

ConnectedHealthInitiative

May 26, 2026

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

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

Re: Comments of the Connected Health Initiative on the Federal Trade Commission and Department of Justice Antitrust Division Request for Public Comment Regarding Making Improvements to the Premerger Notification and Report Form

Dear Chairman Ferguson and Acting Assistant Attorney General Assefi:

The Connected Health Initiative (CHI) respectfully submits the following comments in response to the Federal Trade Commission (FTC) and the Department of Justice (DOJ) Antitrust Division Request for Public Comment Regarding Making Improvements to the Premerger Notification and Report Form.

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs. CHI represents a wide range of stakeholders in digital health, from large and small industry to research universities to payors to patient groups, all of whom come together to advocate for policies that support digital health innovation, access, and affordability. CHI members develop and use connected health technologies across a wide range of use cases, and advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies, where we seek to promote responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial intelligence (AI) in care delivery.

CHI appreciates the Agencies' stocktaking approach to the Hart-Scott-Rodino (HSR) premerger notification process and the Agencies' stated objective of ensuring "that the requirements of the Updated Form do not impose burdens on filers that outweigh the usefulness of the information provided to the Agencies." The connected health sector depends on the availability of investment, partnership, and acquisition pathways to bring digital health products and services to patients and clinicians. The design of the HSR Form, and in particular the scope, granularity, and conditions under which information must be produced, directly affects the cost of capital, the viability of transactions, and ultimately the pace at which patients gain access to digital health innovations.

I. CHI's Guiding Principles for HSR Form Improvements

CHI builds on its positions on premerger review and merger policy previously filed with the Agencies,¹ and offers several principles we believe should inform the Agencies' evaluation of the Updated Form:

- **Acquisitions are frequently pro-competitive.** The vast majority of transactions in digital health are pro-competitive and advance the Quadruple Aim (improving outcomes, reducing costs, augmenting population health management, and supporting the healthcare workforce). The incentive to turn a profit alone should not be held against healthcare organizations when financial transactions are so often required to facilitate growth. In many instances, external investment and related transactions allow for the expansion of services and reallocation of resources to meet the needs and demands of patients and providers – all with the intent of creating a better experience.
- **The Agencies should be cautious about the potential for overbroad regulatory action to discourage pro-competitive and pro-patient transactions in the marketplace.** Often, healthcare businesses are founded with the expectation that they will be acquired after their potential has been sufficiently developed and demonstrated (and for many, this is the only path forward). Such an acquisition can connect founders and entrepreneurs to the scale and resources needed to develop their innovation to its full potential and allow them to move on to develop new businesses equipped with the additional skills and resources from the successful exit. Patients and healthcare workers across the United States have benefited tremendously from the creativity of individuals when combined with the resources and institutional knowledge of businesses that acquire their innovations. A merger that helps produce better products or services for consumers is both a natural and beneficial end for some companies and is healthy from a competition policy perspective.
- **Mergers and acquisitions should be examined individually, considering case-specific variables related to market power and patient needs.** Any changes to U.S. merger policy must retain rigorous economic analysis as a cornerstone of any review or enforcement to provide a transparent and objective method of evaluation in enforcements and allow our communities to predict when their actions will and will not create antitrust enforcement concerns. A premerger reporting form designed around this principle should collect information that is genuinely probative of competitive effects in the specific transaction being reviewed, rather than impose categorical document- and narrative-production obligations whose marginal value to the Agencies' analysis is low and whose marginal cost to filers is high.
- **Under the Federal Trade Commission Act, the Sherman Act, and the Clayton Act, regulators today have the tools they need to address potential anticompetitive behavior in healthcare.** Improvements to the HSR Form should be calibrated to enable the Agencies to use those existing tools more efficiently (in other words, identifying potentially problematic transactions earlier and clearing unproblematic ones faster) and not to expand the universe of information required from filers without a clear, evidence-based showing that such information meaningfully improves competitive analysis.

¹ https://connectedhi.com/wp-content/uploads/2025/01/09.20.2024_CHI-Comments-re-DOJ-FTC-RFI-on-Serial-Acquisitions-.pdf.

With those principles in mind, CHI responds below to the specific questions, and we note that our silence on other questions posed should not be read as endorsement or opposition. As an overarching matter, CHI urges the Agencies to apply a disciplined burden-benefit framework that ensures any future HSR rulemaking retain or add requirements only where the information sought is likely to provide probative value that justifies the incremental cost to filers, and the scope of required information should be proportionate to the transaction's likely competitive risk.

II. The Vacated Updated Form Should Not Serve as the Baseline for Future Rulemaking

At the outset, CHI requests that the analytical baseline for any future rulemaking be the Premerger Notification and Report Form and Instructions in effect prior to the 2025 amendments, and not the Updated Form that took effect on February 10, 2025. On February 12, 2026, the U.S. District Court for the Eastern District of Texas vacated the Updated Form, and on March 19, 2026, the U.S. Court of Appeals for the Fifth Circuit denied the Commission's motion for a stay pending appeal.² As the RFI itself acknowledges, the Agencies are now accepting HSR filings using the pre-2025 Form and Instructions, and the pre-2025 Form should be the operative baseline since using the vacated Updated Form as a presumptive floor would in effect preserve the substance of a rule that has been judicially set aside.

While the Agencies may wish to draw on their experiences with the now-vacated Updated Form where instructive, twelve months of compressed implementation is a thin evidentiary base on which to lock in expanded requirements. CHI requests that the Agencies approach any future rulemaking with a commitment to base proposed requirements on data sufficient to support them.

III. Burdens on Digital Health Filers (RFI Questions 1, 3, 7, and 23)

The Updated Form, as it was implemented between February 2025 and the February 2026 vacatur, imposed materially higher preparation costs than the prior form across nearly every element (narrative descriptions, expanded "regularly prepared" ordinary-course-of-business documents, transaction-rationale documents from a broader set of custodians, expanded prior-acquisitions disclosures, supply-relationship descriptions, and expanded officer and director information, among others). Those costs are borne by digital health filers of all sizes and across all corners of the healthcare ecosystem, and any future rulemaking should retain or add requirements only where the information sought is likely to provide probative value that justifies the incremental cost to filers.

Digital health transactions span a wide range of profiles, from established platforms to growth-stage and earlier-stage companies, and CHI members on both the acquiring and acquired side report that the cost of complying with the Updated Form, both in legal fees and in management time diverted from product development and patient-facing operations, can have a meaningful impact on transaction viability and timing. In the healthcare sector where margins are thin (and getting thinner), the ability to seek investment and be acquired is critical to support healthcare access and offerings.

² See Memorandum Opinion and Order, *Chamber of Commerce v. FTC*, No. 6:25-cv-9, Dkt. 75 (E.D. Tex. Feb. 12, 2026); Order, *Chamber of Commerce v. FTC*, No. 26-40094, Dkt. 44 (5th Cir. Mar. 19, 2026) (denying motion for stay pending appeal).

CHI accordingly urges the Agencies, in any new rulemaking, to incorporate clearly defined materiality thresholds and safe harbors designed to reduce burden for transactions that are unlikely to raise competitive concerns. In response to Question 7, we recommend that the Agencies consider, at a minimum:

- A reduced-information track for transactions below a defined transaction value, that retains the core HSR notice and basic overlap disclosures but does not require the expanded narrative, supply-relationship, prior-acquisition, and ordinary-course document productions added by the vacated Updated Form.
- A reduced-information track for transactions in which neither party derives revenue, or has reasonably forecast revenue within a defined forward period, in a horizontally overlapping product or service market, recognizing that many digital health acquisitions involve complementary rather than overlapping capabilities (e.g., a remote patient monitoring developer acquired by a population-health analytics company).
- A materiality threshold for the production of “regularly prepared” ordinary-course-of-business documents that limits production to documents prepared by or for the principal officer-level decisionmakers actually involved in the transaction, rather than expansive custodian lists drawn from broader corporate hierarchies.
- A materiality threshold for prior-acquisition disclosures that focuses on prior transactions in the same or directly adjacent product or service markets, rather than all prior acquisitions across the filer’s enterprise.

Regarding Question 23, CHI reiterates that overbroad reporting obligations risk discouraging pro-competitive and pro-patient transactions. We therefore urge the Agencies to provide plain-language compliance guidance for the Overlap Description and Supply Relationships Description that filers across the ecosystem can apply consistently.

IV. CHI Input on Various Information Categories

a. Supply Relationships Description (RFI Questions 3(a), 3(b), and 8)

CHI members in the digital health space frequently maintain commercial supply, licensing, and integration relationships with a broad set of counterparties across the healthcare value chain, including electronic health record vendors, cloud-services providers, medical device manufacturers, clinical-decision-support developers, payors, and provider organizations. The Updated Form’s Supply Relationships Description, as implemented, required filers to identify and characterize a wide range of such relationships even where they bear no plausible relationship to the competitive effects of the proposed transaction. Those requirements often sought information that generally is not compiled when evaluating either the acquisition or sale of a company, or the competitive impact of the acquisition or sale of a company, and so fall within the categories the Agencies have identified in Questions 3(a) and 3(b) as candidates for re-examination.

Best practices the Agencies should incorporate for the Overlap Description and Supply Relationships Description (Question 8) include:

- Limiting required descriptions to relationships that are material to the parties’ commercial operations in the most recent fiscal year;
- Permitting filers to use existing internal categorizations of customers, suppliers, and partners rather than building new ones just for the HSR filing;
- Providing safe-harbor language for common digital health relationships (e.g., standards-based interoperability integrations and routine commercial distribution arrangements) that should not, standing alone, trigger expanded supply-relationship disclosure; and
- Clarifying that ordinary-course commercial relationships across the digital health value chain do not, without more, indicate a vertical theory of harm.

b. *Non-Traditional Transaction Structures (RFI Question 13)*

The Agencies indicate in the RFI that they have observed transactions structured as “acqui-hires,” “reverse acqui-hires,” non-exclusive intellectual property licenses, and convertible-security arrangements, and are considering whether the Updated Form and the Commission’s HSR regulations should be modified to capture such structures. CHI recognizes the Agencies’ interest in ensuring that transactions with the practical effect of eliminating a market participant do not escape premerger review through structuring. At the same time, we caution against rules that would sweep in the wide range of legitimate, pro-competitive transactions involving intellectual property licensing, talent mobility, and minority investment that are routine in the digital health sector.

Investments in healthcare services, whether in the form of acquisitions, mergers, or capital infusions, involve both parties agreeing to a legal structure. Physician groups, technology companies, and investors have actively chosen to partner in unique ways to innovate, build, and deploy new treatments and care delivery models. With the growing costs of healthcare and downward pressure from reimbursements, healthcare innovators will continue to require financial partners to continue serving patients. Partnering with business professional organizations and receiving capital from investors, including through acquisitions, helps practices gain efficiencies, reduce overhead costs, streamline administrative tasks, and evaluate current practices for improvement without encroachment into clinical care decision-making.

Many digital health acqui-hires and licensing transactions are genuine talent-and-technology integrations that bring innovations to scale where they can reach more patients, and are not evasion tactics. Non-exclusive licensing arrangements are generally a pro-competitive feature of digital health commerce, and minority and convertible-security investments are a core feature of capital formation across digital health. To the extent the Agencies pursue any changes addressing these structures, policy updates should:

- Be drafted to define the targeted conduct narrowly with reference to identified competitive harm rather than transaction form, and not extend to ordinary-course talent moves, strategic hiring, routine licensing, or ordinary minority investment;
- Include a clear safe harbor for minority investments in digital health companies that do not confer control, recognizing that such investments are an essential source of capital across the digital health ecosystem and that the federal government should not presume that profit alone is the only factor explaining investor participation in healthcare; and

- Provide clear guidance and examples so that filers and their counsel can structure ordinary-course transactions with certainty.

c. *Solely-for-the-Purpose-of-Investment Exemption (RFI Question 12)*

The Agencies ask whether to make explicit that the solely-for-the-purpose-of-investment exemption does not apply when the acquiror uses its ownership of voting securities to influence a corporation’s competitive decision-making. CHI offers two observations from the digital health perspective:

- Any clarification should be drafted with care to avoid chilling the routine participation of investors of all types on the boards of digital health companies. Board participation by such investors is normal, often required as a condition of investment, and overwhelmingly directed at governance and capital-formation matters rather than at influencing the target’s pricing, output, or quality decisions vis-à-vis competitors.
- Any rule should be drafted with reference to identified competitive harm rather than to investor identity or to the existence of overlapping commercial activity, recognizing that ordinary corporate governance participation is routine and pro-competitive. The Agencies should publish illustrative examples to assist filers in applying any clarification.

d. *Structural Transaction Modifications (Responses to RFI Questions 14 and 15)*

CHI agrees that the Agencies and merging parties benefit from early, substantive engagement on potential remedies and that late-breaking restructurings can disrupt orderly review. At the same time, CHI urges the Agencies to be cautious about new or supplemental HSR filing requirements that could deter parties from proposing pro-competitive divestitures or that could lengthen review timelines for transactions in fast-moving digital health markets in which product cycles and capital availability change rapidly. Many digital health transactions are time-sensitive, and prolonged review can itself foreclose the transaction without any underlying competitive concern. Remedy discussions are also often iterative, and require flexibility, since parties may not be able to develop a meaningful remedy proposal until the Agencies identify their theory of harm with sufficient clarity.

In response to Question 15(c), we encourage the Agencies to consider alternatives short of a new supplemental HSR filing, such as targeted supplemental submissions focused on the divestiture package and proposed buyer, voluntary timing agreements, or published guidance specifying the categories of information staff will routinely request when evaluating proposed remedies. These alternatives can address the informational gap the Agencies identify while preserving incentives to propose remedies. In response to Question 15(b), the Agencies should mitigate any deterrent effect on remedy proposals by committing to expedited review of restructuring proposals submitted before substantial compliance with a Second Request and by providing clear, published criteria for the divestiture-buyer vetting the Agencies will undertake.

V. *Use of Artificial Intelligence in HSR Submissions (RFI Questions 18 and 20)*

The Agencies ask about the costs of requiring filers to disclose their use of AI or generative AI in preparing HSR submissions, and about the cost savings that filers may realize through the use of such tools. CHI offers the following observations:

- CHI strongly supports outcome-based and technology-neutral approaches to regulation, particularly with respect to AI. Disclosure obligations that single out AI as a category warranting special scrutiny, absent a demonstrated harm specific to AI use in this context, are inconsistent with that principle, and CHI believes that the pertinent question for HSR purposes is whether the submission is accurate, complete, and responsive, not whether any particular technology was used to assist in its preparation. We accordingly recommend that any AI-related disclosure requirement be limited to a high-level attestation that the filer has implemented reasonable processes (consistent with existing professional-responsibility obligations of counsel) to ensure the accuracy and completeness of the submission, including in any portions of the submission prepared with the assistance of AI tools.
- Generative AI and related tools offer substantial promise to reduce filer burden across HSR preparation, including in document review and tagging, narrative drafting, custodian identification, and overlap analysis. These tools may be especially useful in Second Request compliance, where document review costs can be substantial, and where AI-driven efficiency gains can be the difference between substantially complying with a Second Request on a feasible budget and abandoning a pro-competitive transaction. To the extent the Agencies adopt requirements that would discourage or complicate the use of such tools (for example, expansive workpaper-style disclosure obligations), the cost savings the Agencies could otherwise realize from filer adoption of AI will be foregone. The Agencies should be clear that the standard for the filer’s submission is the substantive standard that has always applied, which is accuracy and completeness.

VI. Ambiguities and Clarifications (RFI Question 6)

CHI suggests the following areas in which clarification would meaningfully reduce compliance uncertainty for digital health filers without diminishing the Agencies’ analytical capacity:

- Clarification of the scope of the “regularly prepared” ordinary-course-of-business document requirement, including (i) the look-back period, (ii) whether and how draft and working documents are within scope, and (iii) the treatment of board and committee materials prepared for unrelated transactions;
- Examples of the Overlap Description and Supply Relationships Description for vertical, complementary, and conglomerate transactions in the digital health context, including transactions involving software-as-a-medical-device, remote monitoring, and AI-enabled clinical-decision-support products;
- Clear guidance on the treatment of pre-revenue digital health targets, including how filers should describe relevant markets and competitive overlaps when the target has no commercial sales but has FDA-cleared or FDA-pending products; and
- Clear guidance on the treatment of FDA regulatory status as part of, or separate from, the competitive analysis, so that filers do not inadvertently mischaracterize markets by reference to regulatory category rather than commercial substitutability.

VII. Additional Improvements (RFI Question 24)

CHI offers two additional recommendations not directly addressed by the RFI’s questions:

- The Agencies should publish, on an annual basis, anonymized aggregate data on the operation of any new Form, including average preparation costs by transaction-value band, average time from filing to early termination or expiration of the waiting period, and the rate at which Second Requests are issued and substantially complied with. Publishing such data would advance the Agencies’ own stated objective in this RFI—ensuring that the Form’s burdens are commensurate with its benefits—and would inform future rulemaking with the kind of empirical evidence that CHI has repeatedly urged the Agencies to develop. As CHI noted in our 2024 comments on serial acquisitions, any merger-policy framework should be informed by a strong evidence base rather than by an assumption that merger activity is inherently anticompetitive.
- The Agencies should provide a dedicated digital health desk or designated points of contact within the Bureau of Competition and the Antitrust Division to support pre-filing consultations for digital health transactions. The digital health sector is characterized by rapidly evolving product categories, novel business models, and regulatory frameworks (FDA, ASTP, CMS, OCR, and DEA, among others) that interact with competitive analysis in ways unfamiliar to many. Dedicated points of contact would improve the quality of filings submitted by digital health companies and reduce the back-and-forth that currently consumes Agency and filer resources alike.

VIII. Conclusion

CHI appreciates the Agencies’ willingness to revisit the Updated Form in light of practical experience and to consider improvements that better calibrate burden to analytical value. The connected health sector is a critical engine of healthcare innovation and a meaningful contributor to lower costs and better outcomes for American patients. A premerger reporting framework that recognizes the pro-competitive value of investment, acquisition, and partnership activity in digital health, while preserving the Agencies’ ability to identify and act on genuinely anticompetitive transactions, will advance both the Agencies’ missions and the broader goal of an innovative, accessible, and affordable American healthcare system.

Sincerely,



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