AAFP

AMERICAN ACADEMY of FAMILY PHYSICIANS

June 12, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

The Honorable Thomas Keane, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C St. SW, 7th Floor
Washington, D.C. 20024

Submitted electronically via regulations.gov

RE: CMS-0062–P; 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

Dear Administrator Oz and National Coordinator Keane:

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,500 physicians and medical students nationally, I write in response to the Department of Health and Human Services' (HHS) Centers for Medicare and Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology's (ONC) proposed rule regarding advancing interoperability and improving prior authorization processes. The AAFP appreciates the Departments introducing proposals to improve the electronic exchange of health care data and streamline prior authorization processes, including expanding these processes to medications. Prior authorization requirements cause barriers to care, delayed care for enrollees, and impose significant administrative burdens on physicians. We applaud CMS and ONC for their thoughtful collaboration throughout the development of this proposed rule, as well as for continuing to include Medicare Advantage organizations in the list of impacted payers in this proposed rule, consistent with previous AAFP advocacy.

The AAFP is the leading U.S. organization dedicated to the specialty of family medicine. AAFP members serve as the primary and continuous source of health care for a growing proportion of the U.S. population, including a disproportionate share of Medicare and Medicaid beneficiaries. Physician practices complete an estimated 40 prior authorization (PA) requests per physician per week, making electronic prior authorization (ePA) reform among the most consequential health IT priorities for our members.[i] We share these comments in support of CMS and ONC's goals as stated in the proposed rule, with recommended modifications to ensure the final regulation fully delivers on its promise to improve ePA processes for patients and family physicians.

1133 Connecticut Ave., NW, Ste. 1100
Washington, DC 20036-1011

info@aafp.org
(800) 794-7481
(202) 232-9033

www.aafp.org

The 2024 CMS Interoperability and Prior Authorization Final Rule was an important step forward, and extending its framework to prescription drugs is both logical and overdue – especially given that medications represent a significant share of the PA burden family physicians experience. In particular, the AAFP supports the adoption of Health Level Seven International (HL7) Fast Healthcare Interoperability Resource (FHIR) Da Vinci Implementation Guides (IGs) for drug PA, the proposed acceleration of PA decision timeframes, and the expansion of payer transparency requirements. We also support the proposed extension of FHIR-based ePA requirements to drug PAs with modifications.

Additionally, we urge CMS and ONC to recognize that while ePA is a critically needed improvement, it alone is insufficient to meaningfully reduce the administrative burden that physicians and patients currently endure. It is the position of the AAFP that a physician's attestation of a clinical diagnosis or order should be sufficient documentation of medical necessity for clinical or imaging services, medications, and/or durable medical equipment (DME). As stated in our response to the 2022 ONC Electronic Prior Authorization RFI, "Electronic prior authorization is just one step in addressing the flaws of utilization management practices, and comprehensive reform is needed to reduce the volume of prior authorizations and ensure patients' timely access to care." **The AAFP strongly believes this proposed rule must be accompanied by a broader CMS commitment to PA volume reduction, standardized clinical criteria, and enforceable payer compliance**. **CMS should further consider appointing an independent body to evaluate PA requirements for appropriateness and impact on patient care, as these decisions should not be left to those who stand to gain financially by denying or delaying appropriate care.**

Among other recommendations detailed below, **the AAFP urges CMS and ONC to:**

- **Strengthen appeal rights and denial transparency requirements to ensure physicians can efficiently challenge inappropriate PA denials for drugs;**
- **Provide appropriate implementation support for small and independent family medicine practices that lack the infrastructure and resources of large health systems; and**
- **Ensure the Da Vinci Implementation Guides adopted in this rule are tested and proven successful in primary care settings before mandatory compliance is required**.

II.A. Interoperability Standards for APIs

CMS and ONC propose a comprehensive update to interoperability requirements by mandating greater standardization, modernization, and alignment of API-based data exchange across impacted payers. The proposal builds on prior rulemaking by requiring impacted payers to implement and maintain interoperability APIs (Patient Access, Provider Access, Provider Directory, Payer-to-Payer, and Prior Authorization APIs) using the HL7 FHIR standard and

associated implementation guides (IGs), while shifting from fixed standard versions to a dynamic framework. Under this approach, payers must use "unexpired" versions of required standards and IGs, allowing CMS and ONC to update technical requirements through future rulemaking without necessitating additional regulatory revisions. This framework is intended to improve scalability, align payer and health IT developer requirements, and reduce fragmentation that arises from inconsistent adoption of API standards. The proposal also elevates previously recommended IGs, including CARIN for Blue Button, PDex, PDex Plan Net, and Da Vinci CRD/DTR/PAS, to required status for specific APIs. This would further standardize data formats and workflows for claims access, provider directories, payer data exchange, and PA.

The rule proposes to establish a dual-standards infrastructure for ePA, distinguishing between drugs covered under a medical benefit and those covered under a pharmacy benefit. For medical-benefit drugs and non-drug items and services, the proposal requires use of FHIR-based APIs (including CRD, DTR, and PAS IGs) to support end-to-end ePA workflows within provider systems. For pharmacy-benefit drugs, the rule proposes mandatory support for NCPDP standards (SCRIPT, Formulary & Benefit, and Real-Time Prescription Benefit). Together, these standards are designed to be complementary and mutually exclusive, ensuring full coverage of all drug categories while minimizing duplicative workflows. The proposal also includes requirements to adopt additional IGs to ensure consistent data exchange across APIs; enhance real-time access to coverage, formulary, and PA information; and support standardized authentication practices. CMS' stated aims for these proposals are to accelerate interoperability, reduce administrative burden, improve workflow integration, and enable more timely and transparent PA processes across CMS programs.

The AAFP appreciates CMS and ONC's ongoing efforts to align interoperability requirements across programs, particularly the coordinated timelines for adoption of both HL7 FHIR-based APIs and NCPDP standards, and we support these proposals. As we have previously noted, consistent, phased implementation of updated NCPDP SCRIPT standards allows physicians and health IT developers to plan for and adopt new functionality in a predictable and manageable manner, which helps reduce administrative burden over time. Given that alignment across stakeholders is essential to realizing the full benefits of interoperability, we also strongly support efforts to ensure that all exchange partners are required to implement these standards on the same timeline. Without such alignment, physicians risk incurring additional costs and workflow disruptions without corresponding improvements in PA efficiency. We encourage CMS and ONC to continue prioritizing cross-agency coordination and standardized implementation timelines to support a more seamless, interoperable, and less burdensome health care system.

The AAFP supports CMS' continued efforts to modernize interoperability infrastructure and improve ePA processes. We strongly support the goal of creating more standardized,

interoperable, and real-time data exchange across payers, clinicians, and health IT systems to improve patients' access to timely care. For the many family physician practices that coordinate care across multiple health plans, hospitals, and pharmacists, the current PA environment remains highly fragmented and administratively burdensome. These proposals to standardize API functionality and data exchange requirements have the potential to reduce duplicative documentation requests, improve visibility into PA requirements, and streamline care coordination for patients. Reports indicate that MA organizations made nearly 53 million PA determinations in 2024 alone, including more than four million full or partial denials, and physician practices continue to experience substantial staffing and workflow burdens associated with manual PA processes.[ii] These reforms are urgently needed to address persistent inefficiencies that delay care and increase administrative strain across the health care system.

These burdens are particularly challenging for practices serving medically underserved and vulnerable populations. Patients with lower incomes, limited access to transportation or broadband, or language barriers are disproportionately affected by delays in medication access, diagnostic testing, and specialty referrals. Fragmented PA processes can exacerbate these disparities by introducing additional administrative barriers to timely care. The AAFP has consistently recognized that ePA systems can improve efficiency and reduce unnecessary administrative burden when implemented consistently and effectively. However, varying payer requirements, inconsistent documentation standards, and reliance on manual submission processes continue to divert clinical and administrative resources away from direct patient care.

The AAFP also urges CMS to recognize that the success of these proposals will depend heavily on vendor readiness, operational dependability, and technical implementation support. Many physician practices, particularly smaller or independent practices, rely on electronic health record (EHR) vendors or third-party intermediaries and may lack the internal technical capacity to rapidly adapt to evolving interoperability requirements. While the proposed rule appropriately places primary responsibility for API functionality and interoperability on impacted payers, CMS should clarify that physicians will not be held responsible for failures attributable to vendors, clearinghouses, or external technology systems. The AAFP further recommends that CMS coordinate implementation timelines closely with ONC certification requirements and establish clear readiness validation or testing expectations prior to enforcement. Without consistent and synchronized enactment across payers and EHR vendors, variability in API performance and implementation schedules could undermine the efficiencies these proposals are intended to achieve. We encourage CMS to consider establishing more uniform minimum implementation expectations across Medicaid managed care organizations and QHP issuers, including standardized data elements, aligned IG timelines, and clearer operational requirements for PA workflows. Absent greater alignment, physicians may continue to face fragmented, payer-specific processes that increase administrative complexity and limit the effectiveness of interoperability investments.

Additionally, the AAFP is concerned that the expansion of API-based exchange and ePA requirements may increase cybersecurity and infrastructure burdens for physician practices. Many practices, particularly in rural or underserved areas, operate with limited IT staffing and rely heavily on third-party vendors to maintain HIPAA compliance and data security. As interoperability requirements expand, CMS should ensure that practices are not expected to absorb unfunded costs associated with cybersecurity enhancements, API integration, or system maintenance. To support successful implementation, CMS should provide clear technical guidance, facilitate alignment with broader federal cybersecurity initiatives, and consider mechanisms to support practice readiness and workforce development.

II.B. Electronic Prior Authorization for Drugs

Proposed Requirement to Incorporate Drugs Covered Under a Medical Benefit into the Prior Authorization API for All Impacted Payers

CMS proposes to require all impacted payers to incorporate PA requirements for drugs covered under a medical benefit into the existing FHIR-based PA API, extending the framework established in the 2024 interoperability rule to include these drug-related requests. This would require payers to make coverage requirements, documentation expectations, and PA decision processes for medical benefit drugs accessible through the API, enabling electronic submission and processing of requests within existing interoperability workflows. The proposal is intended to standardize and streamline PA processes for medical benefit drugs, promote more consistent data exchange across payers and providers, and align drug PA with broader health care interoperability infrastructure. The agencies seek to require that "electronic prior authorization must be available for all drugs covered by any impacted payer for which they require prior authorization, either through the Prior Authorization API or NCPDP SCRIPT standards adopted by the Secretary."

The AAFP strongly supports this proposal and thanks the agencies for pursuing this change. Drug prior authorizations represent a substantial and growing share of the overall PA burden faced by family physicians, who prescribe medications for patients facing acute, chronic, and complex conditions. The continued reliance on phone, fax, and multiple payer portals for drug PA requests imposes significant administrative inefficiencies and burdens that disproportionately impact primary care practices, which are often under-resourced and less likely to have dedicated administrative staff.

The evidence base supporting prior authorization reform is well-established: The American Medical Association's (AMA) most recent physician survey found that 92% of physicians report a negative impact on patient clinical outcomes, 26% report that PA has led to a serious adverse

event in a patient's care, and 21% report that patients often abandon treatment due to the PA process.[iii] Extending ePA to drugs is a meaningful and evidence-based step toward reducing these burdens and improving patient access to timely care, particularly in high-volume, complex prescribing environments.

The AAFP recommends the final rule confirm that these requirements will apply consistently across all impacted payer types, including MA organizations, on a uniform timeline. **Family physicians frequently encounter variation in PA requirements across payers, and the effectiveness of this policy will depend on consistent, system-wide adoption**. Without such alignment, primary care physicians will continue to experience fragmented workflows and administrative burden, limiting the intended benefits of the proposal.

Proposed Requirements to Support the NCPDP SCRIPT Standard for Prior Authorization, Formulary and Benefit Standard, and Real-Time Prescription Benefit Standard for State Medicaid and CHIP Fee-for-Service (FFS) Programs, Medicaid Managed Care Plans, CHIP Managed Care Entities, and Qualified Health Plan Issuers on the Federally-facilitated Exchanges (FFEs)

For drugs covered under the pharmacy benefit, the Department proposes to require impacted payers use specific, unexpired NCPDP standards beginning Oct. 1, 2027, including the SCRIPT standard (including updated versions aligned with ONC certification criteria), the Real-Time Prescription Benefit standard, and the Formulary and Benefit standards. Taken together with the above proposal regarding drugs covered under the medical benefit being incorporated into the Prior Authorization API, these parallel pathways are intended to create a coordinated ePA environment that reflects the differing infrastructure for pharmacy and medical benefit workflows while achieving interoperability across both. The Department also proposes to require reporting of API endpoint information and usage metrics to support oversight of adoption and performance. Collectively, these proposals aim to strengthen interoperability infrastructure, improve transparency, and ensure that ePA for drugs is implemented consistently and effectively across payer types.

The AAFP appreciates and supports CMS and ONC's ongoing efforts to align interoperability requirements across programs, particularly regarding the coordinated adoption of HL7 FHIR-based APIs and NCPDP standards for drugs covered under both medical and pharmacy benefits. As we have previously noted, consistent, phased implementation of updated NCPDP standards will allow physicians and health IT developers to adopt new functionality in a predictable and manageable manner, reducing administrative burden over time. However, the success of these policies will depend on system-wide adoption across all impacted payer types and adherence to aligned implementation timelines. Absent such alignment, primary care physicians may continue to face fragmented workflows, increased costs, and limited improvements in PA

efficiency. **We urge the agencies to closely monitor industry readiness as compliance deadlines approach and to provide targeted technical guidance to payers to support timely and consistent implementation**

Extensions, Exemptions, and Exceptions

The agencies propose that state Medicaid and CHIP FFS programs may request extensions to the proposed compliance date to incorporate drugs covered under a medical benefit into the Prior Authorization API and from the proposed requirement to support an unexpired version of the NCPDP standards that the Secretary has adopted. Additionally, the agencies propose that QHP issuers on FFEs may request an exception from the proposed requirement to support an unexpired version of the NCPDP standards and that a QHP issuer on the FFEs seeking an exception from the Prior Authorization API requirements (or proposed requirement to support an unexpired version of the NCPDP standards) must describe their current or proposed means of conducting prior authorization instead.

The AAFP appreciates that CMS and ONC recognize the implementation challenges faced by state Medicaid and CHIP agencies, and we support the proposed extension and exception pathways to provide needed flexibility. State agencies serve diverse and often vulnerable patient populations while managing limited resources and complex legacy systems, and additional time to implement these requirements in a deliberate and sustainable manner is appropriate. We believe these flexibilities, particularly the availability of multi-year extensions aligned with HIPAA compliance timelines, will help mitigate disruption and support more effective adoption of ePA processes. At the same time, it is critical that these policies ultimately result in improved access to timely care for Medicaid and CHIP patients, who are especially vulnerable to delays and administrative barriers. The AAFP encourages the agencies to continue pairing reasonable flexibility with clear expectations and technical support to ensure that implementation advances both patient care outcomes and system efficiency.

II.C. Improving Communications and Decision Timeframes for Prior Authorizations

Proposed Requirement to Include a Specific Reason for Denial in Response to Prior Authorization Requests for All Drugs

The agencies propose to require state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to communicate a specific reason for denying a prior authorization request for any drugs beginning October 1, 2027, regardless of the method used to submit or respond to the request. A “specific reason” for denial could include information about the specific plan coverage criteria on which the denial was based, why the provided documentation did not support the prescription, or why the drug

was not deemed necessary. This requirement would apply uniformly across all communication channels to ensure that physicians and their care teams receive necessary information to support clinical decision-making and appeals. The agencies indicate that this policy is intended to improve transparency, reduce unnecessary resubmissions, and promote more efficient prior authorization workflows.

The AAFP supports this proposal and the proposed October 1, 2027, compliance date. We agree that requiring payers to provide a specific reason for denial, regardless of the submission or response channel, will improve transparency and reduce unnecessary resubmissions and administrative rework. Physicians and their care teams must receive detailed, clear, and actionable information regarding prior authorization denials to effectively support clinical decision-making and pursue appropriate appeals. As the AAFP stated in its 2022 Electronic Prior Authorization RFI response, standards "should clearly indicate the expected timeline for a response, ensure physicians are able to easily access payers' rationale for denying a request, and outline the process and documentation needed to appeal a decision."

However, the current drug PA environment remains characterized by opaque and inconsistent denial communications, including denials that lack clinical rationale, citation of the coverage criteria applied, or clear instructions for appeal. We believe CMS can strengthen the effectiveness of this proposal by establishing explicit minimum standards for denial transparency and appeal pathways for drug PA, consistent with the goals of reducing physician burden and improving timely access to medically necessary care. We also support continued alignment of compliance and reporting expectations across HHS programs to reduce fragmentation and variability for clinicians and patients. **The AAFP recommends that the final rule require**:

- A standardized, machine-readable denial rationale with each drug PA denial, including the specific coverage criteria applied and the evidence-based guideline or formulary standard used in the determination;
- A structured, FHIR-native appeal pathway through the Da Vinci Prior Authorization Support (PAS) IG that would support submission of appeal documentation within the same electronic workflow used to submit the original PA request;
- A maximum 24-hour response time on expedited appeals for drugs where treatment delay would create a risk of serious adverse health outcomes; and
- More granular public reporting by drug category, demographic group, and plan type to enable better oversight of drug PA denial rates. This would enable CMS, physicians, and the public to more easily identify patterns of inappropriate PA denials.

Prior Authorization Decision Timeframes

CMS proposes that beginning October 1, 2027, QHP issuers on the FFEs must notify the requesting provider of their decision in response to a request for PA for non-drug items and services no later than 7 days after receiving a standard PA request and no later than 72 hours after receiving an expedited PA request. QHP issuers on the FFEs have previously been excluded from this requirement, meaning patients' access to care can potentially be denied based only on the type of insurance they have. The agency also proposes that in response to a drug PA request, QHP issuers on the FFEs must notify a requesting provider of their decision no later than 72 hours after receiving a standard PA request and no later than 24 hours after receiving an expedited PA request, starting October 1, 2027. Additionally, the agency proposes to shorten decision timeframes for drug PA requests to 24 hours for Medicaid and CHIP FFS programs, also with a compliance date of October 1, 2027.

The AAFP supports CMS' proposals to shorten and standardize PA decision timeframes across QHP issuers on the FFEs for both non-drug items and services and prescription drugs, and we support applying these standards beginning October 1, 2027. We support the proposed drug PA timeframes of 72 hours for standard requests and 24 hours for expedited requests, and we agree that extending the 7-day standard and 72-hour expedited timeframe for non-drug PA requests will help ensure that patients' access to medically necessary care is not delayed based solely on coverage type. The AAFP also strongly supports the proposal to shorten Medicaid and CHIP FFS drug PA decision timeframes to 24 hours. **The AAFP strongly agrees with the agencies that shortening and standardizing timeframes for PA decisions across programs can improve access to health care and mitigate the negative impacts of delays, particularly for patients with chronic or complex conditions.**

As part of our support for shortened PA decision timeframes, we urge CMS to extend equivalent timeframe standards to MA drug PA. Family physicians treat significant proportions of MA patients, and inconsistent standards across payer types create confusion and unequal access. The proposed timeframes for Medicaid, CHIP, and QHP plans are appropriate and align with the clinical reality that drug PA delays can directly interrupt a patient's care plan. The AAFP strongly recommends that CMS establish 72-hour standard and 24-hour expedited timeframes for MA drug PA requests in this rule, consistent with the proposed QHP standards. **We strongly support the agencies' suggestion they undertake future rulemaking to propose a requirement for MA organizations to respond to all PA requests for drugs no later than 24 hours, to align with the Medicaid and CHIP requirements for covered outpatient drugs**.

Finally, the AAFP urges CMS to establish automatic approval for PA requests that are not decided within the required timeframes. We believe automatic approval upon deadline expiration would be the most effective mechanism to ensure compliance and would thus prevent physicians and patients from bearing the cost of payer delays through interrupted care and abandoned treatment.

Proposed Changes to Reporting Deadlines and Reporting Levels for Publicly Reported Prior Authorization Metrics for Non-Drug Items and Services for Medicaid Managed Care Plans and CHIP Managed Care Entities

The agencies propose to modify the deadlines for Medicaid managed care plans and CHIP managed care entities to report certain metrics about PAs for non-drug items and services to be no later than 90 days after the end of their contract rating period, as opposed to March 31 of each calendar year. They propose to require the same plans report certain metrics about PAs for non-drug items and services, finalized in the 2024 Interoperability and Prior Authorization final rule, by program, as well as by plan. All proposals would become effective beginning on the effective date of the final rule.

The AAFP supports the proposed changes to reporting deadlines and reporting levels for publicly reported PA metrics. Reporting metrics at both the program and plan levels will provide greater transparency into PA practices and enable more meaningful comparisons across payers and programs. This level of detail is critical to identifying patterns in PA use, including variations that may contribute to administrative burden or delays in patient care. We believe these enhancements will improve accountability and support ongoing efforts to identify and reduce unnecessary or inappropriate PA requirements, thereby decreasing the administrative burden associated with remaining requirements and ultimately improving patients' access to timely, appropriate care.

We recommend HHS actively monitor the implementation and reporting of these requirements to ensure the intended transparency goals are achieved. Our members continue to report that while existing PA transparency data is publicly available, it's often difficult to locate, inconsistent in format, and challenging to interpret in a meaningful way for clinical or operational decision-making. **To address this, the AAFP recommends CMS establish standardized reporting formats, definitions, and delivery mechanisms for PA data**. This could include uniform templates, centralized access, and machine-readable formats that allow for consistent interpretation across payers and programs. Ensuring that reported data are accessible, comparable, and actionable is critical to reducing administrative burden and helping practices make better informed decisions.

Proposed Changes to Publicly Reported Prior Authorization Metrics for Non-Drug Items and Services for Impacted Payers

Beginning on the effective date of the final rule, CMS proposes to require impacted payers report a numeric count of PA requests for certain existing metrics, expanding beyond the current requirements that impacted payers must report the percentage of PAs that were approved, denied, approved after appeal, and approved after the timeframe for review was

extended. In addition, the agency is proposing to add four metrics that are complementary to the existing metrics: total number and percentage of standard PA requests for non-drug items and services that remain denied after appeal during the reporting period; total number and percentage of expedited PA requests for non-drug items and services that remain denied after appeal during the reporting period; total number and percentage of standard PA requests for non-drug items and services for which the timeframe for review was extended, and the request was denied during the reporting period; and total number and percentage of expedited PA requests for non-drug items and services for which the timeframe for review was extended, and the request was denied during the reporting period.

The AAFP supports CMS' proposal to expand publicly reported non-drug PA metrics to include both numeric counts and percentages, as well as additional measures capturing denied requests after appeal and denials following extended review timeframes. We agree with the agency that in order to make these metrics truly useful, CMS and the public must understand the scope of the PA requests, both as an absolute number and as a percentage. Reporting both dimensions will provide a more complete and accurate picture of payer behavior, including the frequency and persistence of denials. We believe the addition of these new metrics will enhance transparency and enable stakeholders to better assess whether PA processes are functioning efficiently and support timely patient care. **The AAFP further recommends that CMS actively monitor implementation and reporting of these enhanced metrics and, in future rulemaking, establish standardized formats, definitions, and delivery mechanisms to ensure that publicly reported PA data are accessible, comparable, and actionable for physicians, policymakers, and other stakeholders**.

<u>Proposed Requirement to Publicly Report Prior Authorization Metrics for Drugs for Impacted Payers</u>

CMS proposes to expand public reporting requirements to include PA metrics for drugs across all impacted payer types, including requiring MA organizations to report metrics for drugs covered under Part B and requiring Medicaid, CHIP, and QHP issuers on the FFEs to publicly report drug PA metrics. Impacted payers would be required to publish these metrics annually, with MA organizations, state Medicaid and CHIP FFS programs, and QHP issuers reporting by March 31 of the following calendar year, while Medicaid and CHIP managed care entities would report within 90 days after the end of their rating period. The proposal would also establish standardized reporting levels, requiring reporting at the contract, state, plan, program, or issuer level to ensure consistent and comparable data across programs. Finally, the agency proposes a 2028 compliance date for reporting of metrics from the 2027 reporting period to allow sufficient time for implementation.

The AAFP supports CMS' proposal to expand publicly reported PA metrics to include drugs across all impacted payer types, as well as the standardized reporting framework and 2028 implementation timeline. We agree that extending these transparency requirements to drug PA will provide a more comprehensive view of payer practices and their impact on patient access to care. As with non-drug metrics, we believe these data are most meaningful when presented as both numeric counts and percentages, enabling stakeholders to fully understand the scope and frequency of PA activity. Standardized reporting at the contract, state, plan, program, and issuer levels will further enhance comparability and accountability across payer types. These changes will strengthen transparency and support more informed oversight of impacted payers, which should lead to the elimination of unnecessary or inappropriate PA requirements.

II.D. Requirements for Issuers that Offer Small Group Market Qualified Health Plans on the Federally-facilitated Small Business Health Options Program Exchanges (p.60)

CMS proposes to expand requirements from the 2024 CMS Interoperability and Prior Authorization final rule to QHP issuers on the Federally-facilitated Small Business Health Options Program (FF-SHOP) Exchanges, with a compliance deadline of January 1, 2028. These proposals apply to the Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization APIs and include requirements to annually report PA metrics at the issuer level in the form, manner, and timeframe specified by the Secretary. Specifically, CMS proposes to require FF-SHOP issuers to support clinician access to patient data and implement patient protections related to data sharing and privacy, in addition to complying with established interoperability timelines and meeting standardized, shorter timeframes for responding to PA requests, including for drugs. The agency also proposes to extend to QHP issuers on the FF–SHOP Exchanges the existing annual exception process available to individual market QHP issuers on the FFEs regarding the Patient Access API. Under this process, an issuer seeking an exception must submit a narrative justification describing why it cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance on clinicians and enrollees, the current or proposed alternative for providing the required information, and a plan and timeline to achieve compliance.

The AAFP supports CMS' proposal to expand interoperability and PA requirements to QHP issuers on the FF-SHOP Exchanges, **as aligned requirements across payer types are essential to reducing administrative complexity and improving consistency for physicians and patients**. Extending these standards to FF-SHOP issuers will help ensure that family physicians can engage with a more predictable and standardized PA and data exchange environment, regardless of payer type. We also support the proposed January 1, 2028, compliance deadline, which provides appropriate flexibility for smaller issuers to implement these requirements in a thoughtful and sustainable manner. At the same time, it is important that these timelines are maintained to ensure timely adoption and to avoid prolonging disparities in access and

workflow efficiency across payers. Additionally, the AAFP does not object to the flexibilities proposed for QHP issuers on the FF-SHOP Exchanges as outlined in the exceptions process; however, we believe it is essential that all issuers ultimately come into compliance with these regulations to ensure consistency across payer types for both patients and physicians. We encourage CMS to continue pairing reasonable flexibility with clear expectations and targeted technical support to ensure that implementation advances both patient care outcomes and system efficiency.

II.E. Reporting Payer API Endpoints and Associated Information for CMS to Publish API Endpoints

CMS proposes to require impacted payers report their API endpoints to the agency no later than 60 days after the effective date of the final rule for each required interoperability API. This requirement would not apply to state Medicaid or CHIP FFS programs granted an extension or to a QHP issuer on the FFEs granted an exception from implementing one or more of the interoperability APIs. Impacted payers would be required to report their API endpoints as an Endpoint Resource, as defined within an already-adopted FHIR standard. CMS further proposes that newly impacted payers would be required to report their API endpoint information no later than 60 days before they begin covering patients under an applicable CMS program. Going forward, impacted payers would be required to notify CMS within one week of any changes to their API endpoints and to annually attest that their reported information remains accurate.

The AAFP supports CMS' proposal to require impacted payers to report their API endpoints and provide timely updates, as these steps are critical to advancing interoperability and improving data exchange across the health care system. **We strongly agree with CMS that it would help everyone in the health care industry for the agency to collect API endpoints and make them publicly available in a standardized format that can easily be accessed and used by app developers, EHR developers, physicians, and payers**. Transparent, standardized reporting of endpoint information will reduce barriers to integration, support more efficient implementation of interoperability tools, and improve clinicians' ability to access actionable data at the point of care. We also support the proposed requirements and timelines for ongoing updates and annual attestations, which will help ensure that this data remains accurate and reliable over time.

<u>API Documentation</u>

CMS proposes to require impacted payers report to the agency the URLs for specific required API documentation. This proposal is intended to ensure that the business and technical documentation requirements established in the 2020 CMS Interoperability and Patient Access final rule and the 2024 CMS Interoperability and Prior Authorization final rule are publicly available and easily discoverable. Required documentation would include a direct URL to the

FHIR capability statement, one or more URLs to a publicly accessible website describing authorization protocols and implementation details, and API registration information. CMS states it would then publish these URLs for centralized, public access. The agency further notes that though these documentation requirements already apply to impacted payers, this proposal is intended to enhance transparency and facilitate broader public accessibility.

The AAFP supports CMS' proposal to require reporting and centralized publication of API documentation URLs, as we believe this approach will improve transparency and access to critical interoperability information across the health care system. The AAFP strongly believes that transparency includes the "easy availability" of data, methodologies, and operational information needed to understand and navigate health care systems. Centralizing access to API documentation will enable physicians, patients, and technology developers to more easily locate and use this information, which in turn reduces barriers to effective data exchange and care coordination. These proposals are also consistent with AAFP's long-standing position that patients and clinicians should be able to access meaningful health care information in real time to support informed decision-making.

Alternative Proposal—National Directory of Healthcare Providers & Services Implementation Guide (IG)

CMS offers an alternate proposal under which impacted payers would be required to use the National Directory of Healthcare Providers & Services (NDH) IG Endpoint Profile as a standardized framework for reporting API endpoint information. Developed to support a national directory infrastructure, the NDH IG provides a FHIR-based framework for sharing information about clinicians, organizations, services, and technical connectivity details. Under this approach, CMS proposes to require impacted payers to report NDH IG Endpoint Profile-compliant resources containing the relevant information for each interoperability API. In cases where a single endpoint supports multiple APIs with the same service address (URL) and related documentation requirements, a single Endpoint Resource could be used to report this information. This approach was designed to support a nationally consistent "source of truth" for provider directory and connectivity information, in pursuit of reducing fragmentation and duplicative reporting across payers and systems.

The AAFP supports the goals underlying CMS' alternative proposal to require impacted payers to adopt the NDH IG as a standardized, FHIR-based framework for managing and sharing provider directory and endpoint information. Provider directory data is currently maintained redundantly across hundreds of payer systems, clearinghouses, and health information networks. Reducing fragmentation in provider directory infrastructure is a long-standing priority for the AAFP, as family physicians routinely experience the downstream impacts of inaccurate, outdated, and inconsistent directory data when patients cannot reliably identify in-

network physicians, PA requests are misrouted, or care coordination is undermined by outdated contact and endpoint information. As we stated in our June 2025 response to the CMS and ASTP/ONC Health Technology Ecosystem Request for Information (RFI), "having a single place to maintain a digital identity and accompanying physician-specific data would be very helpful to family physicians." If implemented with appropriate safeguards and sufficient lead time, the NDH IG could represent meaningful progress toward that goal.

However, the AAFP does not support CMS finalizing this alternate proposal in place of the primary proposal at this time. Instead, we recommend CMS use this alternate proposal as an opportunity to develop a broader, long-term vision for digital identity and directory infrastructure modernization across the health care system. We offer the following priorities and considerations for potential future implementation of the NDH IG:

1) **Prioritize User-Centered Design and Physician Burden Reduction.**
The value of the NDH IG will depend entirely on whether the underlying data is accurate, timely, and consistently maintained. The AAFP is concerned that placing primary reporting responsibility on impacted payers without corresponding requirements for physicians and their EHR vendors to publish and verify endpoint data may perpetuate the "stale directory" problem through a new technical framework. CMS should establish clear governance standards defining which entities bear responsibility for initiating, verifying, and maintaining specific data elements.

   In addition, any physician-facing workflows for updating or attesting to directory data must be designed to minimize administrative burden. As noted in the Health Technology Ecosystem RFI, the AAFP recommends that CMS "not mandate anything before a properly developed system featuring user-centered design has been established" and that mandates follow demonstrated adoption and workflow integration. We believe CMS should adopt a phased implementation approach in which: 1) payers are required to publish NDH Endpoint Profile-compliant resources on a defined timeline; 2) CMS provides technical assistance to physician practices, particularly small and independent practices, to support engagement with NDH-compatible systems; and 3) any physician compliance obligations are introduced only after EHR vendors have integrated NDH workflows into certified products.

2) **Align NDH IG Implementation with Trusted Exchange Framework and Common Agreement (TEFCA) and Existing Endpoint Frameworks.**
CMS should ensure that any NDH IG-based approach is explicitly aligned with the TEFCA endpoint registry and other existing endpoint directories maintained by Qualified Health Information Networks (QHINs). Absent clear alignment, the NDH IG risks becoming an additional parallel reporting requirement layered onto existing frameworks, which

would increase rather than reduce fragmentation and administrative complexity. **The AAFP urges CMS to work with ONC to establish a coordinated federal strategy that consolidates existing endpoint reporting obligations for covered entities participating in TEFCA**. To the extent feasible, CMS should consider positioning the NDH IG Endpoint Profile as part of a broader, harmonized approach to endpoint management across TEFCA and related initiatives, which would ensure that physicians and payers are not required to maintain duplicative or inconsistent directory submissions across multiple systems.

3) **Consider the NDH IG as a Potential Foundation for Broader Digital Infrastructure Modernization**.
In addition to immediate implementation considerations, the AAFP encourages CMS and ONC to consider the longer-term potential of the NDH IG as part of a broader strategy to modernize digital infrastructure across the health care system. Much of today's health IT ecosystem was designed around human-initiated workflows and fragmented data exchange mechanisms, which may not be well-suited to support increasingly automated, interoperable, and real-time data exchange.

   The FHIR-based Endpoint Profile within the NDH IG offers a promising framework for improving how covered entities are identified, discovered, and connected across systems. If implemented at sufficient scale and with reliable, well-maintained data, this approach could support more consistent and efficient exchange of information across stakeholders. Realizing this potential would require continued coordination across CMS, ONC, and industry stakeholders, as well as further development of supporting elements such as standardized identifiers, clearer articulation of endpoint capabilities, and transparent mechanisms for maintaining data quality and availability. We encourage CMS to engage in a multistakeholder process, including physicians, EHR vendors, payers, and health information networks to further explore how the NDH IG could fit into a broader, long-term vision for interoperable digital infrastructure, consistent with the implementation timelines and priorities established in this rule.

4) **Proposed RFI on Governance of Agentic AI in Interoperable Health IT Ecosystems**.
The AAFP recommends that CMS coordinate with ONC to issue an RFI examining the governance of emerging agentic AI systems within FHIR-based health IT ecosystems. AI agents, which can autonomously execute multi-step tasks, initiate transactions, and interact with external systems on behalf of a patient or physician, are increasingly being deployed in clinical and administrative contexts, including PA workflows, referrals, record retrievals, and care coordination. These systems rely on the same foundational infrastructure as other interoperable entities, including discoverable identity, verified endpoints, and clearly defined data exchange capabilities.

As CMS considers the NDH IG framework and broader interoperability strategy, the AAFP encourages the agencies to proactively assess how agentic AI entities should be authenticated, authorized, and governed within these systems. Specifically, we recommend an RFI solicit stakeholder input on: 1) appropriate authentication and authorization standards for AI agents acting on behalf of HIPAA-covered entities; 2) liability considerations when an AI agent initiates or completes a transaction in error; 3) transparency requirements to ensure that patients and physicians understand when they are interacting with an AI system rather than a human or traditional software application; and 4) whether and how AI agent endpoints should be represented, discoverable, and managed within frameworks such as the NDH IG Endpoint Profile.

II.F. Updates to Patient Access, Provider Directory, Provider Access, and Payer-to-Payer APIs; API Usage Metrics

Information About Prior Authorizations for Drugs in the Patient Access, Provider Access, and Payer-to-Payer APIs

CMS refers to the Patient Access, Provider Access, and Payer-to-Payer APIs collectively as the "Access APIs." The agency proposes to require impacted payers include information about PA requests and decisions for all drugs within the data made available through the Access APIs. CMS proposes to amend existing requirements that currently apply to PA for non-drug items and services to ensure that comparable PA information for drugs would also be available. The agency proposes an October 1, 2027, compliance date for MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to meet these requirements.

The AAFP supports CMS' proposal to require impacted payers include information about PA requests and decisions for all drugs within the Access APIs, aligning these requirements with those already established for non-drug items and services. Expanding the availability of this information across patient, physician, and payer access points will improve transparency and support more informed clinical decision-making, care coordination, and continuity of care. The AAFP also supports applying consistent timeframes for making this information available, as alignment across workflows is essential to reducing administrative burden and fragmentation. We believe the proposed October 1, 2027, compliance date provides a reasonable and achievable timeline for implementation.

Reporting Usage Metrics for Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization APIs

b. Proposed Changes to Patient Access API Usage Metrics for Medicaid Managed Care Plans, CHIP Managed Care Entities, and Individual Market QHP Issuers on the FFEs

CMS proposes to revise reporting deadlines for impacted payers to submit aggregated, deidentified Patient Access API usage metrics. For Medicaid managed care plans and CHIP managed care entities, CMS proposes to replace the existing March 31 annual deadline with a requirement to submit data no later than 90 days after the end of each applicable rating period. The agency also proposes to require Medicaid managed care plans and CHIP managed care entities to report certain Patient Access API usage metrics at both the program and plan levels. For QHP issuers on the FFEs, CMS proposes to align reporting with the annual QHP certification process, which would allow issuers to submit Patient Access API usage metrics as part of that process, reducing administrative complexity. These proposed changes would be effective beginning on the effective date of the final rule.

The AAFP supports CMS' proposals to revise Patient Access API reporting deadlines and align submission timelines with existing program structures. Aligning reporting for Medicaid managed care plans and CHIP managed care entities with contract rating periods and for QHP issuers with the QHP certification process will reduce administrative complexity and improve the operational feasibility of these requirements. **In particular, we support the proposal to require reporting of Patient Access API usage metrics at both the program and plan levels. Reporting at this level of granularity will improve transparency into how APIs are functioning across different lines of business and enable CMS, stakeholders, and researchers to identify variation in implementation, utilization, and effectiveness**. This approach will better support accountability and inform future policy changes aimed at improving patient access to data and reducing administrative burden.

The AAFP further recommends that CMS extend this reporting structure to MA organizations by requiring the submission of Patient Access API usage metrics at both the plan and contract levels. Requiring more detailed, plan-level reporting for MA plans would promote consistency across payer types and provide a more comprehensive view of API performance across markets.

c. Proposal to Report Metrics About the Provider Access, Payer-to-Payer, and Prior Authorization API Usage for All Impacted Payers

CMS proposes to require all impacted payers to report usage metrics for the Provider Access, Payer-to-Payer, and Prior Authorization APIs as aggregated, deidentified data to support oversight of adoption and use. The proposal would standardize the reporting level by payer type: MA organizations would report at the contract level; state Medicaid and CHIP FFS programs would report at the state level; Medicaid managed care plans and CHIP managed care entities would report at the plan and program level; and QHP issuers on the FFEs would report

at the issuer level. CMS proposes that reporting begin in 2028 using metrics from the 2027 reporting period.

Additionally, CMS seeks comment on whether these API usage metrics should remain unpublished at the payer-identifiable level (not published by contract, state, plan, program, or issuer), or if the agency should make more detailed information payer available to the public. CMS seeks input on the feasibility of separately reporting Provider Access API usage by individual clinicians versus provider groups, whether Payer-to-Payer API metrics should be disaggregated between old-to-new payer exchanges versus concurrent payer exchanges, and whether there are different metrics that we should consider requiring impacted payers to report.

The AAFP supports CMS' proposal to require reporting of aggregated, deidentified usage metrics for the Provider Access, Payer-to-Payer, and Prior Authorization APIs, and we agree these data are essential to evaluating whether these APIs are being adopted and functioning as intended across payer types. Standardized reporting of API usage will provide CMS and stakeholders with critical insight into utilization patterns, identify gaps in implementation, and support ongoing efforts to improve interoperability and reduce administrative burden for physicians and patients. However, we are concerned that limiting the proposed reporting framework to the contract level for MA organizations does not provide sufficient granularity to meaningfully assess API performance across plans within a contract. **As stated previously, the AAFP recommends that CMS require MA organizations to report usage metrics at both the plan and contract levels**. Requiring plan-level reporting would align MA with other payer categories, improve consistency across payer types, and provide a fuller understanding of how APIs are functioning across diverse markets and enrollee populations.

The AAFP would strongly support CMS significantly expanding the usage metrics it requires impacted payers to report. Below are metric categories with examples of usage metrics the agency could consider requiring in the future:

- Effectiveness (answering the question, "Did APIs improve care/processes?"): Successful transaction rates, completion rate of end-to-end workflows, or reductions in manual workflows (such as decreases in fax/phone-based PAs).
- Timeliness/Performance: API latency (total time the API takes to respond to a request), API response time (amount of time the API takes to react to a request once it's been received), or the abandonment rate (percent of PA requests initiated via API but never completed).
- Data Completeness/Quality: Data completeness rate, such as the percentage of required USCDI elements successfully returned; availability of structured vs. unstructured data; denial rationale completeness, including machine-readable format.

- Clinician Experience: Provider-reported administrative time per PA, including pre- and post-API deployment.
- Metrics should include numbers of total PA requests and responses via all modalities, which would allow proper interpretations of raw API transaction numbers and the ability to track total PA decreases or increases.

We strongly recommend that CMS coordinate with ONC on their interoperability measurement programs so that 1) there is appropriate coordination between measurements of interoperability across HHS, 2) the burden of reporting is minimized, and 3) the value of measurement and the data collected can be maximized.

Removing Drug Formulary Information from the Provider Access and Payer-to-Payer APIs

CMS proposes to remove drug formulary information from the required data elements that impacted payers must make available through the Provider Access API and Payer-to-Payer API. CMS states that including formulary data in these APIs may be unnecessary and operationally burdensome relative to their utility, noting that clinicians and patients are already able to access formulary information through other existing channels, such as payer websites and standard communications. CMS therefore proposes to eliminate this requirement for MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities, while clarifying that payers would still be permitted (though not required) to continue providing formulary data through these APIs if they choose. This change would become effective upon the effective date of the final rule.

The AAFP supports CMS' proposal to remove drug formulary information from the required data set for the Provider Access API and Payer-to-Payer API. While the AAFP strongly believes formulary data are highly valuable and should ultimately be available in interoperable, machine-readable formats, we agree that requiring these data in multiple API contexts may create unnecessary operational burden and complexity without sufficient benefit. Focusing formulary data exchange through the most appropriate and purpose-built channels will better support efficient and sustainable interoperability.

We appreciate CMS' candid recognition that including formulary data in these APIs may be burdensome relative to their utility, particularly given that formulary information will continue to be available through the Patient Access API. **However, CMS' observation that clinicians and patients can access formulary information through existing channels should not be interpreted as evidence that current formulary data access is sufficient. Significant gaps remain in the availability of timely and accurate formulary data at the point of care**. Removal of a duplicative requirement from specific APIs does not diminish – and should not obscure – the broader need to improve formulary data interoperability across the health care system. The

AAFP urges CMS to pair this proposal with a forward-looking commitment to advancing formulary data interoperability through the most appropriate technical pathways and related policy initiatives, and we offer the following recommendations and considerations:

1) **The Value of Timely and Accurate Formulary Data**.
Access to accurate, real-time formulary information is essential for effective prescribing. Family physicians routinely prescribe across multiple payer formularies, and the inability to quickly determine coverage status, including formulary tier, step therapy requirements, and PA criteria, creates administrative burden; contributes to prescribing inefficiencies; and delays patient access to needed medications. When formulary information is incomplete, outdated, or unavailable at the point of care, physicians must rely on manual processes such as phone calls or payer portal navigation, which disrupt clinical workflows and may result in downstream patient cost uncertainty.

   The PDex US Drug Formulary IG, the adoption of which we support in the context of this rulemaking, demonstrates the potential for standardized, machine-readable formulary data exchange. The AAFP encourages CMS and ONC to continue prioritizing the maturation and adoption of FHIR-based formulary standards as the primary mechanism for delivering formulary information to clinicians, ideally within EHR-integrated prescribing workflows.

2) **Additional Work Is Needed to Improve Formulary Data Interoperability**.
Despite recent progress, formulary data interoperability in the U.S. health care system remains limited. Current challenges include inconsistent data refresh cycles across plans; variability in how tiering, PA requirements, and step therapy policies are represented; and insufficient integration of formulary data into EHR-based prescribing workflows. These limitations significantly reduce the practical value of existing formulary information for physicians at the point of care. **The AAFP encourages CMS to consider a phased approach to advancing formulary data interoperability, including more consistent update requirements, standardized data elements, and alignment with ONC certification requirements to ensure that certified EHR systems can readily incorporate and display formulary data within clinical workflows**.

3) **Addressing Mid-Plan-Cycle Formulary Changes**.
The AAFP encourages CMS to use this rulemaking cycle as an opportunity to address the impact of mid-plan-cycle formulary changes on patient access and continuity of care. Family physicians frequently encounter situations in which patients select a health plan based on coverage of specific medications, only to experience formulary changes during the plan year that alter coverage status, increase cost-sharing, or introduce new utilization management requirements. These changes can disrupt treatment regimens,

particularly for patients with chronic conditions, and may result in decreased adherence or delayed care.

We recommend CMS consider establishing a standardized reporting and notification framework for mid-plan-cycle formulary changes, including requirements for payers to report such changes to CMS, provide advance notice to affected enrollees, and offer continuity-of-care protections where appropriate. In addition to improving patient protections, such reporting would help CMS better understand the frequency and impact of mid-year formulary changes and inform future policy development. The AAFP encourages CMS to consider issuing an RFI or incorporating related data collection efforts to support further analysis in this area.

Denial or Discontinuation of Access to the Provider Directory API

CMS proposes to require MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to update their policies governing denial or discontinuation of access to their Provider Directory APIs. This would align documentation requirements and technical standards for Provider Directory APIs with requirements for the Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization APIs. The proposal would become effective beginning on the effective date of the final rule.

The AAFP supports CMS' proposal to require impacted payers to update their policies governing denial or discontinuation of access to the Provider Directory API. **Aligning these policies and associated documentation requirements with those established for other interoperability APIs will promote greater consistency, transparency, and reliability across data exchange pathways**. We agree that harmonizing standards across APIs is essential to reducing fragmentation and ensuring that physicians have stable, predictable access to provider directory information. We also support the proposal to make these changes effective on the effective date of the final rule, as timely implementation will help reinforce consistent expectations across impacted payer types.

II.G. Open Payments Civil Monetary Penalties

CMS proposes to add a definition of "failure to report" to the Open Payments program to clarify the circumstances under which reporting entities may be subject to civil monetary penalties (CMPs). Specifically, "failure to report" would be defined as a reporting entity's failure to accurately or completely provide required information or documentation to HHS, CMS, or the Office of Inspector General in a timely manner, including records requested as part of an audit. Under this proposal, CMS would have the authority to impose a CMP on applicable

manufacturers or group purchasing organizations (GPOs) that fail to provide requested books, contracts, records, documents, and other evidence necessary for audit purposes within 30 calendar days of the audit request. The agency proposes this definition would become effective on the effective date of the final rule.

The AAFP supports CMS' proposal to add a definition of "failure to report" under the Open Payments program and the agency's clarification of its authority to impose CMPs in cases of noncompliance. We agree with CMS that it should be unambiguously clear that the agency may impose a CMP if an applicable manufacturer or GPO fails to grant timely access to documents for the purposes of an audit. **Given that the information reported by entities to the Open Payments program can be verified through audit but CMS currently lacks a clear mechanism to compel compliance with audit requests, we believe this definition is a necessary addition to the regulation**. Establishing this authority will strengthen program integrity, support compliance with statutory reporting requirements, enhance transparency in financial relationships within the health care system, and reduce the potential for fraud, waste, and abuse in CMS programs.

II.H. Modifications to HIPAA Standards Related to Prior Authorization

CMS proposes to adopt HL7 FHIR as the HIPAA Administrative Simplification standard for prior authorization transactions, replacing the X12N 278 Health Care Services Review standard for PA-related transactions across all HIPAA-covered entities. Compliance would be required 24 months after the effective date of the final rule (36 months for small health plans). CMS also proposes to adopt FHIR-based "eligibility for a health plan" inquiry and response standards when used to determine whether PA is required, and to apply the FHIR standards to PA transactions ("referral certification and authorization") using a defined set of FHIR specifications and Da Vinci IGs to support standardized electronic exchanges for determining coverage requirements, assembling documentation, and transmitting requests/responses. These IGs include FHIR R4.0.1, US Core IG STU 6.1.0, SMART App Launch IG 2.0.0, Coverage Requirements Discovery (CRD) IG 2.2.1, Documentation Templates and Rules (DTR) IG 2.2.0, and Prior Authorization Support (PAS) IG 2.2.1.

In addition, CMS proposes to adopt the Da Vinci Clinical Data Exchange (CDex) IG 2.1.0 as the attachments standard for PA transactions, with the same 24 and 36-month compliance structure. The agency further requests comment on whether adopting FHIR for PA transmissions while retaining X12N standards for other referral certification use cases would increase burden by requiring covered entities to support two standards, and whether there are benefits to maintaining the X12N 278 standard for referral certification transmissions. Finally, CMS requests comment on whether CDex should be recommended rather than adopted at this time to allow additional real-world testing before it becomes a required attachment pathway.

The AAFP supports in principle the transition from X12N 278 to FHIR-based standards for prior authorization. The X12N 278 standard, while longstanding, does not support the real-time, integrated, EHR-embedded workflows that are essential to reducing physician administrative burden, whereas FHIR's API-based architecture is designed to enable PA within the clinical workflow rather than as a separate administrative interruption, which is an important requirement for family medicine practices. **However, consistent with AAFP's long-established position that standards should not be mandated until they have undergone robust real-world testing across clinical settings (including small, independent, and rural practices) and with end-user involvement, we urge CMS and ONC to ensure that the FHIR standards and associated IGs adopted under HIPAA are demonstrably effective, adoptable, and efficient in real-world use before mandatory compliance is enforced**.

We recommend CMS and other federal agencies continue engaging the broader health IT community to identify expectations for rigorous real-world testing of health IT standards and IGs, such as needed metrics, methods of accountability, assurance that testing results are impartial, external expert review of testing methods and results, impact on health equity, and public reporting of the outcome. Engaging with end-users to conduct real-world testing will increase the likelihood that these technical approaches will succeed and achieve the goals of improved PA processes and reduced burden for patients, physicians, and payers. **This collaborative approach must include small, rural, independent, and other under-resourced practices to ensure standards are adoptable in all settings, and to highlight areas where these practices may need additional support from CMS or particular considerations amid implementation**.

The AAFP further urges CMS to provide detailed implementation guidance for HIPAA-covered physician practices well in advance of the compliance date. Physician practices are HIPAA-covered entities, but the compliance burden is not symmetrical: small and independent practices typically rely on EHR vendors and other exchange partners to implement HIPAA transaction standards on their behalf, and practices cannot be held responsible for gaps in vendor readiness. **Accordingly, we recommend that CMS establish and publicly communicate vendor readiness milestones at least 12 months before the physician compliance date and that ONC ensure these FHIR standards are incorporated into certification requirements with sufficient lead time for implementation**.

To prevent disruption to PA submissions during the transition and to mitigate risks associated with uneven industry readiness, the AAFP recommends that CMS confirm continued availability of the existing X12N 278 standard for any payer or clearinghouse that is not yet fully compliant with the new FHIR standard. Maintaining this fallback capability is essential to ensuring

continuity of operations and protecting patients and physician practices from unintended delays during implementation.

While the AAFP supports the transition to FHIR-based PA transactions, we urge CMS to recognize that establishing a compliance date alone does not constitute a complete transition strategy. A compliance date defines when covered entities must be capable of using new standards; however, it does not ensure that adoption has reached a sufficient scale to safely discontinue legacy infrastructure. Premature withdrawal of X12N 278 transactions, portal-based submission pathways, or other established methods prior to broad market adoption of FHIR-based workflows risks shifting administrative burden onto physician practices and patients, particularly those with limited technical capacity. **Therefore, we recommend CMS establish a formal, utilization-based framework to guide the transition away from legacy PA standards and submission channels. Rather than permitting discontinuation of these pathways based solely on compliance timelines, CMS should require that payers demonstrate sustained, majority utilization of FHIR-based transactions before retiring alternative methods**.

Specifically, the AAFP recommends that CMS require payers to continue supporting X12N 278 transactions and portal-based PA submission pathways until a defined utilization threshold is met, reflecting a clear majority of PA transactions processed through FHIR-compliant channels. **We recommend that CMS establish this threshold at no less than 75% of applicable PA transactions, measured consistently over a sustained period, prior to permitting discontinuation of legacy submission pathways**.

We do not believe this utilization threshold should be assessed solely at an aggregate, system-wide level, as adoption of FHIR-based transactions will vary significantly across provider types, practice sizes, and technical environments. An aggregate measure may obscure continued reliance on legacy pathways among small, independent, rural, or safety-net practices, which often depend on clearinghouses, payer portals, and other non-API workflows due to vendor readiness constraints and limited IT resources. To address this variation, the AAFP recommends CMS develop segmented utilization metrics, including at a minimum:

- Provider organization type: independent practices, community health centers, rural health clinics, critical access hospitals, and large integrated systems;
- Practice size: fewer than 10 physicians, 10-50 physicians, and greater than 50 physicians; and
- Technical capability: availability of FHIR-enabled certified EHR technology and readiness of vendor infrastructure.

The AAFP further recommends that CMS publicly report these segmented utilization metrics on at least a semi-annual basis following the compliance date and establish a structured review process to evaluate readiness for decommissioning legacy pathways. Under such a

framework, discontinuation of legacy submission methods should occur only after the utilization threshold is met within relevant provider segments or after targeted implementation support has been made available to address persistent adoption barriers. This approach is consistent with our longstanding position that health IT standards transitions should be paced to the readiness of the full practice ecosystem, including under-resourced providers. A utilization-based transition framework would protect practices still in transition, promote timely vendor implementation, and provide CMS with objective evidence that the market is prepared to operate without reliance on legacy PA infrastructure. Compared to a date-based transition alone, this approach is more likely to achieve the intended goals of reducing administrative burden and improving patient access to timely care.

II.J. Adoption of Health Information Technology Standards and Incorporation by Reference

Proposal to Adopt Standards for Use by HHS

ONC proposes to adopt updated and expanded HL7 FHIR-based standards to support a more aligned and interoperable nationwide health IT infrastructure. Specifically, ONC would update previously adopted Da Vinci IGs CRD, DTR, PAS, CARIN IG for Blue Button, and Payer Data Exchange (PDex) to newer versions that incorporate technical refinements, improved alignment with U.S. core data standards, enhanced guidance for workflow integration, and improved handling of API interactions. Additionally, ONC proposes to newly adopt the HL7 Da Vinci CDex IG to enable more standardized exchange of clinical documents and attachments and to allow alignment with proposed HIPAA Administrative Simplification requirements related to PA attachments.

The AAFP supports adoption of the Da Vinci IGs as foundational standards for electronic drug prior authorization. Standardization is essential; the current environment, in which payers maintain distinct PA portals, documentation requirements, and response timelines, creates avoidable administrative complexity that is largely attributable to the absence of consistently implemented standards. **We strongly recommend that ONC require EHR vendors to integrate CRD and DTR workflows directly within prescribing and ordering workflows, rather than as separate modules or external portals**. The value of CRD is realized only when coverage and PA requirements surface at the point of clinical decision-making, and DTR must similarly support pre-population of documentation requirements within the EHR to avoid unnecessary context switching and duplicative data entry during PA submission.

We urge ONC and CMS to confirm that the specific IG versions proposed have been validated through real-world testing in primary care settings prior to the compliance date. As AAFP has previously stated, **only standards and implementation guides that have been proven effective and adoptable through real-world testing should be candidates for mandatory certification**

and utilization. Implementing standards before they are fully vetted can worsen physician burden and contribute to care delays. Primary care practices have higher patient volume, smaller staff, and more limited IT support than hospital outpatient departments, and Da Vinci IG performance in these settings should be demonstrated before compliance is required.

Proposed Expiration Dates for Certain Versions of Adopted Standards

ONC proposes to add an expiration date of January 1, 2028, to current versions of certain adopted standards if the proposals to adopt newer versions of those standards and specifications are finalized. ONC says this approach would establish a single, coordinated transition period during which certified health IT developers and other entities could use either the existing or updated versions of the standards to support implementation and deployment. After January 1, 2028, only nonexpired versions of the relevant standards would be available for use. ONC also offered an alternate proposal in which current standards would be removed and replaced with the new standards proposed here upon the effective date of a final rule, without providing a transition period during which multiple versions of each standard would be available for use.

The AAFP appreciates ONC's objective of promoting consistency and interoperability by establishing a coordinated approach to updating these standards, including the proposal to apply a single expiration date of January 1, 2028, to older versions if newer versions are finalized. **However, consistent with our broader position on standards transitions, we urge ONC and CMS to recognize that a fixed expiration date alone does not ensure that updated standards will be adopted and used at sufficient scale in real-world workflows to permit safe retirement of legacy implementations without disruption**. In particular, the alternate proposal to remove and replace standards upon the effective date of the final rule without a transition period risks accelerating fragmentation and operational disruption by forcing rapid upgrades across exchange partners that may not be uniformly ready.

We therefore recommend that ONC pair any expiration date policy with a utilization- and readiness-based transition framework that demonstrates the updated standards are functioning in production before older versions are effectively decommissioned in practice. Specifically, before relying on expiration dates to drive retirement of prior versions, ONC should require evidence that a meaningful share of applicable transactions are successfully flowing through implementations adhering to the updated standards – potentially at a modest threshold, perhaps 30% – but only if adoption is demonstrated among lower-resourced practice settings alongside larger, highly-resourced systems. To avoid masking persistent reliance on older versions by small, independent, rural, or safety-net practices, ONC should encourage, and CMS should operationalize where applicable, segmented utilization reporting that distinguishes provider organization type, practice size, and technical capability. These data should be used to

guide the pace of transition and any future standards retirement expectations. This approach would preserve ONC's goal of achieving a single baseline standard while ensuring the transition is paced to real-world readiness across the full practice ecosystem, thereby reducing the risk of unintended burden and care disruption.

III. Requests for Information (RFIs)

A) Electronic Event Notifications for Value-Based Care and Care Coordination

Use and Content of Patient Event Notifications

++ What data standards, if any, are hospitals using to send that additional information with patient electronic event notifications? What standards could be used to improve the minimum set of information that currently must be shared?

The AAFP supports the transition toward a data-focused, API-driven interoperability ecosystem and believes that advancing FHIR-based standards and APIs is essential to improving the exchange of clinical information. Currently, many hospitals rely on HL7 v2 for event notifications; however, future improvements should prioritize standardized FHIR-based frameworks that can support robust, structured, and machine-readable data exchange. Consistent implementation across stakeholders is equally important, as variability in how standards are adopted continues to undermine real-world interoperability and limit the usefulness of event notification data in clinical workflows. The AAFP recommends CMS promote alignment on common data standards, such as the United States Core Data for Interoperability as a baseline for content and require all exchange partners (not just clinicians) to implement certified, standardized technologies. Consistent, nationwide application of these standards will be necessary to ensure that event notifications are reliable, comparable, and actionable across care settings.

++ What can CMS do to expand the use of patient event notifications and provider engagement with those notifications to improve patient care?

We support CMS prioritizing policies that ensure clinically relevant information is delivered to the appropriate clinicians in a timely, accurate, and usable manner without introducing additional burden into primary care workflows. Expanding use of event notifications will depend on making them easy to integrate into clinical practice, including by supporting "push"-based delivery of high-value event data to a patient's longitudinal care team rather than requiring physicians to actively retrieve information from external systems. CMS should consider supporting targeted education and implementation resources for physician practices to facilitate effective adoption and use of event notification capabilities, particularly small and independent

practices. In addition, CMS should coordinate closely with ONC to align broader interoperability initiatives, including API requirements and data standards, with Conditions of Participation (CoP) notification requirements. Aligning these policies will help ensure that event notifications function as an integrated component of routine care coordination, rather than as a standalone compliance obligation.

++ What additional information should be included in patient event notifications, beyond the minimum set of information that hospitals are currently required to send (patient name, treating practitioner name, and sending institution name), for more effective and useful patient event notifications to better support transitions of care?

The AAFP believes that effective care coordination requires more data sharing than the minimum identifiers currently included in patient event notifications. Primary care teams require timely access to clinically relevant information to safely manage transitions of care. In particular, the AAFP has identified a set of essential data elements that should be consistently available to primary care teams in value-based and care transition contexts. These include data that pertain specifically to the clinical care of patients, as well as data that are more relevant to fulfilling the contractual requirements of the value-based agreement. While all are important, for the purpose of ensuring high quality, safe, and effective care patient care after a hospital visit, the following data elements are critical:

- Admission, discharge, and transfer notifications (timely ADT alerts)
- Referral feedback and closure information
- Lab and imaging results
- Medication fill notifications

Additional data elements that are essential to fulfilling the contractual obligations of the broader value-based agreement include:

- Accurate and timely patient lists (i.e., up-to-date attribution or panel lists of patients for whom the physician is responsible)
- Comprehensive patient demographic and health status information (e.g., risk scores or key diagnoses)
- Timely feedback on care outcomes or performance, such as quality metrics

Including or providing structured access to this information as part of event notifications would better support safe transitions of care. For example, an admission or discharge alert accompanied by key clinical context, such as diagnoses, medication changes, or follow-up needs, is significantly more actionable than a basic notification. **The AAFP therefore encourages CMS to ensure that event notification systems are integrated with broader interoperability infrastructure (through health information exchanges (HIEs), health data utilities (HDUs), APIs,**

etc.), so that clinicians receive timely, relevant, and actionable information without additional administrative burden and can support seamless continuity of care.

++ What are the challenges with standardizing patient event notifications?

Standardizing patient event notifications is challenged not only by technical limitations but also by inconsistent implementation and misaligned incentives across stakeholders. While technical standards such as HL7 v2 and FHIR exist and are capable of supporting robust data exchange, variability in how these standards are implemented across hospitals, health systems, and vendors continues to create friction in real-world interoperability. Even where "standardized" interfaces or APIs are used, differences in interpretation and deployment often require custom integration, which limits scalability and increases administrative burden. **The AAFP continues to emphasize that new standards must be validated through robust, real-world testing across diverse clinical settings prior to widespread adoption in order to ensure they improve interoperability without introducing unintended operational complexity**.

In addition, the AAFP recognizes that organizational incentives may impede standardization efforts. In some cases, competitive or business considerations may discourage the consistent sharing of information with external providers, particularly those outside a given network or system. As the AAFP has previously noted, "the greatest roadblocks arise when organizations prioritize business interests over the needs of patients and their care teams," resulting in fragmented information exchange and increased burden for physicians responsible for patients' long-term care. Inconsistent implementation of standards and misaligned incentives remain the primary barriers to standardizing patient event notifications. Addressing both technical and policy challenges will be necessary to ensure that notification systems function reliably and support meaningful care coordination across the health care system.

++ What operational or technical challenges could hospitals, CAHs, and REHs face if CMS were to require additional standardized data elements related to patient care to be included with the patient event notifications?

The AAFP cautions that adding new data requirements, if not carefully developed and validated, could impose significant operational and financial burdens on hospitals and other exchange partners. Smaller or resource-limited facilities, including rural hospitals and critical access hospitals, may need to update systems and workflows to capture and transmit additional data elements, which can be technically complex and costly. Where supporting standards are not sufficiently mature or widely adopted, these requirements may also lead to inconsistent implementation and uneven vendor support.

We reiterate that CMS and ONC should avoid mandating new technical requirements before robust real-world testing has demonstrated that they are adoptable, effective, and aligned with clinical workflows across diverse care settings. Absent these safeguards, new data requirements risk introducing additional administrative burden, operational complexity, and market consolidation if smaller providers and vendors are unable to comply. Accordingly, any expansion of required data elements should be limited to those that are mature, standardized, and demonstrably useful for patient care. CMS should also provide clear implementation guidance, sufficient lead time, and targeted support to minimize disruption, particularly for small and rural practices.

++ If additional data elements are included in patient event notifications, how can technology mitigate any additional clinician burden?

The AAFP emphasizes that information in event notifications should be delivered in a manner that integrates seamlessly into clinical workflows. Technology can mitigate additional clinician burden primarily by:

- Automating information flow: Event notifications should operate in the background (e.g., through HIE networks or APIs) to deliver relevant data without requiring manual effort from clinicians. Allowing flexibility in technical approaches such as direct messaging, HIEs, or FHIR-based APIs enables hospitals to adopt methods that best integrate with their systems. The AAFP supports flexible, API-driven approaches, which allow data to flow into EHR systems in near real time without requiring additional steps from physicians.
- Avoiding "notification overload": Technology should prioritize clinically relevant, actionable alerts rather than generating excessive or duplicative notifications. For example, intelligent filtering or routing can ensure that information is delivered to the appropriate member of the care team (e.g., a primary care physician receives discharge information, while a pharmacist receives medication updates).
- Streamlining through standards: Consistent use of standardized data frameworks such as FHIR enable event notifications to integrate directly into EHR workflows rather than appearing as separate messages, faxes, or external alerts. This reduces fragmentation and the need for duplicate data entry.

Embedding notifications within existing EHR workflows and leveraging modern, standards-based APIs will be critical to minimizing additional burden associated with expanded data requirements. We believe CMS should continue to emphasize that event notification systems must support efficient, workflow-integrated information exchange, rather than creating additional notification channels or administrative tasks for physicians and their care teams.

++ Are there privacy or data governance considerations if hospitals include additional information in patient electronic event notifications?

The AAFP firmly agrees with CMS that patient confidentiality is paramount, regardless of the scope or volume of information included in patient event notifications. As additional clinical data elements are incorporated, we believe the agency should ensure that clear and enforceable data governance policies define who may access such information, for what purposes, and under what conditions. Consistent with our Data Stewardship policy, these safeguards should include well-defined data use parameters, appropriate patient consent mechanisms, and robust auditing processes to prevent unauthorized access or misuse.

We strongly believe that the patient-physician relationship depends on trust and confidentiality and should be protected as additional data sharing occurs. Any expansion of information in event notifications should be limited to uses that support care coordination and quality improvement and should not allow for secondary or unrelated uses of patient data. **In addition, privacy protections should extend beyond traditional HIPAA-covered entities to include all actors involved in handling patient information to ensure consistent accountability across the ecosystem, including payers and other intermediaries**. Strengthening privacy safeguards and establishing clear, consistent data governance expectations across all entities involved in data exchange are essential prerequisites to expanding the scope of information included in patient event notifications.

++ Could additional process requirements or guidance (for example, minimums for directory entry updates/corrections/removals or outreach/verification efforts) improve the quality of notifications or the likelihood that notifications are delivered to intended recipients?

The AAFP agrees that accurate and up-to-date provider directory information is essential to ensuring that event notifications are delivered to the appropriate recipients. Improved alignment and standardization of directory data across systems could help reduce misrouted notifications and minimize manual follow-up by physician practices. At the same time, we caution against imposing overly prescriptive new process requirements that may inadvertently increase administrative burden without improving interoperability outcomes. Any new requirements for directory maintenance, verification, or outreach should be carefully designed and informed by real-world implementation experience to ensure they are operationally feasible across diverse care settings. As we have consistently noted, new requirements should not be mandated until underlying systems and workflows are sufficiently developed and validated. **Accordingly, we support CMS prioritizing approaches that promote standardized, interoperable directory infrastructure rather than duplicative or practice-level reporting obligations**. Improvements should focus on reducing fragmentation and administrative

complexity, while ensuring that providers are not responsible for maintaining data across multiple, unaligned systems.

Types of Providers and Entities Receiving Patient Event Notifications

++ What actions should CMS consider, such as updating the hospital CoP, that would encourage or require hospitals to exchange alerts with any ACO and other PAC provider and supplier types or payers to which a patient is attributed or assigned?

The AAFP supports efforts to ensure that care coordination entities, including accountable care organizations (ACOs) and other value-based care participants, receive timely event notifications for patients for whom they are responsible. In many cases, these notifications are functionally routed through the patient's primary care practice, which may be part of an ACO or similar entity. However, clarifying or expanding hospital expectations to explicitly include accountable care entities could strengthen these data flows and improve care coordination. The AAFP has consistently emphasized that value-based care depends on accurate, timely patient attribution and reliable data sharing across all members of the care team. If CMS pursues requirements to expand notification recipients, we recommend the following considerations guide implementation:

- Policy alignment is critical: Notification requirements should be aligned across all exchange partners. CMS should require ACOs, payers, and other entities expected to receive notifications to support compatible, standards-based technology. Without such alignment, hospitals and physicians may face fragmented and incompatible workflows that undermine interoperability.
- Facilitate data "push" to accountable entities: The AAFP believes data and information sharing should take a "push" rather than a "pull" approach, in which patient health data and information is proactively and automatically shared with their primary care physicians to promote coordinated care. CMS should encourage hospitals to integrate notification workflows that include ACO care managers or payer care coordinators, where appropriate, while maintaining appropriate patient privacy protections.
- Utilize intermediaries to streamline data flows: The AAFP strongly supports the use of neutral, centralized data infrastructure such as HIEs and HDUs to facilitate scalable and cost-effective data exchange. Delivery of notifications through these intermediaries is generally more efficient and sustainable than point-to-point interfaces, which can create significant financial and operational burden, particularly for primary care practices.

Overall, the AAFP supports expanding notification requirements to include ACOs and other care coordination entities, provided such expansion is implemented through standardized, interoperable infrastructure that minimizes fragmentation and administrative burden. We believe CMS should ensure that any expanded notification requirements are aligned across

stakeholders, supported by consistent technical standards, and designed to deliver actionable information that improves care coordination and patient outcomes.

++ What challenges prevent hospitals from sharing electronic event notifications with ACOs and other PAC provider and supplier types today?

The AAFP agrees that the primary barriers to sharing electronic event notifications with ACOs and other post-acute care (PAC) providers are not purely technical but also include incentive and organizational challenges. While technical pathways for data exchange often exist, such as through an HIE, participation in bidirectional exchange remains uneven. Some organizations have not prioritized connectivity with external partners, and in some cases, organizations may also be reluctant to share data that they perceive as competitively sensitive, which further limits interoperability. AAFP members report ongoing challenges, including:

- Reliance on legacy communication methods: Continued use of fax and telephone-based workflows in place of automated, real-time notifications limits timely care coordination and undermines the value of existing interoperability infrastructure.
- Information blocking or limited data sharing: Hospitals may fail to share event notifications due to intentional practices or operational inertia. The AAFP continues to urge HHS to monitor whether existing disincentives for information blocking are effectively promoting compliance, while also ensuring that enforcement frameworks do not disproportionately burden independent, rural, or under-resourced physician practices.
- Lack of standardization across payer and ACO relationships: Hospitals often must support multiple, non-standardized workflows to exchange data with different ACOs and payers, which increases operational complexity and limits scalability of notification systems.
- Underutilization of intermediary infrastructure: Limited use of HIEs, HDUs, and other shared infrastructure requires primary care practices to maintain multiple, point-to-point interfaces, which increases both cost and administrative burden.

In addition to technical challenges, misaligned incentives and fragmented implementation approaches continue to limit broader adoption of electronic event notifications. Addressing these barriers will require not only improved technical standardization, but also stronger alignment of incentives, expanded use of shared infrastructure, and continued enforcement of data-sharing requirements to support meaningful care coordination.

++ What challenges do long-term care or PAC providers face in receiving patient event notifications? What steps could CMS take to help address these challenges?

The AAFP recognizes that PAC and long-term care providers remain less fully integrated into the broader interoperability ecosystem, which limits their ability to consistently receive electronic event notifications. While many PAC providers use EHR systems, hospitals continue to report lower rates of data exchange with PAC providers compared to primary care and in-system providers. Key challenges include incomplete connectivity, in which PAC providers may not participate in the same HIE networks or interoperability frameworks as hospitals, as well as continued reliance on manual communication processes, such as phone calls and fax.

To address these challenges, CMS should prioritize policies that expand the use of common, standards-based interoperability frameworks across care settings. This includes ensuring that PAC providers have the capability to receive standardized admission, discharge, and transfer ADT notifications through HL7-based messaging or FHIR-enabled APIs. We recommend the agency encourage and support the use of intermediary infrastructure like HIEs and HDUs to facilitate the routing of event notifications to PAC providers without requiring costly point-to-point interfaces. The AAFP further recommends that CMS take a system-wide approach to improving interoperability by promoting consistent standards, aligning implementation expectations across settings, and supporting participation by PAC providers in shared data exchange networks. Strengthening these foundational capabilities will enable more reliable delivery of event notifications, improve care coordination during transitions, and reduce administrative burden throughout the health care system.

++ What processes are in place for attribution and patient matching between hospitals and ACOs or other value-based care arrangements, payers, PAC facilities, long-term care facilities, social service providers, EMS providers, behavioral health providers, etc.? Are these adequate? What is missing from these processes?

AAFP members consistently report that timely and accurate patient attribution information remains a significant gap in current interoperability infrastructure. In value-based care models, physicians must be able to identify which patients are attributed to them across payers and receive timely notification of relevant care events. While attribution lists and alignment processes exist, they are often not shared in a consistent, timely, or actionable manner. As a result, even when attribution has been established, critical event information may not reliably reach the physician responsible for a patient's longitudinal care. Patient matching presents additional challenges, as variability in identifiers and data quality across systems can result in mismatches, duplicate records, or missed notifications. These limitations are particularly impactful in care transition contexts, where incomplete or inaccurate patient matching can disrupt follow-up care and coordination.

The AAFP believes that current attribution and patient matching processes remain fragmented and insufficient to support effective interoperability. **We recommend CMS prioritize the**

development of more standardized and centralized approaches to patient attribution, including more frequent and consistent updates to attribution lists, as well as improvements in patient matching methodologies. The AAFP supports the use of neutral data intermediaries like HIEs to facilitate more reliable routing of event notifications and ensure that accountable clinicians consistently receive information needed to support patient care.

++ How can improved standardization, sharing, and use of provider directories contribute to better electronic event notifications?

The AAFP agrees with CMS that accurate and up-to-date provider directory information is foundational to ensuring that patient event notifications are routed to the appropriate recipients. Improved standardization and sharing of directory data across systems has the potential to reduce administrative complexity, particularly for small and independent practices that must navigate multiple, fragmented information sources. For example, greater reliance on consistent, regularly updated directory infrastructure could reduce misrouted notifications and minimize the need for manual verification of contact information. **At the same time, the AAFP emphasizes that any efforts to improve provider directory functionality must be designed to reduce administrative burden, and we reiterate that new requirements should not be mandated until the underlying systems and workflows have been sufficiently developed, tested, and demonstrated to be effective in real-world settings**. Overly prescriptive or duplicative requirements risk introducing additional reporting obligations without improving interoperability outcomes. We support CMS prioritizing approaches that promote standardized, shared directory infrastructure aligned with existing interoperability frameworks, while avoiding the creation of new, practice-level reporting or maintenance tasks.

Complementary Policy Approaches

++ In what ways could CMS leverage other programs, such as the Medicare Promoting Interoperability Program, to advance the use of patient event notifications? For instance, what measures could CMS add to the Medicare Promoting Interoperability Program for eligible hospitals and CAHs that assess the degree to which notifications are sent to recipients?

The AAFP urges CMS to prioritize policies that drive meaningful improvements in care coordination rather than introducing additional process measures that may increase administrative burden without improving outcomes. While incorporating event notification measures into the Promoting Interoperability Program may increase visibility, the AAFP cautions against adding new metrics unless they are clearly aligned with improved clinical performance and workflow integration. Family physicians consistently report that redundant or misaligned measures across programs create confusion and administrative burden without corresponding benefit. If CMS elects to incorporate event notification measures, it should ensure alignment

with ONC certification requirements and broader interoperability initiatives so that hospitals and health IT developers have the necessary standardized, certified functionality in place to support effective implementation.

++ What are other ways that CMS could incentivize improved delivery and use of patient event notifications?

The AAFP encourages CMS to consider the following approaches to incentivize improved delivery and use of patient event notifications:

- Align incentives with care coordination outcomes: CMS should incorporate effective care coordination, supported by timely and reliable event notifications, into value-based payment models and care delivery programs. Incentivizing physicians and hospitals that successfully close care transition loops would help ensure that notifications are not only delivered but also used to improve patient outcomes.
- Invest in infrastructure and implementation support: The AAFP supports targeted financial and technical assistance for physician practices, particularly small and independent practices, to adopt interoperable tools. Extending similar support to hospitals, post-acute care providers, and others implementing notification capabilities would improve adoption and reduce disparities in capability across settings. This could include grants, technical assistance, or enhanced payments.
- Minimize additional administrative burden: Any incentive structure should be designed to be straightforward and aligned with existing reporting frameworks. CMS should avoid introducing new, complex reporting requirements and instead consider leveraging existing quality measures or streamlined reporting pathways to support adoption without increasing administrative overhead.
- Leverage intermediary and shared data infrastructure: The AAFP strongly supports the use of neutral, shared infrastructure such as HIEs and HDUs to facilitate efficient and scalable delivery of event notifications. As demonstrated by models such as the Patient-Centered Data Home, these approaches can significantly reduce both cost and administrative burden for primary care practices.[iv]

++ In what ways could CMS coordinate with the Office of the National Coordinator for Health Information Technology (ONC) to establish certification criteria for health IT that would enable authorized users, including authorized ACOs or other value-based care providers, to be able to subscribe to patient event notification alerts?

The AAFP has consistently advised that interoperability solutions must be implemented across all participating stakeholders and should avoid one-sided requirements. If CMS and ONC pursue certification criteria to enable ACOs, payers, and other authorized users to subscribe to patient event notifications, both agencies should coordinate to ensure aligned and equitable

expectations across exchange partners. **Specifically, the AAFP recommends that CMS and ONC not require physicians or hospitals to adopt new technologies unless their exchange partners are also required to implement compatible, standards-based capabilities**.

Accordingly, ONC could incorporate subscription functionality into the Health IT Certification Program, such as certified capabilities that support external subscription to event notification feeds, while CMS could require ACOs, payers, and other participants in federal programs to adopt and use these capabilities. Additionally, CMS and ONC should establish clear technical standards and best practices for subscription-based APIs to ensure reliable, interoperable data exchange with minimal customization. Coordinated policy and implementation across agencies will be critical to ensuring that physicians are not left with certified technology that their exchange partners are unable or unwilling to use.

++ How could CMS leverage the TEFCA network to improve the quality of notifications and/or improve the likelihood that electronic event notifications shared by hospitals are able to reach authorized recipients?

The AAFP views the Trusted Exchange Framework and Common Agreement (TEFCA) as an important step toward establishing a national baseline for interoperability and supports its potential to improve connectivity across the health care ecosystem. However, the AAFP remains cautious that large-scale interoperability initiatives have not consistently translated into usable, workflow-integrated data at the point of care. TEFCA's focus on clinical data exchange is a positive development, but current capabilities may not fully address key elements needed for effective care coordination and value-based care, including timely patient attribution and other non-clinical data necessary to support longitudinal care management.

To improve the delivery and reach of patient event notifications, CMS should consider leveraging TEFCA as a national backbone for routing notifications across participating networks, which would enable authorized providers and entities connected to TEFCA to reliably receive alerts regardless of geography or affiliation. At the same time, TEFCA should be implemented in coordination with existing HIE and HDU infrastructure and supplemented where necessary to address gaps in attribution, data completeness, and workflow integration. The AAFP recommends CMS pursue a coordinated approach that leverages TEFCA's connectivity while ensuring that event notifications deliver timely, actionable information that supports care coordination without introducing additional administrative burden.

Technical Approaches to Patient Electronic Event Notifications

++ What standards-based mechanisms exist or could be improved to support authorized ACOs or other value-based care entities, payers, and other provider types to be able to subscribe to

patient event notification alerts? For example, could certain standards or requirements for patient matching improve event notifications?

The AAFP emphasizes that accurate patient attribution and reliable patient matching are foundational to ensuring that patient event notifications are delivered to the appropriate recipients. In value-based care models, physicians must receive timely notification when attributed patients experience care events. **One significant improvement would be requiring or encouraging payers to share up-to-date patient attribution lists in a standardized format, such as through the HL7 FHIR Da Vinci Attribution List IG**. Standardized attribution data would enable hospitals and other entities to route notifications more reliably to responsible providers. We also support the continued advancement of standards-based APIs and subscription mechanisms that enable authorized users to receive event notifications in a consistent and scalable manner.

The AAFP reiterates that adoption of standards must be consistent across all participants. CMS should ensure that payers, ACOs, and other value-based entities are required to support compatible, standards-based technologies, including subscription capabilities and robust patient matching methods. Improvements in patient matching, including enhanced use of standardized identifiers, would further improve the accuracy and reliability of event notifications. The AAFP encourages CMS to align requirements across hospitals and their exchange partners to ensure that standards for subscription, attribution, and matching are implemented consistently and support timely, actionable care coordination.

Enforcement

++ What additional steps, if any, should CMS take to strengthen existing enforcement mechanisms and address concerns about some hospitals not adhering to the patient event notification requirements?

The AAFP continues to urge CMS and HHS to closely monitor compliance with patient event notification requirements and to strengthen enforcement mechanisms where gaps persist. If hospitals are not consistently adhering to these requirements, CMS should consider enforcing corrective action plans, incorporating compliance into CoPs, and applying more rigorous oversight through targeted audits or survey processes. Given the central role hospitals play in generating and sharing critical patient data, enforcement mechanisms must be sufficient to ensure consistent compliance. CMS should also make clear that failure to send required notifications constitutes a meaningful CoP deficiency and should escalate enforcement as necessary to promote reliable data exchange and support safe, effective care transitions.

++ What additional guidance, technical assistance, or other supports could CMS provide to help hospitals improve compliance and effective use of patient event notifications?

The AAFP supports the publication of clear, concise guidance and practical resources to assist hospitals in complying with patient event notification requirements, particularly for smaller and resource-constrained entities. CMS could consider the following actions:

- Publish clear implementation guidance and best practices: CMS should provide straightforward, actionable guidance on establishing and optimizing notification workflows, including examples from diverse hospital settings that demonstrate successful implementation.
- Provide technical assistance and implementation resources: CMS should offer toolkits, templates (such as data sharing agreements), and guidance on leveraging intermediary infrastructure (e.g., HIEs) to meet CoP requirements efficiently. Targeted technical assistance would be especially valuable for hospitals with limited internal IT capacity.
- Engage end users in resource development: The AAFP strongly encourages CMS to involve physicians and other frontline stakeholders in the development of guidance and tools to ensure they are practical, workflow-aligned, and responsive to real-world care coordination needs.

CMS could further support these efforts by collaborating with ONC to develop a joint implementation "playbook" for patient event notifications and by leveraging existing support channels, such as Quality Improvement Organizations, to disseminate guidance and provide hands-on assistance. Targeted support of this kind would improve compliance, reduce implementation variability, and ultimately strengthen care coordination across the health care system.

C. Improving Implementation of Payer Application Programming Interface Technology

The AAFP strongly supports CMS's intent to improve the consistency and reliability of payer API implementations. As the agency correctly identifies, incomplete or non-conformant API implementations undermine interoperability, threaten patient safety, and impose downstream administrative burden on physicians and practices that depend on these systems functioning as intended. Family physicians are the end-users of payer API data and directly experience the clinical and operational consequences when these systems fail.

Testing Requirements and Transparency

The AAFP supports establishing robust conformance testing requirements for payer APIs and agrees with CMS that transparency of testing results is a critical and achievable near-term step. **Requiring impacted payers to either publish conformance test results or report them to CMS**

for centralized publication would increase accountability and provide physicians, patients, and technology developers with greater confidence in the reliability of the API infrastructure. The AAFP encourages CMS to leverage existing tools, including ONC's Inferno framework, as a foundation for testing requirements, while establishing a clear process for incorporating additional testing tools as standards and implementation approaches evolve.

In addition to conformance testing, the availability of sandbox environments is essential. The AAFP supports requiring impacted payers to implement and maintain accessible sandbox environments for testing. Health IT developers and EHR vendors, particularly those serving primary care, frequently encounter challenges establishing reliable connections to payer APIs in the absence of such environments. Sandbox capabilities would reduce the time and cost of integration, accelerate adoption of interoperable workflows in primary care settings, and reduce the risk of implementation failures that ultimately disrupt patient care.

The AAFP also supports CMS' consideration of interoperability testing across multiple conformant systems. Real-world interoperability depends not only on individual API conformance, but also on the ability of systems to exchange information reliably end-to-end. Testing frameworks should therefore evaluate whether APIs enable the intended data exchange workflows across systems, rather than assessing conformance in isolation. To ensure testing requirements support meaningful oversight rather than checkbox compliance, the AAFP recommends CMS establish minimum thresholds for passing conformance, require re-testing when standards or IGs are updated, and make testing results publicly available in a standardized, machine-readable format to enable comparison across payers.

Certification of Payer API Technology

The AAFP supports the concept of payer API certification as a long-term mechanism to ensure consistent, reliable implementation across the health care ecosystem. Certification could provide a structured accountability framework, reduce variability across payer implementations, and extend the information blocking enforcement framework to payer technology vendors that currently operate outside it. **Incorporating payer-facing technology into the ONC Health IT Certification Program would create a direct pathway for accountability that does not currently exist, which the AAFP supports**.

However, the AAFP urges CMS and ONC to sequence certification carefully and to condition any certification requirement on demonstrated real-world readiness. As the AAFP has consistently stated, standards and IGs should not be mandated until they have been validated through robust real-world testing across diverse clinical settings, including small, independent, and rural practices; we believe this principle applies equally to payer API certification. Establishing

certification requirements before implementations are proven in practice settings risks formalizing incomplete or ineffective solutions.

Accordingly, the AAFP recommends a phased approach to payer API certification. This approach should begin with mandatory conformance testing and public reporting (Tier 1), followed by required sandbox environments to support implementation and integration (Tier 2), and ultimately progress to formal certification under the ONC Health IT Certification Program (Tier 3). Progression to certification should only occur when: 1) relevant FHIR standards and IGs have been validated at scale through real-world testing; 2) testing tools such as Inferno have demonstrated consistent and reproducible conformance assessments; and 3) a sufficient number of payer implementations have successfully met conformance requirements to establish clear benchmarks for compliant implementation. A certification framework should be implemented only when these preconditions are satisfied and when existing oversight mechanisms demonstrate limitations that require formal certification and enforcement.

E. Laboratory Tests and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Items

The AAFP recommends that CMS take additional steps to streamline PA requirements for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and address persistent access barriers. Family physicians routinely encounter payer-driven delays in DMEPOS approvals, including prolonged timelines for essential items such as mobility supports, which can adversely affect patient outcomes and functional status. Available data indicate that DMEPOS disputes represent a substantial share of coverage appeals and a high percentage of denials are overturned, suggesting that initial determinations may not consistently reflect clinical necessity. We therefore recommend CMS require payers to analyze internal appeal and overturn rates and eliminate or modify PA requirements for DMEPOS categories where denials are routinely reversed. A data-driven approach would reduce unnecessary administrative burden and improve timely access to medically necessary equipment.

For laboratory services, the AAFP recommends that CMS promote standardized, efficient, and clinically integrated PA workflows. CMS should allow standardized test requisition forms to serve as sufficient documentation for PA, provided they are aligned with LOINC-coded test identifiers and capable of being transmitted as structured FHIR ServiceRequest resources. Standardizing documentation requirements in this way would reduce variation across payers, minimize duplicative information requests, and better align PA processes with existing clinical workflows.

The AAFP also strongly recommends that CMS require payers to support real-time PA determinations for laboratory tests prior to specimen collection, including through use of the CRD IG. Post-collection denials result in wasted specimens, delayed diagnoses, unreimbursed

services, and unexpected patient costs, all of which undermine care delivery and practice sustainability. Requiring pre-collection, real-time determination would better align payer processes with clinical workflows, reduce avoidable waste, and improve the timeliness and reliability of diagnostic care.

Physician Documentation Burden; Small and Independent Practice Implementation

The AAFP urges CMS to take explicit steps to ensure the proposed rule reduces rather than shifts administrative burden for family physicians and their staff. If implemented without sufficient attention to real-world clinical workflows, ePA risks replicating or exceeding the burden of manual PA by requiring physicians to submit the same documentation in a new format rather than enabling automated exchange of existing clinical data. Consistent with AAFP policy supporting physician choice across practice models and environments, CMS should ensure that implementation of these standards is feasible for small and independent practices, which often lack the resources available to larger systems.

We strongly recommend CMS develop and publish clear guidance that states documentation requirements for drug PA must be derived from existing clinical data elements available in FHIR-compliant EHRs, rather than requiring physicians to complete duplicative or new forms. The Da Vinci DTR workflow is intended to pre-populate documentation from the EHR; however, its success depends on whether payer documentation requirements are aligned with the structured data elements available in primary care EHRs. **To promote transparency and enable consistent implementation, we believe CMS should require payers to publicly document the data elements required for PA and specify which elements are available within ONC-certified EHR data fields**. **Additionally, consistent with the AAFP's longstanding position, CMS should ensure that any documentation standards and workflows are validated through robust real-world testing across diverse practice settings prior to widespread implementation**. Conducting real-world testing across a range of practice environments, including small, independent, and rural practices, will provide critical assurance that these standards are feasible to implement and will reduce, rather than compound, physician burden.

Small and independent family medicine practices face unique implementation challenges. Unlike large health systems, which have dedicated IT and compliance staff, these practices typically rely on EHR vendors to implement new standards and may have limited ability to customize or troubleshoot PA workflows. The AAFP therefore recommends that CMS:

- Provide a dedicated technical assistance program for small practices (fewer than 10 physicians) to support implementation of FHIR-based drug PA standards;
- Require EHR vendors to provide integrated PA workflow functionality as a baseline feature of ONC-certified ambulatory EHRs, rather than as an optional add-on;

- Establish a clear feedback and escalation mechanism through which physicians can report PA workflow failures or EHR non-compliance to CMS for investigation and enforcement; and
- Publish implementation readiness benchmarks at least 12 and 6 months in advance of compliance dates to enable appropriate planning by small and independent practices.

The AAFP also urges CMS to address the use of payer-inserted clinical decision support (CDS) within EHR workflows. While ePA infrastructure may facilitate more timely access to coverage information, it also creates a pathway for payers to introduce coverage-related prompts into clinical workflows at the point of care. Through CDS Hooks, a payer's external service can send automated alerts into a physician's EHR at the moment of ordering or prescribing, potentially steering clinical decisions toward coverage-preferred options without explicit physician review or consent. We have previously raised concerns about this practice, and **we reiterate our recommendation that CMS establish clear guardrails requiring physician consent, transparency, and limitations on payer-inserted CDS to ensure that clinical decision-making remains physician-directed and that additional administrative burden is avoided**.

Enforcement

We urge CMS, in the final rule, to clearly outline how enforcement of these requirements will be conducted. While we understand enforcement authority and procedures will differ across impacted payers, clarity on CMS' plans and intention to enforce these requirements is needed to ensure smooth and timely implementation. The AAFP strongly recommends CMS not rely on physicians or patients to identify and report issues related to API data access or plan compliance with transparency requirements, including status updates, reasons for denials, and required timeframes for PA decisions. **Physicians experiencing a failed API response are not positioned to report that failure through regulatory channels while simultaneously managing patient care, and patients cannot reasonably be expected to identify API non-conformance as the source of a data exchange failure**. CMS should outline a proactive process for identifying and addressing noncompliance rather than waiting for complaints to surface.

We reiterate that additional requirements and enforcement mechanisms on physicians are not needed to promote the use of relevant APIs. Physicians are overwhelmed by administrative requirements and will utilize technology that relieves burden and promotes efficient workflows. CMS should work with ONC and EHR vendors to ensure that these APIs, once thoroughly tested in real-world settings, are widely implemented within EHRs without imposing significant additional cost on physician practices. Removing these barriers to utilization of the APIs will more effectively promote their use among clinicians than penalties, MIPS utilization measures, or other enforcement mechanisms directed at physicians.

Conclusion

Thank you for the opportunity to provide written comments on this important topic and its potential impact on primary care access in the U.S. The AAFP appreciates CMS and ONC introducing proposals to improve the electronic exchange of health care data and streamline prior authorization processes, including expanding these processes to medications. We stand ready to collaborate with the agencies and other stakeholders to advance meaningful reform, including reducing the overall volume of prior authorizations, continuing to standardize clinical criteria, and strengthening enforcement of payer compliance with established requirements.

We respectfully request CMS and ONC adopt the recommended modifications outlined in these comments: strengthen appeal rights and denial transparency, provide dedicated implementation support for small and independent practices, require real-world validation of Da Vinci implementation guides in primary care settings prior to compliance deadlines, extend drug prior authorization timeframe standards to MA, and commit to efforts that meaningfully reduce prior authorization volume as an accompanying reform. With these changes, we believe this regulation has the potential to deliver meaningful, lasting relief for family physicians and their patients by improving care timeliness, reducing administrative burden, and supporting high-quality, patient-centered care. For more information or questions, please contact Mandi Neff, Senior Strategist, Regulatory and Policy, at mneff2@aafp.org.

Sincerely,

Jen Brull, MD, FAAFP
Board Chair
American Academy of Family Physicians

---

[i] American Medical Association. 2025 AMA Prior Authorization Physician Survey. American Medical Association, May 2026. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[ii] Biniek, Jeannie Fuglesten, et al. "Medicare Advantage Insurers Made Nearly 53 Million Prior Authorization Determinations in 2024." KFF, 28 Jan. 2026. https://www.kff.org/medicare/medicare-advantage-insurers-made-nearly-53-million-prior-authorization-determinations-in-2024/.

[iii] Id.

[iv] Civitas Networks for Health. "Patient Centered Data Home®." Civitas Networks for Health, 21 Aug. 2022. https://civitasforhealth.org/patient-centered-data-home/.