

ConnectedHealthInitiative

April 24, 2026

Omeed A. Assefi
Acting Assistant Attorney General
Antitrust Division
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530

Andrew N. Ferguson
Chairman
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Re: Comments of the Connected Health Initiative on the Joint Public Inquiry Regarding Potential Additional Guidance on Collaborations Among Competitors (Docket No. ATR-2026-0001)

Dear Acting Assistant Attorney General Assefi and Chairman Ferguson:

The Connected Health Initiative (CHI, www.connectedhi.org) appreciates the opportunity to respond to the February 23, 2026 joint public inquiry from the Department of Justice (DOJ) Antitrust Division and Federal Trade Commission (FTC) regarding potential additional guidance on collaborations among competitors.¹ CHI supports the Agencies' effort to provide clear and predictable guidance in the wake of the December 2024 withdrawal of the 2000 Antitrust Guidelines for Collaborations Among Competitors (2000 Collaboration Guidelines). The healthcare ecosystem depends on lawful, procompetitive collaborations to develop, validate, and scale the digital health technologies that advance the Quadruple Aim (improving patient outcomes, reducing costs, augmenting population health management, and improving the healthcare workforce experience). Clear guidance from the Agencies reduces compliance costs, encourages procompetitive joint conduct, and benefits American patients, providers, and innovators.

I. Statement of Interest and Summary

CHI is the leading multistakeholder policy and legal advocacy coalition focused on responsible deployment of connected health technologies. CHI's membership spans the full digital health continuum, including developers of digital health management applications, connected devices, remote patient monitoring solutions, AI-enabled clinical decision support tools, telehealth platforms, and health IT infrastructure; along with clinicians, patient advocates, research institutions, and provider organizations. The free, secure flow of health information and a competitive marketplace for health technology are central to achieving improved outcomes for all patients.

¹ <https://www.regulations.gov/document/ATR-2026-0001-0001>.

CHI and its members take antitrust compliance seriously. Notably, CHI maintains an ‘Antitrust Dos and Don’ts’ Checklist on its site that guide our activities and that all participants in CHI activities are expected to follow.²

In response to the Agencies’ request for information, CHI offers the following high-level recommendations:

- The Agencies should issue new guidance built on the foundation of the 2000 Collaboration Guidelines. That document’s rule-of-reason architecture, treatment of efficiencies, recognition of integrated joint ventures, and safety zones provided meaningful predictability for connected health innovators and should be carried forward.
- The Agencies should maintain the original scope of the Collaboration Guidelines and should not extend the new guidance to standard setting, voluntary consensus standards development, or intellectual property (IP) licensing. Those topics already have a longstanding and well-developed vehicle in the Antitrust Guidelines for the Licensing of Intellectual Property, and folding them into horizontal collaboration guidance would create overlap, confusion, and uncertainty that disserve the Agencies’ stated goal of providing transparency and predictability.
- Updated guidance would meaningfully benefit the connected health community in three areas the inquiry specifically identifies: (i) information and data sharing among competitors, (ii) algorithmic pricing and the use of common third-party pricing or analytics tools, and (iii) collaborations involving artificial intelligence (AI) development, evaluation, and deployment. In each of these areas, guidance should preserve broad room for procompetitive collaboration that digital health developers of any size can rely on, while addressing the documented categories of conduct that anticompetitively suppress competition in healthcare markets.

II. The Agencies Should Preserve the Original Scope of the Collaboration Guidelines

The 2000 Collaboration Guidelines were, by design, a set of high-level, generally applicable analytical principles which expressly disclaimed coverage of standard setting and did not purport to address IP licensing as such. That architecture allowed the Agencies to articulate cross-cutting analytical principles, distinguishing per se from rule-of-reason treatment, recognizing efficiencies, addressing the integration of competitively significant activity, and providing safety zones, without becoming entangled in the industry- and agreement-specific complexities of standards development or IP licensing.

CHI strongly supports preserving that scope in any updated guidance because the Agencies already maintain a well-developed and long-standing vehicle for addressing competition issues in IP licensing in the Antitrust Guidelines for the Licensing of Intellectual Property. Those guidelines, and the substantial body of related agency materials, have served the business and legal communities for decades. Bringing IP licensing and voluntary consensus standard setting into horizontal collaboration guidance would overlap with existing vehicles that more appropriately address those topics, create competing analytical frameworks for the same conduct, and undermine the predictability the Agencies are seeking to restore. Further, the foundations of antitrust analysis of IP licensing have not materially changed in ways that warrant repackaging that body of law inside a horizontal collaboration document. To the extent the Agencies see a need to

² <https://connectedhi.com/wp-content/uploads/2024/07/2024-07-19-CHI-Antitrust-Checklist-FINAL.pdf>.

refresh aspects of the IP licensing guidelines, the appropriate vehicle is an update to those guidelines, not the document that addresses cross-sector collaborations among competitors.

CHI also notes that standards development is a unique form of collaborative activity that is best addressed, where appropriate, through dedicated guidance and case law rather than as a subtopic within a horizontal collaboration document. Voluntary consensus standards organizations operate under their own well-established procedural safeguards, and the legal frameworks governing standards-related conduct have evolved through extensive judicial and agency engagement. Folding standards-related topics into the Collaboration Guidelines would risk creating ambiguity about how those existing frameworks continue to apply and could deter beneficial standards participation by small and mid-sized digital health developers.

CHI therefore urges the Agencies to maintain the original scope of the Collaboration Guidelines to best serve the Agencies' stated goals of providing transparency, predictability, and confidence to businesses across the economy, including the connected health sector.

III. Information and Data Sharing Among Competitors

Information and data sharing among competitors is one of the most important and most misunderstood topics in modern competition policy, and an area where updated guidance would provide substantial value to the connected health ecosystem. The connected health sector depends on robust, lawful data sharing to deliver better outcomes – between providers and developers, between developers and payers, across research consortia, through real-world evidence networks, and through patient-mediated channels. At the same time, certain categories of information sharing among competitors have well-recognized potential to facilitate coordination on price or output.

A. Guidance Should Recognize the Procompetitive Nature of Most Healthcare Data Sharing

Updated guidance should make clear that the vast majority of data sharing relevant to connected health is procompetitive and, in many instances, indispensable to the delivery of safe and effective care. CHI urges the Agencies to recognize, in particular:

- Interoperable health data exchange among providers, payers, and authorized third parties, including through FHIR-based application programming interfaces (APIs), is procompetitive. Such exchange enables innovation, lowers entry barriers for smaller developers, and supports patient access to care. Existing federal policy, consistent with the 21st Century Cures Act and its implementing regulations, affirmatively encourages such exchange.
- Real-world evidence and post-market surveillance collaborations, including pooled clinical data, registries, and outcomes research consortia, improve patient safety, support reimbursement determinations, and enable the validation of digital health and AI tools. These collaborations are particularly important for smaller developers that cannot independently assemble large enough datasets to demonstrate clinical utility.

Guidance that treats these forms of collaboration with appropriate clarity will reduce the in terrorem effect that ambiguous antitrust risk currently has on smaller digital health developers, who often lack the resources to absorb the legal costs of uncertainty.

B. Guidance Should Address Documented Categories of Anticompetitive Information Sharing in Healthcare

At the same time, CHI recognizes that certain information-sharing arrangements among competitors raise legitimate competition concerns. CHI is particularly attentive to dominant health technology or data-holding actors practice of selectively withholding, conditioning, or imposing excessive access terms in ways that disadvantage smaller competitors, which is a pattern documented in the information blocking context and the subject of CHI’s sustained advocacy.

Guidance addressing information sharing should distinguish clearly between the broad space of procompetitive data exchange that connected health depends on, and the narrower set of arrangements, often centered on prospective or current pricing or output information shared through a common channel, that warrant heightened scrutiny.

IV. Collaborations Involving Artificial Intelligence

Among the “new technologies and business models” the inquiry identifies, AI is perhaps the most important for the connected health sector. AI-enabled tools are already in widespread use across the digital health continuum, from clinical decision support to ambient documentation, from imaging interpretation to risk stratification, from operational analytics to patient-facing engagement. The development, validation, and responsible deployment of these tools frequently depends on collaboration among multiple firms that may otherwise compete in adjacent product markets.

Guidance should expressly recognize the procompetitive value of several common categories of AI-related collaboration in healthcare:

- Pooled or federated training data arrangements, including consortium-based approaches to assembling sufficiently large and diverse training datasets to support safe and effective health AI tools—particularly for less common conditions or underrepresented populations where no single firm has adequate data.
- Joint evaluation, benchmarking, and post-market surveillance consortia that allow developers, providers, and researchers to assess AI tool performance against common reference datasets or in common real-world conditions.
- Multi-stakeholder efforts to develop common transparency formats, risk-assessment frameworks, and governance practices for AI in clinical care, including alignment with the NIST AI Risk Management Framework and analogous voluntary frameworks.
- Joint pre-competitive research on foundational AI techniques, model architectures, safety mitigations, and evaluation methodologies.

Each of these collaboration types has direct counterparts in pharmaceutical and medical device development, where the Agencies have long recognized the procompetitive nature of collaborative research and development, particularly where commercialization remains separate.

V. Labor Collaborations

CHI recognizes that the healthcare workforce shortage makes legitimate collaborative responses (joint training programs, shared credentialing infrastructure, multi-employer fellowships, and similar workforce development collaborations) increasingly important to maintaining and expanding patient access to care. Guidance should make clear that workforce development collaborations of this kind are generally procompetitive.

VI. Analytical Tools That Should Be Preserved and Updated

In addition to the topic-specific recommendations above, CHI urges the Agencies to preserve and modernize several analytical tools from the 2000 Collaboration Guidelines that worked well for smaller market participants in the connected health sector:

- *Avoid structural shortcuts and speculative harm theories.* ACT has consistently emphasized that competition enforcement should be grounded in rigorous economic analysis. Market structure can be relevant, but it should not substitute for evidence of likely competitive harm. Market definition and concentration measures are tools to assess competitive effects, not ends in themselves, and the guidance should not treat such structural indicators as de facto conclusions. The fact that participants have some market presence, share a business relationship, or operate in adjacent parts of a technology ecosystem does not by itself establish competitive harm. Nor should the fact that firms are potential competitors in a broad or speculative sense make a collaboration suspect. In fast-moving technology markets, static market share snapshots may provide an incomplete picture of competitive dynamics. Entry, product differentiation, multi-homing, switching, innovation cycles, open-source alternatives, and global competition can all affect whether a collaboration is likely to harm or strengthen competition. Updated guidance should therefore avoid bright-line assumptions that discourage collaboration based on structure alone. The Agencies should focus on concrete evidence, market context, and likely effects on consumers, innovation, quality, output, and price.
- *Safety zones.* The 2000 Guidelines' safety zones provided meaningful certainty to smaller participants in research and development collaborations and other joint conduct. Updated safety zones, calibrated to modern market realities, would meaningfully reduce compliance costs for the small and mid-sized digital health developers that comprise the bulk of CHI's membership.
- *Recognition of efficiencies.* Updated guidance should preserve the 2000 Guidelines' substantive engagement with the role of efficiencies in rule-of-reason analysis, recognizing that many connected health collaborations generate efficiencies—lower development costs, faster validation, expanded access—that are not achievable by any single firm acting alone.
- *Distinction between per se and rule-of-reason treatment.* The 2000 Guidelines' clear articulation of when conduct warrants per se treatment versus rule-of-reason analysis remains the right analytical framework. CHI urges the Agencies to maintain that clarity in updated guidance.
- *Concrete illustrative examples.* The 2000 Guidelines' illustrative examples were one of the most useful features of that document for practitioners and small businesses. CHI strongly encourages the Agencies to include updated illustrative examples in any revised guidance, drawing on the modern business models the inquiry identifies.

VII. Conclusion

CHI appreciates the Agencies' effort to restore clear, predictable analytical guidance on collaborations among competitors. CHI and its members welcome the opportunity to meet with the Agencies to discuss these recommendations further.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Scarpelli", written in a cursive style.

Brian Scarpelli
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