ConnectedHealthInitiative

August 31, 2026

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, District of Columbia 20201
Submitted electronically via www.regulations.gov, Docket No. CMS-2026-2344

RE: Comments of the Connected Health Initiative to the Centers for Medicare & Medicaid Services on Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data; Prior Authorization; and Other Provisions (CMS-1850-P)

Dear Administrator Oz:

The Connected Health Initiative (CHI), an initiative of the Association for Competitive Technology (ACT), appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) on its proposed changes to the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) payment system for calendar year (CY) 2027.[1] CHI focuses these comments on the provisions of the proposed rule that bear on the use of software-based, connected, and artificial intelligence (AI)-enabled technologies in Medicare, and on the requests for information through which CMS invites input on the direction of its policy in those areas.

I. Introduction & Statement of Interest

CHI is the leading multistakeholder policy and legal advocacy effort driven by a consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can access the benefits of connected health technologies that improve health outcomes and reduce costs, consistent with the quadruple aim of enhancing population health,

[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; Including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots, 91 FR 41734 (July 7, 2026) (CMS-1850-P) (hereinafter, the "proposed rule").

improving patient experience and health outcomes, improving the experience of clinicians and health care teams, and lowering the overall cost of care.

We are active advocates before Congress, numerous U.S. federal agencies, and states, where we seek to advance responsible pro-digital health policies and laws in areas including reimbursement and payment, privacy and security, effectiveness and quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial and augmented intelligence in care delivery. CHI participates in the American Medical Association's Digital Medicine Payment Advisory Group and in other multistakeholder efforts that work through the coding, valuation, and evidentiary questions raised by this proposed rule.[2]

CHI is a longtime advocate for the increased and responsible use of digital health tools, including telehealth, remote monitoring, clinical software, and AI-enabled technologies, across the Department of Health and Human Services (HHS) and before other agencies with responsibility for the American health care system. We have supported CMS' recent work to build a more connected health technology ecosystem, including its efforts to make it routine for a beneficiary to obtain their own health information in an application of their choosing and to make that information usable by the clinicians who care for them.[3] We have likewise supported CMS' decisions to place digital modalities on equal footing with in-person care where the clinical purpose of a requirement can be met either way, including its decision to make permanent the use of real-time audio-video communications technology to satisfy direct supervision requirements.[4]

Generally, CHI is committed to an OPPS, an ASC payment system, and a broader Medicare program that serve beneficiaries effectively by responsibly leveraging the full range of digital health tools available today, consistent with the quadruple aim. This proposed rule is a significant one for that objective. For the first time, CMS has proposed a framework, which it describes as an interim one, for paying for clinical software as its own category of medical service. How CMS resolves the questions it raises will shape whether software-based and AI-enabled technologies reach Medicare beneficiaries broadly, or whether they remain available principally at large academic centers with the resources to absorb their cost.

[2] See https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group.

[3] See CMS, Health Technology Ecosystem, https://www.cms.gov/initiatives/health-technology-ecosystem/overview; CMS, White House and Tech Leaders Commit to Create Patient-Centric Healthcare Ecosystem (July 30, 2025), https://www.cms.gov/newsroom/press-releases/white-house-tech-leaders-commit-create-patient-centric-healthcare-ecosystem.

[4] CY 2026 Medicare Physician Fee Schedule final rule, CMS-1832-F (published Nov. 5, 2025), making permanent the policy permitting direct supervision through real-time audio-video communications technology.

II. Digital Health's Integral Role in the Future of Medicare and Hospital Outpatient Care

Data and clinical evidence from a wide range of use cases continue to demonstrate that connected health technologies improve patient care, prevent avoidable hospitalizations, reduce complications, and improve the patient and clinician experience. Software-based diagnostic and decision-support tools now perform quantitative analyses that were not previously available at all, or that were available only through subspecialty interpretation concentrated in a small number of institutions. Remote monitoring extends clinical oversight into the intervals between encounters, when most of the course of a chronic illness plays out. Communications technology allows a beneficiary to receive rehabilitative and preventive services at home that they would otherwise forgo for want of transportation.

As a community, we continue to support CMS' efforts to use advanced technology to augment care for every beneficiary. CMS' continued work to advance the range of digital health tools available in Medicare has been substantial, and we welcome the agency's candid recognition in this proposed rule that its existing payment architecture does not fit software-based medical services. CMS observes that Medicare Part B payment systems were built principally to pay for services that consume material resources such as staff time, equipment, supplies, space, and procedural overhead, while the value of a software-based medical service may instead lie in a proprietary algorithm, a trained model, scalable non-material infrastructure, licensing terms, and demonstrated clinical performance.[5]

Despite the demonstrated benefits of connected health technology, statutory restrictions and CMS regulatory and sub-regulatory policy decisions continue to inhibit uptake. Chief among them is the treatment of clinical software as an administrative overhead item rather than as a medical device, cleared or approved by FDA, that produces a clinically meaningful output used in the diagnosis, treatment, or management of a beneficiary's condition. Software as a Medical Device (SaMD) is a device as defined by FDA regardless of whether it is loaded onto and used on general purpose platforms or used as a dedicated ancillary medical device.[6] AI-enabled clinical software is not simple off-the-shelf computer software, and it cannot properly be categorized as an indirect, non-allocable practice expense.[7] That categorization carries real consequences. It determines whether a technology that has been cleared by FDA and validated in the population where it will be used can be furnished to a Medicare beneficiary at all.

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[5] Proposed rule, 91 FR 41734, section X.B, describing the difficulty of valuing services whose cost lies in a licensed algorithm rather than in equipment or supplies, and whose pricing may take the form of a subscription, an enterprise license, or a per-use charge.

[6] 21 U.S.C. 321(h); see also the Medical Device Amendments of 1976, Pub. L. No. 94-295.

[7] CHI, Comments on the CY 2026 Medicare Physician Fee Schedule and Quality Payment Program proposed rule (Aug. 29, 2025), https://connectedhi.com/wp-content/uploads/2025/09/CHI-Comments-CMS-Draft-CY2026-PFS-QPP-29-Aug-2025-1.pdf; CHI, Comments on the CY 2026 OPPS and ASC proposed rule, CMS-1834-P (Sept. 2, 2025), https://connectedhi.com/wp-content/uploads/2025/09/CHI-Comments-re-HHS-Draft-CY2025-OPPS-ASC-Rule-2-Sept-2024.pdf.

Building on the incremental support CMS has extended to these technologies in recent rulemaking, CMS should now use this rule to establish that clinical software is paid for as a service in its own right, on the basis of what it actually costs to develop, validate, license, deliver, and maintain. A payment framework that is durable will be written around capabilities and evidence instead of around particular named products, and it will be consistent across the settings in which a beneficiary may receive the service.

It is essential that hospital outpatient departments, ASCs, and the beneficiaries they serve be able to leverage the wide range of connected health tools and services available today, as well as those in development, to advance the quadruple aim. CHI stands ready to work with CMS on each of the items discussed below.

III. Payment for Software as a Medical Service

CMS proposes to replace the term "Software as a Service" with "Software as a Medical Service" (SaMS), to designate a set of Healthcare Common Procedure Coding System (HCPCS) codes as SaMS, to reassign the separately paid SaMS codes currently mapped to clinical ambulatory payment classifications (APCs) into New Technology APCs at rates approximating their CY 2026 payment, to create a new payment status indicator, "O1," carrying the payment specifications of status indicator "S," and to move a set of algorithm-only analyses of laboratory data off the Clinical Laboratory Fee Schedule (CLFS) and onto the OPPS.[8] CMS describes this as an interim step while it develops a more comprehensive methodology, and it solicits comment on several elements. CHI supports the direction of these proposals and offers the following recommendations.

- **Support for separate payment, and the interim New Technology APC placement.** CHI supports CMS' decision to pay separately for SaMS rather than package it, and supports the interim placement in New Technology APCs of those separately paid SaMS codes for which claims and cost experience is not yet sufficient to support ratesetting in a clinical APC. CHI does not support moving into that series a SaMS service that already carries a payment history, because a service should not be treated as new merely because it is software. New Technology APC placement should be understood and administered as an evidence-generation period, meaning the interval during which claims experience, utilization patterns, and cost information accumulate to a point where a durable rate can be set. That is the same logic that governs the recognition of emerging services in coding more generally, and it applies here. CHI recommends that CMS:
    - State affirmatively that a SaMS code will remain in a New Technology APC until CMS has claims experience sufficient to support ratesetting in a clinical APC, and that CMS will not reassign a SaMS code to a clinical APC on the basis of thin or unrepresentative data. That commitment should run to services placed in the series because their claims experience is genuinely thin, and not to services that already carry a payment history. Congress is considering legislation that would establish a

[8] Proposed rule, 91 FR 41734, sections III.C.4, X.B, and XI.A.

defined minimum period for precisely this reason, and CMS should not adopt a shorter horizon by default.[9]

- Apply the equitable adjustment authority at section 1833(t)(2)(E) of the Act to SaMS as a standing policy rather than case by case.[10] CHI supports CMS' proposal to maintain existing New Technology APC assignments for the services with zero or fewer than 10 claims in the lookback period.[11] The circumstance CMS identifies there, a technology whose claims volume is too thin to support ratesetting, is the ordinary condition of a newly available software-based service and not an exception to it.
- Publish the criteria by which a SaMS code graduates from a New Technology APC to a clinical APC, together with the data CMS relies upon, so that developers and hospitals can anticipate the transition instead of learning of it in an addendum.

- **Retain the payment specifications of status indicator "S" and do not adopt "T"-like multiple procedure discounting.** CMS solicits comment on whether the specifications of status indicator "T," which applies multiple procedure discounting, would be more appropriate for SaMS than the "S"-like specifications CMS proposes for status indicator "O1."[12] CHI recommends that CMS retain the "S"-like specifications. Multiple procedure discounting rests on a resource premise. When two procedures are furnished in the same session, certain material inputs such as room time, patient preparation, setup, and clinical staff time are shared, so the second procedure costs less than the first. CMS has correctly identified that premise as absent from software. When an algorithmic fractional flow reserve analysis is furnished on the same claim as the coronary CT angiogram whose images it analyzes, the analysis consumes no additional room time, no supply, and no additional staff time, and none of its cost falls away because the two services appear together. The marginal cost of a second algorithmic analysis is not reduced by its co-occurrence with the first, because each analysis carries its own license or per-use cost, its own computational cost, and its own validation and maintenance burden. Discounting the second analysis would therefore not capture an efficiency. It would pay below cost, and it would do so most severely for the newest and lowest-volume technologies. To the extent CMS is concerned about the appearance of multiple SaMS codes on a single claim, CHI recommends that CMS address that concern directly through conditions of payment instead of an across-the-board rate reduction, including:

[9] S. 1399, 119th Cong. (2025), which would define "algorithm-based health care services" and assign them to a dedicated New Technology APC for a defined minimum period while claims experience accumulates.

[10] Social Security Act section 1833(t)(2)(E), 42 U.S.C. 1395l(t)(2)(E).

[11] Proposed rule, 91 FR 41734, section III.C.2, identifying the services with either zero claims available for CY 2027 ratesetting or fewer than 10 claims over the preceding four-year lookback period, and proposing to maintain existing New Technology APC assignments for those services.

[12] Proposed rule, 91 FR 41734, section XI.A, proposing new status indicator "O1" (Software as a Medical Service, paid under OPPS; separate APC payment), which would carry the payment specifications of status indicator "S," and soliciting comment on whether the specifications of status indicator "T," which applies multiple procedure discounting, would be more appropriate.

- A requirement that each SaMS service be ordered by, and its output furnished to, an identifiable clinician who is responsible for acting on it.
- Documentation of medical necessity for each analysis furnished, and of the distinct clinical question each analysis was ordered to answer.
- Monitoring of utilization patterns through the claims data that the New Technology APC period is designed to generate, with targeted action where the data show a problem.

- **Define SaMS by regulatory status and clinical function, not by commercial delivery model.** As CHI told the Assistant Secretary for Technology Policy in February, CMS should stop conflating "Software as a Service," which describes a commercial licensing and delivery arrangement, with device-level clinical software, and we appreciate that CMS has moved away from that term.[13] The new term is an improvement, but the definition should do the work. CHI recommends that CMS define SaMS by reference to the software's regulatory status and clinical function, meaning software that meets the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act and that produces a clinically meaningful output used in the diagnosis, treatment, or management of a patient,[14] rather than by how the software is hosted, licensed, or billed. Definitional clarity of this kind serves the same purpose here that a common lexicon serves in other areas of technology policy. It allows developers to determine their eligibility in advance, allows CMS to administer the category consistently, and keeps the category from expanding or contracting with commercial practice. CHI also recommends that CMS:
  - Align its taxonomy with the assistive, augmentative, and autonomous categories already established in CPT Appendix S, so that Medicare payment policy, coding, and the evidentiary expectations attached to each category speak the same language.[15]
  - Confirm that designation of a service as SaMS is a payment classification only and is not a determination regarding the software's regulatory status, its status as a device, or the applicability of any FDA requirement. CMS should also confirm that the absence of a separate clearance or authorization for a particular software component is not by itself disqualifying, so that software operating within an authorized device and software updates that are not independently device-constitutive remain eligible where the service produces a clinically used output.

[13] CHI, Comments to the Assistant Secretary for Technology Policy on the Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (Feb. 23, 2026), https://connectedhi.com/wp-content/uploads/2026/02/CHI-Comments-re-ASTP-RFI-on-AI-in-Clinical-Care-23-Feb-2026-w-appendices.pdf.

[14] Section 201(h) of the Federal Food, Drug, and Cosmetic Act, supra note 6.

[15] AMA Digital Medicine Payment Advisory Group, supra note 2.

- Confirm that the SaMS category is not limited to imaging-derived analyses and describe how software supporting other clinical domains would be evaluated for inclusion.

- **Recognize licensed clinical software as a direct cost and collect the cost data necessary to pay for it.** The interim rates CMS proposes are carried forward from CY 2026 and are not built from an assessment of what SaMS costs. CHI has consistently urged that SaMD be classified as a direct practice expense under medical equipment rather than as "computer software" falling among indirect and non-allocable practice expenses, and the same principle must inform OPPS cost finding.[16] Hospital cost reports and the cost-to-charge ratios derived from them contain no line that captures a per-use license fee, an enterprise subscription, or the cloud infrastructure on which a service depends, and a geometric mean cost computed from claims that do not reflect those inputs will systematically understate the cost of the service. CHI recommends that CMS:
  - Collect cost information for SaMS directly from developers and hospitals, including invoices, subscription and enterprise license terms, and per-use pricing, and state how that information will be used in ratesetting. The conditions of payment described above, including an identifiable ordering clinician, documented medical necessity, and a distinct clinical question for each analysis, should apply alongside whatever cost data CMS collects, enabling CMS to audit utilization against them. CMS has historically declined to accept per-use software pricing as a direct cost input. That position cannot be sustained alongside CMS' own recognition that the value of these services lies in non-material resources.
  - Establish a discrete means by which hospitals can report the cost of licensed clinical software on the Medicare cost report, so that the data underlying future ratesetting improve over time instead of remaining static.
  - Commit to publishing, in advance of the rulemaking in which it proposes permanent rates, the cost and utilization data on which those rates would rest, so that stakeholders can comment on the data and not only on the conclusion.
  - Decline to extend cost data developed for one payment system to another where the underlying inputs differ. Where OPPS-derived amounts are used to price inputs in other Medicare payment systems, CMS should explain the basis for treating those amounts as representative.

- **Do not expand conditional packaging of SaMS.** CHI supports CMS' decision not to package SaMS codes more aggressively, and its decision to preserve current assignments for codes presently subject to conditional packaging in order to avoid disrupting beneficiary access. CHI recommends that CMS go further and state that it does not intend to package separately payable SaMS services into comprehensive APCs or other packaged payments while the interim framework is in effect. Packaging a service whose cost CMS concedes it cannot yet measure would foreclose the very data collection that the New Technology APC

[16] CHI comments on the CY 2026 Medicare Physician Fee Schedule and the CY 2026 OPPS and ASC proposed rules, supra note 7.

placement is meant to accomplish. CHI also asks CMS to describe the pathway by which a conditionally packaged SaMS code may be evaluated for separate payment under status indicator O1.

- **Algorithm-only analyses of laboratory data, beneficiary cost sharing, and contractor pricing.** CMS proposes to remove a set of codes describing algorithmic analyses of previously generated laboratory data from the CLFS on the reasoning that such an analysis is not itself a clinical laboratory test once the underlying result exists, and to assign those codes to New Technology APCs under the OPPS.[17] CHI does not believe CMS has established that reasoning at the level of the individual code, and we urge CMS to work through the codes one at a time and publish the result before finalizing any removal, for the reasons we set out in the companion physician fee schedule docket. If CMS nonetheless proceeds, we ask it to address two consequences that follow:
    - **Beneficiary cost sharing.** Clinical diagnostic laboratory tests paid under the CLFS are not subject to the Part B deductible or to coinsurance, while services paid under the OPPS are subject to beneficiary copayment.[18] A beneficiary who owes nothing for one of these analyses today would, after the reclassification, owe the applicable Part B coinsurance for it. A reclassification that CMS characterizes as technical would therefore impose new out-of-pocket cost on beneficiaries for a service they receive today at no cost sharing. CHI recommends that CMS state expressly what the beneficiary liability consequences are, quantify them in the final rule, and consider whether any mitigation is available, so that beneficiaries do not first learn of the reclassification when they receive a bill.
    - **Contractor pricing.** In the companion physician fee schedule proposed rule, CMS proposes to price certain algorithm-only analyses through the Medicare Administrative Contractors instead of at a national rate.[19] CHI has long urged CMS to adopt national rates for the payment of software-based and AI-enabled services and to move away from contractor pricing, which produces disparate payment for the identical service depending on where a beneficiary happens to live and which gives developers no basis on which to plan. A framework intended to produce consistency should not rest on a pricing mechanism that varies from one contractor to the next.

[17] Proposed rule, 91 FR 41734, section X.B, addressing SaMS analyses performed on laboratory tests, and section III.C.4.

[18] Social Security Act sections 1833(a)(1)(D) and 1833(b)(3), 42 U.S.C. 1395l(a)(1)(D), (b)(3); compare Social Security Act section 1833(t)(8), 42 U.S.C. 1395l(t)(8), governing beneficiary copayment under the OPPS.

[19] CY 2027 Medicare Physician Fee Schedule proposed rule (published July 16, 2026), https://www.federalregister.gov/documents/2026/07/16/2026-14327/medicare-and-medicaid-programs-cy-2027-payment-policies-under-the-physician-fee-schedule-and-other, which proposes to adopt the SaMS terminology, to price certain algorithm-only analyses through the Medicare Administrative Contractors, and which includes a request for information on establishing a consistent Medicare payment framework for SaMS technologies across care settings.

- **Establish a single framework across care settings.** The companion physician fee schedule proposed rule includes a request for information on whether CMS should establish a consistent Medicare payment framework for SaMS technologies across care settings.[20] CHI strongly supports that objective and recommends that CMS pursue it. A beneficiary who receives an algorithmic analysis in a hospital outpatient department, in an ASC, and in a physician's office receives the same service, and the software's cost to the entity furnishing it does not vary with the place of service. CHI recommends that CMS adopt a common definition of SaMS, a common evidentiary framework, and a common approach to cost data across the OPPS, the physician fee schedule, the ASC payment system, and the CLFS, and that it describe in the CY 2028 rulemaking cycle how the interim OPPS policy will converge with the approach taken in the other settings. CHI asks CMS to resolve those cross-setting questions before extending the SaMS classification to additional codes. CHI asks CMS to address expressly how SaMS is recognized in the ASC setting, which the proposed rule does not discuss.
- **Evidence, oversight, and access.** Payment policy for AI-enabled clinical software should rest on a framework that is proportionate to the risk a given tool presents. CHI has published detailed recommendations on this subject.[21] In particular, CHI recommends that CMS:
    - Scale evidentiary expectations to risk. The level of review, assurance, and oversight applied to a tool should be proportionate to the potential harm it presents, drawing on the risk management functions described in the NIST AI Risk Management Framework and on the assistive, augmentative, and autonomous distinctions in CPT Appendix S.[22]
    - Require disclosure of a tool's intended use, intended population, known limitations, and the validation evidence supporting it in the population and practice setting where it will be deployed. Transparency about the basis for a tool's output is the most effective safeguard against automation bias, and it can be provided without requiring disclosure of proprietary model internals. The two are not the same thing, and conflating them will deter participation without improving safety.
    - Preserve the position of a qualified clinician to review, and where appropriate to override, the clinical decisions that an AI-enabled tool informs.
    - CMS should coordinate with FDA, with the Assistant Secretary for Technology Policy, and with the relevant clinical specialty societies, which are best positioned

[20] CY 2027 Medicare Physician Fee Schedule proposed rule, supra note 19.

[21] CHI, Policy Principles for Artificial Intelligence in Health, https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf; CHI, Health AI Roles & Interdependency Framework, https://connectedhi.com/wp-content/uploads/2025/03/CHI-Health-AI-Roles.pdf; CHI, Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem (Oct. 2021), https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf.

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

to identify the uses of AI-enabled technology appropriate to a given field of practice, and should recognize voluntary, consensus-developed certification and assurance mechanisms in its own determinations instead of duplicating them.

- Avoid conditioning payment, participation, or coverage on the use of any particular AI-enabled tool, and avoid technology-specific mandates that reduce the ability of providers to select and scale the tools best suited to their patients.
- Attend to affordability and access. A payment framework that functions only for large health systems will produce a Medicare program in which the availability of a validated technology depends on the size of the institution a beneficiary can reach. Payment and incentive policies must support the infrastructure, personnel, training, and ongoing validation and maintenance that responsible deployment requires, including at rural and smaller facilities.

IV. Recommendations on Other Provisions of the Proposed CY 2027 OPPS and ASC Payment Systems

CHI offers the following views on other provisions of the proposed rule that affect the use of digital health technologies and renews certain recommendations we have made in prior OPPS and ASC rulemaking cycles that remain unaddressed.

- **Cardiac, Intensive Cardiac, and Pulmonary Rehabilitation Furnished in the Home (Section X.D).** CHI supports the delivery of cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services to eligible hospital outpatients in their homes using real-time audio and video communications technology and appreciates CMS' implementation of the authority Congress provided.[23] These are among the most underused services in Medicare, and the reason is not clinical. Eligible beneficiaries do not complete programs that require repeated travel to a facility. CHI recommends that CMS:
  - Support permanence. The current authority expires December 31, 2027. CHI urges CMS to state its support for making home-based delivery of these services permanent, and to use the data generated during the authorized period to inform that recommendation, so that the program does not return to a facility-only design by operation of a sunset date.
  - Confirm that remote monitoring of physiologic parameters may be used to support home-based delivery of these services and that the supervision requirement may be satisfied through real-time audio-video communications technology, consistent with the direct supervision policy CMS has made permanent.[24] CHI reiterates that it

[23] Proposed rule, 91 FR 41734, section X.D. See also the Consolidated Appropriations Act, 2026, which permits cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services to be furnished to eligible hospital outpatients in their homes using real-time audio and video communications technology through December 31, 2027.

[24] 42 C.F.R. 410.27(a)(1)(iv) and 410.32(b)(3)(ii).

does not share the concern CMS has expressed in past rulemaking that virtual supervision inherently gives rise to patient safety issues.

- Collect and publish data on utilization, completion rates, and outcomes for home-based delivery relative to facility-based delivery, so that the question of permanence is decided on evidence.

- **Remote Monitoring in the Hospital Outpatient Setting, Critical Access Hospitals, and Rural Emergency Hospitals.** CMS should extend to the hospital outpatient setting the support it already provides for remote physiologic and remote therapeutic monitoring elsewhere in Medicare. The proposed rule addresses neither service in this setting, and CHI renews the recommendations it has made in each of the last several OPPS rulemaking cycles.[25] Remote monitoring tools must play a central role in CMS' efforts to make its OPPS more efficient and effective, and the gap between the support CMS extends to these services in other payment systems and what is available in the hospital outpatient setting has no clinical justification. CHI recommends that CMS:
  - Permit the care management services captured in the remote monitoring codes to be billed when furnished by a hospital's clinical staff, consistent with CMS' approach to chronic care management, principal care management, transitional care management, and behavioral health integration services.
  - Critical access hospitals and rural emergency hospitals, at the front lines of care for America's most underserved populations, need the ability to monitor key patient-generated health data metrics between encounters. CMS should ensure that these facilities are able to furnish and be paid for remote monitoring on terms comparable to those available to federally qualified health centers and rural health clinics.
  - Take a consistent approach to nascent technologies across the CY 2027 rules. CMS proposes in this rule to hold rates steady for software-based services because the claims and cost data available for them are too thin to support ratesetting, while in the companion physician fee schedule rule it proposes substantial reductions to remote monitoring device supply payment on the ground that the device cost data are inadequate. The evidentiary premise is the same in both cases, and the policy response should not diverge. Where the data are insufficient, CMS should hold rates and collect better data instead of reducing payment. If CMS nonetheless reduces remote monitoring device supply payment in the physician fee schedule on that ground, it should not later import the reduced amounts into the OPPS as though they represented measured cost.
  - Continue to recognize that connected health technologies are a program integrity asset. A monitored patient generates a continuous, time-stamped record of what was measured, when, and by what device. CHI has offered its assistance to the

[25] CHI, Comments on the CY 2026 OPPS and ASC proposed rule, CMS-1834-P (Sept. 2, 2025), https://connectedhi.com/wp-content/uploads/2025/09/CHI-Comments-re-HHS-Draft-CY2025-OPPS-ASC-Rule-2-Sept-2024.pdf; CHI, Comments on the CY 2025 OPPS and ASC proposed rule, CMS-1809-P (Sept. 9, 2024), https://connectedhi.com/wp-content/uploads/2025/01/09.09.2024_CHI-Comments-re-_HHS-Draft-CY2025-OPPS-ASC-Rule.pdf.

HHS Office of Inspector General in developing safeguards that target genuinely improper conduct without impeding the appropriate delivery of beneficial monitoring services, and we make the same offer to CMS.[26]

- **Device Pass-Through Payment and the Alternative Pathway (Section IV.A).** CMS proposes to eliminate the alternative pathway under which a device granted FDA Breakthrough Device designation could obtain transitional device pass-through status without a separate demonstration of substantial clinical improvement, for applications received on or after October 1, 2026.[27] CHI urges CMS to reconsider. Our concern is with connected and software-enabled devices in particular. The alternative pathway exists because the devices most likely to represent a genuine advance are also the devices least likely to have accumulated the comparative clinical evidence that a substantial clinical improvement showing requires. That evidence is generated through use, and use depends on payment. Eliminating the pathway would require the evidence before the use that produces it. CHI recommends that CMS:
    - Retain the alternative pathway, or, at minimum, defer its elimination and state in the final rule, and not in later guidance, what evidence CMS considers sufficient to demonstrate substantial clinical improvement for a technology in the period immediately following FDA authorization, including whether and how real-world evidence, registry data, and validation studies conducted in the intended-use population may be used. CHI is not asking CMS to relax the requirement that a device hold FDA authorization, or to reduce the clinical evidence a manufacturer must ultimately generate. Our concern is the sequence in which CMS expects that evidence to appear.
    - Clarify how devices with essential software or algorithmic components are evaluated under the eligibility criteria at 42 C.F.R. 419.66, including whether the software component and its updates are treated as part of the device or as separately excluded items.[28] The criteria in that section were written for physical devices that contact tissue and are surgically implanted or inserted, and they do not translate cleanly to a device whose therapeutic or diagnostic function is executed in software. CHI recommends that CMS state expressly how the connected and software-enabled components of an otherwise eligible device are treated, so that applicants are not left to infer the answer.
- **Electronic Clinical Quality Measure Validation and Appeals (Sections XV.D and XV.E).** CHI supports the movement of Medicare quality measurement toward electronically specified, digitally captured measures, and supports CMS' proposal to streamline

[26] HHS Office of Inspector General, Billing for Remote Patient Monitoring in Medicare, OEI-02-23-00261 (Aug. 28, 2025), https://oig.hhs.gov/reports/all/2025/billing-for-remote-patient-monitoring/; see also CHI, Letter to the HHS Office of Inspector General regarding Remote Patient Monitoring in Medicare (Aug. 14, 2026), https://connectedhi.com/wp-content/uploads/2026/08/CHI-Letter-to-OIG-re-Remote-Monitoring-14-Aug-2026.pdf.

[27] Proposed rule, 91 FR 41734, section IV.A.2. See also 42 C.F.R. 419.66.

[28] 42 C.F.R. 419.66(b)(3) and (b)(4).

validation and appeals, including by eliminating the resubmission of records already provided.[29] CHI again encourages CMS to adopt measures that advance value and protect against overuse and fraud, while avoiding overburdensome requirements to alleviate provider burnout, and to avoid technology-specific mandates that reduce providers' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries. Validation requirements and the payment consequences attached to them should not take effect until the underlying reporting infrastructure has demonstrated operationally usable performance at realistic scale across the range of facilities subject to the requirement, including small, rural, and independent facilities that entered digital reporting later and with less support than their larger counterparts. CHI recommends that CMS:

  - Confirm the implementation timeline provides a realistic runway, and commit to publishing validation results in aggregate before penalties attach, so that facilities and their technology partners can identify and correct systemic problems before a payment reduction alerts them to one.
  - Move toward a report-once, use-many-times architecture in which quality data are exported from certified health information technology through bulk FHIR and calculated centrally by CMS, instead of requiring each facility to compute and submit measure results separately.[30]
  - Avoid technology-specific mandates and align data elements with the United States Core Data for Interoperability and with the standards CMS is advancing through its health technology ecosystem work, so that a facility's investment in interoperability serves quality reporting instead of sitting alongside it.[31, 32]

- **Request for Information on an Advance Care Planning Electronic Clinical Quality Measure (Section XV.C).** CHI appreciates CMS' consideration of an advance care planning electronic clinical quality measure for the hospital outpatient setting.[33] A measure of this kind is worth developing, and it is also a measure whose feasibility depends almost entirely on how the underlying information is captured. Advance care planning documentation today typically exists as scanned images, uploaded documents, and unstructured narrative, none of which an electronically specified measure can read and none of which is retrievable at the point of care when it is needed. CHI recommends that CMS:
  - Specify from the outset that the measure requires capture of advance care planning information in structured, machine-readable fields mapped to recognized standards and not in free text or attached documents, and align the data elements

[29] Proposed rule, 91 FR 41734, sections XV.D and XV.E.

[30] CHI, Comments to the Department of Health and Human Services on the Health Technology Ecosystem Request for Information (June 16, 2025), https://connectedhi.com/wp-content/uploads/2025/06/HHS-Health-Tech-Ecosystem-RFI-CHI-Ltr-Full-Comments-16-June-2025.pdf.

[31] CMS Health Technology Ecosystem, supra note 3.

[32] HL7 FHIR SMART Application Launch Framework Implementation Guide; see also the United States Core Data for Interoperability (USCDI) and the Trusted Exchange Framework and Common Agreement (TEFCA).

[33] Proposed rule, 91 FR 41734, section XV.C.

with the United States Core Data for Interoperability so that the information is exchangeable across the settings a beneficiary moves through.[34]

- Permit and encourage electronic administration and patient-facing capture, including through patient portals, tablets in the facility, and applications the beneficiary already uses, while ensuring that any electronic administration is designed to recognized accessibility standards and that a non-electronic option always remains available.
- Assess whether the information is retrievable and actionable at the point of care, rather than whether a note exists somewhere in the record. A measure that credits documentation alone will not tell CMS whether the information reached the clinician who needed it.
- Account for the reality that hospital outpatient departments will frequently not be the setting in which the conversation occurred, and design the measure so that a facility is credited for retrieving and honoring an existing plan, not solely for creating a new one.

- **Request for Information on Stratification of the All-Cause Transfer/Admission Measure (Section XVII.C).** CMS requests comment on stratifying the ASCQR Program's All-Cause Transfer/Admission measure to distinguish the phase of care during which a transfer occurs.[35] CHI does not take a position on the clinical design of the measure. We recommend only that, if CMS proceeds, it specify the phase-of-care determination as a discrete, structured data element with clear definitions, rather than leaving it to be derived from narrative documentation or inferred from timestamps that were not recorded for that purpose. Stratification of this kind is only as reliable as the underlying data capture.
- **Expansion of Prior Authorization for Botulinum Toxin Injection Codes (Section XIX).** CHI takes no position on the clinical merits of the proposed expansion.[36] We do urge CMS to attend to the mechanism through which the outpatient department prior authorization process operates. Prior authorization remains one of the most significant sources of delay to timely care and of administrative cost in the health care system, and each expansion of a process that is not electronic and standards-based compounds that cost. CHI recommends that CMS:
  - Commit to an electronic, standards-based outpatient department prior authorization process built on the HL7 FHIR Da Vinci implementation guides, consistent with the direction CMS has set for payers elsewhere, and keep its

[34] HL7 FHIR SMART Application Launch Framework Implementation Guide and the United States Core Data for Interoperability, supra note 32.

[35] Proposed rule, 91 FR 41734, section XVII.C, requesting comment on stratifying the All-Cause Transfer/Admission measure to distinguish the phase of care during which a transfer occurs.

[36] Proposed rule, 91 FR 41734, section XIX; see also section XXIV.E (information collection requirements associated with the expansion).

requirements consistent across CMS programs and aligned with the certification criteria adopted by the Assistant Secretary for Technology Policy.[37]

- Publish the documentation requirements and review criteria applicable to each service category in a publicly accessible location and in plain language, rather than as an undifferentiated list of billing codes, and establish and report against response-time standards. A requirement can be satisfied in form while remaining, in practice, impossible to find or to use. Disclosure that a hospital or physician cannot act upon does not serve the purpose of the requirement.
- Report the volume of requests, approvals, denials, and appeals by service category, using standardized metrics with defined numerators and denominators, so that the burden imposed by each expansion can be measured against the utilization concern that motivated it.

- **Rural Emergency Hospital Quality Reporting Program (Section XVI).** CMS proposes no substantive changes to the Rural Emergency Hospital Quality Reporting Program for CY 2027.[38] CHI notes that rural emergency hospitals have never been eligible for the incentive payments that funded health information technology adoption elsewhere in Medicare and therefore begin from a materially weaker technology base than the facilities whose reporting programs they are being aligned with. As CMS develops that program, it should support, rather than assume, the connectivity and health information technology capability on which any digital reporting requirement depends.

V. Response to the Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data

CMS asks how it can strengthen the standardization and comparability of hospital price transparency data, including how contract mechanisms such as outlier payments, stop-loss provisions, rate tiering, and carve-outs should be reported in the machine-readable file, how the file can be standardized to enhance its utility, and how the consumer-friendly display requirements should be revised.[39] CHI welcomes these questions. Price transparency is in substance a data interoperability problem, and it has been approached principally as a publication requirement. The result is that hospitals have invested substantially in compliance and beneficiaries have gained very little, because the files that satisfy the requirement cannot reliably be read by the applications that would put the information in front of a patient at the moment a decision is made.

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[37] CMS Interoperability and Prior Authorization final rule (CMS-0057-F); see also CHI, Comments on the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (June 2026), https://connectedhi.com/wp-content/uploads/2026/06/CHI-Comments-re-CMS-Drug-Interop-Prior-Auth-Proposed-Rule-15-Jun-2026.pdf.

[38] Proposed rule, 91 FR 41734, section XVI, proposing no substantive changes to the Rural Emergency Hospital Quality Reporting Program for CY 2027.

[39] Proposed rule, 91 FR 41734, section XXIII (Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data), including section XXIII.B (machine-readable file) and section XXIII.C (consumer-friendly display).

The distinction CHI urges CMS to adopt is between a file that is published and a file that is computable. A file becomes useful when a third party can retrieve it, parse it, validate it, and derive from it the amount a particular patient would owe for a particular service under a particular plan. Measuring compliance by publication alone has produced files that meet the letter of the requirement but that no application can use. CHI recommends that CMS measure compliance by whether the file can actually be consumed and offers the following specific recommendations.

- **Standardize the schema and constrain the values.** CHI recommends that CMS publish and require conformance to a formal, versioned schema for the machine-readable file, and that it eliminate free-text wherever an enumerated value can be used instead.[40] Specifically, CMS should:
    - Require standardized payer and plan identifiers drawn from a published value set, so that the same payer is identifiable across every hospital's file. Free-text payer naming is, on its own, sufficient to defeat comparison across facilities.
    - Require standard code sets for the items and services reported, including CPT and HCPCS, National Drug Codes, diagnosis-related groups, and revenue codes as applicable, and require that each rate be associated with the code set and code that identifies it.
    - Require a documented, machine-readable file format with consistent structure. CHI has previously recommended JSON for this purpose, as comma-separated formats struggle to represent nested or complex data and are sensitive to formatting errors, and has recommended that CMS permit standard compression so that file size does not become a barrier to publication or retrieval.[41]
    - Publish a CMS-operated validator against which a hospital can test its file before posting, and against which the public can confirm conformance. A validator would do more to produce usable data than enforcement after the fact, and it would give hospitals a clear standard to build against.
    - Require a stable, predictable location and a machine-readable index for the file, together with a file version and an effective date, so that an application can locate the current file automatically without manual discovery.
- **Encode contract mechanisms as structured attributes, not as prose.** CMS asks how outlier provisions, stop-loss arrangements, rate tiering, and carve-outs should be reported.[42] CHI recommends that CMS require each of these to be expressed as discrete, encoded attributes of the rate to which they apply, including the type of provision, the

[40] 45 C.F.R. 180.50.

[41] CHI, Comments on the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule (July 2, 2025), https://connectedhi.com/wp-content/uploads/2025/07/CHI-Comments-re-Prescription-Drug-Machine-Readable-File-Requirement-in-the-Transparency-in-Coverage-Final-Rule-2-July-2025.pdf.

[42] Proposed rule, 91 FR 41734, section XXIII, supra note 39.

threshold or trigger, the basis on which it is calculated, and the resulting adjustment, instead of a narrative description of the contract term. The purpose of reporting these mechanisms is to allow a rate to be computed, and a description of a stop-loss clause in free text tells a reader that the clause exists without permitting any calculation. CHI recognizes that these are among the more commercially sensitive terms in a contract, and recommends that CMS define the reportable attributes narrowly, limiting them to what is necessary to compute an amount and excluding the surrounding contractual language.

- **Move from files to interfaces.** A published file is a periodic snapshot, while a patient making a decision needs an answer specific to their plan, their benefit design, and their accumulated cost sharing. CHI recommends that CMS work toward standards-based application programming interfaces for price and cost information, built on HL7 FHIR and the SMART application launch framework, so that price information can be retrieved by the applications beneficiaries already use, in the same manner and through the same infrastructure that CMS is advancing for clinical data.[43] That is the direction in which CMS has already committed to move through its health technology ecosystem work, where participants have undertaken to deliver patient-specific estimates of expected out-of-pocket cost reflecting an individual's benefits and cost-sharing responsibilities.[44] Price transparency should be built on that same infrastructure rather than alongside it. In the interim, CHI recommends that CMS treat the machine-readable file as the data layer that makes such an interface possible and design its requirements accordingly.
- **Harmonize with the Transparency in Coverage requirements.** The hospital price transparency and Transparency in Coverage requirements overlap substantially and can require duplicative submissions of the same underlying information in different formats.[45] CHI recommends that CMS harmonize the two frameworks through common schemas, common value sets, common identifiers, and common publication conventions, so that a single body of pricing data serves both and so that developers building against one are building against both. CHI also recommends that CMS avoid requiring the reporting of granular historical pricing data or administrative fee breakdowns, which add substantially to file size and complexity without contributing to a patient's ability to determine what a service will cost.[46]
- **Consumer-friendly display and internet-based price estimator tools.** CMS asks whether it should modify or eliminate the policy under which a hospital that maintains an internet-based price estimator tool is deemed to have met the consumer-friendly display requirements.[47] CHI recommends that CMS retain the deemed compliance policy but condition it. An estimator tool is, for most patients, a better experience than a list of

[43] HL7 FHIR SMART Application Launch Framework Implementation Guide, supra note 32.

[44] CMS Health Technology Ecosystem, supra note 3.

[45] 45 C.F.R. 147.210 and 147.212.

[46] CHI comments on the Prescription Drug Machine-Readable File Requirement in the Transparency in Coverage Final Rule, supra note 41.

[47] 45 C.F.R. 180.60.

shoppable services, and CMS should not discourage hospitals from offering one. An estimator whose outputs cannot be verified against the underlying data, however, gives a patient no way to check what they have been told. CHI recommends that CMS condition deemed compliance on the following:

  - The estimator must be populated from the same standardized data reported in the machine-readable file, so that its outputs can be reconciled against a public source.
  - The estimator must identify the ancillary and bundled items and services that are included in, and excluded from, the estimate it returns, in terms a patient can understand. A patient quoted a price for an imaging study who is not told whether contrast and the radiologist's interpretation are included has not been given a number they can use.
  - The estimator must be accessible without an account, a login, or a portal registration, and must be designed to recognized accessibility standards.
  - Where an estimate is generated or refined using automated or algorithmic methods, that should be evident to the patient, together with a plain-language statement of what the estimate does and does not commit the hospital to.

- **Shoppable services.** CHI recommends that any revision to the shoppable services list be aligned to the machine-readable file schema, so that a service appearing on the list is identifiable by the same codes and payer identifiers used in the file. CHI also asks CMS to consider whether the list is best expressed as a fixed enumeration or as a derived view of the machine-readable data, which would keep the two in agreement automatically and reduce the reporting burden associated with maintaining both.

VI. Conclusion

CHI appreciates the opportunity to submit these comments and urges CMS' thoughtful consideration of the input above. The proposals and requests for information in this rule raise the right questions, and the framework CMS builds for software-based medical services in the coming cycles will determine, for a long time, which validated technologies reach Medicare beneficiaries and which do not. We would welcome the opportunity to work with CMS and other stakeholders as the agency develops policy in response to these questions. Please do not hesitate to contact us with any questions.

Sincerely,

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