Registry of Patient Registries

Agency for Healthcare Research and Quality (AHRQ)

Department of Health and Human Services

RESPONSE TO REQUEST FOR COMMENT

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Submitted to: ***AHRQ Desk Officer***
Office of Management and Budget (OMB)
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INTRODUCTION

As a subsidiary of Chickasaw Nation Industries, Inc. (CNI), CNI Professional Services, LLC (CNIPS) is pleased to present a brief capability summary in response to the request for comment issued for the Registry of Patient Registries Project for the U. S. Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ). CNIPS is a Tribally-owned, SBA-certified 8(a), Limited Liability Company (LLC) established in 2007 under its parent organization Chickasaw Nation Industries, Inc (CNI).

CNI was created in 1996 pursuant to the Oklahoma Indian Welfare Act and established as the Government contracting arm of the Chickasaw Nation. Headquartered in Norman, OK, CNI and its subsidiaries are experienced federal contractors with demonstrated excellence in contract and subcontract management. CNI is one of the largest and most successful corporations of its kind in the United States. Customers receive the backing of an organization that conducts over $250 million worth of business each year for the Federal Government and select private entities.

- 16 Years Federal Consulting Experience
- Past Performance with 9 Federal Departments
- LLC Established in 2007
- SBA-Certified, 8(a) Small Disadvantaged Business
- ISO 9001:2008 Certified
- HL7 & CDISC Members

- Locations
  - Headquartered in Norman, Oklahoma
  - Development Center and Lab in Rockville, MD
- Key Focus Areas
  - Information Technology
  - HL7 Implementation Services
  - Healthcare IT Services

As such, CNIPS brings to this and other requirements the full depth and breadth of our shared corporate intellectual capital, what we term our “Corporate Reach-back” support. This strategically-designed infrastructure is engineered to capture and maintain across our firm the most critical expertise and customer knowledge, and delivers along with it a level of financial and operational stability unique to the small business – and especially 8(a) – industry.

UNDERSTANDING OF THE REQUIREMENT

A patient registry is a system that uses observational research methods to collect data in support of scientific analyses of patient outcomes. Unfortunately, there are no centralized data banks today to store the data generated by patient registries. HHS has deployed the highly successful Clinical Trials Data Bank and website (ClinicalTrials.gov), which is designed to house data associated with experimental studies. The success of ClinicalTrials.gov is obvious given the tremendous volume of data that has been registered since its deployment (90,500 trials) and the amount of web traffic associated with the website. As there is no data bank available to house patient registry information, some users have tried to use ClinicalTrials.gov as a means to record patient registry data. Since the data bank was designed to support clinical trial data, it does not fully address the needs associated with patient registry data.

To more adequately address the specific requirements of patient registry information, HHS is considering the design and development of a Registry of Patient Registries (RoPR) data bank and website.

The RoPR would be compatible with ClinicalTrials.gov and would address the following objectives:

- Provide searchable database of existing patient registries in the United States promoting collaboration, reducing redundancy, and improving transparency;
- Implement standardized data fields and definitions to describe similar health conditions to maximize the potential for data sharing, comparing, and linkage;

- Provide a public repository containing searchable summary results that include data that may not yet have been published in peer-reviewed literature;
- Provide a search facility allowing researchers to identify existing data that can be used in new studies; and
- Serve as an outreach tool for researchers and potential patients interested in participating in patient registries.

The RFC provides additional high-level information regarding the RoPR, stating that the system would provide a web-based interface to input data for storage in the RoPR data bank. Also provided is extensive statistical information regarding the associated overhead and costs, including:

- Development of the RoPR system;
- Project management; and
- Data entry and maintenance effort.

SPECIFIC RESPONSES TO RFC

In the following sections, CNIPS addresses each of the areas where the RFC has solicited industry comment. The comments below are high-level summaries for public dissemination. We welcome the opportunity to provide detailed responses at a later date.

Necessity and Practicality of Proposed Data Collection

CNIPS is currently supporting numerous efforts associated with the collection, collation, and analysis of data in support of multiple projects for the Food and Drug Administration (FDA). One area of specialized expertise for CNIPS is Adverse Events Reporting. As such, we are intimately familiar with the goals/objectives associated with RofPR and feel strongly that the collection of this data is relevant to support the mission of AHRQ—particularly where the data collection is done in a manner that maximizes standardization, data sharing, and data analytics. The resulting data bank will offer tremendous value both within AHRQ and to external healthcare institutions interested in participating in and designing new patient registries.

The Accuracy of the Estimated Cost Burden

CNIPS understands the metrics used to derive the anticipated data collection/maintenance burden. We believe that the estimates are reasonable. However, we also feel it is important to note that this burden has the potential to be reduced depending on the design of the tools provided to collect and maintain RofPR data.

Regarding the cost burden associated with the development of the RofPR, we require additional information associated with the anticipated design and planned development tools. With the limited information provided, CNIPS finds it difficult to comment on this estimate.

Enhancing Data Quality, Utility, and Clarity

CNIPS would like to propose a number of ideas associated with improving data quality, utility and clarity.

Enhancing Quality and Clarity

The RFC has already stated the intent to use "common data fields and definitions". CNIPS has developed systems (such as Adverse Event Reporting Systems) that apply strict controls in this area leveraging data dictionaries. In many cases, applicable data dictionaries exist as off-the-shelf products that can be integrated into systems such as RofPR. Where off-the-shelf dictionaries do not exist, custom-developed dictionaries can be employed to achieve the same objective, like we have created for the FDA. The objective is to ensure that similar health conditions/symptoms are defined in the same terms. This type of consistency facilitates subsequent collaboration, data sharing, and linkages across registries. The use of such dictionaries also results in improved clarity as specific terms have specific meanings.

Enhancing Data Utility

Data utility is generally enhanced when it is easily accessible across authorized user communities and systems. To that end, CNIPS would like to suggest that the RofPR use an XML-based data repository. XML maximizes the ability to readily share data. In addition, when data must be exchanged between systems that are not based on XML, web services can easily be developed to present data to external systems/users in various other standard formats (AHRQ, HL7, etc).

An additional benefit of storing RofPR data in an XML-based repository is enhanced data mining/data analytical abilities. There are a number of off-the-shelf products that can be used to parse XML-based data to identify trends, signals, and other data analytical processes. This ability has the potential to greatly expand the utility of RofPR data. One of the stated objectives of the RofPR system is to provide users with search capabilities. XML-based data provides enhanced value in this area as well. Beyond traditional searches based on Boolean operators, XML supports extended search capabilities such as latent indexing and weighted averages.

Minimize Data Collection/Maintenance Burden

While CNIPS agrees that the utilization of a website as a means of collecting RofPR data is a good idea, we believe that this website should incorporate the data dictionary strategy discussed previously to facilitate data entry and mitigate the potential for data errors. In addition, there are other data entry strategies that should be considered. For example, there is a trend toward the deployment of "mobile applications" that run on smart phones and tablet computers. Our experience has demonstrated that such platforms can be an effective means to solicit data input. In addition, associated user communities may have internal systems to store and manage data associated with patient registries. In many cases, such systems have the ability to export data. As such, it might be appropriate to provide a data import facility based on common data standards.

CNIPS RELEVANT PAST PERFORMANCE

To substantiate our relevant expertise CNIPS would like to provide AHRQ with several examples of pervious projects we have completed that are similar in size and scope to the RofPR.

Electronic Drug Registration and Listing System (eDRLS)

eDRLS is a system used by the Food and Drug Administration (FDA) of Health and Human Services (HHS) to manage Structured Product Labeling (SPL) submissions. The system receives HL7-based SPL submissions from FDA's Electronic Submission Gateway, validates submissions via a validation schematron, and stores validated submissions in an XML-based data repository consisting of over 400 attributes. Additionally, eDRLS manages compliance activities such as:

- producing automated resubmission reminders;
- verifying registered facility and listed product information; and
- responding automatically to out-of-business events.

FDA Adverse Event Reporting System (FAERS)

FAERS provides a data repository for adverse events reporting. It is based on a Commercial-Off-The-Shelf (COTS) package—Oracle Adverse Events Reporting System. The system supports incoming data in a number of formats including XML, E2BM, and paper/web-based forms. FAERS also provides an optimized data warehouse to support data analytics and report generation. The system currently houses information associated with over 7 million cases.

eSubmitter

eSubmitter tool is part of an electronic submissions program that is available for use by sponsors, manufacturers, and importers to create a variety of submission types within the drug, blood, device, radiological health, tobacco and animal drug regulated industries. eSubmitter is a stand-alone application that allows the user to input data which is subsequently compiled resulting in the creation of an output file for electronic submission to the FDA. A number of interactive submissions forms were added to the existing tool to support adverse event reporting (ICSR/E2BM) and Structured Product Labeling (HL7/SPL).

SUMMARY

CNIPS would be happy to provide additional information regarding potential ideas and approaches we believe might have value with regard to the Registry of Patient Registries project. We would welcome the opportunity to demonstrate similar systems we have developed for other HHS clients that have similar requirements. Thank you for the opportunity to provide input regarding this important initiative.