### A MEMORANDUM OF UNDERSTANDING

### BETWEEN

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND THE SECRETARY OF STATE FOR HEALTH AND NHS ENGLAND

### Purpose

This Memorandum of Understanding (MoU) between the U.S. Department of Health and Human Services (HHS) for the United States and the Secretary of State for Health and the NHS England for the United Kingdom (collectively referred to as "the Participants") sets out the framework for the intended ongoing working relationship between NHS England and the U.S. Department of Health and Human Services (HHS) and builds on a previous MoU signed in January 2014 between HHS, NHS England, and the Secretary of State for Health. It has been developed with the contributions of representatives from each organisation and describes a programme of collaboration that further develops the joint work already undertaken to support the sharing of common values and learnings across health information technology (HIT) and health data initiatives. In doing so, the programme of collaboration is able to leverage the strengths of each Participant and recognize opportunities to improve the health IT economy as well as the health and well-being of the population.

All Participants recognise the importance of informatics as a key enabler of health and social care provision and transformation. In particular, the Participants recognise the importance of joint work across the domains of clinical quality indicators, standards harmonisation, open data initiatives, cyber security, and priming their respective markets for innovative new Health IT products and services.

### Introduction

The United Kingdom and the United States have differing health care delivery systems and payment models; however, most systems are facing similar challenges posed by aging populations, increasing levels of co-morbid chronic disease, and the escalating complexity of care delivery and healthcare costs. Despite the differences across healthcare systems, there are often common approaches to addressing these challenges and recognising opportunities for improvement. Approaches can be predicated on the increased availability and cultural willingness to make use of quality health data and health information technology tools by clinicians and to patients, commonly known as e-Health, Health IT (HIT), or digital health. Accordingly the framework set out in this MoU takes account of these common aims and intends to complement respective priorities around key digital strategies. This MoU details ways in which the Participants may work together while also delivering such respective statutory functions and is intended to support the formal collaboration and close working arrangements already in place that allow both countries to learn from the experiences of the other

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and to align approaches on both sides of the Atlantic to inform strategic decision-making both nationally and internationally.

## **The Participants**

The U.S. **Department of Health and Human Services (HHS)** is a cabinet department and its mission is to help provide the building blocks that Americans need to live healthy, successful lives. HHS fulfils that mission every day by providing millions of children, families, seniors and others with access to high-quality health care, by helping people find jobs and parents find affordable child care, by keeping the food on Americans' shelves safe and infectious diseases at bay, and by pushing the boundaries of how society diagnoses and treats disease.

The Secretary of State for Health is responsible for **The Department of Health (DH)** in England. DH in England helps people to live better for longer. It leads, shapes and funds health and care in England, making sure people have the support, care and treatment they need, with the compassion, respect and dignity they deserve. DH is responsible for system wide informatics programmes, projects and services and having overall stewardship and accountability for the success of informatics policy implementation across health and care in England.

NHS England <sup>1</sup> is an executive non-departmental public body. NHS England authorizes clinical commissioning groups (CCG's), which are the drivers of the new, clinically-led commissioning system introduced by the Health and Social Care Act (2012). NHS England also has a parallel duty to assure that CCGs are able to commission safely, use their budgets responsibly, and exercise their functions to improve quality, reduce inequality and deliver improved outcomes within the available resources. In addition, the commitment to digital health transformation is overseen by the National Information Board<sup>2</sup> (NIB) whose aim is to put data and technology safely to work for the benefit of patients, service users, citizens and the caring professionals who serve them and; to help ensure that health and care in this country is improving and achieves sustainability. The NIB is charged with developing the strategic priorities for data and technology in health and care in order to deliver the maximum benefit for all citizens and patients, and to make appropriate recommendations for investment and action.

### **Other Agencies and Interfaces**

The Participants intend to draw on their own and other underlying resources for subject-matter expertise and the implementation of any activities conducted under this MoU (which is intended to be at the discretion of each). Within HHS such resources could include the Office of the National Coordinator for Health Information Technology (ONC); the Food and Drug Administration (FDA), and the Centers for Medicare & Medicaid Services (CMS). NHS England may draw on resources and expertise from NHS Provider Trusts, national regulatory agencies and other national bodies.

<sup>&</sup>lt;sup>1</sup> NHS England is the operational name of the National Health Service Commissioning Board, a statutory body corporate created by the National Health Service Act 2006, as amended in 2012

National Information Board; www.gov.uk/government/organisations/national-information-board

A number of public and private interoperability and architecture initiatives are also underway across the UK and U.S. that may also serve as resources and drivers for success including those of existing standard setting organizations such as the International Organization for Standardization (ISO), the World Health Organization (WHO), Health Level Seven (HL7) and the International Health Terminology Standards Development Organisation (IHTSDO).

The U.S. Office of the National Co-ordinator for Health Information Technology (ONC) is at the forefront of the U.S. Federal Government's health IT efforts and is a resource within its executive branch to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care. ONC is organizationally located within the Office of the Secretary for the HHS. ONC is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. It achieves this in collaboration with HHS agencies and other federal partners through programs such as the ONC Health IT Certification program, the CMS 'Meaningful Use program'<sup>3</sup> and the Veteran Administration's Blue-Button program<sup>®</sup>. ONC is led by the National Coordinator, a position that was initially created in 2004 through an Executive Order. That position and ONC were then legislatively established under the Health Information Technology for Economic and Clinical Health Act<sup>4</sup> (HITECH Act) which is part of the American Recovery and Reinvestment Act of 2009.

The U.S. Centers for Medicare & Medicaid Services (CMS) provides health care coverage to 100 million people through a collection of programs, including Medicare, Medicaid, the Children's Health Insurance Program and through the Health Insurance Marketplace. As an effective steward of public funds, CMS is committed to strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost.

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, the U.S.'s food supply, cosmetics, and products that emit radiation. It is also responsible for advancing public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. It also ensures the security of the food supply and fosters the development of medical products to respond to deliberate and naturally emerging public health threats.

# **Joint Aims and Objectives**

The aims and scope of this MoU are intended to reflect the discussions on topics held at recent bilateral summit meetings, and to recognise the need to economise on innovation and best practices. The potential activities within the framework of this MoU include the following:

<sup>&</sup>lt;sup>3</sup> Meaningful Use Program http://www.healthit.gov/policy-researchers-implementers/meaningful-use.

<sup>&</sup>lt;sup>4</sup> Health Information Technology for Economic and Clinical Health www.healthit.gov/policy-researchers-implementers/hitech-act-0.

Sharing Quality Indicators: This work stream should focus on the both the characteristics and use of patient reported/centred outcomes programmes that yield the biggest impact on the quality of care.

**Open Data:** This work stream should evaluate the lessons learned from this past year's Obesity Data Challenge options for future challenge collaborations. Additionally, the open data teams in each country intend to focus on the development of a catalog/directory of companies showcasing open data with the development of associated case studies.

Interoperability: UK and U.S. interoperability strategies have been compared and an initial table of mutually supported standards developed. These supported standards should be published and additional work should focus on comparison of open APIs to further enable HIT developers to work across both countries and support new models of care.

Health Data Application Showcase: The UK team intends to share with the U.S. team their ongoing work on application endorsement. While not seeking to develop an application endorsement model in the U.S., the U.S. team intends to review the UK process.

Cyber Security: Where relevant and appropriate, the U.S. and UK intend to share strategies to manage and develop respective approaches to cyber security.

#### **Other Activities**

Other activities carried out by Participants may include:

- promoting the exchange of expertise and organising events
- sharing knowledge and capability in design, architecture and standards
- collaboration to ensure effective capability for work stream efficiency
- conference and showcasing
- formation of joint working groups and networks
- collation of outcomes and its application to policy and strategy

### **Principles of Collaboration**

Working relationships may be characterised by the following principles:

- Promoting best practices, patient safety and high quality care;
- Respecting each organisation's independence and Governmental responsibility;
- Working in an open and transparent fashion, acknowledging that each Participant has statutory duties;
- Using human resources efficiently, effectively and economically; and
- Keeping each other fully informed about developments in approaches and methodologies.

## **Operational Governance**

The Participants intend to maintain dialogue with each other and other key stakeholders, particularly around governance, status reporting and monitoring of risks, issues and challenges. Any status reporting is intended to be collated and disseminated to the Board. In addition, senior leads from each Participant are intended to be identified and provide appropriate leadership for each work stream. Interfaces with existing programmes of work impacted by the outcomes of this collaboration are intended to be acknowledged; and expertise/integration sought as needed.

## **Terms and Review**

This MoU does not create legally binding obligations. The MoU may be modified at any time by mutual written consent of each Participant. All activities carried out pursuant to this MoU are at the discretion of each of the Participants and are subject to the availability of appropriated funds in the case of U.S. government Participants, as well as any other applicable laws and regulations that may govern a given Participant. This document does not replace existing business plans, reporting systems or accountability lines of each Participant.

The MoU is effective from the date of the signature of each Participant thereof, and is intended to continue for a period of 24 months unless discontinued by either Participant. A Participant wishing to discontinue this MOU should provide written notice to the other. Its terms may be renewed or modified following a review of the operation of the MoU at the end of the first 24 months. The MoU may be renewed for periods of 12 months at a time.

Signed in Washington DC on February 25, 2016 in two originals.

United States Secretary of Health and Human Services

[signed]

Sylvia Mathews Burwell

For the U.S. Department of Health and Human Services

[signed]

United Kingdom Secretary of State for Health

[signed]

The Rt Hon Jeremy Hunt MP

For NHS England

[signed]

Susannah Fox Chief Technology Officer lan Dodge National Director for Commissioning Strategy

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