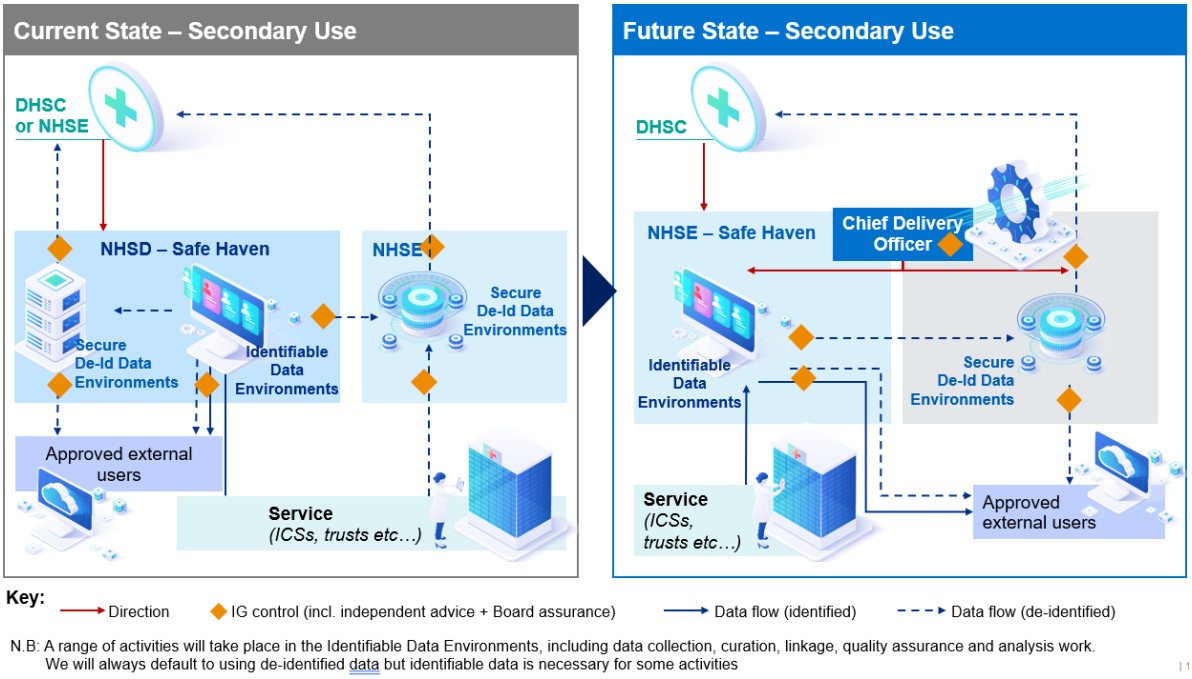
[6] Division 2 on Amendment 116: https://hansard.parliament.uk/lords/2022-03-07/ debates/9D6CE646-2FA6 -4D21-94C3-51CA3EFFA4E1/HealthAndCareBill#1149 and statements in earlier debate on amendment 116, several days before: https://hansard.parliament.uk//Lords/2022-03-03/debates/E2FD0BB1-EE6A-4C9F -A8BD-99FFB987323F/HealthAndCareBill#957

[7] The Lords Amendment to Clause 89 was by this point renumbered as Amendment 57, and the Commons Reason can be seen at the the top of page 6: https://bills.parliament.uk/publications/46087/documents/1713

[8] Entitled 'Government by Diktat: A call to return power to Parliament'

[9] We thank DHSC for eventually responding to requests for a copy of the narrative document, after first drafts of this note had been shared.

[10] [The draft guidance was not considered by the Committee as it is outside its scope.]



The Committee may wish to seek clarity on the flow of directions, and who may decide what to do in what circumstances, under what authority. Will this be what the SI says, or what the above diagram from NHS England says it will do?

NHS Digital does many things – a number of which are for the purposes of direct care, rather than secondary uses, and yet the diagram in the narrative only covers secondary uses of data. Such distinctions are quite crucial, and the governance of all must be clear and explicit. For example, NHS Digital's Board were told on the 1st November 2022 that the GP data collection programme – which has now collapsed twice – had "pivoted" to Direct Care, and so the two most controversial NHS data collections of the last decade would be entirely out of scope of that diagram.

This discrepancy should be brought to the attention of the Government, and the Committee can assess any Government response, or lack thereof.

Specific comments and questions on the SI

In this section, we focus primarily on the changes made to the sections of the Health and Social Care Act 2012 in Chapter 3 which established the Health and Social Care Information Centre.

Section 251B – we note that section 251B(4)(a) offers an opportunity to provide a statutory basis for patient objections or opt-outs, which despite the stated intent to strengthen safeguards post-merger, DHSC has not taken.

Section 253 – while the heading of this Chapter is "NHS England: Health and Social Care Information etc." and pertains to NHS England's "general duties", the SI appears to limit NHSE's obligations solely to its "relevant data functions" – a distinct subset that appears to exclude any or all data functions NHSE performs *other* than those it is taking over from HSCIC. If the goal is consistent, trustworthy use of patients' data by a single public body then it would appear to be unwise to create a 'two tier' categorisation of data functions and the duties around them.

Question: Can DHSC describe the distinction created between "data functions" in some places, and "relevant data functions" in other places, and confirm that how "NHS England" uses data will be subject to <u>all</u> of Part 9 of HSCA 2012, thereby facilitating the simple rename.

Section 255(8) – this subclause illustrates one of the problems caused by merging a body whose functions were specifically bounded into a body with a far wider remit and purpose. As noted above, and as the central commissioning body for the NHS in England, NHSE does much more than establish and maintain information systems; indeed, in some cases, it is one of the primary consumers of what those systems do. And in practice, NHSE has used the functions it performs to expand its powers.

From the edits to 255(8) it is clear that "any" of NHSE's functions will be a *much* wider set of considerations than would have been the case for HSCIC / NHSD, and that – as drafted – these considerations will not be limited to the "relevant data functions" to which NHSE's obligations, such as those in section 253(1), and other safeguards apply.

Question: As we go from two public bodies, enforcing transparency and good governance on the boundary between them, how will good governance and transparency be enforced when NHSE has conflicts between its own interests?

Section 259 – as illustrated by the care.data debacle in 2014 and GPDPR in 2021,[11] HSCIC / NHS Digital could only *require* persons to provide it with information when it had been *directed* to collect that information by the Secretary of State or NHS England, i.e. the independent statutory safe haven could not mandate extraction of data by itself. In the SI as drafted, this significant safeguard and separation of powers appears entirely absent.

Question: NHS Digital can currently only require data under s259 when it has received a formal Direction to collect it; does that safeguard persist?

Given this power has been at the heart of at least two major collapses in public trust, and given it will now be wielded by a body with far wider and greater powers and incentives to use it, it is a significant failure of governance and accountability not to put specific safeguards around it.

We further note that a "request" from NHS England – which commissions services and *pays* organisations – will in practice be received *very* differently than a request from HSCIC / NHSD ever was. And that something is "necessary or expedient" for NHSE, according to its own judgement and with its wider agendas and remit, will be a much lower bar than for an organisation whose remit is solely establishing and maintaining information systems.

While descriptions of the guidance state (emphasis added) *"Where directed by the Secretary of State, NHS England will be able to **require** information from health and adult social care bodies (and those providing services for them), and request data from any other organisation where this is necessary for it [to] comply with a direction"*, this important condition appears to be missing from the Instrument and associated guidance itself.

[11] See https://medconfidential.org/whats-the-story/care-data-2013-2016/ and https://medconfidential.org/whats-the-story/gp-data-2021/

(NHS Digital as a creature of statute would not have a legal basis to make a 'require' request for its own purposes, but NHS England having broad public tasks has multiple legal bases far beyond those of the existing Information Centre, on which the formal guidance and SI are silent.)

Question: Given different documents say (or don't say) different things, could the s259 'require' powers ever be used outside of an explicit Direction to NHS England?

Section 262 – in the edits to this section and subclauses 261(8), DHSC appears to have taken the opportunity to 'tidy up' the processes around dissemination of data to the Secretary of State and as directed by the Secretary of State. (We note NHS England already has its own publishing powers.) While these changes do not in themselves raise concerns, they do highlight that while the SI has been used to 'improve' processes in some ways, opportunities to improve safeguards for patients – such as a statutory basis for objections – have not been taken.

Section 262A – the removal of "under this Act" and replacement with "obtained in connection with the exercise of its relevant data functions" is a significant narrowing of the scope of the advice to which NHS England must have regard from the Confidentiality Advisory Group (CAG) at HRA. As per our comment on s253, it creates a 'two tier' system of oversight / governance around data use.

Section 262A was added by section 122 of the Care Act 2014[12] *as a direct consequence* of past poor governance and data handling by HSCIC, so to narrow the scope of CAG's advice from *all* of the relevant public body's data functions to just some of them seems unwise – especially given the public assurance that CAG's clear independence from NHSD and NHSE has provided.

Section 272 – We assume the deletion of sections 271, 272 and 273 are because NHS England already has these powers or obligations under existing legislation, but see no reference in the SI or the Explanatory Notes as to what replaces section 272, i.e. the "failure by Information Centre to discharge any of its functions". NHS legislation is already complicated enough; if only for public confidence, there should be clear signposting to where these equivalent powers reside.

Section 274 – the SI is drafted to limit obligations upon NHS England to only its "relevant" data functions, not all of them, and in that context section 274(1)(c) seems unusually broad. Of course Secretaries of State may direct public bodies to do whatever they require, but *"requiring NHS England to exercise such of the information functions of **any** health or social care body as may be specified"* seems like a recipe for further take-overs – such as NHSE's stated plan to "incorporate" Shared Care Records into its Federated data Platform.[13]

(Perhaps more optimistically, we note that the powers in this section could be used to fix some of the mess they are creating.)

[12] https://www.legislation.gov.uk/ukpga/2014/23/section/122

[13] https://www.theguardian.com/society/2022/nov/13/controversial-360m-nhs-england-data-platform-lined-up-for-trump-backers-firm

Section 274A – we assume DHSC has shared with the Committee the draft Secretary of State's guidance about NHS England data functions, on which we are happy to provide a further briefing, if helpful.[14]

In summary, and given the stated goal is "at least the same degree of protection, level of safeguards and transparency over data use":

- The guidance fails to address the fundamental change from two statutory bodies and data controllers to one single entity, holding all the data, which (at individual level) is *all* identifiable data.
    - e.g. NHSE currently has to request approval from NHSD like any other data user, for some uses at least, but under the guidance it will not – the guidance only covers data being copied to or accessed by users outside the public body boundary.
- As the national commissioning body for England, NHS England itself cannot *be* the safe haven. As a single corporate entity and data controller, NHSE cannot simply "act as" the safe haven in some respects and ignore it in others.
- Failure to recognise that the abolition of HSCIC / NHSD as a public body is a meaningful act that changes actions for other organisations which engage with those functions.
- No mention of particularly sensitive operations at NHSD which have aroused public concern – such as the National Back Office, and data sharing with the Home Office – and how specific safeguards, including separation, will be managed post-merger.
- DHSC's Guidance and data narrative say they have consulted. What changed as a result of those consultations?[15]

Missing from the SI

The SI relates to "relevant data functions" being conferred on NHS England, focusing primarily on the collection, analysis and dissemination of patient data for secondary uses, but makes no reference to uses of data for direct care purposes – noting that it is some of these functions, or functions deemed to be direct care, which HSCIC / NHSD also performed that have historically drawn public and professional concern.

NHS England already claims some of its uses of data to be "direct care". Assuming it continues to do so, then the SI does not appear to directly address these uses and the necessary governance around them. We note the diagram in page 7 of DHSC's 'data narrative' relating to the "Current State" and "Future State", after the SI comes into force, describes only the secondary uses of data.

This omission is significant because patients' data used for direct care must by definition and for clinical safety reasons be identifiable data. Neither the diagram nor the SI provide any clarity on the governance of such uses. Clearly ICSs and NHS Trusts use patients' identifiable data to provide

[14] [The draft guidance was not considered by the Committee as it is outside its scope.]
[15] Changing the date on documents to reflect that some people got them in December, and some in January, shouldn't count.

them with direct care; how will the 'new' NHS England, that has no direct relationship with patients, manage and safeguard such uses?

The SI in effect collapses two organisations into one, but fails to address specific consequences that will arise post-merger because NHS England is a single public body and a single data controller. The most obvious of these is that whatever sensible security measures NHSE adopts, e.g. de-identification or pseudonymisation, because of the information of which NHSE will be data controller, all of the patient data it holds at individual level will be identifiable special category personal data.

The Committee may recall public outcry at the GPDPR programme in 2021.[16] What NHS Digital could not dispute was that once it had extracted data, even in pseudonymised form, it would be fully able to re-identify any patient's GP data. The governance arrangements around that programme failed to satisfy patients, the profession or Parliament – and nothing in the SI or associated documents appears to attend to this same consequence. While pre-merger, NHS England could point to the separation of the two bodies (itself and NHSD) and legitimately argue that in some cases – depending on the treatment of the data by NHSD – data it received from NHSD was not fully identifiable, this could never be the case when all of the data is in the control of a single body.

DHSC's and NHSE's answer to this appears to be some sort of internal organisational separation between Directorates, but this does not address the inescapable fact that NHS England is a single data controller. Neither the SI nor DHSC's draft Guidance attend to this fundamental governance issue, which speaks to public trustworthiness of the new arrangements and where we would have expected clarity in both the SI and Guidance.

For example, referring again to the diagram on page 7 of DHSC's 'data narrative' in relation to secondary uses of data by NHS England, the role of "Chief Delivery Officer" would appear to be critical for public assurance. Given these are occurring within a single public body, we would expect specific obligations on the transparency (i.e. publication) of all CDO decisions, and of all approved *internal* uses / users – which do not appear on the diagram – as well as clear lines of accountability.

Where there are two organisations, one can hold the other to account. While merging two sets of governance processes into one may appear more 'efficient', preserving the desirable (sometimes necessary) effects of the separation of powers and/or functions requires additional effort that is not evident around this SI.

medConfidential, January 2023

[16] https://medconfidential.org/whats-the-story/gp-data-2021/

Parliamentary brief
bma.org.uk

BMA

BMA briefing – The Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023

January 2023

About the BMA

The BMA is a professional association and trade union representing and negotiating on behalf of all doctors and medical students in the UK. It is a leading voice advocating for outstanding health care and a healthy population. It is an association providing members with excellent individual services and support throughout their lives.

Summary

The Regulations, as the BMA understands them, will abolish the Health and Social Care Information Centre (known as NHS Digital) and transfer its data functions to NHS England. The BMA believes the transfer of data functions to NHS England will have hugely significant implications for the management and protection of patient data. The BMA is concerned that the change may diminish existing safeguards and good governance of patient data.

Role of NHS Digital

- One of NHS Digital's primary functions is to collect, process and disseminate patient data under the framework of the Health and Social Care Act 2012 (s252 – 265). NHS Digital plays a crucial role as the statutory safe haven and custodian of patient data. It has a well-established system of governance and independent oversight for handling requests for access to data.

- Requests for access to health data, including requests from NHS England, are considered by the Independent Group Advising on the release of Data (IGARD). IGARD is an independent and expert committee that reviews requests for NHS Digital data and provides independent recommendations to NHS Digital about their internal processes.

- IGARD is a crucial safeguard within the data access process. IGARD's role as an independent scrutiniser provides reassurance to the public about the safety and appropriate use of their data and that access to data is not a 'free for all'. All data releases are published in a data release register.

BMA concerns

It is unclear whether NHS England can perform the role of 'safe haven' for patient data. The BMA is concerned that the Regulations may result in diminished standards of safeguards and governance for data held by NHS England. Our concerns are two-fold:

Loss of separation between the organisation which holds the data and the organisation which seeks to use it

- The Regulations transfer the vast quantities of patient data held by NHS Digital to NHS England. Such a transfer removes the boundary between the holder and custodian of data and an organisation which seeks access to data. As a non-departmental public body, NHS Digital has a degree of separation from government which will now be lost. The new arrangements will bring patient data much closer to government and more likely to be subject to political pressure.

Safeguards and good governance of data access decisions

- It is vital that the strong protections which govern data access and use which currently exist within NHS Digital continue. The protections must apply whether requests for data access come from inside or outside NHS England.

- One crucial aspect of good governance is the continuation of independent oversight (including lay involvement) of both internal and external requests for data. To provide reassurance to doctors and the public that processes for data access are trustworthy such an important safeguard should be enshrined within legislation.

- The BMA is concerned about the approach the DHSC will take to the issuance of guidance with regard to NHS England's data functions and how there is no clear commitment to consultation with the profession and others prior to the issuance of that guidance and no clear obligation on NHS England to follow that guidance, only having to "have regard" for such guidance. Without robust safeguards and oversight processes, agreed from the outset, there is the very real risk of damage to public trust in the work of the NHS and how it handles patient data. Additionally, the BMA would seek to ensure continuing representation of the profession where they are data controllers of data that would be extracted to NHSE and as such would value being consulted on, and involved in the production of guidance.

Response from the Department of Health and Social Care

SLSC questions

The Explanatory Memorandum says at para 7.13 that various pieces of guidance are to be prepared:

When is this guidance to be produced?

Statutory guidance is being developed currently for publication as soon after the transition of NHS Digital's statutory functions as possible; ideally by that point. It will set out our expectations for how NHS England will protect people's data.

A draft communications document which has some key messages in relating to how people's data will be protected also been shared with stakeholders (this is not, however, a statutory document).

Is a draft currently available?

The latest draft has been shared with the Committee with these answers[1] – it is however still subject to change and improvement, as we addressing comments received from stakeholders.

How is it being consulted on and with whom?

The draft guidance has been shared for views, with the National Data Guardian, the Information Commissioner's Office, NHS Digital, NHS England, the NHS Digital Independent Group Advising on and Release of Data (IGARD), MedConfidential, and we are addressing issues people have raised; the Committee's comments would also be welcome.

Given that the Regulations are to come into effect the day after making - and the EM indicates a wish to do this as soon as possible:

What are the current state of the transfer arrangements?

The transfer regulations are being considered in Parliament; NHS Digital and NHS England are working closely on the operational transition arrangements which are being managed through the New NHSE England Day 1 Readiness Programme under the responsibility of the Chief Delivery Officer for NHS England, Mark Cubbon.

A draft statutory Transfer Scheme is being finalised to legally transfer staff, assets etc.

What transfer date is planned and

[1] [The draft guidance was not considered by the Committee as it is outside its scope.]

Parliamentary process permitting, the intention is to transfer the functions on 1st February 2023.

What information is being provided to those who may wish to use NHS data in future?

The submission references various draft items that have been circulated and in particular an illustration that shows the difference between the current and future arrangements for such secondary use of the data.

This is taken from the draft communications narrative mentioned above, which has been developed to provide a basis for communicating how data will continue to be protected once the statutory functions of NHS Digital have transferred to NHS England. NHS England will also be assuming responsibility for publishing full guidance for those who wish to access data, as NHS Digital does currently.

One of the statutory requirements which will transfer from NHS Digital to NHS England is the requirement under section 257 of the Health and Social Care Act 2012, which these regulations will amend, to publish procedures for the making and consideration of requests under section 255, that is, requests to establish a system for the collection or analysis of information.

They are concerned that it is unclear what the legal basis for the authority of the Chief Delivery Officer will be in authorising secondary use, can you point to this in the instrument please?

The organisation's authority derives from its statutory functions, and the relevant direction received from the Secretary of State (or alternatively, a section 255 request). The Chief Delivery Officer is the organisation's Senior Information Risk Officer (SIRO) and as per the current NHS Digital arrangement, the SIRO will be responsible for making information sharing decisions as part of the internal governance the organisation puts in place, rather than this being a specific statutory requirement in itself. As in NHS Digital, the SIRO is responsible for the information governance team. From the merger date, the current NHS Digital Executive Director of Privacy, Transparency, Ethics & Legal and the PTEL function will report into the SIRO and provide support and advice to the SIRO to enable them to discharge their responsibilities.

They are also concerned that future governance will lack an independent element in deciding which data uses to approve. Can you please clarify the system planned as patient records should be treated as highly confidential material.

The statutory guidance recommends NHS England to ensure it has processes and procedures in place for obtaining independent advice when exercising the transferred

data functions. This is compared to the current situation in which there are no requirements of any sort for NHS Digital to have such oversight.

The arrangements for obtaining independent advice should support oversight and scrutiny of the relevant functions of NHS England's Board. The arrangements may include, but are not limited to:

- appointing members to relevant committees and sub-committees who have specialist data protection and data security expertise
- obtaining independent advice from specialists and experts

NHS England should also have procedures in place for how it will obtain advice from the Confidentiality Advisory Group (CAG) - NHS England will be under a statutory obligation, again, transferred from NHS Digital, to have regard to any advice given to it by the CAG.

Are any patient opt-outs permitted for those who do not wish their data to be used in this way?

The National Data Opt-Out prevents confidential patient information from leaving health and care organisations without consent for purposes of research and planning in line with the policy. NHS England will continue to uphold opt-outs in line with national policy.

The national data opt-out does not apply to the disclosure of confidential patient information where the information is required by law or a court order. It therefore will not apply where NHS England is directed by the Secretary of State to collect information. The national data opt-out policy also outlines areas where national data opt-outs do not apply to NHS Digital's use of data. These will transfer to NHS England with NHS Digital's functions.

There are concerns that revised sec 253 will make a distinction between "data functions" and "relevant data functions" is this an intentional distinction?

There is no distinction: the term 'relevant data functions' is used in the drafting of the regulations to allow specific reference to all the functions which are being transferred from NHS Digital which specifically include the handling of data. The term 'data functions' (without 'relevant') does not appear anywhere in the regulations other than in headings.

If so, how will the new system operate homogenously with two distinct classes of data - please explain.

This is not about two different types of data – the regulations apply to all the data which NHS Digital currently handles, and all future information systems it is directed, or requested, to establish, plus the system delivery functions transferring which involve data, like the Spine or the NHS App.

Under the single system envisaged by these Regulations how will good governance and transparency be enforced on occasions when NHSE has conflicts between its own interests?

In the absence of an example of how NHS England has an internal conflict, NHS England's priority is of course to comply with the law, both in relation to how it operates to deliver these functions, and how it meets wider data protection law. Under section 260 of the Health and Social Care Act 2012 there is an obligation to publish certain types of information and that directions can include requirements as to the form, manner and timing of this.

The new operating model has been designed to minimise conflicts of interests by separating the functions that use data and design and build systems and data platforms from those who provide advice and assurance on information governance and compliance with the legal framework. The Transformation Directorate, where the Product, Platform, IT Operations and Data and Analytic Services sit are in a different Directorate to the Information Governance and Legal functions which sit in the Delivery Directorate and the Caldicott Guardian function which sits in the Medical Directorate.

Will there be any changes in the type of data collected? Or its status - is the current distinction between information requested (=optional) and required (=must be provided) to be maintained?

The regulations do not change the rules as to what data the organisation can collect or the circumstances in which it can request or require data. Section 259 sets out what information NHS England may require to be shared with it. It is this which therefore governs when data must be provided and when it is optional. These functions are transferred to NHS England unchanged.

What safeguards will be incorporated to ensure that health and/or care bodies, particularly small ones, are not swamped with requests for data that is "nice to have" as opposed to essential for the good governance of the NHS?

Under section 13F of the National Health Service Act 2006, NHS England, in exercising its functions, must have regard to the desirability of securing, so far as consistent with the interests of the health service, that any other person exercising functions in relation to the health service or providing services for its purposes is free to exercise those functions or provide those services in the manner it considers most appropriate, and that unnecessary burdens are not imposed on any such person.

The regulations also amend section 253 of the Health and Social Care Act 2012, including a provision that 'NHS England must seek to minimise the burdens it imposes

on others when exercising its relevant data functions other than those under the Medicines and Medical Devices Act 2021.'

In practice, no direction is agreed unless a burden assessment is carried out first and it is approved by the Data Alliance Partnership Board as a collection that is necessary, to ensure that unnecessary burden is not imposed. NHS England and NHS Digital are both members of the DAPB and this process will continue following the merger. Part of the consultation process for any direction also includes consulting with those who provide the data and therefore the burden would be considered as part of the consultation process and efforts made to minimise burden,

Finally, every data collection has to be funded by NHS England internally and therefore when there are many calls on internal funding, resources to support data collections need to be secured either as part of programme budgets or directorate budgets and will constrain NHS England to necessary collections only.

The submission states that "NHS Digital can currently only require data under s259 when it has received a formal Direction to collect it"; does that safeguard persist?

NHS Digital can require data under section 259 when it has been directed under section 254 and in certain specific circumstances only (set out in section 259) when it has been requested under section 255. The same safeguards will exist. NHS England will be directed by the Secretary of State, as NHS Digital is currently directed, to establish information systems. It will not be able to direct itself or establish an information system without a direction. Directions will continue to be published. The circumstances under which NHS Digital can require data to be provided under section 259 in order to comply with a section 255 request remain the same.

The submission also expresses concern about the merger removing a perceived distinction between data for secondary use and direct data for clinical use:

The regulations do not distinguish between different uses of data and do not change the current situation.

NHS Digital processes data for direct care every day as part of the national IT systems it operates e.g., SPINE, Summary Care Record, Personal Demographic Service, e-prescribing and e-referrals. All of these functions transfer to NHS England and will continue to be operated in the same way as they are now. The exercise of these functions, which are system delivery functions delivered on behalf of the Secretary of State will in future also be subject to the Statutory Guidance.

For data collected for one purpose to be used for a different purpose an appropriate legal basis would be required e.g., a direction and NHS England would need to ensure that appropriate transparency notices are in place. There are other considerations if data collected for one purpose is used for another. For example, if identifying patient

data collected for direct care are used for secondary purposes then it may be necessary to apply national data opt-outs. If data collected for secondary purposes is used for direct care then clinical safety risks must be considered. NHS Digital and NHS England are experienced in handling these issues which exist in the current system.

What security features will ensure that all released data for secondary use is anonymised

Releases of data for secondary use will be subject to the same level of control as they are within NHS Digital. Unless the recipient has a legal basis under the common law duty of confidentiality to receive confidential patient data, the process for approving access will require that the data are anonymised in the hands of the recipient. As with releases from NHS Digital, this will include minimising the data released, ensuring that appropriate technical and organisational security is in place, and contractual controls restricting how and where data may be processed and the purposes for which it may be used through putting in place data sharing agreements (DSAs).

NHS England will seek independent advice on its data access processes from a Data Advisory Group (DAG) and its members and, where there are no DAG approved precedents which apply, on specific requests for data to be released. It will also audit selected data recipients to ensure that they are meeting their obligations under their DSAs.

The NHS, including NHS Digital and England, are investing in Secure Data Environments (SDEs). SDEs are data storage and access platforms that uphold the highest standards of privacy and security of data, when used for research and analysis. They allow approved users to access and analyse specific data, without the data leaving the environment. The technology removes the need for data to be moved and access is fully controlled and auditable, which reduces the possibility of data misuse or theft. SDEs will become the standard method for approved users to access specific NHS data, greatly increasing the level of protection in place.

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Please note that where the recipient does have an appropriate legal basis – such as consent from the individuals involved or support from the Confidential Advisory Group

under Regulation 5 of the *Health Service (Control of Patient Information) Regulations* - identifiable data may be released for secondary uses.

What governance features will ensure that data shared with other parts of government - for example the Home Office - is properly authorised and handled

The same rules for data would apply regardless of the organisation requesting. All requests from external bodies for data would be considered in the same way. Currently NHS Digital shares PDS tracing data with law enforcement agencies under strict processes and precedents managed by the National Back Office (NBO) team. A summary of disclosure by the NBO is published on the NHS Digital website on the Data Use Register pages. These processes will continue. Any change to the processes or precedents would be subject to information governance controls and assurance and independent advice from the Data Advisory Group.

What assurances can DHSC give that in the merger to improve efficiency, current safeguards to ensure the correct handling of the different types of data are not reduced?

The statutory provisions which currently apply in NHS Digital will be transferred, by these regulations, to NHS England, and the statutory guidance will allow us to make additional recommendations relating to how the organisation protects data (currently, NHS Digital only has the statutory requirements in legislation, without any guidance).

Part of the arrangements required by the guidance will be for the Board to expressly have oversight and scrutiny of how the organisation exercises the functions which have transferred from NHS Digital. There will also be a requirement for NHS England to produce an annual report providing assurance over how it has exercised its transferred functions

It is intended that the guidance will include arrangements for oversight and scrutiny of how the organisation exercises the functions which have transferred from NHS Digital, and this will be essential to ensuring there is an independent view on the effectiveness of the organisation. The merger is not being undertaken in the interests of making savings or efficiencies, but, as the Laura Wade-Gery review indicated, to simplify the system, and provide unified leadership for digital transformation in the NHS.

The submission also references a number of undertakings given from the despatch box during the passage of the Health and Care Bill - what assurances can DHSC provide that this instrument meets all the undertakings given?

During passage of the Health and Care Bill 2022, there were some concerns raised in the House of Lords in relation to the planned use of the transfer power in the Bill, to transfer the functions of NHS Digital to NHS England. Each is given below as a heading, with how we have addressed these, either in the regulations, or in the statutory guidance.

Ensuring continuity in arrangements, particularly relating to transparency

The regulations transfer the statutory functions of NHS Digital to NHS England, including all the provisions which apply to how the organisation handles people's data. The same rules will apply as to how data is collected, and how it can be disseminated. The same provisions will apply requiring transparency as to how data is collected, e.g., NHS England will:

- publish its procedures for receiving and considering requests to establish information systems, and for requests to access data;
- report to Parliament annually on its exercise of the data functions;
- publish all directions.

Ensuring there is governance to prevent NHS England from marking its own homework, and have oversight of its exercise of its statutory powers internally

Within the merged organisation, responsibility for ensuring data is protected and managed appropriately will lie with the Chief Delivery Officer, as discussed above. It is intended that this will be separate from accountability for handling the data and undertaking analysis, which will sit in the Transformation Directorate. An important element of the arrangements will be that any *internal* requests for new data flows or to use data for new purposes will be subject to a rigorous process of scrutiny, comparable to that for external requests (for example for research or public planning purposes). It is also likely that a Secretary of State Direction will place particular requirements on the organisation in relation to internal uses of data.

Ensuring that NHS England would not be able to initiate data collections without the correct legal permission

NHS Digital is not allowed to initiate the collection of people's information without formal direction from the Secretary of State. This protocol will continue after the transfer of its functions into NHS England. NHS England will need a Direction from the Secretary of State before it can establish an information collection. Directions will be published (as they are now) and subject to the same rules as apply to NHS Digital currently. All the existing directions which NHS Digital is implementing will be transferred to NHS England to ensure continuity in data collections (again, they can be revoked by direction of the Secretary of State).

Ensuring the National Data Guardian and Information Commissioner's Office would be consulted

The National Data Guardian and the Information Commissioner's Office have been consulted on the proposals to transfer NHS Digital's functions, the draft regulations, and the draft statutory guidance.

Ensuring that a data usage register would be published, covering all projects accessing patient-level data and showing which data was accessed

It is intended that this will build on the current Data Uses Register, and mesh with current transparency requirements, requiring publication of what data is shared, and why. There will also be quality assurance of arrangements through audits of how data is used.