Health and Human Services (HHS) Fiscal Year 2023 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, and in our Quality Indicators. 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.

AHRQ Quality Indicators - https://qualityindicators.ahrq.gov/
AHRQ Data Tools – MEPS and HCUP https://datatools.ahrq.gov/nhqdr/

2) Centers for Disease Control and Prevention (CDC)

National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)

Division of STD Prevention (DSTDP)

Building on previous years' work, DSTDP's Surveillance and Data Science Branch has been exploring a syphilis registry model leveraging Fast Healthcare Interoperability Resources (FHIR) and open-source common data models. This registry would be helpful for case investigations of syphilis and consolidating the information retrieved from EHRs. Syphilis-related patient information was retrieved for diagnoses, laboratory test types and results, treatment, and pregnancy status.

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.

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 45 staff contributing their expertise to approximately 24 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.

Center for Laboratory Systems and Response (CLSR)

Division of Laboratory Systems (DLS)

DLS leads CDC's Public Health Laboratory Electronic Test Orders and Results (ETOR) Initiative. A key component of this work is implementing standard vocabulary, format, and transport mechanisms to ensure data interoperability between partners. Standards in use are listed below.

DLS supports the Laboratory Response Network (LRN) by providing comprehensive informatics and data exchange solutions to move data from LRN member laboratories to CDC. Standards in use are listed below.

DLS manages the review of LOINC In Vitro Diagnostic (LIVD) Test Code Mapping files used to identify and facilitate reporting of laboratory test results between laboratories and public health agencies. Standards in use are below.

- **Health Level Seven (HL7)**
  - CDC utilizes several different resources to work within HL7 global standards for transferring clinical and administrative health data between application; applied in work with ETOR and LRN DE.
  - Laboratory Orders from EHR (LOI) Release 1, STU Release 4 - US Realm
  - Laboratory Results Interface (LRI), Release 1 STU Release 4 - US Realm
  - HL7 Vocabulary
  - Electronic Laboratory Reporting (ELR) HL7 v 2.5.1 Implementation Guide: ELR Reporting to Public Health (US Realm), Release 2, HL7 Informative Document (May 2014)
- **Logical Observation Identifiers Names and Codes (LOINC)**
  - Representing Laboratory Tests (includes Ordered, Performed) and clinical observations, including surveys and ask at order entry (AOE) questions; or,

when using the LOINC Answer codes also result values or answers to survey/ask AOE questions. Oversight from Regenstrief and used within DLS for LRN DE and ETOR.
    - LOINC (Logical Observation Identifiers Names and Codes)
- **Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT)**
    - Representing Laboratory Values/Results, specimen and could be other clinical concepts like symptoms, diseases etc.; used within DLS for LRN DE and ETOR.
    - SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms)
- **Unified Code for Units of Measure (UCUM)**
    - Representing units of measure in a standardized way, with oversight from Regenstrief and use within DLS for LRN DE and ETOR.
    - Unified Code for Units of Measure (UCUM)
- **Logical Observation Identifiers Names and Codes (LOINC) In Vitro Diagnostic (IVD) Mapping (LIVD) on FHIR or from IICC**
    - Representing details for Laboratory IVD Tests - performed test, includes ordered test, result values, specimen type, with use within DLS for LIVD webpage
    - Logical Observation Identifiers Names and Codes (LOINC) In Vitro Diagnostic (IVD) Mapping (LIVD) on FHIR or from IICC
- **Blood Culture Contamination Quality Measure**
    - Quality measure to protect patients during the diagnostic process by monitoring adult blood culture contamination (BCC) rates.
    - Preventing Adult Blood Culture Contamination: A Quality Tool for Clinical Laboratory Professionals | CDC
- **Laboratory Quality Standards**
    - The Clinical Laboratory Improvement Amendments of 1988 (CLIA) has several requirements for establishment or verification of clinical test method performance. The Clinical & Laboratory Standards Institute (CLSI) creates voluntary guidelines for sensitivity, accuracy, precision, and linearity of test methods. In addition, CLIA uses a quality systems approach and CLSI has a suite of relevant quality management system (QMS) documents that can be used to meet CLIA requirements. Several DLS personnel participate in document development committees that create and update evaluation protocols and QMS documents, and other documents that describe best practices for CLIA laboratories that are used by CDC and others.
- **Next-Generation Sequencing Quality Initiative**
    - The CDC/Association of Public Health Laboratories NGS QI (Next-Generation Sequencing Quality Initiative) utilizes the CLSI QMS standards to ensure the accuracy, reliability, and consistency of NGS testing processes. These standards are applied and built upon to ensure quality in all stages and steps of laboratory testing for public health and clinical applications.

        - Standards for reporting and interoperability of metadata include those promulgated by the American College of Medical Genetics (ACMG) and Global Alliance for Genomics and Health (GA4GH). These standards help promote transparency, reproducibility, and interoperability in NGS research.
    - **CMS to CDC Data Stream**
        - DLS is utilizing a design standard, representation state transfer (REST) for its application programming interface (API) as an architecture for data transfer from the Centers for Medicare & Medicaid Services to CDC.
    - For analysis of population-level data for public health trending and interventions, DLS/QSSB data analysis utilizes Observational Health Data Sciences and Informatics (OHDSI) and the OMOP Common Data Model.

Office of Public Health Data, Surveillance, and Technology (OPHDST)

- National Notifiable Diseases Surveillance System (NNDSS)
    - Specific Notifiable Disease Reporting to Public Health (Final Guides): https://ndc.services.cdc.gov/message-mapping-guides/
    - 2024 NNDSS Event Code List (Release 1): https://ndc.services.cdc.gov/wp-content/uploads/National_Notifiable_Diseases_Surveillance_System_Event_Code_List_2024_v1_2023DEC01.xlsx
    - PHIN VADS Value Set Link to the NNDSS 2024 Event Code List: https://phinvads.cdc.gov/vads/ViewValueSet.action?id=DAA542A7-9D50-4706-9AA6-1DBFDDFF9D2D
- National Syndromic Surveillance Program (NSSP)
    - HL7 Version 2.5.1 Implementation Guide: Syndromic Surveillance, Release 1 – US Realm, Standard for Trial Use, July 2019; **Current Document searchable at HL7.org*: http://www.hl7.org/; ***login or sign up required for download;* Access Instructions: go to Standards and then Standards for Trial Use, scroll to or search Syndromic Surveillance guide (close date July 26, 2021).
    - PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 (April, 2015): https://www.cdc.gov/nssp/documents/guides/syndrsurvmessagguide2_messagingguide_phn.pdf
    - 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, 2015: https://www.cdc.gov/nssp/documents/guides/erratum-to-the-cdc-phin-2.0-implementation-guide-august-2015.pdf
    - PHIN 2.0 Implementation Guide Meaningful Use Clarifying Document (PDF available on NIST Website): https://hl7v2-ss-r2-testing.nist.gov/ss-r2/api/documentation/doc?name=NIST-SS-Clarifications-and-Validation-Guidelines-V1-6.pdf

Data Policy and Standards (DPSD)

The Centers for Disease Control and Prevention's (CDC) new Data Policy and Standards Division (DPSD) in the Office of Public Health Data Surveillance and Technology (OPHDST) is working collaboratively across the centers and externally to improve data sharing and interoperable data exchange between state, tribal, local, and territorial (STLT) federal, and health care partners. The focus of the work includes:

- Ensure Core Data Sources are more complete, rapidly exchanged to support collective ability to detect, monitor, investigate and respond to public health threats
- Ensure access, exchange and use of interoperable data across the healthcare and public health ecosystem

DPSD plays an active role in the CDC Advisory Committee to the Director (ACD) Data and Surveillance Workgroup (DSW) Report, including developing consensus based defining definitions for the minimum data necessary (MDN) to support emergency response for six core areas of public health surveillance including**: case data; laboratory-based diagnostic testing data, syndromic surveillance/emergency department data; immunization/vaccine administration data; hospital capacity data; and death data/vital statistics**. These established MDN data sets reduce the burden on our STLT partners in the beginning of an emergency response by establishing standardized data collection across CDC for the exchange of data on confirmed, probable, and suspected cases.

In addition to establishing standardized MDN requirements, the OPHDST coordinates comments and feedback to the Office of the National Coordinator for Health IT (ONC) on United States Core Data for Interoperability (USCDI) and USCDI+ for public health specific use cases, across the Agency. The USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. Healthcare data is a large dataset that Public Health can leverage to identify and respond to emerging health threats and apply interventions.

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

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

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 data standards can be found here: https://www.cdc.gov/cancer/npcr/standards.htm.

CDC Diabetes Prevention Recognition Program (DPRP)

The Centers for Disease Control and Prevention established the CDC Diabetes Prevention Recognition Program (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 subsequent translation 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 (https://www.niddk.nih.gov/about-niddk/research- areas/diabetes/diabetes-prevention-program-dpp). CDC updates the DPRP Standards every 3 years based on new information available in the scientific literature, insights gained through analysis of DPRP data, lessons learned from best practices in the field, and public comment.

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 based on requirements in the DPRP Standards CDC reviews these data and provides feedback to each organization. DPRP evaluation data to date show evaluated participants attended an average of 18 core sessions (organizations are required to offer a minimum 22 core sessions) and 9 core maintenance sessions (organizations are required to offer a minimum 6 core maintenance sessions) in the National DPP lifestyle change program. Participant risk reduction, determined using outcomes associated with weight, physical activity minutes, and HbA1c, was seen in 52.8% of all evaluated participants. This risk reduction included 48.5% who achieved at least a 5% weight loss; 34.5% who achieved at least a 4% weight loss combined with at least 150 min/week on average, of physical activity; and 1% to date who had at least a 0.2% reduction in HbA1c (of those who submitted HbA1c information*). As of March 11, 2024, there are 1,499 CDC-recognized organizations that have collectively enrolled 753,764 participants nationwide since the program's inception.

*Note: The CDC Diabetes Prevention Recognition Program Standards and Operating Procedures describe in detail the DPRP requirements and explain how an organization may apply for, earn, and maintain CDC recognition (https://www.cdc.gov/diabetes/prevention/pdf/dprp- standards.pdf) to offer the National DPP lifestyle change program. The current (2021) DPRP Standards are undergoing revision; we expect the 2024 Standards to be finalized and made available to the public in May.

Division for Heart Disease and Stroke Prevention (DHDSP):

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.

National Center for State, Tribal, Local, and Territorial Public Health Infrastructure and Workforce (NCSTLTPHIW)

The Centers for Disease Control and Prevention (CDC) National Center for State, Tribal, Local, and Territorial Public Health Infrastructure and Workforce (NCSTLTPHIW) has been a key supporter in the development, launch and support of the voluntary accreditation program for public health departments. The Public Health Accreditation Board (PHAB), a non-profit accrediting body, leads the accreditation program which launched in September 2011. Until the establishment of PHAB, there had been no national accreditation program for public health departments. The initial national consensus standards were released in July 2011 (Version 1.0), an update (Version 1.5) was released in 2014, and PHAB released the Version 2022 Standards and Measures in FY22 with support from CDC to produce and vet the new standards. CDC has been involved as a partner and funder of this initiative to provide support to

PHAB's accreditation and continuous improvement activities as evidenced through its accreditation page at (https://www.cdc.gov/publichealthgateway/accreditation/). The first cohorts of health departments were accredited in early 2013. As of the end of FY 2023:

- PHAB has accredited 434 health departments—41 states, six tribes, and 387 local health departments (including 320 individually accredited local health departments and 67 county health departments through a centralized state application).
- 88% of the U.S. population is served by an accredited health department (HD).
- PHAB began reaccrediting sites in 2018; 108 sites have been reaccredited.
- 531 HDs, including 43 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. Annual evaluation findings consistently report short- and long-term benefits to participating in accreditation. June 2023 evaluation data indicate that the program has stimulated quality improvement (95% of accredited health departments agree), improved accountability and transparency (88%), improved the capacity of the department to provide high-quality programs and services (81%), and improved collaboration across units within the health department (88%) one year after accreditation. Four years after accreditation, accredited health departments report that the program has helped health departments use health equity as a lens for identifying and addressing health priorities (73%), strengthened the utilization of resources (63%), and strengthened relationships with key partners in other sectors (e.g., health care, social services, education) (76%). More information about the accreditation program can be found at (http://www.phaboard.org) and aggregate accreditation data about health department capacity, searchable by PHAB domain, theme, and health department characteristics, can be found at the PHAB data portal at (www.phabdata.org).

3) Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services (CMS) works with partners in a voluntary manner to develop, evaluate, and apply national standards and consensus-based standards. Below is a summary of significant standards at CMS used to increase the electronic exchange of health information between covered entities and to measure performance for quality initiatives including healthcare provider public reporting and value-based purchasing programs.

The National Standards Group (NSG) within the Office of Burden Reduction & Health Informatics at 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): (https://www.nacha.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 Center 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 (https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualitymeasures) that have been reviewed through a consensus process, and can be considered consensus-based standards. Battelle Memorial Institute (Battelle), a not- for-profit, nonpartisan organization offering free membership to participate in consensus-based entity (CBE) activities, meets the NTTAA definition of a consensus-based organization. CMS currently contracts Battelle to execute a public and transparent consensus development process to endorse and maintain performance measures.

Battelle's Endorsement & Maintenance (E&M) process (https://p4qm.org/EM) includes an open call for candidate consensus standards (i.e., performance measures); multi-stakeholder review of scientific and statistical evidence against the established endorsement criteria; discussion and evaluation of measures by multi-stakeholder experts including patients and caregivers; and opportunities for stakeholder feedback and public comments throughout the process. The E&M process also includes an opportunity for stakeholders and the public to appeal a decision on measures after they receive consensus-based endorsement. These processes are consistent with the NTTAA and OMB Circular A-119.

- CMS Quality Measures: https://mmshub.cms.gov/
- Partnership for Quality Measurement: https://p4qm.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 (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 additional 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 FY2023, 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 2023e:

Date	Federal Register Notice
August 2, 2023	FR Notice (List #59) [Docket No. FDA-2004-N-0451] https://www.govinfo.gov/content/pkg/FR-2023-08-02/html/2023-16418.htm
August 7, 2023	FR Notice (List #60) [Docket No. FDA-2004-N-0451] https://www.govinfo.gov/content/pkg/FR-2023-08-07/html/2023-16770.htm

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.

Effective September 19, 2023, the U.S. Food and Drug Administration's Accreditation Scheme for Conformity Assessment (ASCA Program) was converted from a pilot to a permanent program as authorized by Medical Device User Fee Amendments of 2022 (MDUFA V). 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 Program 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. 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 ASCA Program continues to be implemented through guidances outlining program specifications that 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.

As of November 20, 2023, CDRH has provided ASCA recognition to 5 Accreditation Bodies and granted ASCA-accreditation to 101 testing laboratories under the scope of standards and methods included in the ASCA Pilot.

CDRH will continually report annually on the progress of the ASCA Program and work with stakeholders for further input on programmatic improvements and/or considerations for expansion.

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 issue certifications of foreign food facilities for FDA-regulated food, which includes human food, and animal food. In 2015, FDA issued regulations (21 CFR Part 1 subpart M) establishing the Accredited Third-Party Certification Program. The regulations describe 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 regulations, 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: Guidance for Industry and FDA Staff."

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 FY23, the FDA has recognized 4 accreditation bodies which have accredited 11 certification bodies. FDA maintains an online registry of accreditation bodies recognized, and certification bodies accredited, under this program.

FSMA also gives us express authority to establish a laboratory accreditation program for the analyses of human and animal foods. FDA issued a final rule in December 2021 establishing the Laboratory Accreditation for Analyses of Foods (LAAF) program. The final rule specifies 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. Under the LAAF program, FDA recognizes accreditation bodies that accredit laboratories to the standards established in the final rule ("LAAF accredit"); only LAAF-accredited laboratories may conduct the food testing covered by the final rule. The final rule incorporates by reference two voluntary consensus standards: ISO/IEC 17011:2017 forms the foundational requirement for accreditation bodies, and ISO/IEC 17025:2017 forms the foundational requirement for food testing laboratories. As of the end of FY23, FDA has recognized 7 accreditation bodies that have accredited 23 testing laboratories. FDA maintains an online registry of accreditation bodies recognized, and laboratories accredited, under this program.

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(IFSH), has been an ISO/IEC 17043 accredited proficiency testing laboratory 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 a 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 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 USP pharmaceutical analysis monographs using USP reference materials.

ORA/ORS laboratories are accredited to ISO/IEC 17025:2017 standards. The FDA Forensic Chemistry Center (FCC), the ORS forensics specialized lab, is accredited to the standards of ANSI-ASQ National Accreditation Board (ANAB) in the field of Forensic Science Testing. 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.

Each laboratory conforms to the core requirements of a Quality Management System 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 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 advances 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 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 2023, 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." Minor deficiencies identified during the audit have no impact on the integrity of testing or standards production. The reference materials produced and calibrated by DBSQC included influenza antigens and sheep antisera for influenza vaccine potency testing, as well as tetanus and diphtheria antitoxin for flocculation tests. Reagents for egg-propagated, cell-propagated and recombinant A(H1N1)pdm09, A(H3N2) and B/Victoria-lineage seasonal influenza vaccine components as well as A(H2N3), A(H5N6), A(H5N8), A(H7N9) and A(H9N2) pandemic reagents were prepared and calibrated by CBER; DBSQC also collaborated with the WHO Essential Regulatory Laboratories at MHRA, UK; TGA, Australia; and NIID, Japan to calibrate influenza reagents produced to support influenza vaccine manufacturing world-wide.

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 re-accreditation in September 2023; 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, LIB has reviewed over 393 protocols for lot release in conjunction with ELISA potency tests and shipped over 4,000 references to manufacturers of allergenic products during FY 2023.
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 clinical and nonclinical study data and terminologies (e.g., MedDRA, SNOMED CT, WHO Drug Global)
- HL7 v3 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
- Pharmaceutical Quality (PQ) and Chemistry & Manufacturing Controls (CMC) data standards
- Bioresearch Monitoring Data Standards
- BioCompute Objects for High-throughput Sequencing Data
- For more information, see Study Data for Submission to CDER and CBER | FDA and FDA Data Standards Advisory Board | FDA
- ICH Q1/Q5C Guidance on stability: This revision will combine CBER regulated complex biologics such as vaccines and Cell and Gene Therapy product to the list of small molecules and well characterized biological products regulated by CDER, to provide harmonized advice to sponsors.

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. CBER awarded a contract to Nexight Group and the Standards

Coordinating Body (SCB) in 2017 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. This contract has been extended to 2024 with deliverables to include the identification of needed standards, the conduct of feasibility assessments for needed standards, maintenance of the standards web portal that allows for stakeholders to search form standards under development and standards available, and stakeholder outreach to experts for input on standards under development.

To encourage the use of standards for regenerative medicine products, CBER published the final guidance Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies on October 19, 2023 (https://www.fda.gov/media/159237/download). This guidance describes a standards recognition program for regenerative medicine therapies (SRP-RMT) at FDA's Center for Biologics Evaluation and Research (CBER) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products regulated by CBER when such standards are appropriate. CBER encourages the use of appropriate standards in the development of CBER-regulated products. The use of recognized VCS can assist stakeholders in more efficiently meeting regulatory requirements and increasing regulatory predictability for RMT products. This program is modeled after the formal standards and conformity assessment program or S-CAP for medical devices. CBER will post a list of recognized standards on the regenerative medicine therapies portion of the FDA website https://www.fda.gov/vaccines-blood-biologics/standards-development-regenerative-medicine-therapies .

Center for Drug Evaluation (CDER)

CDER launched the pharmaceutical quality standards recognition program on July 26, 2023. This program allows internal FDA staff and external stakeholders to propose pharmaceutical quality standards for recognition by CDER, providing industry with additional resources for pharmaceutical development and manufacturing. CDER issued the final guidance for this program, CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality and launched a new portal (https://cdernextgenportal.fda.gov) to facilitate submission of standards for potential recognition. This program is intended to promote innovation in pharmaceutical development and manufacturing. Additional information can be found on the program's webpage (https://www.fda.gov/drugs/cder-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality-cder-quality).

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. In 2022, FDA has collated and addressed all public comments for the draft RWD guidance and is revising the document to prepare for publication of the final guidance. FDA further explored opportunities to adapt HL7 Fast Healthcare Interoperability Resources (FHIR) for Real World Data submissions through engagement with HL7 Vulcan Accelerator Track, resulting in the development of draft Implementation guides (IG) for two use cases (Acute Coronary Syndrome and Anti-TNFa Treatment in Patients with Crohn's Disease). In 2023, the final RWD guidance was completed and is expected to publish by the end of first quarter in 2024. FDA continued its engagement with the HL7 Vulcan Accelerator testing and refining the FHIR RWD Implementation Guide (IG). The IG was balloted and published as Standard for Trial Use (STU) in May. FDA will continue to explore and evaluate approaches to standardize RWD for regulatory submission in 2024 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 (FRN) detailing the FHIR mapping of all Phase 1 PQ/CMC data elements is in the clearance process. In 2022, FDA published a FRN requesting for comments on the Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Exchange, and later addressed public comments resulting in revisions to PQCMC Phase 1 data elements and the completion of the PQ/CMC Phase 1 Interim Implementation Guide. In 2023, FDA published a FRN announcing the establishment of an open docket on matters related to PQ/CMC Data Elements and Controlled Terminologies, which entails a new process for release of relevant information for public comment where each update will be made available on the public-facing FDA

PQCMC webpage designated as a new “Chapter” that contributes to a growing set of draft data elements and terminology. The Agency completed development of all Phase 1 PQCMC data elements, and the standardization of the remaining Phase 2 elements is underway and will continue in 2024.

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. In 2022, FDA jointly established the Global IDMP Working Group (GIDWG) with WHO-UMC and EMA to conduct and report on projects leading to the establishment of a framework for the global implementation of the ISO IDMP standards and maintenance of global identifiers. The GIDWG initiated 5 pilot projects to identify challenges and mitigation to establish common grounds, business rules, and processes to facilitate global IDMP implementation. In 2023, FDA published the final IDMP Guidance: “Identification of Medicinal Products: Implementation and Use”. This guidance explains the FDA’s position and progress on aligning the Agency’s standards to IDMP standards, with the goal of harmonizing the standards for international exchange of medicinal product data. FDA continues to collaborate with EMA, WHO, WHO-UMC to establish a framework for maintenance of Global Substance and Global Pharmaceutical Product Identifiers.

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 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, 2015 Edition, and 2015 Edition Cures Update 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 has certified to the requirements that were due in 2023 for the ONC 2015 Edition Cures Update per ONC's timeline in the Federal Register. The IHS is continuing work to comply with the requirements due in 2024 as well. 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

National Cancer Institute (NCI)

The Nanotechnology Characterization Laboratory (NCL) (https://www.cancer.gov/nano/research/ncl) is part of the Frederick National Laboratory for Cancer Research operated by Leidos Biomedical Research Inc. (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 82 assays and 5 characterization guides for nanomaterial characterization, termed NCL's Assay Cascade. All NCL assays are published on the NCL website and are free to download: https://www.cancer.gov/nano/research/ncl/protocols-capabilities

Over 500 nanomaterials of varied 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:

- PCC-23: Detection of Residual DMSO in nanoformulations using gas chromatography with direct injection and flame ionization detection

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

- ISO/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 active participants of the standards organizations ASTM International and ISO, which develop voluntary consensus standards. Several of the NCL's protocols have been adapted as ASTM standards:

- ASTM E2524-22: Standard Test Method for Analysis of Hemolytic Properties of Nanoparticles
- ASTM E2525-22: Standard Test Method for Evaluation of the Effect of Nanoparticulate Materials on the Formation of Mouse Granulocyte-Macrophage Colonies
- ASTM E2526-22: Standard Test Method for Evaluation of Cytotoxicity of Nanoparticulate Materials in Porcine Kidney Cells and Human Hepatocarcinoma Cells
- ASTM E3351-22: Standard Test Method for Detection of Nitric Oxide Production In Vitro

Efforts are also ongoing to bring two additional NCL protocols through ASTM as Standard Methods or Standard Guides. These efforts are continuing into 2024. The standards under development are:

- ASTM WK76862: Standard Guide for Identification of Nanoparticle's Ability to Induce Infusion Reactions
- ASTM WK76860: Method for the Preparation and Analysis of Culture Supernatants for the Presence of Cytokine Biomarkers by Nanoparticles in Human Whole Blood Cultures

NCL staff also serve as subject matter experts in various nanotech-related working groups within these organizations. In addition to working to promote NCL's assay to standards, the NCL also contributed to the development of several other standards:

- ISO 29701:2010 Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems — Limulus amebocyte lysate (LAL) test
- ISO TS 21362: Nanotechnologies — Analysis of nano-objects using asymmetrical-flow and centrifugal field-flow fractionation.
- ASTM E3297-21: Standard Test Method for Lipid Quantitation in Liposomal Formulations

Using High Performance Liquid Chromatography (HPLC) with a Charged Aerosol Detector (CAD)
- ASTM E3324-22: Standard Test Method for Lipid Quantitation in Liposomal Formulations Using Ultra-High-Performance Liquid Chromatography (UHPLC) with Triple Quadrupole Mass Spectrometry (TQMS)

Staff are also currently working with ASTM International and ISO on the preparation and adoption of new standards:

- ASTM standard for endotoxin measurements in nanoformulations
- ASTM WK68060: Analysis of Liposomal Drug Formulations using Multidetector Asymmetrical- Flow Field-Flow Fractionation
- ASTM WK75607: Standard Guide for Characterization of Encapsulation, Extraction, and Analysis of RNA in Lipid Nanoparticle Formulations for Drug Delivery
- ASTM WK76861: Standard Practice for In vivo analysis of nanoparticle-mediated physiological changes accompanying hypersensitivity reactions
- ASTM WK83164: Analysis of Lipid Nanoparticle Formulations Using Multi-Detector Asymmetrical-Flow Field-Flow Fractionation
- ASTM WK86057: New Standard Test Method for Measuring Sulfate and Ammonium Ion Concentrations in Liposome Drug Formulations
- ISO standard, Nanotechnologies—Total and free drug quantitation in doxorubicin hydrochloride liposomal formulations
- ISO/DTS 4958: Nanotechnologies - Vocabulary – Liposomes

National Library of Medicine (NLM)

The National Library of Medicine (NLM) is a leader in biomedical informatics and computational health data science research and the world's largest biomedical library. With a mission to acquire, collect, preserve, and disseminate materials relevant to research, medicine, and public health, NLM makes the world's biomedical data and information discoverable and accessible to all: scientists, clinicians, students, educators, librarians, and the public. NLM's biomedical information services enable data- driven scientific discovery, health care, and public health. In addition, NLM's innovative research programs develop and apply novel computational approaches to accelerate biomedical discovery and advance health care across disease areas.

As the central coordinating body within the U.S. Department of Health and Human Services for clinical terminology standards for health data interoperability, NLM plays a critical role in promoting health data interoperability through the development, maintenance, and dissemination of health data standards. In this role, NLM works across the National Institutes of Health and Federal Government to advance the interoperable exchange of health data for care and quality reporting in support of federal health information technology (IT) interoperability requirements, and of research.

In FY 2023, NLM continued to support improvements in health data standards, services for standards- based information sharing, and use of standards in its literature services.

NLM continued to support the improvement of three standards used to assure the precise and current representation of terms and codes needed for clinical care and research:

1) SNOMED CT® (Systematized Nomenclature of Medicine Clinical Terms): Supported expansion by adding nearly 10,000 concepts and the addition of over 550 concepts to enable users to capture information specific to the U.S. health care system.
2) LOINC® (Logical Observation Identifiers, Names and Codes): Added nearly 2,600 new terms to support the provision of high-quality interoperable laboratory information
3) RxNorm: Added nearly 250 new terms to facilitate the prescription and monitoring of therapeutics and vaccinations in electronic health record (EHR) systems that support payment as well as care management.

NLM also continued to support services that facilitate standards-based information sharing for health care and public health.

1) MedlinePlus Connect provides patients and clinicians with direct, tailored access to MedlinePlus resources automatically through EHR systems, patient portals, and other health information technology (IT) systems at the point of care. In FY 2023, MedlinePlus Connect responded to nearly 190 million electronic requests from health IT systems.

2) Value Set Authority Center is a repository and authoring tool for value sets, or lists of codes and corresponding terms, from NLM-hosted standard clinical vocabularies (such as SNOMED CT®, LOINC®, and RxNorm), that define clinical concepts to support effective and interoperable health information exchange. In FY 2023, in collaboration with the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology, NLM published value set specifications for the 2023 electronic clinical quality measures (eCQMs); the Health Level Seven International (HL7) Consolidated Clinical Document Architecture (C-CDA) value sets; and, a trial release of the HL7 Fast Healthcare Interoperability Resources (FHIR®) eCQM value sets in preparation for CMS's planned 2025 public release of the FHIR eCQM value sets.

Lastly, NLM continued to employ use of and provide support for the Journal Article Tag Suite (JATS), an application of NISO Z39.96-2021, which defines a set of XML elements and attributes for tagging journal articles and describes three article models. NLM hosted the JATS-Con Conference in support of JATS users in June 2023. NLM also supported the NISO JATS Standing Committee as it worked on the next version of JATS, which is expected to be released in 2024.

7) Office of the National Coordinator for Health Information Technology (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.

One way in which ONC encourages the consistent use of health IT standards is through ONC's Health IT Certification Program which is composed of functional requirements known as “certification criteria.” Health IT standards are part of the certification criteria. Developers certify their Health IT Modules by demonstrating conformance to these certification criteria, using test procedures (that may have associated test tools and/or test data) approved by the National Coordinator. Additionally, ONC provides clarifications to certification criteria through Certification Companion Guides (CCG) designed to assist with health IT product development.

One of the standards used in certification criteria is the United States Core Data for Interoperability (USCDI) which 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 USCDI Version 1 and created an annual process for updating the USCDI based on public input. In 2023, ONC published USCDI Version 4 after going through the annual process and is now working on developing USCDI Version 5.
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 webpage 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. In 2023, ONC announced the “Approved Standards for 2023,” which includes USCDI v3. Please see the SVAP Approved Standards on the ONC Certification Program SVAP webpage.

ONC provides some funding and works with the standards development organization named the Regenstrief Institute, in their development of Logical Observations Identifiers, Names and Codes (LOINC), a health IT standard for reporting and ordering laboratory tests, measurements, and other observations.

Another standard development organization that ONC works closely with and provides funding to is Health Level Seven (HL7) to support the development and ongoing maintenance of Fast Healthcare Interoperability Resources (FHIR) standard and related implementation guides along with their Consolidated Clinical Document Architecture (CCDA) standard. These standards are referenced in ONC’s certification program and enables nationwide interoperability.

Additionally, ONC works with Integrating the Healthcare Enterprise (IHE) a non-profit organization that creates guidance, called "profiles", by combining a variety of standards and documents how they work together in order to support a specific use case. ONC's focus with IHE has largely been related to updating IHE profiles to use the HL7 FHIR standard.

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/standards-version-advancement-process
https://www.healthit.gov/topic/standards-version-advancement-process-svap
https://www.healthit.gov/topic/certification-ehrs/certification-health-it

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

The Substance Abuse and Mental Health Services Administration (SAMHSA) works closely with other Department of Health and Human Services (HHS) agencies, including the Centers for Medicare and Medicaid Services' (CMS), contracted consensus-based entity (CBE), in matters related to quality measures and alignment of those measures. The current CBE for quality measurement is Battelle's Partnership for Quality Measurement (PQM)™. The PQM uses a consensus-based process involving a variety of experts - clinicians, patients, measure experts, and health information technology specialists - to ensure informed and thoughtful endorsement reviews of qualified measures to be used for federal reporting.

SAMHSA collaborates with a number of federal partners, including, CMS, as well as private and other public stakeholders, as part of workgroups and governance groups that provide input to HHS on quality measures that will be included in CMS and SAMHSA public reporting efforts. Specifically, SAMHSA is a federal liaison or working group member working with CMS and other stakeholders on the following:

- Child and Adult Health Care Quality Measures that are the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) and the Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set). The most current iterations of these measures can be found at:

  2023 and 2024 Core Set of Adult Health Care Quality Measures for Medicaid (Adult Core Set): https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child- health-care-quality-measures/adult-health-care-quality-measures/index.html

  2023 and 2024 Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set): https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult- and-child-health-care-quality-measures/childrens-health-care-quality-measures/index.html

- Health Home Quality Measures, the most current iteration of which may be found at:

  2023 and 2024 Core Set of Health Care Quality Measures for 1945 Medicaid Health Home Programs (1945 Health Home Core Set): https://www.medicaid.gov/sites/default/files/2023-

03/2023-health- home-core-set_0.pdf

- Electronic Clinical Quality Measures (eCQM) governance group. Information about CMS eCQMs may be found at https://ecqi.healthit.gov/ecqms

Some of these measures have been used in different stages of "Meaningful Use" and are now part of the Merit-based Incentive Payment System (MIPS). The 2024 MIPS Quality Measures can be found at: https://qpp.cms.gov/resources/resource-library

SAMHSA also collaborates with both CMS and the Office of the Assistant Secretary for Planning and Evaluation, to update and revise the Behavioral Health Clinic (BHC) quality measures used for the Certified Community Behavioral Health Clinic (CCBHC) demonstration. The vast majority of those measures are derived from the Adult and Child Medicaid Core Set and MIPS measures, nearly all of which are consensus-based.

In the past year, SAMHSA also has been working under an Interagency Agreement with CMS to maintain three CBE-endorsed measures in the substance use disorder treatment field.

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2023. Please note, GUS which are still in effect from previous years should continue to be listed, and you do not need to report your agency's use of a GUS where no similar VCS exists.

Start by reviewing Table 1: Current Government Unique Standards FY2023.

To add a new GUS, please include:

1. **The name of the GUS;**
2. **The name(s) and version(s) of the VCS(s) that might have been used, but after review, found to be inappropriate;**
3. **A brief rationale on why the VCS(s) was not chosen.**

To rescind a GUS, (if they are no longer in use or have been replaced by a voluntary consensus standard) please:

1. **Cross out the standard from Table 1.**
2. **Add a 'Rationale for Rescinding' explaining why the standard was rescinded. The rationale can be simply the name of the VCS replacing the GUS.**

Please record below the total number of GUS currently in use. This number should include the previous total plus any new GUS added, and minus any GUS rescinded:

Current total GUS = 1

Table 1: Current Government Unique Standards FY2023

(1) Government Unique Standard

FDA Guidelines on Aseptic Processing (2004) [Incorporated: 2004]

Voluntary Standard

ISO 13408-1 Aseptic Processing of Health Care Products, Part 1, General Requirements

Rationale

FDA is not using the ISO standard because the applicability of these requirements is limited to only portions of aseptically manufactured biologics and does not include filtration, freeze-drying, sterilization in place, cleaning in place, or barrier-isolator technology. There are also significant issues related to aseptically produced bulk drug substance that are not included in the document