

Explainer to the Revised 2024-25 Affiliate Agreement.

2023-08-29

This companion document to the newly revised Affiliate Agreement is provided so that you can find new or changed language without necessarily going through a red-lined comparison version that can be difficult to read. It is NOT a legal document or should be considered to be a binding component of the Affiliate Agreement. It draws the readers attention to the sections affected, and provides a rationale for the proposed changes.

Approval Process

The approval process for the new Affiliate Agreement has several steps:

1. Drafting and Discussion with HL7 International Council (IC) members (has been ongoing since 2021).
2. Review of the proposed Draft Agreement by the Affiliate Engagement Committee, a sub-committee of the Board of Directors. (completed)
3. Review of the proposed draft by the HL7 Executive Committee, including officers of the organization and some Board Members for comment and revision, with subsequent endorsement for submission to the HL7 IC. (completed)
4. Distribution of the final draft to the HL7 International Council for final review and a vote to recommend the agreement to the HL7 Board of Directors (in advance of, and voted on at the Sept 2023 WGM).
5. Recommendation of the Affiliate Agreement to the Board of Directors for their approval. (currently scheduled for the HL7 2023 WGM Board Meeting).

General Overview

Much of the historical Affiliate Agreement language is retained in the new agreement, however there are two new subsections in Section 7 “Obligations of the Affiliate”. These are sections 7.2.1 and 7.3 “Participation”.

For the purposes of clarity, all references to the word “certification” have been reworded to say “professional certification” as some readers of the agreement have confused this with “product certification”. At the time of this document’s approval, product certification is not defined or provided as a service by HL7 International.

Otherwise, specific subsection changes, and their implications, are listed below.

Specific Agreement Additions or Changes

Section 6.4.3 – Organizational Member Use of licensed Standards

This section has been revised to clarify what “HL7 Licensed standards apply to and what the rights and privileges are for use of them by Organizational Members of the Affiliate.

6.4.3.1 Has been revised to define Licenses standards as those that are not provided using an “open” licensing model, as is the case with HL7 FHIR. This explicitly reference certain legacy standards still in use within the Affiliate’s jurisdiction.

6.4.3.2 Has been revised to provide examples of what constitutes an organization.

6.4.3.3 Has been added in response to questions from the HL7 Executive Committee on what the implications are for organizations that have an HL7 International Organizational membership, and for those that wish to use HL7 licensed products in more than one country. The rationale provided to the Executive Committee is that:

- “external” organizations should still be required to acquire an Affiliate membership if they are implementing in its country, as they will, by definition:
 - Be encouraged to participate in Affiliate activities and development of country Implementation Guides.
 - be implementing specifications that have been localized as necessary to meet the regulatory constraints and enablers.
 - be aligned with that country’s obligations for the use of related specified national standards (such as licensed terminologies).

Section 6.10.2 “Other material provided by the Affiliate”

- Section 6.10.2 and been modified to recognized that “Baseline” or “Core” implementation guides are being developed and declared without necessarily going through the HL7 Affiliate governance and due diligence processes. Where that occurs those implementation guides cannot be named or declared as official HL7 Affiliate guides.
- Conversely, if such implementation guides are taken through the affiliate due diligence and balloting process (see section 7.2.1 for the principles), then they can be considered official HL7 specifications.

PLEASE NOTE:

- a) This may have implications to the tooling used for creating the implementation guides, as these documents are generated from many artifacts. This may require that code within the tooling is changed to appropriately name the resulting generated guide.
- b) Section 6.5 “Trademarks and Copyright” remains unchanged. Official trademarks and copyright marks must be respected and receive approval for from HL7 International and / or the HL7 Affiliate.
- c) Section 6.9 “Localization” of the Affiliate Agreement remains unchanged, and requires affiliates to make available to HL7 a copy of specifications / guides they produce.

Section 7.1.4.3 Has been modified to reference the use of an online Form for Section B of the Annual Report that Affiliates are required to provide as part of the agreement.

Section 7.2 “Governance”.

This section has a new opening sub-section 7.2.1 about striving to adhere to SDO due diligence principles.

- Recently, for ANSI audit purposes, all of the GOM entries specifically related to HL7’s obligations to ANSI as an accredited Standards Development Organization were extracted into a document called [HL7 Essential Requirements](#). This document begins with a section on SDO Due Process, and begins with a set of guiding principles. These principles have been added to the Affiliate

Agreement partly because the affiliates are an extension of HL7 as an SDO and should exhibit the same principles in the work they do locally, but mostly because the behaviours detailed by the principles and related processes are what make HL7 standards authoritative, not just in the U.S., but globally.

Section 7.3 “Participation”

This a new section, defining what it means for an Affiliate to be an active participant in HL7.

It is intended to address several of the challenges that the HL7 Membership Director and the International Council Co-Chairs have experienced in contacting inactive or lapsed Affiliates, as well as solving for the difficulty in achieving quorum for almost every meeting.

Sub-section 7.3.1.6 is the specific paragraph related to achieving quorum for decision making of the International Council.

NOTE: The status’ “Active” and “Inactive” do not currently exist in the GOM and will need to be added before the next calendar year begins. These status’ may also the Affiliate Engagement Committee to identify Affiliates that may need assistance before the fall into "Lapsed" as an affiliate.

While this is explicitly stated in the new Affiliate Agreement, it is actually within the governance of the IC as a component of its Decision Making Practices (DMP). This mechanism was raised at the August 2023 virtual IC meeting was moved, seconded, and approved with one abstention and no negatives.

Section 7.6 “Protection of Intellectual Property, Copyright, and Trademark”.

The new version of the Affiliate Agreement has removed a clause in 7.6 that requires Affiliates to enforce HL7 IP and licensing. As volunteer member organizations that are dependent on Member fees to operate and function, no Affiliate is in a position, practically or legally, to enforce HL7’s IP or license agreement. The Affiliate members do agree to make HL7 International aware if there are issues they discover.

Section 13.4 Requiring Affiliate Chairs to have active (free) HL7 Confluence accounts.

This clause has been added, as the global distribution of affiliates and associated time zones means the International Council often cannot achieve quorum for operational or financial decisions. The IC frequently uses online voting on Confluence, and also shares important documents with the Affiliates using that mechanism. A confluence ID is also required to complete the new online Form B as part of the Affiliate’s Annual Reporting Cycle.