U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Funding Opportunity Announcement

Closing the Gap between Standards Development and Implementation-Maturing the Consolidated Clinical Document Architecture (C-CDA) and Fast Healthcare Interoperability Resources (FHIR) Standard

Application Due Date: August 31, 2017

Anticipated Award Date: September 11, 2017

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Executive Summary

The Office of the National Coordinator for Health Information Technology (ONC) intends to award a sole source cooperative agreement to Health Level Seven International (HL7) to close any gaps between development and implementation of standards; develop broad and more comprehensive testing infrastructures; and disseminate additional guidance back to the health information technology (health IT) developers and health care providers. This award will consist of a five year period of performance, totaling $750,000.

The consistent implementation of standards within health IT systems is necessary to achieve interoperability among health care providers and across many different use cases. Standardized ways to format and structure data as well as represent its meaning in an unambiguous and computable way is critical to enable health care providers to send, receive, find, and use patient data when and where it is needed. Founded in 1987, Health Level Seven International (HL7), an American National Standards Institute (ANSI) accredited standards development organization (SDO) has developed and maintained a standards and implementation guidance for the exchange, integration, sharing, and retrieval of electronic health information in support of clinical practice.

HL7 and the health IT industry have worked diligently to update the Consolidated Clinical Document Architecture (C-CDA) Standard to Release 2.1 and Fast Healthcare Interoperability Resources (FHIR) standard Version 3. The FHIR standard's data-focused approach is increasingly being leveraged by industry to support the Application Programming Interface (API) requirements in ONC's 2015 Edition certification criteria[1]. The C-CDA has been included in the ONC health IT certification regulations since 2012 and is also referenced in ONC's recently published 2017 Interoperability Standards Advisory Reference Edition. Moreover, the 21st Century Cures Act[2] (the Cures Act) was signed into law and expanded the scope and conditions on which certifications to health IT must be granted, including specific conditions of certification around information blocking, application programming interfaces, and "real world" testing.

The following goals are important to continue to mature these standards:

- Improve consistency of C-CDA Implementations across Health IT developers
- Improve the use and consistency of semantic information in C-CDA
- Additional Support for developers implementing the C-CDA specification
- Publish the latest release of FHIR standard
- Comprehensive planning to ensure support for adoption of FHIR standard
- Add new capabilities to the latest version of the FHIR standard to support API based access and push of data for large number of patients in support of provider-focused exchanges and other value-added services
- Develop or upgrade existing FHIR reference server implementation with the new capabilities developed for "Bulk Access and Push"

[1] See Sections (g)(7)-(g)(9) of the 45 CFR Part 170 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Final Rule https://www.gpo.gov/fdsys/pkg/FR-2015-10-16/pdf/2015-25597.pdf

[2] See Section 4002(a) of the 21st Century Cures Act, P. L. 114-255, (Dec. 13, 2016), which amends Section 3001(c)(5) of the Public Health Service Act.

A. Program Description/Purpose

Background Information

When a computer system receives electronic health information from another system, it needs to be able to process the information without time-consuming human intervention. This can only occur if the sending system has used a consistent data format that is known to – and expected by – the receiving system. Given the vast number of systems that exchange electronic health information expecting each to negotiate agreed-upon exchange formats with all other systems with which it interacts is impractical. To address this issue, stakeholders in the health IT ecosystem have organized themselves under the auspices of SDOs to develop standardized data formats pertaining to specific purposes. SDOs are primarily responsible for developing and maintaining the technical standards and any accompanying implementation specifications/profiles that provide additional implementation instructions to developers based on the particular purpose for which the standard is intended to be used. These organizations include, but are not limited to: HL7, the National Council for Prescription Drug Plans (NCPDP) and Integrating the Healthcare Enterprise (IHE). HL7 is the only SDO responsible for developing and maintaining many technical standards of significance to the C-CDA and FHIR specifications and their accompanying implementation guides. Additionally, HL7 members include organizations that are actively engaged in implementing the standards used within health IT systems.

HHS has adopted many such standards in regulation and required their implementation for the purposes of certification under the 2014 and 2015 Editions of certification criteria that are apart of the ONC Health IT Certification Program. Specifically, the 2015 Edition includes application programming interface certification criteria that require the use of C-CDA and permit the use of FHIR. Moreover, the 21st Century Cures Act[3] (the Cures Act) was signed into law and expanded the scope and conditions on which certifications to health IT must be granted, including specific conditions of certification around information blocking, application programming interfaces, and "real world" testing.
This cooperative agreement reflects ONC's intention to work directly with HL7 in order to advance greater standardization and interoperability in areas of nationwide interest and to specifically ensure that the C-CDA and the FHIR standard can be implemented consistently by the health IT community, with associated comprehensive testing resources, and gain broad industry adoption.

Consolidated Clinical Document Architecture (C-CDA)

The Consolidated Clinical Document Architecture (C-CDA) is a specification that was created in 2012 to help simplify implementations and contains commonly used HL7's Clinical Document Architecture (CDA) templates. CDA is the base standard which provides a common architecture for the creation of electronic clinical document. Though much of the industry has implemented C-CDA there remains significant variability in its implementation. This variability impacts interoperability overall and limits a receiving system's ability to fully process the information and properly integrate the information into a patient record. At the same time, health care providers have adopted, implemented, and are using health IT systems to send summary of care records formatted according to the C-CDA at a steadily increasing rate. Implementation experience and feedback from the field indicates that more guidance on how to

[3] See Section 4002(a) of the 21st Century Cures Act, P. L. 114-255, (Dec. 13, 2016), which amends Section 3001(c)(5) of the Public Health Service Act.

consistently implement the C-CDA specification is needed in order to support interoperability among health IT systems.

Fast Healthcare Interoperability Resources (FHIR)

HL7's FHIR standard is maturing rapidly as the industry preferred standard for patient and provider-focused exchanges via application programming interfaces (APIs). In fact, most health IT developers are supporting FHIR Standard Version 2 based Implementation Guide, *Argonaut Data Query Implementation Guide version 1.0.0*[4] to provide data-centric access to patient-focused applications. Additionally, a majority of health IT developers have used the FHIR standard to meet the API certification criteria that are part of ONC's 2015 Edition certification criteria.[5]

Since FHIR's initial publication in 2012, the FHIR standard has undergone rapid revisions culminating in the release of the version 3 of the FHIR standard in March 2017. In each of the prior releases, the FHIR standard has not only matured in content, but has also undergone substantial improvements in infrastructure capabilities, such as workflow, search and transport capabilities, to make it robust and ready for use by industry to perform different health information exchange scenarios.

There are several activities currently underway in HL7 to add new support to the FHIR standard in time for the next ballot cycle, which is scheduled for early 2018. The activities include updating the FHIR standard to support new use cases especially targeted to support provider-to-provider health information exchange, the exchange of large amounts of information, development of implementation guidance documents and reference implementations to support health IT developers implement the standard consistently and test tools to perform conformance testing of FHIR based health IT systems.

Additionally, the next version of the FHIR standard is expected to provide "normative" guidance on the matured resources within the FHIR standard, that will make them backward compatible with future versions of the standard. The "normative" standard is targeted primarily towards promoting the large scale adoption by the healthcare industry and rapidly transitioning the health IT systems from using older standards to the new standards that meet modern interoperability needs.

Purpose

To support advancements in the technical standards necessary to achieve interoperability among health IT systems and to reach the milestones identified in the Nationwide Interoperability Roadmap[6] and 21st Century Cures Act. Specifically, this cooperative agreement will advance the implementation consistency and readiness of the current and new versions of the C-CDA and FHIR technical standard for adoption by the healthcare industry
by achieving the following goals:

- Improve consistency of C-CDA Implementations across health IT developers
- Improve the use and consistency of semantic information in C-CDA
- Additional support for developers implementing the C-CDA specification

[4] http://www.fhir.org/guides/argonaut/r2/
[5] https://chpl.healthit.gov/#/collections/apiDocumentation

[6] From the Interoperability Vision for the Future section of "Connecting Health & Care for the Nation: A Shared Nationwide Roadmap"http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf

- Publish the latest release of FHIR standard
- Comprehensive planning to ensure support for adoption of FHIR standard
- Add new capabilities to the latest version of the FHIR standard to support API based access and push of data for large number of patients in support of provider-focused exchanges and other value-added services
- Develop or upgrade existing FHIR reference server implementation with the new capabilities developed for "Bulk Access and Push"

Structure and Approach

Key Goals, Tasks, Deliverables, and Timeline

The goals and tasks listed below are explicitly for C-CDA and FHIR. It should also be noted these goals are based on the recipient working closely with the support offices in this effort and additional tasks may be required to achieve the outlined goals.

Year 1

Goal 1: Implementation Plan

Provide a detailed implementation plan of how it intends to accomplish each of the tasks for each of the goals stated below. The final plan should incorporate the feedback provided by ONC on the recipient's initial plan submitted with their application.

Goal 2: Publish the latest release of FHIR Standard[9]

Under this cooperative agreement HL7 will publish and release the latest FHIR Draft Standard for Trial Use (DSTU).

- Task 1: HL7 monitors the ballot reconciliation activities and provides additional technical support as needed to the working groups, to complete the standard development process in timely manner.

- Task 2: HL7 provides administrative support for the publication of the balloted FHIR STU standard

Goal 3: Comprehensive planning to ensure support for adoption of FHIR Standard

HL7 is expected to begin thoughtful planning and infrastructure development for sustained adoption of FHIR standard.

- Task 1: HL7 develops governance and infrastructure to support development and maintenance of FHIR Profiles.

- Task 2: HL7 develops testing platform to support development of FHIR compliant systems.

Goal 4: Add new capabilities to the latest version of the FHIR standard to support API based access and push of data for large number of patients in support of provider-focused exchanges and other value-added services

Current FHIR API specifications have focused on patient-focused use cases that involve accessing resources for a single patient. While these APIs have defined common interactions (create, read, search, etc.) for either single resources or related resources via Compartments[7], they may not be useable for accessing data across large number of patients (called "Bulk Access and Push') required for provider-focused exchanges, population-level services and other value-added services being envisioned to be supported by the Cures Act.

In addition to being able to access data for large number of patients, provider-focused exchanges also have additional requirement of needing to make sure that the user has the appropriate authorization to be able to invoke the API and that the data is being accessed for appropriate purposes only, such as for treatment, payment, etc.

HL7 should enhance the FHIR infrastructure resources[8] to define new APIs and services to support the "Bulk Access and Push" use case.

- Task 1: HL7 adds new capabilities in the standard, including but not limited to: APIs for "Bulk Access and Push"; new APIs around passing the purpose of data query; and automated data access over time that are necessary for effectively using the FHIR standard for provider-focused exchanges and other value-based services.

- Task 2: HL7 updates the latest version of the FHIR standard, existing implementation guides or develops new implementation guide to enable implementation of the capabilities into existing health IT products.

Goal 5: Develop or upgrade existing FHIR reference server implementation with the new capabilities developed for "Bulk Access and Push"

HL7 should demonstrate the use of APIs developed for "Bulk Access and Push" by updating existing open source, publicly available FHIR server.

- Task 1: HL7 supports the upgrade of existing open source and publicly accessible FHIR server (based on version 2.0 or later) that has implemented the capability of "Bulk Access and Push" in the context of service oriented architecture.

- Task 2: HL7 provides how-to guides, software snippets and other development support for health IT developers to upgrade their servers with the capability.

Goal 6: Improve the use and consistency of C-CDA Implementations across Health IT Developers

It is anticipated that an outcome of this cooperative agreement is that health IT systems will implement the C-CDA specification in a ***single and consistent*** manner to exchange, at a minimum, a common set

[7] FHIR Compartments: http://hl7.org/fhir/compartmentdefinition.html
[8] FHIR Infrastructure resources: http://hl7.org/fhir/services.html

of clinical data elements, such as those specified by ONC in its regulations. Another anticipated outcome of this cooperative agreement is to have health IT systems implement C-CDA with consistent semantic information and with greater semantic accuracy[9]. Additionally, HL7 must respond accurately and promptly to developer questions on implementing C-CDA specifications, and provide additional support for developers implementing the C-CDA Specification, as needed.

- Task 1: *CDA Examples Task Force*[10] developed artifacts are used by HL7 to develop additional implementation guidance for ***single*** and ***consistent*** implementation of C-CDA.

- Task 2: HL7 organizes Implementation-a-thons to identify real-world implementation inconsistencies. And, based on the results, develops detailed guidance for developers and implementers on any identified barriers to interoperability.

- Task 3: HL7 will implement improvements to the current C-CDA ERRATA process.

- Task 4: HL7 provides guidance for use of terminology and vocabulary standards for specific sections and entries in C-CDA from large coding systems used in C-CDA, including but not limited to: Systemized Nomenclature of Medicine-Clinical Terms (SNOMED-CT); RxNorm; and Logical Observation Identifiers Names and Codes (LOINC).

- Task 5: Provide regular updates to best practices and quantitative scoring criteria for the ONC C-CDA Scorecard

- Task 6: It is anticipated that HL7 will develop requirements for development of a new C-CDA publication approach to allow for C-CDA templates to progress at a rate similar to FHIR maturity model

- Task 7: HL7 provides administrative support for the publication of a balloted C-CDA Standard for Trial Use standard

- Task 8: Develop any necessary additional guidance to improve implementation of C-CDA 1.1, 2.1 or newer versions (e.g. Companion Guide).

Years Two (2) through Five (5)

The continuation of this cooperative agreement in Years 2 through 5 is subject to the availability of funds. Moreover, the goal/task structure provided in Years 2 through 5 may be modified based on new regulations and legislation impacting the awarding agency. However, the overarching purpose, scope, and intent of the cooperative agreement will remain intact.

[9] "Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative" by John D. D'Amore et.al., *http://jamia.oxfordjournals.org/content/21/6/1060*

[10] http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

Year 2

Goal 1: Updated Implementation Plan

HL7 must provide a detailed implementation plan of how it intends to accomplish each of the tasks for each of the goals stated below. The updated plan should incorporate the feedback provided by ONC on the recipient's prior year plan.

Goal 2: Publish the latest release of FHIR Standard[9]

Under this cooperative agreement HL7 will publish and release the latest FHIR Draft Standard for Trial Use (DSTU).

- Task 1: Continue to monitors the ballot reconciliation activities and provides additional technical support as needed to the working groups, to complete the standard development process in timely manner.

- Task 2: HL7 provides administrative support for the publication of the balloted FHIR STU standard

Goal 3: Comprehensive planning to ensure support for adoption of FHIR Standard

HL7 is expected to begin thoughtful planning and infrastructure development for sustained adoption of FHIR standard.

- Task 1: HL7 refine governance and infrastructure to support development and maintenance of FHIR profiles.

- Task 2: HL7 refine testing platform to support development of FHIR compliant systems.

Goal 4: Improve the use and consistency of C-CDA Implementations across Health IT Developers

- Task 1: *CDA Examples Task Force*[11] developed artifacts are used by HL7 to develop additional implementation guidance for ***single*** and ***consistent*** implementation of C-CDA.

- Task 2: HL7 continue organizing Implementation-a-thons to identify real-world implementation inconsistencies. And, based on the results, develops detailed guidance for developers and implementers on any identified barriers to interoperability.

- Task 3: Provide regular updates to best practices and quantitative scoring criteria for the ONC C-CDA Scorecard

- Task 4: Continue to iterate on requirements for development of a new C-CDA publication approach to allow for C-CDA templates to progress at a rate similar to FHIR maturity model

- Task 5: HL7 provides administrative support for the publication of a balloted C-CDA Standard for Trial Use

[11] http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

- Task 6: Develop any necessary additional guidance to improve implementation of C-CDA 1.1, 2.1 or newer versions (e.g. Companion Guide).

Year 3

Goal 1: Updated Implementation Plan
HL7 must provide a detailed implementation plan of how it intends to accomplish each of the tasks for each of the goals stated below. The updated plan should incorporate the feedback provided by ONC on the recipient's prior year plan.

Goal 2: Publish the latest release of FHIR Standard[9]

Under this cooperative agreement HL7 will publish and release the latest FHIR Draft Standard for Trial Use (DSTU).

- Task 1: Continue to monitors the ballot reconciliation activities and provides additional technical support as needed to the working groups, to complete the standard development process in timely manner.

- Task 2: HL7 provides administrative support for the publication of the balloted FHIR STU standard

Goal 3: Comprehensive planning to ensure support for adoption of FHIR Standard

HL7 is expected to begin thoughtful planning and infrastructure development for sustained adoption of FHIR standard.

- Task 1: HL7 refine governance and infrastructure to support development and maintenance of FHIR profiles.

- Task 2: HL7 refine testing platform to support development of FHIR compliant systems.

Goal 4: Improve the use and consistency of C-CDA Implementations across Health IT Developers

- Task 1: *CDA Examples Task Force*[12] developed artifacts are used by HL7 to develop additional implementation guidance for ***single*** and ***consistent*** implementation of C-CDA.

- Task 2: HL7 organizes Implementation-a-thons to identify real-world implementation inconsistencies. And, based on the results, develops detailed guidance for developers and implementers on any identified barriers to interoperability.

- Task 3: Provide regular updates to best practices and quantitative scoring criteria for the ONC C-CDA Scorecard

[12] http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

- Task 4: Continue to iterate on requirements for development of a new C-CDA publication approach to allow for C-CDA templates to progress at a rate similar to FHIR maturity model

- Task 5: HL7 provides administrative support for the publication of a balloted C-CDA Standard for Trial Use

- Task 6: Develop any necessary additional guidance to improve implementation of C-CDA 1.1, 2.1 or newer versions (e.g. Companion Guide).

Year 4

Goal 1: Updated Implementation Plan
HL7 must provide a detailed implementation plan of how it intends to accomplish each of the tasks for each of the goals stated below. The updated plan should incorporate the feedback provided by ONC on the recipient's prior year plan.

Goal 2: Publish the latest release of FHIR Standard[9]

Under this cooperative agreement HL7 will publish and release the latest FHIR Draft Standard for Trial Use (DSTU).

- Task 1: Continue to monitors the ballot reconciliation activities and provides additional technical support as needed to the working groups, to complete the standard development process in timely manner.

- Task 2: HL7 provides administrative support for the publication of the balloted FHIR STU standard

Goal 3: Comprehensive planning to ensure support for adoption of FHIR Standard

HL7 is expected to begin thoughtful planning and infrastructure development for sustained adoption of FHIR standard.

- Task 1: HL7 refine governance and infrastructure to support development and maintenance of FHIR profiles.

- Task 2: HL7 refine testing platform to support development of FHIR compliant systems.

Goal 4: Improve the use and consistency of C-CDA Implementations across Health IT Developers

- Task 1: HL7 refine governance and infrastructure to support development and maintenance of FHIR profiles.

- Task 2: HL7 refine testing platform to support development of FHIR compliant systems.

- Task 3: *CDA Examples Task Force*[13] developed artifacts are used by HL7 to develop additional implementation guidance for ***single*** and ***consistent*** implementation of C-CDA.

- Task 4: HL7 organizes Implementation-a-thons to identify real-world implementation inconsistencies. And, based on the results, develops detailed guidance for developers and implementers on any identified barriers to interoperability.

- Task 5 Provide regular updates to best practices and quantitative scoring criteria for the ONC C-CDA Scorecard

- Task 6: Continue to iterate on requirements for development of a new C-CDA publication approach to allow for C-CDA templates to progress at a rate similar to FHIR maturity model

- Task 7: HL7 provides administrative support for the publication of a balloted C-CDA Standard for Trial Use

- Task 8: Develop any necessary additional guidance to improve implementation of C-CDA 1.1, 2.1 or newer versions (e.g. Companion Guide).

Year 5

Goal 1: Updated Implementation Plan
HL7 must provide a detailed implementation plan of how it intends to accomplish each of the tasks for each of the goals stated below. The updated plan should incorporate the feedback provided by ONC on the recipient's prior year plan.

Goal 2: Publish the latest release of FHIR Standard[9]

Under this cooperative agreement HL7 will publish and release the latest FHIR Draft Standard for Trial Use (DSTU).

- Task 1: Continue to monitors the ballot reconciliation activities and provides additional technical support as needed to the working groups, to complete the standard development process in timely manner.

- Task 2: HL7 provides administrative support for the publication of the balloted FHIR STU standard

Goal 3: Comprehensive planning to ensure support for adoption of FHIR Standard

HL7 is expected to begin thoughtful planning and infrastructure development for sustained adoption of FHIR standard.

[13] http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

- Task 1: HL7 refine governance and infrastructure to support development and maintenance of FHIR profiles.

- Task 2: HL7 refine testing platform to support development of FHIR compliant systems.

Goal 4: Improve the use and consistency of C-CDA Implementations across Health IT Developers

- Task 1: HL7 refine governance and infrastructure to support development and maintenance of FHIR profiles.

- Task 2: HL7 refine testing platform to support development of FHIR compliant systems.

- Task 3: *CDA Examples Task Force*[14] developed artifacts are used by HL7 to develop additional implementation guidance for ***single*** and ***consistent*** implementation of C-CDA.

- Task 4: HL7 organizes Implementation-a-thons to identify real-world implementation inconsistencies. And, based on the results, develops detailed guidance for developers and implementers on any identified barriers to interoperability.

- Task 5: Provide regular updates to best practices and quantitative scoring criteria for the ONC C-CDA Scorecard

- Task 6: Continue to iterate on requirements for development of a new C-CDA publication approach to allow for C-CDA templates to progress at a rate similar to FHIR maturity model

- Task 7: HL7 provides administrative support for the publication of a balloted C-CDA Standard for Trial Use

- Task 8: Develop any necessary additional guidance to improve implementation of C-CDA 1.1, 2.1 or newer versions (e.g. Companion Guide).

Structure and Approach

Year and Goal Number	Goal Description	Deliverable	Due Date
Year 1: Goal 1	Provide a detailed final implementation plan	Detailed Implementation Plan from HL7 (includes specific list of goals, tasks, and deliverables approved by ONC)	2 weeks after award date and monthly updates thereafter

[14] http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force

Year and Goal Number	Goal Description	Deliverable	Due Date
Year 1: Goal 2	***Publish the latest release of the FHIR standard*** *Monitors the ballot reconciliation activities and provides additional technical support as needed to the working groups, to complete the standard development process in timely manner.* *Provides administrative support for the publication of the balloted FHIR STU standard as soon as possible.*	*Publish the latest FHIR standard*	September 2018 or a mutually agreed upon date
Year 1: Goal 3	***Comprehensive planning to ensure support for adoption of FHIR standard***	*HL7 develops governance documents and infrastructure to support creation and maintenance of FHIR profiles.* *HL7 develops testing platform to support development of FHIR compliant systems.*	January 30th, 2018
Year 1: Goal 4	***Add new capabilities to the latest version of the FHIR standard to support API based access and push of data for large number of patients in support of provider-focused exchanges and other value-added services***	*HL7 adds new capabilities in the standard, including (but not limited to) APIs for "Bulk Access and Push", new APIs around passing the purpose of data query, and automated data access over time that are necessary for effectively using FHIR standard for provider-focused exchanges and other value-based services.* *HL7 updates the latest version of the FHIR standard, existing implementation guides or develops new implementation guide to enable implementation of the capabilities into existing.*	May 30th, 2018

Year and Goal Number	Goal Description	Deliverable	Due Date
Year 1: Goal 5	***Develop or upgrade existing FHIR reference server implementation with the new capabilities developed for "Bulk Access and Push" capability.***	HL7 supports the upgrade of existing open source and publicly accessible FHIR server (based on version 2.0 or later) that has implemented the capability of "Bulk Access and Push" in the context of service oriented architecture. HL7 provides how-to guides, software snippets and other development support for health IT developers to upgrade their servers with the capability.	May 30th, 2017
Year 1: Goal 6	***Improve consistency of C-CDA Implementations across Health IT Developers implementers on any identified barriers to interoperability.***	*HL7 to use CDA Examples Task Force developed artifacts to develop additional implementation guidance for single and consistent implementation of C-CDA.* *HL7 to organize implementation workshops to identify real-world implementation inconsistencies. And, based on the results, develops detailed guidance for developers and 1.* *Implement improvements to the current C-CDA ERRATA process.* *HL7 develops additional guidance for use of terminology and vocabulary standards for specific sections and entries in C-CDA from large coding systems used in C-CDA, including but not limited to Systemized Nomenclature of Medicine-Clinical Terms (SNOMED-CT), RxNorm and Logical Observation Identifiers Names and Codes (LOINC).*	All projects completed by September 2018 or an earlier date agreed upon by ONC and HL7

Year and Goal Number	Goal Description	Deliverable	Due Date
Year 1: Goal 6, continued	***Improve consistency of C-CDA Implementations across Health IT Developers implementers on any identified barriers to interoperability.***	*Provide regular updates to best practices and quantitative scoring criteria for the ONC C-CDA Scorecard* *Develop requirements for development of a new C-CDA publication approach to allow for C-CDA templates to progress at a rate similar to FHIR maturity model* *HL7 provides administrative support for the publication of a balloted C-CDA STU standard* *Develop any necessary additional guidance to improve implementation of C-CDA 2.1 or newer*	All projects completed by September 2018 or an earlier date agreed upon by ONC and HL7
Years 2-5	***Updated Implementation Plan***	*Detailed Implementation Plan from HL7 (includes specific list of goals, tasks, and deliverables approved by ONC)*	2 weeks after award date and monthly updates thereafter
Years 2-5: Goal 2	***Publish the latest release of theFHIR standard***	*Publish the latest FHIR standard.*	Date to be determined after coordination between project officer and recipient
Years 2-5: Goal 3	***Comprehensive planning to ensure support for adoption of FHIR standard***	*HL7 refine governance and infrastructure to support development and maintenance of FHIR profiles.* *HL7 refine testing platform to support development of FHIR compliant systems.*	Date to be determined after coordination between project officer and recipient

Year and Goal Number	Goal Description	Deliverable	Due Date
Years 2-5: Goal 4	***Improve the use and consistency of C-CDA Implementations across Health IT Developers***	*CDA Examples Task Force developed artifacts are used by HL7 to develop additional implementation guidance for single and consistent implementation of C-CDA.* *HL7 continue organizing Implementation-a-thons to identify real-world implementation inconsistencies. And, based on the results, develops detailed guidance for developers and implementers on any identified barriers to interoperability.* *Provide regular updates to best practices and quantitative scoring criteria for the ONC C-CDA Scorecard* *Continue to iterate on requirements for development of a new C-CDA publication approach to allow for C-CDA templates to progress at a rate similar to FHIR maturity model* *HL7 provides administrative support for the publication of a balloted C-CDA Standard for Trial Use* *Develop any necessary additional guidance to improve implementation of C-CDA 1.1, 2.1 or newer versions (e.g. Companion Guide).*	Date to be determined after coordination between project officer and recipient

B. Funding Opportunity Award Information

Key Award Parameters

Title:
Closing the Gap between Standards Development and Implementation - Maturing the Consolidated Clinical Document Architecture (C-CDA) and Fast Healthcare Interoperability Resources (FHIR)

Federal Funding Agency**:** Department of Health and Human Services
Office of the National Coordinator for Health Information Technology

Announcement Type: Cooperative Agreement.

Application Type: New

Funding Opportunity Announcement Number: NAP-AX-17-004

Catalog of Federal Domestic Assistance (CFDA) Number*:* *93.826*

Legislative Authority: Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, Division H, Title II

This is a non-competitive funding opportunity and is restricted to the HL7 organization as designated in Section C. Organizations not designated as such are not eligible to apply for this opportunity, and therefore should not submit an application. Applications submitted by organizations not designated below will not be considered.

Approximate Amount of Available Funding (inclusive of direct and indirect costs):

Anticipated Number of Awards: 1

Approximately Amount of Each Award: $750,000

Project Period: 9/11/2017 to 9/10/2022

Budget Period(s): 9/11/2017 to 9/10/2018

Funding of future non-competing continuation awards is conditioned on the availability of funds, satisfactory progress by the recipient, and an awarding office determination that continued funding of the award is in the best interests of the Government.

The recipient may anticipate a total budget of $750,000 from ONC for the first year. Continued funding will be contingent on the recipient continuing to meet all the milestones and the availability of funds.
In accepting an ONC award, the recipient assumes legal, financial, administrative, and programmatic responsibility for administering the award in accordance with the terms and conditions of the award, as well as applicable laws, rules, regulations, and Executive Orders governing HHS assistance awards, all of which

are incorporated into this award by reference. Failing to comply with these requirements may result in suspension or termination of the award and/or ONC's recovery of award funds.

Cost-Sharing Requirements: There are no matching or cost share requirements for this program.

Program Income:
There are four potential ways in which ONC may require that a recipient apply program income as specified in the Notice of Grant Award (NGA): 1) **deduct** it from total allowable project/program costs to determine the net allowable costs on which the Federal share of costs is based; 2) **add** it to funds otherwise available for the project, generally resulting in an increase to the total approved budget; 3) use it to meet a **matching or cost sharing** requirement; or 4) a **combination** of these alternatives.

Costs paid by program income generally are subject to the applicable cost principles and other Federal requirements and must be disbursed for project purposes **before** requesting additional payments of Federal funds. In the event program income remains at the end of the award, the additional income is considered part of the award funding and must be returned to ONC.

Intergovernmental Review: This program is excluded from Executive Order 12372

Key Dates

Milestone	Date
FOA Released	August 1, 2017
Applications Due	August 31, 2017
Anticipated Award Date	September 11, 2017
Anticipated Project Start Date	September 11, 2017

Roles and Responsibilities Under a Cooperative Agreement

The funding instrument used for this project will be the cooperative agreement, an assistance mechanism, in which substantial ONC programmatic involvement is anticipated during the project period. Under the cooperative agreement, the ONC purpose is to support and stimulate the recipient's activities by involvement in, and otherwise working jointly with, each recipient in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this premise, the dominant role and prime responsibility resides with the recipient for the project as a whole. To facilitate appropriate involvement, during the period of this cooperative agreement, ONC and the recipient will be in contact monthly and more frequently when appropriate.

Specific activities in which ONC may assume substantial involvement include, but are not limited to:

- ♦Releasing funds based on achievement of performance goals/project milestones

♦Reviewing and approving substantive provisions of proposed subawards or subcontracts

♦Reviewing and accepting deliverables

♦Providing tactical guidance and feedback during project execution

♦Ending an activity if performance goals/project milestones are not met

♦Meeting with recipient(s) monthly at a minimum, and more frequently as requested by the recipient(s) or ONC

C. Eligibility Information

Eligible Applicants: Eligible applicants must have the following experience:

- Must have the appropriate rights and tools to be the American National Standards Institute (ANSI) accredited standards developing organization responsible for developing and maintaining many technical standards of significance to the C-CDA and FHIR specifications and their accompanying implementation guides
- Must have a relationship with organizations that are actively engaged in implementing the standards used within health IT systems.

Sole Source Justification

The primary responsibility of SDOs are the development and maintenance of health IT technical standards, as well as any accompanying implementation specifications that provide additional implementation instructions for developers. Health Level 7 International is the exclusive standards development organization with the ability, authority, and intellectual property rights to develop and maintain the C-CDA specification and FHIR standard. HL7 is the single organization responsible for the development and maintenance of the C-CDA and the FHIR standard and solely governs the processes by which these standards and accompanying implementation guidance are issued and updated. Attempting to complete these or any future tasks specific to HL7 standards with another SDO or organization would require HL7 engagement to ballot and publish a final product. Thus, HL7's involvement is both fundamental and necessary to publish an HL7 standard or implementation guide

Additionally, HL7 members include organizations that are actively engaged in implementing the C-CDA and FHIR standard in health IT systems, and hence can provide necessary feedback in timely manner through a well-established and ANSI-accredited process for consensus standards development. The goals and expected outcomes of this cooperative agreement can only be achieved accurately and in a timely manner by HL7.

Furthermore, it is ONC's intent to broadly coordinate with health IT industry stakeholders to improve and advance the technical standards and specifications required for interoperability. Working directly with HL7 will enable this coordination to be more effective and efficient and will enable broad industry consensus to be more rapidly achieved when done through HL7's processes. As a result, it is ONCs assertion that HL7 is the only organization that can successfully deliver the goals articulated in this cooperative agreement.

D. Application and Submission Information

Application Package

The following documents comprise, as applicable, the application package. Additional information regarding each of these documents is further provided.

- Project Abstract
- Project Narrative
- Form SF-424, Application for Federal Assistance
- Form SF-424A, Budget Information for Non-Construction Programs
- Form SF-424B, Assurances for Non-Construction Programs
- Form SF-LLL, Disclosure of Lobbying Activities
- Budget Narrative
- Letters of Commitment
- Proof of Non-Profit Status (if, applicable)

Appendix A, Tips for Writing a Strong Application, can be used as a resource.

The Project Narrative and Budget Narrative sections of the application must be double-spaced, on 8-1/2" X 11" plain white paper with 1" margins on all sides, and use either Cambria or Times New Roman font size of not less than 11 point. Smaller font sizes may be used to fill in the Standard Forms, exhibits, and figures, though all text in forms, exhibits, and figures must not be smaller than 8 point font.

Project Abstract

Applicants shall include a one-page abstract that is no more than 500 words. This abstract is often distributed to the public and Congress and represents a high-level summary of the project. As a result, applicant should prepare a clear, accurate, concise abstract that can be understood without reference to other parts of the application and that provides a description of the proposed project, including: the project's goal(s), objectives, overall approach, anticipated outcomes, products, and duration.

The applicant shall place the following information at the top of the Project Abstract (this information is not included in the 500 word maximum):

- Project Title
- Applicant Name
- Physical Address
- Contact Name
- Contact Phone Numbers (Voice, Fax)
- E-Mail Address
- Web Site Address, if applicable

Project Narrative

The project narrative provides the most substantive information regarding the proposed project in a clear and concise manner. To that end, the project narrative should address the elements articulated in the Program Description/Purpose and Structure and Approach sections of this FOA. The project narrative should also align with the Performance Goals/Program Milestones and Merit Review Evaluation criteria presented in this FOA (e.g., organizational experience, past performance).

The Project Narrative must be double-spaced, formatted to 8 ½" x 11" (letter-size) pages, 1" or larger margins on all sides, and a font size of not less than 11 point. The maximum length allowed for the Project Narrative is 20 pages. A Project Narrative that exceeds the 20-page limit will not be accepted. Resumes of Key Personnel, if requested, are not counted as part of the Project Narrative and are not included in the 10-page limit. The specific sections that must be included in the Project Narrative are detailed below.

Form SF-424, Application for Federal Assistance

Appendix B provides line-by-line instructions to complete the form. Please note that the SF-424 is used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some or all of the information on these forms. Accordingly, when completing the form, please use the instructions in Appendix B in lieu of the standard instructions attached to SF-424.

Form SF-424A, Budget Information for Non-Construction Programs

Appendix C provides line-by-line instructions to complete the form. Please note that the SF-424A is used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some or all of the information on these forms. Accordingly, when completing the form, please use the instructions in Appendix C in lieu of the standard instructions attached to SF-424A. All direct and indirect costs must be allowable, allocable, reasonable and necessary.

Form SF-424B, Assurances for Non-Construction Programs

This form contains laws and other assurances applicants must comply with under the discretionary funds programs administered by the Office of the National Coordinator for Health Information Technology. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

Form SF-LLL, Disclosure of Lobbying Activities

This form contains the name and address of lobbying registrants. Please note that a duly authorized representative of the applicant organization must sign the disclosure form. Failure to complete and sign the form may result in civil penalties ranging from $10,000 to $100,000.

Budget Narrative

The budget narrative describes how the proposed budget, as articulated in the SF-424A, aligns with the applicant's project narrative. That is to ensure that costs are realistic (not artificially too low) and reasonable (not inflated) in view of programmatic requirements. Appendix D provides a template to complete the budget narrative populated with *sample* information.

When more than 33% of a project's total budget falls under a contractual expense, a detailed budget narrative/justification must be provided for each sub-contractor or sub-recipient. Applicants requesting funding for multi-year grant programs are required to provide a combined multi-year budget narrative/justification, as well as a detailed budget narrative/justification for each year of potential grant

funding. A separate budget narrative/justification is also required for each potential year of grant funding requested.

The full Budget Narrative/Justification should be included in the application immediately following the SF 424 forms. The Budget Narrative must be double-spaced, formatted to 8 ½" x 11" (letter-size) pages, 1" or larger margins on all sides, and a font size of not less than 11 point.

The duration of this award is for a maximum of 5 years. The budget and justification must reflect the costs for the initial 12- month budget period.

Applicants must submit a proposal which covers the full 5-year project period. Although initial funding awarded through this FOA will cover only the first 12-month budget period of the 60 month project period, applicants must still submit an estimated budget for each budget period (years 1, 2, 3, 4, and 5). In subsequent years, recipients will be able to revise their budgets, based on actual funding available from HHS, as part of their non-competing continuation applications which will be required from all recipients prior to the end of each budget period. The budget proposal must include:

1. An explanation of how the proposed budget supports the proposed Project and is reasonable to meet the Project's needs;
2. How proposed costs support Project activities; and
3. A description of how the proposed expenditures align with Project Plan.

Please see the Budget Detail in Appendix B for instructions for completing the SF424, and Appendices C through E for instructions for completing the SF424A, Budget Narrative, Justification, and other required forms. A non-competing continuation application is a financial assistance request (in the form of an application or performance/progress report) for a subsequent budget period within a previously approved project period for which a recipient does not have to compete with other applicants. Approval of this application will allow the recipient to continue implementing their project plan and to receive its next 12-month increment of funding. Non-competing continuation applications should be submitted no later than 90 days before the end of the current budget period (i.e., if the budget period will end on August 10, submit the non-competing continuation application by May 10). Exact due dates will be laid out in the terms and conditions that accompany each recipient's Notice of Grant Award.

Continued funding throughout the 5 year project period will be contingent on timely submission of the non-competing continuation application, strong performance during the previous budget period(s), funding availability, and the recipient's ability to continue meeting all eligibility requirements laid out in this FOA. Due to their non-competitive nature, continuation applications will not be reviewed or scored by an Objective Review Committee. Instead, all continuation applications will be reviewed by ONC staff. Strong performance during the previous budget period(s) will be evaluated by looking at a) the recipient's ability to meet their performance metrics, b) the quality and timeliness of its report submissions, c) the recipient's compliance with the terms and conditions provided with their Notice of Award including compliance with all applicable statutory and regulatory requirements, and d) the recipient's ability to communicate with and respond in a timely manner to requests from its project officer throughout the project period.

Letters of Commitment

Include letters of commitment confirming the support to the project (should it be funded) made by key collaborating organizations and agencies. Any organization that is specifically named to have a significant coordination role in carrying out the project should be considered an essential collaborator

such as interstate, intrastate, and regional partners. At a minimum, the letter must explain the demonstrated commitment to the project and how they will advance coordination and collaboration among critical stakeholders. See Appendix E for an example letter of commitment.

These letters should not be considered as part of the page limit. Signed letters of commitment should be scanned and included as attachments.

Indirect Cost Agreement(s)

Applicants that have included indirect costs in their budgets must include a copy of the current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency. This is optional for applicants that have not included indirect costs in their budgets. Further, if any sub-contractors or sub-recipients are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

Application Submission Instructions

1) You must access the electronic application for this program via http://www.grants.gov. You can search the downloadable application page by the Funding Opportunity Announcement Number NAP-AX-17-004or CFDA number *93.826.*

2) Applicants will be able to download a copy of the application packet and complete it off-line. In order to complete the application, an organization must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number. A DUNS number can be obtained via http://fedgov.dnb.com/webform and typically takes 1 to 2 business days. Please plan accordingly.

3) Completed applications are uploaded into Grants.gov. APPLICATIONS WILL NOT BE ACCEPTED THROUGH ANY OTHER WEBSITE, AND WILL NOT BE ACCEPTED THROUGH PAPER MAIL, COURIER, OR DELIVERY SERVICE.

In order to upload applications into Grants.gov:

a) An applicant must be registered in the System for Award Management (SAM), at sam.gov, which requires having a DUNS number. The SAM registration process takes 7 to 10 business days so please plan accordingly. If you have already registered with SAM, but have not renewed your registration in the last 12 months, you must renew your registration.

The following website depicts the SAM registration process:
http://www.grants.gov/web/grants/applicants/organization-registration.html

b) An applicant must be registered in Grants.gov which can take several days. To that end, applicants are strongly encouraged to register and test Grants.gov logins and passwords well in advance of the application deadline date. For assistance with www.grants.gov, please contact them at support@Grants.gov or 1-800-518-4726. Resources are available 24 hours a day/7 days a week.

A depiction of the Grants.gov application process can be found at
http://www.grants.gov/web/grants/applicants/apply-for-grants.html

4) After electronically submitting your application, Grants.gov will generate an email tracking number and date of receipt verification confirming that the application was received, the date and time the application was received, and a tracking number. This notification does not ensure that your application could be opened and read -- only that the application was received.

5) ONC opens the application submission in Grants.gov, to ensure the application can be downloaded and read during the application review processes. ONC issues an email to the applicant indicating the files were received and able to be successfully opened and read.

The deadline for the submission of applications under this Funding Opportunity Announcement is 11:59 PM Eastern Standard Time on August 31, 2017. Applications that fail to meet the application deadline will not be reviewed and will receive no further consideration.

Restrictions on Oral Conversations

This funding announcement is subject to restrictions on oral conversations during the period of time commencing with the submission of a formal application by an individual or entity and ending with the award of the competitive funds. Federal officials may not participate in oral communications initiated by any person or entity concerning a pending application for a competitive grant or other competitive form of federal financial assistance, whether or not the initiating party is a federally registered lobbyist.

This restriction applies unless:

- The communication is purely logistical
- The communication is made at a widely attended gathering
- The communication is to or from a federal agency official and another federal Government employee
- The communication is to or from a federal agency official and an elected chief executive of a state, local, or tribal government, or to or from a federal agency official and the Presiding Officer or Majority Leader in each chamber of a state legislature
- The communication is initiated by the federal agency official

E. Application Review Information

Screening Review

If the applicant does not meet the following screening criteria, the application will be eliminated and will not be sent forward for merit review:

- The applicant meets the eligibility criteria
- The application is received by the required deadline through http://www.grants.gov
- The application contains all required components (e.g., Project Abstract, Project Narrative, SF-424)
- The application meets the formatting and length requirements. The Project Narrative must not exceed 20 pages. The Project Abstract and resumes do not count as part of the Project Narrative length limitation.
- Appendices and attachments are not used as a mechanism to exceed page limits of the Project Narrative

Merit Review

An independent review panel, of at least three individuals, will evaluate applications that meet the screening criteria identified above. These reviewers will be experts in their field from academic institutions, non-profit organizations, and local and Federal government agencies. Reviewers will review, evaluate, and score applications, in accordance with the criteria identified below:

1. Discussion and Understanding of the Project – 25 points maximum
   The applicant demonstrates knowledge and understanding of the implementation challenges of the technical standards specified in the cooperative agreement. The applicant provides guidance that specifies solutions to overcome these challenges and leads to consistent implementation and adoption of technical standards.

2. Technical Approach – 25 points maximum
   The applicant must demonstrate and provide evidence of technical experience for identifying, assessing and determining improvements to be made to technical standards and specifications listed in the cooperative agreement. The applicant's approach is succinct and logical and demonstrates methods consistent with the tasks to be accomplished. The applicant must propose a clear and detailed actionable plan which includes specific list of activities to achieve the goals and tasks specified in the cooperative agreement.

3. Personnel Qualification and Past Performance – 25 points maximum
   The technical experts to perform tasks on this Funding Opportunity Announcement (FOA) must have the expertise to be able to successfully complete the tasks. The applicant must demonstrate ability to successfully manage projects of similar size and ability to engage with health IT industry stakeholders. Evidence of past work must be provided in the personnel resumes as an appendix to the applicant's proposal.

4. Implementation Plan – 15 points maximum
   The applicant must provide a draft implementation plan that includes a detailed plan to carry out each of the activities proposed in the response, monthly progress meetings, progress reports and a timeline for draft and final deliverables for each of the goals with specific dates identified.

5. Budget Plan –10 points maximum

   The applicant must provide a detailed breakdown on how they plan to spend the allotted resources to complete the tasks outlined in the cooperative agreement based on the guidance provided by ONC in section G of the cooperative agreement.

MAXIMUM TECHNICAL SCORE = 100 POINTS

Pre-Award Risk Assessment

ONC is required to conduct a risk assessment to assess the risk posed by a potential recipient, prior to issuing an award. In doing so, ONC will take into account the applicant's financial stability, quality of management systems, history of performance, reports and findings from audits, and the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities. To facilitate this assessment, ONC may review information available in systems, such as the Excluded Parties List System, review documentation, such as previous audits, and/or desk reviews or site visits conducted from previous awards. ONC may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirement s (45 CFR Part 75.205.)

F. Federal Award Administration Information

Award Decisions

The final award decision will be made by the National Coordinator for Health Information Technology taking into consideration several factors such as the results of the merit review process, results of the pre-award risk assessment, compliance with programmatic and grants management requirements; the reasonableness of the estimated costs, available funding, program priorities; and the likelihood that the proposed project will result in the benefits expected. The applicant will receive a summary of the objective review panel's assessment of the application's strengths, weaknesses, and score.

Notice of Grant Award

The successful applicant will receive a letter of notification acknowledging that an award was funded, but does not provide authorization for the applicant to begin performance and expend funds associated with the award.

Following this notice, the successful applicant will receive a Notice of Grant Award (NGA). The NGA will include, at a minimum, the following:

- Legal name and address of the organization or institutions to whom ONC has issued an award
- Award number assigned by ONC
- Project period, specifying the amount of time ONC intends to support the project without requiring re-competition for funds
- Total amount of financial assistance approved by ONC during the project period
- Budget period, specifying the increments in which the project will be funded, subject to the availability of funds
- Applicable award terms and conditions
- Performance goals, indicators, milestones, or expected outcomes (such as outputs, or services performed or public impacts of any of these) with an expected timeline for accomplishment

The recipients' Authorized Representatives will receive the NGA electronically from ONC. The recipient accepts the award by drawing down funds. By accepting an ONC award, the recipient assumes legal, financial, administrative, and programmatic responsibility for administering the award in accordance with the terms and conditions of the award, as well as applicable laws, rules, regulations, and Executive Orders governing HHS assistance awards, all of which are to be incorporated into the award by reference. Failure to comply with these requirements may result in suspension or termination of the awards and/or ONC's recovery of award funds.

Terms and Conditions

Incorporated by Reference

The NGA is subject to, by reference, the terms and conditions incorporated in the following documents:

- 45 CFR, Part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements For HHS Awards
  http://www.ecfr.gov/cgi-bin/text-idx?SID=06a0b0411d1520fae5e2799030e64ebf&node=pt45.1.75&rgn=div5

- HHS Grants Policy Statement
  https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf

Specific terms and conditions, incorporated by reference above, are further delineated below due to their importance in terms of integrity, achieving programmatic objectives, and/or sound financial stewardship of federal funds.

Performance Reporting

ONC Program Progress Reports (PPR) are due quarterly. The PPR will address, to the extent applicable:

- degree to which performance goals were attained (actual performance versus targeted performance)
- data source and validation method for performance measures
- opportunities to address performance deficiencies
- accomplishments
- next steps
- challenges
- barriers
- recommendations to address challenges and barriers

ONC will provide specific guidance regarding the content and format of the PPR before the reports are due.

Financial Reporting

Expenditures must be reported, on a semi-annual basis, using the SF-425, Federal Financial Report (FFR). Reports are due to HHS no later than April 30 of each year the award is active for funds expended between October and March, and no later than October 31 for funds expended between April and September. The semi-annual FFR will be submitted using the Online Data Collection (OLDC) system. ONC will not accept reports sent directly to the ONC Grants mailbox.

The FFR Cash Transaction Report, a subset of the SF-425, Federal Financial Report, is submitted via the Payment Management System (PMS) every calendar quarter for the life of the award. The report must be submitted within 30 days after the end of the quarter (January 31, April 30, July 31, and October 31).

Federal Funding and Accountability and Transparency Act of 2006

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of ONC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all sub-awards over $25,000.

Funding Restrictions

Funds cannot be used for the following purposes:

- To supplant or replace current public or private funding
- To supplant ongoing or usual activities of any organization involved in the project
- To purchase or improve land, or to purchase, construct, or make permanent improvements to any building
- To reimburse pre-award costs

Conflict of Interest

The term "organizational conflict of interest" means that the applicant, including its chief executives, directors, consultants, sub recipients, or any other personnel that are substantially involved in the performance of this assistance agreement, has interests which:

- May diminish its capacity to give impartial, technically sound, objective assistance and advise in performing this tasks;
- May otherwise result in a biased work product under this assistance agreement; or,
- May result in an unfair competitive advantage to itself or others.

In accordance with Section 75.112 of Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, all applicants and non-federal entities must disclose, in writing, any potential conflict of interest (COI) that they have with the awarding agency and/or any other pass-through entities. The applicant shall notify the ONC grants management officer (GMO) when they believe an actual or potential COI may exist.

If, after award, a recipient discovers a COI, with respect to the assistance agreement, it shall make an immediate and full disclosure in writing to the ONC GMO. The disclosure shall include identification of the actual or potential conflict, the manner in which it arose, and a description of the action the recipient has taken, or proposed to take, to avoid, eliminate, or neutralize the conflict.

In the event the recipient was aware of an organizational COI, prior to award of the assistance agreement, and did not disclose the conflict to the GMO, or becomes aware of an organizational COI after award of this assistance agreement and does not disclose the COI within ten (10) days of becoming aware of such conflict, the Government may terminate the assistance agreement and the recipient shall not be entitled to reimbursement of any costs incurred in performing the assistance agreement.

The rights and remedies of the Government, under this term and condition, shall not be exclusive and are in addition to any other rights and remedies provided to the Government under law, regulation, or any other available enforcement mechanism.

Non-Disclosure Requirements

The federal award may require the recipient to have access to information relating to any and all aspects of grants management operations that may be of a technical, legal, sensitive and/or confidential nature and which may be the sole property of the U.S. Government. To mitigate risks associated with such access, the recipient shall ensure that all its personnel, including chief executives, directors, consultants, sub recipients, or any other personnel substantially involved in the performance of this award sign a non-disclosure agreement prior to the commencement of any work on the award.

In addition, recipients shall put in place appropriate procedures for the protection of such information and shall be liable to the Government for any misuse or unauthorized disclosure of such information by its personnel.

The rights and remedies of the Government, under this term and condition, shall not be exclusive and are in addition to any other rights and remedies provided to the Government under law, regulation, or any other available enforcement mechanism.

Mandatory Disclosures

In accordance with Section 75.113, Mandatory Disclosures, of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards. The non-Federal entity or applicant for a Federal award must disclose, in a timely manner, in writing to the Federal awarding agency or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Failure to make required disclosures can result in any of the remedies described in Section 75.371 of the Uniform Requirements including suspension or debarment.

Intangible Property

Intangible property, as defined in OMB's, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards means property having no physical existence, such as trademarks, copyrights, patents and patent applications and property, such as loans, notes and other debt instruments, lease agreements, stock, and other instruments of property, ownership (whether the property is tangible or intangible).

(a) Title to intangible property (see §75.2 Intangible property) acquired under a Federal award vests upon acquisition in the non-Federal entity. The non-Federal entity must use that property for the originally-authorized purpose, and must not encumber the property without approval of the HHS awarding agency. When no longer needed for the originally authorized purpose, disposition of the intangible property must occur in accordance with the provisions in §75.320(e).

(b) The non-Federal entity may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a Federal award. The HHS awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

(c) The non-Federal entity is subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401.

(d) The Federal Government has the right to:

(1) Obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and

(2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes

(e) Freedom of Information Act (FOIA). (1) In response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under a Federal award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS awarding agency must request, and the non-Federal entity must provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the HHS awarding agency obtains the research data solely in response to a FOIA request, the HHS awarding agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the Federal agency and the non-Federal entity. This fee is in addition to any fees the HHS awarding agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

(2) Published research findings means when:

(i) Research findings are published in a peer-reviewed scientific or technical journal; or

(ii) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law. "Used by the Federal Government in developing an agency action that has the force and effect of law" is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(3) Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: Preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples). Research data also do not include:

(i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

(f) The requirements set forth in paragraph (e)(1) of this section do not apply to commercial organizations

For any work owned by a third party that was licensed by the recipient under this award, the recipient will assure that said license also reserves for the Government a royalty free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes and to authorize others to do so.

Records Retention

Recipients generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of three (3) years from the date the final FFR is submitted. For awards where the FFR is submitted at the end of the competitive segment, the three-year retention period will be calculated from the date the final FFR, for the entire competitive segment, is submitted.

45 CFR Part 75.361 provides exceptions and qualifications to the three (3) year retention requirement. For example, if any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records must be retained until all litigation, claims, or audit findings involving the records have been resolved and final action taken. This section also specifies the retention period for other types of grant-related records, including indirect cost proposals and property records. See 45 CFR 75.335for record retention and access requirements for contracts under grants.

Modifications

Modifications and/or amendments to the cooperative agreement must be effective upon the mutual agreement of both parties, except where ONC is authorized under the Terms and Conditions of award, 45 CFR Part 75, or other applicable regulation or statute to make unilateral amendments.

Audit Requirements

The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, Subpart F, Audit Requirements sets forth standards for obtaining consistency and uniformity among Federal agencies for the audit of non-Federal entities expending Federal awards. In general, a non-Federal entity that expends $750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit. Subpart F provides further guidance including the manner in which expenditures are determined, the distinction between a single audit and a program-specific audit, frequency of audits, and roles and responsibilities in the conduct of audits.

G. Points of Contact

ONC Grants Management Officer
Carmel Halloun
330 C Street, S.W.
Washington, D.C. 20201

ONC Project Officer
Matthew Rahn
330 C Street, S.W.
Washington, D.C. 20201

ONC E-Mail Address
Comments and inquiries can be directed to the e-mail address: SDOFOA@hhs.gov, with the specific subject line:
" Closing the Gap between Standards Development and Implementation - Maturing the Consolidated Clinical Document Architecture (C-CDA) and Fast Healthcare Interoperability Resources (FHIR) Standards".

DUN and Bradstreet
http://www.dnb.com/
800.234.3867

System for Award Management (SAM) Customer Support
https://www.sam.gov
Federal Service Desk -- www.fsd.gov
866-606-8220

Grants.Gov Customer Support
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HHS Office of the Inspector General
The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS or 1-800-447-8477) for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Information also may be submitted by e-mail to hhstips@oig.hhs.gov or by mail to Office of the Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Ave., SW, Washington, DC 20201. Such information is treated as sensitive and complainants may decline to give their names if they choose to remain anonymous.

Tips for Writing a Strong Application

Include DUNS Number. You must include a DUNS Number to have your application reviewed. To obtain a DUNS number, access Dun & Bradstreet's website (http://www.dnb.com) or call 1-866-705-5711. Please include the DUNS number in item 8c on the application face page.

Keep your audience in mind. Reviewers will use only the information contained in the application to assess the application. Be sure the application and responses to the program requirements and expectations are complete and clearly written. Do not assume that reviewers are familiar with the lead recipient organization. Keep the review criteria in mind when writing the application.

Prepare early. Start preparing the application early. Allow plenty of time to gather required information from various sources.

Follow the instructions in this guidance carefully. Place all information in the order requested in the guidance. If the information is not placed in the requested order, you may receive a lower score.

Be brief, concise, and clear. Make your points understandable. Provide accurate and honest information, including candid accounts of problems and realistic plans to address them. If any required information or data is omitted, explain why. Make sure the information provided in each table, chart, attachment, etc., is consistent with the proposal narrative and information in other tables.

Be organized and logical. Many applications fail to receive a high score because the reviewers cannot follow the thought process of the lead recipient or because parts of the application do not fit together.

Be careful in the use of attachments. Do not use the attachments for information that is required in the body of the application. Be sure to cross-reference all tables and attachments to the appropriate text in the application.

Carefully proofread the application. Misspellings and grammatical errors will impede reviewers in understanding the application. Be sure that page limits are followed. Limit the use of abbreviations and acronyms, and define each one at its first use and periodically throughout application. Make sure you submit your application in final form, without markups.

Print out and carefully review an electronic application to ensure accuracy and completion. When submitting electronically, print out the application before submitting it to ensure appropriate formatting and adherence to page limit requirements. Check to ensure that all attachments are included before sending the application forward.

Ensure that all information is submitted at the same time. We will not consider additional information and/or materials submitted after your initial submission, nor will we accept e-mailed applications or supplemental materials once your application has been received.

Instructions - SF-424, Application for Federal Assistance

This is a standard form required for use as a cover sheet for submission of pre-applications and applications and related information under discretionary programs. Some of the items are required and some are optional at the discretion of the applicant or the federal agency (agency). Required fields on the form are identified with an asterisk (*) and are also specified as "Required" in the instructions below.

Item	Field Name	Information
1.	Type of Submission:	(Required) Select one type of submission in accordance with agency instructions. • Pre-application • Application • Changed/Corrected Application - Check if this submission is to change or correct a previously submitted application. Unless requested by the agency, applicants may not use this form to submit changes after the closing date.
2.	Type of Application:	(Required) Select one type of application in accordance with agency instructions. • New - An application that is being submitted to an agency for the first time. • Continuation - An extension for an additional funding/budget period for a project with a projected completion date. This can include renewals. • Revision - Any change in the federal government's financial obligation or contingent liability from an existing obligation. If a revision, enter the appropriate letter(s). More than one may be selected. If "Other" is selected, please specify in text box provided. A. Increase Award B. Decrease Award C. Increase Duration D. Decrease Duration E. Other (specify)
3.	Date Received:	Leave this field blank. This date will be assigned by the Federal agency.
4.	Applicant Identifier:	Enter the entity identifier assigned by the Federal agency, if any, or the applicant's control number if applicable.
5a.	Federal Entity Identifier:	Enter the number assigned to your organization by the federal agency, if any.
5b.	Federal Award Identifier:	For new applications leave blank. For a continuation or revision to an existing award, enter the previously assigned federal award identifier number. If a changed/corrected application, enter the federal identifier in accordance with agency instructions.

Item	Field Name	Information
6.	Date Received by State:	Leave this field blank. This date will be assigned by the state, if applicable.
7.	State Application Identifier:	Leave this field blank. This identifier will be assigned by the state, if applicable.
8.	Applicant Information:	Enter the following in accordance with agency instructions:
	a. Legal Name:	(Required) Enter the legal name of applicant that will undertake the assistance activity. This is the organization that has registered with the Central Contractor Registry (CCR). Information on registering with CCR may be obtained by visiting www.Grants.gov.
	b. Employer/Taxpayer Number (EIN/TIN):	(Required) Enter the employer or taxpayer identification number (EIN or TIN) as assigned by the Internal Revenue Service. If your organization is not in the US, enter 44-4444444.
	c. Organizational DUNS:	(Required) Enter the organization's DUNS or DUNS+4 number received from Dun and Bradstreet. Information on obtaining a DUNS number may be obtained by visiting www.Grants.gov.
	d. Address:	Enter address: Street 1 (Required); city (Required); County/Parish, State (Required if country is US), Province, Country (Required), 9-digit zip/postal code (Required if country US).
	e. Organizational Unit:	Enter the name of the primary organizational unit, department or division that will undertake the assistance activity.
	f. Name and contact information of person to be contacted on matters involving this application:	Enter the first and last name (Required); prefix, middle name, suffix, title. Enter organizational affiliation if affiliated with an organization other than that in 7.a. Telephone number and email (Required); fax number.

Item	Field Name	Information
9.	Type of Applicant: (Required) Select up to three applicant type(s) in accordance with agency instructions.	A. State Government B. County Government C. City or Township Government D. Special District Government E. Regional Organization F. U.S. Territory or Possession G. Independent School District H. Public/State Controlled Institution of Higher Education I. Indian/Native American Tribal Government (Federally Recognized) J. Indian/Native American Tribal Government (Other than Federally Recognized) K. Indian/Native American Tribally Designated Organization L. Public/Indian Housing M. Nonprofit N. Private Institution of Higher Education O. Individual P. For-Profit Organization (Other than Small Business) Q. Small Business R. Hispanic-serving Institution S. Historically Black Colleges and Universities (HBCUs) T. Tribally Controlled Colleges and Universities (TCCUs) U. Alaska Native and Native Hawaiian Serving Institutions V. Non-US Entity W. Other (specify)
10.	Name Of Federal Agency:	(Required) Enter the name of the federal agency from which assistance is being requested with this application.
11.	Catalog Of Federal Domestic Assistance Number/Title:	Enter the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested, as found in the program announcement, if applicable.
12.	Funding Opportunity Number/Title:	(Required) Enter the Funding Opportunity Number and title of the opportunity under which assistance is requested, as found in the program announcement.
13.	Competition Identification Number/Title:	Enter the competition identification number and title of the competition under which assistance is requested, if applicable.
14.	Areas Affected By Project:	This data element is intended for use only by programs for which the area(s) affected are likely to be different than the place(s) of performance reported on the SF-424 Project/Performance Site Location(s) Form. Add attachment to enter additional areas, if needed.
15.	Descriptive Title of Applicant's Project:	(Required) Enter a brief descriptive title of the project. If appropriate, attach a map showing project location (e.g., construction or real property projects). For pre-applications, attach a summary description of the project.

Item	Field Name	Information
16.	Congressional Districts Of:	15a. (Required) Enter the applicant's congressional district. 15b. Enter all district(s) affected by the program or project. Enter in the format: 2 characters state abbreviation - 3 characters district number, e.g., CA-005 for California 5th district, CA-012 for California 12 district, NC-103 for North Carolina's 103 district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all. If the program/project is outside the US, enter 00-000. This optional data element is intended for use only by programs for which the area(s) affected are likely to be different than place(s) of performance reported on the SF-424 Project/Performance Site Location(s) Form. Attach an additional list of program/project congressional districts, if needed.
17.	Proposed Project Start and End Dates:	(Required) Enter the proposed start date and end date of the project.
18.	Estimated Funding:	

(As applicable) Enter the amount requested, or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines, as applicable. If the action will result in a dollar change to an existing award, indicate only the amount of the change. For decreases, enclose the amounts in parentheses.

Applicants should review matching principles contained in 45 CFR 75.306 before completing Item 18. All budget information entered under item 18 should cover the upcoming budget period. For sub-item 18a, enter the federal funds being requested. Sub-items 18b-18e is considered matching funds. The dollar amounts entered in sub-items 18b-18f must total at least *[cite percentage or fraction]* of the amount of federal funds being requested (the amount in 18a). For sub-item 18f, enter only the amount, if any, which is will be used as part of the required match.

There are two types of match: 1) non-federal cash and 2) non-federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-recipients, contractors and consultants, are considered matching funds. Generally, most contributions from sub-contractors or sub-recipients (third parties) will be non-federal in-kind matching funds. Volunteered time and use of facilities to hold meetings or conduct project activities may be considered in-kind (third party) donations. Examples of non-federal cash match include budgetary funds provided from the applicant agency's budget for costs associated with the project.

Indirect charges may only be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency. State governments should enter the amount of indirect costs determined in accordance with HHS requirements. If indirect costs are to be included in the application, a copy of the approved indirect cost agreement must be included with the application. Further, if any sub-contractors or sub-recipients are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

Item	Field Name	Information
19.	Is Application Subject to Review by State Under Executive Order 12372 Process?	(Required) Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. Select the appropriate box. If "a." is selected, enter the date the application was submitted to the State.
20.	Is the Applicant Delinquent on any Federal Debt?	(Required) Select the appropriate box. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of federal debt include; but, may not be limited to: delinquent audit disallowances, loans and taxes. If yes, include an explanation in an attachment.
21.	Authorized Representative:	To be signed and dated by the authorized representative of the applicant organization. Enter the first and last name (Required); prefix, middle name, suffix. Enter title, telephone number, email (Required); and fax number. A copy of the governing body's authorization for you to sign this application as the official representative must be on file in the applicant's office. (Certain federal agencies may require that this authorization be submitted as part of the application.)

Instructions - SF-424A, Budget Information for Non-Construction Programs

Standard Form 424A is designed to accommodate applications for multiple grant programs; thus, for purposes of this program, many of the budget item columns and rows are not applicable. You should only consider and respond to the budget items for which guidance is provided below. Unless otherwise indicated, the SF 424A should reflect a two year budget.

Section A Budget Summary
Line 5: Leave columns (c) and (d) blank. Enter TOTAL federal costs in column (e) and total nonfederal costs (including third party in-kind contributions and any program income to be used as part of the recipients match) in column (f). Enter the sum of columns (e) and (f) in column (g).

Section B Budget Categories
Column 3: Enter the breakdown of how you plan to use the federal funds being requested by object class category (see instructions for each object class category below).

Column 4: Enter the breakdown of how you plan to use the non-federal share by object class category.

Column 5: Enter the total funds required for the project (sum of Columns 3 and 4) by object class category.

Separate Budget Narrative/Justification Requirement

You must submit a separate Budget Narrative/Justification as part of your application. When more than 33% of a project's total budget falls under a contractual expense, a detailed budget narrative/justification must be provided for each sub-contractor or sub-recipient. Applicants requesting funding for multi-year grant programs are required to provide a combined multi-year budget narrative/justification, as well as a detailed budget narrative/justification for each year of potential grant funding. A separate budget narrative/justification is also required for each potential year of grant funding requested.

In your Budget Narrative/Justification, you should include a breakdown of the budgetary costs for all of the object class categories noted in Section B, across three columns: federal; non-federal cash; and non-federal in-kind. Cost breakdowns, or justifications, are required for any cost of $1,000 or more. The Budget Narratives/Justifications should fully explain and justify the costs in each of the major budget items for each of the object class categories, as described below. Non-federal cash as well as, sub-contractor or sub-recipient (third party) in-kind contributions designated as match must be clearly identified and explained in the Budget Narrative/Justification The full Budget Narrative/Justification should be included in the application immediately following the SF 424 forms.

Line 6a: Personnel: Enter total costs of salaries and wages of applicant/recipient staff. Do not include the cost of consultants. Consultant costs should be included under 6h, Other. In the Budget Narrative/Justification: Identify the project director, if known. Specify the key staff, their titles, brief summary of project related duties, and the percent of their time commitments to the project in the Budget Narrative/Justification.

Some Points to Consider:

- ♦ Is the basis for determining each employee's compensation described (annual salary and % time devoted)?
- ♦ Is each position identified by title/responsibility?
- ♦ Are time commitments and the amount of compensation stated and reasonable?
- ♦ Are salary increases anticipated during the grant period and are they justified (COLA, etc.)?
- ♦ Are any personnel costs unallowable?
  - o Dual Compensation
  - o Federal Employee

Line 6b: Fringe Benefits: Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate. In the Justification: Provide a breakdown of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, etc.

Some Points to Consider:

- ♦ Is the amount specified as a separate line item?
- ♦ Is each type of benefit indicated separately or does the organization have an approved fringe benefit rate?
- ♦ Are fringe increases contemplated during the grant period?
- ♦ Are any fringe costs unallowable?

Line 6c: Travel: Enter total costs of out-of-town travel (travel requiring per diem) for staff of the project. Do not enter costs for consultant's travel - this should be included in line 6h. In the Justification: Include the total number of trips, destinations, purpose, and length of stay, subsistence allowances and transportation costs (including mileage rates).

Line 6d: Equipment: Enter the total costs of all equipment to be acquired by the project. For all recipients, "equipment" is nonexpendable tangible personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. If the item does not meet the $5,000 threshold, include it in your budget under Supplies, line 6e. In the Justification: Equipment to be purchased with federal funds must be justified as necessary for the conduct of the project. The equipment must be used for project-related functions; the equipment, or a reasonable facsimile, must not be otherwise available to the applicant or its subrecipients. The justification also must contain plans for the use or disposal of the equipment after the project ends.

Some Points to Consider:

- ♦ Are equipment items specified by unit and cost?
- ♦ Is the request reasonable and allowable under the project?
- ♦ Does the organization have a procurement policy in place?
- ♦ Is a lease vs. purchase study necessary (vehicles, large items of equipment)?
- ♦ Are purchases distinguishable from rentals?

Line 6e: Supplies: Enter the total costs of all tangible expendable personal property (supplies) other than those included on line 6d. In the Justification: Provide general description of types of items included.

Some Points to Consider**:**

- ♦ Are supplies listed separately?
  - o Office
  - o Training
  - o Research
  - o Other types of supplies
- ♦ How was cost determined?
- ♦ Is the basis for the cost reasonable? Monthly estimates are sufficient
- ♦ Are costs consistently treated?

Line 6f: Contractual: Enter the total costs of all contracts, including (1) procurement contracts (except those, which belong on other lines such as equipment, supplies, etc.). Also include any contracts with organizations for the provision of technical assistance. Do not include payments to individuals or consultants on this line. In the Budget Narrative/Justification attach a list of contractors indicating the name of the organization, the purpose of the contract, and the estimated dollar amount. If the name of the contractor, scope of work, and estimated costs are not available or have not been negotiated, indicate when this information will be available. Whenever the applicant/recipient intends to delegate more than 33% of a project's total budget to the contractual line item, the applicant/recipient must provide a completed copy of Section B of the SF 424A Budget Categories for each sub-contractor or sub-recipient, and separate Budget Narrative/Justification for each sub-contractor or sub-recipient for each year of potential grant funding.

Some Points to Consider:

- ♦ Is the type of each service to be rendered described?
- ♦ For Consultants/Individuals
  - o Is an hourly, daily or weekly base rate given?
  - o Are rates allowable, justified, reasonable and comparable to market?
- ♦ Is the total amount for any contract in excess of $150,000?
  - o Is procurement method described?
  - o If the contract is not competitively bid, has a sole source justification been provided?

Note: The competitive process must be used if goods and services will be provided through a contract (e.g., vendor or consultant). All costs associated with contracts should be included in this category. Sub awards are made to entities carrying out part of the program effort, goals and objectives. Sub awards are to be listed individually in the "Other" cost category.

Line 6g: Construction: Leave blank since construction is not an allowable cost under this program.

Line 6h: Other: Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to: insurance, medical and dental costs (i.e. for project volunteers this is different from personnel fringe benefits); non-contractual fees and travel paid directly to individual consultants; local transportation (all travel which does not require per diem is considered local travel); postage; space and equipment rentals/lease; printing and publication; computer use; training and staff development costs (i.e. registration fees). If a cost does not clearly fit under another category, and it qualifies as an allowable cost, then rest assured this is where it belongs. In the Justification: Provide a reasonable explanation for items in this category. For individual consultants, explain the nature of services provided and the relation to activities in the project. Describe the types of activities for staff development costs.

Some Points to Consider:

- ♦ Are items listed by major type (space rental, printing, phone, maintenance, etc.)?
- ♦ Are all costs justified, reasonable and allowable?
- ♦ Is there a reasonable basis for costs?
- ♦ List each sub award and amount of award
- ♦ Provide description of activities to be performed
- ♦ Describe method used to select the sub award and type of agreement to be awarded
- ♦ Provide a separate budget and budget narrative for each sub award

Note: Costs for contractual arrangements (vendors, consultants) should be budgeted in the "Contractual" cost category.

Line 6i: Total Direct Charges: Show the totals of Lines 6a through 6h.

Line 6j: Indirect Charges: Enter the total amount of indirect charges (costs), if any. If no indirect costs are requested, enter "none." Indirect charges may be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency.

Budget Narrative/Justification: State governments should enter the amount of indirect costs determined in accordance with HHS requirements. An applicant that will charge indirect costs to the grant must enclose a copy of the current indirect cost rate agreement. If any sub-contractors or sub-recipients are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.

If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

Line 6k: Total: Enter the total amounts of Lines 6i and 6j.

Line 7: Program Income: As appropriate, include the estimated amount of income, if any, you expect to be generated from this project. Program income must be used as additional program costs and cannot be used as match (non-federal resource).

Section C Non-Federal Resources - Not applicable

Section D Forecasted Cash Needs - Not applicable.

Section E Budget Estimate of Federal Funds Needed for Balance of the Project
Line 20: Section E is relevant for multi-year grant applications, where the project period is 24 months or longer. This section does not apply to grant awards where the project period is less than 17 months.

Section F Other Budget Information
Line 22: Indirect Charges: Enter the type of indirect rate (provisional, predetermined, final or fixed) to be in effect during the funding period, the base to which the rate is applied, and the total indirect costs. Include a copy of your current Indirect Cost Rate Agreement.

Line 23: Remarks: Provide any other comments deemed necessary.

Appendix D

Budget Narrative/Justification Template (with SAMPLE information)

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Personnel Salary	$40,000	$5,000		$45,000	♦Project Administrator Jane Doe = .3FTE @ $50,000/year = $15,000 $10,000 = Federal funds and $5,000 = non-federal cash ♦Project Director John Smith = 1FTE @ $30,000/year = $30,000 Federal funds **TOTAL: $45,000**
Fringe Benefits	$12,600	0	0	$12,600	Fringes benefit rate is 28% of salary as follows. All Federal Funds FICA (7.65%)= $3,442 Health Insurance (12%) = $5,400 Dental Insurance (5%) = $2,250 Life Insurance (2%) = $900 Workers Comp Insurance (.75%) = $338 Unemployment Insurance (.6%) = $270 **TOTAL: $12,600** ($45,000 * 28%)

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Travel	$4,120	$1,547		$5,667	♦Travel to two annual recipient meetings: All Federal funds. Airfare: 2 people x 2 trips $750/per round trip = $3,000 Lodging: 2 nights per trip x 2 people x $100/night x 2 trips = $800 Per Diem: 2 days per trip x 2 people x $40/day x 2 trips = $320 **Subtotal: $4,120** ♦Out-of-town site visits. Non-federal cash. Car mileage: 3 trips x 2 people x 350 miles/trip x $.365/mile = $767 Lodging: 3 trips x 2 people x 1 night/trip x $50/night = $300 Per Diem: 3 trips x 2 people x 2days/trip x $40/day = $480 **Subtotal: $1,547** **TOTAL: $5,667**
Equipment	0	0	0	0	No equipment requested
Supplies	$1,340	$2,160		$3,500	♦Laptop computer for use in client intakes – Federal Funds = $1,340 ♦Consumable supplies (paper, pens, etc.) – Non-federal cash $100/mo x 12 months = $1,200 ♦Copying – Non-federal cash $80/mo x 12 months = $960 **TOTAL: $3,500**
Contractual	$150,000		$50,000	$200,000	Contracts to A,B,C Contractor A to deliver supplies – Federal funds = $75,000 Contractor B to print materials – Federal funds= $75,000 Contractor C for logistical support– Non-Federal = $50,000 **TOTAL: $200,000**

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Other	$11,250	$2,000		$13,250	♦ Subaward to ABC to conduct training – Federal funds = $10,000 ♦ Printing brochures – Federal funds (25,000 @ $0.05 each) = $1,250 ♦ Registration fee for annual ABC conference – Non-federal cash = $200 ♦ Postage – Non-Federal Cash ($150/mo x 12 months) = $1,800 **TOTAL** **$3,250**
Indirect Costs	$12,000	$1,000	$1,000	$14,000	♦ Rent – Federal funds ($1,000/mos. x 12 months) = $12,000 ♦ Utilities – Non-federal cash = $1,000 ♦ Administrative Support – Non-Federal In-Kind 100 hours x $10/hour = $1,000 **TOTAL** **$14,000**
TOTALS	**$231,310**	**$11,707**	**$51,000**	**$294,017**	

Appendix E

Letter of Commitment Template

Matthew Rahn
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C. Street, 7th Floor, Office, S.W.
Washington, DC 20201

Date

Dear Mr. Rahn,

[Name of organization/group submitting the letter] is very interested in addressing [insert the issue being addressed by the grant application] and [state why the issue is a concern].

(State knowledge of proposal, knowledge of agency submitting proposal, and encouragement of funding entity to provide resources to address issue identified above).

(State that the need to address the issue is significant and how other resources to address the need are insufficient to address or impact the need).

(Describe your capacity and resources to produce required deliverables or services for the applicant)

(State how the organization will coordinate with appropriate partners to ensure efficient and effective use of grant funds).

(Conclude with general statement of confidence in and support for the organization seeking assistance, based on past experience with the applicant entity, reputation for effectiveness).

(Provide the following information for the point of contact in the supporting organization).
Name
Title
Agency
Division (if applicable)
State
Address
Phone
Fax Number
Email