



# Health Level Seven International

## Affiliate Agreement

### HL7 [Affiliate Name]

#### Preamble

The mission of HL7 International and its Affiliates is to provide standards that empower global health data interoperability.

HL7 International's vision is: A world in which everyone can securely access and use the right health data when and where they need it.

The Affiliate is a legal entity that:

- Supports HL7's vision, mission and strategic goals and works to advance them locally.
- Represents its members at HL7 International and within its Territory on HL7 matters as described below and in section 7.8.
- Participates in HL7 International's standards development processes.
- Promotes the relevance and fitness of the HL7 Protocol Specifications, HL7 Educational Material and Other HL7 Material to the appropriate Governmental agencies and health standards accrediting body within its Territory.
- Distributes, translates, and localizes the HL7 Protocol Specifications as appropriate.
- Conforms with HL7 International processes and tools relevant to the Affiliate.
- Reports on relevant local government and other topics relevant to HL7 strategy and products.
- Promotes HL7 standards, educates, informs, and supports current and potential users within its Territory to promote consistent and widespread usage of the standards; and
- Reports back to the HL7 Board of Directors on local topics relevant to HL7 International.

## 1 Parties to the Agreement

### 1.1 This Agreement is between:

Health Level Seven International (“HL7 International”), 3300 Washtenaw Avenue, Suite 227, Ann Arbor, Michigan 48104-4261, USA

and

[Affiliate Name] (“the Affiliate”), [Affiliate Address]

each being a party (“Party”) and both being the parties (“Parties”).

## 2 Purpose

- 2.1 This Affiliate Agreement (the "Agreement") is a contract that confers the rights and obligations of the Affiliate within its Territory ([insert Territory]) for the term of this Agreement.
- 2.2 The Affiliate Agreement entered jointly by the Affiliate and HL7 International governs the Affiliate relationship subject to the Rules defined below and in Appendices A and B.
- 2.3 The Affiliate is at legal entity dedicated to advancing the acceptance and usage of HL7 Protocol Specifications.

## 3 Term of the Agreement

- 3.1 The Term of this Agreement is from January 1, 2024, to December 31, 2025. As used below, the word "Term" refers to the initial, and any renewal, period under this Agreement.

## 4 Entire Agreement

- 4.1 Except as otherwise provided herein, this Agreement and its Appendices constitute the entire agreement and complete understanding of the Parties hereto and supersedes all prior agreements between the Parties.
- 4.2 Documents and policies referenced by this Agreement will be to a specific version of that document or policy. Changes to these referenced documents or policies will require an amendment to this Agreement following the procedure given in section 9. Notwithstanding the foregoing, a reference to the Rules shall mean a reference to the most current version of the Rules, without requiring any amendment to this Agreement.

## 5 Jurisdiction

- 5.1 This Agreement is interpreted by and construed under the federal laws of the United States of America and the laws of the State of Michigan.

## 6 Rights of the Affiliate

HL7 International grants the following rights to the Affiliate, subject to the Rules and any conditions described in this section.

- 6.1 Participation in the governance of HL7 International as from time to time provided in the Rules, including.
  - 6.1.1 Affiliate's voting members, to the extent specified by section 6.2.1, are entitled to participate in the governance of HL7 International through the nomination and election of persons to positions as specified in the Rules.
  - 6.1.2 The Affiliate is entitled to a single voting membership on the HL7 International Council through the Affiliate Designated Representative.
  - 6.1.3 Members of the Affiliate are eligible to be elected co-chairs of work groups (WG) of HL7 International and serve on HL7 International Board-appointed committees, upon verification of membership with the Affiliate. NOTE: Eligibility to run for WG co-chair requires membership in HL7 International and/or the HL7 Affiliate that serves the country where the member has primary residence. If there is no affiliate in their country, the individual must be a member of HL7 International in order to be eligible to run for or hold a WG co-chair position.
- 6.2 Voting in HL7
  - 6.2.1 For HL7 International Review and Normative Ballots and the election of Officers of the HL7 International Board of Directors, the number of votes allotted to the Affiliate as specified in the HL7 Governance and Operations Manual.
- 6.3 HL7 Membership Dues
  - 6.3.1 The Affiliate shall establish a Membership Dues Schedule identifying its membership categories, and the fees payable and the number of member votes that may be exercised within the Affiliate by a member in each membership category.
  - 6.3.2 The Affiliate shall declare and advise HL7 International of the equivalence between its membership categories and the HL7 International membership categories as defined in the Rules.
- 6.4 HL7 Protocol Specifications
  - 6.4.1 HL7 International grants to the Affiliate a non-transferable, royalty-free, non-exclusive license and right to use the HL7 Protocol Specifications.
  - 6.4.2 Except as provided for in section 6.12.2, HL7 International grants to the Affiliate a non-transferable, royalty-free, exclusive (except as to HL7 International) license and right to distribute and provide access to the HL7 Protocol Specifications to members of the Affiliate in good standing.

- 6.4.3 Affiliate's Organizational Members are entitled to use of licensed HL7 Standards within the Affiliate's Territory.
- 6.4.3.1 "Licensed HL7 Standards" include HL7 2.x legacy and current versions, HL7 v3, CDA and other HL7 standards that are not part of an open licensing model.
  - 6.4.3.2 "Organizational Member" means Affiliate members such as: health service delivery organizations, health ministries, software product vendors, and systems integration companies.
  - 6.4.3.3 Organizations that have HL7 International USD memberships who also choose to be a member of an Affiliate must obtain an organizational membership under the terms defined by the Affiliate. This Affiliate membership entitles the external organization to participate in Affiliate governance and localization that affects how HL7 interoperability standards, including FHIR, are implemented within the context of the Affiliate's national ecosystem and legislative constraints and enablers.
- 6.4.4 Affiliate's right to provide access to HL7 International Protocol Specifications, as described above, is always subject to the Affiliate complying with the obligations specified in section 7.6.
- 6.4.5 Unless specifically authorized by HL7 International, the Affiliate is not authorized to reproduce, sell or distribute HL7 Protocol Specifications to non-members of the Affiliate.

## 6.5 Trademarks and Copyright

- 6.5.1 HL7 International grants to the Affiliate a non-transferable, non-exclusive, royalty-free (except as provided in section 7 below) license to use HL7 International Trademarks for official Affiliate business only, subject to compliance with the trademark obligations specified in section 7.6.1.2.
- 6.5.2 Rights afforded to Affiliates by HL7 International are not inherited automatically by members of that Affiliate. Members of Affiliates are not authorized to use HL7 International Trademarks or Logos without written permission from HL7 International. The usage of Affiliate Trademarks or Logos, including those derived from the HL7 International Logo, is determined by the Affiliates themselves. Affiliate agrees to share insight on these rules with their members and include these links on the Affiliate's website:

<http://www.hl7.org/legal/trademarks.cfm>

[www.hl7.org/documentcenter/public/legal/FHIR\\_Trademark\\_Policy.pdf](http://www.hl7.org/documentcenter/public/legal/FHIR_Trademark_Policy.pdf)

- 6.5.3 The Affiliate is also free to develop its own trademarks and domain names, provided such trademarks and domain names:
  - 6.5.3.1 Are not confusingly similar to the HL7 International Trademarks or domain names, or those of other Affiliates; and,
  - 6.5.3.2 Are approved in advance of use or registration, by the HL7 International Executive Committee, if such proposed trademarks or domain names involve HL7 International names or terms.

## 6.6 HL7 Educational Materials

- 6.6.1 HL7 Educational Materials that are copyrighted and solely owned by HL7 International shall be made available, directly to the Affiliate Designated Representative within two (2) weeks of the publication or presentation of such Materials. Additional HL7 Educational Materials may be made available to the Affiliate Designated Representative when (1) the faculty instructor has assigned copyright or joint copyright of the tutorial material to HL7 International to distribute to the chairs of the Affiliates, or (2) when the faculty instructor provides written permission for HL7 International to distribute to the Affiliates without assigning copyright.
- 6.6.2 Use of these HL7 Educational Materials is strictly limited to educational sessions and activities conducted by the Affiliate and its agents only within their territory. Agents of HL7 International and Affiliates shall have authorized access to Microsoft PowerPoint presentations of the HL7 Educational Materials that are copyrighted and solely owned by HL7 International for use in educational sessions and activities conducted by the Affiliate and its agents but may only distribute such materials as paper copies and by non-changeable electronic means.
- 6.6.3 Any and all use of these copyrighted educational materials outside of HL7 International or educational sessions and activities conducted by the Affiliate and its agents represents an infringement of the copyright and violates this Agreement.

## 6.7 Professional Certification

- 6.7.1 HL7 Professional Certification Tests will only be produced and administered electronically by HL7 International and its third-party testing service. HL7 Affiliates may facilitate but not proctor HL7 Certification Tests within its Territory via electronic means or paper/pencil methods.
- 6.7.2 HL7 International shall pay to the Affiliate once a year 25% of fees received from all Affiliate members and 10% of fees received for non-members from within its Territory who sit for the HL7 Professional Electronic Certification Tests at HOST Centers or Online Testing. Affiliate

members shall receive HL7 International member rates for HL7 Electronic Certification Testing.

- 6.7.3 HL7 International grants the Affiliate the exclusive right (except for HL7 International) to administer and proctor professional certification tests based on Affiliate Localizations and Implementation Guides particular to its Territory subject to the obligations set out in section 7.7. To be clear, the Affiliate has the option of producing certification tests for Affiliate Localizations and Implementation Guides electronically or via paper/pencil testing.

## 6.8 Translation

- 6.8.1 Subject to section 7 and section 10, HL7 International hereby grants the Affiliate the exclusive right to create, reproduce, distribute and control the use of Translations in its Territory.
- 6.8.2 The Affiliate is authorized to enter into formal agreements with third parties (including but not limited to other Affiliates) to create, reproduce, publish, and distribute Translations in its Territory, provided the Translations are balloted by the membership of the Affiliate, where deemed appropriate by the Affiliate.

## 6.9 Localization

- 6.9.1 Subject to section 7 and section 10, HL7 International hereby grants the Affiliate the exclusive right to create, reproduce, distribute and control the use of Affiliate Localizations in its Territory. Affiliate Localizations of HL7 Protocol Specifications require a successful ballot at the Affiliate level. HL7 Affiliates are authorized to produce formal and balloted HL7 Affiliate Localizations subject to the terms in section 7.4 and published as “HL7 (country) Localization (HL7 standard).”
- 6.9.2 The Affiliate is authorized to enter into formal agreements with third parties (including but not limited to other Affiliates) to create, reproduce, publish, and distribute Affiliate Localizations, provided the Affiliate Localizations are balloted by the membership of the Affiliate.
- 6.9.3 The Affiliate is authorized to offer free open access to its Affiliate Localizations for use in its Territory.

## 6.10 Other Material Produced by the Affiliate

- 6.10.1 The Affiliate may produce, distribute and author in its name and under its copyright, newsletters, minutes, Implementation Guides, tutorial manuals, and other materials relating to HL7 International Materials, provided that, to the extent that any such material includes excerpts of HL7 International Material, the Affiliate’s use of such excerpts shall be subject to the applicable obligations set out in section 7.

6.10.2 HL7 International grants the Affiliate the exclusive right to formally declare what Implementation Guides are considered to be the HL7-endorsed “base” or “core” implementation rules for the Affiliate's territory. These are usually called (in English): "HL7 [standard name] (country) Base / Core Implementation Guide”.

6.10.2.1 These base / core IGs shall derive from the standard as published by HL7 International. In the case of FHIR implementation guides, they should be developed in accordance with [FHIR Community Process](#) principles.

6.10.2.2 Only guides and specifications that have been taken through the formal HL7 Due Diligence and voting process, either by the Affiliate or at the HL7 International level, can be labelled as HL7 official specifications.

## 6.11 Attendance at HL7 International Events

6.11.1 Members of the Affiliate may, and are encouraged to, attend any HL7 International sponsored event. Registration fees will be assessed at the HL7 International membership rate.

6.11.2 HL7 International will provide one (1) complimentary meeting registration at each of the HL7 International Working Group Meetings and Plenary Meetings for the Affiliate Designated Representative.

## 6.12 Conditions

6.12.1 All rights granted to the Affiliate under section 6 are conditional on the Affiliate complying with its obligations defined in section 7.

6.12.2 If the Affiliate fails to comply with any of its material obligations as defined in section 7, HL7 International may, by giving notice in writing, suspend any or all of the rights granted to the Affiliate under section 6, provided that:

(a) the suspension of rights shall continue only until Affiliate cures its failure to comply, and

(b) in determining which rights to suspend, HL7 International shall take into account the severity of the failure to comply, as determined in its sole judgment.

(c) For clarity and as noted in section 7.1.6, failure to submit payments and/or the required reports by the due date will result in the Affiliate immediately being placed in lapsed status until such time that the payment and/or required reports have been submitted.

6.12.3 HL7 International will not grant any third party the right to distribute or provide access to the HL7 Protocol Specifications within the Affiliate's

Territory except as provided by licenses to HL7 Organizational Members under the Rules or in exceptional circumstances, in which latter case HL7 International will provide the Affiliate with 90 days notice of its intent to grant such right.

### 6.13 Notice

6.13.1 HL7 International will provide the Affiliate with notice of all substantive changes to the Rules and the HL7 International License Agreement and, wherever possible, such notice shall be given at least 15 days before such changes come into effect.

## 7 Obligations of the Affiliate

The Affiliate accepts the obligations to HL7 International in section 7 and agrees that failure to comply with them may result in suspension of the Affiliate's rights under section 6.12.2 or termination of the Agreement for cause under section 10.2.

7.1 Fees and Payments. The Affiliate agrees that:

- 7.1.1 It will forward to HL7 International on an annual basis the greater value of either \$1,000 or 20% of all Membership Fees collected by the Affiliate during the Membership Year just ended or terminated.
- 7.1.2 It is not the intent of HL7 International to profit from the Affiliate, but to cover those expenses incurred by HL7 International to support its activities and contribute to the development of HL7 Standards, Tools, Implementation Guides, Educational Materials, to support HL7's Strategic Initiatives and to fund the complimentary WGM registrations provided to Affiliate Chairs. In accordance with the provisions of section 9, this percentage or fixed fee provided for above may be adjusted from time to time.
- 7.1.3 Affiliate will make the annual payments referred to above within ninety (90) days following the beginning of the Affiliate's fiscal or Membership Year and within ninety (90) days following the termination of this Agreement. Consequently, the Affiliate shall declare to HL7 International the applicable definition of fiscal or Membership Year.
- 7.1.4 The Affiliate will accompany the annual payment with:
  - 7.1.4.1 A financial statement showing the calculation of fees based on the Affiliate's preceding fiscal or Membership year.
  - 7.1.4.2 The Affiliate's membership categories: and the criteria and membership fees associated with those categories of membership.

- 7.1.4.3 The named voting members of each organization and the number of members in each membership category at the end of the Affiliate's preceding fiscal or membership year.
- 7.1.4.4 An on-line Form B report, to be completed on the Affiliate's HL7 International Confluence Space, detailing that Affiliate's activities and achievements for the preceding year and additional monitoring information, as required by HL7 International to facilitate the provision of summaries of activity across all Affiliates.
- 7.1.4.5 A copy of the register of licensed parties that downloaded the HL7 Protocol Specifications, if required under section 7.6.1.6.

7.1.5 Affiliate agrees to make all payments to HL7 International in US Dollars. The Affiliate will also pay all bank fees related to wiring funds for its annual dues to HL7 International. Failure to submit the full payments and/or the required reports by the due date will result in the Affiliate immediately being placed in lapsed status until such time that the payment and/or required reports have been submitted.

## 7.2 Governance

7.2.1 The Affiliate strives to adhere to international SDO principles for due diligence in developing standards:

### 7.2.1.1 Openness

Participation shall be open to all parties who are directly and materially interested in the activity in question. There shall be no undue financial barriers to participation. Voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted based on technical qualifications or other such requirements.

### 7.2.1.2 Lack of dominance

The standards development process shall not be dominated by any single interest category, individual or organization. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.

### 7.2.1.3 Balance

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance.

### 7.2.1.4 Coordination and harmonization

Good faith efforts shall be made to resolve potential conflicts between and among published specifications.

#### 7.2.1.5 Notification of standards development

Timely and adequate notice of specification development activity shall be announced in media suitable to demonstrate that a meaningful opportunity for participation, debate and deliberation by all directly and materially interested parties in a fair and equitable manner was provided.

#### 7.2.1.6 Consideration of views and objections

Prompt consideration shall be given to the written views and objections of all participants.

#### 7.2.1.7 Consensus Vote

Evidence of consensus in accordance with these requirements and the accredited procedures of the standards developer shall be documented.

#### 7.2.1.8 Appeals

Written procedures shall contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural appeals regarding any action or inaction. Procedural appeals include whether a technical issue was afforded due process.

#### 7.2.1.9 Written procedures

Written procedures shall govern the methods used for standards development and shall be available to any directly and materially interested party.

### 7.2.2 The Affiliate agrees to operate according to the following basic governance principles:

#### 7.2.2.1 Open membership. Membership in the Affiliate shall be open to all persons and entities with an interest in health informatics standards within its Territory that comply with at least one of the following criteria:

7.2.2.1.1 Individuals with primary residence within the Affiliate's territory or possess a current passport from the Affiliate's territory.

7.2.2.1.2 Organizations with primary residence within the Affiliate's territory and/or their employees who possess a current passport from the Affiliate's territory.

7.2.2.1.3 Members of HL7 International

7.2.2.1.4 Members of another HL7 Affiliate where the person has primary residence (personal members) or their organization has primary operations (corporate members)

7.2.2.1.5 Individuals and organizations with primary residence in countries that have no HL7 Affiliate (apart from the USA)

Individuals or organizations with primary residence in the USA who are not members of HL7 International are not eligible to join an HL7 Affiliate. However, individuals can continue to be members of any HL7 Affiliate to which they belonged at the time when their primary country of residence became the USA.

Individuals or organizations with membership in more than one affiliate and/or HL7 International will receive all eligible rights and duties from each.

7.2.2.2 Democratic election of the executive and technical leadership of the Affiliate.

7.2.2.3 Establishment and operation of the Affiliate as a not-for-profit organization.

7.2.2.4 Balloting rules that are consensus-based; majority-qualified (e.g. more than 60% affirmative of the combined "yes" and "no" votes); and include an obligation to seek satisfactory resolution of negative votes.

7.2.3 The Affiliate agrees to create written policies for each of the above principles which are approved by vote of the Affiliate's membership. These policies and the Bylaws or other governing document(s) of Affiliate shall be provided to HL7 International and filed with this Agreement. The Affiliate agrees to abide by the same policies, procedures, and Bylaws of HL7 International if it does not adopt its own and notify HL7 International if this is its intention.

7.2.4 The Affiliate agrees to immediately notify HL7 International of any substantial changes in the above policies or governing documents, and to provide copies of same.

7.2.5 The Affiliate agrees to hold elections for officers as per established policies of the Affiliate and provide HL7 International with the results of the elections. If no specific election policies are provided by the Affiliate, the policies and procedures used by HL7 International will be used.

7.2.6 HL7 International recognizes and acknowledges the Affiliate's responsibility to operate in accordance with the laws within its Territory.

- 7.2.7 The Affiliate endeavors to ensure that the Affiliate’s representatives cast their votes to reflect the diversity of views of the members of the Affiliate, when voting on HL7 International matters.

### 7.3 Participation

- 7.3.1 The Affiliate endeavours to participate actively in HL7 International matters to ensure they remain a member in good standing of the organization. This includes:

- 7.3.1.1 Each Affiliate shall provide to HL7 and maintain current contact information (email and telephone) for at least two HL7 voting members of the Affiliate for purposes related to the governance structure of the Affiliate. Communications between the HL7 Membership Director and the Affiliate will be copied to both contacts.
- 7.3.1.2 The Affiliate shall be responsive to requests for information from the HL7 Membership Director and the HL7 International Council co-chairs. This means the Affiliate will respond with 14 days of the request.
- 7.3.1.3 HL7 International shall establish an HL7 Affiliate Confluence space where Affiliates annual Form B reports will be posted.
- 7.3.1.4 The Affiliate is permitted and encouraged to use Confluence as a working area for their own members and meetings.
- 7.3.1.5 The Affiliate should participate in HL7 International Council virtual and in-person meetings as much as possible within the constraints of affordability and differences in global time zones.  
The HL7 International Council will endeavor to vary virtual meeting times to permit International Affiliate members to participate at reasonable local times of day (between 06:00 to 22:00 hours local time)
- 7.3.1.6 If the Affiliate has not participated in 3 International Council meetings and/or IC e-Votes in the previous 12 months, their status will be changed to “Inactive” and, until they meet these criteria, they are no longer counted in the quorum thresholds for International Council decision making.

### 7.4 Translation

- 7.4.1 The Affiliate is responsible for all costs incurred by the Affiliate in producing and distributing Translations.

- 7.4.2 Any Translation produced by or for the Affiliate shall be jointly copyrighted by HL7 International and the Affiliate.
- 7.4.3 For the utmost clarity, all copyright in and legal title to any original HL7 International Material from which a Translation is produced remains with HL7 International.
- 7.4.4 The Affiliate shall ensure that any Translation produced by the Affiliate:
- (a) is accurate and consistent with the English original content, and
  - (b) bears all legends and copyright notices from time to time required by HL7 International, including a legend stating that in the event of any inconsistency between the Translation and the English original content, the English original content shall prevail over the Translation.
- 7.4.5 For the avoidance of doubt, HL7 International shall not have the right to pre-approve Translations, or amendments to Translations.
- 7.4.6 The Affiliate hereby grants HL7 International a fully paid, non-exclusive license to distribute during the Term any Translation produced by or for the Affiliate, where such license is subject to any reasonable conditions imposed by the Affiliate at the time the Translation is Registered with HL7 International, and provided that HL7 International:
- (a) acknowledges the Affiliate's joint ownership of the copyrighted Translation, and
  - (b) preserves any notices and legends reasonably required by the Affiliate that are not inconsistent with this Agreement.
- 7.4.7 Upon their completion, translated versions of the HL7 Protocol Specifications and all other translated HL7 materials shall be promptly forwarded to HL7 International for publication to its members as Affiliate Material, subject to the provisions of section 8.3.

## 7.5 Localization

- 7.5.1 The Affiliate is responsible for all costs incurred by the Affiliate in producing and distributing Affiliate Localizations.
- 7.5.2 Any Localization produced by or for an Affiliate shall:
  - 7.5.2.1 Not involve alteration of original HL7 International Material other than to the minimum extent necessary to meet the unique local requirements within the Affiliate's Territory.
  - 7.5.2.2 Be developed in conformance with applicable localization rules.
  - 7.5.2.3 Be done as a work under a copyright jointly owned by HL7 International and the Affiliate.
  - 7.5.2.4 Bear all legends and copyright notices from time to time required by HL7 International.
  - 7.5.2.5 Be delivered to HL7 International prior to its being released more widely by the Affiliate.
  - 7.5.2.6 Be balloted according to the Affiliate's balloting rules.
- 7.5.3 For the avoidance of doubt, HL7 International shall not have the right to pre-approve Affiliate Localizations, or amendments to Affiliate Localizations, but shall be entitled to enforce its rights under this Agreement (e.g., by adding any notices or disclaimers required).
- 7.5.4 The Affiliate hereby grants HL7 International a fully paid, non-exclusive license to distribute during the Term any Affiliate Localization produced by or for the Affiliate where such license is subject to any reasonable conditions imposed by the Affiliate at the time the Affiliate Localization is Registered with HL7 International, and provided that HL7 International shall:
  - (a) acknowledge the Affiliate's co-ownership of the copyright in the Affiliate Localization, and
  - (b) preserve any notices and legends reasonably required by the Affiliate and not inconsistent with this Agreement.

## 7.6 Protection of Intellectual Property, Copyright and Trademark

- 7.6.1 The Affiliate agrees to:
  - 7.6.1.1 Adhere to the IP Policy (see Appendix B) in relation to HL7 International Materials.

- 7.6.1.2 Require its members to comply with the terms of the IP Policy and the HL7® International License Agreement as from time to time in force.
- 7.6.1.3 The Affiliate agrees to use commercially reasonable efforts to protect HL7 International's Intellectual Property rights.
- 7.6.1.4 Promptly informing HL7 International of any breach or noncompliance with this Agreement, the HL7 International License Agreement or any other agreement upon which such a breach or noncompliance may affect HL7 International's rights.
- 7.6.1.5 Declaring to HL7 International, at the discretion of the Affiliate, one of the following options to distribute the HL7 Protocol Specifications to members of the Affiliate within its Territory:
  - 7.6.1.5.1 Via a secure channel of the Affiliate's website, available only to the Affiliate's members, subject to each member's acceptance of the terms of the then current version of the HL7 International License Agreement when accessing HL7 Protocol Specifications via the secure channel.
  - 7.6.1.5.2 By allowing its members to access HL7 Protocol Specifications via the HL7 International website for use within its Territory. HL7 International shall make available to the Affiliate such access information as may be appropriate to allow the Affiliate to enable such access by its members.
- 7.6.1.6 Under option 7.6.1.5.1 above, make reasonable efforts to maintain a current register of licensed parties, their contact details, and the HL7 Protocol Specifications (or parts thereof) that were downloaded.

7.6.2 Regarding trademarks, the Affiliate agrees:

- 7.6.2.1 To recognize the validity of all HL7 International Trademarks; and to comply with HL7 International's instructions regarding the use of the HL7 International Trademarks (see Appendix B);
  - 7.6.2.2 That all goodwill existing in and created by use of the HL7 International Trademarks (including all goodwill associated therewith) remains the exclusive property and benefit of HL7 International; and
- 7.5.3.3 To use the most current version of the HL7 International logo as provided by HL7 International

## 7.7 Member Compliance

7.7.1 The Affiliate agrees to advise its members of, obtain their agreement to and take all reasonable steps to ensure their compliance with, the following:

7.7.1.1 That no ownership rights to HL7 International Material or HL7 International Trademarks are transferred to any other party.

7.7.1.2 When participating in HL7 International activities, to abide by the prevailing HL7 International Governance and Operations Manual (GOM), available at the HL7 International website (see Appendix B).

## 7.8 Professional Certification

7.8.1 The Affiliate shall not claim or imply HL7 International accreditation of any professional certification test conducted and proctored under section 6.7.3 (in relation to Affiliate Localizations and Implementation Guides particular to the Affiliate's Territory), unless the right to claim such accreditation is specifically granted by HL7 International in writing.

7.8.2 When exercising the right to conduct professional certification testing under 6.7.3 (in relation to Affiliate Localizations and Implementation Guides particular to the Affiliate's Territory), the Affiliate agrees to comply with the following process:

7.8.2.1 Prior to performing any certification testing on material that is for Affiliate Localizations and/or Implementation Guides, the Affiliate will forward all such material to the HL7 International's Director of Education, who will oversee a quality control review of the material by the Education Advisory Council and other experts as deemed appropriate.

7.8.2.2 HL7 International's Director of Education will notify the Affiliate of all approved material for Certification Testing Extensions (for Affiliate Localizations and/or Implementation Guides).

7.8.2.3 Affiliate agrees to not perform certification testing on material that is not explicitly approved by the HL7 Director of Education.

7.8.2.4 As required in 14.2, all communications between the Affiliate and HL7 International shall be in English, including the certification testing extensions the Affiliate is seeking.

## 7.9 Representation

7.9.1 Except as otherwise approved in writing by HL7 International, the Affiliate shall not make any statements on behalf of HL7 International, or purport or imply that it has any authority to speak on behalf of, or bind, HL7 International.

7.9.2 Affiliate grants to HL7 International a non-exclusive, royalty-free license to use and reproduce Affiliate trademarks as referenced in section 6.5.3, provided that appropriate copyright statements are included. Such use and reproduction shall be subject at all times to appropriate inspection and quality control measures imposed by the Affiliate.

#### 7.10 Conditions

7.10.1 The requirement that the Affiliate comply with obligations under this section 7 are conditional on the Affiliate receiving the rights that HL7 International grants to the Affiliate under section 6.

7.10.2 If HL7 International fails to comply with any of its material obligations as specified in section 6, the Affiliate may by giving notice in writing, be temporarily relieved of its obligations as defined in this section 7, provided that:

(a) the suspension of obligations shall continue only until HL7 International cures its failure to comply, and

(b) in determining which obligations to suspend, the Affiliate shall take into account the severity of the failure to comply, as determined in its sole judgment.

## 8 Proprietary Rights

8.1 The Affiliate agrees that no original HL7 International document may be altered without the written authorization of HL7 International, except as provided for in this Agreement.

8.2 No local change or additions to the HL7 Protocol Specifications shall be made without the written approval of HL7 International, except for the production of Affiliate Localizations in accordance with section 6.9.

8.3 HL7 International agrees not to alter any of the Affiliate Material provided by the Affiliate other than:

(a) with the written authorization of the Affiliate, or

(b) to ensure that such Affiliate Material conforms to the requirements of this Agreement.

## **9 Amendment of Agreement**

- 9.1 HL7 International may propose amendments to this Agreement at any time by action of the HL7 International Board of Directors.
- 9.2 The Affiliate or the HL7 International Council may propose amendments to this Agreement at any time.
- 9.3 Any changes to this Agreement proposed by the Affiliate or the International Council shall be referred to a task force appointed by the International Council that shall invite a representative of HL7 International to participate.
- 9.4 Each party will be given sixty (60) days to execute amendments to this Agreement.
- 9.5 Any amendment to this Agreement is only valid upon the execution of an amendment signed by both Parties.
- 9.6 If agreement cannot be reached on proposed amendments, either party may employ the Termination provisions afforded in section 10 or the Dispute Resolution provisions afforded in section 11.

## **10 Termination**

- 10.1 Either Party may terminate this Agreement without cause upon ninety (90) days written notice.
- 10.2 Either Party may terminate this Agreement for cause, effective immediately, should a material breach occur which remains uncured for a period of thirty (30) days after written notice of the breach is given.
- 10.3 In the event of any termination, except upon a breach by HL7 International, the Affiliate shall remain liable for paying any accrued dues and fees through the effective date of termination.
- 10.4 Notwithstanding the termination of this Agreement, all provisions respecting the protection of HL7 International's and the Affiliate's intellectual property rights shall remain in effect. However, except as otherwise provided in this Agreement, the Affiliate rights and obligations under this Agreement shall cease at midnight on the date of termination (in the time zone of the Affiliate's corporate head office).
- 10.5 In the event of termination of the Agreement as described above, the Affiliate will immediately be restricted from using or distributing any HL7 International Material, expressly including, but not limited to, any of the following without expressed written consent from HL7 International:
  - 10.5.1 HL7 International Trademarks;
  - 10.5.2 Any Affiliate logo or trademark comprising any of the HL7 International Trademarks or anything confusingly similar to the HL7 International Trademarks; and
  - 10.5.3 All print and electronic copies of HL7 International Materials.

- 10.6 Within sixty (60) days of termination, regardless of the grounds, the Affiliate shall tender a written certification to HL7 International confirming that the Affiliate has ceased all use of HL7 International Materials noted in section 10.5.
- 10.7 HL7 International and the Affiliate agree that from and after the termination of this Agreement, neither Party shall have any right to publish, distribute, sell, license or otherwise make available to third parties (including members of HL7 International or the Affiliate) anywhere in the world, any Translations or Affiliate Localizations produced by the Affiliate; provided, however, that specific uses by either Party may be permitted with the prior written permission of the other Party, which permission may be withheld or be made subject to conditions at the sole discretion of such Party.

## **11 Dispute Resolution**

- 11.1 In the event of any dispute, claim, question, or disagreement arising from or relating to this Agreement or the breach thereof, the Parties hereto shall use the following process:
- 11.1.1 The Parties shall use their best efforts to settle the dispute, claim, question, or disagreement. To this effect, they shall consult and negotiate with each other in good faith and, recognizing their mutual interests, attempt to reach a just and equitable solution satisfactory to both Parties.
- 11.1.2 In the event that the Parties are unable to resolve the dispute in accordance with section 11.1.1, either Party shall be entitled to require that the dispute be escalated to a mutually agreeable mediator, which request shall be agreed to by the other Party.
- 11.1.3 If they do not reach such solution within a period of sixty (60) days in accordance with sections 11.1.1 and 11.1.2, then, upon notice by either Party to the other, all disputes, claims, questions, or differences shall be finally settled by binding arbitration administered by the American Arbitration Association in accordance with the provisions of its Commercial Arbitration Rules.

## **12 Disclaimer of Warranties**

- 12.1 The Parties to this Agreement make no expressed or implied warranties other than those contained in this Agreement.
- 12.2 Both Parties acknowledge that both Parties are membership organizations, and that all HL7 International Material and Affiliate Material is developed by their members, individually or collectively, without warranty. Accordingly, the Parties agree that:
- (a) all HL7 International Material and Affiliate Material licensed or made available to the other Party under this Agreement is provided "AS IS" and without warranty of any nature whatsoever, and
- (b) under no circumstances shall either Party have any liability for and claims, losses,

damages, attorneys fees, or otherwise (collectively, "Losses") to the other Party, its directors, officers, employees, members or agents, or to any third party, with respect to any use of, or reliance on, any HL7 International Material and Affiliate Material, including without limitation as a result of any Losses relating to the infringement, or alleged infringement, of the intellectual property rights of any third party.

### 13 Affiliate Chair

- 13.1 At the time of the execution of this Agreement the Affiliate shall inform HL7 International of the person who is Affiliate Chair and subsequently shall inform HL7 International of any change of Affiliate Representatives & Co-Chairs.
- 13.2 At the time of the execution of this Agreement the Affiliate shall inform HL7 International of the names of any additional voting members of the Affiliate and subsequently shall inform HL7 International of any change of voting members.
- 13.3 At the time of the execution of this Agreement the Affiliate shall inform HL7 International of the names of any individual members of the Affiliate who are co-chairs of HL7 International Work Groups and subsequently shall inform HL7 International of any change in the membership status of those individuals or if any co-chairs of HL7 International Work Groups join the Affiliate.
- 13.4 In order to fulfil the reporting requirements of Section 7.1.4.4, and to participate in International Council e-votes, all Affiliate Chairs are required to maintain an active HL7 International Confluence Account.

### 14 Miscellaneous

- 14.1 Upon execution of this Agreement, HL7 International shall make available, directly to the Affiliate Chair or the Affiliate Designated Representative, access to approved HL7 Protocol Specifications and Other HL7 Material through the HL7 web site.
- 14.2 All communications between the Parties shall be in English.

### 15 Signatories

**HL7 International**

**HL7 [Affiliate Name]**

Signed: \_\_\_\_\_

Signed \_\_\_\_\_

—

Charles Jaffe, MD PhD  
Chief Executive Officer  
HL7 International

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Signed: \_\_\_\_\_

—

Mark McDougall  
Executive Director  
HL7 International

Date: \_\_\_\_\_

Signed: \_\_\_\_\_

—

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

## Appendix A: Definitions

The following definitions apply for the purposes of this Agreement:

<b>Term</b>	<b>Definition</b>
<b>Affiliate Chair</b>	The person nominated as Chair of the Affiliate under section 13.1.
<b>Affiliate Designated Representative</b>	The Affiliate Chair or such other Affiliate member in good standing as may be nominated by the Affiliate Chair from time to time.
<b>Affiliate Localization</b>	Work product made by constraining and/or supplementing HL7 Protocol Specifications, HL7 Educational Materials and /or Other HL7 Material to meet the specific needs within the Affiliate’s Territory but not including a Translation. Affiliate Localizations of HL7 Protocol Specifications require a successful ballot at the Affiliate level. HL7 Affiliates are authorized to produce formal and balloted HL7 Affiliate Localizations subject to the terms in section 7.4, and published as “HL7 (country) Localization (HL7 standard).”
<b>Affiliate Material</b>	Material developed by the Affiliate including, but not limited to, Affiliate Localizations, Implementation Guides, Translations, trademarks, educational materials, and newsletters. See related, HL7 International Material.
<b>GOM</b>	The HL7 Governance and Operations Manual which serves as the declarative source of business process for HL7 International.
<b>HL7</b>	The collective of HL7 International and HL7 International Affiliates.
<b>HL7 Professional Certification Tests</b>	HL7 International instruments and processes via which individuals are accredited as achieving specified levels of understanding of specific HL7 Protocol Specifications.
<b>HL7 Professional Certification Test Extensions</b>	Material tested is above and beyond what is covered in the HL7 Professional Certification Tests and limited to Affiliate Localizations and Implementation Guides particular to the Affiliate’s territory.
<b>HL7 Educational Materials</b>	Materials presented at tutorials during the Working Group Meetings, Education Summits and other educational resources provided by HL7 International.

<b>Term</b>	<b>Definition</b>
<b>HL7 International License Agreement</b>	The HL7® International License Agreement Reminder (see Appendix B) and any other terms and conditions relating to licensing and use of HL7 International Material including any that are displayed at the time that a person orders or downloads such Material, that appear as legends or notices on such Material, or that otherwise accompany such Material at the time of receipt by the person.
<b>HL7 International Council</b>	The collective leadership of the Affiliates as defined in the GOM.
<b>HL7 International Material</b>	HL7 Protocol Specifications, HL7 Educational Material and Other HL7 Material. See related, Affiliate Material.
<b>HL7 International Trademarks</b>	Any and all registered and unregistered trademarks, service marks, certification marks and logos from time to time owned by HL7 International.
<b>HL7 Organizational Member</b>	The category of membership privileges granted to a corporate entity acquiring an HL7 membership for commercial purposes as defined in the HL7 Bylaws.
<b>HL7 Protocol Specifications</b>	Work products of HL7 International as defined in the HL7 International Governance and Operations Manual, as referenced in Appendix B.
<b>Implementation Guides</b>	HL7 Implementation Guides (IG) provide guidance to facilitate implementation of published HL7 standards. The IGs may specify constraints (removal of non-mandatory features) and may specify terminology where it is not mandated. The intent of an IG is to ensure that generated artifacts are fit for a specific purpose while maintaining interoperability.
<b>Membership</b>	The fact or status of being a member of an HL7 organization with concomitant rights and obligations.
<b>Membership Fees</b>	Fees received / collected by an Organization (e.g. HL7 International, Affiliate) in order to become a member of that organization.
<b>Membership Dues Schedule</b>	Membership fees charged by the Affiliate to different categories of their members.

<b>Term</b>	<b>Definition</b>
<b>Membership Year</b>	A fixed period of twelve (12) months which is used to define the period during which the Affiliate is a member of HL7 International. This period is used for the calculation and invoicing of the Affiliate's membership fees as well as membership renewal. This period may be specified by the Affiliate and may be different to the fiscal year of HL7 International and / or the Affiliate.
<b>Other HL7 Material</b>	Newsletters, minutes, Implementation Guides, tutorial manuals, Ambassador presentations, HL7 Primers and other materials prepared by HL7 International and relating to HL7 International, its mission, vision, strategies and outputs.
<b>Registered</b>	Only when pertaining to materials created by the Affiliate: Formal notification by the Affiliate to HL7 International of the existence of materials created under the terms of this Agreement (versus sending actual materials).
<b>Rules</b>	GOM, Bylaws, and IP Policy, as per Appendix B. In the event of any contradiction or ambiguity between the terms of this Agreement and any Rules document, the terms of the Rules document shall control.
<b>Territory</b>	The geographic area within which the Affiliate operates and provides services to its members as identified in section 2.1. A Territory can equate to one country, multiple countries or even areas within a country, but Territories do not overlap.
<b>Translation</b>	Work product made by translating the HL7 Protocol Specifications, HL7 Educational Materials or Other HL7 materials into another language, without otherwise modifying, constraining or supplementing that content.

## Appendix B: References

The following external documents are referenced in this Agreement:

<b>Reference Document Inventory</b>
HL7 International Bylaws (“Bylaws”) <a href="http://www.hl7.org/about/bylaws.cfm">http://www.hl7.org/about/bylaws.cfm</a>
HL7 International Governance and Operations Manual (“GOM”) <a href="http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf">http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf</a>
HL7 Policy Governing the use of HL7® International Standards and Other Intellectual Property (“IP Policy”) <a href="http://www.hl7.org/legal/ippolicy.cfm">http://www.hl7.org/legal/ippolicy.cfm</a>
HL7 owned trademarks <a href="http://www.hl7.org/legal/trademarks.cfm">http://www.hl7.org/legal/trademarks.cfm</a>
HL7® International License Agreement Reminder, as provided with HL7 International Materials (note: this is a click-through agreement accepted whenever a member downloads HL7 International Materials) <a href="http://www.HL7.org/permalink/?AffiliateIPClickLicense">http://www.HL7.org/permalink/?AffiliateIPClickLicense</a>