

ConnectedHealthInitiative

September 25, 2026

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Submitted via email to MACBIS-Enterprise-Services@cms.hhs.gov and
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RE: Comments of the Connected Health Initiative on the *Medicaid Enterprise Systems (MES) IT Standards Request for Information* [Notice ID 269888]

Dear Mr. Blackshire:

The Connected Health Initiative (CHI), an initiative of the Association for Competitive Technology (ACT), appreciates the opportunity to respond to the request for information (RFI) issued by the Centers for Medicare & Medicaid Services (CMS) on its new Medicaid Enterprise Systems (MES) IT Standards initiative.¹ CMS invites input from standards development organizations (SDOs) and industry experts as well as from states and vendors, and several of the questions in section D of the RFI reach directly into the work of the digital health community, including how MES standards should relate to the interoperability rules that already apply across the Department of Health and Human Services (HHS), how CMS should govern and update its standards, and how consent and privacy standards should develop as more data moves through application programming interfaces (APIs). CHI responds below to questions SE-1, SE-2, SE-3, SE-4, SE-7, and SE-8, and to the part of question V-9 that asks what data standardization is needed for artificial intelligence (AI) to be used safely and effectively for Medicaid populations. Each heading identifies the question labels to which the discussion responds, as the RFI requests. We take no position on the remaining questions, which are directed to state Medicaid agencies and to MES vendors and systems integrators.

CHI's comments are organized as follows:

- I. Executive Summary**
- II. Introduction and Statement of Interest**
- III. Emerging Standards for Connected Health Data and Identity (SE-1)**
- IV. Governance, Versioning, and Technical Debt (SE-2 and SE-8)**
- V. Harmonizing MES Standards With HHS Interoperability Rules (SE-3)**
- VI. Pitfalls to Avoid in Large-Scale Standardization (SE-4)**

¹ Centers for Medicare & Medicaid Services, Medicaid Enterprise Systems (MES) IT Standards Request for Information, Notice ID 269888 (posted Aug. 10, 2026, modified Aug. 13, 2026), <https://sam.gov/opp/5b4624b3c64a4b24b546ff87174749cd/view>.

- VII. **Consent Management and Data Segmentation (SE-7)**
- VIII. **Data Standardization Prerequisites for AI (V-9)**
- IX. **Conclusion**

I. Executive Summary

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to connected health technologies that improve health outcomes and reduce costs. Our members build the software and devices that Medicaid beneficiaries and their clinicians increasingly rely on, and our recommendations on this RFI are summarized here.

- **Emerging standards for connected health data and identity (SE-1).** Medicaid programs pay for remote monitoring and other connected health services but usually receive little of the underlying data in structured form. CHI recommends that CMS include established standards for device and patient-generated data, including the HL7 FHIR Personal Health Device implementation guide, in its landscape analysis, and that it align identity and access expectations for MES with the levels CMS has already set in its Interoperability Framework.
- **Governance, versioning, and technical debt (SE-2 and SE-8).** CHI recommends that CMS rely on voluntary consensus standards developed through open processes, adopt new versions on a published schedule tied to state planning cycles, allow states and vendors to move to a newer approved version before it becomes required, as the Standards Version Advancement Process allows in the ONC Health IT Certification Program, and set a retirement date for each superseded version so that older versions do not stay in use indefinitely.
- **Harmonization with HHS interoperability rules (SE-3).** Medicaid regulations already condition enhanced federal funding on alignment with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC), and state Medicaid fee-for-service programs are already implementing FHIR APIs under the CMS Interoperability and Prior Authorization final rule. CHI recommends that CMS treat those standards as the baseline for the MES program, adopt the same versions HHS uses elsewhere and change them on the same schedule, and add Medicaid-specific requirements only as profiles or extensions of those standards.
- **Pitfalls to avoid (SE-4).** The most common failure in past efforts has been a national standard that each state then modifies through its own companion guide, which brings back the variation the standard was meant to remove. CHI recommends that CMS limit state-specific variation to documented differences in state policy, avoid requiring standards before they have been proven in production, rely on automated conformance testing rather than narrative documentation, weigh the cost of each requirement to smaller vendors, and sequence the program with the deadlines states already face.
- **Consent management and data segmentation (SE-7).** CHI recommends that CMS prioritize the FHIR Consent resource and HL7's FHIR Data Segmentation for Privacy implementation guide, that it support segmentation where law or a patient's request requires it without requiring segmentation where the revised 42 CFR Part 2 rule does not, and that it encourage states to express differences in state privacy law as machine-readable policies rather than custom system logic.
- **Data standardization prerequisites for AI (V-9).** CHI recommends that CMS give priority to consistent definitions for the data elements AI tools use most often, that data exchanged

through MES APIs carry provenance information, that documentation of AI tools be scaled to the risk of the use, and that where AI supports eligibility, prior authorization, or other coverage functions, an adverse determination continue to rest with a qualified human reviewer.

II. Introduction and Statement of Interest

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs through digital health innovation. CHI aims to realize an environment in which Americans see improvements in their health through policies that allow connected health technologies to advance outcomes and reduce costs. Our members develop and deploy connected health technologies across a wide range of use cases, including telehealth platforms, remote physiologic and remote therapeutic monitoring, software as a medical device, prescription digital therapeutics, clinical decision support, and AI-enabled diagnostic and workflow tools. We advocate before Congress, numerous federal agencies, and state legislatures and agencies on coverage and payment, privacy and security, health data interoperability, FDA regulation of digital health, and the role of AI in care delivery. For more information, see <https://connectedhi.com>.

CHI has developed, with the participation of clinicians, developers, health systems, and patient organizations, a set of publicly available resources on the responsible development and use of health AI, including our Policy Principles for Artificial Intelligence in Health, our Good Machine Learning Practices, and our Health AI Roles and Interdependency Framework, which allocates responsibility for safety and efficacy across the AI value chain.² CHI is also an appointed member of the American Medical Association's Digital Medicine Payment Advisory Group.

Medicaid is one of the largest payers for the services our members support, and much of the administrative work behind those services, from provider enrollment to claims, encounter data, and prior authorization, runs through a state's MES. States spent \$9.0 billion on MES in fiscal year 2025, with 82 percent of that amount going to contractors,³ and the variation CMS describes among states that perform the same Medicaid functions shows up for our members as different companion guides, data requirements, and interfaces in each state where they operate. For a smaller technology company, that variation can decide whether serving Medicaid beneficiaries in a given state is feasible, so a standards program that reduces it would widen the range of tools available to Medicaid beneficiaries and the clinicians who treat them.

III. Emerging Standards for Connected Health Data and Identity (SE-1)

SE-1 asks which emerging standards show the most promise for longstanding challenges in Medicaid technology, particularly in identity management, data quality, and cloud security, and

² Connected Health Initiative, Policy Principles for Artificial Intelligence in Health, <https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf>. CHI's Health AI Roles and Interdependency Framework and Good Machine Learning Practices white paper are also available at <https://connectedhi.com>.

³ Medicaid and CHIP Payment and Access Commission, State Medicaid Enterprise Systems, Issue Brief (July 2026), <https://www.macpac.gov/wp-content/uploads/2026/07/Issue-Brief-State-Medicaid-Enterprise-Systems-FINAL.pdf>.

CHI's recommendations focus on data from connected devices and on identity, where our members' experience is most direct.

- **Include device and patient-generated data in the landscape analysis.** Many state Medicaid programs pay for remote physiologic and remote therapeutic monitoring, yet the readings behind those services usually reach the state only as a billing code on a claim. The HL7 FHIR Personal Health Device implementation guide, which builds on the IEEE 11073 family of device standards, already defines how measurements from personal health devices are represented and exchanged.⁴ CHI recommends that CMS include it and related standards for patient-generated health data in the “Identify” phase of the program, so that later phases can consider where structured device data would support care management and quality measurement for Medicaid beneficiaries.
- **Align identity and access expectations with the CMS Interoperability Framework.** CMS has already set identity expectations for networks and applications that participate in its Interoperability Framework, including identity proofing at Identity Assurance Level 2 and authentication at Authenticator Assurance Level 2 as defined in the National Institute of Standards and Technology (NIST) digital identity guidelines.⁵ CHI recommends that the MES standards adopt the same levels for beneficiary and provider access, so that beneficiaries and providers can use a credential they already hold rather than a separate login for each state system, and so that developers do not have to support different identity requirements for Medicare and Medicaid.

IV. Governance, Versioning, and Technical Debt (SE-2 and SE-8)

SE-2 asks how CMS should structure governance so that it can update its standards quickly while keeping them stable for state and vendor planning cycles, and SE-8 asks how the standards lifecycle can avoid accumulating technical debt, and because the same design choices address both questions, CHI responds to them together.

- **Rely on voluntary consensus standards.** Federal policy directs agencies to use voluntary consensus standards in place of government-unique standards wherever practical,⁶ and HL7, X12, the National Council for Prescription Drug Programs (NCPDP), and similar organizations already maintain the standards that MES functions depend on, through open processes in which states, vendors, providers, and patient advocates can take part. CHI recommends that CMS adopt those standards by reference and, where it identifies a gap, bring the gap to the relevant SDO rather than write a CMS-specific specification. CMS can also support state participation in those processes, which would give the SDOs better information about how Medicaid programs actually use their standards.

⁴ HL7 International, Personal Health Device Implementation Guide, <https://hl7.org/fhir/uv/phd/>.

⁵ Centers for Medicare & Medicaid Services, Interoperability Framework, <https://www.cms.gov/initiatives/health-technology-ecosystem/overview/interoperability-framework>; see also National Institute of Standards and Technology, Digital Identity Guidelines, Special Publication 800-63.

⁶ National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, § 12(d), 110 Stat. 775 (1996) (15 U.S.C. § 272 note); Office of Management and Budget, Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities (revised Jan. 27, 2016).

- **Publish a predictable adoption schedule.** States plan MES investments through Advance Planning Documents (APDs) that span several years, and vendors plan product releases on similar horizons. CHI recommends that CMS adopt new versions on a published cycle, for example once a year, with enough lead time before any version becomes required to fit state procurement and APD timelines.
- **Allow early adoption of newer versions.** The Standards Version Advancement Process in the ONC Health IT Certification Program allows developers of certified health IT to use newer versions of adopted standards that ONC has approved, without waiting for rulemaking.⁷ CHI recommends that CMS use a similar mechanism for MES, so that a state or vendor ready to move to a newer version can do so without falling out of compliance, and so that CMS approves each version once for all states rather than state by state.
- **Set retirement dates for superseded versions.** Technical debt builds up when older versions stay in use indefinitely alongside newer ones. CHI recommends that each approved version carry a planned retirement date, set with input from states and vendors, and that Streamlined Modular Certification recognize any version that is current when an implementation began, so that a state is not penalized for a version change that occurs during a long implementation.

V. Harmonizing MES Standards With HHS Interoperability Rules (SE-3)

SE-3 asks how CMS should harmonize its MES-specific standards with broader HHS and ONC interoperability rules, and much of the foundation for that harmonization is already in place. CMS's regulations already condition enhanced federal funding for MES on a state's alignment with, and incorporation of, standards and implementation specifications adopted by ONC.⁸ State Medicaid and CHIP fee-for-service programs are impacted payers under the CMS Interoperability and Prior Authorization final rule, which requires them to implement FHIR-based Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization APIs, with most API requirements taking effect on January 1, 2027.⁹ CMS has also proposed to extend the prior authorization requirements to drugs and to adopt FHIR standards for prior authorization transactions under the Health Insurance Portability and Accountability Act (HIPAA).¹⁰ CHI recommends that the MES program build on this foundation in the following ways.

- **Use the HHS standards as the baseline.** CHI recommends that the MES standards incorporate by reference the standards and implementation guides HHS has already adopted, including the version of the United States Core Data for Interoperability (USCDI) and the US Core and SMART App Launch implementation guides adopted in the ONC certification program, the implementation guides named in the Interoperability and Prior

⁷ Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology, Standards Version Advancement Process, <https://healthit.gov/certification-health-it/certification-criteria/standards-version-advancement-process-svap/>.

⁸ 42 C.F.R. § 433.112(b)(12); see also 42 C.F.R. § 433.112(b)(10), (13), (16) (modularity and open interfaces, reuse among states, and interoperability with health information exchanges, public health agencies, and human services programs).

⁹ Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes, 89 Fed. Reg. 8758 (Feb. 8, 2024) (CMS-0057-F).

¹⁰ Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs, 91 Fed. Reg. 19890 (Apr. 14, 2026) (CMS-0062-P; RIN 0938-AV44).

Authorization rules, and the HIPAA transaction standards. Where CMS needs a Medicaid-specific requirement, it should take the form of a profile or extension built on those standards rather than a separate specification.

- **Keep versions synchronized across programs.** A state Medicaid agency, a Medicaid managed care plan, and a Medicare Advantage organization often exchange data with the same providers through the same vendors. If the MES program requires a different version of a standard than the Interoperability and Prior Authorization rules or the ONC certification program, vendors will have to support both, and the cost will reach states through their vendor contracts. CHI recommends that CMS adopt the same version of a shared standard across these programs and change versions on the same schedule.
- **Align with the CMS Interoperability Framework and the National Provider Directory.** The CMS Interoperability Framework expects participating networks to use FHIR APIs that conform to US Core and USCDI version 3 and to publish their participants and endpoints in the CMS National Provider Directory.¹¹ CHI recommends that the MES standards use the same conventions, and that CMS consider how state provider directories can draw on and contribute to the national directory rather than duplicate it.
- **Coordinate through one published HHS process.** CHI recommends that CMS and the Assistant Secretary for Technology Policy and ONC (ASTP/ONC) coordinate MES standards through a standing, published process, so that states, vendors, and SDOs can see when a change in one program will affect another and can comment on both at the same time.

VI. Pitfalls to Avoid in Large-Scale Standardization (SE-4)

SE-4 asks what pitfalls CMS should avoid based on experience with other large-scale standardization efforts. CHI's members implement standards for Medicare, commercial payers, and many state Medicaid programs, and the RFI's own questions point to several of the problems they encounter most often.

- **National standards that states then modify through companion guides.** The HIPAA transaction standards were meant to give every payer a single format, but CMS's questions about state-specific 834 variants (V-11) and state-specific plan codes (SA-13) show how much variation has returned through companion guides and local code sets. CHI recommends that CMS limit state-specific variation to documented differences in state policy, require any state extension to be published in a central location and to conform to the base standard, and review periodically whether each variation is still needed.
- **Requiring standards before they are ready.** A standard that has not been tested in production can impose costs on every state and vendor at once when defects appear. CHI recommends that CMS require only standards that have reached a stable, balloted release and have been demonstrated in production by more than one implementer, and that it use pilots, connectathons, and voluntary early adoption for standards that are still maturing.
- **Certification that measures documentation rather than outcomes.** The RFI notes that reviews of APDs and certification packages have surfaced recurring technical deficiencies. CHI recommends that compliance checkpoints rely wherever possible on automated conformance testing against published test suites, such as the Inferno testing tools

¹¹ Centers for Medicare & Medicaid Services, Interoperability Framework, <https://www.cms.gov/initiatives/health-technology-ecosystem/overview/interoperability-framework>.

ASTP/ONC already maintains for FHIR APIs, because narrative documentation adds cost for states and vendors without showing whether a system exchanges data correctly.

- **Requirements that shut out smaller vendors.** Modular procurement was meant to widen the range of vendors that states can use, but certification, security authorization, and state-by-state variation all impose fixed costs that fall hardest on smaller companies. CHI recommends that CMS consider what each new requirement will cost a small vendor to meet, and that it favor requirements a vendor can satisfy once and reuse across states, such as a single conformance test result, over requirements that each state must assess separately.
- **Adding new mandates to limited state capacity.** States are implementing the Interoperability and Prior Authorization APIs and other federal requirements on overlapping timelines.¹² CHI recommends that CMS sequence the MES standards with those deadlines and count the work states have already done to meet them toward compliance with the MES program.

VII. Consent Management and Data Segmentation (SE-7)

SE-7 asks which emerging standards for patient consent management and data segmentation CMS should prioritize as data sharing grows through FHIR and other APIs. HHS revised the 42 CFR Part 2 regulations in 2024 to align them more closely with HIPAA, including by permitting a single patient consent for future uses and disclosures for treatment, payment, and health care operations, with compliance required by February 16, 2026.¹³ Because Medicaid covers a large share of people receiving substance use disorder treatment, Medicaid programs are among the organizations most affected, and wider data sharing through APIs should come with privacy and security safeguards and granular data segmentation,¹⁴ and CHI recommends the following for the MES program.

- **Prioritize FHIR-based consent and security labeling standards.** CHI recommends that CMS prioritize the FHIR Consent resource for recording and exchanging patient consent, and HL7's FHIR Data Segmentation for Privacy implementation guide, which uses security labels to identify sensitive data and the handling it requires.¹⁵ Because these standards are developed through HL7's consensus process, a state that adopts them can exchange consent and sensitivity information with providers, health information exchanges, and managed care plans without negotiating a separate format with each.
- **Match segmentation requirements to the legal framework.** The revised Part 2 rule provides that a Part 2 program, covered entity, or business associate that receives records under a single consent for treatment, payment, and health care operations is not required

¹² Medicaid and CHIP Payment and Access Commission, State Medicaid Enterprise Systems, Issue Brief (July 2026).

¹³ Confidentiality of Substance Use Disorder (SUD) Patient Records, 89 Fed. Reg. 12472 (Feb. 16, 2024).

¹⁴ Comments of the Connected Health Initiative, Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity [RIN 0955-AA09; 90 FR 60970] (Feb. 27, 2026), <https://connectedhi.com/wp-content/uploads/2026/03/CHI-Comments-re-HTI-5-Proposed-Rule-27-Feb-2026.pdf>.

¹⁵ HL7 International, FHIR Data Segmentation for Privacy Implementation Guide, <https://hl7.org/fhir/uv/security-label-ds4p/>; HL7 International, FHIR Consent Resource, <https://hl7.org/fhir/R4/consent.html>.

to segregate or segment those records.¹⁶ CHI recommends that the MES standards support segmentation where federal or state law or a patient's request requires it, without requiring states and vendors to segment data where the law does not, which would add cost and could slow care coordination.

- **Express state privacy rules as data rather than custom code.** State privacy laws for sensitive conditions differ, and CHI recommends that CMS encourage states to express those differences as machine-readable policies and labels applied to standard data rather than as custom system logic, so that a vendor can support many states' rules with a single product.

VIII. Data Standardization Prerequisites for AI (V-9)

Question V-9 is directed to vendors, and CHI responds only to its second part, which asks what data standardization prerequisites are needed for AI to be used effectively, safely, and ethically for Medicaid populations. State Medicaid programs are beginning to use AI in eligibility, claims processing, and prior authorization, and our members develop AI tools for care management and clinical decision support that draw on Medicaid data. CHI's Policy Principles for Artificial Intelligence in Health and its Health AI Roles and Interdependency Framework, which maps responsibilities across the AI value chain to the NIST AI Risk Management Framework,¹⁷ inform the following recommendations.

- **Standardize the data elements AI tools rely on.** An AI tool trained or evaluated on data from one state can perform differently in another if the same data element is defined, coded, or populated differently. Resolving the inconsistencies CMS asks about in SA-11 is therefore also a precondition for reliable AI, and CHI recommends that CMS give priority to consistent definitions for the data elements used most often in eligibility, utilization, and care management, drawing on USCDI and the Transformed Medicaid Statistical Information System (T-MSIS) where they apply.
- **Preserve data provenance.** Organizations deploying AI tools need to know where data came from, when it was recorded, and how it was transformed in order to judge whether a tool's output can be relied on. CHI recommends that the MES standards call for provenance information to travel with data exchanged through MES APIs, using the FHIR Provenance resource and related standards.
- **Support documentation that lets states evaluate tools.** States and managed care plans need information about how an AI tool was developed, what data it was trained and tested on, and how it performs across the populations Medicaid serves. CHI recommends that CMS encourage documentation scaled to the risk of the use, consistent with the NIST AI Risk Management Framework, rather than a single uniform disclosure for every tool.
- **Keep adverse coverage determinations with qualified reviewers.** Where AI tools support eligibility, prior authorization, or other coverage functions, CHI recommends that an adverse determination continue to rest with a qualified human reviewer who can consider the individual's circumstances, and that the data standards support that review by making the inputs behind a tool's recommendation available to the reviewer.

¹⁶ 42 C.F.R. § 2.12(d)(2)(i)(C).

¹⁷ National Institute of Standards and Technology, Artificial Intelligence Risk Management Framework (AI RMF 1.0), NIST AI 100-1 (Jan. 2023).

IX. Conclusion

CHI appreciates CMS's decision to begin the MES IT Standards initiative by asking states, vendors, and other stakeholders what is working and what is not, and we support the program's goals of reducing fragmentation, preventing vendor lock-in, and helping states adopt modern, standards-based systems. CMS can reach those goals most effectively by building on the standards HHS has already adopted, relying on voluntary consensus standards and a predictable version cycle, and limiting state-specific variation to what state policy requires. Doing so would lower costs for states, open the Medicaid market to a wider range of technology companies, including smaller ones, and give Medicaid beneficiaries and their clinicians access to the same connected health tools available in other programs.

We look forward to working further with CMS, states, and other stakeholders as the program moves into its next phases, and we would welcome the opportunity to discuss any of these recommendations in greater detail.

Sincerely,



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