Department of Health and Human Services (HHS) Fiscal Year 2021 Agency Report

1. Please provide a summary of your agency's activities undertaken to carry out the provisions of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" and the National Technology Transfer and Advance Act (NTTAA). The summary should contain a link to the agency's standards-specific website(s) where information about your agency's standards and conformity assessment related activities are available.

1) Agency for Healthcare Research and Quality (AHRQ)

The mission of AHRQ is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. AHRQ uses voluntary consensus standards in our national Medical Expenditure Panel Survey, in our Healthcare Costs and Utilization Project, in our Quality Indicators, and in AHRQ's United States Health Information Knowledgebase. AHRQ supports the U.S. standards developing organizations (SDOs) through participation in relevant workgroups. By improving the uniformity, accuracy, validity and digitization of health data used for research and decision making, AHRQ increases the robustness of its research findings and the usability of tools developed based on these findings.

2) Centers for Disease Control and Prevention (CDC)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

CDC Centers, Divisions, and Programs work with partners in a voluntary and consensus manner to develop, evaluate, and apply standards for data capture and dissemination. Below is a summary of significant standards for communications, messaging, data structuring and transport. CDC endeavors to follow industry or community agreed upon standards with subtle content level modifications to accommodate the complex and varied demands of public health whenever possible. During the development process, CDC works with local public health departments, academia, non-profits, and healthcare industry and information technology partners to collaboratively achieve consensus.

Type / Domain Document Transaction Standard(s) Used Status

- Communications and Directory HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US

- Cancer Reporting:
  (Stage 3 MU) HL7 CDA Published
  Communications and Directory Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries (March 2014)

- Cancer Reporting:
  (Stage 2 MU) HL7 CDA Published
  Communications and Directory Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries (August 2012)

- Cancer Reporting
  (Stage 2 MU) HL7 CDA Published
  Communications and Directory PHIN Communication and Alerting (PCA) Guide Version 1.3 (April 27, 2010) Public Health Alerting EDXL V 1.0
  CAP V1.1 Published
  Communications and Directory PHIN Directory Exchange Implementation Guide Version 1.0 (May 16, 2007)
  Public Health Directory Exchange DSML 1.0 Published

- ELR HL7 Version 2.5.1 Implementation Guide:Electronic Laboratory Reporting to Public Health (US Realm), Release 2, HL7 Informative Document (May 2014)
  (HL7 account required) Electronic Laboratory Reporting to Public Health HL7 2.5.1 Published

- NNDSS https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html
  Specific Notifiable Disease Reporting to Public Health (Final Guides) HL7 2.5.1 Published
  Syndromic Surveillance (HL7 Standard for Trial Use) Syndromic Surveillance Message Mapping Guides
  Syndromic surveillance transmissions from healthcare providers to public health HL7 Version 2.5.1,
  ICD-10-CM,
  SNOMED-CT,
  LOINC,
  Rx Norm,
  UCUM,
  CPT4 HL7 Standard for Trial Use v.1. Available on the HL7 website (membership required.
  Syndromic Surveillance PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 (April, 2015)

- Erratum to the PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings ADT Messages A01, A03, A04 and A08 Optional ORU^R01 Message Notation for Laboratory Data HL7 Version 2.5.1 (Version 2.3.1 Compatible) Release 2.0 April 21, 2015pdf icon
  PHIN 2.0 Implementation Guide Meaningful Use Clarifying Document (PDF available on NIST Website)external icon
  Sending data from emergency department, urgent, ambulatory care and inpatient settings to public health authorities

- Certifying 2014 Edition Meaningful Use electronic health record technology HL7 2.5.1 Published as CDC version 2.0

Center for State, Tribal, Local, and Territorial Support (CSTLTS)

The Centers for Disease Control and Prevention (CDC) Center for State, Tribal, Local, and Territorial Support (CSTLTS) has been a key supporter in the development, launch and support of the voluntary accreditation program for public health departments. A non-profit accrediting body, the Public Health Accreditation Board (PHAB), was established to lead the accreditation program which launched in September 2011. CDC has been involved as a partner and funder of this initiative to provide support to PHAB's accreditation and continuous improvement activities. As part of this effort, PHAB engaged hundreds of public health practitioners in developing and testing all elements of the program, including the standards and accreditation assessment process. The PHAB standards and assessment process meet the definitions of OMB Circular A-119, regarding voluntary consensus standards and conformity assessment processes.

Until the establishment of PHAB, there had been no national accreditation program for public health departments. The program is intended to "improve and protect the health of the public by advancing the quality and performance of public health departments.". The first cohorts of health departments were accredited in early 2013. As of the end of FY 2021:

• PHAB has accredited 394 health departments—39 states, five tribes, and 350 local health departments (including 283 individually accredited local health departments and 67 county health departments through a centralized state application).
• 89% of the U.S. population is served by an accredited health department (HD).
• PHAB began reaccrediting sites in 2018; 51 sites have been reaccredited.
• 506 HDs, including 42 SHDs, are formally in the accreditation process (applied or accredited) and are demonstrating how they meet the national standards.

All documents related to the accreditation program (the standards, assessment process guidance, glossary, etc.) are available at www.phaboard.org. The initial national consensus standards were released in July 2011 (Version 1.0) and an update (Version 1.5) was released in 2014. CDC participated in PHAB efforts to support requirements for reaccreditation, published manuscripts about its support of accreditation in a journal, and has been collaborating to explore a variety of topics to inform updates to the Standards and Measures. In FY21, CDC supported PHAB in producing and vetting the Version 2022 Standards and Measures, which are being finalized to reflect public comments and planned for release in 2022. CDC's interest and support regarding this accreditation program is evidenced through its accreditation page at https://www.cdc.gov/publichealthgateway/accreditation/.

Evaluation data to date show very positive findings about benefits and impact. A PHAB survey in July 2020 found that more than 80% of accredited health departments indicated that, overall, accreditation has helped their response to the COVID-19 pandemic. Annual evaluation findings also consistently report short- and long-term benefits to participating in accreditation. June 2021 evaluation data indicate that the program has stimulated quality improvement (95% of accredited health departments agree), improved accountability and transparency (89%), improved the capacity of the department to provide

high quality programs and services (85%), and improved collaboration across units within the health department (88%) one year after accreditation. Four years after accreditation, the program has helped health departments use health equity as a lens for identifying and addressing health priorities (73%) and strengthened the utilization of resources (68%). More information about the positive impact of the accreditation program can be found by reviewing data and reports available through PHAB's website.

Division of Cancer Prevention and Control (DCPC)

CDC's National Program of Cancer Registries (NPCR) works to measure progress in preventing and treating cancer, a leading cause of death in the United States. Established by Congress through the Cancer Registries Amendment in 1992, NPCR collects data on cancer occurrence (including the type, extent, and location of the cancer), the type of initial treatment, and outcomes. Today, through NPCR, CDC supports central cancer registries in 46 states, the District of Columbia, Puerto Rico, the U.S. Pacific Island Jurisdictions, and the U.S. Virgin Islands. These data represent 97% of the U.S. population. NPCR follows the data collection and quality standards in the North American Association of Central Cancer Registries (NAACCR) consensus documents. Annually, these data are evaluated for quality, completeness, and timeliness according to the National Data Quality Standard for 23-month data and the Advanced National Data Quality Standard for 12-month data. Data also are evaluated according to the USCS Publication Standard before publication. NPCR standards can be found here.

National Center for Health Statistics (NCHS)

The National Center for Health Statistics (NCHS) participates in health data standards activities providing public health representation in the development, maintenance, and implementation of national healthcare standards. These activities support the divisions within NCHS and have included standards and implementation projects within the Division of Vital Statistics (DVS) and the Division of Health Care Surveys (DHCS). The Classification and Public Health Data Standards Staff (CPHDSS) supports the development of national standards for the center and has worked with NCHS divisions in representing their standards development work at national level standards development organizations. In support of the agency wide data modernization initiative, divisions mentioned below are actively working on standards development efforts to provide a mechanism utilizing information obtained from health IT systems for public health reporting.

Division of Vital Statistics (DVS)

The Division of Vital Statistics (DVS) in collaboration with CPHDSS is working with HL7 to maintain and create mortality and natality national reporting standards. The mortality standards include the continued maintenance and updates of the Vital Records Death Reporting (VRDR) FHIR implementation guide (IG). Over the course of 2021 and beyond, the VRDR FHIR IG is being updated to include the inter-jurisdictional exchange content that jurisdictions utilize to exchange data among each other and with NCHS. This work will include substantial changes to this specification and these updates will be tested in May 2022. Related to natality reporting the Birth and Fetal Death (BFDR) FHIR standard was balloted through HL7 in January in 2021 and has been published as a standard for trial use. It is also being utilized by two state pilot projects who are currently creating a SMART on FHIR application to test data quality in receiving medical

birth information from an EMR. Listings of the aforementioned published HL7 standards can be found here: http://www.fhir.org/guides/registry/ Lastly, recent development of a Medicolegal Death Investigation (MDI) FHIR standard is underway and will balloted through HL7 in May 2022. This standards development project will aim to support the Medical Examiner and Coroner (ME/C) community in helping improve the timeliness of these types of data. An initiative to support these development efforts is known as the National Vital Statistics System (NVSS) Community of Practice. The NVSS CoP not only supports the development of national standards but also provides resources to jurisdictions on the modernization of their electronic registration systems. Further information on jurisdictional participation for vital records offices can be found here: https://www.cdc.gov/nchs/nvss/modernization/cop.htm

Division of Health Care Statistics (DHCS)

The Division of Health Care Statistics in collaboration with CPHDSS is working with HL7 to maintain the existing CDA National Health Care Surveys Standards (see: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=385). To that end NCHS has worked with the HL7 Public Health Working Group to resolve comments on STU Releases 1.2 and 3.0 of the National Health Care Surveys CDA Standards and work is in progress to ballot two "dot releases" of these standards which are expected to result in the new National Health Care Surveys CDA Standards Releases 2.1 and 3.1 in January 2022.

While maintaining its CDA healthcare interoperability standards, DHCS--in collaboration with CPHDSS and CDC CSELS colleagues--is developing new HL7 FHIR standards as part of the Making EHR Data More Available for Research and Public Health (MedMorph) Project, a PCOR Trust Fund funded project. DHCS's National Health Care Surveys are one of the three core public health use cases in the MedMorph Project. In January 2021 MedMorph successfully balloted a HL7 MedMorph Reference Architecture (RA) Implementation Guide (IG). This MedMorph RA IG establishes a common framework (e.g., FHIR resources, FHIR APIs, FHIR operations, security mechanisms) that will be leveraged by multiple public health and research use cases. On December 10, 2020, the Health Care Surveys Content Implementation Guide Standard for Trial Use (STU) ballot process was started. (see: http://hl7.org/fhir/us/health-care-surveys-reporting/2022Jan/index.html) This Content IG is designed to work "hand in glove" with the MedMorph RA IG to allow a low burden way for health care providers to use their EHR's FHIR APIs to submit National Health Care Surveys to NCHS. The content that the Health Care Surveys Content IG specifies is highly aligned with the United States Core Data for Interoperability (USCDI) which is operationalized in the IG vi HL7 US Core Resource Profiles. It is anticipated that the CDA National Health Care Surveys IG Releases will remain in use for the next several years as the Health Care Survey FHIR Content IG is piloted in 2022 and then more fully adopted in 2023 and beyond.

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Division for Heart Disease and Stroke Prevention

As much as possible, DHDSP works to follow existing standards in public health activities and surveillance. A current project leverages existing CMS eClinical Quality Measures (http://hl7.org/fhir/us/cqfmeasures/) to develop use cases for public health surveillance of

hypertension control (CMS165) and diabetes control (CMS122) from EHR data, using electronic case reporting technology (http://build.fhir.org/ig/HL7/case-reporting/) aligned with the FHIR reference architecture known as Making EHR Data More Available for Research and Public Health (MedMorph). MedMorph refers to a common framework (including FHIR resources, FHIR APIs, FHIR operations, and security mechanisms) that can be used in many public health use cases.

CDC Diabetes Prevention Recognition Program (DPRP)

The Centers for Disease Control and Prevention (CDC) established the CDC Diabetes Prevention Recognition Program (DPRP) (https://www.cdc.gov/diabetes/prevention/lifestyleprogram/index.html) as part of the National Diabetes Prevention Program (National DPP) (https://www.cdc.gov/diabetes/prevention/index.html). The DPRP is the quality assurance arm of the National DPP. It provides information about the location and performance of type 2 diabetes prevention programs across the US. This includes organizations delivering the National DPP lifestyle change program in-person, online, via distance learning, and through a combination of these delivery modes. The purpose of the DPRP is to recognize organizations that have demonstrated their ability to effectively deliver a proven type 2 diabetes prevention lifestyle change program.

The DPRP assures the quality of recognized organizations and provides standardized reporting on their performance. The original 2012 DPRP Quality Standards were based on successful efficacy and effectiveness studies. In one such efficacy study, the US Diabetes Prevention Program research trial (DPP), participants in the lifestyle intervention losing 5-7% of their bodyweight experienced a 58% lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention (see https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-preventionprogram-dpp/Documents/DPP_508.pdf). The current standards, though still grounded in the earlier research, incorporate innovations from further translational studies, best practices, and expert opinion.

The DPRP has three key objectives:

- Assure program quality, fidelity to scientific evidence, and broad use of an effective type 2 diabetes prevention lifestyle change program throughout the United States;
- Develop and maintain a registry of organizations that are recognized for their ability to deliver the National DPP lifestyle change program to people at high risk;
- Provide technical assistance to organizations to assist staff in effective program delivery and in problem-solving to achieve and maintain recognition status.

Program delivery organizations must also track results and send data to CDC every 6 months to show that they are having an impact on preventing or delaying type 2 diabetes. CDC reviews these data and provides feedback to each organization. DPRP evaluation data to date show that evaluated participants attended an average of 18 core sessions and 8 core maintenance in the National DPP lifestyle change program. Participant risk reduction, determined using participant outcomes associated with weight, physical activity minutes, and HbA1c, was seen in 51.8% of all

evaluated participants. This risk reduction included 47.7% who achieved at least a 5% weight loss; 35.6% who achieved at least a 4% weight loss combined with at least 150 min/week, on average, of physical activity; and 0% to date who had at least a 0.2% reduction in HbA1c*. As of January 5, 2022, there are 2,114 CDC-recognized organizations that have collectively enrolled 584,994 participants nationwide since the program's inception.

National Institute for Occupational Safety and Health (NIOSH)

The National Institute for Occupational Safety and Health (NIOSH) encourages its employees with relevant expertise to participate as approved representatives in the development of national and international standards activities as part of voluntary consensus standards committees. NIOSH currently has 51 staff contributing their expertise to approximately 22 major committee organizations (e.g., ANSI, ISO, ASTM, NFPA). Participation by NIOSH staff on such committees affords the Institute an opportunity to ensure standards are established using sound evidence-based science, as well as to help facilitate the transfer of NIOSH research findings into improved occupationally-related health and safety practices, procedures, and policies. A list of NIOSH-approved participation in established voluntary consensus standards committees can be found at: http://od.niosh.cdc.gov/Consensus-Standards/Consensus-Standards.html.

The Office of Laboratory Science and Safety (OLSS)

The Office of Laboratory Science and Safety encourages its employees with relevant expertise to participate as approved representatives in the development of national and international standards activities as part of voluntary consensus standards committees. OLSS currently has 1 staff contributing their expertise to 2 major committee organizations (i.e., ANSI and ISO). Participation by OLSS staff on such committees affords an opportunity to ensure standards are established using sound scientific and management expertise, as well as to help facilitate awareness of internationally recognized technical laboratory standards in OLSS's mission to promote excellence in scientific research, safety practices, procedures, and policies.

National Center for HIV, Viral Hepatitis, STD, and TB Prevention

The Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) is a supporter in the development and implementation of interoperability standards for health data through the United States Core Data for Interoperability (USCDI). NCHHSTP subject matter experts (SMEs) contributed to the following USCDI version 3 use cases: patient demographics-country of usual residence and immunization administered date. Further, NCHHSTP SMEs promoted use of USCDI value sets for sexual orientation and gender identity (SOGI) data elements when collaborating with CDC's Center for Surveillance, Epidemiology, and Laboratory Services (CSELS) to have these SOGI data elements included as optional data elements within the National Notifiable Disease Surveillance System (NNDSS).

Division of Sexual Transmitted Disease Prevention (DSTDP)

DSTDP is developing a standards-based syphilis and congenital syphilis registry model leveraging Fast Healthcare Interoperability Resources (FHIR). FHIR is a standard describing data formats and elements and an application programming interface (API) for exchanging electronic health records (EHR). To date, FHIR has been used to enhance electronic case reports, specifically obtaining data on patient diagnoses, symptoms, medications and demographics.

Division of Tuberculosis Elimination (DTE)

DTE's Clinical Research Branch (CRB), through the Tuberculosis Trials Consortium (TBTC), conducts programmatically relevant clinical trials to improve treatment options and outcomes for tuberculosis disease and latent tuberculosis infection. CRB serves as the sponsor for these clinical studies, and, as such, has the regulatory responsibility to submit trial data to the US Food and Drug Administration conforming to Clinical Data Interchange Standards Consortium (CDISC) standards. Data for all TBTC studies are collected in Clinical Data Acquisition Standards Harmonization (CDASH) format and transformed to the Study Data Tabulation Model (SDTM) for submission to FDA.

3) Centers for Medicare and Medicaid Services (CMS)

The National Standards Group (NSG) within the Office of Burden Reduction & Health Informatics at the Centers for Medicare & Medicaid Services (CMS) is responsible for adopting and enforcing national standards and operating rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification provisions to increase the electronic exchange of health information between covered entities. HIPAA covered entities include health plans, health care providers and health care clearinghouses, as defined in HIPAA. Representatives from NSG participate with several national standards development organizations as they develop and/or update the standards and operating rules in preparation for the next version to be considered for adoption. NSG is committed to enforcing adoption of electronic standards by all covered entities, including those organizations in the private and public sector, as electronic transaction standards will increase efficiency in health care.

The specific transactions (for business operations) developed by these organizations include enrollment, eligibility, claims, claim status, electronic funds transfer, remittance advice, prior authorization, and attachments. NSG staff participate in workgroups of the standards setting organizations listed below:

- Health Level 7 (HL7): www.HL7.org
- National Council for Prescription Drug Programs (NCPDP): www.ncpdp.org
- American Dental Association: www.ada.org
- American Medical Association: www.ama-assn.org
- Accredited Standards Organization, Insurance (X12N): www.x12.org
- Council for Affordable Quality Healthcare (CAQH) Committee for Operating Rules for Information Exchange (CORE) CAQHCORE: www.caqh.org

- NACHA (the Electronic Payments Association): www.nacha.org
- The Designated Standards Maintenance Organization (DSMO): www.hipaa-DSMO.org

NSG consults with numerous other stakeholder groups, such as the NUCC, NUBC, WEDI, and regularly engages with the National Committee on Vital and Health Statistics, advisory body to the Secretary.

The Quality Measurement and Value-Based Incentives Group (QMVIG) in the Centers for Clinical Standards and Quality (CCSQ) at CMS selects performance measures for use within its various quality initiatives including healthcare provider public reporting and value-based purchasing programs. CMS prefers selecting performance measures that have been reviewed through a consensus process, and can be considered consensus-based standards. National Quality Forum (NQF), a not-for-profit, nonpartisan, membership-based organization, meets the NTTAA definition of a consensus-based organization. CMS currently contracts NQF to execute a public and transparent consensus development process to endorse and maintain performance measures. NQF's consensus development process (CDP) includes an open call for candidate consensus standards (i.e., performance measures); multi-stakeholder review of scientific and statistical evidence against NQF-endorsement criteria; discussion and evaluation of measures by multi-stakeholder experts including patient and caregiver advisors; and opportunities for stakeholder feedback and public comments throughout the process. The CDP also includes a process for stakeholders and the public to object to measures after they receive NQF-endorsement. NQF's processes are consistent with the NTTAA and OMB Circular A-119.

1) CMS Quality Measures: http://www.cms.gov/QualityMeasures/
2) National Quality Forum: http://www.qualityforum.org/

4) Food and Drug Administration (FDA)

FDA is responsible for protecting public health by helping to bring safe and effective medical products and foods to the U.S. public; and advancing public health by ensuring the public has the most accurate, science-based information they need to use medicines and foods to improve and maintain their health. Standards help to ensure data and process consistency and enable use of advanced technology and analytics in FDA's performance of its mission. Where feasible, FDA participates in the development of, and uses voluntary consensus standards to help facilitate consistent and predictable product manufacturing and assessment, regulatory testing, clinical trial data exchange, and product labeling, just to name a few examples. Information exchange with our stakeholders promotes efficiency and awareness in the standards setting processes. The Agency looks for the appropriate time, process, and forum by which we can engage with standard development organizations. By doing so, FDA can facilitate standard setting activities and not hinder or duplicate efforts that are already underway in complementary bilateral or multilateral discussions. The use of voluntary consensus standards can increase predictability, streamline premarket review, and facilitate market entry for safe

and effective products, including products of emerging technologies, under FDA regulatory authority.

In addition, FDA participates actively in the standard setting process of the Codex Alimentarius, which for over 50 years has provided governments with a venue for adoption of food standards to facilitate safety and fair-trade practices. Codex is a joint body of the Food and Agricultural Organization of the United Nations and of the World Health Organization, and the standards developed through this body are recognized by the World Trade Organization. FDA supports Codex through the participation of experts and delegates representing the United States and through hosting meetings, along with the (The U.S. Department of Agriculture's (USDA) USDA Food Safety and Inspection Service. While FDA is not obligated to adopt the standards, Codex provides greater assurances of the safety of food imports, as many countries that export to the United States will adopt Codex standards.

Standards developed through interactions with various standard development bodies, including VCS organizations and/ or industry consortia, can provide benefit to both the Agency and our stakeholders in multiple ways such as:

- Standards can assist regulatory reviewers with assessment of products and product applications;
- Standards can assist industry with methodologies they can adopt for the assessment of their products;
- Standards often result in better utilization of limited internal resources;
- International standards can be used by multiple regulatory regions that can facilitate global harmonization, to the extent feasible;
- Direct participation by a broad group of stakeholders in development of standards can result in consensus among users, practitioners, manufacturers, and government regulators on safety and effective use of regulated products;
- Reduction in the costs and in transcription errors resulting from manual data entry such as for registrations and listing and adverse event reporting; and
- Reduction in the cost for incorporating new electronic processes such as electronic food and device labeling by leveraging existing exchange standards, business processes and information technology (IT) systems.

FDA policy is to help develop and use voluntary consensus standards wherever possible in the management of products FDA regulates. FDA supports the letter and spirit of the National Technology Transfer and Advancement Act (NTTAA) and the Office of Management and Budget (OMB) Directive. For more information about FDA's policies and procedures related to standards management, please see our Staff Manual Guide 9100.1 at: https://www.fda.gov/media/79684/download

For more information about FDA data standards and the FDA Data Standards Advisory Board, please see: http://www.fda.gov/ForIndustry/DataStandards/default.htm

Center for Devices and Radiological Health (CDRH)

CDRH gained authority under the 21st Century Cures Act to enhance its Standards Recognition Program. A final guidance titled Recognition and Withdrawal of Voluntary Consensus Standards published on September 15, 2020 notes that FDA will publish its rationales about recognition decisions, respond to recognition requests within 60 days and establish transition times to revised recognized standards (when appropriate). Finally, the guidance reflects FDA's commitment to periodically update the Recognized Standards Database with pending recognitions. This means that once FDA conveys its intention to recognize a standard it will appear in the standards recognition database. Manufacturers may cite it in premarket submissions and will no longer need to wait for the publication of a *Federal Register* notice.

During FY2021, in accordance with section 514(c), 21 U.S.C. 360d(c), FDA/CDRH published the following notices to the Federal Register to announce the addition, withdrawal, correction, and/or revision of certain consensus standards the Agency will recognize for use towards a declaration of conformity in premarket submissions and other requirements for medical devices:

Publications in the Federal Register related to Modifications to the List of Recognized Standards is available at
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm

Standards recognitions published during FY 2021

Date	Federal Register Notice
March 3, 2021	FR Notice (List #54) [Docket No. FDA-2004-N-0451] https://www.fda.gov/media/146431/download
April 29, 2021	FR Notice (List #55) [Docket No. FDA-2004-N-0451] https://www.fda.gov/media/148113/download

Access to the current FDA List of Recognized Consensus Standards, as published and updated in the Federal Register, can be found at
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Conformity Assessment

In general, conformity assessment activities for FDA-regulated products are conducted under applicable regulations and guidance that are informed by our standards development efforts described above. Standards may become part of conformance activities as they may provide an acceptable approach to ensure compliance with applicable laws and regulations.

CDRH's Standards and Conformity Assessment Program (S-CAP) has launched a voluntary pilot called the 'Accreditation Scheme for Conformity Assessment,' or ASCA. Conceptualized to promote a least burdensome approach to medical device review, ASCA was developed in conjunction with the device manufacturing industry, standards development organizations and conformity assessment entities. The ASCA Pilot relies upon international consensus standards (ISO/IEC 17011 and ISO/IEC 17025) augmented by additional ASCA specifications and is designed to increase FDA's confidence in testing methods and results from ASCA-accredited testing laboratories. Ultimately the ASCA Pilot is expected to make device review more efficient, ensuring patients have access to safe and effective

medical devices without unnecessary delay. The final guidances outlining program specifications can be found on the ASCA Pilot web page and listed below:

- **ASCA Pilot program guidance:** *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance*
- **Basic Safety and Essential Performance standards-specific guidance:** *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*

- **Biocompatibility standards-specific guidance:** *Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*

The docket number: for these guidances are under docket FDA-2019-D-3805 published on September 25, 2020.

Under the ASCA Pilot, at the end of FY21, CDRH has provided ASCA recognition to 5 Accreditation Bodies and granted ASCA-accreditation to 77 testing laboratories under the scope of standards and methods included in the ASCA Pilot.

Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM)

The FDA Food Safety Modernization Act (FSMA) gives the Agency explicit authority to establish a program for accreditation of conformity assessment bodies (identified in the statute as third-party auditors) to conduct food safety audits and to issue certifications for FDA-regulated food, which includes human food, pet food, and non-medicated animal feed. FSMA established the "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications," program at 21 CFR part 1 subpart M. The regulation describes the framework, procedures and requirements for accreditation bodies seeking recognition by the FDA, as well as requirements for third-party certification bodies seeking accreditation under the program. Accreditation bodies and third-party certification bodies may use documentation of their conformance with ISO/IEC 17011:2004, ISO/IEC 17021:2011, and ISO/IEC 17065:2012 in meeting the requirements of the regulation, supplemented as necessary (e.g., to meet the conflict of interest, reporting, and notification standards in section 808 of the FD&C Act). FDA recommendations on third-party certification body qualifications for accreditation to conduct food safety audits and to issue food and/or facility certifications under the voluntary third-party certification program are contained in a guidance document entitled, "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards."

As part of these recommendations, FDA cited ISO/IEC 17021:2011 and ISO/IEC 17065:2012, which are voluntary consensus standards on accreditation that are widely used in determining the qualifications of third-party conformity assessment bodies that audit and certify the food industry. As of the end of FY21, the FDA has recognized 4 accreditation bodies which have accredited 13 certification bodies. FDA maintains an online registry of recognized accreditation bodies and accredited certification bodies.

FSMA also gives us express authority to establish a laboratory accreditation program for the analyses of human and animal foods. FDA issued a proposed rule in November 2019 that would implement this program. The proposed rule would establish the oversight, uniformity, and standards necessary to help ensure that the results of certain food testing of importance to public health are reliable and accurate. As proposed, FDA would recognize accreditation bodies that would then accredit laboratories to conduct food testing. The proposed rule would incorporate by reference two voluntary consensus standards: ISO/IEC 17011:2017 would form the foundational requirement for accreditation bodies, and ISO/IEC 17025:2017 would form the foundational requirement for food testing laboratories. The comment period closed in July 2020; FDA expects to issue a final rule establishing this program in late 2021.

FDA's Moffett Proficiency Testing Laboratory (Moffett PT), located within CFSAN's Office of Food Safety, Division of Food Processing Science and Technology and part of the Institute for Food Safety and Health, has been an ISO/IEC 17043 accredited proficiency testing provider since February 2017 but has been in operation within FDA in varying capacities since the 1950s. This PT program's scope of work is expansive as it is the official PT provider for FDA's inter-/intra-agency programs (CVM Veterinary Laboratory Investigation and Response Network, Office of Regulatory Affairs (ORA) Office of Regulatory Science (ORS) Quality Assurance programs/dietary supplement adulteration, FDA/USDA Food Emergency Response Network) as well as regulatory and food safety programs for milk, shellfish, vitamins, and food microbiology. FDA's Moffett PT incorporates both food microbiological and chemical analytes and matrices based on the historical, current, and emerging food safety and defense requirements of the FDA. Microbiological PT schemes, for example, include bioterror agents such as *B. anthracis* (attenuated), *Y. pestis* (attenuated) or *F. tularensis* (attenuated strains) and food pathogens such as *Listeria*, *Salmonella*, *Vibrio* and others in variety of food products. Chemical PT schemes include glyphosate, tetramine, thallium, aflatoxin B1, carbamates, ricin and other toxins in a variety of food products. In addition, FDA's Moffett PT schemes include detection for fraudulent weight loss and erectile dysfunction drugs in dietary supplements. Moffett PT's expansive ISO/IEC 17043 accredited scope of work has greatly contributed to the groundwork built by FSMA for model laboratory standards, accreditation, and capacity/capability building of the nation's food laboratory networks.

Office of Regulatory Affairs (ORA)

Through self-coordinated or collaborative method development & research to support regulatory testing, the ORA Office of Regulatory Science (ORS) laboratory network actively contributes to the repertoire of consensus analytical methods that are published in the AOAC's compendium of the Official Methods of Analysis. According to 21CFR2.19, the Official Methods of Analysis of the AOAC INTERNATIONAL are specified to be used in cases where a method of analysis is not prescribed in the regulation.

Within the framework of a current FDA-USP Cooperative Research and Development Agreement (CRADA), ORA/ORS Laboratories also conduct analytical work aimed at updating and harmonizing USP pharmaceutical analysis monographs using USP reference materials.

ORA/ORS laboratories are accredited to ISO/IEC 17025 standards. The FDA Forensic Chemistry Center (FCC), the ORS forensics specialized lab, is accredited to the standards of ANSI-ASQ National Accreditation Board (ANAB) / American Society of Crime Lab Directors or ASCLD. Each laboratory conforms to the core requirements of a Quality Management System (QSM) which includes the

design and maintenance of a proficiency testing and exercise schedule. This proficiency testing program of ORA/ORS laboratories is called the National Check Sample Program and aims to provide an assessment of laboratory proficiency in performance of analytical methods in the accreditation scope. Some proficiency tests utilized in the National Check Sample Program are internally generated sample panels prepared with third party vendor standard materials while other proficiency tests are obtained commercially.

ORA/ORS laboratories also conform to well established method validation and verification criteria such as ICH, USP, AOAC standards when qualifying their analytical methods.
Each laboratory in the ORA/ORS network is audited by an ISO/IEC 17025:2017 accreditor. In addition, the ORA/ORS labs specialized in pharmaceutical testing are also audited by the Pharmaceutical Inspection Convention and Pharmaceutical Co-operation Scheme (PIC/S) for conformance to established PIC/S standards.

ORA/ORS Laboratories are also active members of the Integrated Consortium of Laboratory Networks (ICLN) and CODEX International; and adopt consensus standards developed by these organizations that pertain to specialized testing areas such as veterinary drug residue testing, radiation testing, and pesticide testing.

ORA/ORS in coordination with CFSAN and CVM supports ISO/IEC 17025 accreditation of state food testing laboratories through the Manufactured Food Regulatory Program and the Flexible Funding Model. The program is aimed to advance the nationally integrated food safety system (IFSS) specifically with regards to microbiological and chemical food analyses. This includes preparing state laboratories for accreditation enhancements. Data generated by awarded state laboratories will be available to inform FDA in its enforcement actions, surveillance, and response to foodborne outbreaks. These ISO accredited laboratories can aid FDA with additional resources and exceptional data to maintain the safety of the food chain.

More detailed information on the Manufactured Food Regulatory Program and other standards-related programs managed by ORA can be accessed via the links below:

- Manufactured Food Regulatory Program Standards
- Flexible Funding Model
- National Integrated Food Safety System – Laboratory Capacity Building
- Voluntary National Retail Food Regulatory Program Standards
- Animal Feed Regulatory Program Standards

Center for Biologics Evaluation and Research (CBER)

In September of 2021, the Center for Biologics Evaluation and Research's (CBER) Division of Biological Standards and Quality Control (DBSQC), which is in the Office of Compliance and Biologics Quality, was audited for ISO 17025:2017: "General requirements for the Competence of Testing and Calibration Laboratories" for the biological and chemical testing for product lot release, and ISO 17034:2016: "General Requirements for the Competence of Reference Material Producers." These reference materials included influenza antigens and sheep antisera for influenza vaccine potency testing, as well as tetanus and diphtheria antitoxin for flocculation for DTaP vaccines. No deficiencies were identified during the audit.

CBER's Laboratory of Immunobiochemistry (LIB), in the Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, was also audited for ISO 17025: 2017 in August 2021; no deficiencies were identified. The scope of accreditation for the LIB covers the "ELISA Competition Assay for Quantitative Determination of Relative Potency of Allergenic Extracts." Additionally, in October 2020 LIB released E7-Orchard Grass Reference and in August 2021 released C14-Cat Hair Reference.

CBER coordinates with CDER to implement data standards related to the following:

- Real World Data and Real World Evidence
- Identification of Medicinal Products
- CDISC standards for study data and terminologies (e.g., MedDRA, SNOMED, WHO Drug Global)
- HL7 v 3 and FHIR for exchange of data for numerous use cases including labeling, drug registration and listing, and other use cases
- HL7 ICSR for adverse event data
- ICH eCTD v 4 for content of regulatory submissions

The 21st Century Cures Act was signed into law in December, 2016. Section 3036 directs the FDA to collaborate with the National Institute of Standards and Technology (NIST) and FDA stakeholders to coordinate and prioritize standards development for regenerative medicine and regenerative medicine advanced therapies. In September 2017, CBER awarded a one-year contract to Nexight Group and the Standards Coordinating Body (SCB) to establish a collaboration consisting of FDA, NIST, and stakeholders, to coordinate the development and implementation of the processes and criteria to identify and prioritize standards that have a high impact on the quality and safety of regenerative medicine products and determine whether the development of any specific standard is feasible. The deliverables for this contract included written reports and webinars. In October 2018, this contract was extended through March 2019 to build on the foundation set by the original contract. The deliverables for the extended contract include the conduct of a two-day workshop on the development of documentary standards and reference materials applicable to regenerative medicine products. The goals of the workshop were to 1) build awareness of standards development processes and the value of engaging in standards development; 2) share knowledge of in-process standards advancement or development efforts; 3) identify experts who could be tapped to support/engage in future standards development; 4) identify working group members willing to commit to advance individual potential standards. In September 2020, FDA initiated another contract with Nexight Group and SCB to further support the development of standards for regenerative medicine products. Under the contract Nexight Group/SCB will conduct feasibility assessments for specific standards identified as needed standards by industry stakeholders. They will also develop an educational curriculum for the implementation of existing standards applicable to regenerative medicine products.

In March 2019, CBER published a final Guidance Document: Standards Development and the Use of Standards on Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation . This guidance document provides information to CBER stakeholders on CBER's policy for utilizing voluntary standards to satisfy regulatory requirements such as product characterization and potency.

In addition to biologics, CBER has regulatory oversight for products that meet the definition of a medical device. As such, CBER participates in the S-CAP medical devices managed by CDRH and the ASCA Pilot Program.

Center for Drug Evaluation (CDER)

Section 3022 of the 21st Century Cures Act directs FDA to "establish a program to evaluate the potential use of Real World Evidence (1) to help to support the approval of a new indication for a drug approved under section 505(c); and (2) to help to support or satisfy post-approval study requirements." Real World Evidence (RWE) is generated from data sources other than those typical of clinical trials used for drug approval. RWE sources include, but are not limited to, healthcare records, insurance claims, or dedicated registries for drugs or diseases. The interest in using RWE stems from its potential to facilitate more timely and cost-effective demonstrations of efficacy, safety, and the ability to understand drug effects across a wider population than currently possible with traditional clinical trials, thus providing improved benefits to the public.

As part of the 21st Century Cures directives, FDA is to create a framework establishing the RWE program, along with Guidance documents for industry, informed by communications with stakeholders from industry and the public. To fulfil these mandates, in 2017 CDER established a committee and associated workgroups dedicated to this effort with participation from multiple FDA Centers. Throughout 2017 and 2018, these groups have (1) developed a draft RWE Framework that was published in December 2018; (2) established workgroups to develop Guidance on a range of topics pertinent to the use of this data; (3) reviewed the range of RWE already in use for FDA submission; (4) and engaged with stakeholders from industries and the public through participation in meetings and workshops focused on the use of RWE for clinical research and regulatory submissions. Meetings were facilitated by stakeholders including the Margolis Center for Health Policy at Duke University and the National Academies of Sciences. Attending stakeholders at various meetings included a spectrum of representatives from the pharmaceutical industry, healthcare, academia, patient organizations, standards development organizations such as Health Level 7 (HL7) and Clinical Data Interchange Standards Consortium (CDISC), and other members of the general public. In 2019 the Center began examining the ability of current submission data standards to accommodate real-world data and develop a roadmap to optimizing these standards in the future for real-world data submission. As with other FDA data standards activity, consensus-based standards such as those from CDISC and HL7 are being explored. In 2020, FDA developed the draft guidance "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products" that was published in September 2021. Another draft guidance focusing on data standards considerations for submission of studies containing RWD was developed in 2021. FDA will continue to explore and evaluate approaches to standardize RWD for regulatory submission in 2022 and beyond.

FDA is also working to standardize submissions for the information submitted in Electronic Common Technical Document (eCTD) Module 3 covering Pharmaceutical Quality, Chemistry, Manufacturing, and Controls (PQ/CMC). In 2017, a Federal Register Notice was published documenting structured data and associated vocabularies for approximately one-third of Module 3 information. In 2019, development began for Phase 1 of the PQCMC effort by using HL7 FHIR as the exchange standard to represent an initiate set of eCTD Module 3 structured data for submissions. In 2020, the Center initiated Phase 2 of the development effort to standardize the remaining information for eCTD

Module 3. Development continued into 2021 and a Federal Register Notice detailing the FHIR mapping of all Phase 1 PQ/CMC data elements is in the clearance process.

ISO Identification of Medicinal Product (IDMP) is a suite of five related standards to identify and describe medicinal products and to exchange of product information between partners to support pharmacovigilance, product shortage, and other regulatory activities. The Integrity Product Domain and Global Substance Registration System are built based on ISO 11615/ISO 11616 and ISO 11238 respectively to be the master repository for CDER regulated medicinal products and FDA regulated substances. To enable pharmacovigilance across multiple jurisdictions or at global level, FDA continues to participate in the revision and enhancement of IDMP standards with ISO TC 215, and to collaborate with other regulators for harmonized approach for IDMP development.

5) Indian Health Service (IHS)

The primary mission of the Indian Health Service (IHS) is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level. Standards and conformity assessment activities are an integral part of the effective operations of the IHS in achieving its mission. There are health-related standards that are used for numerous purposes in the health industry. The IHS has used them for privacy/security, interoperability, compliance/accreditation, and certification.

Privacy and security standards are used throughout IHS and comply with Department of Homeland Security (DHS) requirements. Privacy and security standards are used for other purposes beyond those related to patient and employee data. The IHS also uses privacy and security standards to address communication of biomedical diagnostic and therapeutic information for digital imaging, telemedicine, national drug codes, energy-efficient and environmentally friendly construction, and for reporting medical services and procedures.

Interoperability is achieved within IHS through following standards from various development organizations, e.g. the use of Health Level Seven (HL7) schemas and International Classification of Disease, Tenth Edition (ICD-10) codes. The HL7 standard allows interoperability among health information systems both within and beyond the IHS healthcare environment, such as immunization data exchange (including COVID-19) to various state and federal partners. ICD-10 is a clinical cataloging system used by IHS and its providers, coders, information technology professionals in addition to insurance carriers, government agencies and others use to properly note diseases on health records, track epidemiological trends, and assist in medical reimbursement decisions. It brings interoperability among disparate systems for information sharing.

Accreditation is a process of review in which healthcare organizations participate to demonstrate the ability to meet predetermined criteria and standards of accreditation established by a professional accrediting agency. DirectTrust Agent accreditation recognizes excellence in health data processing and transactions. It ensures compliance with industry-established standards, HIPAA regulations and the Direct Project. Accreditation granted by the DirectTrust Agent Accreditation Program for Health Information Service Providers from the Electronic Healthcare Network Accreditation Commission (EHNAC) and DirectTrust is valid for a two-year period; thereafter, a re-accreditation process take place.

Certification is a process by which an accreditation body assess and verifies the attributes of a product in accordance with established requirements or standards. Over the past decade the IHS successfully achieved certification of its Electronic Health Record for both ambulatory and inpatient settings against the 2011, 2014, and 2015 Edition standards published by the Office of the National Coordinator for Health Information Technology (ONC). This has allowed IHS, Tribal and Urban Indian healthcare organization hospitals and providers to qualify for various Centers for Medicare and Medicaid Services (CMS) Meaningful Use incentives authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act and to participate in CMS Quality Payment Programs. IHS is currently undertaking the process to complete the requirements for the ONC 2015 Edition Cures Update, per ONC's timeline in the Federal Register. The IHS has utilized and incorporated numerous information technology standards promulgated by development organizations and specified in the various ONC Final Rules in order to meet the rigorous certification requirements.

The IHS Office of Information Technology maintains a website that references a number of the standards and policies in use by the agency that can be found at:
https://www.ihs.gov/oit/standardspolicy/

6) National Institutes of Health (NIH)

National Cancer Institute (NCI)

The Nanotechnology Characterization Laboratory (NCL) is part of the Frederick National Laboratory for Cancer Research operated by Leidos Biomedical Research (contractor) for the National Cancer Institute (NCI). The NCL is guided by the NCI's Alliance for Nanotechnology in Cancer, Cancer Imaging Program, the Division of Cancer Treatment and Diagnosis. The laboratory is dedicated to supporting the extramural research community.
The mission of the NCL is to advance the science of nanoparticle characterization. As part of these efforts, the NCL has developed more than 70 assays for nanomaterial characterization, termed NCL's Assay Cascade. All NCL assays are published on the NCL website and free to download: https://ncl.cancer.gov/resources/assay-cascade-protocols. Over 450 nanomaterial platform types have passed through the NCL Assay Cascade. The laboratory updates existing assays on a regular basis, and develops and validates new assays to meet the needs of the nanotechnology research community. This year, one new protocol was added to our catalogue:

- ITA-29: Detection of nanoparticles' ability to stimulate toll-like receptors using HEK-Blue reporter cell lines

In addition to these assays, NCL commonly applies the following voluntary standards and guides:

- ISO Standard: TR 10993-22:2017: Biological evaluation of medical devices — Part 22: Guidance on nanomaterials
- ISO 10993-4:2017 Biological Evaluation of Medical Devices - Part 4: Selection Of Tests For Interactions With Blood
- USP <85> Bacterial Endotoxins Test, December 2012

NCL team members are also active participants of the standards organizations ASTM International and ISO, which develop voluntary consensus standards. NCL staff serve as subject matter experts in

various nanotech-related working groups within these organizations. NCL has contributed to the development of ISO 29701:2010 **"**Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems — Limulus amebocyte lysate (LAL) test", and is currently working on a second ISO standard, "Nanotechnologies—Total and free drug quantitation in doxorubicin hydrochloride liposomal formulations." Efforts are also ongoing to bring 10 NCL protocols through ASTM as Standard Methods or Standard Guides. These efforts are continuing into 2022. The standards under development are:

- **WK76862** Guide for the Identification of Nanoparticles Ability to Induce Infusion Reactions
- **WK76861** Method for the In vivo analysis of nanoparticle-mediated physiological changes accompanying hypersensitivity reactions
- **WK76860** Method for the Preparation and Analysis of Culture Supernatants for the Presence of Cytokine Biomarkers by Nanoparticles in Human Whole Blood Cultures
- **WK76878** Method for the analysis of nanoparticle effects on human platelets in vitro
- **WK76821** Practice for the Synthesis and Assembly of Nucleic Acid Nanoparticles
- **WK76822** Method for the Preparation and Analysis of Culture Supernatants for the Presence of Cytokine Biomarkers by Nucleic Acid Nanoparticles in Human Peripheral Blood Mononuclear Cells
- **WK76823** Guide for the Evaluation of Immunostimulatory Properties of Nucleic Acid Nanoparticles (NANPs)
- Method "In vitro Analysis of Nanoparticle Hemolytic Properties" (a revision of **ASTM E2524-08** (2013) previously developed by the NCL)
- Method "In vitro Analysis of Nanoparticle Effects on CFU-GM" (a revision of **ASTM E2525-08** (2013) previously developed by the NCL)
- Method "Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells" (a revision of ASTM **E2526-08** (2013) previously developed by the NCL)

National Library of Medicine (NLM)

The National Library of Medicine (NLM) has been a center of information innovation since its founding in 1836. The world's largest biomedical library, NLM maintains and makes available a vast print collection and produces electronic information resources on a wide range of topics. NLM also supports and conducts research, development, and training in biomedical informatics and health information technology. In addition, the Library coordinates the 8,000-member Network of the National Library of Medicine that promotes and provides access to health information in communities across the United States.

NLM is active at a national level in the creation, review, and ongoing maintenance of standards related to the basic functions of a library including interlibrary loan, collection preservation, bibliographic control, and database creation and access. NLM's goal is to ensure these standards are workable for the library community as a whole. NLM participates in the National Information Standards Organization (NISO). Because NISO decisions feed into the decision-making process of the American National Standards Institute (ANSI), the official U.S. representative to the International Organization for Standardization (ISO), NLM's activities extend to the development of standards at an international level.

One example of an important NISO standard developed by NLM is the Journal Article Tag Suite,[1] which is an outgrowth of NLM's work on the PubMed Central journal article archive. Another example is NLM's participation in the development of NISO's new Recommended Practice: *PIE-J: Presentation & Identification of E-Journals*.[2] Pie-J provides guidance to publishers of electronic journals on the presentation and identification of electronic journals to ensure long-term online accessibility to scholarly journals even after titles and publishers change.

For more than four decades, NLM has conducted and supported groundbreaking research and development related to the representation, interpretation, and use of biomedical knowledge in electronic forms including electronic health records (EHRs). NLM has been the central coordinating body for clinical terminology standards within the Department of Health and Human Services (HHS) since 2004. In this role, NLM is the official depository and distribution center for clinical terminologies, responsible for integrating them within the Unified Medical Language System (UMLS) Metathesaurus and for developing and maintaining mappings between designated standard clinical terminologies and important related terminologies, including the HIPAA code sets. NLM works with (and, in some cases, provides funding to) vocabulary developers, message standards development organizations, other Federal agencies, and users of standards to fulfill its role as the central coordinating body for clinical terminology standards and to respond to recommendations from the Health Information Technology Advisory Committee. Clinical terminology standards and resources supported or produced by NLM includes:

- **UMLS Metathesaurus** – Produced by NLM, this resource incorporates many different vocabularies, classifications, and code sets. While not a standard in and of itself, it is an important resource to help the research and healthcare community understand the breadth of available standards and how they relate to one another;
- **LOINC (Logical Observations Identifiers Names and Codes)** – NLM funds the ongoing maintenance and free distribution of this standard with codes names and other information for reporting and ordering laboratory tests, measurements, survey instrument and other kinds of observations (accessible within the UMLS Metathesaurus and from the Regenstrief Institute). LOINC can be accessed worldwide via a web tool (SearchLOINC) which enables searches for tests and measures, their descriptions, units of measure, synonyms, and tests/measures. LOINC can also be downloaded as a whole or as its component parts including the LOINC tables, Hierarchy, Document Ontology, linguistic variations, mappings between RadLex (Radiology codes) and LOINC codes, and mappings between IEEE instrument codes and LOINC codes. LOINC works closely with HL7 FHIR. It includes a standard FHIR vocabulary server and the LOINC content is all provided on FHIR's own vocabulary server. LOINC supports sets of variables, including laboratory panels such as CBC, and survey instruments. LOINC panels provide information needed to generate a FHIR questionnaire (data collection form) and can support all the special features of FHIR questionnaires, i.e., skip logic, pre-population from FHIR medical records, etc. FHIR questionnaires can be generated on the fly as web data input forms;

[1] http://www.niso.org/apps/group_public/project/details.php?project_id=93
[2] https://www.nlm.nih.gov/bsd/policy/piej_niso_practices.html

- **SNOMED CT** – NLM is the US representative to SNOMED International and as such pays the annual fee that permits U.S.-wide use of SNOMED CT (comprehensive clinical healthcare terminology; accessible within the UMLS Metathesaurus and in native format from NLM) and creation and distribution of the U.S. Edition of SNOMED CT;
- **RxNorm** – NLM produces and distributes RxNorm (terminology for clinical drugs; accessible both within the UMLS Metathesaurus and separately from NLM). RxNorm provides normalized names for clinical drugs and links to many drug vocabularies commonly used in pharmacy management and drug interaction software. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary. NLM provides several web-based programs for retrieving data from several drug sources including RxNorm API, RxTerms API, RxClass API, and Drug Interaction API. Another resource, RxNav, is a browser for several drug information sources, including RxNorm, RxTerms and MED-RT. These programs are quite popular. For example, the RxNav API receives more than 1.6 billion API queries annually.
- **UCUM (Unified Code for Units of Measure)** – Developed by the Regenstrief Institute with funding from NLM UCUM is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units.

LOINC, SNOMED CT, RxNorm and UCUM form a suite of key clinical terminology standards that have been designated for use in the U.S. healthcare systems over the past 20 years:

- **Consolidated Health Informatics** (CHI; active 2001 - 2007) - eGov project designated the suite as U.S. Government-wide clinical standards for use in U.S. Federal Government healthcare systems.
- **Healthcare Information Technology Standards Panel** (HITSP; active 2005 - 2010) - identified the suite in various interoperability specifications for use throughout the U.S. healthcare spectrum. The suite was required for use in U.S. Federal Government healthcare systems, recommended for use in the private sector.
- **Health Information Technology for Economic and Clinical Health (HITECH) Act** - In July 2010 the suite were named as standards to support stage 1 meaningful use in the "Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology" Final Rule. Subsequent final rules for EHR certification criteria (2011, 2014, and 2015 Editions) each expanded the requirements for use of the suite to support meaningful use.
- **United States Core Data for Interoperability (USCDI)** – Established by the Office of the National Coordinator for Health Information Technology (ONC) as part of the Cures Act Final Rule, USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. A USCDI data element is the most granular level at which a piece of data is exchanged. The USCDI specifies the set of coding systems that are required for use in US electronic medical record systems to support interoperable health information exchange. In this system, SNOMED CT, LOINC, and RxNorm and UCUM are all required for use for designated purposes.

- **Interoperability Standards Advisory (ISA)** – Established by the Office of the National Coordinator for Health Information Technology (ONC), ISA is the model by which ONC coordinates the identification, assessment, and public awareness of interoperability standards and implementation specifications for use in healthcare systems. ISA specifies LOINC, SNOMED CT, and RxNorm and UCUM as the preferred coding system for designed purposes.
- **Health Level Seven (HL7) Standards for Genetics** – LOINC has been selected as the core structure of three HL7 standards genetics including 1) HL7 V2 specification for cytogenetics, 2) laboratory reporting of genetic variants, and 3) HL7 FHIR specification for clinical genetic reports.
- **LOINC In Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests** – Announced by HHS on June 4, 2020, LIVD is new laboratory data reporting guidance for COVID-19 testing. LIVD uses LOINC and SNOMED CT to identify and report SARS-CoV-2 test results in electronic reporting systems to facilitate timely and quality data reporting to state and federal public health agencies (https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html). It was an essential ingredient in the quick (few days) generation of COVID-19 test codes produced by the collaboration between CDC, FDA, Regenstrief (LOINC), SNOMED International, APHL and the IVD industry connectivity consortium.
- **Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)** – NLM has been an active proponent of the FHIR standard that is now supported at the National Institutes of Health (NIH) level to support data science (see https://datascience.nih.gov/fhir-initiatives). Both the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) include requirements for use of FHIR in recent rulemaking related to the 21st Century Cures Act. NLM's specific focus is on exploring the creation of FHIR-compliant API for clinical research use, starting by standardizing phenotype data for several large population cohort studies archived within the database of Genotypes and Phenotypes (DbGap). NLM has also developed several software tools to facilitate use of FHIR (https://lhcforms.nlm.nih.gov). Users and developers downloaded some of these tools nearly 100,000 times in 2021. NLM's National Center for Biotechnology Information (NCBI) maintains databases of genetic variants (ClinVar, dbSNP) that are required coding systems for HL7 FHIR genetic reporting (http://ncbi.nlm.nih.gov).

In addition, SNOMED CT is the standard for selected data elements in international genetic information resources, including the NIH Genetic Testing Registry and the ClinVar database of clinically significant human variations. It is also being used in an increasing number of clinical research studies.

NLM, on behalf of HHS, is the U.S. Member of the International Health Terminology Standards Development Organisation (IHTSDO; using the trading name SNOMED International) which owns, maintains, and distributes SNOMED CT internationally and promotes global standardization of health information. As the US Member, NLM produces and distributes:

- **US Edition to SNOMED CT** – combination of the U.S. Extension and the International Release of SNOMED CT. The U.S. Edition to SNOMED CT is the version of SNOMED CT cited as CMS Promoting Interoperability program requirements. The US Extension is a formal extension of the International Release that allows NLM to provide both rapid access to SNOMED CT concepts needed by U.S. stakeholders, as well as standard terminology needed for U.S. clinical use cases (e.g. regulatory or legislatively mandated terms specific to the U.S.) that are not generally useful in other countries.
- **CORE Problem List Subset of SNOMED CT** – updated 4 times per year (with each new release of SNOMED CT and the UMLS Metathesaurus). The Subset is designed to facilitate the use of SNOMED CT for coding of problem list data in EHRs and to enable more meaningful use of EHRs to improve patient safety, health care quality, and health information exchange. Development and distribution of this initial subset was used as a model for development of other frequency-based subsets to facilitate implementation of SNOMED CT, LOINC, and RxNorm throughout the U.S. including:
    - SNOMED CT Route of Administration
    - Nursing Problem List Subset of SNOMED CT
    - Universal Laboratory Order Codes from LOINC and Common UCUM Codes (both created in conjunction with the Regenstrief Institute)
    - RxNorm Current Prescribable Content
- **Mappings** - between standard clinical vocabularies, HIPAA code sets, and other key vocabularies used in Federal health information systems. The mappings are intended to facilitate development and implementation by health care providers of EHRs that capture clinical data at the point of care and subsequently support generation of required HIPAA code set data for claims and other administrative transactions. Mappings maintained and distributed by NLM:
    - **SNOMED CT to ICD-10** – updated and expanded in conjunction with the IHTSDO
    - **SNOMED CT to ICD-10-CM** – builds on and makes use of the tools and policies developed for the IHTSDO mapping project.
    - **ICD-9-CM to SNOMED CT** – Designed to further facilitate the transition from ICD-9-CM to SNOMED CT, NLM makes available maps from heavily used ICD-9-CM procedure codes to SNOMED CT as well as the map from heavily used ICD-9-CM diagnostic codes to SNOMED CT. Both maps are based on in-patient claims data obtained from CMS.
- **Nursing Resources for Standards and Interoperability** - a resource for anyone interested in nursing terminologies for systems development. The page describes the role of SNOMED CT and LOINC in implementing meaningful use, specifically for the nursing and care domain.

As the U.S. Member of the IHTSDO NLM also:

- **Makes available the U.S. SNOMED CT Content Request System (USCRS**) in support of the U.S. Extension to SNOMED CT. USCRS is a mechanism for U.S. stakeholders to request changes to SNOMED CT (e.g. new concepts or enhancements to existing concepts). The long-term goal is to allow the establishment of a network for U.S. contributions to the development of SNOMED

CT by both government agencies and private sector organizations and enable collaboration with other IHTSDO member countries in the development of SNOMED CT content and subsets.

- **Facilitates alignment and harmonization** - NLM continues working with the IHTSDO to facilitate alignment and harmonization between SNOMED CT and other key health terminologies, most notably with LOINC.

NLM provides access to several additional resources to make standards more accessible:

- **MedlinePlus Connect** - a free service that delivers consumer-oriented information about relevant conditions and disorders, health and wellness, and prescription and over-the-counter medications to patients, families, and health care providers via EHR systems. The system works by accepting specific requests from EHR systems and providing in response links to relevant consumer health information from NLM's MedlinePlus system. To facilitate the connection, NLM mapped all MedlinePlus health topics pages to standard coding systems used in EHRs. Specifically, MedlinePlus Connect responds to requests for information based on diagnosis (problem) codes (SNOMED CT CORE Problem List Subset, ICD-9-CM, ICD-10-CM), medication codes (RxNorm, NDC), and lab test codes (LOINC). Code requests will then receive relevant health information from MedlinePlus, Genetics Home Reference, and other reliable health resources.
- **Value Set Authority Center (VSAC)** - NLM, in collaboration with the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare & Medicaid Services (CMS) created VSAC, which was launched in early FY2013. The system has since been expanded to include an authoring tool that allows users to author value sets in a collaborative environment. NLM continues working with ONC and CMS to enhance and expand VSAC to meet the community's needs.
- **AccessGUDID (Global Unique Device Identification Database)** – NLM, in conjunction with the Food and Drug Administration (FDA), introduced AccessGUDID in FY2015. This web resource contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).
- **Newborn Screening laboratory reporting** – NLM, in collaboration with CDC, FDA, Health Resources and Services Administration (HRSA), and other NIH institutes and centers, as well as with the American Public Health Laboratory (APHL) and many state public health departments develop and maintain an HL7 v.2.5.1 laboratory reporting guide for newborn screening result reporting. The guide leverages LOINC, SNOMED CT, and HL7 messaging structures to support the timely communication of newborn screening results and conditions.
- **NIH Common Data Elements (CDE) Repository** - developed and maintained by NLM on behalf of NIH, the CDE repository provides access to structured human and machine-readable definitions of data elements that have been recommended or required by NIH for use in research and other purposes. The repository helps facilitate standardization by providing tooling (search, browse, compare) that can be used in the harmonization and de-duplication of data elements.

NLM works closely with the HHS Office of the National Coordinator for Health Information Technology (ONC) to ensure NLM's vocabulary harmonization and standards efforts are in sync with those of ONC and the Health Information Technology Advisory Committee (HITAC). NLM participates in the HITAC and has participated in its predecessors, the Health IT Policy Committee and the Health IT Standards Committee as a member. HITAC assumes responsibility for evaluating vocabularies and information models needed to achieve greater interoperability across healthcare systems, to "Promote Interoperability", and other federal requirements. NLM also participates in the Federal Health IT Coordinating Council.

NLM participates in the International Organization for Standards (ISO) Health Informatics Technical Committee (ISO/TC 215) to provide advice at the national (ANSI) and international (ISO) levels. This groups scope is "standardization in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.

A complete list of NLM's activities relating to health information technology and health data standards is available from the NLM Website at http://www.nlm.nih.gov/healthit.html.

7) Office of the National Coordinator (ONC)

Standards are an integral component of ONC's mission to support the development of a nationwide health information technology (health IT) infrastructure that allows for electronic use and exchange of information in a scalable manner, promotes the adoption of interoperable health IT in a cost effective manner, and provides leadership in the development, recognition, and implementation of standards and certification of health IT products. The consistent use of health IT standards is a necessary requirement to achieve interoperability of health information, which is a central key to reducing health care costs.

The United States Core Data for Interoperability (USCDI) is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. It establishes a baseline set of data that can be commonly exchanged across care settings for a wide range of uses. In 2020, ONC published a Draft USCDI Version 1 (USCDI v1) and the associated data classes and data elements for public comment as part of the ONC Cures Act notice of proposed rulemaking. ONC created an annual process for updating the USCDI based on public input. In 2021, ONC published USCDI Version 2 after going through the annual process and is now working on developing USCDI Version 3. Additionally, ONC continues to use the Health Information Technology Advisory Committee (HITAC) to review proposed drafts of the USCDI as one means to get expert feedback before finalizing each version.

The USCDI's impact is not limited to health IT products certified under the ONC Health IT Certification Program. The ONC Cures Act Final Rule provisions related to "information blocking" also reference the USCDI as the initial scope of electronic health information (EHI) healthcare providers, health information networks and exchanges, and developers of certified health IT need to consider when it comes to the access, exchange, and use of EHI. Please see the USCDI v2 and the USCDI Fact Sheet for more information.

The Standards Version Advancement Process (SVAP) enables health IT developers to voluntarily incorporate newer versions of specific ONC-regulated standards and implementation specifications into their products under the ONC Health IT Certification Program, including future versions of the USCDI. The SVAP advances interoperability by permitting developers of certified health IT to implement newer versions of standards and specifications than currently adopted in regulation. In 2020, ONC established an annual public comment process for SVAP-eligible standards and implementation specifications. As part of ONC's ongoing charge to coordinate across federal and industry stakeholders, this year it was determined that it was necessary to adjust the SVAP timeline. Instead of the comment period being from September to November as was done in 2020, starting in 2021, the comment period will be held from January to May of each year. ONC will announce approved standards for SVAP in June each year with them becoming effective for Certification Program use in August of that year. To facilitate the timeline shift, the 2021 comment period, due to end September 30, 2021 was extended to May 2, 2022. Additionally, the announcement of next version of approved standards for SVAP will be delayed by approximately six months, from January 2022 to June 2022. With the updated timeline, and since the entire SVAP process will conclude within the same calendar year, the naming convention will be modified to match the year in which the SVAP is approved by the National Coordinator. Hence, the next release of standards approved via SVAP will be named as "Approved Standards for 2022" instead of 2021. Please see the SVAP Approved Standards on the ONC Certification Program SVAP webpage.

Related Links:
https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin
https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
https://www.healthit.gov/isa/sites/isa/files/2021-07/USCDI-Version-2-July-2021-Final.pdf
https://www.healthit.gov/cures/sites/default/files/cures/2020-03/USCDI.pdf
https://www.healthit.gov/isa/standards-version-advancement-process
https://www.healthit.gov/topic/standards-version-advancement-process-svap
https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
https://www.healthit.gov/sites/default/files/facas/2021-01-13_Draft%20USCDI_Version_2_Presentation.pdf
https://www.healthit.gov/isa/ONDEC
https://www.healthit.gov/topic/standards-version-advancement-process-svap

8) Substance Abuse and Mental Health Services Administration (SAMHSA)

The Substance Abuse and Mental Health Services Administration (SAMHSA) is a member of the National Quality Forum (NQF), a voluntary consensus body for performance measurement. SAMHSA works with NQF, as well as public and private-sector partners, as part of NQF's Measure Application Partnership to recommend quality measures to the Department of Health and Human Services (HHS) for federal reporting.

Additionally, SAMHSA works with NQF, as well as private and public stakeholders, as part of the Medicaid and Children's Health Insurance Program Scorecard Workgroup that provides input to HHS on quality measures that will be included in the Centers for Medicare and Medicaid Services (CMS) public reporting efforts.

As a member of the NQF, SAMHSA collaborates with a number of federal partners, including, the office of the Assistant Secretary for Planning and Evaluation, and CMS, to develop behavioral health quality measures that address key gaps in the field related to substance use and mental health disorders. Some of these measures have been used in different stages of "Meaningful Use" and are now part of the Medicaid Adult Core Set of Measures.

These Adult Healthcare Quality measures can be found at: https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html

2021 Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set): https://www.medicaid.gov/medicaid/quality-of-care/downloads/2021-adult-core-set.pdf

2. Please list the government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards during FY 2021. Please note that GUS which are still in effect from previous years should continue to be listed, thus the total number in your agency's report will include all GUS currently in use (previous years and new as of this FY): 0