Health and Human Services (HHS) Fiscal Year 2024 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) Administration for Children and Families (ACF)

The Administration for Children and Families (ACF) actively implements the provisions of OMB Circular A-119 and the National Technology Transfer and Advancement Act (NTTAA) by integrating voluntary consensus standards (VCS) and conformity assessment practices into its IT governance, procurement, and operations.

Key Activities:

- Standards Adoption: ACF applies NIST frameworks (e.g., SP 800-53, SP 800-207) and other voluntary standards across cybersecurity, cloud modernization, and data initiatives, particularly in support of Zero Trust implementation.
- Conformity Assessment: Security assessments, ATO processes, and vendor evaluations are aligned with conformity assessment practices to ensure systems meet federal standards for security and performance.
- Standard Contract Language: All IT acquisitions include mandatory language requiring contractor adherence to applicable standards, including NIST guidance, Zero Trust principles, and federal cybersecurity requirements.
- Coordination and Reporting: ACF coordinates with HHS OCIO and other federal partners to ensure consistent application and reporting of standards-based practices.

Public Access:
Information about standards and conformity assessment efforts is available via the HHS OCIO website:
https://www.hhs.gov/about/agencies/asa/ocio/index.html

2) Assistant Secretary for Technology Policy (ASTP)

Office of the National Coordinator for Health IT

Standards are an integral component of ASTP'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 ASTP encourages the consistent use of health IT standards is through the ONC 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, ASTP 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, ASTP published USCDI Version 1 and created an annual process for updating the USCDI based on public input. In 2024, ASTP published USCDI Version 5 after going through the annual process and is now working on developing USCDI Version 6. Additionally, ASTP 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 ASTP Health IT Certification Program. The ASTP 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 ASTP-regulated standards and implementation specifications into their products under the ASTP 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, ASTP established an annual public comment process for SVAP-eligible standards and implementation specifications. In 2024, ASTP announced the "Approved Standards for 2024," which includes USCDI v4. Please see the SVAP Approved Standards on the ASTP Certification Program SVAP webpage.

ASTP 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 ASTP 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 (C-CDA) standard. These standards are referenced in ASTP's certification program and enables nationwide interoperability.

Additionally, ASTP 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 to support a specific use case. ASTP'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

3) Centers for Disease Control and Prevention (CDC)

Office of Public Health Data Surveillance and Technology (OPHDST)

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 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 Division (DPSD)

CDC's Data Policy and Standards Division (DPSD) in the Office of Public Health Data Surveillance and Technology (OPHDST) is working collaboratively across the Agency, with federal partners, state, tribal, local, and territorial (STLT) partners, and healthcare to improve data sharing and interoperable data exchange. The focus of the work includes:

- Ensuring core data sources are more complete and rapidly exchanged to support the 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 developing consensus-based definitions for the minimal 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 STLT health departments at 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, OPHDST coordinates comments and feedback from across CDC to the Assistant Secretary for Technology Policy/ Office of the National Coordinator for Health IT (ASTP) on United States Core Data for Interoperability (USCDI) and USCDI+ for public health specific use cases. USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. Inclusion of public health use cases in USCDI and USCDI+ make mission-critical data more consistent, compatible, and usable for interoperable public health and healthcare purposes.

Office of Laboratory Systems and Response (OLSR)

Division of Laboratory Systems (DLS)

Electronic Test Orders and Results: 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 include: Health Level 7 (HL7) Standards, Logical Observation Identifiers Names and Codes (LOINC), Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT), Unified Code for Units of Measure (UCUM)

Laboratory Response Network Data Exchange: 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 include: HL7 Standards, LOINC, SNOMED CT, UCUM

LOINC In Vitro Diagnostic Test Code Mapping: DLS manages the 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 include: LOINC, SNOMED CT, UCUM

Forum on Adoption of Standards for Laboratory Data Exchange: CDC hosts the Forum on Adoption of Standards for Laboratory Data Exchange and Interoperability to help address a CLIAC recommendation from November 2021. The goal of this forum is to provide a space for organizations to develop new relationships and discuss challenges and successes related to the adoption of laboratory standards. Participants include Federal partners, healthcare-related software vendors, and professional groups.

Blood Culture Contamination Quality Measure: Quality measure to protect patients during the diagnostic process by monitoring adult blood culture contamination (BCC) rates.

Laboratory Quality Standards: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) has several requirements for establishing or verifying 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 the CDC and others.

- **Committees/Workgroups**
  - Document Development Committee
    - DDC on Clinical Validation Workgroup
    - DDC on Validation of External Transport Systems Workgroup
    - DDC on Respiratory Specimen Collection Workgroup
    - DDC on Total Analytical Error
    - DDC on Verification of Comparability of Patient Results Within One Health Care System
    - DDC on Laboratory Safety Management
  - U.S. TAG to ISO/TC212 Workgroup
  - Evaluation Protocols (EP) Glossary Workgroup
  - Consensus Council
  - Expert Panel on Point-of-Care Testing (POCT)

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, representational 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.

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 (DTBE)

DTBE's Tuberculosis Trials Consortium (TBTC) conducts programmatically relevant clinical trials to improve treatment options and outcomes for tuberculosis disease and latent tuberculosis infection. DTBE 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.

In 2022, CDC released new interim guidance for a 4-month treatment regimen to treat drug-susceptible TB disease that is as effective as the standard 6-month regimen for TB treatment. This was the first successful short treatment regimen for drug susceptible TB disease identified in almost 40 years. Shortening treatment for TB disease can benefit patients, families, healthcare providers and health systems. In the same year, CDC published a two-year study demonstrating electronic directly observed therapy (eDOT) was at least as effective as traditional in-person DOT for ensuring high adherence to treatment while enabling patient-centered care for TB disease.

National Center for Chronic Disease Prevention and Health Promotion

National Program of Cancer Registries (NPCR)

CDC's National Program of Cancer Registries (NPCR) provides data that public health officials, clinicians, researchers, and policymakers rely on to measure progress in preventing and treating cancer, the second leading cause of death in the United States. Established by Congress through the Cancer Registries Amendment in 1992, NPCR collects nationwide data on cancer occurrence (including the type, extent, and location of the cancer), the type of initial treatment, and outcomes. Today, through NPCR, CDC provides funding and technical assistance to 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 promotes the development and implementation of consensus data standards (i.e., North American Association of Central Cancer Data Dictionary) with other partners to accelerate timely, actionable insights. Annually reported cancer data from 50 central cancer registries are evaluated for quality, completeness, and timeliness according to the NPCR National Data Quality Standards and the United States Cancer Statistics Publication Standards. These standards can be found here: NPCR Data Standards.

Consensus data standards for collection and exchange of cancer data include:

- HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm
    - Previous versions:
        - Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries (March 2014)
        - Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries (August 2012)
    - SVAP requirement for § 170.205(i)(2); § 170.315(f)(4) - Transmission to cancer registries
- HL7 FHIR Central Cancer Registry Reporting Content Implementation Guide v1.0.0
- HL7 FHIR Cancer Pathology Data Sharing v2.0.0
- 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
- Communications and Directory PHIN Directory Exchange Implementation Guide Version 1.0 (May 16, 2007); DSML 1.0
- NAACCR Standards for Cancer Registries Volume 5: Laboratory Electronic Reporting for Pathology
- NAACCR Data Standards and Data Dictionary v25

CDC Diabetes Prevention Recognition Program (DPRP)
The Centers for Disease Control and Prevention established the CDC Diabetes Prevention Recognition Program as part of the National Diabetes Prevention Program (National DPP). 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. 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 adults with prediabetes or at high risk for type 2 diabetes.
- 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 55.5% of all evaluated participants. This risk reduction included 48% who achieved at least a 5% weight loss; 39.7% who achieved at least a 4% weight loss combined with at least 150 min/week on average, of physical activity; 51.9% who achieved a minimum 4% weight loss combined with at least 17 sessions attended; and 1.6% to date who had at least a 0.2% reduction in HbA1c (of those who submitted HbA1c information*). As of May 7, 2025, there are 1,499 CDC-recognized organizations that have collectively enrolled 626,202 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 to offer the National DPP lifestyle change program.

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 to develop use cases

for public health surveillance of hypertension control (CMS165) and diabetes control (CMS122) from EHR data, using electronic case reporting technology 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.

4) Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services (CMS) works voluntarily with partners to develop, evaluate, and apply national and consensus-based standards. Below is a summary of significant standards used or adopted by CMS to increase the electronic exchange of health information for administrative, financial, quality reporting, and value-based purchasing programs. Organizations using these standards include HIPAA-covered entities (payers, healthcare clearinghouses, certain covered providers), payers regulated by CMS, Medicare providers covered under the Promoting Interoperability and Merit-Based Incentive programs, and entities engaged in Alternative Payment Models, among others.

Centers, Offices, and Groups within CMS engaged with standards development organizations include the Center for Clinical Standards and Quality (CCSQ), the Center for Medicare and Medicaid Innovation (CMMI), the Center for Consumer Information and Insurance Oversight (CCIIO), the Center for Medicare (CM), the Office of Healthcare Experience and Interoperability (OHEI) which includes the Health Informatics and Interoperability Group and National Standards Group, the Office of Enterprise Data and Analytics (OEDA), and the Office of Information Technology (OIT), which includes the claims payment group.

The National Standards Group (NSG) within the Office of Healthcare Experience & Interoperability at CMS is responsible for adopting and enforcing the use of national standards, code sets, identifiers, 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 the adoption of electronic standards by all covered entities, including those organizations in the private and public sectors, as electronic transaction standards will increase healthcare efficiency.

The Center for Medicare uses the adopted HIPAA standard for its eligibility system and transactions. The Center for Consumer Information and Insurance Oversight uses a modified version of the enrollment transaction for the employers participating in its program. It is not the HIPAA standard but a modified version that meets the needs of CCIIO. The staff in CCIIO are active participants in the X12 enrollment workgroup to develop a version of the transaction that meets federal requirements. The Center for Medicare also collaborates with ASTP/ONC to adopt a standard for pharmacy prior authorization under the Part D program, specifically the NCPDP SCRIPT standard, and coordinates with NCPDP on its development, use, updates, and education for payers and PBMs.

The standards development organizations in which CMS employees are engaged and which develop and maintain many of the HIPAA standards, including those for enrollment, eligibility, claims, claim status,

electronic funds transfer, remittance advice, prior authorization, and attachments, are listed below. CMS staff, including those from OHEI, participate in workgroups of the standards-setting organizations:

- Health Level 7 (HL7): (www.HL7.org) – FHIR standards and Implementation Guides
- National Council for Prescription Drug Programs (NCPDP): (www.ncpdp.org) – Pharmacy standards
- Accredited Standards Organization, Insurance (X12N): (www.x12.org) – EDI administrative standards

Organizations responsible for code sets:

- American Dental Association: (www.ada.org) – The ADA manages the dental code set adopted under HIPAA.
- American Medical Association (www.ama-assn.org) chairs the National Uniform Claim Committee (NUCC), which is responsible for designing and maintaining the standardized health insurance claim form. The AMA also manages the CPT code set for billing, which has been adopted under HIPAA.
- National Uniform Billing Committee is chaired by the American Hospital Association. The NUBC maintains the UB-04 data set for institutional healthcare providers. It is the standard billing form and data set for institutional providers and data sets.

Organizations responsible for Operating Rules:

- 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/)

The CMS Quality Measurement and Value-Based Incentives Group (QMVIG) in the Center for Clinical Standards and Quality (CCSQ) selects performance measures 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 allows 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

The Health Informatics and Interoperability Group at CMS has adopted the HL7 Fast Healthcare Interoperability Resources standards and Implementation Guides for APIs under the Interoperability and Patient Access and Interoperability and Prior Authorization final rules in 2020 and 2024, respectively, to enable patients, providers, and payers a more efficient method to exchange real-time information. The use of these standards aligns with the final rules of the ASTP/ONC. A list of the standards and implementation guides is available from the web link below and are updated in accordance with the ONC Standards Version Advancement process to enable impacted payers to use a more up-to-date version when the National Coordinator approves those. We do not list all the standards and IGs here, but we point to the weblink, where all are available for each required API.

- https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/implementation-guides-and-standards

5) 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 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 FY2024, 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 2024:

Date	Federal Register Notice
June 24, 2024	FR Notice (List #62) [Docket No. FDA-2004-N-0451]
Federal Register, Volume 89 Issue 121 (Monday, June 24, 2024)	
March 1, 2024	FR Notice (List #61) [Docket No. FDA-2004-N-0451]

https://www.govinfo.gov/content/pkg/FR-2024-03-01/html/2024-04376.htm

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 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.

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

Human Foods Program (HFP) and Center for Veterinary Medicine (CVM)

As of October 1, 2024, the unified Human Foods Program (HFP), a new model for field operations and other modernization efforts is now in effect. The reorganization establishes the HFP by realigning the functions of the Center for Food Safety and Applied Nutrition, the Office of Food Policy and Response, as well as key functions from the Office of Regulatory Affairs (ORA) under one program.[1] [2]

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[1] https://www.fda.gov/news-events/press-announcements/fdas-unified-human-foods-program-new-model-field-operations-and-other-modernization-efforts-go

[2] https://www.fda.gov/news-events/press-announcements/fdas-reorganization-approved-establishing-unified-human-foods-program-new-model-field-operations-and

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 FY24, the FDA has recognized 4 accreditation bodies which have accredited 9 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 FY24, FDA has recognized 8 accreditation bodies that have accredited 47 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.

Regarding pharmacovigilance, CVM personnel actively participate in the VICH pharmacovigilance expert working group. The full title of VICH is the "International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. VICH is a trilateral (EU-Japan-USA) program that encourages participation from other global regions. The efforts of the working group members have culminated in the development of an internationally harmonized adverse event message, associated data standards, and 5 international PV VICH guidelines that has successfully been implemented in multiple regions and has facilitated exchange of safety information globally. One established data standard by VICH is Veterinary Dictionary of Drug Regulatory Activities (VeDDRA). VeDDRA is a list of clinical terms used for reporting suspected adverse events (AEs) in animals and humans to veterinary medicinal products and the list is updated annually. AE reporting using VEDDRA terminology ensures different regions and industry are all using the same terminology when reporting AEs. In addition, VICH working groups have established additional standards and maintenance procedures for VICH GL30 vocabulary lists which are harmonized lists of terms used as data elements in AE reporting.

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 2024, 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." No deficiencies were identified during the audit. 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 internally audited for ISO 17025: 2017 re-accreditation in September 2024; 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 451 protocols for lot release in conjunction with ELISA potency tests and shipped over 4,000 references to manufacturers of allergenic products during FY

2024. Finally, LIB replaced references C16-Cat, C16b-Ras, E12-Ber, and E10-Ti during FY 2024 as part of the Reference Replacement Maintenance Program.

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)
- ICH M11, the Clinical Electronic Structured Harmonized Protocol
- 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
- ICH M4Q(R2) to standardize Quality information submitted within eCTD modules 2 and 3
- 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/downloadThis 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. Since implementation of the SRP-RMT, CBER has reviewed and recognized 23 standards.

Center for Drug Evaluation (CDER)

CDER recognized the following pharmaceutical quality standards through the Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality:

1. ASTM Standard Test Method for Measuring the Size of Nanoparticles in Aqueous Media Using Dynamic Light Scattering.
2. Standard Practice for Process Step to Inactivate Rodent Retrovirus with Triton X-100 Treatment.
3. Standard Practice for Process for Inactivation of Rodent Retrovirus by pH.

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). The final RWD guidance was published in December 2023. 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 of 2023. In 2024, the RWD standardization initiative completed a CDER-CBER reviewers evaluation of its prioritized RWD data domains and data elements identified for supporting the needs of RWD research and regulatory submissions. Based on reviewer feedback, the revised data domains and elements will be share with the public for comments in a Federal Register Notice (FRN) that is targeted for publication in Q1 of 2025. FDA will continue to explore and evaluate approaches to standardize RWD for regulatory submission in 2025 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. By the end of 2023, the Agency completed development of all Phase 1 PQCMC data elements. In 2024, FDA completed technical developments and conducted two tests of PQCMC FHIR IG content at the January and September HL7 Connectathon. The Stage 1 FHIR IG for "Pharmaceutical Quality - Chemistry, Manufacturing and Controls (PQ-CMC) Submissions to FDA" passed HL7 ballot in May 2024 and the agency has completed adjudication of all ballot comments. In 2025, the initiative is expected to proceed through the HL7 process for approval to publish the Stage 1 IG which will have an official version, Standard for Trial Use (STU) v1.0.0.

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. In 2024, based on the established framework and business rules, the GIDWG completed the Global PhPID End-to-End test which successfully assigned Global Substance IDs to 96% of the 150 selected substances and Global PhPIDs to 90% of the 2,947 medicinal products provided by nine regulators. This initiative will continue in 2025 with the expected completion of ISO IDMP standards revisions (ISO 11615, ISO 11616, TS 20443, and TS 20451), while ensuring the implementation of a harmonized approach to generating global PhPIDs and the process of linking similar medicinal products across regions is compatible with, and supported by, the standards currently used by the FDA.

Center for Tobacco Products (CTP)

Catalyzed by NTTAA and OMB circular A-119 and to encourage the appropriate use of voluntary consensus standard, CTP is preparing to draft a guidance for industry and develop a CTP standards recognition program. The initial focus is on testing methods but may expand the scope in the future to include other types of standards such as software or human factors testing standards.

In partnership with Clinical Data Interchange Standards Consortium (CDISC), CTP developed data standards to facilitate tobacco product research and scientific review. On June 10, 2024, CDISC released Tobacco Implementation Guide v1.0, a foundational data standard that can help optimize scientific accuracy and review efficiency. The guide was developed by a multidisciplinary team from CTP, tobacco industry stakeholders, and CDISC, and included public/community review. This initial version of the Guide implements several data models, including Clinical Data Acquisition Standards Harmonization, Study Data Tabulation Model, and Analysis Data Model.

6) Health Resources and Services Administration (HRSA)

As part of required Health Center Program data reporting, the Health Resources and Services Administration (HRSA) collects information on clinical quality measurements that align with Centers for Medicare & Medicaid Services standards and participates in the Electronic Medical Record workgroup to support these standards. Through the Uniform Data System (UDS+) interoperability data collection pilot initiative, currently paused, HRSA worked with the Assistant Secretary for Technology Policy's Office of the National Coordinator to create a health center-specific implementation guide through HL7 that uses USCDI and USCDI+ standards. By using already accepted HHS-wide and industry wide clinical measurement and reporting standards, HRSA ensures limited reporting burden along with increased consistency and standardization for federally qualified health centers.

HRSA UDS+ implementation guide: UDS Plus Home Page - HRSA 2024 Uniform Data System (UDS) Patient Level Submission (PLS) (UDS+) FHIR IG v2.0.0

7) National Institutes of Health

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.

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 2024, 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 more than 9,000 concepts and the addition of more than 200 concepts to enable users to capture information specific to the U.S. health care system.

2) LOINC® (Logical Observation Identifiers, Names and Codes): Added over 2,000 new terms to support the provision of high-quality interoperable laboratory information.

3) RxNorm: Added nearly 300 new terms to facilitate sharing of over-the-counter and prescription drug-related information in support of care management and payment activities in health care.

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 2024, MedlinePlus Connect responded to more than 250 million electronic requests from health IT systems.

2) Value Set Authority Center: 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 2024, in collaboration with the Centers for Medicare & Medicaid Services and the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, NLM published value set specifications for the 2024 electronic clinical quality measures (eCQMs) and the Health Level Seven International (HL7) Consolidated Clinical Document Architecture (C-CDA) 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 supported the NISO JATS Standing Committee by acting as a vital resource in the 2024 release of JATS version 1.3.

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

SAMHSA collaborates with various agencies within the Department of Health and Human Services , including the Centers for Medicare and Medicaid Services (CMS), to align and enhance quality measures in behavioral health care. A key partner in this endeavor is the CMS-contracted consensus-based entity, currently Battelle's Partnership for Quality Measurement (PQM™). PQM employs a consensus-driven process that involves clinicians, patients, measure experts, and health information technology specialists to review and endorse quality measures for federal reporting.

In 2024, SAMHSA's involvement with PQM included development and refinement quality measures for Certified Community Behavioral Health Clinics. The *Quality Measures for Behavioral Health Clinics Technical Specifications and Resource Manual* provides detailed specifications for these measures, many of which are endorsed by consensus-based entities like PQM. This manual outlines the collaborative efforts between SAMHSA, CMS, and other partners to ensure that quality measures are evidence-based, feasible, and aligned with federal reporting requirements.

Additional SAMHSA activities in 2024 include:

- Participation in the 2024 Medicaid and Children's Health Insurance Program Core Set Quality Measure Workgroups- SAMHSA served as a federal liaison in updating and implementing the 2024 Core Sets:
    - 2024 Adult Core Set
    - 2024 Child Core Set
- Support for the 2024 Health Home Core Set:
  SAMHSA contributed to the 2024 quality measures supporting integrated care through Medicaid Health Home Programs-
    - 2024 Health Home Core Set
- Governance and Endorsement of 2024 Electronic Clinical Quality Measures (eCQMs): SAMHSA participated in the 2024 governance of electronic clinical quality measures eCQMs used across Medicaid and Medicare, including the Merit-Based Incentive Payment System-
    - 2024 CMS eCQMs
    - 2024 Merit-Based Incentive Payment System Quality Measures
- Maintenance of Endorsed Substance Use Disorder Measures:
  Under a 2024 Interagency Agreement with CMS, SAMHSA continued to maintain three PQM-endorsed quality measures specific to substance use disorder treatment, supporting consistency and reliability in national behavioral health reporting.

SAMHSA's 2024 efforts reflect its commitment to scientific integrity and stakeholder engagement. These activities help ensure that behavioral health services are evaluated through measures that are not only valid and reliable but also aligned with broader federal health care improvement goals.

2. Please record any government-unique standards (GUS) your agency began using in lieu of voluntary consensus standards (VCS) during FY 2024. 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.

Current total GUS = 1

Table 1: Current Government Unique Standards FY2024

(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