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To: Honorable Tom Keane. Assistant Secretary for Technology Policy and National Coordinator for Health IT, U.S. Department of Health and Human Services
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Dear Dr. Tom Kean,

The Massachusetts Health Data Consortium (MHDC) appreciates the opportunity to comment on the Health Data, Technology, and Interoperability: *ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5) Proposed Rule.* We hope our insights and perspectives are useful as the Assistant Secretary for Technology Policy and National Coordinator for Health Information Technology advances its commitment to modernizing the Health Information Technology (IT) Certification Program to reduce low-value regulatory burden and advance Application Programming Interface (API)-forward interoperability.

MHDC strongly supports ASTP/ONC's vision of modernizing the Health IT Certification Program to reduce low-value regulatory burden and advance API-forward interoperability. Moreover, MHDC aims to help ASTP/ONC realize its goals of clarifying and strengthening information-blocking policy, so that access to electronic health information works not just in principle, but in on-the-ground practice.

Indeed, as interoperability continues to evolve from document-centric exchange toward API-forward workflows, the central challenge is no longer technical feasibility, but operational reliability at scale. MHDC therefore believes the success of HTI-5 will hinge on whether the final rule will provide sufficient clarity and continuity to enable predictable, secure, and reusable integration across the ecosystem as certification requirements are modernized.

For more than four decades, MHDC has served as a trusted, neutral convener that advances health information exchange, interoperability, and administrative simplification across Massachusetts and nationally. As a result of our merger with the New England Healthcare Exchange Network, MHDC now supports secure data exchange and automation for over 4,000 health professionals across more than 200 organizations.

Our recommendations draw on MHDC's long history of successfully engaging payers, providers, vendors, and exchanges in real-world exchange environments. Most importantly, all our comments are intended to support ASTP/ONC's objectives by highlighting practical considerations to strengthen the operational reality of interoperability.

**General Comments and Key Recommendations**

Based on MHDC's extensive experience, collaborations, and a careful examination of implementations and outcomes, we have concluded that burden reduction will succeed only if it decreases total friction across the ecosystem – not if it shifts cost, risk, or bespoke integration work onto providers, payers, exchanges, and implementers.

To ensure that well-intentioned deregulation succeeds in strengthening the operational reality of interoperability, MHDC therefore recommends that the HTI-5 final rule should:

- **Prevent burden shifting** by pairing removed or revised regulations with clear crosswalks, responsibility assignment, and post-final-rule evaluation;
- **Preserve an interoperability floor** during the transition to APIs, so that baseline exchange remains predictable and reusable;
- **Maintain trust through minimum, testable security expectations** to avoid gaps as legacy criteria are removed; and
- **Provide an executable implementation roadmap** with timelines and "removed → replaced by" crosswalks to reduce uncertainty, renegotiation, and rework.

MHDC also urges ASTP/ONC to address the operational barriers that most directly impede scalable exchange in practice, particularly for payer-provider workflows such as prior authorization and quality exchange. MHDC therefore recommends that the final rule should:

- **Prevent "pay-to-play" access to electronic health information (EHI)** by establishing enforceable guardrails on fees and licensing terms, with clear examples of prohibited practices and clarified enforcement expectations;
- **Make information-blocking updates administrable** with practical examples, checklists, and workable documentation expectations that discourage strategic delay and procedural blocking; and
- **Preserve multi-path exchange and choice** by ensuring that the Trusted Exchange Framework and Common Agreement (TEFCA) is effective where it fits, without becoming a ceiling that slows adoption of technically superior API-based exchange for high-volume workflows.

**Burden Reduction**

MHDC urges ASTP/ONC to ensure that deregulatory actions do not shift burdens downstream, weaken trust, or undermine the predictability and scalability of the interoperability efforts stakeholders already rely upon. To ensure burden reduction across the ecosystem, MHDC recommends that ASTP/ONC:

- Clearly state that Health IT developers now bear responsibility for any displaced capability or safeguard.
- Establish a post-final-rule evaluation approach (e.g., adoption, cost, interoperability outcomes) to confirm that burden truly decreases rather than shifting downstream to providers and health plans.

MHDC fervently favors deregulation where it removes outdated or low-value requirements but cautions against changes that:

- Disrupt progress already made in standards-based interoperability.
- Shift developers' operational burden to providers, payers, and exchanges.
- Undermine trust by weakening baseline security expectations.
- Create uncertainty as the industry begins to operationalize APIs at scale.

In practice, burden shifts tend to show up as:

- Custom or one-off interfaces/integration work developed at the customer's expense.
- Contracting delays and prolonged negotiations stalling progress for data exchange.
- Variable conformance and inconsistent vendor behavior.

- Additional onboarding testing and re-testing with providers and vendor customers.
- Manual workaround workflows to compensate for missing capabilities.

The context for MHDC's comments is that interoperability is still in an early operational phase for many organizations, particularly payer-provider exchange using newer standards and technologies. So regulatory resets should strive to foster stability as well as promote progress during this transitional period.

**Interoperability and API-Forward Exchange**

The use of Fast Healthcare Interoperability Resource (FHIR) APIs allows for real-time data exchange of the right data at the right time with authorized stakeholders. MHDC supports a "FHIR-first" approach and the prioritization of open, non-proprietary APIs as the foundation for future interoperability. MHDC also favors modernizing certification toward API-based exchange rather than document-centric approaches.

At the same time, MHDC cautions that removing too many core requirements without clear replacements risks fragmentation. Historically, certification has provided a minimum interoperability floor that reduces bespoke integrations and inconsistent vendor behaviors, so interoperability is not optional by design and does not depend on one-off commercial arrangements. MHDC therefore recommends that ASTP/ONC:

- Clearly define the minimum "interoperability floor" that all certified products must continue to support following proposed removals and consolidations.
- Clarify how removed certification criteria will be replaced by API-forward requirements over time.
- Offer transition guidance, so organizations can confidently plan investments.

Consistent baseline behavior is especially valuable for such MHDC-facilitated use cases as: care coordination and referrals; patient access and consumer-facing workflows; payer-provider exchange for prior authorization and quality reporting; and public-interest reporting and other trusted exchange functions.

MHDC also urges ASTP/ONC to discourage models that require network-by-network or connection-by-connection API arrangements. Interoperability at scale depends on predictable, reusable integration patterns over bilateral connections.

**Preventing Pay-to-Play Access to EHI**

MHDC's members experience real-world interoperability challenges when access to EHI is available in principle but is priced or contractually structured in ways that prevent scalable use, particularly for payer-provider workflows like prior authorization and quality reporting.

MHDC favors clarifying information-blocking provisions but cautions that agreements used to fulfill access, exchange, or use requests – including manner-requested agreements – must not become mechanisms for excessive or discriminatory pricing. MHDC therefore recommends that ASTP/ONC:

- Adopt enforceable guardrails for fees and licensing terms used to fulfill access, exchange, or use requests, including by applying existing fee and licensing constraints to manner-requested agreements (or otherwise ensuring the final standard is equally enforceable).
- Provide examples of prohibited or suspect practices (e.g., value-based, per-member, or per-transaction tolls for prior authorization with APIs, revenue sharing unrelated to cost recovery, forced bundling, take-it-or-leave-it terms that aren't objectively justified).
- Clarify enforcement expectations, so requestors and vendors understand where acceptable cost recovery ends, and information blocking begins.

MHDC also encourages ASTP/ONC to consider providing anonymized examples of pricing structures and contract terms encountered in the field, along with the concrete impacts of these practices (e.g., delayed integrations, increased administrative time, longer prior authorization turnaround, inability to scale quality exchange).

**Security of Health Information and Trust**

MHDC supports embedding modern security into API-based exchange. We are concerned, however, that removing or restructuring privacy and security certification criteria without clearly defined replacement baselines may weaken trust. MHDC therefore recommends that ASTP/ONC:

- Specify minimum security expectations for API-based exchange (e.g., for authentication, authorization, audit logging, incident response touchpoints).
- Provide a transition plan to avoid a security gap between removed legacy criteria and fully defined API-forward security requirements.
- Retain targeted, audit-related capabilities until replacement requirements are more mature and testable.
- Ensure alignment with HIPAA privacy and security requirements, as many actors are still required to adhere to by law.

Inconsistent vendor security expectations frequently lead to delays and require security reviews, special contract language, or additional security addenda during onboarding - adding cost and slowing implementation.

**Certification Program Changes and Decision-Support Interventions (DSI)**

MHDC supports reducing low-value certification burden, while retaining guardrails for DSI and security-related requirements. MHDC also supports transparency and governance expectations for artificial intelligence (AI)-enabled DSIs and cautions against eliminating transparency mechanisms without clear replacement approaches. MHDC therefore stresses the need for:

- Clear governance expectations.
- Testing scenarios appropriate to ensure the risk of appropriate interventions.
- Guardrails to prevent DSIs and AI from interfering with EHI access for patient care.

**Information Blocking: Administrability and Operational Reality**

MHDC favors clarifying information-blocking definitions and exceptions, so that the rules are administrable, enforceable, and aligned with real-world operations – particularly for automated access and API-based exchange. MHDC therefore recommends that ASTP/ONC:

- Provide practical examples and checklists for invoking key exceptions, especially infeasibility and manner-requested-related scenarios.
- Set clear and workable documentation expectations for demonstrating good-faith compliance, without creating undue administrative overhead.
- Ensure that the final rule discourages strategic delay tactics and procedural blocking (e.g., protracted negotiations, moving targets, shifting requirements).

Operational guidance, with clear examples illustrating common implementation failure modes – and how the final rule would resolve them – would meaningfully improve predictability for all parties.

**Trusted Exchange Network and Common Agreement (TEFCA)**

MHDC views TEFCA as a valuable pathway for many use cases and favors a multi-path approach to interoperability. Policy should encourage exchange through the most-appropriate pathway for each use case

– i.e., TEFCA, APIs, or other mechanisms where they fit – without creating unintended "single-network ceiling" dynamics. MHDC therefore recommends that ASTP/ONC:

- Clarify practical expectations for entities participating in TEFCA, while also enabling API-based exchange.
- Ensure that final policy does not inadvertently treat TEFCA as a ceiling that may slow adoption of technically superior manner-requesters of exchange.
- Ensure that policy does not discourage the use of technically superior or operationally appropriate exchange mechanisms.

For payer-provider workflows, MHDC encourages ASTP/ONC to distinguish where TEFCA is helpful (e.g., broad query-based exchange) versus where direct API exchange is operationally superior (e.g., high-volume prior authorization and quality exchange).

**Conditions and Maintenance of Certification: Keep the Signal, Cut the Noise**

MHDC favors reducing reporting requirements that have not produced commensurate value, while preserving a small set of meaningful interoperability signals. Narrow reporting can be acceptable if it focuses on real API use, reliability, and usability – not check-the-box activity.

Examples of meaningful interoperability signals include API uptime and availability; latency and response-time performance; adoption rates and active use (e.g., active apps/clients); successful transactions versus error rates; onboarding timelines from request to production exchange. MHDC therefore recommends that ASTP/ONC:

- Define reporting measures with sufficient specificity to enable comparability.
- Publish guidance on how reporting will be interpreted/used to improve outcomes.
- Confirm that less reporting does not reduce accountability for poor interoperability.

**Implementation and Timing**

MHDC urges ASTP/ONC to publish a consolidated, executable implementation of a roadmap. Clear crosswalks and timelines are needed to reduce stakeholder uncertainty, renegotiation, and re-scoping (i.e., the opposite of burden reduction). Clear implementation guidance also materially reduces cost by enabling budgeting, contracting, product roadmaps, and compliance planning to proceed without repeated rework. The roadmap should include:

- A consolidated implementation timeline with milestone dates and a clear description of what changes at each deadline date.
- A crosswalk showing what was removed or revised, what replaces it (if anything), and the policy objective each requirement previously served.
- Clarity on who bears responsibility for any displaced capability or safeguard.
- Worked examples for high-impact use cases (e.g., patient access, payer-provider exchange, prior authorization, quality exchange).
- A post-final-rule evaluation plan (e.g., adoption, cost, interoperability outcomes) to verify that total ecosystem burden decreases.

**Conclusion**

MHDC is grateful for ASTP/ONC's leadership in modernizing health IT policy and reducing low-value regulatory burden. We urge ASTP/ONC to ensure that HTI-5 strengthens the operational reality of interoperability by preserving trust, preventing burden shifting, discouraging pay- to-play EHI access, and providing a clear, executable transition roadmap and input for HTI-6, as appropriate.

Respectfully submitted,

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