

A MEMORANDUM OF UNDERSTANDING

BETWEEN

**THE US DEPARTMENT OF HEALTH AND HUMAN SERVICES,
THE SECRETARY OF STATE FOR HEALTH, NHS ENGLAND,
And THE HEALTH AND SOCIAL CARE INFORMATION CENTRE**

HEREINAFTER REFERRED TO AS “THE PARTICIPANTS”

Purpose

This Memorandum of Understanding (MoU) sets out the framework for the intended working relationship between NHS England, the Health and Social Care Information Centre (HSCIC), and the US Department of Health and Human Services (HHS). It has been developed with the contributions of representatives from each organisation and describes a programme of collaboration with objectives set around sharing common values across health information technology (HIT) and health data. In doing so, the programme of collaboration should leverage the strengths of each Participant and identify 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 improvement. In particular, the Participants recognise the importance of the development of clinical outcome indicators, standards harmonisation and increased interoperability, open data initiatives, advancing Health IT adoption, 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.

The MoU is intended to set out principles for the Participants to follow in the course of their working relationships. The Participants expect that the MoU may be supported by protocols or other documents not included here that set out a detailed work programme as well as any operational and governance considerations for how the Participants plan to work together.

This collaboration is the result of previous summits, the aims of which were to allow both countries to learn from the experiences of the other and to align approaches on both sides of the Atlantic. Throughout, the summits aimed to feed into the areas of cooperation identified in the December 7, 2010 United States and European Commission Memorandum of Understanding,¹ and which 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 fulfills 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 England² 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. NHS England is also charged with using its powers to commission activities to deliver key elements of the information strategy *The Power of Information*³. Key themes include patient control of their health information and access to the information they need to improve their health and wellbeing. It also seeks to rollout information systems that are designed to support clinicians and other front-line staff to deliver safe, high quality care.

The Health and Social Care Information Centre is an executive non-departmental public body and also acts as the agent for the Department of Health on the Open Data agenda. It provides specialist input into developing standards and products as well as identifying opportunities for making better use of information assets, and in addition; providing contractual delivery of the Secretary of State's priorities relating to the Department of Health's Informatics Strategy "The Power of Information: putting all of us in control of the health and care information we need" (2012).

¹ United States and European Commission Memorandum of Understanding: Co-operation Surrounding Health Related Information and Communication Technologies (2010) www.healthit.gov/sites/default/files/HHS_EC_MOU_CooperationHealthInfo_and_ComTechSigned.pdf

² 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

³ The Power of Information: putting all of us in control of the health and care information we need" (2012) www.gov.uk/government/publications/giving-people-control-of-the-health-and-care-information-they-need.

Other Agencies and Interfaces

The Participants intend to draw on their own and other underlying resource for subject-matter expertise and the implementation of any activities conducted under this MOU (which would 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 and The Health and Social Care Information Centre, may potentially be able to draw on resources and expertise from NHS Provider Trusts and regulatory agencies.

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

Other existing and future arrangements may also drive success. For example, the UK as part of the European Union is also engaged with the US under the 2010 European Commission and United States Memorandum of Understanding⁴ which is further outlined in the “Transatlantic eHealth/Health IT Cooperation Roadmap.”⁵ Given these cooperative drives, one can expect complementary overlap in work on the development of a Health IT workforce, and internationally recognized interoperability standards; especially in the vocabulary and content of patient-mediated exchange. The Participants intend to align their respective efforts where they overlap through common membership between the two initiatives, and to inform strategic decision making both nationally and internationally.

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 HIT Certification program, the CMS ‘Meaningful Use program’⁶ and the Veteran Administration’s Blue-Button program[®]. 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 Act⁷ (HITECH Act) which is part of the American Recovery and Reinvestment Act of 2009.

The U.S. Centers for Medicare & Medicaid Services (CMS) - CMS provides health care coverage to 100 million people through a collection of programs, including Medicare, Medicaid, the Children's Health

⁴ United States and European Commission Memorandum of Understanding: Co-operation Surrounding Health Related Information and Communication Technologies (2010) www.healthit.gov/sites/default/files/HHS_EC_MOU_CooperationHealthInfo_and_ComTechSigned.pdf

⁵ Transatlantic ehealth/health IT Cooperation Roadmap (2013) www.healthit.gov/sites/default/files/HHS-EC-Roadmap-Executive-Summary-Draft-2013_02_19.docx.

⁶ Meaningful Use Program <http://www.healthit.gov/policy-researchers-implementers/meaningful-use>.

⁷ Health Information Technology for Economic and Clinical Health www.healthit.gov/policy-researchers-implementers/hitech-act-0.

Insurance Program and, soon, 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. FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. It is also responsible for advancing the 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 Acts and Objectives

The aims and scope of this MoU are intended to reflect prior decisions and discussions on topics held at bilateral summit meetings, and to recognise the need to economise on innovation and best practices. The potential activities foreseen within the framework of this MoU include the following:⁸

Sharing Quality Indicators

Review a set of jointly decided quality indicators that are currently in place.

Identify alignments across existing UK and US repositories and topics with the potential for further collaboration and harmonisation, particularly in the area of longitudinal patient indicators.

Liberating Data and Putting It to Work

Discuss and identify areas of collaboration around Open Data and data transparency of secondary stores.

Examine potential areas for mutual learning and harmonisation concepts in supporting patient's to access and use their health data in managing their care.

Lever shared interests and accelerate the development of standards and interoperability that enhance patient care and create more open markets.

Adopting Digital Health Record Systems

Explore ways to maximize the successful widespread adoption of digital records.

Encourage the development of a robust Health IT workforce and reduce the administrative burden on front-line staff.

⁸ The HHS-NHS Collaborative Work Programme gives additional details about these potential activities. For further reference, see HHS and NHS England, HSCIC, Bilateral Health IT and Open Data Collaboration: Work Programme 2013 (appended separately and available from HHS ONC, NHS England and HSCIC).

Priming the Health IT Market

Discuss the state of the Health IT Marketplace, including: barriers to innovation, regulatory approaches for patient and clinician health applications, certification approaches for suppliers, and strategies to support small to medium enterprises; increasing the collaboration and uptake of health systems.

Other Activities

Other activities undertaken 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 would 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 and that sometimes cooperation may not be necessary;
- Using human resources efficiently, effectively and economically; and
- Keeping each other fully informed about developments in their approach 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 would be collated and disseminated to the Board. In addition, senior leads from each Participant would be identified and provide appropriate leadership for each work stream. Interfaces with existing programmes of work impacted by the outcomes of this collaboration would be acknowledged; and expertise/integration sought as required.

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 undertaken 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 US 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/Government Office 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 a period of 12 months at a time.

Signatories

Signed in duplicate on 23rd January 2014 at the ONC Annual Meeting, Washington, and Richmond House, London; respectively via live video conference

United States Government
Secretary of State for Health

United Kingdom Government
Secretary of State for Health

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Kathleen G Sebelius
Secretary of Health and Human Services

.....
The Rt Hon Jeremy Hunt MP
Secretary of State for Health

Under-signatories

For the US Department of
Health and Human Services

For NHS England

For the Health and Social Care
Information Centre

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Bryan Sivak
Chief Technology Officer, HHS

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Tim Kelsey
National Director for
Patients and Information

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Kingsley Manning
Chair HSCIC