AEGIS

Response to Request for Information

Health and Human Services
Office of the National Coordinator
for Health Information Technology

Entitled:
Electronic
Prior Authorization Standards,
Implementation Specifications, and
Certification Criteria

Federal Registry: RIN 0955–AA04
Response

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Overview

AEGIS.net, Inc. (AEGIS) is a Small Business Administration (SBA) designated small business with primary offices in Rockville, Maryland. Founded in 1996, we provide a variety of Information Technology (IT) solutions to commercial industry, the Department of Defense, and federal civilian agencies of the U.S. Government. AEGIS' core services consist of:

- Software Functional and Performance Testing
- Application Design and Development
- Organizational Performance / Process Improvement
- Project Management and Methodology

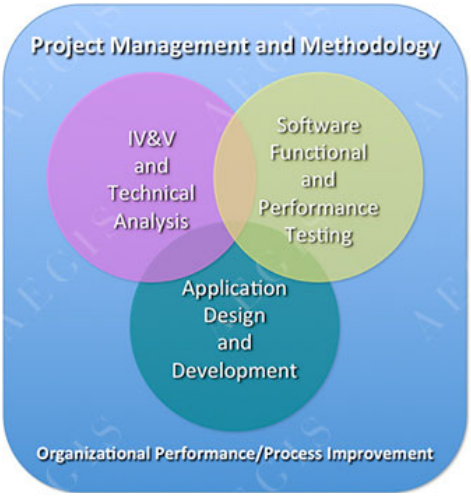


Figure 1: AEGIS Core Capabilities

AEGIS employs our process-driven approach to IT projects, called the *AEGIS Shield Methodology*. Based on these processes, AEGIS is certified as an **ISO 9001:2015, ISO 20000-1:2018, and ISO 27001:2013**.

RFI Response

B.1. Company's experience in healthcare and related domains

Experience

Our journey supporting Healthcare IT has spanned more than two (2) decades, beginning when our principals united to found AEGIS after supporting a small-to-medium health plan vendor named AMISYS with group benefits, membership and a claims processing platform. From that initial glimpse into the Healthcare scene, AEGIS' exposure has grown to support various government programs such as HHS/ONC and the NHIN (Nationwide Health Information Network), HHS/PHS US Public Health Service (Commissioned Corps), Department of Veterans Affairs (VHA) and the MyHealtheVet Program, the VA and DoD Virtual Lifetime Electronic Record (VLER) Health Program, and SSA and the MEGAHIT Program. From government to commercial customers, AEGIS has supported the US Behavioral Care industry continuously for nearly twenty years, with Medco, Value Options Healthcare, and most recently Beacon Health Options (now owned by Anthem BCBS).

- Both in Healthcare and in many of AEGIS' other IT Services, successful IT Service Delivery has seen quality and testing inextricably linked.

Our approach and support of the US Healthcare and Standards community has spanned more than a decade. Initially with the HHS/ONC and NHIN, AEGIS was engaged to build and deploy an Interoperability Test Lab (initially dubbed the ONC "InteropLab"), a Sandbox approach leveraging the NHIN Connect Open Source Initiative (NHIN Reference Implementation), followed by AEGIS' Developers

Integration Lab (DIL) technology, now a patented[1] approach and technology which focused on supporting "Interoperability Testing seeking to validate that multiple systems implementing a particular standard or set of standards can all communicate with one another". The DIL further defined an approach to mitigate standards-based implementation by introducing "Interoperability Test-Driven-Development (ITDD), which applies the same principles by incorporating automated testing of interoperability into the development lifecycle." For more than five (5) years, the DIL showcased how TDD could be leveraged to accelerate standards-based adoption, supporting Sequoia (formerly Healtheway) so that eHEX participants were able to "self-service" test their implementation and conformance on a daily basis for free. Other successful programs such as Walgreens and the VA National Immunization Program became a showcase to Healthcare Standardization and Interoperability, most importantly, validating for the VA and the ONC that they were on the correct path.

The AEGIS DIL Technology initially made an appearance at the IHE Connectathon in 2012 and 2013 in support of the ONC VLER Support Program, and, later in support of HHS/OPA and Family Planning IHE Questionnaire and Questionnaire-Response implementation. HHS/OPA was further selected to appear in the HIMSS 2015 Interoperability Showcase and the implementers showcased how they leveraged IHE and the AEGIS DIL (Test-Driven-Development) to accelerate their adoption and mitigate interop issues.

Next the AEGIS team took those lessons learned, as well as input from the user community, and reimagined the DIL 2.0 as Touchstone v1.0, with a focus toward supporting HL7 FHIR. AEGIS delivered this to the HL7 FHIR Connectathon community in October 2015, alongside the FHIR DSTU2 Standards definition and specifications for FHIR Testing and the FHIR level one resource FHIR TestScript that ensures "a structured set of tests against a FHIR server or client implementation to determine compliance against the FHIR specification".

With more than a decade as an HL7 Corporate Member, and Contributor, eight (8+) years supporting HL7 FHIR and numerous HL7 Corporate sponsorships (including being an HL7 Benefactor sponsor), HL7 Workgroup Meeting sponsor and HL7 FHIR Connectathon sponsor, AEGIS has significantly invested in the future of FHIR through the approach of supporting better "continuous" testing with Touchstone. Recognized as an integrated-Ecosystem, Touchstone now celebrates a community of more than 900 Organizations spanning 54 Countries worldwide. AEGIS has dedicated resources (FHIR Specification experts, FHIR Implementation experts, Healthcare Profile geeks, and Healthcare Testing specialists) to contribute to the global FHIR Community by advancing numerous FHIR Testing initiatives. Many made their initial appearances at the HL7 FHIR Connectathon events, including supporting the Da Vinci and CARIN Alliance (Blue Button) Accelerators which went on to have several HIMSS Interop Showcase appearances.

[1] AEGIS Automated Conformance and Interoperability Test Lab – Patent US20130297973A1

B.2. Electronic Prior Authorization Standards Request for Comments

ONC seeks public comments on whether to adopt additional standards, implementation specifications, and certification criteria as part of the Certification Program to ensure that technology is available to providers for the automated, electronic completion of prior authorization tasks.

Yes. We do recommend adopting additional certification criteria.

AEGIS.net has been involved in and hosted certification testing programs both in the United States and internationally for many years. In our experience, participation in the process of designing new guidance, new workflows, and new technologies used in the exchange of healthcare information is highly dependent on **whether or not the guidance is mandated**. This mandate may come from an industry group or the government. While we would like to see collaboration and vigorous testing of planned guidance on a voluntary basis, our experience has shown that **the real work in molding specifications comes after it has been directed for use**.

To that end, while we hold no opinion on the differing specifications that implementers may use to fulfill the Burden Reduction rules, we respectfully submit that in order for the specifications for Burden Reduction to mature at a meaningful pace, **ONC must provide a mandate via a certification program**.

B.2.1 CERTIFIED HEALTH IT FUNCTIONALITY

Should ONC adopt a certification criterion for prior authorization that accounts for the full, HIPAA compliant workflow for prior authorization transactions including translation from FHIR to the X12 standard? Or should ONC adopt certification criteria that include only the workflows up to the point of translation?

Our recommendation would be to certify up to the point of translation. This would still meet the community where it is today by allowing implementers to use X12 functionality with translations and plan to align development of future requirements, e.g. (Da Vinci PAS) FHIR, in concert with supporting a certification criterion for prior authorization.

If ONC were to propose to include these functional capabilities as part of the Certification Program, how should a new certification criterion (or multiple certification criteria) be structured, including technical requirements, attributed standards, and implementation specifications? ONC's experience adopting certification criteria suggests that, at times, combining related functions into a single Health IT Module is most appropriate, while in other cases, health IT functionalities are best represented by separate certification criteria, despite being functionally related. For instance, under a single criterion, different

products and services in the market may be "tightly coupled" for the purposes of certification, even when they can be purchased and implemented separately. We seek the public's input on which functional capabilities for prior authorization should be tested and certified together as part of one certification criterion, and which capabilities should be separated into different certification criteria.

Our recommendation would be for separate certification criteria.

We find that once ONC adds a specification or implementation guide to their certification program criteria, implementers come to the table and help move the guides forward through increased participation and testing. As there is great expense in having to develop to a specification, implementers often wait to see which criteria they are required (by regulatory or industry mandate) to meet before embarking on any development projects.

ONC has a multi-module model in Patient Access, where they point to existing implementation guides and specifications and have separate criteria for different business functions. In the case of burden reduction, the solution set tends to fall into three functional areas: coverage discovery, information gathering and data preparation, and the prior authorization process. These areas may each be covered by a separate Health IT module, so it could make logical sense for each to be covered under separate certification criteria. Implementers could then certify to each certification criterion (functional module) applicable to them.

B.2.2 IMPLEMENTATION SPECIFICATIONS FOR PRIOR AUTHORIZATION

What is the current readiness of the three FHIR-based Da Vinci IGs described above [the HL7® FHIR® Da Vinci Coverage Requirements Discovery (CRD), Documentation Templates and Coverage Rules (DTR), and Prior Authorization Support (PAS) IGs] for adoption as part of certification criteria for health IT?

These implementation guides are still in the early stages of community engagement, but this highlights the pattern we saw when building tests against specifications such as the Da Vinci Formulary implementation guide. In the absence of a mandate, very few implementers participated in the Formulary work groups or at FHIR Connectathons in the Da Vinci Formulary track. It was not until CMS pointed to the specification for Patient Access that implementers became involved and started addressing issues, testing, and maturing the guide(s). Based on our experiences with both Da Vinci Formulary and Da Vinci Plan-net (Provider Directory), we see the CRD and DTR in a similar situation. The Da Vinci Prior Authorization IG has seen wider community engagement, but the workflows defined are still in need of implementer collaboration, and we expect that if they become the basis of a certification program, they will mature at a rapid pace.

Given limited testing of these specifications to date, what would be a feasible timeline for use of these IGs in production for prior authorization transactions?

Based on our experience with the Patient Access guides, we would expect something in the area of 18-24 months would be needed by most implementers to design to these specifications, test thoroughly, and potentially re-implementing to a more mature version of the specifications.

What, if any, additional changes are needed for these IGs prior to adoption as part of certification criteria for health IT?

We recommend that the IGs add testing artifacts to remove ambiguity and ensure implementers fully understand and have implemented the functional requirements. These testing artifacts need to include suites of TestScript resources paired with test data to enable system-to-system interoperability acceptance testing. We expand on this recommendation in section B.3.

If the existing IGs are not yet ready for adoption, should ONC still propose certification criteria? Should ONC consider proposing certification criteria incorporating the FHIR Release 4 base standard but delay adopting implementation specifications until a later date? What are the potential risks of this approach?

The sooner ONC defines certification criteria for the existing IG's, the faster they will be ready for adoption. The healthcare interoperability community has demonstrated a preference for waiting until a mandate for the adoption of new functionality before taking serious strides towards adoption. As a result, getting to "ready for adoption" is accelerated by such mandates, not a prerequisite for them.

If possible, ONC should include in the certification criteria the need for explicit acceptance testing, using the testing artifacts described above.

B.3. The Role Testing serves in Standards, Implementation and Certification

AEGIS makes the following public comments on the role testing serves in the standards, implementation specifications, and certification to ensure continuous interoperability across the US Healthcare integrated ecosystem.

We urge ONC and the implementer community to examine the evidence that adding testing to implementation guides and certification programs produces valuable results.

This creates a cadence which aligns IG development with test cases being defined, along with sample messages and test data. This would enable the RI development process to benefit from defined test methods. With test artifacts in place, test tooling and the ability to calibrate and validate the testing is made faster.

A few data points the Healthcare Community may want to consider in reviewing the future proposed process of Testing:

- JMIR Research published by Mitre, AEGIS, and HHS/ONC –
  Conducted a two (2) year study into best-practices and best-in-breed approaches to Validation and Testing of Fast Healthcare Interoperability Resources Standards Compliance: Data Analysis https://medinform.jmir.org/2018/4/e10870/
- HL7 FHIR Standards and Specifications currently references approaches to testing FHIR Implementations - http://www.hl7.org/fhir/testing.html
- HL7 FHIR Standard – Resources / Profiles FHIR TestScript - http://www.hl7.org/fhir/testscript.html
- FHIR Testing Programs currently being supported
  - HL7 Da Vinci Accelerators – Touchstone (FHIR TestScript)
  - Drummond CMS Certification and Testing Program – Touchstone (FHIR TestScript)
  - Ontario Health (Pan Canadian) Patient Summary (IPS) – Touchstone
  - Nictiz – Netherlands national FHIR Implementation (Medmij) – Touchstone
  - MedCom – Denmark national FHIR Implementation programs – Touchstone
  - ONC g.10 – Final Rule (21st Century Cures Act) – Inferno
  - ONC US Core – IG's (Profiles) – Inferno, Touchstone
- Implementers will require testing both FHIR Clients and Servers roles
  - FHIR Server testing support – Inferno, Touchstone, Crucible
  - FHIR Client testing support – Touchstone
  - FHIR Negative testing support – Touchstone
  - FHIR (Complex) Workflow(s) (multi-actor, multi-organization) Patient Care Coordination exercises such as Prior Authorization - Touchstone

Qualified Testing Programs

Testimony about the value of certification processes built on strong testing programs:

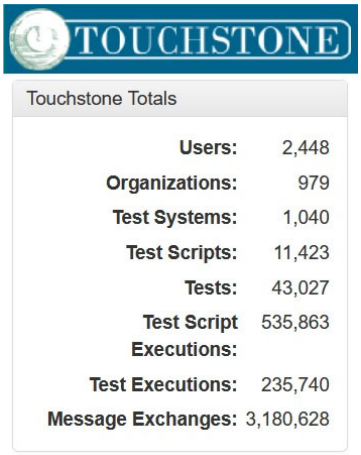
> *"Nictiz is the Dutch competence centre for electronic exchange of health and care information. We help healthcare move forward with standards based semantic interoperability. The proof of the pudding is in the eating, so a key factor in our portfolio is qualification testing. This is a prerequisite before entering some of the Dutch main infrastructures. Qualification testing builds trust in the system as a whole. For FHIR we have leveraged the AEGIS Touchstone platform from the start. We have done so in favor of extending our home grown solution for HL7 V3/CDA, and after careful selection process. We test vendor implementations for use cases like medication, primary care, patient summary and a dozen others. Over the years AEGIS has treated Nictiz not only as a valued customer but also as a partner in making healthcare better."*
>
> Alexander Henket
> Team Lead HL7
> Nictiz

> "As the leading Health IT testing and certification organization, when Drummond Group prepared to develop and launch comprehensive FHIR testing and certification services, a survey of the FHIR testing platforms available revealed that Touchstone stood out as the most robust and comprehensive technology. Drummond has incorporated Touchstone as a cornerstone of the future of its FHIR testing and certification for our certification against both ONC and CMS Final Rules requiring FHIR API implementation and any future FHIR testing and certification initiative. It is a core component of our business, and should be considered for widespread adoption of FHIR testing across the board."
>
> Timothy Bennett
> Director of Strategic Healthcare Initiatives
> Drummond Group

The Healthcare Community may need to specifically define the rubric to be used to "qualify" testing and conformance to a set of standards and specifications such as Prior Authorization. As an example, the Touchstone team works with the industry (Drummond, and FHIR Connectathon attendees) in order to calibrate the Testing artifacts (TestScript) to ensure the test results correlate with the type of condition of failure. Note: in more than 50% of the Test Executions completed with a status 200 OK [meaning the message was received], **the FHIR message (information exchange) was found to be non-conformant** to the FHIR IG or the FHIR data context for testing the patient information exchange. Complex data rules

become guidelines to “assertions” (test rules). Following the FHIR message exchange, the message is evaluated by these rules to judge compliance with the FHIR specification beyond the FHIR Validation Service (note – FHIR Validation services are not workflow or data context aware).

Touchstone as an example of a Global Community and Integrated-Ecosystem.



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Few implementers reference (FHIR) Version numbers at the standards level, IG, or profile level as a required part of their implementation. This risks introducing ecosystem level breaking changes in the future as standards evolve. To mitigate these types of risks, robust testing which addresses not only point-in-time Interoperability, but plan for “future proofing” solutions are a necessity for “Continuous Interoperability” which further demonstrates the value of rigorous testing.