June 15, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0938-AV44
Submitted electronically via http://www.regulations.gov

Dear Administrator Oz:

The Workgroup for Electronic Data Interchange (WEDI) writes today in response to the "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges" (CMS-0062-P) proposed rule published in the April 14, 2026, edition of the *Federal Register*.

WEDI was formed in 1991 by then Department of Health and Human Services (HHS) Secretary Dr. Louis Sullivan to identify opportunities to improve the efficiency of health data exchange. Named in the Health Insurance Portability and Accountability Act (HIPAA) legislation as an advisor to the Secretary of HHS, WEDI is the leading multi-stakeholder authority on the use of health information technology (IT) to efficiently improve health information exchange, enhance care quality, and reduce costs. With a focus on advancing standards for electronic administrative transactions, and promoting data privacy and security, WEDI is recognized and trusted as a formal advisor to the Secretary. Our diverse membership includes health plans, providers, standards development organizations (SDOs), vendors, federal and state government agencies, and patient advocacy organizations.

WEDI supports and shares CMS's goals of leveraging health IT's advanced capabilities and functions to decrease burden and streamline processes to improve the quality of care while minimizing administrative costs. We applaud CMS's decision to tackle the challenge of expanding its existing effort to improve the interoperability and burden associated with prior authorization (PA) processes and requirements by including drugs. Setting a uniform set of standards for industry to adopt is a crucial step toward enabling the efficient exchange of health information and the automation of PA workflows.

To address this proposed rule, WEDI conducted a Member Position Advisory (MPA) event on May 19, 2026, convening over 140 individuals representing health plans, providers, clearinghouses, vendors, SDOs, and other intermediaries. Through surveys, interviews, and live events, the MPA process is designed to solicit WEDI member input on topical issues, public and private sector proposals, and government regulations. WEDI's MPA process has proven to be an effective method for gathering broad cross-industry perspectives and gaining consensus from the individuals who participate in the process.

Overarching Key Comments and Recommendations

WEDI's work is driven by the goal of easing administrative burden, putting patients at the center of their care, implementing consensus-based, mature standards that support automation, and maintaining appropriate safeguards for privacy, security, and confidentiality. WEDI broadly supports the direction and purpose of this proposed rule, and we applaud the work of CMS to improve health information exchange and reduce administrative burden for all stakeholders.

This proposed rule expands upon the CMS Interoperability and Prior Authorization final rule (CMS-0057-F) published on February 8, 2024, which WEDI generally supported. It emphasizes improving health information exchange and facilitating patient, provider, and payer access to health records. At the same time, it proposes improvements to PA processes with the goal of reducing burden and keeping patients at the center of their care.

WEDI's comments on this proposed rule are based on key guiding principles that are integral and essential considerations of any regulatory action. Specifically, meeting the goals of this proposed rule and the expected future CMS and Office of the National Coordinator for Health Information Technology (ONC) regulatory action requires that relevant stakeholders have ready access to several essential capabilities and functions. It is important to design a transition to automation that:

- Promotes seamless, automated data exchange through mature, clear, and unambiguous standards that have been thoroughly tested and demonstrate meaningful return on investment (ROI).
- Integrates the data exchange easily within the payer, provider, and other end-users' workflows.

1. Implementation Guide Versions

The challenge the government faces when naming specific versions of implementation guides (IG) in a proposed rule is balancing the need to name an IG that is established with the need to avoid having the industry adopt an outdated IG. This challenge is exacerbated with the protracted nature of the rulemaking process. **WEDI recommends that CMS, in collaboration with ONC, identify a "floor" for standards with identification of initial IG versions that support the functionality required by the final rule.**

With the potential of there being multiple versions of IGs, caution is needed to not permit the use of so many different versions of an IG that health IT developers, payers, and providers are

unable to support them. It is our understanding that organizations expect to support two versions during a transition period. There may occasionally be the potential need to support three versions at one time, but this must be for a short, limited amount of time due to the complexity involved. **We urge CMS to work with WEDI, the SDOs, and the broader industry to identify the appropriate number of IGs that the industry would reasonably be able and required to support.**

The following is one option of a process for adoption of updated published versions of each IG named in the regulation and subsequent incorporation into regulatory requirements:

- Where these updated versions are required to meet the final rule requirements, the updates shall be established as the floor and the timelines in the final rule should apply.
- Updated versions of IGs can offer enhanced functionality while maintaining backwards compatibility. Those organizations subject to the final rule can implement the enhanced functionality but they must do so in a manner compliant with the updated IG version. At the same time, the organization is required to support all functionality in the "floor" version of the standard. The "floor" requirement can be updated to a more recent version of the IG, but that must be done officially through government regulation. This approach prevents entities from being left behind in the push to the latest versions and functionality.

A second, and preferable, option would have CMS carefully review the availability of updated IGs throughout the rulemaking process and seek to name the most current version of the IG in the final rule. This will ensure the industry implements and takes advantage of the most up-to-date IG. Should the requirements of the most up-to-date IG differ significantly from what was proposed by CMS, the agency has the option of releasing an Interim Final Rule with Comment and solicit public input on the changes.

Fundamentally, the challenge is the pace at which standards and technology are changing. Each new standard version provides some added value and level of automation. The constantly moving needle and the number of systems that need to be updated is daunting for organizations. Being able to tie the value proposition between what is the floor and an updated version is critical. Organizations that see the value will understand the importance of moving to newer versions.

2. Expired vs. Unexpired Terms

This proposed rule introduces new concepts of "expired" and "unexpired" versions of standards and IGs into the regulatory framework. **WEDI requests that CMS provide additional clarification as to the meaning of these terms and whether they are based on regulatory policy or SDOs' development process.** If the terms have a regulatory policy meaning, CMS must provide guidance on how that policy mandate is applied for moving from expired to unexpired versions. If the terms are based on SDOs' development process, CMS should work with each one to identify the criteria for their determination of when a standard or IG is expired or unexpired and provide guidance for the industry related to the application of those criteria.

3. Cadence for Regulatory Updates

WEDI recommends that CMS identify a clear process for incremental, timely upgrades to newer versions of standards and IGs as they are determined to be ready for adoption. Interoperability should be viewed as a continual learning process, where standards mature over time necessitating a method for a regular cadence for ongoing updates that become smoother and more seamless over time.

Following the transition to a baseline set of standards, a known and predictable standards upgrade cycle is necessary, such as yearly or bi-yearly. Once the industry has successfully moved into an incremental schedule, changes to standards should be driven primarily by demonstrated value to the industry. This ensures that updates are meaningful, manageable, and aligned with real-world operational needs.

WEDI further suggests that HHS publish a consolidated implementation roadmap that maps the potentially overlapping regulatory requirements and compliance timelines into a single sequence for payers, providers, health IT developers, clearinghouses, and intermediaries.

Finally, **WEDI encourages CMS to work closely with appropriate industry stakeholders, including WEDI, to define and maintain the most effective cadence for standards implementation.** A collaborative approach will help ensure that the upgrade process remains practical, sustainable, and capable of supporting the ongoing evolution of interoperable, automation-enabled standards.

4. Naming Compliance Dates

WEDI has concerns about the naming of specific dates as compliance dates within this proposed rule. We believe compliance dates should be identified as a number of days or months after the effective date of the final rule. At the time of this proposed rule, it is unknown when a final rule will be published and whether the proposed timing will be appropriate. For example, if the final rule is not published until September 2027, it would be inappropriate for the proposed October 1, 2027, dates to stand. Impacted payers, vendors, and providers must be given sufficient time following the publication of the final rule to reasonably implement the requirements.

WEDI strongly recommends that CMS remove specific compliance dates in the final rule and instead identify compliance dates as a number of days or months after the effective date of the final rule.

5. Timing of Compliance Dates

Stakeholders have raised concerns about the timing of compliance dates that coincide with high-risk operational periods, e.g., January 1. The proposed compliance dates of January 1, 2028, overlap with yearly organizational system changes and demands that must be completed in the fourth quarter. Including changes of the magnitude proposed in this rule at the same time would be particularly challenging. Organizations would prefer to have major regulatory

implementations roll out at times that allow for more focus to mitigate issues and maximize success, such as during the second or third quarter. **WEDI recommends that CMS work with industry stakeholders to identify time periods when regulatory implementations would be best timed to prevent overlap with high-risk operational periods.**

6. Overlapping and Numerous Regulatory Requirements

There is significant concern across the industry regarding the timing and overlap of the many regulatory requirements that organizations are currently facing. While stakeholders may recognize the necessity and value of implementing these new technologies and functionalities, they are struggling with the ability to implement them all simultaneously while meeting aggressive compliance deadlines. The multiple major regulatory changes are creating considerable strain on resources, technology planning, and implementation timelines. The concern is not whether these efforts are worthwhile, but whether the industry can realistically execute them effectively within the proposed timeframes.

These requirements must be more than a compliance exercise as they are ushering in a broader shift toward more modern technologies that can reduce administrative burden, improve operational efficiency, and better support providers, payers, patients, and care teams throughout the patient care journey. It is critical for the industry to be aware of the long-term value of these investments and not approach them solely as “check-the-box” regulatory obligations. If implemented successfully, these modern capabilities have the potential to strengthen coordination between payers, providers, vendors, clearinghouses, and patients while improving the overall health care experience.

This transformation, however, also introduces uncertainty and complexity for all stakeholders. The implementation of new methods of data exchange requires substantial investments in technology, operational changes, and workforce readiness across the health care ecosystem. These challenges extend beyond payers to include vendors, clearinghouses, and providers that must also develop the technical capabilities needed to fully participate in the new environment. Without sufficient coordination, realistic timelines, and widespread adoption, the industry risks making significant investments without fully realizing the intended benefits and ROI.

We urge CMS, in collaboration with ONC, to coordinate mandates and compliance dates and develop a regulatory roadmap that ensures a smooth and effective glide path for all entities impacted by these requirements.

7. Education

There is a clear need for CMS to conduct comprehensive education and outreach on the various components of CMS-0062-P to ensure stakeholders fully understand both the policy requirements and the long-term operational benefits associated with their implementation. While there is already some education available across the industry, including education and online resources available from WEDI, on CMS-0057-F, which is the precursor to many of these proposals, CMS-led efforts will provide additional guidance and signal the significance of these requirements.

Education and communication initiatives by CMS should clearly promote the benefits of these technologies and standards in reducing administrative burden, improving operational efficiency, and improving the patient experience. It should also demonstrate how the policies and standards outlined in this proposed rule support broader health care modernization efforts and can ultimately streamline workflows for payers, providers, and patients. Providing practical implementation guidance, use cases, and coordinated stakeholder engagement opportunities would further help organizations prioritize adoption efforts and better align internal resources to support the successful implementation.

We recommend that CMS work with organizations like WEDI and others to disseminate up-to-date and actionable educational resources. We urge the agency to consider expanded resources for the CMS webpage, stakeholder-specific newsletter inserts, "open door" virtual forums, presentations by CMS officials at industry events, and other methods of communicating regulatory and implementation updates.

Specific Comments on the Proposed Rule

ePA FOR DRUGS UNDER PHARMACY BENEFITS (Page 19901)

***Proposal**: Require impacted payers to support ePA for drugs covered under a pharmacy benefit using unexpired versions of the National Council for Prescription Drug Programs (NCPDP) SCRIPT, NCPDP Real-Time Prescription Benefit (RTPB), and NCPDP Formulary & Benefit (F&B) standards in alignment with existing requirements for Medicare Part D sponsors with a compliance date of October 1, 2027.*

WEDI Comment:

The centerpiece of this proposed rule is the inclusion of electronic PA (ePA) for drugs under both the pharmacy benefit plan and medical benefit plans. WEDI fully supports the inclusion of ePA for drugs, as we emphasized in our comments on the CMS-0057-F proposed rule. We understand the importance of timely prescribing and filling of medications and the impact of delays on a patient's health and outcomes. We appreciate that CMS acknowledged the importance of adding ePA for drugs and we are optimistic about the benefits to come from this once these provisions are implemented by the industry.

The adoption and use of standards that facilitate real-time exchange of medication PA requests and responses will replace the often time-consuming manual processes between prescribers and pharmacists, along with improving patient care. When integrated into a pharmacy management system, ePA streamlines the approval process and patients can start their medications sooner, bringing increased patient satisfaction, improved adherence to medication regimens, and fewer visits to the emergency department.

WEDI supports the proposal to require impacted payers conduct ePAs for drugs covered under pharmacy benefits using the unexpired NCPDP SCRIPT, NCPDP RTPB, and NCPDP F&B standards. In addition to the overall benefits, the inclusion of ePA for drugs will align with current Medicare Part D requirements.

In discussions about the NCPDP standards, clarifications were made about the differences in the functionality of the NCPDP RTPB and NCPDP F&B standards. NCPDP representatives confirmed that both NCPDP RTPB and NCPDP F&B are necessary for conducting ePAs. The NCPDP F&B standard provides information to the prescriber at the plan level and allows the electronic health record (EHR) to present information for the prescriber to assess the individual's plan information. The NCPDP RTPB standard provides plan information specific to the individual's benefits, as well as formulary alternatives. Co-pay and other financial information available through the NCPDP RTPB standard are important for the individual as the drug is being prescribed. The two standards are complementary to each other, and it is important to maintain them and the information they provide for a workflow and efficiency perspective at the prescriber level. WEDI strongly supports the adoption of both the NCPDP RTPB and NCPDP F&B and not the NCPDP RTPB without the NCPDP F&B standard.

We are also aware there are times when the prescription is received by the pharmacy before the ePA is submitted. The pharmacist can initiate the ePA, in addition to the prescriber. The NCPDP SCRIPT standard supports notifying providers involved in that patient's care that an ePA has been requested, preventing duplicative requests for the same medication. This is added value to the NCPDP SCRIPT standard in supporting efficient and timely care for patients and an area where additional education on the functionality of the NCPDP SCRIPT standard would be greatly beneficial for prescribers and patients.

Additionally, the "Health Data, Technology, and Interoperability: Electronic Prescribing, Real - Time Prescription Benefit and Electronic Prior Authorization (HTI-4)" final rule updates the "electronic prescribing" certification criterion that supports the availability of certified health IT to enable the exchange of prescription information among prescribers, pharmacies, intermediaries, and payers. EHRs will be certified on real-time pharmacy benefits and ePA capabilities consistent with the NCPDP SCRIPT and NCPDP RTPB standards.

The value of the NCPDP RTPB standard has expanded to the patient as the understanding of the functionality of the standard has grown. While the NCPDP RTPB presents benefits for prescribers in the form of real-time workflows and patient cost information, patients have access to price transparency and cost information prior to arriving at the pharmacy. The NCPDP RTPB standard has the opportunity for better patient engagement and collaborative decision making, which can lead to better care delivery and patient outcomes. **WEDI recommends that CMS do more to educate, promote, and encourage prescribers and patients, in collaboration with NCPDP, on the benefits of the NCPDP RTPB standard, as the value of the transaction goes well beyond conducting drug ePAs.**

UPDATE TO HEALTH IT STANDARDS (Page 19906)

Proposal*: Require impacted payers to support updated versions of standards adopted in 45 CFR 170.215, including CARIN for Blue Button® IG, Payer Data Exchange (PDex) IG, PDex Plan Net IG, PDex U.S. Drug Formulary IG, Coverage Requirements Discovery (CRD) IG, Documentation Templates and Rules (DTR) IG, and Prior Authorization Support (PAS) IG with a compliance date of October 1, 2027.*

WEDI Comment:

WEDI has no specific comments on the proposed requirement for impacted payers to support the CARIN IG for Blue Button®, PDex, PDex Plan Net, PDex U.S. Drug Formulary, CRD, DTR, and PAS IGs.

We are aware that the PDex STU 2.2.0 has been approved for publication and will include the new Provider Access (v2). As it is the most current version of PDex, **WEDI recommends that CMS consider it for adoption in the final rule, if 2.2.0 is finalized prior to the publication of this final rule. If PDex STU 2.2.0 is not adopted in this final rule, it should not be allowed until future rulemaking naming the standard is promulgated.**

ePA FOR DRUGS UNDER MEDICAL BENEFIT (Page 19923)

Proposal*: Require impacted payers to support ePA for drugs covered under a medical benefit through the: (i) CRD IG Version 2.0.1—STU 2, proposed to expire on January 1, 2028, or Version 2.2.1—STU 2.2; (ii) DTR IG Version 2.0.1—STU 2, proposed to expire on January 1, 2028, or Version 2.2.0—STU 2.2; and (iii) PAS IG Version 2.0.1—STU 2, proposed to expire on January 1, 2028, or Version 2.2.1—STU 2.2 with a compliance date of October 1, 2027.*

WEDI Comment:

WEDI recommends the proposal to require impacted payers conduct ePAs for drugs covered under medical benefits using the CRD, DTR, and PAS IGs be finalized. While most drugs are covered under a patient's pharmacy benefit plan, some drugs are covered under the patient's medical benefits, which is why it is important to adopt standards for ePA and prevent gaps in the ability to conduct ePAs. The adoption of standards for ePA for drugs, as discussed above, will improve patient care, as well as benefit prescribers, pharmacists, and health plans.

Drugs covered under the medical benefit are often expensive, as they are typically specialty medications that treat serious health conditions, such as oncology and autoimmune diseases. Care delays can impact a patient's health and outcomes. We appreciate that CMS acknowledged the importance of adding ePA for drugs and we are optimistic about the benefits to come from this once these provisions are implemented by the industry.

Action has already been taken by some stakeholders to implement the technology and functionality to conduct ePAs for drugs. One WEDI payer member shared that they had already begun incorporating medical-benefit drugs in their ePA processes and have already started looking at the adoption of the CRD, DTR, and PAS IGs. Another WEDI vendor member shared that many of its payer clients are already exploring how best to implement drugs under the medical benefits inside of their ePA solutions.

With respect to the proposed versions of standards for the CRD, DTR, and PAS IGs, we are aware that the Health Level Seven (HL7®) Da Vinci Project started working on this burden reduction suite of IGs in 2019. They have gone through cycles involving gathering requirements, building the specifications, testing and piloting the IGs, and applying the lessons learned to

further mature them. Our understanding of Da Vinci's position is to have IGs recommended until there is enough maturity to require them. Through an extensive effort in 2025, Da Vinci made significant updates and refinements to the versions recommended for adoption in CMS-0057-F, resulting in CRD Version 2.2.1, DTR Version 2.2.0, and PAS Version 2.2.1. These IGs have gone through Connectathon testing, HIPAA exception testing, and operational pilots and deployments. These versions proposed to move forward as required IGs represent the most up-to-date work. **WEDI suggests that CMS continue working with HL7 and impacted industry stakeholders to ensure the most appropriate versions of the CRD, DTR, and PAS IGs are advanced.**

CMS should also consider convening a multi-stakeholder initiative, including providers, payers, pharmacies, PBMs, EHR developers, pharmacy standards experts, HL7 Da Vinci participants, NCPDP, patient representatives, and other appropriate stakeholders to discuss nationally consistent guardrails for routing drug PA requests.

Specific to this proposal, **WEDI requests that CMS increase its education and outreach efforts to target smaller and mid-size health plans to support them in their work to implement these requirements.** We understand that this type of work, even with vendor support, is onerous for smaller, less-resourced organizations, including state Medicaids.

REASON FOR DENIAL OF DRUG PA (Page 19933)

Proposal*: Require impacted payers communicate to providers a specific reason for denying PA requests for all drugs regardless of the format the PA request was made with a compliance date of October 1, 2027.*

WEDI Comment:

WEDI supports the proposed requirement for impacted payers to report to the prescriber the specific reason for the denial of a PA request for all drugs regardless of the format the PA request was made. NCPDP maintains standard denial reason codes and reporting of them is accommodated in the NCPDP standard. Reporting the specific denial reasons are significant for the ordering prescriber, as well as the patient, to understand what the next step will be in the patient's drug treatment. Knowing why a medication PA request was denied helps them to appeal the decision or determine another course of treatment.

During WEDI's discussion of this proposal, the potential to move this compliance date to earlier than October 1, 2027, was raised, since there is no specific technical capability that needs to be implemented to support this requirement. Health plans did express concerns with this suggestion. While the specific technical changes for this requirement may not be as substantial as other proposals, the volume of changes that will be necessary for this proposal in conjunction with other regulatory requirements needs to be accounted for in setting this compliance date. As discussed above, the industry would benefit from a coordinated glide path that identifies the numerous regulatory requirements and operational changes necessary to accomplish them and coordinate the compliance dates accordingly.

To balance both providers' and payers' needs, **WEDI requests that CMS strongly encourage payers to begin reporting PA denial reasons for drugs as soon as they can.** Additionally, **WEDI recommends that CMS further engage with stakeholders on the question of the minimum amount of time needed for implementation of various regulatory requirements, including system changes, technical capabilities, and code value updates.**

TIMEFRAMES FOR DRUG ePA DECISIONS (PAGE 19934)

Proposal*: Require state Medicaid FFS, state CHIP FFS, Medicaid managed care plans, and CHIP managed care plans return drug ePA decisions not later than 24 hours after receipt of the request and QHP issuers on the Federally-Facilitated Exchanges (FFEs) return standard ePA requests not later than 72 hours and expedited requests not later than 24 hours after the request with a compliance date of October 1, 2027.*

WEDI Comment:

WEDI has no specific comments on the proposed timeframes in which the impacted payers would be required to return a drug ePA decision.

The need for real-time PA for acute patients being discharged from the hospital was identified by WEDI members as a critical part of care coordination. In some cases, for a patient to be discharged home or to a lower cost care setting, prescriptions must be provided to the patient. Getting an ePA decision synchronized with the discharge, especially on the weekend, can be difficult and if unable to be completed, can result in the patient remaining in the hospital. **WEDI requests that CMS further explore this scenario and identify actions that can be taken to better support ePA for patients based on the site of care or patient admission status.**

PA REPORTING METRICS FOR NON-DRUGS (Page 19940)

Proposal: *Require impacted payers publicly report on their website revised and new PA metrics for non-drug items and services effective the date of the final rule with varying reporting deadlines by payer type.*

WEDI Comment:

WEDI supports these proposed revised and new metrics for impacted payers to report on their processed PA requests and decisions for non-drug items and services. We agree that reporting a total number with the percentage will give users better information about the data. This richer data will better enable patients to analyze their payer to understand their own requests or when considering changing health plans. For example, seeing the total number and percentage of PA requests approved, denied, and approved after appeal will be valuable to patients as they consider their own health needs.

While these metrics are good, we believe there are more that could be reported to give patients even greater detail that could support their own health care needs. One example is to have separate total numbers and percentages for the service level, or category of services. For a patient with a certain health condition considering a new health plan, knowing a health plan's PA

metrics for a service, or drug, category relevant to that disease is important. A patient expecting to undergo a knee replacement would be better informed seeing that 95% of 1,000 PA requests for joint replacements were approved, instead of 95% of 1,000 all PA requests were approved.

Another metric that would be useful for CMS and industry stakeholders would be the number of PA requests that were satisfied after the CRD or DTR inquiry, and how many required the PAS submission. These numbers could demonstrate actual burden or burden reduction, as completing an inquiry at the CRD or DTR point saves time and effort for the provider and payer.

Another metric that could identify burden or burden reduction would be to measure the number and percentage of PA requests that are submitted using the CRD, DTR, and PAS IGs vs. portals, faxes, and phone. This information would again be especially useful for the industry and CMS as it continues to drive change through regulatory policies.

WEDI recommends that CMS explore additional metrics that can provide more detailed information for patients and the industry for understanding PA needs and burden reduction. CMS should review the metric sections of the CRD, DTR, and PAS IGs for additional information on potential new metrics.

IMPACTED PAYERS (PAGE 19949)

Proposal*: Include small group market Qualified Health Plans (QHPs) on the Federally-facilitated Small Business Health Options Program (FF-SHOP) Exchanges.*

WEDI Comment:

WEDI has no specific comments on the proposal to expand the "impacted payers" by adding QHPs participating in the FF-SHOP. Broadening the number of impact payers and increasing the number of individuals who will benefit from the technologies and efficiencies proposed in this rule is significant.

We, however, remain concerned that requiring only some health plans to implement these proposed requirements creates the fragmentation that HIPAA was enacted to eliminate. Consequences of this bifurcation are: (i) provider confusion as to payers' different standards and requirements based on their status as an impacted payer and (ii) lack of adoption of the proposed standards and technology due to not wanting to maintain different standards and workflows for the payers with which they interact.

Many payers are implementing the interoperability and PA requirements previously finalized in CMS-0057-F across all lines of business, as a result of the June 2025 voluntary commitment[1] by 57 health plans to streamline and simplify PA. WEDI commends this important commitment and believes it will close much of the gap between impacted payers and non-impacted payers, but we anticipate that some confusion will remain.

[1] https://ahiporg-production.s3.amazonaws.com/documents/202506_AHIP_Report_Prior_Authorization.pdf

WEDI requests that CMS encourage adoption of the interoperability and PA requirements proposed in this rule and the finalized requirements in CMS-0057-F by non-impacted payers through its various levers. CMS can accomplish this by promoting the benefits of these technologies and standards in reducing administrative burden, improving operational efficiency, and improving the patient experience.

PAYER REPORTING OF API ENDPOINTS (Page 19957)

Proposal*: Require impacted payers submit to CMS their application programming interface (API) endpoints for each interoperability API for CMS to publish in a centralized location. Alternatively, impacted payers would be required to report all National Directory of Healthcare Providers & Services Implementation Guide (NDH IG) Endpoint Profile compliant resources containing relevant information for each interoperability API. The compliance date would be 60 days after the effective date of the final rule.*

WEDI Comment:

WEDI supports the proposal for impacted payers to report their API endpoints to CMS to be published in a centralized location. We are also aware there have been multiple iterations of the NDH IG and it is currently published and available for use. In developing an endpoint directory, CMS should consider including a process for the reporting of endpoint failures, outside of the proposed requirement for impacted payers to update any changes to endpoints within one week and verify the information annually. Users of the endpoints may encounter failures that the impacted payer may not be aware of. Having a reconciliation process to ensure that failing or error prone endpoints are identified and are addressed in a timely manner will strengthen the directory and ensure its success.

WEDI suggests that CMS continue working with impacted payers and payer associations on the development and implementation of a national endpoint directory. We urge the agency to reduce the administrative burden associated with reporting and managing endpoint information. In addition, we urge the agency to work with impacted stakeholders to ensure the needs of end users are achieved.

WEDI also encourages CMS to consider the option of including a metric on the reporting of endpoints.

API USAGE METRICS (Page 19969)

Proposal*: Requiring impacted payers report to CMS or states, depending on payer, specific API usage metrics identified in the proposed rule beginning in 2028 for the 2027 reporting period with varying deadlines based on payer requirements.*

WEDI Comment:

WEDI supports the proposal for impacted payers to report to CMS or states specific API usage metrics as identified in the proposed rule. These metrics will provide value in understanding which APIs are being used and how frequently they are being used. Pairing these metrics with

additional information could identify if the APIs are leading to fewer manual workflows and overall reducing burden.

Specific to the metrics, the following questions would be helpful for CMS to address:

- What is the definition of a unique provider when a provider could be in a group practice or organization?
- How do the metrics address multiple PA requests with one PAS response where one or more services may be approved and one or more are denied? We are aware that the PAS IG has the capability for line-item approvals, but will the approvals and denials in a single PAS response be parsed when reporting the data in the metrics?

Finally, **WEDI encourages CMS to publicly report API usage and performance metrics in a way that provides usable information for patients.**

DRUG FORMULARY IN PROVIDER AND PAYER-TO-PAYER APIs (Page 19974)

***Proposal**: Remove drug formulary information as data impacted payers are required to make available via the Provider Access and Payer-to-Payer APIs effective the date of the final rule.*

WEDI Comment:

WEDI supports the proposal to remove drug formulary information as data impacted payers are required to make available via the Provider Access and Payer-to-Payer APIs. Additionally, **WEDI recommends that the Drug Formulary be made an open API.**

PROVIDER DIRECTORY API (Page 19975)

***Proposal**: Require impacted payers to update their Provider Directory APIs denial or discontinuation policies effective the date of the final rule.*

WEDI Comment:

WEDI has no specific comments on the proposal to require impacted payers to update their Provider Directory APIs' denial or discontinuation policies effective the date of the final rule. **We do recommend that the Provider Directory API be an open API.**

STANDARDS FOR AUTHORIZATIONS (Page 19986)

***Proposal**: Require adoption of the HL7 Fast Healthcare Interoperability Resources (FHIR®), US Core IG, SMART App Launch IG, CRD IG, DTR IG, and PAS IG standards for ePA transactions, replacing the current X12 Request for Review and Response (278) transaction applying to all HIPAA covered entities with a compliance date of 24 months after the effective date of the final rule, and 36 months for small health plans.*

WEDI Comment:

WEDI supports the proposal to adopt the HL7 FHIR, US Core IG, SMART App Launch IG, CRD IG, DTR IG, and PAS IG standards for ePA transactions, replacing the current X12 278 transaction for all HIPAA covered entities with a compliance date of 24 months after the effective date of the final rule, and 36 months for small health plans. **WEDI requests that CMS take into consideration aligning the timing of this requirement with any potential compliance date in future rulemaking on the adoption of the X12 Version 008060 transaction standards.**

WEDI also requests clarification regarding whether replacing the X12 278 with the FHIR APIs would require all "covered entities" defined in HIPAA to support the FHIR APIs. If all HIPAA covered entities are required to conduct ePA using FHIR APIs, **we urge the agency to work with impacted stakeholders to ensure a smooth transition is achieved**. Similarly, we ask that CMS provide clarification that in finalizing this proposal the requirement to conduct ePAs for drugs covered under medical benefits will apply to all HIPAA covered entities, not just impacted payers, once the compliance date is reached.

STANDARDS FOR REFERRAL CERTIFICATION (Page 19986)

Alternative Proposal*: Require adoption of the HL7 FHIR, US Core IG, SMART App Launch IG, CRD IG, DTR IG, and PAS IG standards for request and response to obtain a referral certification, replacing the current X12 278 transaction by all HIPAA covered entities with a compliance date of 24 months after the effective date of the final rule, and 36 months for small health plans.*

WEDI Comment:

WEDI heard the following points of view from our members on this alternative proposal to require adoption of the HL7 FHIR, US Core IG, SMART App Launch IG, CRD IG, DTR IG, and PAS IG standards for request and response to obtain a referral certification, replacing the current X12 278 transaction.

- *The PA APIs do support the referral use case and referrals are typically less intensive to process by the payer. If implementing the PA APIs for PA, the technology is available to conduct the referral request and response.*
- *The X12 278 is currently very functional for both the providers and payers that use it.*
- *There will be some amount of disruption and implementation effort for organizations currently using the X12 278 for referrals to switch to the PA API. How much effort to complete that switch is unknown at this time.*
- *Having two standards for the same transaction is not optimal, and in this case would require payers to support and maintain two standards.*
- *The implementation and use of the X12 278 is in some cases very good, and in some cases inconsistent.*
- *Given that the PA API IGs support both PA and referrals, it seems reasonable to move forward with this alternative proposal.*

- *For smaller and less-resourced organizations with limited experience with FHIR, a slower transition to a new standard, allowing for more time to update workflows, would be better before mandating a replacement of the existing standard. Otherwise, these organizations are likely to change back to manual or direct data entry workflows.*
- *For providers that use a solution for referrals that is outside of the EHR, there would be the potential for financial burden to either change solutions or engage with a vendor that can convert their existing X12 278 into the PA API for submission.*

Given these varying points, **WEDI recommends that CMS not finalize this alternative proposal at this time and conduct additional outreach with stakeholders prior to finalizing any plan for addressing the referral standards.**

ELIGIBILITY FOR A HEALTH PLAN (19986)

Proposal*: Require adoption of the HL7 FHIR, US Core IG, SMART App Launch IG, and CRD IG standards for the health care eligibility inquiry and response when used to determine if a PA is required, replacing the current X12 Health Care Eligibility Benefit Inquiry and Response (270/271) transaction by all HIPAA covered entities with a compliance date of 24 months after the effective date of the final rule, and 36 months for small health plans.*

WEDI Comment:

WEDI heard from our members the following questions and points of view on this proposal to require adoption of the HL7 FHIR, US Core IG, SMART App Launch IG, and CRD IG standards for the health care eligibility inquiry and response when used to determine if a PA is required, replacing the current X12 270/271 transaction and applying to all HIPAA covered entities.

- *How does using the CRD IG for eligibility improve on the current workflow and functionality of the X12 270/271? Is there something in the CRD process that is essential for PA notification that is not available in the X12 270/271?*
- *There is the potential for confusion about when an eligibility inquiry is being done just to determine if a PA is needed vs. when checking for eligibility information.*
- *Additional clarification and guidance will be needed to understand when to use which standard.*
- *How will the requester know when to use the HL7 standards vs. the X12 standard?*
- *If the requester submits an X12 270 for a general eligibility inquiry and the health plan identifies that a PA is required, along with the other benefits information, can the health plan return the information about the need for a PA in the X12 271 or would that be considered a HIPAA violation?*
- *Submitting an X12 270 to inquire about the need for a PA is a subset of the overall scope and purpose of the transaction and information returned in the X12 271.*
- *If this proposal is finalized, there will be two standards for conducting a similar transaction. Having multiple ways to do the same function across different payers will be burdensome and costly.*
- *Smaller and less-resourced organizations do not benefit from economies of scale during these changes and may struggle to upgrade to FHIR-based capabilities. What cost*

burdens will these organizations incur in being required to switch from the X12 270/271 to the CRD IG and what is the ROI for them?

- *A thoughtful approach to changing any existing standard, especially one that is foundational and widely used, to a new standard is necessary.*
- *Regardless of the size or abilities of organizations, the industry needs to find a balance between moving forward with new technology and not leaving organizations behind in terms of what they are able to support.*
- *In creating different workflows and standards between public programs and commercial health plans, are we driving providers away from participation in public programs because of the burden of meeting separate requirements?*
- *What role could ONC EHR certification play in supporting this change and ensuring that providers' systems can support the CRD IG for eligibility PA requests?*

Based on these questions and concerns, **WEDI recommends that CMS not finalize this proposal at this time and conduct additional outreach with stakeholders** to further explore the: (i) functional differences between the X12 270/271 and CRD IG, and how the CRD IG is an improvement from the current X12 270/271; (ii) benefits gained from replacing the X12 270/271 with the CRD IG; (iii) cost burden for the industry to switch from the X12 270/271 to the CRD IG; (iv) clarification needed by the industry on when to use the X12 270/271 vs. the CRD IG; and (v) guidance and educational resources needed by CMS to support the industry in successfully transitioning to the CRD IG for PA inquiries and responses.

ATTACHMENTS FOR ePA AUTHORIZATIONS AND REFERRALS (Page 19995)

Proposal*: Require adoption of HL7 FHIR Da Vinci Clinical Data Exchange (CDex) IG by all HIPAA covered entities to exchange files in various formats with a compliance date of 24 months after the effective date of the final rule and 36 months for small health plans.*

WEDI Comment:

WEDI supports the adoption of the CDex IG for the purpose of exchanging files for PA attachments by all HIPAA covered entities with a compliance date of 24 months after the effective date of the final rule and 36 months for small health plans.

In naming a standard for submitting additional information to support a PA request, CMS needs to emphasize that attachments are to be used only when there is additional documentation needed by the payer that was not submitted in the DTR IG. The DTR is a questionnaire intended to pull data systematically from an EHR to populate the questionnaire for a response, eliminating human intervention from the process. The CDex IG is used after that point when the PAS request is being processed and the DTR did not provide enough information to support the final processing of the PAS.

The CDex IG cannot be used as a substitute for DTR. The concern is not to create two different methods for submitting additional documentation and allowing organizations to choose which method they want to use. The overwhelming majority of supporting information should be submitted through the DTR IG questionnaire. Any need for the use of CDex should be limited to outliers, such as answering a question that came up after review of the DTR response. The PAS

IG explains the methodology of sequencing the CRD, then DTR, and then submitting the PAS. If the payer needs additional documentation that was not provided or requested at the DTR stage, that is the use case for submitting attachments, i.e., CDex.

WEDI requests that CMS provide guidance on the differences between the DTR and CDex IGs for the submission of information to support a PA request. CMS may also want to consider a metric identifying the number of attachment requests made with each PA request to monitor the use of CDex vs. DTR.

Direct Data Entry (Page 19999)

Request for comments on the current exception allowing HIPAA covered entities to use direct data entry.

WEDI recommends the continued exception for direct data entry (DDE) should be maintained for HIPAA covered entities for two important reasons. The first is to serve as a redundant administrative transaction option in the event of a cybersecurity incident, system outage, or other disruption to normal electronic data exchange channels. As health care organizations face increased risks of cyberattacks, having a backup, alternative method for administrative transactions preserves continuity of patient care and business operations when automated systems, clearinghouses, or other network connections are unavailable.

This secure fallback allows providers to continue conducting essential transactions with health plans, reducing delays in care, payment disruptions, and administrative backlogs during emergency situations. The expectation would not be to require organizations to build an alternative input method for security and disaster recovery planning alone. The point is to allow a DDE or portal option that a payer or vendor already has in place to be retained as part of their disaster recovery plan. Preserving the DDE exception strengthens the overall resilience of the health care ecosystem by providing an important layer of operational redundancy, when needed, that benefits providers, payers, and patients.

The second need for maintaining the DDE option is for small, rural, and low-volume providers. Requiring all providers to submit transactions through a clearinghouse or implement fully automated electronic transaction capabilities would impose disproportionate costs on organizations that may process only a limited number of transactions with certain payers.

For many small physician practices, rural providers, critical access hospitals (CAHs), and other resource-constrained providers, the expense of purchasing, implementing, maintaining, and upgrading software systems or incurring the expenses of a clearinghouse or intermediary outweighs the benefits of automation when transaction volumes are low. The DDE exception gives these providers a practical, cost-effective means of participating in electronic administrative processes without creating undue financial or operational burdens. Without the DDE option, they may drop to a more manual process of paper and traditional mail slowing the transaction exchange and most importantly, impacting care delivery for patients.

In addition, some providers may see only a small number of patients covered by a particular payer each year, such as vacation area providers. In these circumstances, investing in

dedicated connectivity, software development, testing, and maintenance for a specific payer is often not economically justified. DDE allows these providers to continue serving patients with any payer while maintaining compliance with administrative requirements. Eliminating the exception could create barriers to participation, particularly in underserved and rural communities where providers already face significant workforce and financial challenges. Other benefits of DDE include the ability for providers to make quick corrections on claims that may have been submitted with errors and view claim results before the remittance transaction is received.

The DDE exception also benefits payers by providing a mechanism for receiving transactions from providers that otherwise might be unable or unwilling to establish full electronic connectivity. By offering a DDE option, payers can reduce the number of paper-based submissions, phone calls, and manual inquiries that are more costly and less efficient to process. DDE serves as an important bridge that supports broad provider participation, improves data quality compared to non-electronic alternatives, and helps ensure that administrative transactions can be completed even when transaction volumes do not justify more sophisticated technical integrations. Maintaining this flexibility supports both provider access and operational efficiency across the healthcare ecosystem. Again, DDE is a choice, not a requirement, and should continue to be allowed.

To shift more providers from DDE to direct connections, CMS could encourage providers through various incentives, such as credit in CMS quality programs, tax incentives, etc., while continuing to allow the use of DDE. CMS should also evaluate the following potential options:

- Development of an all-payer portal to decrease the burden on providers in managing various payers' portals.
- Adoption of the X12 Implementation Acknowledgement (999) and Technical Acknowledgement (TA1) to create a more complete set of HIPAA transactions and support full-spectrum data exchange, as an alternative to DDE portals.
- Creation of a CMS Innovation Center pilot on integrating EHRs and portals for transactions that require the inclusion of clinical data.

Requests for Information

#1: ELECTRONIC EVENT NOTIFICATIONS FOR VALUE-BASED CARE AND CARE COORDINATION (PAGE 20006)

WEDI supports CMS's goal of improving the timeliness, utility, and reach of electronic event notifications. Current CMS policy already establishes a national floor: hospitals, psychiatric hospitals, and CAHs with systems conformant to the applicable content exchange standard must send notifications at emergency department (ED) registration or inpatient admission and at ED and inpatient discharge or transfer, and the notifications must include at least the patient name, treating practitioner name, and sending institution name. CMS guidance also makes clear that hospitals should make every attempt to notify applicable post-acute providers and identified responsible practitioners, may notify additional entities, such as those identified through Accountable Care Organization (ACO) attribution lists, may use intermediaries, and

may implement the requirement using HL7 messaging, Consolidated Clinical Document Architecture, or FHIR-based APIs; fax is not considered an acceptable electronic exchange method in this context.

WEDI believes CMS should now build on that floor in a phased and practical manner. The policy direction should be to standardize the signal, improve recipient discovery and attribution, support more modern technical approaches over time, and avoid turning event notifications into high-burden document exchanges.

WEDI further recommends that CMS frame patient electronic event notifications as a patient safety and continuity-of-care function, not merely as an administrative requirement. The policy objective should be to ensure that timely, standardized, system-generated, and clinically actionable information reaches the care teams patients rely on during vulnerable transitions, particularly patients with complex, progressive, disabling, or chronic conditions.

WEDI also encourages CMS to treat event notifications as cross-sector care coordination infrastructure. The policy should recognize that timely event data may be needed not only by hospitals and primary care practices, but also by payers, ACOs, post-acute and long-term care partners, behavioral health providers, emergency medical services (EMS) and community paramedicine, pharmacists, and other authorized care team members who can act on that information to support safer transitions, medication access, and value-based care performance.

Use and Content of Patient Event Notifications

With respect to the questions on use and content, WEDI's view is that many hospitals are already sending more than the current minimum where their EHR, health information exchange (HIE), or intermediary workflow supports richer admission, discharge, and transfer (ADT) content, but implementation remains uneven. The market is still largely anchored in HL7 v2 ADT workflows, and in practice some ADT messages are not received timely, may route through multiple intermediaries, or may lack critical information needed to make the alert actionable. ONC's data brief on health information organization (HIO) standards adoption shows that a majority of HIOs reported routinely receiving HL7 v2 ADT messages, while only a small portion reported routinely using HL7 FHIR APIs to receive and send data or make data available.[2]

Accordingly, WEDI recommends that CMS standardize a modest "core payload" beyond today's minimum, while preserving flexibility for richer optional content where available. That core payload should include, at a minimum, the event type, event date and time, encounter location, admission, transfer, discharge, or ED status, sending facility, receiving facility if known, discharge destination if available, responsible contact if available, and a concise clinical context field, such as chief complaint, reason for visit, or reason for hospitalization. CMS should also encourage standardized indicators for high-risk transitions, such as recent ED visits, unplanned admission, complex chronic condition, medication access risk, or other risk flags that can be generated without new manual clinician documentation. CMS should also encourage inclusion of a pointer, query pathway, or link to richer clinical content, such as a discharge summary or medication-related transition information, where available, rather than requiring the full clinical

[2] Standards Adoption Among Health Information Exchange Organizations. October 2024. ONC Health IT. https://healthit.gov/data/data-briefs/standards-adoption-among-health-information-exchange-organizations/

content to travel in the notification itself. WEDI does not recommend that CMS convert event notifications into a substitute for a full transition-of-care record.

To operationalize this approach, CMS should consider a “core plus” framework. The core payload should include a nationally consistent set of required elements that can be generated from existing registration, ADT, and discharge workflows. CMS should also define optional standardized extensions that support complex or chronic care coordination, medication management, and other high-value transition needs without mandating condition-specific disclosures or converting event notifications into full transition-of-care documents.

CMS should specifically consider medication-related care coordination as a high-value optional extension. Discharge events frequently create medication access, PA, and adherence risks. When permitted by law, consistent with patient preferences, and technically available, notifications should be able to route to authorized pharmacists or pharmacies and/or include or link to discharge medication, medication reconciliation, coverage or PA status, and prescription fill-status information. CMS should not mandate all these elements as part of the base notification but should encourage standards alignment so pharmacy-related status information can be queried or subscribed to by appropriate EHR, pharmacist, payer, and care management workflows.

WEDI also recommends that CMS continue to permit multiple standards-based implementation paths in the near term. Given the state of the market, HL7 v2 ADT should remain a viable compliance path. At the same time, CMS should signal the long-term direction of travel by encouraging implementation approaches that support greater standardization, filtering, subscription management, recipient-specific delivery logic, and the ability to query more relevant and timely information when an event occurs. CMS has already recognized technical flexibility in this area, and WEDI believes that flexibility should be preserved while the market matures.[3]

The principal challenges with standardizing patient event notifications are not limited to message syntax. They include uneven data availability at the moment the alert is triggered, inconsistent recipient directories, variable attribution files, differing privacy and consent workflows, limited post-acute, pharmacy, payer, and community-based recipient readiness, and the cost of upgrading production interfaces. These challenges are likely to be greatest for rural hospitals, CAHs, rural emergency hospitals, and other resource-constrained providers. For that reason, CMS should phase in any new required data elements, begin with a narrow core payload, and avoid imposing manual clinician documentation steps to support compliance.

WEDI also emphasizes that common data standards, while necessary, are not sufficient on their own. Transitional care depends on many different actors, including acute care, post-acute care (PAC), long-term services and supports (LTSS), and behavioral health providers, intermediaries, payers, and community partners. These entities are often fragmented or disconnected, and technical standards will not achieve their intended impact unless they are paired with practical workflow, governance, and routing guidance.

[3] https://www.cms.gov/files/document/faqs-interoperability-patient-access-and-cop-event-notifications-may-2021.pdf

If CMS does require additional data elements, burden should be mitigated through automation. WEDI recommends that any future requirements be limited to data that already exists in registration, ADT, or discharge workflows and can be auto populated. CMS should avoid requiring clinicians to enter free text specifically to satisfy an event notification requirement. The right policy standard is that the alert should be generated from existing operational data, not from new manual work.

CMS should also address the avoidable burden created when hospital staff must pull information from the EHR, copy it into a discharge note, and then transmit it by telephone, fax, or other manual process to downstream partners that must re-enter the same information into their own systems. Future policy should prioritize curated, relevant, machine-generated information and simplified workflows that reduce duplicative entry, data degradation, and delays in connecting patients to needed support.

Technology should also support filtering and configuration so clinicians and care teams can turn notifications on or off, suppress duplicative alerts, and receive only clinically relevant categories of notifications consistent with their role and workflow. This is particularly important if CMS encourages medication-related or pharmacy-status notifications; these can be highly valuable for transitions of care, but they should be configurable and targeted to avoid unnecessary alert fatigue.

WEDI also agrees that privacy and governance considerations are significant. CMS should preserve the existing framework that notifications must be sent only to the extent permitted by federal and state law and not inconsistent with the patient's expressed privacy preferences. CMS should also issue additional operational guidance for sensitive data scenarios, particularly behavioral health and other specially protected information. CMS's current guidance already recognizes patient refusal and requires that a refusal be documented; that principle should remain central as CMS considers richer notification content.[4]

Expanded notification content should be governed through patient-centered trust mechanisms, including clear authorization pathways, role-based and purpose-specific access, transparent patient preference management, and protections against unnecessary or stigmatizing disclosures. CMS should reinforce that privacy safeguards and broader notification utility are complementary goals: patients are more likely to support information sharing when it meaningfully improves care coordination and outcomes.

Finally, WEDI supports more explicit process guidance on recipient directory quality, including expectations for onboarding, updates, corrections, removals, verification, and stale record remediation. The quality of a notification is only as strong as the quality of the recipient directory and endpoint information behind it.

Types of Providers and Entities Receiving Patient Event Notifications

With respect to the questions on recipients, WEDI believes ACOs and payers that receive notifications today generally do so through HIEs, regional or national intermediaries, direct HL7

[4] https://www.cms.gov/files/document/qso-21-18-hospitals-cahs.pdf

feeds, or vendor-supported notification services. Where implemented well, those notifications are used meaningfully for care management, discharge follow-up, avoidance of duplicate testing, medication reconciliation, benefit navigation, and timely outreach after an acute event.

For payers, notification use should not be framed narrowly as administrative oversight. In value-based care, payers may have member-level care management responsibilities, delegated care coordination functions, post-discharge support programs, pharmacy and medication access support, transportation or LTSS coordination, and quality improvement obligations that depend on timely knowledge of hospitalization, discharge, and transfer events.

Recent published experience supports that view. In a 2025 JAMA Network Open qualitative study, care managers in an ACO-supported ED response program received electronic notification when an attributed patient registered in the ED and used the alert to provide real-time, structured clinical information to the ED team; the study evaluated the operational strengths and weaknesses of that model and illustrates that event notifications can be used meaningfully in value-based care workflows.[5]

WEDI recommends that CMS clarify, rather than narrow, the set of recipients that may appropriately receive notifications. CMS's interpretive guidance already states that hospitals are expected to make every attempt to notify applicable post-acute providers and identified responsible practitioners and also notes that the requirement does not limit a hospital's ability to notify additional entities based on hospital policy, including those identified through ACO attribution lists. WEDI supports building on that principle. CMS should expressly confirm that authorized ACOs, other entities participating in value-based arrangements, payers, pharmacists, and other care team participants with a legitimate treatment, care coordination, medication management, or quality improvement role may be appropriate recipients where permitted by law and consistent with patient preferences.[6]

WEDI believes CMS should prioritize recipients in tiers. The highest-priority expansion categories are post-acute providers, home health, hospice, behavioral health providers, accountable entities in value-based arrangements, payers supporting active care management, and pharmacists or pharmacies involved in transition-related medication management. CMS may also wish to encourage notifications to EMS, community paramedicine partners, and social service organizations in targeted use cases, but WEDI would not broadly mandate all recipient categories at this time because recipient readiness, privacy governance, endpoint availability, and workflow integration are still uneven. CMS should avoid defaulting eligibility for notifications solely to primary care, payer, or attribution-based arrangements when those categories do not reflect the care teams that patients with complex needs actually rely upon.

At the same time, CMS should explicitly recognize that effective patient-centered care often extends beyond hospitals, ACOs, and primary care. Policies and guidance should support routing, when authorized and legally permissible, to specialty care teams and multidisciplinary clinics; PAC, home health, palliative, and hospice providers; community, clinical, and specialty pharmacists and pharmacies; durable medical equipment suppliers; EMS and community

[5] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2837374
[6] https://www.cms.gov/files/document/qso-21-18-hospitals-cahs.pdf

paramedicine partners; behavioral health providers; and community-based or social service organizations involved in care transitions.

Pharmacy participation deserves particular attention. Pharmacists are often the first care team members to learn whether a prescribed discharge medication was obtained, delayed, changed, or abandoned. Event notifications paired with prescription fill-status information can help close post-discharge medication gaps, support medication reconciliation, and identify PA or coverage barriers while the care transition is still active. CMS should work with pharmacy standards stakeholders to identify how existing pharmacy messaging and EHR functionality can support these workflows without over-alerting clinicians.

Hospitals also need clearer guidance on authorization and attribution. In practice, authorization is often operationalized through established treatment relationships, attribution rosters, contractual value-based arrangements, or patient-identified responsible practitioners or entities. WEDI recommends that CMS recognize those mechanisms explicitly and avoid creating a model that depends on bespoke manual authorization workflows for every recipient type. CMS should also clarify that existing payer and state infrastructure can support more efficient routing and lower-intensity coordination. Examples include LTSS systems, behavioral health systems, Medicaid and Medicare Advantage care management infrastructure, regional health information organizations, HIEs, state or regional care coordination hubs, and other established networks that already connect portions of the ecosystem. Strengthening those networks may be more scalable than relying exclusively on downstream, high-intensity, one-off coordination workflows.

WEDI further believes that attribution and patient matching remain core barriers to broader notification exchange. The HL7 Da Vinci Member Attribution (ATR) List Implementation Guide is directly relevant here. The ATR guide explains that current member attribution exchanges are often handled through CSV, text files, email, and SFTP and that there are no widespread standards in use today for these exchanges; it was designed to support exchange of member attribution lists, requests for changes, and notifications of changes to those lists for value-based care, quality reporting, and payer-provider data exchange use cases. WEDI believes ATR is well suited to determine who should receive a notification, but it should not be treated as the notification payload standard itself.[7]

Attribution approaches should be modernized to reflect real-world care relationships, including specialty and longitudinal care teams, not only primary care or payer-assigned relationships. Patient matching and authorization processes should be patient-directed, transparent, scalable across multiple provider and community partner types, and designed to reduce hospital administrative burden while honoring patient preferences.

Complementary Policy Approaches

With respect to CMS's questions on complementary policy approaches, WEDI supports using other CMS programs to reinforce the use and value of event notifications. In particular, CMS should consider a staged approach within the Medicare Promoting Interoperability Program for

[7] https://build.fhir.org/ig/HL7/davinci-atr/

eligible hospitals and CAHs. CMS already used the Medicare Promoting Interoperability Program to advance ePA, stating in the 2024 interoperability and PA final rule that the Electronic Prior Authorization measure is intended to further enable electronic exchange of health information to improve quality and care coordination. WEDI believes CMS could build a comparable staged approach for event notifications.[8]

WEDI does not recommend a simple binary measure that asks only whether notifications are sent. Instead, CMS should consider a staged attestation or performance framework that progresses over time from capability, to use, to timeliness, to deliver quality. Examples could include the percentage of eligible events for which a notification was generated, the percentage successfully delivered, the percentage delivered within the required timeframe, and the percentage delivered to at least one authorized external recipient such as a PAC provider, primary care provider, or attributed accountable entity.

CMS should also consider measures or attestations that evaluate whether notifications are received, routed internally, reconciled with attribution or care management workflows, and used for patient outreach or transition support. Success should be measured by effective delivery, receipt, and use of notifications, not only by the technical capability to send them.

In addition, CMS should use value-based models, Medicaid managed care contracts, and technical assistance programs to encourage higher-quality notification exchange. For many organizations, particularly small and rural providers, targeted support will be more effective than a purely punitive framework.

CMS should also emphasize education and implementation support. Stakeholders note that ADT notifications are still not used as broadly or effectively as they could be, even though real-time or near-real-time event data allows organizations to act quickly and improve care coordination. CMS, ONC, WEDI, NCPDP, HL7, state HIEs, and other stakeholders should develop educational materials and implementation playbooks that explain the care coordination value of event data, appropriate recipient types, privacy-sensitive routing, standards options, and how to use notification information to trigger concrete follow-up actions.

WEDI also strongly supports coordination with ONC on health IT certification criteria that could enable standardized subscriptions, recipient directory management, attribution list exchange, audit logging, privacy preference handling, conformance testing, configurable notification preferences, and incorporation of relevant pharmacy status information where available through appropriate standards. The policy question is not simply whether a hospital can generate an alert, but whether the surrounding infrastructure allows authorized users to subscribe, receive, reconcile, and act on alerts consistently and securely.

The Trusted Exchange Framework and Common Agreement™ (TEFCA™) is also a promising complement to local and regional notification infrastructure. The TEFCA public information now shows more than 21,000 organizations live on TEFCA, representing more than 81,000 unique connections, with more than 889 million documents shared since go-live. WEDI believes TEFCA could improve the likelihood that notifications reach authorized recipients, especially where

[8] https://www.cms.gov/files/document/cms-0057-f.pdf

hospitals and recipients do not share the same regional HIE or vendor network. CMS should work with ONC and the Recognized Coordinating Entity to define how TEFCA can serve as a scalable transport and trust layer for notifications, while recognizing that local HIE infrastructure will remain important.[9]

CMS should coordinate with ONC to evaluate how TEFCA can function as a trust and routing infrastructure for authorized event notifications, not merely as a network-of-networks for document exchange. TEFCA-related implementation should support accurate and maintained directories, reliable delivery to authorized recipients, and inclusive routing models that do not unintentionally exclude specialty, home-based, or community-based care partners.

Technical Approaches to Patient Electronic Event Notifications

With respect to the technical questions, WEDI believes the most widespread technical approach in production today remains HL7 v2 ADT sent directly or through HIEs and intermediaries. That approach has the benefit of being mature, operationally familiar, and already embedded in hospital workflows. Its drawbacks are that it can be highly customized, may lack critical information, may not always be received timely, directory logic is often inconsistent, and it does not by itself solve subscription management, recipient discovery, standardized filtering, or payer/pharmacy/community partner routing. ONC's HIO data brief reinforces that HL7 v2 ADT remains a current market baseline.[10]

WEDI does, however, see meaningful future value in more advanced FHIR-based approaches. The HL7 Da Vinci Unsolicited Notifications Implementation Guide was specifically developed to support communication of relevant notifications that affect patient care and value-based or risk-based services, including traditional ADT notification use cases. The HL7 Subscriptions R5 Backport guide was published to bring the redesigned FHIR R5 Subscriptions Framework into FHIR R4 environments, specifically to support broader compatibility and adoption. Together, these tools offer a more standardized path for subscription-based notification workflows and can allow an alert to be paired with the ability to query more relevant and timely information when an authorized recipient needs to act.[11]

Those approaches should also support subscription-based access for authorized recipients, so that organizations can receive the notifications they are permitted and expected to act upon without building a series of one-off bilateral connections. For example, a provider, pharmacist, payer, or care management entity with a treatment, care coordination, or value-based arrangement relationship to a specific patient should be able to subscribe to targeted notifications for that patient, subject to applicable law, patient preferences, and appropriate governance. Subscription models should include practical safeguards for filtering, recipient preferences, audit logging, and alert fatigue management.

WEDI also encourages CMS to consider the market dynamics of event notification services. In some communities, event notification remains a niche service with limited vendor options and separate subscriber costs. Incorporating notification workflows into broader FHIR-based

[9] https://rce.sequoiaproject.org/
[10] https://healthit.gov/data/data-briefs/standards-adoption-among-health-information-exchange-organizations/
[11] https://build.fhir.org/ig/HL7/davinci-alerts/

exchange channels, rather than requiring stand-alone event-notification products, could lower costs and expand access for providers, payers, and other authorized care team participants.

WEDI recommends that CMS encourage and pilot these more advanced approaches rather than immediately require them as the sole path to compliance. CMS should keep the Conditions of Participation (CoP) as the business requirement, preserve HL7 v2 ADT as a viable path in the near term, and use certification, demonstrations, and incentive programs to move the market toward subscription-capable, standards-based notification models over time.

CMS should also recognize that technical maturity varies across recipient types. PAC, LTSS, behavioral health, pharmacy, social service, rural, and small-provider organizations may require additional technical assistance, onboarding support, and workflow guidance to receive and act on notifications in a consistent way.

WEDI also recommends that CMS pair any future technical requirements with conformance testing. ONC's HealthIT.gov testing environment already includes a Subscriptions Test Kit that verifies conformance to the FHIR Subscriptions framework and for R4 systems, the Subscriptions R5 Backport approach. CMS should build on that type of tooling as it considers future requirements.[12]

Enforcement

With respect to enforcement, WEDI believes the existing CoPs have been effective in establishing a national baseline expectation that event notifications are part of hospital participation requirements. That baseline matters. At the same time, survey-based compliance alone does not fully answer whether notifications are reaching the right recipients in a timely and usable manner.

WEDI therefore recommends that CMS strengthen enforcement through a combination of survey oversight and operational accountability. CMS should consider requiring organizations to maintain auditable logs of notification generation, transmission, delivery status, failed delivery remediation, and recipient onboarding records. CMS should also consider complaint-based review and targeted audits where there is evidence that hospitals are not making reasonable efforts to reach applicable recipients.

WEDI recommends, however, that CMS pair any strengthened enforcement with clear guidance, examples, and technical assistance before relying heavily on punitive mechanisms. Enforcement should focus on whether hospitals and intermediaries are making reasonable, documented efforts to deliver usable notifications to appropriate recipients, not on penalizing organizations for gaps that result from immature directories, unclear attribution, or recipient readiness limitations.

WEDI also recommends that CMS supplement enforcement with more guidance, education, and technical assistance. Hospitals would benefit from model workflows for attribution management, provider directory maintenance, recipient verification, pharmacy and medication-

[12] https://fhir.healthit.gov/test-kits/subscriptions/

management use cases, privacy-sensitive scenarios, and transition planning for rural and small-hospital implementation. Stronger operational guidance will do more to improve real-world performance than a compliance standard that is technically correct but operationally vague.

Finally, CMS should consider developing illustrative use cases, including patients with complex and progressive conditions, post-acute transitions, behavioral health transitions, medication access and fill-status follow-up, EMS and community paramedicine interactions, and home-based care, to demonstrate how policy intent translates into real-world patient benefit. These use cases would help implementers understand how notification content, routing, authorization, privacy, standards, and follow-up workflows should operate together.

#2: INCREASING HEALTH CARE RESILIENCY (PAGE 20008)

WEDI appreciates the opportunity to continue supporting the practical implementation of policy and technology in the health care space. The following are comments regarding specific questions and general recommendations we believe will assist the health care industry in preventing cyberattacks and mitigating the impact of a cyberattack on health care data exchange.

As we have for years, WEDI has provided helpful industry support on numerous topics, but especially on best practices and methods to tackle challenges associated with privacy, security, cybersecurity, and now cyberattacks (or becoming more cyber secure), to improve readiness to prevent or handle ransomware and other similar threats.

WEDI continues to educate the industry that the single most impactful step in being health care resilient begins with the initial HIPAA Security Rule and the ability for an organization to understand all of the sensitive data it uses, discloses, and handles, and to conduct initial and ongoing related Risk Assessment and analyses of the risks associated with that data as it creates it, receives it, maintains it, and transmits it. This is a common theme in the HHS Office for Civil Rights (OCR) Corrective Action Plans, and an issue we collectively raise tirelessly. An organization's ability to understand its business model, the data it handles, the expectations of the people who handle that data, and the accurate and complete inventory of the technology that supports it is paramount.

The initial Privacy and Security Regulations themselves resulted in organizations assigning distinctly different resources based on the requirements, e.g., legal, compliance, and IT. Instead of singling out specific resources, organizations must approach the ability to be health care resilient by using a broad enterprise-wide team, including varied disciplines, and ensuring that senior level focus and support are in place. With the constant threat of ongoing cyberattacks now also fueled with powerful AI, these basic approaches have never been more important. Ongoing training of all workers, whether the topic is phishing campaigns, or shadow AI usage, are imperative in this landscape.

Of most concern to WEDI is the rural and smaller health care providers, health plans, and business associates that lack IT resources and funding. The Health Information Technology for Economic and Clinical Health Act (HITECH) Regional Extension Center model was hugely

successful in promoting a repeatable process to assist providers in moving from paper to electronic charting. This same type of model could be used to support those lacking in privacy, security, and cybersecurity resources and expertise. WEDI could assist in further brainstorming about this concept.

Organizations, in addition to WEDI, that provide ongoing education to the industry in these areas include but are not limited to the 405.d HHS Health Care Sector Coordinating Council effort and the Administration for Strategic Response and Preparedness. We often refer to the materials provided by these efforts to aid our industry in gaining further resilience. Standards used include HIPAA, HITECH, National Institute of Standards and Technology (NIST) 800-66; NIST 800-171, NIST 800-53, and the NIST Cyber Security Framework. While these are all incredibly helpful, they are written to stand alone. Organizations need to better understand how all these standards work together, and which specific requirements are appropriate for their unique business model, data handling, IT sophistication, resources, etc.

The newly launched CMS Medicare App Library further shows how interoperability momentum is raising the "bar" for those technical app developers most likely not subject to HIPAA. Third parties, business associates, and other vendors in the health care data exchange ecosystem must also promote ongoing privacy, security, and cybersecurity improvements, including the use of ongoing threat and risk management, communications as negative events take place, and the ability to "prove trust" via independent third-party audits.

Many payers and providers must use point-to-point connections to move data between themselves. However, the increased number of point-to-point connections exponentially increases the security threats associated with them. Use of third parties, clearinghouses, intermediaries, or other vendors present both relief and challenges. The current technical environment, leveraging the use of APIs to provide additional information faster may also exacerbate the threats, while offering efficiencies at the same time. Our industry needs additional support to work through these challenges. Discussions about the need to improve the authentication and identity of organizations, including the use of verifiable organization identity, appear to be a promising approach to improving trust within the ecosystem chain as data travels from point-to-point. WEDI stands ready to aid the industry to implement these complex issues.

In summary, **WEDI recommends that CMS prioritize making event notification policies timely, actionable, configurable, and routed in a manner that supports the recipient's workflow.** CMS should encourage notification systems that allow providers and care teams to filter, configure, suppress duplicates, and access notifications on demand.

Cyber Resiliency Recommendations

1. Create an Office of National Cybersecurity Policy

The federal government should create a new office called The Office of National Cybersecurity Policy (ONCP); an office led by a "Cyber Policy Czar." While we appreciate that there currently is an Office of the National Cyber Director (ONCD), this office is restricted to performing in an advisory capacity, with no authority to harmonize and coordinate actions taken by other federal agencies before during or after a cyberattack.

We believe an ONCP could be modelled on the existing Office of National Drug Control Policy (ONDCP) and be a component of the Executive Office of the President. ONDCP leads and coordinates the nation's drug policy and is responsible for the development and implementation of the National Drug Control Strategy and Budget. ONDCP coordinates across multiple federal agencies overseeing a $44 billion budget as part of a whole-of-government approach to combat drug supply changes and illegal drug threats[13].

The recommended ONCP would not replace any existing agency or usurp any other agency's jurisdiction or function, but rather drive a centralized process of cyber incident reporting, coordinating harmonization efforts across federal agencies stakeholder education (with a focus on under resourced organizations), steer funding for stakeholder cyber preparedness, develop and deploy national contingency planning, and serve as the point agency for industry recovery following a major cyber incident.

2. **Conduct Select Audits and Educate the Industry**

HHS, through OCR, should conduct proactive, comprehensive select audits of the health care sector. Past OCR audit programs have reviewed policies and procedures adopted and employed by covered entities and their business associates to meet selected standards and implementation specifications of the Privacy, Security, and Breach Notification Rules. Audits present an opportunity to examine mechanisms for compliance, identify best practices, and discover risks and potential vulnerabilities. Specifically, OCR should conduct audits of those covered entities and business associates that experienced a cyberattack. Gaining first-hand knowledge of how the attack occurred, systems impacted, contingencies adopted, and post-attacks steps taken could be leveraged to assist other organizations. Through these select audits, OCR can identify best practices that will provide guidance targeted to address compliance challenges.

The aim of the new round of select audits would be to identify cyberattack vulnerabilities of HIPAA covered entities and business associates. Rather than conduct these select audits for enforcement purposes, we recommend they be conducted to assess the effectiveness of the current security controls and security gaps and identify lessons learned to update controls as appropriate to mitigate risk across the health care infrastructure.

De-identified results from these audits should be leveraged in an educational campaign to better prepare covered entities and business associates to address cyber threats. Educational campaigns should be targeted at specific stakeholder groups, sectors that are more frequently targeted by cyber criminals, and those that have limited resources. We encourage HHS to work with industry groups such as WEDI as well as stakeholder-specific professional associations to expand the reach of these important messages.

[13] https://www.whitehouse.gov/ondcp/

3. **Establish a Voluntary Audit Program**

OCR should be directed to establish a program that would permit covered entities and business associates to voluntarily undergo a security audit. This program could be modeled on the Department of Labor's Occupational Safety and Health Administration's (OSHA's) Voluntary Protection Program (VPP)[14] designed to promote effective worksite-based safety and health. In the VPP, management, labor, and OSHA establish cooperative relationships at workplaces that have implemented a comprehensive safety and health management system. The VPP sets performance-based criteria for a managed safety and health system, invites sites to apply, and then assesses applicants against these criteria. OSHA's verification includes an application review and a rigorous onsite evaluation by a team of OSHA safety and health experts.

OCR could emulate the approach adopted by OSHA by developing a program that would allow covered entities to have their security policies and procedures reviewed by OCR and any weaknesses detected. Those submitting their policies and procedures for voluntary review should not be subject to enforcement action should any deficiencies be identified during the audit. Rather, the organization should be given sufficient time to correct any issues. This program would be especially important for smaller organizations that do not have the resources required to engage a third-party accreditation or certification vendor.

4. **Accredit the Accreditation and Certification Programs**

HHS should consider developing minimum privacy, security, and cybersecurity standards for third-party accreditation and certification entities. We recognize that there is tremendous value in having independent entities review and accredit or certify that an organization has met or exceeded its proprietary set of security requirements. We also recommend an analysis be undertaken to evaluate the current accreditation and certification bodies, both for profit and not-for-profit organizations, providing services in this space to understand how they are governed, what public and private sector standards are used as "baselines," and how are these standards are measured and kept current as regulations and best practices change.

Further, the minimum requirements for these accreditation and certification programs should be inclusive of the use of standards that include post attack actions including the implementation of best practices, policies, and procedures related to: (i) Identifying and communicating with all trading partners that could potentially be impacted by the cyberattack; (ii) Disaster recovery programs to mitigate the impact of a cyberattack on the organization and its trading partners; and (iii) Contingency plans to ensure that the organization and its trading partners can continue data exchange following a cyberattack. Given our interconnected health care industry, every effort should be made to expand the coordination of testing programs.

5. **Implement Administrative Actions**

As cyberattacks have shown, data exchange processes can be significantly obstructed during these events. When a health plan, clearinghouse, or supporting vendor is cyberattacked, vital data exchange processes can be impacted. Claims from providers may not be able to be

[14] https://www.osha.gov/vpp

adjudicated, insurance eligibility verifications may not be able to be performed, PAs may not be able to be submitted, electronic prescriptions may not be able to be conveyed, and payments and remittances may not be able to be transmitted.

These data exchange processes are vital to health care administration and can even affect patient care delivery. Implementing alternative data exchange pathways with the attacked health plan, clearinghouse, or supporting vendor is critical, as is facilitating enrollment in an alternative clearinghouse or vendor, if necessary.

The industry appreciated the actions taken by HHS following the Change Healthcare cyberattack in February 2024[15]. Building on this, following a major cyber incident HHS should have in place and be ready to implement some or all these actions to immediately assist data exchange processes between providers and health plans. These actions could include:

- Expedite new electronic data interchange enrollment. Recent cyberattacks have spotlighted challenges related to enrollment. Providers seeking to move to an alternative vendor for their administrative transactions may encounter significant difficulties changing from one clearinghouse to another for claims processing and other transactions during these outages. It can take weeks or even months for providers to reenroll with another partner, significantly delaying their ability to conduct transactions. Exacerbating these challenges, vendors may also require exclusive contracts. Should that entity be the target of an attack, providers may not have easy access to transfer their data exchange requirements to an alternative vendor.

  With this lesson learned from recent cyber incidents, Medicare Administrative Contractors (MACs) should be encouraged to have in place a process for providers to request a new enrollment for the switch. State Medicaid and CHIP agencies and Medicaid and CHIP managed care plans should also be encouraged to expedite enrollment solutions. Solutions could include the waiving of wet signature requirements on paper enrollment forms, the adoption of bulk enrollment processes to support health systems with numerous clinicians to enroll, and mandated turnaround time for enrollments. HHS should also issue guidance and best practices for non-regulated entities encouraging them to develop expediated enrollment processes.

- Accept Paper Claims. HHS should encourage and assist MACs to be prepared to accept paper claims from providers who need to file them due to the impact of a cyberattack or other incident that impacts their ability to conduct administrative transactions. For some designated period following a cyberattack, MACs should be encouraged to accept paper submissions if a provider needs to file claims in that method.

- Relax or Eliminate PA Requirements. HHS should encourage the removal or relaxation of PA, other utilization management, and timely filing requirements should an MA organization, Part D sponsor, or one of their direct trading partners incur a cyberattack or

[15] https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-373d22c37842?find-by-timestamp=2025-01-02T05:49:59Z&url=https:%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2024%2F03%2F05%2Fhhs-statement-regarding-the-cyberattack-on-change-healthcare.html&timestamp=2025-01-02T07:03:02Z

other incident that impacts their ability to conduct administrative transactions. During a major system outage HHS should encourage all health plans to take similar actions.

- Provide Advance Funding. Should other administrative actions not have the effect of maintaining data exchange processes and continuing claim payments, CMS should explore requiring the MAC or other federally controlled plan directly impacted by the cyberattack to offer accelerated and advance payments (AAPs) to providers most affected by major cyberattack. Other non-impacted plans should be encouraged to offer AAPs, should the breadth of the outage warrant such as action. We note as well that the current requirement is for a maximum 30-day payment amount, with repayment in full required 90 days after the AAP is issued. HHS should consider expanding the AAP to a maximum of a 60-day payment amount and a 180-day repayment timeframe.

- Delay or Waive Data Reporting Requirements for Plans and Providers. HHS should adjust the timing requirements, or waive when appropriate, for plan and provider data reporting requirements, similar to the flexibility afforded during natural disasters. Further, HHS should make permanent a "cyberattack" option in the Merit-based Incentive Payment System (MIPS) Extreme and Uncontrollable Circumstances Exception Application to provide relief to providers impacted by a cybersecurity incident.

- Issue Communication Guidance**.** One of the challenges the industry faces during and after a cyberattack is communication between the entity attacked and its trading partners. HHS should issue guidelines for how and when entities hit with a cyberattack should communicate with its trading partners. This guidance should also include recommendations related to the impacted entity's alternative data exchange pathways, options for enrolling with an alternative vendor, any available loan programs or advanced payments, contact information should they wish to reach out to the impacted entity, and any other pertinent information.

  We urge HHS to work with WEDI, the Health Sector Coordinating Council, the Administration for Strategic Response and Preparedness, and other appropriate public and private sector organizations to assist with disseminating effective, actionable communications across the sector.

- Explore Opportunities to Increase Cybersecurity Funding. HHS should explore opportunities to leverage existing federal incentive programs and create new incentive or grant programs to increase funding for covered entities to invest in cybersecurity. These programs should be targeted at smaller, less resourced entities.

6. Implement an Annual National Health Care Cyber "Fire Drill"

HHS should designate a week as "National Health Care Cyber Fire Drill Week." This would be a designated period, e.g., a week, where HHS, or an ONCP, would lead the health care industry in promoting cyber awareness and action. Health care organizations would be encouraged not only to test internal systems and processes but also to work with their critical trading partners to identify and test systems, alternative data exchange pathways, and contingency plans.

The Fire Drill should focus on: (i) Improving overall cyber hygiene; (ii) Internal testing; (iii) Employee training; (iv) External testing; (v) Contingency planning; (vi) Disaster recovery planning; (vii) Backup systems and disaster recovery testing; (viii) Business continuity testing, e.g., trading partner outreach; and (ix) Awareness of available cybersecurity resources.

#4: STEP THERAPY (PAGE 20013)

WEDI is pleased to provide comments on this RFI focused on how technology can improve current step therapy processes. We contend that step therapy can be streamlined by replacing manual verification and fragmented communication with automated, standards-based exchange of clinical and coverage information among providers, payers, pharmacies, and patients.

Key opportunities include:

- **Real-time benefit and step therapy requirement checks**
  APIs could allow providers and pharmacies to automatically determine: (i) Whether step therapy applies; (ii) Required first-line therapies; (iii) Patient-specific coverage rules; (iv) Preferred alternatives, and (v) Exceptions criteria. Instead of administrative or clinical staff searching payer portals or formularies, key requirements could appear directly in prescribing workflows.

- **Automated retrieval of relevant clinical information**
  Many step therapy decisions depend on information already available in clinical systems. Technology could automatically pull: (i) Diagnosis history; (ii) Medication history; (iii) Previous treatment failures; (iv) Allergies and contraindications; (v) Lab results; and (vi) Comorbid conditions. This has the potential of reducing both duplicate data entry and manual chart review.

- **Electronic documentation of prior treatment history**
  Data sharing between providers, pharmacies, and payers could help establish whether a patient has already met step requirements by identifying: (i) Previously prescribed medications; (ii) Fill history; (iii) Medication adherence information; (iv) Prior adverse events; and (v) Lack of clinical response. This may reduce situations where patients repeat therapies they have already tried unsuccessfully.

- **Integrated decision support at the point of prescribing**
  Clinical and payer decision-support tools could provide real-time alerts regarding: (i) Step therapy requirements; (ii) Covered alternatives; (iii) Required documentation; and (iv) Potential exceptions pathways. The goal here would be for providers to address issues before prescriptions are submitted.

- **Automated exception and PA workflows**
  Technology could support electronic submission of: (i) Exception requests; (ii) Clinical rationale; and (iii) Supporting documentation. As an example, if a patient previously failed a required therapy, the system could automatically include relevant evidence.

- **Real-time status tracking and notification**
  Providers, pharmacies, and patients could receive updates regarding: (i) Submission status; (ii) Approval decisions; (iii) Requests for additional information; and (iv) Expected timelines. Combined, these could reduce phone calls and repeated status checks.

- **Interoperable exchange across organizations**
  Structured data exchange using common standards could reduce fragmentation between payers, providers, pharmacies, pharmacy benefit managers, and EHRs. Improved interoperability should lead to a reduction in repeated requests for information.

- **Patient-facing transparency tools**
  With the appropriate transparency tools, patients could access information regarding: (i) Current step requirements; (ii) Medication status; (iii) Approved alternatives; and (iv) Next steps in the process. Transparency tools could reduce confusion and improve medication adherence.

- **Analytics and continuous improvement**
  Improved access to structured data could lead to identification of the following: (i) Frequent denial reasons; (ii) High-burden therapies; (iii) Delays in medication access; (iv) Variability across plans; and (v) Opportunities to simplify policies.

Payer-to-Payer API

Specifically, the payer-to-payer API could improve the step therapy process by reducing information gaps when a patient changes health plans. Today, step therapy often restarts because the new payer may not have access to the patient's medication history, PA records, or evidence that previous therapies were tried and failed.

Key improvements related to use of the payer-to-payer include:

- **Preserving medication history across payer transitions**
  The API can transmit historical pharmacy and claims data showing: (i) Medications previously prescribed; (ii) Duration of treatment; (iii) Adherence patterns; and (iv) Discontinuation reasons. This can help establish that a patient already completed required therapy steps.

- **Reducing duplicate "fail-first" requirements**
  If a new payer receives evidence that a patient already tried and failed a required medication, it could avoid requiring the patient to repeat ineffective therapies. This could reduce delays in treatment and avoid unnecessary clinical burden.

- **Supporting automated step therapy determinations**
  API data could feed payer decision systems to automatically identify whether step requirements have already been satisfied, whether exceptions apply, and whether a PA should be expedited. This has the potential of moving processes away from manual chart review and fax exchanges.

- **Reducing provider administrative work**
  Staff frequently spend time gathering records from prior plans and resubmitting documentation. Structured data exchange, as stated above, could reduce manual processes and repeat PA submissions.

- **Improving continuity of care**
  Patients with chronic conditions can experience disruptions when switching insurers. Access to prior treatment history may help maintain ongoing therapy without interruption.

- **Creating better data for clinical decision-making**
  Payers and providers could have more complete longitudinal histories, including diagnoses, PAs, claims, and medication utilization. This supports more individualized treatment decisions. There are also implementation considerations. A payer-to-payer API alone may not fully solve step therapy challenges because much of the information needed for decisions can be missing or inconsistently coded. The greatest benefit would likely come from combining payer-to-payer exchange with provider APIs, standardized PA data, and consistent clinical data elements for documenting step therapy outcomes.

#5: LABORATORY TESTS AND DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES ITEMS (PAGE 20014)

Laboratory Testing

PA requirements for laboratory testing can create significant administrative burden through manual documentation and payer-specific workflows while introducing delays that may postpone diagnosis, treatment decisions, and patient access to appropriate care. The burden of PA for laboratory tests is often described across four major areas: administrative workload, delays in care, financial impact, and clinical disruption. However, automation opportunities, if implemented, could improve the authorization process for payers, providers, and the patients they serve.

Laboratory authorizations can require manual activities such as: (i) Verifying whether authorization is required; (ii) Determining payer-specific medical necessity criteria; (iii) Gathering supporting documentation; (iv) Completing forms or payer portal submissions; (v) Conducting phone calls and follow-up; (vi) Responding to requests for additional information; and (vii) Tracking authorization status. Many organizations rely on a mix of portals, faxes, emails, and phone calls.

Automation Opportunities

APIs could improve PA for laboratory tests by replacing fragmented, manual processes with automated, standards-based exchange of coverage, clinical, and authorization information. Because laboratory testing often serves as the gateway to diagnosis and treatment decisions, reducing friction at this stage can have positive downstream effects across the entire care delivery environment.

Key opportunities include:

- **Real-time identification of authorization requirements**
  APIs could allow ordering systems to automatically determine: (i) Whether PA is required; (ii) Medical necessity criteria; (iii) Test-specific documentation requirements; and (iv) Coverage limitations and/or therapeutic alternatives. Rather than staff manually checking payer portals or policy documents, requirements could appear directly within the ordering workflow.

- **Automated population of authorization requests**
  Laboratory PA requests often require information already available in the EHR. APIs could potentially pull: (i) Diagnosis codes; (ii) Relevant clinical history; (iii) Previous laboratory results; (iv) Medication history; (v) Encounter information; (vi) Family history; and (vii) Ordering provider information. Capturing this information could reduce duplicate data entry and lower administrative effort.

- **Electronic submission of supporting clinical information**
  Instead of faxing notes or attaching PDFs, APIs could support transmission of structured clinical information such as: (i) Prior test results; (ii) Pathology findings; (iii) Imaging reports; (iv) Genetic risk information; (v) Clinical notes; and (vi) Standardized questionnaires. Structured data may also reduce errors caused by incomplete documentation.

- **Real-time decision support at the point of ordering**
  Payer and clinical decision-support APIs could identify issues before a request is submitted, such as: (i) Missing information; (ii) Incorrect coding; (iii) Non-covered indications; (iii) Frequency limitations; and (v) Preferred alternatives. As an example, if a molecular test requires prior failed therapies or specific clinical criteria, the system could alert the ordering provider immediately.

- **Faster or automated approvals**
  Some laboratory tests could potentially be adjudicated automatically if criteria are clearly met. Examples include routine follow-up testing with established coverage rules, standard genetic screening scenarios, and repeat monitoring tests meeting payer criteria. We note that more complex cases could still move to clinical review.

- **Electronic requests for additional information**
  When additional documentation is needed, APIs could enable: (i) Specific identification of missing elements; (ii) Direct transmission back into the ordering workflow; and (iii) Faster responses without phone calls or faxes. Combined, APIs could reduce repetitive back-and-forth communication.

- **Real-time status visibility**
  APIs could allow providers, laboratories, and patients to track: (i) Submitted status; (ii) Pending review status; (iii) Approval decisions; (iv) Denials and rationale; and (v) Authorization expiration dates. Real-time status visibility reduces or eliminates manual status checks.

Benefits of Automated PA

Automation of the PA process for laboratory tests and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) could generate significant benefits for patients, providers, and payers by reducing administrative friction, accelerating care delivery, and improving decision-making. The greatest benefits are likely to be achieved when automation is supported by interoperable standards-based APIs, standardized coverage criteria, and real-time exchange of clinical documentation. In those circumstances, PA can evolve from a largely manual administrative process to a streamlined clinical workflow that improves access to care while reducing burden across the health care ecosystem.

Benefits for Patients

- ***Faster access to care and treatment.*** *Automated authorization workflows can enable near real-time determinations for routine and well-defined requests, reducing delays in diagnostic testing and access to needed equipment.*

- ***Improved health outcomes.*** *Timely approval of laboratory tests can support earlier diagnosis and intervention, while prompt access to DMEPOS can improve mobility, independence, recovery, and management of chronic conditions.*

- ***Reduced treatment interruptions.*** *Automation can minimize delays caused by missing documentation, manual reviews, and communication gaps between stakeholders.*

- ***Greater transparency.*** *Patients may benefit from improved visibility into the status of authorization requests and expected timelines.*

Benefits for Health Care Providers

- ***Reduced administrative burden.*** *Automated submission, validation, and status-checking can significantly decrease staff time spent on phone calls, faxes, and manual data entry.*

- ***Fewer documentation errors.*** *Integration with EHRs and standardized APIs can automatically populate required clinical information, reducing resubmissions and denials.*

- ***Additional time for patient care.*** *Clinical and administrative staff can redirect resources from PA processing to direct patient services.*

- ***Improved workflow efficiency.*** *Real-time eligibility checks and automated determination rules can allow providers to know immediately whether a PA is required and whether the request meets coverage criteria.*

Benefits for Payers

- ***Lower operational costs.*** *Automation reduces manual review requirements for routine requests and allows staff to focus on more complex cases.*

- ***More consistent determinations.*** *Standardized decision support and electronic rules can improve consistency and reduce variation in PA decisions.*

- ***Improved data quality.*** *Structured electronic submissions can provide more complete and accurate clinical information than faxed or paper-based requests.*

- ***Enhanced program integrity.*** *Automated systems can more effectively identify requests that require additional review while expediting requests that clearly meet coverage criteria.*

Specific Opportunities for Laboratory Tests

- *Automated PA could support rapid approval of commonly ordered tests when clinical criteria are clearly documented in the patient's record.*
- *Electronic exchange of diagnostic information could reduce unnecessary repeat testing caused by delays or missing records.*

- *Faster access to advanced diagnostic testing may facilitate earlier disease detection and more targeted treatment plans.*

Durable Medical Equipment

Authorizations for durable medical equipment (DME) authorizations can create a unique set of burdens as it combines complex documentation requirements with fragmented workflows across providers, suppliers, and payers, often leading to administrative costs and delays in patient access to medically necessary equipment.

DME authorizations could be significantly improved through APIs by shifting from document-heavy, manual workflows toward real-time, structured data exchange between providers, suppliers, payers, and EHR systems. The burden of PA for durable medical equipment is often particularly significant because requests frequently involve multiple stakeholders—physicians, suppliers, health plans, and patients—and often require detailed documentation beyond a standard clinical order.

API-enabled DME PA has the potential to replace fragmented portal- and fax-based workflows with automated, standards-based, real-time exchange of coverage requirements, clinical data, authorization requests, and status information—reducing payer and provider burden while accelerating patient access to medically necessary equipment.

DME Automation Opportunities include:

- **Real-time coverage and requirements discovery**
  APIs could allow DME suppliers and ordering providers to automatically determine: (i) Whether PA is required; (ii) Patient coverage status; (iii) Applicable medical necessity criteria; (iv) Documentation requirements; and (v) Alternative covered products. Instead of staff searching payer portals or PDFs, this information could be exposed directly

inside clinical workflows.

- **Automatic pre-population of authorization requests**
  APIs could pull information already available in the EHR such as diagnosis and procedure codes, clinical notes, medication history, functional assessments, prior treatment history, and other pertinent information. This can reduce duplicate data entry and lower administrative burden.

- **Clinical documentation attachment through structured data**
  Current DME authorizations often rely on faxed documents and free-text narratives. APIs could transmit structured clinical data, standardized questionnaires, images and supporting records, and eSignatures. This could improve consistency and reduce incomplete submissions.

- **Real-time rules checking**
  Using payer decision-support APIs, systems could flag issues before submission including missing documentation, incorrect coding, non-covered items, quantity limitations, and alternative product suggestions. This would permit provider administrative staff to correct problems before sending the request to the payer.

- **Near real-time determinations**
  For straightforward requests that meet predefined criteria, APIs could support automated approvals in seconds or minutes rather than days.

- **Patient transparency**
  Patient-facing APIs could allow individuals to see the status of the submitted authorization, expected timelines, approved equipment, and any next steps required in the process. This increased transparency may reduce confusion and calls to providers and payers.

(We note, however, that more complex DME requests could still be required to move to a more complex clinical review.)

Within current interoperability efforts, the API framework created under the CMS-0057-F Rule provides many foundational concepts—such as PA support APIs and standardized FHIR-based exchange—that could potentially extend to DME workflows, although we re4cognize that currently many DME transactions remain outside today's most mature implementation pathways.

A persistent challenge is that DME often requires nuanced documentation (functional assessments, home environment considerations, physician narratives, etc.). APIs alone would not solve that complexity; the larger opportunity is combining APIs with standardized clinical data elements and common implementation guides.

Conclusion

WEDI commends CMS for seeking to continue to advance interoperability and improve PA processes. These are challenging areas of health care, and it is critical to address both if we are to reduce health care costs for payers and providers, increase efficiency, and improve the care delivery process for all patients. This drive for innovation must also be balanced with providing the users with products that function to meet the complete needs for delivering patient care.

We appreciate the opportunity to share our perspective on this proposed rule. We hope our comments and recommendations will serve to assist CMS as it moves forward with these proposals. Please contact Robert Tennant, WEDI Executive Director, at rtennant@WEDI.org with any questions on these comments and recommendations.

Sincerely,
/s/
Merri-Lee Stine
Chair, WEDI

cc: WEDI Board of Directors