

This letter is addressed to the HTA, the CTO and the chair of the TSC on behalf of the FMG. It addresses concerns about the introduction of alternate URIs for terminologies that already had mandated URIs assigned.

The purpose of the letter is to achieve a common understanding of HTA's responsibility for engaging with external organizations around the official URI to be used in identifying those organization's code systems in HL7 standards. While the FMG does not have specific interest in the OIDs used to identify code systems in CDA and v3 messages or the codes used to identify code systems in HL7 v2, the principles described here should apply to those as well. Endorsement from their respective management groups and methodology work groups can be obtained if necessary.

The FMG very much appreciates the HTA's engagement with terminology authorities to ensure that products are licensed under terms that maximize their availability to implementers. Where URIs do not yet exist, we appreciate the HTA's work to establish implementation-friendly URIs that will hopefully permanently resolve to useful guidance for a code system.

However, the HTA was never asked to seek URIs for code systems that already had URIs assigned and published by the HL7 specification, nor were they ever asked to negotiate changes to existing URIs.

The mandate of the HTA to seek approved URIs for code systems should **only** apply for those code systems that do not already have one assigned and in use by the community. Once assigned, a URI **shall not** be changed without the approval of the responsible management group and shall only occur after consultation with the implementation community that would be impacted by the change. URIs that have been developed contrary to this policy need to be immediately removed.

Changes to system URIs are absolute breaking changes to interoperability. Our standards are designed this way – intentionally so. We fully expect implementation to hard-code system URIs in their code and persist them in databases, document stores, test data, clinical decision support rules and other places. Changes to URIs invalidate all this existing data and code and require modification and re-testing.

Depending on the scale of adoption of the code system, this can mean 10s or even 100s of millions of dollars in costs. That is not hyperbole. The quote to put out a new release of a relatively small system adopted by only a few provinces in Canada was quoted at over 1 million due to the need to re-test all of the revised systems and ensure that data had been appropriately converted. FHIR is now in production in hundreds of thousands of systems throughout the world (though obviously not all code systems have this degree of penetration).

If there is any doubt about the real impact of changing URIs on implementers, try going into a major v3 implementer (e.g., Infoway, NHS or NICTIZ) and telling them that, based on a

requirement from SNOMED International, they need to change all of their systems and data to use a new OID for SNOMED. Introducing such disruption for implementations is directly at odds with the HL7 Board's strategic goal of improving support for implementers under the Re-envisioning Initiative.

We recognize that there have been changes to URIs of FHIR code and identifier systems in the past - including a wholesale migration to <http://terminology.hl7.org> of the v2, v3 and most FHIR terminologies. However, this change was linked to a specific release of FHIR, where inter-version transformations are already necessary. It was not introduced mid-release into an environment where implementers would have no ability to cope. It was also done after considerable discussion with the implementer community. (And with a promise that such a wholesale change would never happen again.)

Whether the HTA believes that implementer dependence on URI permanence **should** be the case or not is irrelevant. This is how systems have been designed for 30+ years and works well. The notion that systems would interpose a level of indirection and "look up" the current URI for a particular code system before using it is completely impractical and is not a practice of even a tiny fraction of existing implementations, if any. The FHIR infrastructure work group and the FHIR management group would certainly never contemplate trying to impose such a requirement and, even if this was done, it would not help with impact on existing systems.

HL7's principal purpose is to provide interoperability standards that have utility to the implementer community. The HTA's obligation is to support that objective with respect to the terminology artifacts needed for our standards. It is not acceptable for the HTA to take action that is specifically contrary to the design of HL7's standards and to our promises to the community. Whether the HTA believes the promises should have been made or not, they are implicit in the design of all of our standards. V2 falls apart if LOINC stops being "LN". V3 falls apart if SNOMED stops being 2.16.840.1.113883.6.96. FHIR URIs are no less critical.

The only changes we have made to OIDs in the 20-ish years of v3's history have been in situations where the object in question had multiple OIDs accidentally assigned, or where a code system that was initially believed to be a single code system was subsequently found to actually be multiple code systems. Some of these changes were painful, but were accepted by the community due to technical necessity.

The FMG is not aware of a legal nor moral necessity to seek input from a terminology provider as to the URI, OID, code or symbol used to represent that code system in HL7's exchange standards. None of the licensing terms of any of the terminologies for which URIs have been issued impose any such requirement. Furthermore, if the organizations were not asked for URIs, they might not, in many cases, even be aware of what URIs were in use. (As an aside, in most cases, the URIs currently in use were based on discussions in the past with individuals within the responsible terminology organizations.)

The presence of URIs on the HTA pages that conflict with those in the FHIR specification creates confusion in the implementer community and carries an immediate risk of implementer

creating software that uses incorrect, non-conformant and non-interoperable URIs for code systems. This will, at minimum, create unnecessary costs for implementers and loss of credibility for HL7 as a standards organization. At worst, it could result in patient harm.

We understand that having negotiated new URIs, it will impact the HTA's – and possibly HL7's – credibility with certain terminology providers to revert to the previously published URIs. However, given the cost to our implementer community of URI changes, it is a credibility loss we will have to accept.

We respectfully and urgently ask that the HTA – with the TSC's direction if necessary – immediately remove all references to code system URIs that are inconsistent with those published in the core specification, cease discussions with terminology providers about URIs where there are already URIs assigned, and refrain discussing the publishing of any URI without first ensuring that no prior URI is registered or in use, or first obtaining the explicit permission of the relevant management group.

Sincerely,

Lloyd McKenzie & David Hay with the approval of the FHIR Management Group