

United States interoperability and patient access regulations

In 2020, the US Department of Health and Human Services released two data sharing regulations aimed at making it easier for patients to access their personal health and claims information from providers and insurers.

Overview

The new regulations are designed to support **MyHealthEData**, the US government initiative that aims to give consumers control over their own health information. The regulations come from the Centers for Medicare and Medicaid Services (CMS) and the **Office of the National Coordinator for Health IT (ONC)**. In New Zealand, although the purpose behind data portability is not entirely the same as in the US, the direction of enabling consumer access to personal health data very much is.

The two US regulations are:

1. **CMC Interoperability and Patient Access Final Rule.** This requires insurer/payer data holders to implement a secure, standards-based patient access API that allows consumers to easily access claims, encounter data and clinical information through third-party apps. Besides patient access APIs, other requirements include provider directory APIs, GP2GP-like services, transfer of care event notifications, and the ability to name and shame providers who don't have published API endpoints or who otherwise block information.
2. **ONC Cures Act Final Rule.** The **21st Century Cures Act (2016)** is designed to help accelerate medical product development and bring new innovations and advances to patients faster and more efficiently. As part of this, the new regulations require the healthcare industry to adopt standardised APIs for patient access and uses such as the above. There are requirements for user experience, interoperability, and privacy and security. Information blocking is basically prohibited, and the **eight exceptions** are framed that way. These commonsense exceptions relate to preventing harm, privacy and security, content, licensing and fees (covering reasonable costs to develop/host APIs). Other jurisdictions, such as the UK, propose standard API participation agreements, more carrot than stick, to achieve the same things.

Relevance to New Zealand

The required API standards specified by the above are **HL7® FHIR® R4**, **SMART on FHIR**, **OAuth 2.0** and **OpenID Connect**. These standards are already HISO-endorsed and can be used with confidence in National Health Index (NHI) and Health Provider Index (HPI) API development, as well as the future national Health Information Platform (nHIP). Our **HISO statements of**

endorsement and new interoperability roadmap in development will reinforce that these are the standards everyone must adopt.

The US regulations are supported by a mix of US-specific implementation guides and we would need to develop equivalents of these. The **ONC-published interoperability roadmap** has been a source of information for our interoperability roadmap, along with the Australian interoperability roadmap and the Global Digital Health Partnership interoperability work.

US Core Data for Interoperability (USCDI) defines minimum requirements for the interoperable personal health data set that patient access APIs need to support. It covers identity and demographics, care team, care plan, allergies and adverse reactions, immunisations, problems, smoking status, procedures, vitals, lab results and diagnostic reports - essentially the same scope as nHIP.

The USCDI is a useful example of how we could present nHIP data requirements in a simple, neutral format. It has been derived from the **JIC Patient Summary Standards Set** which has already been endorsed by HISO and is a basis for the development of NZ FHIR profiles and implementation guides.

The **ONC API conditions of certification** relating to published specifications, fees and a marketplace around APIs will be a useful reference for nHIP.